This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as ‘believes’, ‘expects’, ‘anticipates’, ‘projects’, ‘intends’, ‘should’, ‘seeks’, ‘estimates’, ‘future’ or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

1. Pricing and product initiatives of competitors;
2. Legislative and regulatory developments and economic conditions;
3. Delay or inability in obtaining regulatory approvals or bringing products to market;
4. Fluctuations in currency exchange rates and general financial market conditions;
5. Uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
6. Increased government pricing pressures;
7. Interruptions in production;
8. Loss of or inability to obtain adequate protection for intellectual property rights;
9. Litigation;
10. Loss of key executives or other employees; and
11. Adverse publicity and news coverage.

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Group

Thomas Schinecker
Chief Executive Officer
HY 2023 performance

Outlook
HY 2023: Strong base business growth in both divisions

**Group sales -2% at CER due to expected COVID-19 sales decline**

- Strong Pharma growth (+8% at CER) driven by Vabysmo, Ocrevus, Hemlibra, Evrysdi, Phesgo, Tecentriq and Polivy
- Strong Diagnostics base business growth (+6% at CER)
- COVID-19 sales decline in line with guidance

**Profitability impacted by base effect in first HY; FY guidance confirmed**

- Core EPS down -5% due to COVID-19 sales decline and Ultomiris patent settlement in 2022

**Pharma milestones achieved in Q2; New partnerships strengthening pipeline**

- Pharma approvals: Columvi (glofitamab) in 3L+ DLBCL in the US / EU; Elevidys (delandistrogene moxeparvovec) in the US*
- Positive Phase III (OCARINA II) results for Ocrevus 6m SC in RMS / PPMS, positive Phase II (FENopta) results for fenebrutinib in RMS, and positive Phase I/II (MORPHEUS) results for tiragolumab + Tecentriq + Avastin in 1L HCC
- Partnering: In-licensed zilebesiran (AGT-targeting siRNA) for mild-moderate hypertension and KSQ-4279 (USP1 inhibitor) for solid tumors

**Upcoming newsflow 2023**

- Pharma late-stage read-outs: Ph III (EMBARK) for Elevidys in DMD; line extensions for Tecentriq, Venclexta, Alecensa, Xolair, Phesgo
- Diagnostics: CCM Vertical, LightCycler Pro, Anti-HEV IgG/IgM, HBeAg Quant, and IL-6 Neonatal sepsis

Growth rates at CER (Constant Exchange Rates); CCM=cobas connection module; DLBCL=diffuse large B-Cell lymphoma; RMS=relapsing multiple sclerosis; PPMS=primary-progressive multiple sclerosis; HCC=hepatocellular carcinoma; NME=new molecular entity; AGT=angiotensinogen; siRNA=small interfering RNA; DMD=Duchenne muscular dystrophy; *Accelerated US approval by partner company Sarepta
**HY 2023: Strong base business impacted by COVID-19 sales decline**

*Currency headwinds further increased in Q2*

<table>
<thead>
<tr>
<th></th>
<th>2023 CHFbn</th>
<th>2022 CHFbn</th>
<th>Change in %</th>
<th>Excl. C19¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals Div.</td>
<td>22.7</td>
<td>22.3</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Diagnostics Div.</td>
<td>7.1</td>
<td>9.9</td>
<td>-29</td>
<td>-23</td>
</tr>
<tr>
<td>Roche Group</td>
<td>29.8</td>
<td>32.3</td>
<td>-8</td>
<td>-2</td>
</tr>
</tbody>
</table>

CER=Constant Exchange Rates; totals may include differences due to rounding; ¹ Pharmaceuticals Division sales excluding Ronapreve, Diagnostics Division base business
Quarterly sales: COVID-19 and AHR impact as expected

Q4 2023 to be impacted by Ronapreve base effect of roughly CHF 1.1bn

YoY growth rates at CER (Constant Exchange Rates); *Q2 2020 sales severely impacted by COVID-19 pandemic onset; \(^1\) AHR: Avastin, Herceptin, Rituxan/MabThera
HY 2023: Base business largely compensates for COVID-19 impact

Portfolio diversification progresses as ophthalmology franchise gains momentum

CHFm

-2% at CER

FY 2022

Dia base business
Dia COVID-19 sales
Pharma base business
Ronapreve sales
AHR erosion
Fx
FY 2023

32,295
-2,695
+2,360
+9
-635
-1,976
29,779

Diversification of Roche portfolio

FY 2018

CHF 28.1bn

FY 2023

CHF 29.8bn

CER=Constant Exchange Rates; ¹AHR: Avastin, Herceptin, Rituxan/MabThera
HY 2023: Base businesses in both divisions grow high single digit

COVID-19 impact to reduce significantly by end of Q1 2024

Growth rates at CER (Constant Exchange Rates)
HY 2023: Results impacted by Ultomiris settlement and COVID-19

**Group sales**

<table>
<thead>
<tr>
<th>Year</th>
<th>CHFbn</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>30.7</td>
</tr>
<tr>
<td>2022</td>
<td>32.3</td>
</tr>
<tr>
<td>2023</td>
<td>29.8</td>
</tr>
</tbody>
</table>

-2% at CER

**Core operating profit**

<table>
<thead>
<tr>
<th>Year</th>
<th>CHFbn</th>
<th>% of sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>11.7</td>
<td>37.9%</td>
</tr>
<tr>
<td>2022</td>
<td>12.7</td>
<td>39.2%</td>
</tr>
<tr>
<td>2023</td>
<td>10.9</td>
<td>36.6%</td>
</tr>
</tbody>
</table>

0% at CER excl. Ultomiris

-6% at CER

**Core EPS**

<table>
<thead>
<tr>
<th>Year</th>
<th>CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>10.56</td>
</tr>
<tr>
<td>2022</td>
<td>11.76</td>
</tr>
<tr>
<td>2023</td>
<td>10.10</td>
</tr>
</tbody>
</table>

-2% at CER excl. Ultomiris

-5% at CER

CER=Constant Exchange Rates

HY 2023: Results impacted by Ultomiris settlement and COVID-19
Young portfolio: New launches exceed 50% of sales

Keeping historic launch momentum with two NMEs approved in 2023

Young portfolio defined as all launches since end of 2015; * Elevidys: Accelerated US approval by partner company Sarepta; ** Venclexta sales booked by AbbVie and therefore not included
New partnerships signed to strengthen Pharma pipeline
Entering hypertension and adding to the early portfolio in DNA damage response (DDR)

Zilebesiran (angiotensinogen siRNA)
- siRNA targeting angiotensinogen, the precursor protein of all angiotensin peptides
- Consistent and durable blood pressure control with potential for improved adherence\(^1\)
- Currently in two Ph II (KARDIA-1/2); data expected in mid-2023 and early 2024, respectively

KSQ-4279 (USP1 inhibitor)
- First-in-class small molecule inhibitor of ubiquitin-specific protease 1 (USP1)
- USP1 is involved in DNA damage response mechanisms, which are distinct from PARPi and other targeted therapies
- Currently in Ph I in patients with advanced solid tumors

\(^1\) Desai et al. N Engl J Med 2023;389:228-38; HTN=hypertension; siRNA=small interfering RNA; AGT=angiotensinogen; SC=subcutaneous; PARPi=poly (ADP-ribose) polymerase; zilebesiran in partnership with Alnylam Pharmaceuticals; KSQ-4279 in partnership with KSQ Therapeutics
Invitation to Roche Pharma Day 2023
Additional IR events: ECTRIMS 2023, Digitalization Day and ASH 2023

Roche Pharma Day on Sep 11
London / hybrid event

11:30 - 15:30 CEST / 10:30 - 14:30 BST
05:30 - 09:30 am EDT / 02:30 - 06:30 am PDT

Presenters include:

- **Thomas Schinecker**, CEO Roche Group
- **Teresa Graham**, CEO Roche Pharmaceuticals
- **Levi Garraway**, Chief Medical Officer and Head of Global Product Development
- **Charlie Fuchs**, Senior Vice President and Global Head of Oncology and Hematology
- **Paulo Fontoura**, Senior Vice President and Global Head of Neuroscience, Immunology, Ophthalmology, Infectious and Rare Diseases Clinical Development
- **Christopher Brittain**, Vice President and Global Head Product Development Ophthalmology

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiogenesis 2023</td>
<td>Monday, 13 February</td>
<td>16:30 to 18:00 CET</td>
</tr>
<tr>
<td>Roche ESG Day</td>
<td>Tuesday, 23 May</td>
<td>15:30 to 17:00 CEST</td>
</tr>
<tr>
<td>EHA 2023</td>
<td>Monday, 12 June</td>
<td>16:30 to 17:30 CEST</td>
</tr>
<tr>
<td>Roche Pharma Day</td>
<td>London, Monday, 11 September</td>
<td>10:30 to 14:30 BST</td>
</tr>
<tr>
<td>ECTRIMS 2023</td>
<td>October</td>
<td>TBA</td>
</tr>
<tr>
<td>Roche Digitalization Day</td>
<td>Virtual, Wednesday, 29 November</td>
<td>TBA</td>
</tr>
<tr>
<td>ASH 2023</td>
<td>Virtual, December</td>
<td>TBA</td>
</tr>
</tbody>
</table>
2023 performance

Outlook
# 2023: Upcoming newsflow

## Pharma

<table>
<thead>
<tr>
<th>Drug Combination</th>
<th>Phase</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tiragolumab + Tecentriq in 1L</td>
<td>Q4 2023/ Q1 2024</td>
<td></td>
</tr>
<tr>
<td>Tiragolumab + Tecentriq + chemo in 1L Esophageal</td>
<td>2024</td>
<td></td>
</tr>
<tr>
<td>Tecentriq + Avastin in adjuvant HCC</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Tecentriq in adjuvant SCCHN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tecentriq + chemo in adjuvant TNBC</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Tecentriq neoadjuvant/adjuvant TNBC</td>
<td>2024</td>
<td></td>
</tr>
<tr>
<td>Phesgo OBI in HER2+ BC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alecensa in adjuvant ALK+ NSCLC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venclexta + azacitidine in 1L high risk MDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venclexta + dexamethasone in R/R MM (t11;14)</td>
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<td></td>
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</table>

## Diagnostics

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anto-HEV IgG and Anti-HEV IgM</td>
<td>Anti-HEV IgM: Immunoassay aiding in diagnosis of acute HEV infection in clinic. Anti-HEV IgG: Immunoassay aiding in detection of a recent or past HEV infection.</td>
</tr>
<tr>
<td>HBeAg Quant</td>
<td>Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B</td>
</tr>
<tr>
<td>IL-6 Neonatal sepsis (claim extension)</td>
<td>Immunoassay with dedicated claim aiding in diagnosis of sepsis in neonates</td>
</tr>
</tbody>
</table>

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DME=diabetic macular edema; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer; HCC=hepatocellular carcinoma; MM=multiple myeloma; PCR=polymerase chain reaction; SC=subcutaneous; DR=diabetic retinopathy; RMS=relapsing MS; PPMS=primary progressive MS; PNH=Paroxysmal nocturnal hemoglobinuria; TNBC=triple negative breast cancer; SCCHN=squamous cell carcinoma of head and neck; DMD=Duchenne muscular dystrophy; OBI=on-body injector; BC=breast cancer; MDS=Myelodysplastic syndrome; R/R=relapsed / refractory; IVD=in vitro diagnostics; HEV=Hepatitis E Virus
2023 sales outlook confirmed

Sales drivers

Pharma: Key products with strong growth and momentum from ongoing launches

Diagnostics: Base business with solid growth

COVID-19 sales for Diagnostics and Pharma expected to decline by roughly CHF 5bn

AHR\(^2\) sales expected to erode by roughly CHF 1.6bn

Group sales growth\(^1\)

Low single digit decline

\(^1\) At Constant Exchange Rates (CER); \(^2\) AHR=Avastin, Herceptin, Rituxan/MabThera
2023 outlook confirmed

- **Group sales growth**
  - Low single digit decline

- **Core EPS growth**
  - Broadly in line with sales decline

- **Dividend outlook**
  - Further increase dividend in Swiss francs

---

1 At Constant Exchange Rates (CER)
Pharmaceuticals Division

Teresa Graham
CEO Roche Pharmaceuticals
## HY 2023: Pharmaceuticals Division sales

All regions delivering strong growth, intensifying currency headwinds in Q2

<table>
<thead>
<tr>
<th></th>
<th>2023</th>
<th>2022</th>
<th>Change in %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHFm</td>
<td>CHFm</td>
<td>CHF</td>
</tr>
<tr>
<td>Pharmaceuticals Division</td>
<td>22,681</td>
<td>22,347</td>
<td>1</td>
</tr>
<tr>
<td>United States</td>
<td>11,743</td>
<td>11,363</td>
<td>3</td>
</tr>
<tr>
<td>Europe</td>
<td>4,105</td>
<td>4,104</td>
<td>0</td>
</tr>
<tr>
<td>Japan</td>
<td>2,210</td>
<td>2,202</td>
<td>0</td>
</tr>
<tr>
<td>International</td>
<td>4,623</td>
<td>4,678</td>
<td>-1</td>
</tr>
</tbody>
</table>

CER = Constant Exchange Rates
HY 2023: Pharmaceuticals Division
Core operating profit impacted by Ultomiris patent settlement

<table>
<thead>
<tr>
<th></th>
<th>2023</th>
<th>% sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>22,681</td>
<td>100.0</td>
</tr>
<tr>
<td>Other revenue</td>
<td>806</td>
<td>3.6</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>-4,107</td>
<td>-18.0</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>-5,617</td>
<td>-24.8</td>
</tr>
<tr>
<td>SG&amp;A</td>
<td>-3,444</td>
<td>-15.3</td>
</tr>
<tr>
<td>OOI&amp;E</td>
<td>699</td>
<td>3.1</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>11,018</td>
<td>48.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2023 vs. 2022</th>
<th>CER growth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>-2% in CHF</td>
</tr>
<tr>
<td></td>
<td></td>
<td>COGS + PC: +1%</td>
</tr>
</tbody>
</table>

CER=Constant Exchange Rates; COGS=costs of goods sold; PC=period costs; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense
HY 2023: Strong momentum for key growth drivers

Vabysmo nearing CHF 1bn in H1; Polivy with strong launch in 1L DLBCL

Absolute values and growth rates at Constant Exchange Rates (CER); DLBCL=diffuse large B cell lymphoma
**HY 2023: Oncology portfolio growing +4%**

**HER2 franchise**
- Kadycya (0%) growth in International compensating for US/EU
- Perjeta (+9%) driven by US and International
- Phesgo (+69%): 35% conversion in early launch countries**

**Tecentriq**
- Growth (+12%) driven by adjuvant NSCLC and 1L HCC

**Hematology franchise**
- Gazyva (+22%): Growth driven by 1L CLL
- Polivy (+114%): Strong 1L DLBCL uptake, especially in US, EU and JP
- Lunsumio: 3L+ FL launch and geographic expansion ongoing
- Columvi: US/EU launch in 3L+ DLBCL ongoing

**Alecensa**
- Strong growth (+10%) and 1L ALK+ NSCLC leadership in all markets

---

HY 2023 Oncology sales: CHF 9.8bn, CER growth +4%; CER=Constant Exchange Rates; * Includes sales of Zelboraf, Cotellic, Rozlytrek, Gavreto and Tarceva; ** Phesgo conversion rate is based on volumes (vials) and includes all launch countries after the 2nd quarter after the launch (38 countries); HCC=hepatocellular carcinoma; NSCLC=non-small cell lung cancer; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; ALK=anaplastic lymphoma kinase; Polivy in collaboration with Seagen
Tiragolumab: Positive early results in 1L HCC

**Ph III in 1L HCC initiated**

### Development program

<table>
<thead>
<tr>
<th>Indication</th>
<th>Ph I</th>
<th>Ph II</th>
<th>Ph III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1L NSCLC: PD-L1 high</td>
<td>SKYSCRAPER-01</td>
<td>Results in Q4 / Q1</td>
<td></td>
</tr>
<tr>
<td>Stage III unresectable NSCLC</td>
<td>SKYSCRAPER-03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Necroadj NSCLC</td>
<td>SKYSCRAPER-08</td>
<td></td>
<td></td>
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<tr>
<td>1L NSq NSCLC</td>
<td>SKYSCRAPER-06</td>
<td></td>
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</tr>
<tr>
<td>NSCLC</td>
<td>CITYSCAPE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locally advanced ESCC</td>
<td>SKYSCRAPER-07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L ESCC (China)</td>
<td>SKYSCRAPER-08</td>
<td>Results in H1 2024</td>
<td></td>
</tr>
<tr>
<td>2L PD-L1+CC</td>
<td>SKYSCRAPER-04</td>
<td>Results in H2 2023</td>
<td></td>
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<tr>
<td>SCCHN</td>
<td>SKYSCRAPER-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L uHCC</td>
<td>SKYSCRAPER-14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid tumors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R/R MM or R/R NHL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Ph I/II (MORPHEUS) results in 1L HCC

- **ORR**
  - Tiragolumab: 43% (95% CI: 27.0, 59.1)
  - Atezolizumab + Bevacizumab: 11% (95% CI: 1.4, 34.7)

- **PFS**
  - HR 0.42 (95% CI: 0.22, 0.82)

- **Readout of SKYSCRAPER-01 in 1L NSCLC is event-driven and expected for Q4/Q1**
- **Ph III (SKYSCRAPER-14) in 1L HCC initiated**

- Tiragolumab + Tecentriq + Avastin with PFS benefit of 58% (HR=0.42) and ORR of 43%
- Treatment benefit of tiragolumab supported by benchmarking vs IMbrave150 data
- No new safety signals

---

Finn R, et al. J Clin Oncol 2023;41(Suppl):4010; Cheng A-L et al. J Hepatol 2022;76(4):862-873; *per RECIST v 1.1; SCLC=small cell lung cancer; NSCLC=non small cell lung cancer; ESCC=esophageal squamous cell carcinoma; NSq=non squamous; HR=hazard ratio; CI=confidence interval; PFS=progression free survival; ORR=objective response rate; CC=cervical cancer; SCCHN=squamous cell head and neck carcinoma; HCC=hepatocellular carcinoma; R/R=relapsed/refractory; MM=multiple myeloma; NHL=Non-Hodgkins lymphoma
**Columvi: Approval in 3L+ DLBCL in US and EU achieved**

*First and only bispecific offering fixed-duration treatment in 3L+ DLBCL*

### Ph II results for Columvi in 3L+ DLBCL

- **CRR / ORR of 40% / 52% with a median DoR of 26.9 months**
- **Off-the-shelf treatment option that provides durable response rates**
- **NCCN guideline inclusion as category 2A achieved**

### CD20 x CD3 development program

- **Columvi**
  - Indication: 3L+ DLBCL
  - Readout: US/EU approved

- **Columvi + GemOx**
  - Indication: 2L+ DLBCL (SCT-ineligible)
  - Readout: STARGLO, Readout 2024

- **Columvi + CD19x4-1BBL**
  - Indication: r/r NHL

- **Columvi + CD19xCD28**
  - Indication: r/r NHL

- **Columvi + Polivy + R-CHP**
  - Indication: 1L DLBCL
  - Readout: Ph III to initiate in 2023

- **Lunsumio**
  - Indication: 3L+ FL
  - Readout: US/EU approved

- **Lunsumio + Polivy**
  - Indication: 2L+ DLBCL (SCT-ineligible)
  - Readout: SUNMO, Readout 2024

- **Lunsumio + lenalidomide**
  - Indication: 2L+ FL
  - Readout: CELESTIMO, Interim analysis 2024

- **Lunsumio + Polivy + r/r CLL**

- **Lunsumio + Polivy**
  - Indication: 1L DLBCL (elderly/unfit)

- **Lunsumio + Polivy**
  - Indication: 1L DLBCL (elderly/unfit)

---

Dickinson M, et al. Hematol. Oncol. 2023;41 (S2):144-6; CRR=complete response rate; ORR=overall response rate; DoR=durability of response; NR=not reached; HR=hazard ratio; CI=confidence interval; R/R=relapsed refractory; FL=follicular lymphoma; DLBCL=diffuse large B-cell lymphoma; CLL=chronic lymphocytic leukemia; SCT=stem cell transplantation; NHL=non-Hodgkin’s lymphoma; GemOx=gemcitabine oxaliplatin; R-CHP=rituxan + cyclophosphamide + hydroxydaunorubicin + prednisone; NCCN=national comprehensive cancer network
**Tecentriq: First PD-(L)1 with pivotal SC results filed in US and EU**

**US PDUFA set for September 15th**

---

**Q2 update**

**Lung franchise (NSCLC, SCLC)**
- US/EU: Adjuvant NSCLC launch ongoing

**GI franchise (HCC)**
- US/ROW: Further growth in 1L HCC, nearing peak penetration

**Outlook 2023**
- US/Great Britain approvals for Tecentriq SC expected
- Ph III (IMvoke010) results in adjuvant SCCHN expected in Q4
- Ph III (SKYSCRAPER-01) Tecentriq + tiragolumab in 1L PD-L1+ NSCLC final OS results expected in Q4 / Q1

---

CER=Constant Exchange Rates; SC=subcutaneous; NSCLC=non-small cell lung cancer; HCC=hepatocellular cancer; SCLC=small cell lung cancer; SCCHN=squamous cell carcinoma of head and neck; PDUFA=prescription drug user fee act; OS=overall survival; ROW=rest of world
Hemophilia A: Hemlibra, the global SoC, keeps expanding
US/EU-5 patient share reached 39%

Q2 update

• ~21,000 patients treated globally
• Hemlibra continues to penetrate across all approved patient segments
• SPK-8011 pivotal Ph III gene therapy initiated
• Key data at ISTH 2023 presented:
  • Strong Hemlibra prophylaxis and QoL results
  • Ph I/II safety data for NXT-007
  • Ph I/II 3-year QoL and joint health data for SPK-8011

Outlook 2023

• US/EU: Further patient share gains in non-inhibitors

CER=Constant Exchange Rates; QoL=quality of life; SoC=standard of care
Immunology: Sales impacted by Esbriet erosion

Ph III (OUtMATCH) Xolair in food allergy readout expected in H2 2023

**Q2 update**
- Ph III (ARNASA) astegolimab in COPD initiated
- Ph III (IMAGINATION) ASO factor B in IgA nephropathy initiated

**Actemra (+2%)**
- No COVID-19 related sales
- Shift from IV to SC ongoing, SC share at ~60%

**Esbriet (-78%)**
- Generic competition in US/EU

**Xolair (+4%)**
- Growth driven by CSU

**Outlook 2023**
- Ph III (OUtMATCH) Xolair in food allergy results expected
- US approval of Xolair autoinjector expected

---

CER=Constant Exchange Rates; RA=rheumatoid arthritis; IV=intravenous; SC=subcutaneous; COPD=chronic obstructive pulmonary disease; CSU=chronic spontaneous urticaria; ASO=antisense oligonucleotide; IgA nephropathy=immunoglobulin A nephropathy
Astegolimab: First in class anti-ST2 mAb in COPD enters Ph III

Early results show benefit in key endpoints throughout broad patient population

Astegolimab (anti-ST2 mAb)

- Astegolimab binds both soluble ST2 and membrane bound ST2 (IL-33) receptor
- IL-33 blockade may impact airway remodeling in COPD patients
- No biologics currently approved in COPD

Ph IIa (COPD-ST2OP) results

- Ph IIa (COPD-ST2OP): AER reduction of -22% (-37% in EOS low), reduction in SGRQ of -3.3 and increased FEV$_1$ by +40 ml
- Pivotal Ph III program includes up-scaled Ph IIb (ALIENTO) and newly initiated Ph III (ARNASA); results expected in 2025
- Broad patient population including former and current smokers, and EOS low to high

Ph III (ARNASA) trial design

- Ph III (ARNASA) trial design
  - Screening (n=1290)
    - Astegolimab SC Q2W
    - Astegolimab SC Q4W
    - Placebo
  - Follow-up
  - 1:1:1 R
  - Weeks 0 52 60
  - Former & current smokers, EOS low to high
  - Primary: AER at 52 weeks
  - Secondary: SGRQ, FEV$_1$, E-RS, annualized rate of severe COPD exacerbation

1 Yousuf AJ, et al. Lancet Respir. Med. 2022;10 (5):469-77; mAb=monoclonal antibody; ST2=suppression of tumorigenicity 2; IL-33=interleukin-33; COPD=chronic obstructive pulmonary disease; R=randomization; SC=subcutaneous; Q2W/Q4W=every 2/4 weeks; EOS=eosinophils; RR=rate reduction; AERR=annualized exacerbation rate reduction; SGRQ=St. George’s respiratory questionnaire; FEV$_1$=forced expiratory value; E-RS=evaluating respiratory systems
Multiple Sclerosis: Positive Ph III results for Ocrevus 6m SC

Twice a year, 10 min injection to further improve treatment experience and expand usage

Q2 update

- Ocrevus with 22% patient share globally (>300k pts treated)
- Market leader in US and EU-5
- Higher retention rate than other MS medicines
- Ph III (OCARINA II) for Ocrevus 6m SC met all primary and secondary endpoints
- Ph III (GAVOTTE/MUSETTE) high-dose Ocrevus fully recruited
- Positive Ph II (FENopta) results for fenebrutinib in RMS

Outlook 2023

- US/EU: Further market share gains expected
- Ph III (OCARINA II) results to be filed globally

CER=Constant Exchange Rates; MS=multiple sclerosis; SC=subcutaneous; 6m=every 6 months; RMS=relapsing MS
Fenebrutinib: Strong Ph II data highlight potential in MS
Highly selective and the only reversible, non-covalent BTKi in Ph III

**Ph II (FENopta) results in RMS**

- Significantly reduced brain lesions in RMS patients, meeting primary and secondary endpoints, with patients on fenebrutinib 4x more likely to be free from new T1 Gd+ and N/E T2 lesions at weeks 4, 8 and 12 vs placebo
- Safety profile consistent with previous and ongoing trials across >2,400 patients
- Ph III trials (FENhance 1/2) in RMS and (FENtrepid) in PPMS ongoing

**Ph III program**

- **Indication**
  - RMS vs placebo: FENopta
  - RMS vs teriflunomide: FENhance 1/2
  - PPMS vs Ocrevus: FENtrepid

**Total new T1 Gd+ lesions by week and combined**

<table>
<thead>
<tr>
<th>Week</th>
<th>No. of patients</th>
<th>Adjusted mean number of new T1 Gd+ lesions</th>
<th>Adjusted rate of new T1 Gd+ lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>36</td>
<td>0.35 (0.22 to 0.48)</td>
<td>22% (-92% to 68%)</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>0.30 (0.22 to 0.48)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>34</td>
<td>0.22 (0.14 to 0.30)</td>
<td>92% (65% to 98%)</td>
</tr>
<tr>
<td></td>
<td>67</td>
<td>0.20 (0.14 to 0.30)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>33</td>
<td>0.15 (0.11 to 0.21)</td>
<td>69% (34% to 85%)</td>
</tr>
<tr>
<td></td>
<td>63</td>
<td>0.15 (0.11 to 0.21)</td>
<td></td>
</tr>
</tbody>
</table>

*Results were estimated from a negative binomial model controlling for baseline T1 Gd+ lesion status (presence or absence) and included log number of scans as an offset. Arrows indicate relative reduction (95% CI) of lesions; MS=multiple sclerosis; BTKi=Bruton’s tyrosine kinase inhibitor; RMS=relapsing multiple sclerosis; PPMS=primary progressive multiple sclerosis; Gd=gadolinium-enhancing; N/E T2 = new/enlarging T2-weighted; CI=confidence interval.
Spinal muscular atrophy: Evrysdi on track to become global #1
4 year follow-up data confirm strong efficacy and safety profile in infants

Q2 update
• >8,500 patients treated worldwide; retention rate in first 12 months of ~90% globally
• US: Market leader with growth driven by switch and naive patient starts, including patients <2 months old
• Ex-US: Continued strong growth and share gains in all major markets; #1 in Japan
• Ph II/III (FIREFISH) 4 year follow-up data confirming strong efficacy / safety profile in infants shown at CURE SMA

Outlook 2023
• Continued growth and market share gains
• EU: Positive CHMP opinion for Ph II (RAINBOWFISH) in <2 months old infants; EU label extension expected

CHFm
0 50 100 150 200 250 300 350 400 450
Q2 21 Q2 22 Q2 23

US  Europe  International  Japan

YoY CER growth
+65%  +36%

CER=Constant Exchange Rates; SMA=spinal muscular atrophy
Elevidys: US approval for first DMD gene therapy by partner Sarepta

**Ph III (EMBARK) results in Q4, needed for EU filing & US label extension**

- Positive functional and clinically meaningful results up to 4 years after treatment with consistent safety profile in >50 patients
- US accelerated approval in 4 and 5 year old ambulatory patients achieved by Sarepta in Q2
- Roche planning to file in selected countries referencing to the US approval

**Development program**

<table>
<thead>
<tr>
<th>Study</th>
<th>DMD subgroup</th>
<th>Ph I</th>
<th>Ph II</th>
<th>Ph III</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>101</td>
<td>Ambulatory, 4-7 yrs.</td>
<td></td>
<td></td>
<td>✔️</td>
<td>US approval (Sarepta)</td>
</tr>
<tr>
<td>102</td>
<td>Ambulatory, 4-7 yrs.</td>
<td></td>
<td></td>
<td>✔️</td>
<td>US approval (Sarepta)</td>
</tr>
<tr>
<td>103 (ENDEAVOR)</td>
<td>Ambulatory, 3-18 yrs Non-ambulatory, all ages</td>
<td></td>
<td></td>
<td>✔️</td>
<td>US approval (Sarepta)*</td>
</tr>
<tr>
<td>301 (EMBARK)</td>
<td>Ambulatory, 4-7 yrs.</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
<td>EU filing and US label extension</td>
</tr>
<tr>
<td>302 (ENVOL)</td>
<td>Ambulatory, 0-3 yrs.</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>Expansion to younger DMD pts</td>
</tr>
<tr>
<td>303 (ENVISION)</td>
<td>Ambulatory, 8-18 yrs Non-ambulatory, all ages</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>Expansion to older ambulatory and non-ambulatory DMD pts</td>
</tr>
</tbody>
</table>

- Ph III (ENVISION) in older ambulatory and all ages non-ambulatory patients started in Q2 2023
- Ph II (ENVOL) in 0-3 year old ambulatory patients to initiate in H2 2023
- Ph III (EMBARK) results in Q4 2023; data to be filed in the EU and to facilitate non-age-restricted expansion of the US label

Elevidys (delandistrogene moxeparvovec) accelerated US approval by partner Sarepta Therapeutics; ¹ Zaidman, et al. MDA 2023; *For study 103 (ENDEAVOR) only cohort 1 was used; **Functional data from patients who received the 1.33x10^14 vg/kg dose of delandistrogene moxeparvovec and the propensity-score-weighted EC cohort were compared; DMD=Duchenne muscular dystrophy; NSAA=North Star Ambulatory Assessment; LSM=least-squares mean; EC=external control; SE=standard error
Ophthalmology: Vabysmo nearing CHF 1 bn sales in H1
US market share reaches 15% in nAMD and 9% in DME*

Q2 update
- US: ~30% naive patients, ~70% switches (mostly from aflibercept)
- JP/UK/CH/AUS: Double-digit market share in early launch countries
- Filed for third indication RVO in US

Outlook 2023
- Continued launches in EU and ROW countries and global market share gains in nAMD and DME
- US PDUFA for Vabysmo in RVO set for 22nd December; EU filing expected in Q3
- New Vabysmo data to be presented at ASRS 2023:
  - Post-hoc data indicates less fibrosis vs. aflibercept in DME
  - Real-world data reinforcing 1L benefits in nAMD and DME
  - New clinical results on positive anatomical outcomes in nAMD and DME

*Based on May 2023 patient claims data; CER=constant exchange rate; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; RVO=retinal vein occlusion; RWO=rest of world; PDUFA=prescription drug user fee act; Eylea (aflibercept) is a registered trademark/product of Regeneron
Zilebesiran: Roche enters partnership with Alnylam in hypertension
New MoA with tight upstream blockade of AGT pathway and best in disease potential

Zilebesiran (angiotensinogen siRNA)

- siRNA targeting angiotensinogen, the precursor of all angiotensin peptides
- Consistent and durable blood pressure control with potential for improved adherence
- Liver-specific activity may avoid RAAS escape

Ph I results in hypertension\(^1\)

- Positive Ph I results: >90% reduction of serum angiotensinogen for up to 6 mos at single SC dose of zilebesiran ≥100mg; >20 mmHg blood pressure reduction for 3-6 mos
- Two Ph II studies (KARDIA-1/2): Monotherapy study in mild/moderate hypertension and add-on study to SoC in uncontrolled hypertension; data expected in mid-2023 and early 2024, respectively

\(^1\) Desai et al. N Engl J Med 2023;389:228-38; MoA=mode of action; SC=subcutaneous; RAAS=renin angiotensin aldosterone system; siRNA=small interfering RNA; AGT=angiotensinogen; AngI/II=angiotensin I/II; ACE=angiotensin-converting enzyme; ABPM=ambulatory blood pressure monitoring; SoC=standard of care; zilebesiran in partnership with Alnylam Pharmaceuticals
**2023: Key late-stage newsflow***

<table>
<thead>
<tr>
<th>Compound</th>
<th>Indication</th>
<th>Milestone</th>
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</thead>
<tbody>
<tr>
<td><strong>Regulatory</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemlibra</td>
<td>Moderate hemophilia A</td>
<td>EU approval</td>
</tr>
<tr>
<td>Polivy + R-CHP</td>
<td>1L DLBCL</td>
<td>US approval</td>
</tr>
<tr>
<td>Vabysoy</td>
<td>RVO</td>
<td>US approval/EU filing</td>
</tr>
<tr>
<td>Tecentriq</td>
<td>Subcutaneous administration</td>
<td>US approval/EU filing</td>
</tr>
<tr>
<td>Columvi (glofitamab)</td>
<td>3L+ DLBCL</td>
<td>US/EU approval</td>
</tr>
<tr>
<td>Xofluza</td>
<td>Influenza (paediatric 1+ yrs.)</td>
<td>EU approval</td>
</tr>
<tr>
<td>Tecentriq + Avastin</td>
<td>Adjuvant HCC</td>
<td>Ph III IMbrevate050</td>
</tr>
<tr>
<td>Tecentriq + chemo</td>
<td>Neoadjuvant / adjuvant TNBC</td>
<td>Ph III GeparDouce/NSABP B-59 2024</td>
</tr>
<tr>
<td>Tecentriq</td>
<td>Adjuvant SCCHN</td>
<td>Ph III IMvolve010</td>
</tr>
<tr>
<td>Tecentriq + chemo</td>
<td>Adjuvant TNBC</td>
<td>Ph III IMpassion030</td>
</tr>
<tr>
<td>Tiragolumab + Tecentriq</td>
<td>1L PDL1+ NSCLC</td>
<td>Ph III SKYSCRAPER-01 Q4 2023 / Q1 2024</td>
</tr>
<tr>
<td>Tiragolumab + Tecentriq + chemo</td>
<td>1L esophageal cancer</td>
<td>Ph III SKYSCRAPER-08 (China only) 2024</td>
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<tr>
<td>Venclexa + dexamethasone</td>
<td>t(11;14) R/R MM</td>
<td>Ph III CANOVA</td>
</tr>
<tr>
<td>Venclexa + azacitidine</td>
<td>1L high risk MDS</td>
<td>Ph III VERONA</td>
</tr>
<tr>
<td>Alecensa</td>
<td>Adjuvant ALK+ NSCLC</td>
<td>Ph III ALINA</td>
</tr>
<tr>
<td>Phesgo OBI (on body injector)</td>
<td>HER2+ BC</td>
<td>Ph I (pivotal)</td>
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<tr>
<td>Crovalimab</td>
<td>PNH</td>
<td>Ph III COMMODORE 1/2</td>
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<tr>
<td>Columvi + GemOx</td>
<td>2L+ DLBCL</td>
<td>Ph III STARGLO</td>
</tr>
<tr>
<td>Lunsumio + Polivy</td>
<td>2L+ DLBCL</td>
<td>Ph III SUNMO</td>
</tr>
<tr>
<td>Elevidys (Delandistrogene moxeparvovec)</td>
<td>DMD</td>
<td>Ph III EMBARK</td>
</tr>
<tr>
<td>Ocrevus 6m SC</td>
<td>RMS / PPMS</td>
<td>Ph III OCARINA II</td>
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<tr>
<td>TNKase</td>
<td>Stroke patients 4.5-24h</td>
<td>Ph III TIMELESS</td>
</tr>
<tr>
<td>Susvimo</td>
<td>DR</td>
<td>Ph III PAVILION</td>
</tr>
<tr>
<td>Susvimo</td>
<td>DR</td>
<td>Ph III PAVILION</td>
</tr>
<tr>
<td>Xolair</td>
<td>Food allergy</td>
<td>Ph III OutMATCH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phase III / pivotal readouts</th>
<th></th>
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<td>Ph III SKYSCRAPER-01 Q4 2023 / Q1 2024</td>
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<tr>
<td>Xolair</td>
<td>Food allergy</td>
<td>Ph III OutMATCH</td>
</tr>
</tbody>
</table>

**Additional 2023 newsflow:**
- **Fenebrutinib:** Positive Ph II (FENopta) results in RMS
- **Elevidys** US approval in DMD for 4 and 5 years old (Sarepta)
- **Tiragolumab + Tecentriq + Avastin:** Positive Ph I/II (MORPHEUS) results in 1L HCC

*Outcome studies are event-driven: timelines may change*
## HY 2023: Diagnostics Division sales

*Good base business growth, partially offsetting COVID-19 sales decrease*

<table>
<thead>
<tr>
<th></th>
<th>2023</th>
<th>2022</th>
<th>Change in %</th>
<th>Excl. C19¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHFm</td>
<td>CHFm</td>
<td>CHF</td>
<td>CER</td>
</tr>
<tr>
<td>Diagnostics Division</td>
<td>7,098</td>
<td>9,948</td>
<td>-29</td>
<td>-23</td>
</tr>
<tr>
<td>Core Lab</td>
<td>3,935</td>
<td>3,875</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Molecular Lab</td>
<td>1,118</td>
<td>1,980</td>
<td>-44</td>
<td>-40</td>
</tr>
<tr>
<td>Diabetes Care</td>
<td>723</td>
<td>832</td>
<td>-13</td>
<td>-5</td>
</tr>
<tr>
<td>Pathology Lab</td>
<td>687</td>
<td>652</td>
<td>5</td>
<td>12</td>
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<tr>
<td>Point of Care</td>
<td>635</td>
<td>2,609</td>
<td>-76</td>
<td>-74</td>
</tr>
</tbody>
</table>

CER=Constant Exchange Rates; ¹ Diagnostics Division base business
Diagnostics Division sales growth by quarter

**Good base business growth**

Growth rates and absolute values at CER (Constant exchange Rates) of the respective year; ¹Quarterly sales growth excluding COVID-19 sales
HY 2023: Diagnostics Division highlights

Good base business growth, partially offsetting COVID-19 sales decrease

CER=Constant Exchange Rates; POC=point of care; EMEA=Europe, Middle East and Africa

**Core Lab**
- EMEA: +10%
- North America: +10%
- Asia-Pacific: -40%
- Latin America: -40%
- **YoY CER growth +10%**

**Molecular Lab**
- EMEA: -40%
- North America: -40%
- Asia-Pacific: -5%
- Latin America: -5%

**Diabetes Care**
- EMEA: +12%
- North America: +12%
- Asia-Pacific: -5%
- Latin America: -5%

**Pathology Lab**
- EMEA: +10%
- North America: +10%
- Asia-Pacific: -40%
- Latin America: -40%

**Point of Care**
- EMEA: +10%
- North America: +10%
- Asia-Pacific: -74%
- Latin America: -74%

- Immunodiagnostics (+11%)
- Clinical Chemistry (+10%)
- Custom biotech (-8%)

- Cervical Cancer (+24%)
- Blood Screening (+13%)
- Virology base business (+5%)
- COVID-19 (-88%)

- Blood glucose monitoring (-3%)
- Insulin delivery systems (-29%)

- Advanced staining (+10%)
- Companion diagnostics (+20%)

- POC Immunodiagnistics (-89%)
- POC Molecular (-40%)
HY 2023: Diagnostics Division regional sales

Good base business growth across all regions impacted by lower COVID-19 sales

North America
-30%
~27% of divisional sales

EMEA
-22%
~35% of divisional sales

Latin America
0%
~7% of divisional sales

Asia Pacific
-23%
~31% of divisional sales

Growth rates at CER (Constant exchange Rates); EMEA=Europe, Middle East and Africa
**HY 2023: Diagnostics Division**

*Core operating profit decline due to drop in COVID-19 sales*

<table>
<thead>
<tr>
<th></th>
<th>2023 CHFm</th>
<th>% sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>7,098</td>
<td>100.0</td>
</tr>
<tr>
<td>Other revenue</td>
<td>31</td>
<td>0.4</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>-3,349</td>
<td>-47.2</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>-832</td>
<td>-11.7</td>
</tr>
<tr>
<td>SG&amp;A</td>
<td>-1,342</td>
<td>-18.9</td>
</tr>
<tr>
<td>OOI&amp;E</td>
<td>13</td>
<td>0.2</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>1,619</td>
<td>22.8</td>
</tr>
</tbody>
</table>

**2023 vs. 2022 CER growth**

- Core operating profit: -45% in CHF
- Sales: -23%
- Other revenue: -26%
- Cost of sales: -26%
- R&D: 2%
- SG&A: -2%
- OOI&E: -35%
- -36% in CHF

*CER=Constant Exchange Rates; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense*
cobas® i601 analytical mass spectrometry unit and assay menu

**Fully integrated and automated solution with more than 40 IVD assays at launch**

Seamless integration into cobas® pro integrated solutions

- Fully automated solution reduces need for specialized labor
- High throughput of up to 100 samples / hr in random access

IVD assay menu of more than 60 assays in 2 launch waves\(^1\)

- Launch menu complimentary to immunoassay offering
- Mass spec technology offering high sensitivity and specificity
- CE launch planned for end of 2024 (FDA approval expected in 2025)

Fully automated and integrated solution with IVD kits replacing labor intensive LDT mass spectrometry

---

\(^1\)More than 40 IVD assays in established areas for clinical mass spec testing (steroids, therapeutic drug monitoring & vitamin D) at launch, more than 20 add. assays to follow in wave 2; LDT=Laboratory Developed Test
Driving access to essential diagnostics
WHO prequalification for HPV molecular test expands access in LMICs

WHO 2030 cervical cancer elimination goals
- 90% of girls fully vaccinated against HPV by age 15
- 70% of women screened for HPV by age 35 and again at age 45
- 90% of women identified with lesions receive treatment

Implications for LMICs and Roche
- WHO PQ enables LMICs requiring PQ to use cobas® HPV test in cervical cancer elimination programs
- Affiliates covering WHO PQ countries leverage cobas® 6800/8800 installed base for cervical cancer screening tenders
- Roche to strengthen partnerships with governments and drive policy on HPV and multi-disease testing

Achieving the WHO goals will help prevent 74 million new cases of cervical cancer in 78 LMICs

91% of adult women in LMICs have never been screened for cervical cancer

HPV is the cause of more than 99% of cervical cancer; WHO=World Health Organization; HPV=Human papillomavirus; LMIC=Low- and middle-income countries; PQ=prequalification;1 Canfell et al. (2020) The Lancet;2 Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: WHO (2020)
IDH1 R132H & ATRX (Glioma) assays
Enable better treatment decisions for patients with brain cancer

Classification pathway of adult-type diffuse gliomas

- Globally more than 340k patients estimated in 2025 with brain cancer, of which ~75% are malignant gliomas
- Testing IDH1 & ATRX mutation status enables clinicians to:
  - Provide personalized care and a more informed prognosis
  - Select targeted therapies and determine eligibility for clinical trials
  - Enable rapid diagnosis and access to testing
- Tests run on automated BenchMark series of instruments
- Expands Roche neuropathology portfolio to 29 biomarkers

1Only available in the US; aligned with the WHO guidelines for glioma classification; 2Simplified overview based on 2021 WHO Classification of CNS Tumors; 3WHO GCO statistics and Wood et al. (2019) Diagnostic Pathology; 4IDH1/2 Mutations in Glioma: ESMO Biomarker Factsheet (2016); 5Diagnosis can be made without 1p/19q testing if diffuse astrocytic-appearing WHO grade 2/3 tumor has IDH-mutation and loss of ATRX nuclear expression and/or strong, diffuse p53 immunopositivity
## Diagnostics key launches 2023

<table>
<thead>
<tr>
<th>Area</th>
<th>Product</th>
<th>Description</th>
<th>Markets</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instruments</strong></td>
<td><strong>Automation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core Lab</td>
<td>CCM Vertical</td>
<td>Modular transportation system, integrated into the existing cobas connection modules, allowing for overhead sample transportation over different work areas or different floors enabling effective use of lab space</td>
<td>Global</td>
<td></td>
</tr>
<tr>
<td></td>
<td>cobas pro integrated solutions</td>
<td>Scalable and modular serum work area analyzer for mid to high volume clinical chemistry and immunoochemistry testing</td>
<td>China</td>
<td></td>
</tr>
<tr>
<td></td>
<td>cobas pure integrated solutions</td>
<td>Serum work area analyzer for low to mid volume clinical chemistry and immunoochemistry testing on a footprint of two square meters</td>
<td>China</td>
<td></td>
</tr>
<tr>
<td>Molecular Lab</td>
<td>LightCycler Pro</td>
<td>Flexible real-time PCR instrument with dual IVD and research mode as well as enhanced system features</td>
<td>US &amp; CE</td>
<td></td>
</tr>
<tr>
<td>Point of Care</td>
<td>cobas pulse</td>
<td>Handheld device combining professional glucose meter and a digital platform to host digital clinical decision support applications (from Roche and third parties)</td>
<td>US</td>
<td></td>
</tr>
<tr>
<td>Pathology Lab</td>
<td>IDH1 R132H (IDH Glioma)</td>
<td>Neuropathology Immunohistochemistry (IHC) solution supporting the detection of tumor cells with the IDH1 R132H mutation aiding pathologists to render a diagnosis of gliomas</td>
<td>US</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anti-HEV IgG and Anti-HEV IgM</td>
<td>Anti-HEV IgG: Immunoassay aiding in the diagnosis of acute HEV infection in clinical settings; Anti-HEV IgM: Immunoassay aiding in the detection of a recent or past HEV infection and enabling accurate seroprevalence determinations. The two assays expand the hepatitis panel (HAV, HBV, HCV, HEV) on the same analytical platform</td>
<td>CE</td>
<td></td>
</tr>
<tr>
<td>Core Lab</td>
<td>HBeAg Quant</td>
<td>Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B viral infection</td>
<td>CE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IL-6 Neonatal sepsis (claim extension)</td>
<td>Only immunoassay available on the market with dedicated claim and supporting evidence aiding in diagnosis of sepsis in neonates, with potential to reduce newborn mortality</td>
<td>CE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ruo Amyloid Plasma Assays (pTau181 &amp; ApoE4)</td>
<td>Two qualitative immunoassays measuring the phosphorylated Tau 181 protein and apolipoprotein E4 in human plasma for research use only</td>
<td>US</td>
<td></td>
</tr>
<tr>
<td>Pathology Lab</td>
<td>Ruo Digital Pathology Algorithm: PD-L1 SP142</td>
<td>Digital pathology algorithm aiding pathologists in scoring PD-L1 (SP142) breast samples, ensuring a standardized approach and an adjunctive tool to augment diagnostic confidence for research use only</td>
<td>Global</td>
<td></td>
</tr>
<tr>
<td></td>
<td>navify Algorithm Suite</td>
<td>Digital solution providing access to an open library of certified IVD-based clinical algorithms</td>
<td>Selected markets¹</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Menu for navify Algorithm Suite</td>
<td>Certified clinical algorithms for oncology applications such as colon and liver cancers</td>
<td>Selected markets¹</td>
<td></td>
</tr>
<tr>
<td></td>
<td>cobas infinity lab 3.05</td>
<td>Next-generation lab middleware enabling ecosystem of cloud-based solutions for quality control and instrument maintenance</td>
<td>Global</td>
<td></td>
</tr>
<tr>
<td></td>
<td>navify Marketplace</td>
<td>Digital marketplace offering lab customers full range of innovative applications (from Roche and third parties)</td>
<td>Selected markets¹</td>
<td></td>
</tr>
<tr>
<td></td>
<td>navify Sample Tracking</td>
<td>Open digital solution offering sample tracking beyond the lab setting (from IVD-sample creation to lab reception) to improve testing traceability and quality</td>
<td>Selected markets¹</td>
<td></td>
</tr>
</tbody>
</table>

¹Selected markets: 14 countries with first releases; CE=European conformity; RUO=research use only; PCR=polymerase chain reaction; IVD=in vitro diagnostic; IDH=isocitrate dehydrogenase; HEV=Hepatitis E virus; HAV=Hepatitis A virus; HBV=Hepatitis B virus; HCV=Hepatitis C virus
Finance

Alan Hippe
Chief Financial Officer
HY 2023: Highlights

**Business**

- Group sales -2% due to COVID-19 sales erosion in Diagnostics
- Pharma with strong momentum for key growth drivers; Strong Diagnostics base business growth (+6%)
- Core operating profit down by -6% and Core EPS -5% due to base effect from Ultomiris patent settlement in 2022

**Cash flow**

- Operating Free Cash Flow of CHF 8.0bn, -8% due to lower operating profit, partly offset by positive net working capital movement
- Net debt increased by CHF 2.3bn vs. YE 2022

**Net financial result**

- Core net financial result worsened by -75m driven by higher interest expenses

**IFRS**

- Net income -9% driven by the COVID-19 sales decline and Ultomiris patent settlement in 2022

**Currency impact on results**

- Negative currency impact of -6%p on sales, -8%p on core operating profit and -9%p on Core EPS

Growth rates and variances at CER (Constant exchange Rates)
New Income Statement Presentation effective Jan 2023
Improving comparability, reducing complexity, reinforcing alignment

Changes in Income Statement presentation

• Improve external comparability and simplify messaging by using “Selling, General & Administration” costs, from merging “Marketing & Distribution” and “General & Administration”.

• Reinforcing alignment with latest developments on Revenue by using “Other revenues”, instead of “Royalties and Other Operating Income”. Introducing a line “Other operating income / expense” for non-revenue income and expenses that do not fall into the regular functional costs.

• Simplify and standardise reporting by removing allocations from Corporate to the Divisions and various reporting lines for functions with global accountability such as informatics, human resources, and finance.

Consequences

• Sales, Group Operating Profit and EPS metrics are unaffected.

• No change to Core Reporting Concept.

• Allocation changes will reduce costs allocated to Divisions and increase Divisional margins (around 4.0-5.0 %points).
## HY 2023: Group performance

*Sales decline of -2% and Core EPS decline of -5%*

<table>
<thead>
<tr>
<th></th>
<th>2023 CHFm</th>
<th>2022 CHFm</th>
<th>Change in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>29,779</td>
<td>32,295</td>
<td>-8</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>10,911</td>
<td>12,668</td>
<td>-14</td>
</tr>
<tr>
<td>as % of sales</td>
<td>36.6</td>
<td>39.2</td>
<td></td>
</tr>
<tr>
<td>Core net income</td>
<td>8,587</td>
<td>10,160</td>
<td>-15</td>
</tr>
<tr>
<td>as % of sales</td>
<td>28.8</td>
<td>31.5</td>
<td></td>
</tr>
<tr>
<td>Core EPS (CHF)</td>
<td>10.10</td>
<td>11.76</td>
<td>-14</td>
</tr>
<tr>
<td>IFRS net income</td>
<td>7,563</td>
<td>9,161</td>
<td>-17</td>
</tr>
<tr>
<td>as % of sales</td>
<td>25.4</td>
<td>28.4</td>
<td></td>
</tr>
<tr>
<td>Operating free cash flow</td>
<td>8,031</td>
<td>9,782</td>
<td>-18</td>
</tr>
<tr>
<td>as % of sales</td>
<td>27.0</td>
<td>30.3</td>
<td></td>
</tr>
<tr>
<td>Free cash flow</td>
<td>6,128</td>
<td>7,097</td>
<td>-14</td>
</tr>
<tr>
<td>as % of sales</td>
<td>20.6</td>
<td>22.0</td>
<td></td>
</tr>
</tbody>
</table>

CER=Constant Exchange Rates; All numbers in CHFm, except Core EPS in CHF
HY 2023: Base business largely compensates for COVID-19 impact

Portfolio diversification progresses as ophthalmology franchise gains momentum

CHFm

-2% at CER

32,295
+ 421
-2,695
+ 2,360
+ 9
- 635
- 1,976
29,779

Dia base business
Dia COVID-19 sales
Pharma base business
Ronapreve sales
AHR erosion\(^1\)
Fx
HY 2022

Diversification of Roche portfolio

HY 2018
CHF 28.1bn

HY 2023
CHF 29.8bn

Diagnostics
Neuroscience
Oncology
Diagnostics
Other pharma
Ophthalmology
Infectious diseases
Neuroscience
Hematophilia A
Oncology
Immunology
Immunology
AHR

CER=Constant Exchange Rates; \(^1\)AHR: Avastin, Herceptin, Rituxan/MabThera
### HY 2023: Group operating performance

Core operating profit lower by -6% driven by the Ultomiris patent settlement

<table>
<thead>
<tr>
<th></th>
<th>2023 CHFm</th>
<th>abs. CER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>29,779</td>
<td>-540</td>
</tr>
<tr>
<td>Other revenue</td>
<td>837</td>
<td>-685</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>-7,456</td>
<td>+1,093</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>-6,449</td>
<td>-486</td>
</tr>
<tr>
<td>SG&amp;A</td>
<td>-6,505</td>
<td>-392</td>
</tr>
<tr>
<td>OOI&amp;E</td>
<td>705</td>
<td>+305</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>10,911</td>
<td>-704</td>
</tr>
</tbody>
</table>

**2023 vs. 2022 CER growth**

- Sales: -2%
- Other revenue: -44%
- Cost of sales: -12%
- R&D: 8%
- SG&A: 6%
- OOI&E: 73%
- Core operating profit: -6%

**-14% in CHF**

CER=Constant Exchange Rates; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense
HY 2023: Other revenue

Lower revenue driven by base effect of the Ultomiris patent settlement in 2022

CER=Constant Exchange Rates

HY 2023: Other revenue decreased by -44% at CER
HY 2023: Core operating profit and margin

1 At CER=Constant Exchange Rates; 2 At CER excluding 2022 Ultomiris patent settlement
HY 2023: Core net financial result

Worsening driven by higher interest expenses and Fx losses

CHFm

-558

HY 2022

Equity securities
Net interest income
Fx G/L
Interest expenses¹
Other

+151
+76
-85
-147
-19

HY 2023

-582

CER=Constant Exchange Rates; Fx G/L=exchange rate gains and losses ¹incl. amortization of debt discount and net gains on interest rate derivatives
HY 2023: Group Core tax rate

Increase in core tax rate mainly due to the impact from the resolution of tax disputes in HY 2022 partially offset by lower profits in high tax jurisdictions in 2023.
HY 2023: Core EPS development

Decrease of -4.6% driven by base effect of the Ultomiris patent settlement in 2022

At Constant Exchange Rates (CER); ¹ Core operating profit excl. impacts from Ultomiris patent settlement; ² Net impact from the Ultomiris patent settlement: gross income, net of income tax and non-controlling interests; ³ Excluding the effects of the Ultomiris patent settlement on the 2022 tax rate; ⁴ Other (net) include effects from changes in: financial income/expense (excl. equity securities), non-controlling interests and diluted number of shares
## HY 2023: Non-core and IFRS income

*Non-core operating expenses broadly in line with prior year*

<table>
<thead>
<tr>
<th></th>
<th>2022 CHFm</th>
<th>2023 CHFm</th>
<th>Change in %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core operating profit</strong></td>
<td>12,668</td>
<td>10,911</td>
<td>-1,756</td>
</tr>
<tr>
<td>Global restructuring plans</td>
<td>-266</td>
<td>-678</td>
<td>-412</td>
</tr>
<tr>
<td>Amortisation of intangible assets</td>
<td>-468</td>
<td>-358</td>
<td>110</td>
</tr>
<tr>
<td>Impairment of intangible assets</td>
<td>-423</td>
<td>-260</td>
<td>163</td>
</tr>
<tr>
<td>M&amp;A and alliance transactions</td>
<td>17</td>
<td>-1</td>
<td>-18</td>
</tr>
<tr>
<td>Legal &amp; Environmental</td>
<td>19</td>
<td>150</td>
<td>131</td>
</tr>
<tr>
<td><strong>Total non-core operating items</strong></td>
<td>-1,121</td>
<td>-1,147</td>
<td>-26</td>
</tr>
<tr>
<td><strong>IFRS Operating profit</strong></td>
<td>11,547</td>
<td>9,764</td>
<td>-1,784</td>
</tr>
<tr>
<td><strong>Total financial result &amp; taxes</strong></td>
<td>-2,386</td>
<td>-2,201</td>
<td>185</td>
</tr>
<tr>
<td><strong>IFRS net income</strong></td>
<td>9,161</td>
<td>7,563</td>
<td>-1,599</td>
</tr>
</tbody>
</table>

*CER = Constant Exchange Rates; ¹ incl. goodwill; ² incl. pension plan settlements*
2023 results

Focus on cash and balance sheet

Outlook
HY 2023: Operating free cash flow and margin

% of sales

30.3%  27.0%  43.1%  42.2%

30.3%  27.0%  43.1%  42.2%

-2.0%p¹  -0.1%p¹  19.1%  5.7%

-8%¹  +8%¹  -0.1%p¹  -11.5%p¹

CHFm

Roche Group

2022  9,782  2023  8,031

2022  9,638  2023  9,562

Pharma Division

2023  1,902  402

1 At CER=Constant Exchange Rates
HY 2023: Group Operating Free Cash Flow

OFCF down -8% driven by lower Core operating profit due to base effect from Ultomiris patent settlement in 2022, partly offset by positive NWC movement.

CHFm

9.782

-946

+235

-161

+99

-978

HY 2022

HY 2023

OFCF lower by -8%/773m at CER

OP, net of cash adjustments

NWC movement

Investments in PP&E

Investments in IA

Foreign exchange

CER=Constant Exchange Rates; OP=Operating Profit; NWC=Net Working Capital; PP&E=Property, Plant & Equipment incl. increase of lease liability paid; IA=Intangible Assets
HY 2023: Group net debt development

Net debt higher by CHF -2.3bn vs. year end 2022

Free Cash Flow CHF 6.1bn
vs. 7.1bn in 2022

Net debt
31 Dec 2022
Operating
Free
Cash Flow
Non-Operating
Free
Cash Flow
Dividends, M&A and Alliance transactions and other
Net debt
30 June 2023

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>-15.6</td>
<td>-1.6</td>
<td>-0.3</td>
<td>-7.8</td>
<td>0.0</td>
<td>0.0</td>
<td>-0.6</td>
</tr>
</tbody>
</table>

Net debt higher by CHF -2.3bn vs. year end 2022

<table>
<thead>
<tr>
<th>Thereof investments in innovation:</th>
<th>2023</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intangible Asset</td>
<td>-0.2</td>
<td>-0.3</td>
</tr>
<tr>
<td>Equity</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>-0.2</td>
<td>-0.3</td>
</tr>
</tbody>
</table>
Balance sheet 30 June 2023

Equity ratio at 36% (31 Dec 22: 36%); net debt to assets at 21% (31 Dec 22: 18%)
2023 results

Focus on cash and balance sheet

Outlook
Expected 2023 currency impact

Assuming the 30 June 2023 exchange rates remain stable until end of 2023, 2023 impact is expected to be (%p):

<table>
<thead>
<tr>
<th></th>
<th>Q1</th>
<th>HY</th>
<th>Sep YTD</th>
<th>FY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>-4</td>
<td>-6</td>
<td>-6</td>
<td>-7</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>-8</td>
<td></td>
<td>-9</td>
<td></td>
</tr>
<tr>
<td>Core EPS</td>
<td>-9</td>
<td></td>
<td>-10</td>
<td></td>
</tr>
</tbody>
</table>

Assumed avg. YTD 2023

1 On group growth rates
2023 outlook confirmed

- **Group sales growth**\(^1\): Low single digit decline
- **Core EPS growth**\(^1\): Broadly in line with sales decline
- **Dividend outlook**: Further increase dividend in Swiss francs

\(^1\) At Constant Exchange Rates (CER)
Doing now what patients need next
Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
# Changes to the development pipeline

**Q2 2023 update**

## New to phase I

<table>
<thead>
<tr>
<th>NMEs</th>
<th>Description</th>
</tr>
</thead>
</table>
| 4 | RG6449 HBsAg MAb – chronic hepatitis B  
RG6353 HLA-G CD3 TCB – solid tumors  
RG6537 AR degrader – mCRPC  
CHU SAIL66 – solid tumors |

## New to phase II

<table>
<thead>
<tr>
<th>NME</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RG6536 vixarelimab – IPF &amp; SSc-ILD</td>
</tr>
<tr>
<td>1 AI</td>
<td>RG6171 giredestrant – endometrial cancer</td>
</tr>
</tbody>
</table>

## New to phase III

<table>
<thead>
<tr>
<th>NME</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RG6114 inavolisib - post CDKi HR+ BC</td>
</tr>
</tbody>
</table>

## New to registration

<table>
<thead>
<tr>
<th>NME (US &amp; EU)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG6107 crovalimab – PNH*</td>
<td></td>
</tr>
<tr>
<td>1 AI (US)</td>
<td>RG7716 Vabysmo – BRVO/CRVO</td>
</tr>
</tbody>
</table>

## Removed from phase I

<table>
<thead>
<tr>
<th>NMEs</th>
<th>Description</th>
</tr>
</thead>
</table>
| 4 | RG6007 HLA-A2-WT1 x CD3 – AML  
RG7637 – psychiatric disorders  
RG6392 – oncology  
SQZ PBMC vaccine – solid tumors |

## Removed from phase II

<table>
<thead>
<tr>
<th>NME</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RG6358 SPK-8016 – hemophilia A with inhibitors to factor VIII</td>
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</tbody>
</table>

## Removed from phase III

<table>
<thead>
<tr>
<th>NME</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RG3625 TNKase – stroke</td>
</tr>
</tbody>
</table>

## Approvals

<table>
<thead>
<tr>
<th>NME (US &amp; EU)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG6026 Columvi (glifitamab) – 3L+ DLBCL</td>
<td></td>
</tr>
</tbody>
</table>

*US filing acceptance pending

Status as of July 27, 2023
### Roche Group development pipeline

<table>
<thead>
<tr>
<th>Phase I (49 NMEs + 12 Als)</th>
<th>Phase II (23 NMEs + 10 Als)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG6026 Columnvi (glofitamab) monotherapy + combos</td>
<td>RG6026 Columnvi (glofitamab) + chemo</td>
</tr>
<tr>
<td>RG6058 tiragolumbum monocombos</td>
<td>RG6058</td>
</tr>
<tr>
<td>RG6076 englumafusp alfa (CD19-4-1BBL) combos</td>
<td>RG6065</td>
</tr>
<tr>
<td>RG6114 inavolisib</td>
<td>RG6117 CD25 MAbs</td>
</tr>
<tr>
<td>RG6165 EGFrVIII CD3</td>
<td>RG6128 Luminamo</td>
</tr>
<tr>
<td>RG6169 FAP-CD40 + T</td>
<td>RG6171</td>
</tr>
<tr>
<td>RG6171 aligrendart monotherapy + combos</td>
<td>RG6171</td>
</tr>
<tr>
<td>RG6180 autogene cevumeran + T</td>
<td>RG6176</td>
</tr>
<tr>
<td>RG6185 belvarafenib + Cotetil + T</td>
<td>RG6186</td>
</tr>
<tr>
<td>RG6189 FAP-CD40 + T</td>
<td>RG6194</td>
</tr>
<tr>
<td>RG6194 runiniotamab</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6234 foritamig</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6226 Phesgo OBI</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6229 CD25 MAb combos</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6232 IL15/IL15Ra A + T</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6333 divaripas (KRAS G12C) monocombos</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6344 BRAF inhibitor (3)</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6353 HLA-G CD3 TCB</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6411</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6435 SHP2i combos</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6440 Anti-laten TGF-β1 (SOF10)</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6512 Fixa x FX</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6524 DLL3 trispecific</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6562 camonsertib</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6567 AR degrader</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG6538 P-BCMA-ALL01</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG7446 Morphus platform</td>
<td>RG6216</td>
</tr>
<tr>
<td>RG7601 Venclexta + azacitidine</td>
<td>RG6216</td>
</tr>
</tbody>
</table>

### Status as of July 27, 2023

New Molecular Entity (NME) | cilbitamab + T
---|---
metabolism | solid tumors
neuroscience | solid tumors
oncology / hematology | solid tumors
immunology | solid tumors
ophthalmology | solid tumors
Infectious Diseases | solid tumors

- New developed in November 2022
- New developed in March 2023
- New developed in September 2023
- New developed in December 2023

**Phase I**
- Columnvi (glofitamab) + chemo
- CD25 MABs
- IL15/IL15Ra
- divaripas (KRAS G12C)
- BRAF inhibitor (3)
- HLA-G CD3 TCB
- SHP2i combos
- Anti-laten TGF-β1 (SOF10)
- Fixa x FX
- DLL3 trispecific
- camonsertib
- AR degrader
- P-BCMA-ALL01
- Morphus platform
- Venclexta + azacitidine

**Phase II**
- Columnvi (glofitamab)
- CD25 MABs
- IL15/IL15Ra
- divaripas (KRAS G12C)
- BRAF inhibitor (3)
- HLA-G CD3 TCB
- SHP2i combos
- Anti-laten TGF-β1 (SOF10)
- Fixa x FX
- DLL3 trispecific
- camonsertib
- AR degrader
- P-BCMA-ALL01
- Morphus platform
- Venclexta + azacitidine

**Additional Indications (AI)**
- lupus nephritis
- multiple myeloma
- colorectal cancer
- chronic hepatitis B
- complicated urinary tract infection
- retinal disease
- glioblastoma
- squamous cell carcinoma
- amyloidosis
- Alzheimer’s disease
- post-traumatic stress disorder
- familial Alzheimer’s healthy pts
- geographic atrophy
- geographic atrophy
- geographic atrophy

**Combination platform**
- Roche Group development pipeline
- Roche Genentech
- Chugai Pharma
- OpReGen
- Poseida Therapeutics
- Repare Therapeutics
- IONIS Pharmaceuticals
- T-Cellentrix
- OpReGen
- OnBody Delivery System
- developed in Immunology
- developed in Immunology
### Roche Group development pipeline

<table>
<thead>
<tr>
<th>Phase III (8 NMEs + 38 AIs)</th>
<th>Registration US &amp; EU (1 NME + 4 AIs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RG3502</strong> Kadcyla + T</td>
<td>Xolair</td>
</tr>
<tr>
<td><strong>RG6026</strong> Columvl (glofitamab) + chemo</td>
<td>RG6149 Gazyva</td>
</tr>
<tr>
<td><strong>RG3502</strong> Kadcyla + T</td>
<td>Xolair</td>
</tr>
<tr>
<td><strong>RG6026</strong> Columvl (glofitamab) + chemo</td>
<td>RG6149 Gazyva</td>
</tr>
<tr>
<td><strong>RG6058</strong> tiragolumab + T</td>
<td>RG6159 Gazyva</td>
</tr>
<tr>
<td><strong>RG6058</strong> tiragolumab + T</td>
<td>RG6159 Gazyva</td>
</tr>
<tr>
<td><strong>RG6107</strong> crolvalimab</td>
<td>RG6152 Xofluza</td>
</tr>
<tr>
<td><strong>RG6114</strong> inavolisib</td>
<td>RG6152 Xofluza</td>
</tr>
<tr>
<td><strong>RG6171</strong> giredestrant</td>
<td>RG6154 Enspryn</td>
</tr>
<tr>
<td><strong>RG6330</strong> divarasis (KRAS G12C)</td>
<td>RG6156 Elevidys</td>
</tr>
<tr>
<td><strong>RG7446</strong> Tecentriq + platinum chemo</td>
<td>RG7485 fenebrutinib</td>
</tr>
<tr>
<td><strong>RG7446</strong> Tecentriq + platinum chemo</td>
<td>RG7485 fenebrutinib</td>
</tr>
<tr>
<td><strong>RG7446</strong> Tecentriq + platinum chemo</td>
<td>RG7485 fenebrutinib</td>
</tr>
<tr>
<td><strong>RG7446</strong> Tecentriq + platinum chemo</td>
<td>RG7485 fenebrutinib</td>
</tr>
<tr>
<td><strong>RG7601</strong> Venclexta</td>
<td>RG6321 Susvimo</td>
</tr>
<tr>
<td><strong>RG7828</strong> Lunsumio + lenalidomide</td>
<td>RG6179 anti-IL-6</td>
</tr>
<tr>
<td><strong>RG7833</strong> Alecensa</td>
<td>RG6179 anti-IL-6</td>
</tr>
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</table>

Status as of July 27, 2023
## NME submissions and their additional indications

### Projects in phase II and III

<table>
<thead>
<tr>
<th>Year</th>
<th>Projects</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2023</td>
<td>RG6026</td>
<td><strong>Columvi</strong> (glofitamab) + chemo 2L DLBCL</td>
</tr>
<tr>
<td>2023</td>
<td>RG6058</td>
<td><strong>tiragolumab</strong> + T 1L PD-L1 high NSCLC</td>
</tr>
<tr>
<td>2023</td>
<td>RG6058</td>
<td><strong>tiragolumab</strong> + T 1L esophageal cancer (CN)</td>
</tr>
<tr>
<td>2023</td>
<td>RG6114</td>
<td>inavolisib 1L HR+ BC</td>
</tr>
<tr>
<td>2023</td>
<td>RG6356</td>
<td>Evioids (delandistrogene mossaparvovec) DMD (EU)</td>
</tr>
<tr>
<td>2023</td>
<td>RG6321</td>
<td>Susvimo DME (US)</td>
</tr>
<tr>
<td>2024</td>
<td>RG6058</td>
<td><strong>tiragolumab</strong> + T Stage III unresectable 1L NSCLC</td>
</tr>
<tr>
<td>2024</td>
<td>RG6321</td>
<td>Susvimo DR (US)</td>
</tr>
<tr>
<td>2024</td>
<td>RG6107</td>
<td>crovalimab aHUS</td>
</tr>
<tr>
<td>2025</td>
<td>RG6058</td>
<td><strong>tiragolumab</strong> + T+/- chemo NSCLC neoadj/adj</td>
</tr>
<tr>
<td>2025</td>
<td>RG6114</td>
<td>inavolisib post CDKI HR+ BC</td>
</tr>
<tr>
<td>2025</td>
<td>RG6139</td>
<td>totemiomig (PD1xLAG3) solid tumors</td>
</tr>
<tr>
<td>2025</td>
<td>RG6107</td>
<td>crovalimab sickle cell disease</td>
</tr>
<tr>
<td>2025</td>
<td>RG6171</td>
<td>giredestrant endometrial cancer</td>
</tr>
<tr>
<td>2025</td>
<td>RG6171</td>
<td>giredestrant ER+ BC adj</td>
</tr>
<tr>
<td>2026 and beyond</td>
<td>RG6102</td>
<td>trontinemab Alzheimer’s</td>
</tr>
</tbody>
</table>

### New Molecular Entity (NME) submissions and their additional indications

1. **NME** submissions and their additional indications
2. Projects in phase II and III
3. 2023-2025: **Columvi** (glofitamab) + chemo 2L DLBCL
4. **tiragolumab** + T 1L PD-L1 high NSCLC
5. **tiragolumab** + T 1L esophageal cancer (CN)
6. inavolisib 1L HR+ BC
7. Evioids (delandistrogene mossaparvovec) DMD (EU)
8. Susvimo DME (US)
9. crovalimab aHUS
10. **tiragolumab** + T Stage III unresectable 1L NSCLC

### Timeline

- **2023**: Columvi (glofitamab) + chemo 2L DLBCL
- **2024**: Tiragolumab + T 1L PD-L1 cervical cancer
- **2025** and beyond: Various projects including Giredestrant, Trontinemab, and others

### Additional Details

- Indicates submission to health authorities has occurred
- Unless stated otherwise, submissions are planned to occur in US and EU
- T = Tecentriq

---

**Key Notes**

- **Tecentriq**
- First filed in China
- IONIS managed

---

4. **Indicates submission to health authorities has occurred**
5. Unless stated otherwise, submissions are planned to occur in US and EU
6. T = Tecentriq
7. First filed in China
8. IONIS managed

---

**Status as of July 27, 2023**
AI submissions for existing products

Projects in phase II and III

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
OBI=On-Body Delivery System, filing timeline based on data from interim analysis
*also known as pediatric nephrotic syndrome (PNS)

Status as of July 27, 2023
## Major pending approvals 2023

### US

<table>
<thead>
<tr>
<th>Approval</th>
<th>Name</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG7446</td>
<td>Tecentriq SC</td>
<td>all approved indications Filed Nov 2022</td>
</tr>
<tr>
<td>RG7716</td>
<td>Vabysmo</td>
<td>BRVO/CRVO Filed May 2023</td>
</tr>
<tr>
<td>RG6107*</td>
<td>crovalimab</td>
<td>PNH Filed June 2023</td>
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</table>

### EU

<table>
<thead>
<tr>
<th>Approval</th>
<th>Name</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG7916</td>
<td>Evrysdi</td>
<td>SMA presymptomatic pediatric &lt;2mo Filed Nov 2021</td>
</tr>
<tr>
<td>RG1569</td>
<td>Actemra</td>
<td>SS-ILD Filed Aug 2022</td>
</tr>
<tr>
<td>RG7446</td>
<td>Tecentriq SC</td>
<td>all approved indications Filed Nov 2022</td>
</tr>
<tr>
<td>RG6107</td>
<td>crovalimab</td>
<td>PNH Filed Aug 2022</td>
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</table>

### China

<table>
<thead>
<tr>
<th>Approval</th>
<th>Name</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG6264</td>
<td>Phesgo</td>
<td>HER-2+ BC Filed July 2022</td>
</tr>
<tr>
<td>RG6107</td>
<td>crovalimab</td>
<td>PNH Filed Aug 2022</td>
</tr>
<tr>
<td>RG6026</td>
<td>Columvi (glofitamab)</td>
<td>3L+ DLBCL Filed Dec 2022</td>
</tr>
<tr>
<td>RG7716</td>
<td>Vabysmo</td>
<td>nAMD/DME Filed June 2023</td>
</tr>
</tbody>
</table>

### Japan-Chugai

<table>
<thead>
<tr>
<th>Approval</th>
<th>Name</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG6264</td>
<td>Phesgo</td>
<td>HER-2+ BC/CC Filed Sept 2022</td>
</tr>
<tr>
<td>RG1569</td>
<td>Actemra</td>
<td>Cytokine release syndrome (CRS) Filed Feb 2023</td>
</tr>
<tr>
<td>RG7716</td>
<td>Vabysmo</td>
<td>BRVO/CRVO Filed April 2023</td>
</tr>
<tr>
<td>RG6107</td>
<td>crovalimab</td>
<td>PNH Filed June 2023</td>
</tr>
</tbody>
</table>

---

**Status as of July 27, 2023**

- **New Molecular Entity (NME)**
- **Additional Indication (AI)**
- **Oncology / Hematology**
- **Immunology**
- **Infectious Diseases**
- **Metabolism**
- **Neuroscience**
- **Ophthalmology**
- **Other**
- **SC=Subcutaneous**
- **US filing acceptance pending**
## Major granted approvals 2023

### US

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG7596</td>
<td>Polivy 1L DLBCL (US)</td>
<td>April 2023</td>
</tr>
<tr>
<td>RG6026</td>
<td>Columvi (glofitamab) 3L+ DLBCL</td>
<td>June 2023</td>
</tr>
</tbody>
</table>

### EU

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG6152</td>
<td>Xofluza influenza pediatric</td>
<td>Jan 2023</td>
</tr>
<tr>
<td>RG6013</td>
<td>Hemlibra moderate hemophilia A</td>
<td>Jan 2023</td>
</tr>
<tr>
<td>RG6413+ RG6412</td>
<td>Ronapreve* SARS-CoV-2 hospitalized</td>
<td>May 2023</td>
</tr>
<tr>
<td>RG6026</td>
<td>Columvi (glofitamab) 3L+ DLBCL</td>
<td>July 2023</td>
</tr>
</tbody>
</table>

### China

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG7596</td>
<td>Polivy 1L DLBCL</td>
<td>Jan 2023</td>
</tr>
<tr>
<td>RG6152</td>
<td>Polivy r/r DLBCL</td>
<td>Jan 2023</td>
</tr>
<tr>
<td>RG6152</td>
<td>Xofluza influenza pediatric &lt;12 years</td>
<td>March 2023</td>
</tr>
<tr>
<td>RG7916</td>
<td>Evrysdi SMA presymptomatic pediatric &lt;2mo</td>
<td>June 2023</td>
</tr>
</tbody>
</table>

### Japan-Chugai

- RG6026: Columvi (glofitamab) 3L+ DLBCL June 2023

**Status as of July 27, 2023**
Roche Group development pipeline

**Marketed products development programmes**

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
### Hemlibra (emicizumab, RG6013)

**Factor VIII mimetic for treatment of hemophilia A**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Hemophilia A patients without inhibitors to factor VIII</th>
<th>Hemophilia A patients with and without inhibitors to Factor VIII, dosing every 4 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III HAVEN 3</td>
<td>Phase III HAVEN 4</td>
</tr>
<tr>
<td># of patients</td>
<td>N=135</td>
<td>N=46</td>
</tr>
<tr>
<td>Design</td>
<td>Patients on FVIII episodic treatment prior to study entry:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM A:</strong> Hemlibra prophylaxis qw</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM B:</strong> Hemlibra prophylaxis q2w</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM C:</strong> Episodic FVIII treatment; switch to Hemlibra prophylaxis possible after 24 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patients on FVIII prophylaxis prior to study entry:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM D:</strong> Hemlibra prophylaxis qw</td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Number of bleeds over 24 weeks</td>
<td>• Number of bleeds over 24 weeks</td>
</tr>
<tr>
<td>Status</td>
<td>• Study met primary and key secondary endpoints Q4 2017</td>
<td>• Pharmacokinetic run-in data at ASH 2017</td>
</tr>
<tr>
<td></td>
<td>• FDA granted Breakthrough Therapy Designation April 2018</td>
<td>• Positive interim analysis outcome reported Q4 2017</td>
</tr>
<tr>
<td></td>
<td>• Data presented at WFH 2018</td>
<td>• Data presented at WFH 2018</td>
</tr>
<tr>
<td></td>
<td>• Filed in US (priority review) and EU in Q2 2018</td>
<td>• Interim data filed in US and EU in Q2 2018</td>
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<tr>
<td>CT Identifier</td>
<td>NCT02847637</td>
<td>• Approved in US Q4 2018 and EU Q1 2019</td>
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<tr>
<td></td>
<td>NCT03020160</td>
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</table>
## Hemlibra (emicizumab, RG6013)

**Factor VIII mimetic for treatment of hemophilia A**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Hemophilia A patients with and without inhibitors to Factor VIII</th>
<th>Hemophilia A mild to moderate patients without inhibitors to Factor VIII</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III HAVEN 5</td>
<td>Phase III HAVEN 6</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=85</td>
<td>N=70</td>
</tr>
</tbody>
</table>
| **Design** | Patients with Hemophilia regardless of FVIII inhibitor status on prophylactic or episodic treatment prior to study entry:  
  - **ARM A**: Hemlibra prophylaxis qw  
  - **ARM B**: Hemlibra prophylaxis q4w  
  - **ARM C**: No prophylaxis (control arm) | Patients with mild or moderate Hemophilia A without FVIII inhibitors  
  - Hemlibra qw (1.5mg/kg), q2w (3.0mg/kg) or q4w (6.0mg/kg) (patients preference) |
| **Primary endpoint** | • Number of bleeds over 24 weeks | • Safety and efficacy |
| **Status** | • FPI Q2 2018  
  • Recruitment completed Q1 2019  
  • Filed in China Q2 2020  
  • Approved in China Q2 2021 | • FPI Q1 2020, recruitment completed Q1 2021  
  • Interim data presented at ASH 2021 and primary data presented at ISTH 2022  
  • Filed in EU Q4 2021  
  • Data presented at ASH 2022  
  • Approved in EU for moderate Hemophilia A Q1 2023 |
| **CT Identifier** | NCT03315455 | NCT04158648 |

In collaboration with Chugai  
ASH=American Society of Hematology; ISTH=International Society on Thrombosis and Haemostasis

78
Alecensa (alectinib, RG7853)

New CNS-active inhibitor of anaplastic lymphoma kinase

<table>
<thead>
<tr>
<th>Indication</th>
<th>Treatment-naïve ALK+ advanced NSCLC</th>
<th>Adjuvant ALK+ NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III ALEX</td>
<td>Phase III ALINA</td>
</tr>
<tr>
<td># of patients</td>
<td>N=286</td>
<td>N=257</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Alecensa 600mg BID</td>
<td>• ARM A: Alecensa 600mg BID</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Crizotinib 250mg BID</td>
<td>• ARM B: Platinum-based chemotherapy</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Progression-free survival</td>
<td>• Disease-free survival</td>
</tr>
<tr>
<td>Status</td>
<td>• Data presented at ASCO 2017, 2018, ESMO 2017, 2018 and 2019 (final PFS and updated OS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data published in NEJM 2017; 377:829-838</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Approved in US Q4 2017 (priority review) and in EU Q4 2017</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• FPI Q3 2018</td>
<td>• Recruitment completed Q4 2021</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT02075840</td>
<td>NCT03456076</td>
</tr>
</tbody>
</table>

In collaboration with Chugai

ALK=anaplastic lymphoma kinase; CNS= Central nervous system; NSCLC=non-small cell lung cancer; OS=Overall survival, PFS=Progression-free survival; ASCO=American Society of Clinical Oncology; NEJM=New England Journal of Medicine; ESMO=European Society for Medical Oncology
Kadcyla (trastuzumab emtansine, RG3502)
First ADC for HER2-positive breast cancer

<table>
<thead>
<tr>
<th>Indication</th>
<th>HER2-positive early breast cancer (BC) high-risk patients</th>
<th>HER2-positive early breast cancer (BC) high-risk patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III KATHERINE</td>
<td>Phase III ASTEFANIA</td>
</tr>
<tr>
<td># of patients</td>
<td>N=1,484</td>
<td>N=1,700</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Kadcyla 3.6mg/kg q3w</td>
<td>• ARM A: Kadcyla plus Tecentriq</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Herceptin</td>
<td>• ARM B: Kadcyla plus placebo</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Invasive disease-free survival</td>
<td>• Invasive disease-free survival</td>
</tr>
<tr>
<td>Status</td>
<td>• Stopped at pre-planned interim data analysis for efficacy Q4 2018</td>
<td>• FPI Q2 2021</td>
</tr>
<tr>
<td></td>
<td>• Data presented at SABCS 2018</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• BTD granted by FDA in Q1 2019</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Filed in US (under RTOR) and EU Q1 2019</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Approved in US Q2 2019 and in EU Q4 2019</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data published in NEJM 2019; 380:617-628</td>
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</tr>
<tr>
<td>CT Identifier</td>
<td>NCT01772472</td>
<td>NCT04873362</td>
</tr>
</tbody>
</table>

In collaboration with ImmunoGen, Inc.
ADC=antibody drug conjugate; BTD=Breakthrough therapy designation; HER2=Human Epidermal growth factor Receptor 2; SABCS=San Antonio Breast Cancer Symposium; RTOR=Real time oncology review; NEJM=New England Journal of Medicine
Phesgo (pertuzumab/trastuzumab, RG6264)
FDC of Perjeta and Herceptin for subcutaneous administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>HER2-positive early breast cancer (BC)</th>
<th>HER2-positive breast cancer (BC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III FeDeriCa</td>
<td>Phase II PHranceSCa</td>
</tr>
<tr>
<td># of patients</td>
<td>N=500</td>
<td>N=160</td>
</tr>
</tbody>
</table>
| Design | Phesgo in combination with chemotherapy in neoadjuvant/adjuvant setting  
\hspace{1em} **ARM A:** Perjeta IV plus Herceptin IV plus chemotherapy  
\hspace{1em} **ARM B:** Phesgo plus chemotherapy | \hspace{1em} **ARM A:** Perjeta and Herceptin IV followed by Phesgo  
\hspace{1em} **ARM B:** Phesgo followed by IV |  
\hspace{1em} **ARM A:** Phesgo administered using a handheld syringe with hypodermic needle (SC)  
\hspace{1em} **ARM B:** Phesgo administered using the on-body delivery system (OBI) |
| Primary endpoint | Trough Serum Concentration (C\text{trough}) of Perjeta during cycle 7 | Percentage of patients who preferred Phesgo |  
\hspace{1em} AUC0-62*, C\text{max}** |
| Status |  
\hspace{1em} Primary endpoint met Q3 2019  
\hspace{1em} Data presented at SABCS 2019  
\hspace{1em} Data published in Lancet Oncology 2021 Jan;22(1):85-97 |  
\hspace{1em} Final analysis completed, 85% patients preferred Phesgo  
\hspace{1em} Data presented at ESMO 2020  
\hspace{1em} Data published in *Eur J Cancer* 2021 Jul;152:223-232 |  
\hspace{1em} FPI Q2 2022 |
| CT Identifier | NCT03493854 | NCT03674112 | NCT05275010 |

SC with Halozyme’s rHuPH20/ Halozyme’s human hyaluronidase; *In collaboration with West Pharmaceuticals; *AUC0-62= comparability of area under the time–concentration curve from the start of dosing to 63 days; **C\text{max}=maximum serum concentration for pertuzumab and trastuzumab within Phesgo; FDC=Fixed-dose combination; Phesgo=FDC of Perjeta and Herceptin for SC administration; HER2=Human Epidermal growth factor Receptor 2, IV=intravenous; SC=Subcutaneous; SABCS=San Antonio Breast Cancer Symposium; *Eur J Cancer=European Journal of Cancer; ESMO=European Society for Medical Oncology
# Tecentriq (atezolizumab, RG7446)

**Anti-PD-L1 cancer immunotherapy – lung cancer**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Adjuvant NSCLC</th>
<th>Periadjuvant NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III IMpower010</td>
<td>Phase III IMpower030</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=1,280</td>
<td>N=450</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Following adjuvant cisplatin-based chemotherapy</td>
<td>ARM A: Tecentriq plus platinum-based chemotherapy; ARM B: Platinum-based chemotherapy</td>
</tr>
</tbody>
</table>
|                       | • ARM A: Tecentriq | • ARM A: Tecentriq plus platinum-based chemotherapy  
|                       | • ARM B: Best supportive care | • ARM B: Platinum-based chemotherapy |
| **Primary endpoint**  | Disease-free survival | Event-free survival |
| **Status**            | Recruitment completed Q3 2018; Study met primary endpoint Q1 2021; Data presented at ASCO, WCLC and ESMO 2021; Filed in US (priority review) and EU Q2 2021; Approved in US Q4 2021 and EU Q2 2022 | FPI Q2 2018; Recruitment completed Q3 2021 |
| **CT Identifier**     | NCT02486718    | NCT03456063       |

NSCLC=non-small cell lung cancer; PD-L1= Programmed death-ligand 1; ASCO=American Society of Clinical Oncology; ESMO= European Society for Medical Oncology; WCLC= World Conference on Lung Cancer

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## Tecentriq (atezolizumab, RG7446)
### Anti-PD-L1 cancer immunotherapy – lung cancer

<table>
<thead>
<tr>
<th>Indication</th>
<th>1L maintenance extensive-stage SCLC</th>
<th>Stage IV NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III IMforte&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Phase Ib/III IMscin001&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=450</td>
<td>N=371</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td><strong>ARM A</strong>: Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin</td>
<td>Phase Ib</td>
</tr>
<tr>
<td></td>
<td><strong>ARM B</strong>: Platinum-etoposide + Tecentriq followed by maintenance Tecentriq</td>
<td>Phase III</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>• Progression-free survival and overall survival</td>
<td>• Observed concentration of Tecentriq in serum at cycle 1</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td><strong>FPI Q4 2021</strong></td>
<td><strong>FPI Phase Ib Q4 2018 and FPI Phase III Q4 2020</strong></td>
</tr>
<tr>
<td></td>
<td>• Recruitment completed Q1 2022</td>
<td>• Study met its primary end point Q3 2022</td>
</tr>
<tr>
<td></td>
<td>• Data presented at ESMO-IO 2022</td>
<td>• Filed in US and EU Q4 2022</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT05091567</td>
<td>NCT03735121</td>
</tr>
</tbody>
</table>

<sup>1</sup>In collaboration with Jazz Pharma, <sup>2</sup>SC with Halozyme’s rHuPH20/ Halozyme’s human hyaluronidase  
NSCLC=non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; SCLC=small cell lung cancer, SC=Subcutaneous, IV=Intravenous; ESMO-IO=European Society for Medical Oncology-Immuno-Oncology
<table>
<thead>
<tr>
<th>Indication</th>
<th>Adjuvant squamous cell carcinoma of the head and neck (SCCHN)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III IMvoke010</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=406</td>
</tr>
</tbody>
</table>
| **Design** | - **ARM A:** Tecentriq 1200mg q3w  
- **ARM B:** Placebo |
| **Primary endpoint** | - Event-free survival and overall survival |
| **Status** | - FPI Q1 2018  
- Recruitment completed Q1 2020 |
| **CT Identifier** | NCT03452137 |

SCCHN=squamous cell carcinoma of the head and neck
## Tecentriq (atezolizumab, RG7446)

*Anti-PD-L1 cancer immunotherapy – urothelial carcinoma*

<table>
<thead>
<tr>
<th>Indication</th>
<th>High-risk non-muscle-invasive bladder cancer (NMIBC)</th>
<th>ctDNA+, high-risk muscle-invasive bladder cancer (MIBC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III ALBAN</td>
<td>Phase III IMvigor011</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=516</td>
<td>N=495</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>• <strong>ARM A:</strong> BCG induction and maintenance</td>
<td>• <strong>ARM A:</strong> Tecentriq monotherapy</td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM B:</strong> Tecentriq plus BCG induction and maintenance</td>
<td>• <strong>ARM B:</strong> Placebo</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>Recurrence-free survival</td>
<td>Recurrence-free survival</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>FPI Q4 2018</td>
<td>FPI Q2 2021</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT03799835</td>
<td>NCT04660344</td>
</tr>
</tbody>
</table>

**BCG**=Bacille Calmette-Guérin; **PD-L1**=Programmed cell death-ligand 1
# Tecentriq (atezolizumab, RG7446)

**Anti-PD-L1 cancer immunotherapy – hepatocellular carcinoma**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Adjuvant hepatocellular carcinoma (HCC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III IMbrave050</td>
</tr>
<tr>
<td># of patients</td>
<td>N=668</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Tecentriq plus Avastin</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Active surveillance</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Recurrence-free survival</td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q4 2019</td>
</tr>
<tr>
<td></td>
<td>• Recruitment completed Q4 2021</td>
</tr>
<tr>
<td></td>
<td>• Study met its primary endpoint Q1 2023</td>
</tr>
<tr>
<td></td>
<td>• Data presented at AACR 2023 and ASCO 2023 (PROs)</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT04102098</td>
</tr>
</tbody>
</table>

PD-L1=Programmed cell death-ligand 1; AACR=American Association for Cancer Research; PROs=Patient-reported outcomes
## Tecentriq (atezolizumab, RG7446)

**Anti-PD-L1 cancer immunotherapy – breast cancer**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Previously untreated metastatic triple negative breast cancer (TNBC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td></td>
</tr>
<tr>
<td>Phase III</td>
<td>IMpassion130</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=902</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>ARM A: Tecentriq plus nab-paclitaxel</td>
</tr>
<tr>
<td></td>
<td>ARM B: Placebo plus nab-paclitaxel</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>Progression-free survival and overall survival (co-primary endpoint)</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Study met co-primary endpoint of PFS in both PD-L1+ and ITT populations Q3 2018</td>
</tr>
<tr>
<td></td>
<td>Primary PFS and interim OS data presented at ESMO 2018 and ASCO 2019</td>
</tr>
<tr>
<td></td>
<td>Data published in NEJM 2018; 379:2108-2121</td>
</tr>
<tr>
<td></td>
<td>US accelerated approval Q1 2019 – US indication voluntarily withdrawn Q3 2021</td>
</tr>
<tr>
<td></td>
<td>Approved in EU Q3 2019</td>
</tr>
<tr>
<td></td>
<td>Final OS presented at ESMO Asia 2020</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT02425891</td>
</tr>
</tbody>
</table>

Carbo/gem=gemcitabine and carboplatin; ITT=Intention to treat; PD-L1=Programmed cell death-ligand 1; PFS=Progression-free survival; OS=Overall survival; ESMO=European Society for Medical Oncology; ASCO=American Society of Clinical Oncology; NEJM=New England Journal of Medicine
# Tecentriq (atezolizumab, RG7446)

**Anti-PD-L1 cancer immunotherapy – breast cancer**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Neoadjuvant triple negative breast cancer (TNBC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III IMpassion031</td>
</tr>
<tr>
<td># of patients</td>
<td>N=333</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Tecentriq plus nab-paclitaxel</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Placebo plus nab-paclitaxel</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Percentage of participants with pathologic complete response</td>
</tr>
<tr>
<td>Status</td>
<td>• Study met primary endpoint Q2 2020</td>
</tr>
<tr>
<td></td>
<td>• Data presented at ESMO 2020</td>
</tr>
<tr>
<td></td>
<td>• Data published in Lancet 2020;396 (10257):1090-1100</td>
</tr>
<tr>
<td></td>
<td>• Filed in EU Q4 2020 - application withdrawn Q3 2021</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03197935</td>
</tr>
</tbody>
</table>

*PD-L1=Programmed cell death-ligand 1; ESMO=European Society for Medical Oncology, IDMC=Independent Data Monitoring Committee*
### Venclexta (venetoclax, RG7601)

**Novel small molecule Bcl-2 selective inhibitor – chronic lymphocytic leukemia**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Untreated chronic lymphocytic leukemia (CLL) patients with coexisting medical conditions</th>
<th>Untreated fit chronic lymphocytic leukemia (CLL) patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III CLL14</td>
<td>Phase III CristaLLo</td>
</tr>
<tr>
<td># of patients</td>
<td>N=445</td>
<td>N=165</td>
</tr>
</tbody>
</table>
| Design | • **ARM A**: Venclexta plus Gazyva  
  • **ARM B**: Chlorambucil plus Gazyva | • **ARM A**: Venclexta plus Gazyva  
  • **ARM B**: Fludarabine plus cyclophosphamide plus Rituxan or bendamustine plus Rituxan |
| Primary endpoint | • Progression-free survival | • MRD negativity rate in peripheral blood at 15 months |
| Status | • Study met primary endpoint Q4 2018  
  • BTD granted by FDA Q1 2019  
  • Filed in US (under RTOR) Q1 2019 and EU Q2 2019  
  • Data presented at ASCO 2019, ASH 2019, 2020 and EHA 2021, 2022; 6-year data presented at EHA and ICML 2023  
  • Data published in *NEJM* 2019; 380:2225-2236  
  • Approved US Q2 2019 and EU Q1 2020 | • FPI Q2 2020  
  • Recruitment completed Q1 2023 |
| CT Identifier | NCT02242942 | NCT04285567 |

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

Bcl-2=B-cell lymphoma 2; BTD=Breakthrough therapy designation; MRD=Minimal Residual Disease; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology; EHA=European Hematology Association; RTOR=Real time oncology review; NEJM=New England Journal of Medicine
**Venclexta (venetoclax, RG7601)**

*Novel small molecule Bcl-2 selective inhibitor – multiple myeloma*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Relapsed or refractory multiple myeloma (MM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I</td>
</tr>
<tr>
<td># of patients</td>
<td>N=117</td>
</tr>
<tr>
<td>Design</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose escalation cohort: Venclexta dose escalation</td>
</tr>
<tr>
<td></td>
<td>Safety expansion cohort (t11;14): Venclexta expansion</td>
</tr>
<tr>
<td></td>
<td>Combination cohort: Venclexta plus dexamethasone</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Safety and maximum tolerated dose</td>
</tr>
<tr>
<td>Status</td>
<td>Data presented at ASCO 2015, 2016 and ASH 2016</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT01794520</td>
</tr>
</tbody>
</table>
# Venclexta (venetoclax, RG7601)

**Novel small molecule Bcl-2 selective inhibitor – myelodysplastic syndromes**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Relapsed or refractory myelodysplastic syndromes (MDS)</th>
<th>Treatment-naive myelodysplastic syndromes (MDS)</th>
<th>Newly diagnosed higher-risk myelodysplastic syndrome (MDS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase Ib</td>
<td>Phase Ib</td>
<td>Phase III VERONA</td>
</tr>
<tr>
<td># of patients</td>
<td>N=70</td>
<td>N=129</td>
<td>N=500</td>
</tr>
</tbody>
</table>
| Design | Cohort 1:  
- ARM A: Venclexta 400 mg  
- ARM B: Venclexta 800 mg  
Cohort 2:  
Venclexta plus azacitidine | Dose escalation cohort:  
Venclexta plus azacitidine dose escalation | Safety expansion cohort:  
ARM A: Venclexta plus azacitidine  
ARM B: Placebo plus azacitidine |
| Primary endpoint | Safety, efficacy, Pharmacokinetics and Pharmacodynamics | Safety, Pharmacokinetics, RPTD | Overall survival |
| Status |  
- FPI Q1 2017  
- Recruitment completed Q1 2022  
- Data published in *Am J Hematol* 2023 Feb;98(2):272-281 |  
- FPI Q1 2017  
- Data presented at ASH 2019, 2020 and ASCO 2021  
- BTD granted by FDA July 2021  
- Recruitment completed Q1 2022 |  
- FPI Q4 2020  
- Recruitment completed Q3 2022 |
| CT Identifier | NCT02966782 | NCT02942290 | NCT04401748 |

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute  
Bcl-2=B-cell lymphoma 2; BTD=Breakthrough therapy designation; RPTD=Recommended phase II dose; ASH=American Society of Hematology
Polivy (polatuzumab vedotin, RG7596)
ADC targeting CD79b to treat B cell malignancies

<table>
<thead>
<tr>
<th>Indication</th>
<th>1L DLBCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III POLARIX</td>
</tr>
<tr>
<td># of patients</td>
<td>N=879</td>
</tr>
</tbody>
</table>
| Design                | • ARM A: Polivy plus R-CHP  
                        | • ARM B: R-CHOP |
| Primary endpoint      | Progression-free survival |
| Status                | • Data presented at ASH 2021 and 2022  
                        | • Filed in EU, Japan and China Q4 2021 and in the US Q3 2022 
                        | • Published in NEJM 2022 Jan 27;386(4):351-363  
                        | • Approved in EU Q2 2022, Japan Q3 2022, China Q1 2023 and US April 2023 |
| CT Identifier         | NCT03274492 |

In collaboration with Seagen Inc.
DLBCL=diffuse large B cell lymphoma; R-CHP=Rituxan, cyclophosphamide, hydroxydoxorubicin, prednisone; R-CHOP=Rituxan, cyclophosphamide, doxorubicin, vincristine, and prednisone; ASH=American Society of Hematology, NEJM=New England Journal of Medicine
# Gavreto (pralsetinib, RG6396)  
**Highly selective RET inhibitor**

<table>
<thead>
<tr>
<th>Indication</th>
<th>RET+ NSCLC, thyroid cancer and other advanced solid tumors</th>
<th>1L RET fusion-positive, metastatic NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I/II ARROW</td>
<td>Phase III AcceleRET Lung</td>
</tr>
<tr>
<td># of patients</td>
<td>N=647</td>
<td>N=250</td>
</tr>
<tr>
<td>Design</td>
<td><strong>Part I:</strong> Gavreto 30-600mg dose escalation</td>
<td><strong>ARM A:</strong> Gavreto 400mg</td>
</tr>
<tr>
<td></td>
<td><strong>Part II:</strong> Gavreto 400mg dose expansion</td>
<td><strong>ARM B:</strong> Platinum-based chemotherapy +/- pembrolizumab</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Safety and efficacy</td>
<td>Progression-free survival</td>
</tr>
<tr>
<td>Status</td>
<td>Filed in US and EU for RET fusion-positive NSCLC and US for RET-mutant MTC and RET fusion-positive thyroid cancer</td>
<td>Study initiated in Q1 2020</td>
</tr>
<tr>
<td></td>
<td>Approved in US Q3 2020 in RET fusion-positive NSCLC, in Q4 2020 in RET-mutant MTC and RET fusion-positive thyroid cancer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Updated data presented at ASCO 2021 and 2022</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Approved in EU for RET fusion-positive NSCLC Q4 2021</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Filing withdrawn in EU Q4 2022 for RET-mutant MTC and RET fusion-positive thyroid cancer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>US Approval withdrawn Q2 2023 for RET-mutant medullary thyroid cancer</td>
<td></td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03037385</td>
<td>NCT04222972</td>
</tr>
</tbody>
</table>

In collaboration with Blueprint Medicines  
NSCLC=non-small cell lung cancer; MTC=medullary thyroid cancer; RET=Rearranged during transfection; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology
**Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)**  
**Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously**

<table>
<thead>
<tr>
<th>Indication</th>
<th>3L+ FL, 3L+ DLBCL &amp; other relapsed or refractory NHL</th>
<th>1L DLBCL</th>
<th>Relapsed or refractory DLBCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I/II</td>
<td>Phase Ib/II</td>
<td>Phase Ib/II</td>
</tr>
<tr>
<td># of patients</td>
<td>N=746</td>
<td>N=160</td>
<td>N=262</td>
</tr>
</tbody>
</table>
| Design | • Dose escalation of Lunsumio monotherapy and in combination with Tecentriq  
• Expansion cohorts for r/r FL, r/r DLBCL and SC in r/r NHL  
• Lunsumio plus CHOP  
• Lunsumio plus CHP plus Polivy  
• Lunsumio plus CHP-Polivy vs Rituximab plus CHP-Polivy  
• Lunsumio plus Polivy, randomised cohorts  
• **ARM A:** Lunsumio SC plus Polivy  
• **ARM B:** Rituximab plus Polivy | • Safety, tolerability, dose/schedule, PK and response rates | • Safety/tolerability and response | • Safety/tolerability and response |
| Primary endpoint | | | |
| Status | • Data in r/r NHL presented at ASH 2018, 2019, and in r/r FL at ASH 2020, 2021 and 2022  
• BTD granted by FDA Q2 2020  
• Filed in EU and rolling submission in US Q4 2021; Filed in US (priority review) Q2 2022  
• Approved in EU Q2 2022 and US Q4 2022  
• FL data published in the *Lancet Oncology* 2022 Aug:23(8):1055-1065  
• FPI Q1 2019  
• Recruitment completed Q2 2021  
• Data for Lunsumio plus CHOP presented at ASH 2020  
• FPI Q3 2018  
• Recruitment completed Q1 2023  
• Initial data presented at ASCO 2021 and ASH 2021, 2022 | • FPI Q1 2019  
• Recruitment completed Q2 2021  
• Data for Lunsumio plus CHOP presented at ASH 2020  
• FPI Q3 2018  
• Recruitment completed Q1 2023  
• Initial data presented at ASCO 2021 and ASH 2021, 2022 |
| CT Identifier | NCT02500407 | NCT03677141 | NCT03671018 |

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; r/r=relapsed/refractory; NHL=non-Hodgkin’s lymphoma; R=Rituximab; SC=subcutaneous; CHOP=cyclophosphamide, doxorubicin, vincristine, and prednisone; CHP=cyclophosphamide, doxorubicin, and prednisone; PK=Pharmacokinetics; BTD=Breakthrough Therapy Designation; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology
**Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)**

*Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously*

<table>
<thead>
<tr>
<th>Indication</th>
<th>1L DLBCL &amp; 2L DLBCL following 1L induction</th>
<th>Relapsed or refractory 2L+ FL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I</td>
<td>Phase Ib</td>
</tr>
<tr>
<td># of patients</td>
<td>N=188</td>
<td>N=27</td>
</tr>
<tr>
<td>Design</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Cohort A</strong>: Lunsumio monotherapy (after a response to prior systemic chemotherapy)</td>
<td>• Lunsumio plus lenalidomide safety run-in for phase III</td>
</tr>
<tr>
<td></td>
<td>• <strong>Cohort B</strong>: Lunsumio monotherapy (1L treatment in elderly/frail)</td>
<td>• Lunsumio SC plus lenalidomide</td>
</tr>
<tr>
<td></td>
<td>• <strong>Cohort C</strong>: Lunsumio SC plus Polivy in 1L elderly/unfit</td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Safety/tolerability and response</td>
<td>• Safety/tolerability and response</td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q2 2019 – Cohort B</td>
<td>• FPI Q3 2020</td>
</tr>
<tr>
<td></td>
<td>• FPI Q3 2019 – Cohort A</td>
<td>• Initial data presented at ASH 2021 and 2022</td>
</tr>
<tr>
<td></td>
<td>• FPI Q1 2021 – Cohort C</td>
<td>• Recruitment completed Q2 2023</td>
</tr>
<tr>
<td></td>
<td>• Recruitment completed Q1 2023</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Initial data presented at ASH 2020 (Cohort B) and ASH 2022</td>
<td></td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03677154</td>
<td>NCT04246086</td>
</tr>
</tbody>
</table>

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; SC=subcutaneous; ASH=American Society of Hematology
# Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

**Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously**

<table>
<thead>
<tr>
<th>Indication</th>
<th>2L+ FL</th>
<th>Relapsed or refractory CLL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III CELESTIMO</td>
<td>Phase Ib/II</td>
</tr>
<tr>
<td># of patients</td>
<td>N=400</td>
<td>N=56</td>
</tr>
</tbody>
</table>
| Design | • ARM A: Lunsumio plus lenalidomide  
• ARM B: Rituxan plus lenalidomide | • Lunsumio monotherapy (3L+ CLL) |
| Primary endpoint | • Progression-free survival | • Safety, dose-limiting toxicity and RPTD |
| Status | • FPI Q4 2021 | • FPI Q1 2022 |
| CT Identifier | NCT04712097 | NCT05091424 |

FL=follicular lymphoma; r/r=relapsed/refractory; RPTD=Recommended Phase II Dose; CLL=Chronic lymphocytic leukemia
# Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

*Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously*  

<table>
<thead>
<tr>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2L+ SCT ineligible DLBCL</strong></td>
</tr>
</tbody>
</table>

| Phase/study | Phase III  
|-------------|-----------  
| **SUNMO** |  

| # of patients | N=222  
|---------------|-----  

<table>
<thead>
<tr>
<th>Design</th>
</tr>
</thead>
</table>
| - **ARM A**: Lunsumio plus Polivy  
| - **ARM B**: R + GemOx |  

<table>
<thead>
<tr>
<th>Primary endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Progression-free survival</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>- FPI Q2 2022</td>
</tr>
</tbody>
</table>

| CT Identifier | NCT05171647 |  

---

DLBCL=diffuse large B cell lymphoma; SCT=stem cell transplant; R=Rituxan/MabThera; GemOx=Gemcitabin und Oxaliplatin
**Columvi (glofitamab, CD20-TCB, RG6026)**

*Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Relapsed or refractory Non-Hodgkin’s lymphoma (NHL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase I</td>
</tr>
<tr>
<td># of patients</td>
<td>N=700</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td></td>
</tr>
</tbody>
</table>
| | **Cohort 1**: Single-agent dose escalation study | | **Columvi SC**  
**Part 1 dose escalation** |
| | • Initial dose escalation  
• Expansion cohort in r/r DLBCL  
• Expansion cohort in r/r FL  
• All patients will receive pretreatment with a single dose of Gazyva (1000mg) |
| | **Cohort 2**: Columvi plus Gazyva (i.e. continuous treatment with Gazyva) | | |
| | **Primary endpoint** | | |
| | • Efficacy, safety, tolerability and PK | | • Safety |
| | | | | • ARM A: FPI Q2 2018  
• ARM B: FPI Q4 2020  
• Recruitment completed Q2 2022  
• Data presented at ASH 2019, 2021 |
| | **Status** | | |
• Filed in EU Q2 2022 and US Q4 2022  
• Approved in Canada Q1 2023, US Q2 2023 and EU July 2023 | | • FPI Q3 2021 |
| | **CT Identifier** | NCT03075696 | NCT03533283 | ISRCTN17975931 |

DLBCL = diffuse large B cell lymphoma; FL = Follicular lymphoma; r/r = Relapsed or refractory; SC = subcutaneous; PK = Pharmacokinetics; ASCO = American Society of Clinical Oncology; ASH = American Society of Hematology; EHA = European Hematology Association; ICML = International Conference on Malignant Lymphoma; NEJM = New England Journal of Medicine
**Columvi (glofitamab, CD20-TCB, RG6026)**

*Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Non-Hodgkin’s lymphoma (NHL)</th>
<th>2L+ SCT-ineligible DLBCL</th>
<th>1L ctDNA high risk DLBCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase Ib</td>
<td>Phase III STARGLO</td>
<td>Phase II</td>
</tr>
<tr>
<td># of patients</td>
<td>Part I: 15-60</td>
<td>N=270</td>
<td>N=40</td>
</tr>
<tr>
<td></td>
<td>Part II: ~66-104</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Design      | • **Part I:** Dose-finding for the combination of Columvi plus G/R-CHOP in r/r indolent NHL  
  • **Part II:** Dose expansion Columvi plus G/R-CHOP or R-CHOP in 1L DLBCL  
  • **Part III:** Columvi plus R-CHOP plus Polivy  
  | • **ARM A:** Columvi plus gemcitabine and oxaliplatin, followed by up to 4 cycles of Columvi monotherapy  
  • **ARM B:** Rituxan in combination with gemcitabine and oxaliplatin  
  A single dose of Gazyva will be administered 7 days prior to the first dose of Columvi  
  | • Columvi plus R-CHOP (Columvi is introduced as a consolidation to R-CHOP at cycle 3-8 in patients ctDNA+ at cycle 2)  
| Primary endpoint | • Safety                    | • Overall survival       | • EOT PET-CR            |
| Status      | • Part I: FPI Q1 2018  
  • Part II: FPI Q1 2021  
  • Recruitment completed Q1 2023  
  • Data presented at ASH 2021, 2022 and ASCO 2023  
  | • FPI Q1 2021  
  • Recruitment completed Q1 2023  
  | • FPI Q1 2022  
| CT Identifier | NCT03467373                  | NCT04408638               | NCT04980222             |

DLBCL=diffuse large B cell lymphoma; SCT=stem cell transplant; CHOP=cyclophosphamide, doxorubicin, vincristine and prednisone; R=Rituxan/MabThera; G=Gazyva; NHL=Non-Hodgkin’s lymphoma; ctDNA=circulating tumor DNA; ASH=American Society of Hematology; EOT PET-CR=End of treatment PET-complete response rate
### Columvi (glofitamab, CD20-TCB, RG6026)

**Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously**

<table>
<thead>
<tr>
<th>Indication</th>
<th>2L+ SCT-eligible DLBCL</th>
<th>2L+ SCT-eligible DLBCL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase Ib</td>
<td>Phase Ib</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=40</td>
<td>N=112</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>• Columvi plus R-ICE (single-arm study)</td>
<td>• Columvi IV plus CELMoD (CC-220 and CC-99282) &lt;br&gt; • Lunsumio SC plus CELMoD (CC-220 and CC-99282)</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>• Objective response rate within 3 cycles</td>
<td>• Safety, DLT, RPTD</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>• FPI Q4 2022</td>
<td>• FPI Q4 2022</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT05364424</td>
<td>NCT05169515</td>
</tr>
</tbody>
</table>

DLBCL = diffuse large B cell lymphoma; DLT = Dose-limiting toxicity; RPTD = Recommended Phase II Dose; R-ICE = Rituxan plus ifosfamide, carboplatin, and etoposide; IV = Intravenous; SC = Subcutaneous
# Ocrevus (ocrelizumab, RG1594)

**Humanized monoclonal antibody selectively targeting CD20+ B cells**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Relapsing multiple sclerosis (RMS)</th>
<th>Primary progressive multiple sclerosis (PPMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III OPERA I</td>
<td>Phase III OPERA II</td>
</tr>
<tr>
<td># of patients</td>
<td>N=821</td>
<td>N=835</td>
</tr>
<tr>
<td>Design</td>
<td>96-week treatment period:</td>
<td>120-week treatment period:</td>
</tr>
<tr>
<td></td>
<td>• ARM A: Ocrevus 2x300mg IV followed by 600mg IV q24w</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ARM B: Interferon β-1a (Rebif)</td>
<td>• ARM A: Ocrevus 2x300mg IV q24w</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• ARM B: Placebo</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Annualized relapse rate at 96 weeks versus Rebif</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Annualized relapse rate at 96 weeks versus Rebif</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Sustained disability progression versus placebo by EDSS</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>• Primary endpoint met Q2 2015, OLE ongoing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data presented at ECTRIMS 2015, AAN and ECTRIMS 2017, AAN and EAN 2018</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data published in NEJM 2017; 376:221-234</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data published on COVID-19 in Mult Scler Relat Disord on Ocrevus treated people with MS, doi.org/10.1016/j.msard.2020.102725</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Primary endpoint met Q3 2015</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data presented at ECTRIMS 2015, AAN and ECTRIMS 2017, AAN and EAN 2018</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data published in NEJM 2017; 376:209-220</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Approved in US Q1 2017 and EU Q1 2018</td>
<td></td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT01247324</td>
<td>NCT01412333</td>
</tr>
</tbody>
</table>

IV=intravenous; EDSS=Expanded Disability Status Scale; OLE=Open label extension; ECTRIMS=European Committee for Treatment and Research in Multiple Sclerosis; AAN=Annual Meeting of the American Academy of Neurology; EAN=European Academy of Neurology; NEJM=New England Journal of Medicine
# Ocrevus (ocrelizumab, RG1594)

**Humanized monoclonal antibody selectively targeting CD20+ B cells**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Relapsing and primary progressive multiple sclerosis (RMS &amp; PPMS)</th>
<th>Primary progressive multiple sclerosis (PPMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase IIIb ENSEMBLE PLUS</td>
<td>Phase IIIb ORATORIO-HAND</td>
</tr>
<tr>
<td># of patients</td>
<td>N=1,225</td>
<td>N ~ 1,000</td>
</tr>
<tr>
<td>Design</td>
<td>Substudy of ongoing phase IIIb, open-label, single-arm ENSEMBLE study</td>
<td>120-week treatment period:</td>
</tr>
<tr>
<td></td>
<td>Shorter two-hour infusion time</td>
<td>ARM A: Ocrevus 600mg IV q24w</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARM B: Placebo</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Safety, measured by the proportion of patients with IRRs following the first randomised 600 mg infusion</td>
<td>Time to upper limb disability progression confirmed for at least 12 weeks</td>
</tr>
<tr>
<td>Status</td>
<td>Filed in US and EU Q1 2020</td>
<td>FPI Q3 2019</td>
</tr>
<tr>
<td></td>
<td>Approved in EU Q2 2020 and US Q4 2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data published <em>Neurol</em>, <em>Neuroimmunol</em> and <em>Neuroinflamm</em> Sept 2020; 7(5), e807</td>
<td></td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03085810</td>
<td>NCT04035005</td>
</tr>
</tbody>
</table>

IV=intravenous; IRR=Infusion Related Reaction
# Ocrevus (ocrelizumab, RG1594)

**Humanized monoclonal antibody selectively targeting CD20+ B cells**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Primary progressive multiple sclerosis (PPMS)</th>
<th>Relapsing multiple sclerosis (RMS)</th>
<th>PPMS &amp; RMS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase IIIb GAVOTTE</td>
<td>Phase IIIb MUSETTE</td>
<td>Phase III Ocarina II¹</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N ~ 699</td>
<td>N ~ 786</td>
<td>N ~ 232</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>120-week treatment period:</td>
<td>120-week treatment period:</td>
<td>120-week treatment period:</td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM A</strong>: Ocrevus 600mg IV q24w</td>
<td>• <strong>ARM A</strong>: Ocrevus 600mg IV q24w</td>
<td>• <strong>ARM A</strong>: Ocrevus IV</td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM B</strong>: Ocrevus 1200mg if BW &lt;75kg or 1800mg if BW ≥75kg q24w</td>
<td>• <strong>ARM B</strong>: Ocrevus 1200mg if BW &lt;75kg or 1800mg if BW ≥75kg q24w</td>
<td>• <strong>ARM B</strong>: Ocrevus SC</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>• Superiority of Ocrevus higher dose versus approved dose on cCDP</td>
<td>• Superiority of Ocrevus higher dose versus approved dose on cCDP</td>
<td>• Serum Ocrevus area under the concentration-time curve (AUCW1-12) at week 12</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>• FPI Q4 2020</td>
<td>• FPI Q4 2020</td>
<td>• FPI Q2 2022</td>
</tr>
<tr>
<td></td>
<td>• Recruitment completed Q2 2023</td>
<td>• Recruitment completed Q4 2021</td>
<td>• Recruitment completed Q4 2022</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT04548999</td>
<td>NCT04544436</td>
<td>NCT05232825</td>
</tr>
</tbody>
</table>

¹SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase
cCDP=composite confirmed disability progression; IV=intravenous; SC=Subcutaneous
**Evrysdi (risdiplam, RG7916)**

**Oral SMN2 splicing modifier**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Phase II/III</th>
<th>Phase II/III</th>
<th>Phase II</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FIREFISH</strong></td>
<td>N=21 (Part 1), 41 (Part 2)</td>
<td>N=51 (Part 1), 180 (Part 2)</td>
<td>N=174</td>
</tr>
</tbody>
</table>
| **SUNFISH** | Infants with type 1 SMA  
Part I (dose-finding): ≥4 weeks  
Part II (confirmatory): 24 months | Adult & pediatric patients with type 2 or 3 SMA:  
Part I (dose-finding): At least 12 weeks  
Part II (confirmatory): 24 months | Adult and pediatric patients with previously treated SMA type 1, 2 and 3 |
| **JEWELFISH** | Adult & pediatric patients with type 2 or 3 SMA:  
Part I (dose-finding): ≥4 weeks  
Part II (confirmatory): 24 months | | |

### Design
- **Primary endpoint**
  - Safety, tolerability, PK/PD and efficacy
  - Safety, tolerability, PK/PD and efficacy
  - Safety, tolerability, PK/PD

### Status
- **Part I data published in NEJM 2021; 384:915-923**
- **Part II data published in NEJM 2021; 385:427-435**
- **3-year data presented at EPNS 2022 and 4-year data presented at Cure SMA and EAN 2023**

- **Part I 12-month data presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019**
- **Part II 1-year data presented at AAN 2020, Part I 2-year data at WMS 2020**
- **Part I data published in NEJM 2021; 384:915-923**
- **Part II 2-year data presented at AAN 2021**
- **Part II 1-year data published in NEJM 2021; 385:427-435**

- **Part II 1-year data published in Lancet Neurology, 2022; 21 (1) 42-52**
- **Part II 1-year data presented at SMA Europe 2020, 2-year data at MDA 2021, 3-year data at MDA 2022 and 4-year data at MDA and EAN 2023**
- **Part II 1-year data presented in CureSMA Annual SMA Conference; EPNS = European Paediatric Neurology Society; ODD = Orphan drug designation**

### CT Identifier
- NCT02913482
- NCT02908685
- NCT03032172

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In collaboration with PTC Therapeutics and SMA Foundation

SMA=Spinal muscular atrophy; SMN=survival motor neuron; PK/PD=Pharmacokinetics/Pharmacodynamics; PRIME=priority medicines; AAN=American Academy of Neurology; WMS=World Muscle Society; EAN=European Academy of Neurology; NEJM=New England Journal of Medicine; MDA=Muscular Dystrophy Association; CureSMA=Annual SMA Conference; EPNS=European Paediatric Neurology Society; ODD=Orphan drug designation
# Evryrsdi (risdiplam, RG7916)

**Oral SMN2 splicing modifier**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Spinal muscular atrophy (SMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II RAINBOWFISH</td>
</tr>
<tr>
<td># of patients</td>
<td>N=25</td>
</tr>
<tr>
<td>Design</td>
<td>Infants aged from birth to 6 weeks who have been genetically diagnosed with SMA but are not yet presenting with symptoms</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Proportion of participants with two copies of the SMN2 gene and baseline CMAP&gt;=1.5 millivolt who are sitting without support</td>
</tr>
</tbody>
</table>
| Status | FPI Q3 2019  
Recruitment completed Q1 2022  
Initial data presented at CureSMA, WMS 2021, MDA and WMS 2022  
Filed in US and EU Q4 2021  
Approved in US Q2 2022 |
| CT Identifier | NCT03779334 |

In collaboration with PTC Therapeutics and SMA Foundation  
SMN=survival motor neuron; CMAP=compound muscle action potential; WMS=World Muscle Society; CureSMA=Annual SMA Conference; MDA=Muscular Dystrophy Association;
## Enspryng (satralizumab, RG6168, SA237)

*Anti-IL-6 receptor humanized monoclonal antibody*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Neuromyelitis optica spectrum disorder (NMOSD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td><strong>Phase III SAKuraStar</strong></td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=95</td>
</tr>
</tbody>
</table>
| **Design** | Enspryng monotherapy:  
  - **ARM A**: Enspryng 120mg SC monthly  
  - **ARM B**: Placebo SC monthly | Add-on therapy of Enspryng:  
  - **ARM A**: Enspryng 120mg SC monthly  
  - **ARM B**: Placebo SC monthly  
  - Both arms on top of baseline therapies: azathioprine, mycophenolate mofetil or oral corticosteroids |
| **Primary endpoint** | Efficacy (time to first relapse), safety and PK/PD | Efficacy (time to first relapse), safety and PK/PD |
| **Status** |  
  - Primary endpoint met Q4 2018  
  - Data presented at ECTRIMS 2019  
  - Published in Lancet Neurology 2020; 19(5): 402-412 |  
  - Primary endpoint met Q3 2018  
  - Data presented at ECTRIMS 2018 and AAN 2019  
  - Published in *NEJM* 2019; 381:2114-2124  
  - BTD granted by FDA Q4 2018  
  - Filed in EU Q3 2019; US acceptance of filing Q4 2019  
  - Approved in US Q3 2020 and EU Q2 2021 |
| **CT Identifier** | NCT02073279 | NCT02028884 |

**Trials managed by Chugai (Roche opted-in)**

BTD=Breakthrough therapy designation; PK/PD=Pharmacokinetics/Pharmacodynamics; SC=Subcutaneous; ECTRIMS=European Committee for Treatment and Research in Multiple Sclerosis; AAN=American Academy of Neurology; NEJM=New England Journal of Medicine
# Enspryng (satralizumab, RG6168, SA237)

## Anti-IL-6 receptor humanized monoclonal antibody

<table>
<thead>
<tr>
<th>Indication</th>
<th>Generalised myasthenia gravis (MG)</th>
<th>Myelin oligodendrocyte glycoprotein antibody disease (MOG-AD)</th>
<th>Autoimmune encephalitis (AIE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III Luminesce</td>
<td>Phase III METEOROID</td>
<td>Phase III CIELO</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=240</td>
<td>N=152</td>
<td>N=152</td>
</tr>
</tbody>
</table>
| **Design** | • ARM A: Enspryng plus standard of care  
• ARM B: Placebo plus standard of care | • ARM A: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses q4w  
• ARM B: Placebo | • ARM A: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses q4w  
• ARM B: Placebo |
| **Primary endpoint** | • Mean change from baseline in total MG-ADL score at week 24 in AChR+ population | • Time from randomization to the first occurrence of a MOG-AD relapse | • Efficacy (proportion of participants with mRS score improvement ≥ 1 from baseline and no use of rescue therapy at week 24) and safety |
| **Status** | • ODD granted in US Q1 2021  
• FPI Q4 2021 | • FPI Q3 2022  
• ODD granted by FDA in Q4 2021 | • FPI Q3 2022  
• ODD granted for NMDAR AIE in US Q3 22 |
| **CT Identifier** | NCT04963270 | NCT05271409 | NCT05503264 |

In collaboration with Chugai

MG-ADL= Myasthenia Gravis Activities of Daily Living; AChR=Acetylcholine receptor; MOG-AD=Myelin Oligodendrocyte Glycoprotein Antibody Disease, mRS=Modified Rankin Scale; AIE=Autoimmune encephalitis; NMDAR AIE= Anti-N-Methyl-D-Aspartic Acid Receptor Autoimmune Encephalitis; ODD=Orphan drug designation
**TNKase (RG3625, tenecteplase)**

*Small molecule tissue plasminogen activator*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Stroke patients between 4.5 and 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III TIMELESS</td>
</tr>
<tr>
<td># of patients</td>
<td>N=456</td>
</tr>
</tbody>
</table>
| Design | - **ARM A:** Tenecteplase (0.25 mg/kg, maximum 25 mg) single bolus injection  
- **ARM B:** Placebo |
| Primary endpoint | Ordinal modified Rankin scale (mRS) score after 90 days |
| Status | - FPI Q1 2019  
- Recruitment completed Q4 2022  
- Study did not meet its primary endpoint Q2 2023 |
| CT Identifier | NCT03785678 |
# Gazyva (obinutuzumab, RG7159)

## Immunology development program

<table>
<thead>
<tr>
<th>Indication</th>
<th>Lupus nephritis</th>
<th>Membranous nephropathy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II NOBILITY</td>
<td>Phase III REGENCY</td>
</tr>
<tr>
<td># of patients</td>
<td>N=126</td>
<td>N=252</td>
</tr>
<tr>
<td>Design</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• ARM A: Gazyva 1000mg IV plus MFF/mycophenolic acid</td>
<td>• ARM A: Gazyva 1000mg IV (6 doses through Week 52) plus MFF</td>
<td>• ARM A: Gazyva 1000mg IV on top of renin-angiotensin inhibitors</td>
</tr>
<tr>
<td>• ARM B: Placebo IV plus MFF/mycophenolic acid</td>
<td>• ARM B: Gazyva 1000 mg IV (5 doses through Week 52) plus MFF</td>
<td>• ARM B: Tacrolimus treatment for 12 months</td>
</tr>
<tr>
<td>• ARM C: Placebo IV plus MFF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Percentage of participants who achieve complete renal response (CRR)</td>
<td>• Percentage of participants who achieve complete renal response (CRR)</td>
<td>• Percentage of patients who achieve complete remission at week 104</td>
</tr>
<tr>
<td>Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Primary endpoint met Q2 2019</td>
<td>• FPI Q3 2020</td>
<td>• FPI Q2 2021</td>
</tr>
<tr>
<td>• BTD granted by the FDA Q3 2019</td>
<td>• Recruitment completed Q1 2023</td>
<td></td>
</tr>
<tr>
<td>• Data presented at ASN and ACR 2019</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Published in <em>Ann Rheum Dis</em> 2022 Jan;81(1):100-107</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT02550652</td>
<td>NCT04221477</td>
</tr>
</tbody>
</table>

In collaboration with Biogen

BTD=Breakthrough therapy designation; IV=Intravenous; ASN=American Society of Nephrology; ACR=American College of Rheumatology; MFF=mycophenolate mofetil
# Gazyva (obinutuzumab, RG7159)

## Immunology development program

<table>
<thead>
<tr>
<th>Indication</th>
<th>Systemic lupus erythematosus (SLE)</th>
<th>Childhood onset idiopathic nephrotic syndrome*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III ALLEGORY</td>
<td>Phase III INShore</td>
</tr>
<tr>
<td># of patients</td>
<td>N=200</td>
<td>N=80</td>
</tr>
<tr>
<td>Design</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
|  | ARM A: Gazyva 1000mg IV on Day 1 and Weeks 2, 24 and 26.  
ARM B: Placebo IV | ARM A: Gazyva plus oral steroids  
ARM B: Mycophenolate mofetil (MMF) plus oral steroids |
| Primary endpoint | Percentage of participants who achieve Systemic Lupus Erythematosus Responder Index (SRI) at week 52 | Percentage of participants with sustained complete remission at 1 year |
| Status | FPI Q4 2021 | FPI Q1 2023 |
| CT Identifier | NCT04963296 | NCT05627557 |

In collaboration with Biogen

*also known as pediatric nephrotic syndrome (PNS); IV=Intravenous
# Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

**Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Systemic lupus erythematosus (SLE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I</td>
</tr>
<tr>
<td># of patients</td>
<td>N=50</td>
</tr>
</tbody>
</table>
| Design      | • ARM A: Lunsumio SC on either Day 1 or on Days 1 and 8  
             | • ARM B: Fractionated (divided) dose of Lunsumio SC on Days 1 and 8 |
| Primary endpoint | Safety                           |
| Status      | • FPI Q1 2022                      |
| CT Identifier | NCT05155345                      |
**Xolair (omalizumab, RG3648)**

*Humanized monoclonal antibody that selectively binds to IgE*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Food allergy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Phase/study</th>
<th>Phase III OUTMATCH¹</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th># of patients</th>
<th>N=225</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Design</th>
<th>Xolair by SC injection either q2w or q4w for 16 to 20 weeks</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Primary endpoint</th>
<th>Number of participants who successfully consume ≥600mg of peanut protein without dose-limiting symptoms</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Status</th>
<th>FPI Q3 2019</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>CT Identifier</th>
<th>NCT03881696</th>
</tr>
</thead>
</table>

In collaboration with Novartis; ¹ Sponsor of the study is the National Institute of Allergy and Infectious Diseases (NIAID)

IgE=Immunoglobulin E; SC=Subcutaneous
# Susvimo (PDS, RG6321)

**First eye implant to achieve sustained delivery of a biologic medicine**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Wet age-related macular degeneration (wAMD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III Archway</td>
</tr>
<tr>
<td># of patients</td>
<td>N=418</td>
</tr>
<tr>
<td>Design</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>ARM A:</strong> PDSq24w</td>
</tr>
<tr>
<td></td>
<td><strong>ARM B:</strong> Intravitreal ranibizumab q4w</td>
</tr>
<tr>
<td></td>
<td>Patients from LADDER or Archway receive refills of ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change in BCVA from baseline at the average of week 36 and week 40</td>
</tr>
<tr>
<td>Status</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Study met primary endpoint Q2 2020</td>
</tr>
<tr>
<td></td>
<td>Data presented at ASRS 2020, 44/48 week data at Angiogenesis 2021 and 2-year data at Angiogenesis 2022</td>
</tr>
<tr>
<td></td>
<td>Filed in US (PRIME) and EU Q2 2021</td>
</tr>
<tr>
<td></td>
<td>Approved in US Q4 2021</td>
</tr>
</tbody>
</table>

**CT Identifier**

| NCT03677934 | NCT03683251 | NCT04657289 |

**BCVA=best corrected visual acuity; wAMD=wet age-related macular degeneration; ASRS=American Society of Retinal Specialists; PDS=Port Delivery System with ranibizumab; PRIME=Priority review**
## Susvimo (PDS, RG6321)

**First eye implant to achieve sustained delivery of a biologic medicine**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Diabetic macular edema (DME)</th>
<th>Diabetic retinopathy (DR) without center-involved diabetic macular edema (DME)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III Pagoda</td>
<td>Phase III Pavilion</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=545</td>
<td>N=160</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>• <strong>ARM A:</strong> PDS q24w</td>
<td>• <strong>ARM A:</strong> Intravitreal ranibizumab (X2) followed by PDS implant (refill q36w)</td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM B:</strong> Intravitreal ranibizumab q4w</td>
<td>• <strong>ARM B:</strong> Q4w comprehensive clinical monitoring until participants receive PDS (refill q36w)</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>• Change in BCVA from baseline at the average of week 48 and week 52</td>
<td>• Percentage of participants with a ≥2-step improvement from baseline on the ETDRS-DRSS at Week 52</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>• FPI Q3 2019</td>
<td>• FPI Q3 2020</td>
</tr>
<tr>
<td></td>
<td>• Recruitment completed Q2 2021</td>
<td>• Recruitment completed Q3 2021</td>
</tr>
<tr>
<td></td>
<td>• Study met its primary endpoint Q4 2022</td>
<td>• Study met its primary endpoint Q4 2022</td>
</tr>
<tr>
<td></td>
<td>• Data presented at Angiogenesis 2023</td>
<td>• Data presented at Angiogenesis 2023</td>
</tr>
</tbody>
</table>

| **CT Identifier**                              | NCT04108156                                                                                 | NCT04503551                                                                  |

BCVA=best corrected visual acuity; ETDRS=Early Treatment Diabetic Retinopathy Study; DRSS=Diabetic Retinopathy Severity Scale; PDS=Port Delivery System with ranibizumab
### Vabysmo (faricimab, RG7716)

**Bispecific antibody to simultaneously bind Ang-2 and VEGF-A**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Center-involving diabetic macular edema (CI-DME)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phase III YOSEMITE</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=940</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ARM A: Faricimab q8w</td>
</tr>
<tr>
<td></td>
<td>ARM B: Faricimab PTI up to q16w</td>
</tr>
<tr>
<td></td>
<td>ARM C: Aflibercept, q8w</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change from baseline in BCVA at 1 year</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Study met primary endpoint Q4 2020</td>
</tr>
<tr>
<td></td>
<td>Data presented at Angiogenesis 2021</td>
</tr>
<tr>
<td></td>
<td>Filed in US and EU Q2 2021</td>
</tr>
<tr>
<td></td>
<td>Published in the Lancet 2022 Feb 19;399(10326):741-755.</td>
</tr>
<tr>
<td></td>
<td>2-year data presented at Angiogenesis 2022</td>
</tr>
<tr>
<td></td>
<td>Approved in US Q1 2022 and EU Q3 2022</td>
</tr>
<tr>
<td></td>
<td>Post-hoc data indicating fast retinal drying presented at ARVO 2023</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT03622580</td>
</tr>
</tbody>
</table>

Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor; PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity, ARVO=Association for Research in Vision and Ophthalmology
**Vabysmo (faricimab, RG7716)**

*Bispecific antibody to simultaneously bind Ang-2 and VEGF-A*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Wet age related macular degeneration (wAMD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III TENAYA</td>
</tr>
<tr>
<td># of patients</td>
<td>N=671</td>
</tr>
<tr>
<td>Design</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ARM A: Faricimab 6.0mg q16w flexible after 4 IDs</td>
</tr>
<tr>
<td></td>
<td>ARM B: Aflibercept 2.0mg q8w after 3 IDs</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change from baseline in BCVA week 40, 44 &amp; 48</td>
</tr>
<tr>
<td>Status</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Study met primary endpoint Q1 2021</td>
</tr>
<tr>
<td></td>
<td>Data presented at Angiogenesis 2021</td>
</tr>
<tr>
<td></td>
<td>Filed in US and EU Q2 2021</td>
</tr>
<tr>
<td></td>
<td>Published in Lancet 2022 Feb 19;399(10326):729-740</td>
</tr>
<tr>
<td></td>
<td>Approved in US Q1 2022 and EU Q3 2022</td>
</tr>
<tr>
<td></td>
<td>2-year data presented at ASRS 2022</td>
</tr>
<tr>
<td></td>
<td>Post-hoc data indicating fast retinal drying presented at ARVO 2023</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03823287</td>
</tr>
</tbody>
</table>

BCVA=best corrected visual acuity; Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor; IDs=initiating doses; ASRS=American Society of Retina Specialists, ARVO=Association for Research in Vision and Ophthalmology
# Vabysmo (faricimab, RG7716)

**Bispecific antibody to simultaneously bind Ang-2 and VEGF-A**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Macular edema (ME) secondary to branch retinal vein occlusion (RVO)</th>
<th>Macular edema (ME) secondary to central retinal vein occlusion (RVO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III BALATON</td>
<td>Phase III COMINO</td>
</tr>
<tr>
<td># of patients</td>
<td>N=570</td>
<td>N=750</td>
</tr>
<tr>
<td>Design</td>
<td><strong>ARM A</strong>: Faricimab, q4w/PTI</td>
<td><strong>ARM A</strong>: Faricimab, q4w/PTI</td>
</tr>
<tr>
<td></td>
<td><strong>ARM B</strong>: Aflibercept, q4w</td>
<td><strong>ARM B</strong>: Aflibercept, q4w</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td><strong>Change from baseline in BCVA at week 24</strong></td>
<td><strong>Change from baseline in BCVA at week 24</strong></td>
</tr>
<tr>
<td>Status</td>
<td><strong>FPI Q1 2021</strong></td>
<td><strong>FPI Q1 2021</strong></td>
</tr>
<tr>
<td></td>
<td>Recruitment completed Q1 2022</td>
<td>Recruitment completed Q1 2022</td>
</tr>
<tr>
<td></td>
<td>Study met its primary endpoint Q4 2022</td>
<td>Study met its primary endpoint Q4 2022</td>
</tr>
<tr>
<td></td>
<td>Data presented at Angiogenesis 2023</td>
<td>Data presented at Angiogenesis 2023</td>
</tr>
<tr>
<td></td>
<td>Filed in US Q2 2023</td>
<td>Filed in US Q2 2023</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT04740905</td>
<td>NCT04740931</td>
</tr>
</tbody>
</table>

PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity; Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor
<table>
<thead>
<tr>
<th>Indication</th>
<th>Influenza</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td></td>
</tr>
<tr>
<td>Phase III miniSTONE 1 (0-1 year old)</td>
<td>Phase III miniSTONE 2 (1-&lt;12 years old)</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=30</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Healthy pediatric patients from birth to &lt;1 year with influenza-like symptoms receive Xofluza on Day 1</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>Safety</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>FPI Q1 2019</td>
</tr>
<tr>
<td></td>
<td>Filed in US Q1 2020 and EU Q4 2021</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT03653364</td>
</tr>
</tbody>
</table>
Roche Group development pipeline

Marketed products development programmes

**Roche Pharma global development programmes**

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
## Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

**Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT**

<table>
<thead>
<tr>
<th>Indication</th>
<th>1L NSCLC PD-L1 TPS&gt;50%</th>
<th>Stage III unresectable 1L NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III SKYSCRAPER-01</td>
<td>Phase III SKYSCRAPER-03</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=500-560</td>
<td>N=800</td>
</tr>
</tbody>
</table>
| **Design** | • **ARM A:** Tiragolumab plus Tecentriq  
• **ARM B:** Placebo plus Tecentriq | • **ARM A:** Tiragolumab plus Tecentriq for up to 12 months  
• **ARM B:** Durvalumab for up to 12 months |
| **Primary endpoint** | Overall survival and progression-free survival | Progression-free survival |
| **Status** | • FPI Q1 2020  
• Recruitment completed Q3 2021  
• Study did not meet one of its primary endpoints, PFS, Q2 2022 | • FPI Q3 2020  
• Recruitment completed Q2 2023 |
| **CT Identifier** | NCT04294810 | NCT04513925 |

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; TPS=Tumor Proportion Score; PFS=Progression-free survival
## Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

**Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Metastatic and/or recurrent PD-L1+ cervical cancer (CC)</th>
<th>Neoadjuvant and adjuvant NSCLC</th>
<th>1L non-squamous NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II SKYSCRAPER-04</td>
<td>Phase II SKYSCRAPER-05</td>
<td>Phase III SKYSCRAPER-06</td>
</tr>
<tr>
<td># of patients</td>
<td>N=172</td>
<td>N=82</td>
<td>N=540</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Tiragolumab plus Tecentriq</td>
<td>• ARM A: (PD-L1 high) neoadjuvant tiragolumab plus Tecentriq followed by adjuvant tiragolumab plus Tecentriq or adjuvant chemotherapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ARM B: Tecentriq</td>
<td>• ARM B: (PD-L1 all-comers) neoadjuvant tiragolumab plus Tecentriq plus chemo followed by adjuvant tiragolumab plus Tecentriq</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ARM A: Tiragolumab plus Tecentriq plus pemetrexed plus chemotherapy followed by maintenance tiragolumab plus Tecentriq plus pemetrexed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ARM B: Placebo plus pembrolizumab plus pemetrexed plus chemotherapy followed by maintenance placebo plus pembrolizumab plus pemetrexed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Objective response rate</td>
<td>• Pathologic complete response, major pathological response and safety</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• FPI Q2 2020</td>
<td>• Objective response rate, progression-free survival and overall survival</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q2 2020</td>
<td>• FPI Q2 2021</td>
<td>• FPI Q4 2020</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT04300647</td>
<td>NCT04832854</td>
<td>NCT04619797</td>
</tr>
</tbody>
</table>

**NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1**
**Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)**

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

<table>
<thead>
<tr>
<th>Indication</th>
<th>Locally advanced esophageal cancer (EC)</th>
<th>1L esophageal cancer (EC)</th>
<th>1L recurrent/metastatic PD-L1 positive squamous cell head and neck carcinoma (SCCHN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III SKYSCRAPER-07</td>
<td>Phase III SKYSCRAPER-08</td>
<td>Phase II SKYSCRAPER-09</td>
</tr>
<tr>
<td># of patients</td>
<td>N=750</td>
<td>N=500</td>
<td>N=120</td>
</tr>
</tbody>
</table>
| Design | • ARM A: Tiragolumab plus Tecentriq  
• ARM B: Tecentriq plus placebo  
• ARM C: Placebo plus placebo | • ARM A: Tiragolumab plus Tecentriq plus cisplatin and paclitaxel  
• ARM B: Placebo plus placebo plus cisplatin and paclitaxel | • ARM A: Tiragolumab plus Tecentriq  
• ARM B: Tecentriq plus placebo |
| Primary endpoint | • Progression-free survival (A vs C)  
• Overall survival (A vs C, hierarchical, B vs C hierarchical) | • Overall survival and progression-free survival | • Objective response rate |
| Status | • FPI Q3 2020 | • FPI Q4 2020  
• Recruitment completed Q4 2021 | • FPI Q1 2021  
• Recruitment completed Q2 2022 |
| CT Identifier | NCT04543617 | NCT04540211 | NCT04665843 |

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1
## Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)
### Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

<table>
<thead>
<tr>
<th>Indication</th>
<th>Locally advanced, recurrent or metastatic solid tumors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase II SKYSCRAPER-11</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=60</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>• Tiragolumab plus Tecentriq IV FDC</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>• Safety</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>• FPI Q2 2023</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT05661578</td>
</tr>
</tbody>
</table>

**NSCLC**=Non-small cell lung cancer; **FDC**=Fixed-dose combination; **IV**=Intravenous
Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)
Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

<table>
<thead>
<tr>
<th>Indication</th>
<th>Solid tumors</th>
<th>NSCLC</th>
<th>Relapsed or refractory multiple myeloma (MM) or r/r B-cell NHL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I</td>
<td>Phase II CITYSCAPE</td>
<td>Phase I</td>
</tr>
<tr>
<td># of patients</td>
<td>N=540</td>
<td>N=135</td>
<td>N=52</td>
</tr>
<tr>
<td>Design</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Phase Ia</strong>: Dose escalation and expansion of tiragolumab</td>
<td>• ARM A: Tecentriq plus tiragolumab</td>
<td>• <strong>Phase Ia</strong>: Tiragolumab monotherapy</td>
</tr>
<tr>
<td></td>
<td>• <strong>Phase Ib</strong>: Dose escalation and expansion of tiragolumab in combination with Tecentriq and/or other anti-cancer therapies</td>
<td>• ARM B: Tecentriq monotherapy</td>
<td>• <strong>Phase Ib</strong>: Tiragolumab plus daratumumab (r/r MM) or rituximab (r/r NHL)</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Safety, tolerability, PK variability and preliminary efficacy</td>
<td>• Overall response rate and progression-free survival</td>
<td>• Safety, tolerability, PK/PD and preliminary efficacy</td>
</tr>
<tr>
<td>Status</td>
<td>• Data presented at AACR 2020</td>
<td>• Data presented at ASCO 2020 and WCLC and ESMO IO 2021</td>
<td>• FPI Q2 2019</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT02794571</td>
<td>NCT03563716</td>
<td>NCT04045028</td>
</tr>
</tbody>
</table>

BTD=Breakthrough therapy designation; MM=Multiple myeloma; NSCLC=Non-small cell lung cancer; r/r=Relapsed refractory; NHL=Non-Hodgkin’s lymphoma; PK=Pharmacokinetics; PD=Pharmacodynamics; ASCO=American Society of Clinical Oncology; AACR=American Association for Cancer Research; WCLC=World Conference on Lung Cancer; ESMO IO=European Society for Medical Oncology - Immuno-Oncology
**Inavolisib (RG6114, GDC-0077)**

*A potent, orally available, and selective PI3Ka inhibitor*

<table>
<thead>
<tr>
<th>Indication</th>
<th>PIK3CA-mutant HR-positive metastatic breast cancer (mBC)</th>
<th>post CDKi HR-positive breast cancer</th>
<th>PIK3CA mutant solid tumors and metastatic ER+ HER2-negative breast cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III INAVO120</td>
<td>Phase III INAVO121</td>
<td>Phase I</td>
</tr>
<tr>
<td># of patients</td>
<td>N=400</td>
<td>N=400</td>
<td>N=256</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Inavolisib plus palbociclib plus fulvestrant</td>
<td>• ARM A: Inavolisib plus fulvestrant</td>
<td>Monotherapy and in combination with standard of care (letrozole; letrozole plus palbociclib; fulvestrant) • <strong>Stage 1:</strong> Dose escalation • <strong>Stage 2:</strong> Dose expansion</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Placebo plus palbociclib plus fulvestrant</td>
<td>• ARM B: alpelisib plus fulvestrant</td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Progression-free survival</td>
<td>• Progression-free survival</td>
<td>• Safety, tolerability and pharmacokinetics</td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q1 2020</td>
<td>• FPI Q2 2023</td>
<td>• FPI Q4 2016 • Preclinical/molecule discovery data presented at AACR 2017 • Data presented at SABCS 2019, 2020 and 2021</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT04191499</td>
<td>NCT05646862</td>
<td>NCT03006172</td>
</tr>
</tbody>
</table>

ER=Estrogen receptor; HR=Hormon receptor; HER2=Human Epidermal growth factor Receptor 2; PI3K=Phosphoinositide 3-Kinase; AACR=American Association for Cancer Research; SABCS=San Antonio Breast Cancer Symposium; CDKi= Cyclin-dependent kinase inhibitor
### Giredestrant (SERD (3), RG6171, GDC-9545)

**A selective estrogen receptor degrader or downregulator**

<table>
<thead>
<tr>
<th>Indication</th>
<th>ER+ HER2-negative metastatic breast cancer (mBC)</th>
<th>ER+ HER2-negative Stage I-III operable breast cancer (BC)</th>
<th>Neoadjuvant ER-positive breast cancer (BC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I</td>
<td>Phase I</td>
<td>Phase II coopERA Breast Cancer</td>
</tr>
<tr>
<td># of patients</td>
<td>N=181</td>
<td>N=75</td>
<td>N=221</td>
</tr>
<tr>
<td>Design</td>
<td>Dose escalation and expansion at RPTD</td>
<td>Open-label, pre-operative administration</td>
<td>ARM A: Giredestrant followed by giredestrant plus palbociclib</td>
</tr>
<tr>
<td></td>
<td>Giredestrant monotherapy and in combination</td>
<td></td>
<td>ARM B: Anastrozole followed by anastrozole plus palbociclib</td>
</tr>
<tr>
<td></td>
<td>with palbociclib and/or LHRH agonist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Safety</td>
<td>Safety, tolerability and PK/PD</td>
<td>Safety, tolerability and PK/PD</td>
</tr>
<tr>
<td>Status</td>
<td>FPI Q4 2017</td>
<td>FPI Q3 2019</td>
<td>FPI Q3 2020</td>
</tr>
<tr>
<td></td>
<td>Data presented at SABCS 2019, 2021 and ASCO 2020, 2021</td>
<td>Data presented at ASCO 2021</td>
<td>Data presented at ESMO and SABCS 2021; ASCO 2022; Data (biomarker subgroup analysis) presented at ESMO 2022</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03332797</td>
<td>NCT03916744</td>
<td>NCT04436744</td>
</tr>
</tbody>
</table>

**ER**=Estrogen receptor; **HER2**=Human Epidermal growth factor Receptor; **RPTD**=Recommended phase II dose; **LHRH**=Luteinizing hormone-releasing hormone; **PK/PD**=Pharmacokinetics/Pharmacodynamics; **SABCS**=San Antonio Breast Cancer Symposium; **ASCO**=American Society of Clinical Oncology
# Giredestrant (SERD (3),RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

<table>
<thead>
<tr>
<th>Indication</th>
<th>1L ER-positive metastatic breast cancer (mBC)</th>
<th>Adjuvant ER-positive breast cancer (BC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III persevERA Breast Cancer</td>
<td>Phase III lidERA Breast Cancer</td>
</tr>
<tr>
<td># of patients</td>
<td>N=978</td>
<td>N=4,100</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Giredestrant plus palbociclib</td>
<td>• ARM A: Giredestrant monotherapy</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Letrozole plus palbociclib</td>
<td>• ARM B: Tamoxifen or aromatase inhibitor</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Progression-free survival</td>
<td>Invasive disease-free survival</td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q4 2020</td>
<td>• FPI Q3 2021</td>
</tr>
<tr>
<td></td>
<td>• Recruitment completed Q1 2023</td>
<td></td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT04546009</td>
<td>NCT04961996</td>
</tr>
</tbody>
</table>

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor
# Giredestrant (SERD (3), RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

<table>
<thead>
<tr>
<th>Indication</th>
<th>1L ER-positive/HER2-positive breast cancer (BC)</th>
<th>Grade 1 endometrial cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III heredERA</td>
<td>Phase II endomERA</td>
</tr>
<tr>
<td># of patients</td>
<td>N=812</td>
<td>N=45</td>
</tr>
<tr>
<td>Design</td>
<td>Induction Phesgo plus taxane followed by maintenance with either:</td>
<td>Giredestrant once a day (QD) on days 1 to 28 of each 28-day cycle for 6 cycles</td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM A</strong>: Giredestrant plus Phesgo</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM B</strong>: Phesgo</td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Progression-free survival</td>
<td>Percentage of participants who have regression by 6 months</td>
</tr>
<tr>
<td>Status</td>
<td>FPI Q2 2022</td>
<td>FPI Q2 2023</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT05296798</td>
<td>NCT05634499</td>
</tr>
</tbody>
</table>

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor; Phesgo=FDC of Perjeta and Herceptin for SC administration
# Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)

**A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Advanced or metastatic solid tumors with a KRAS G12C mutation</th>
<th>2L NSCLC</th>
<th>2L, 1L metastatic colorectal cancer (mCRC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase I</td>
<td>Phase II/III B-FAST*</td>
<td>Phase Ib INTRINSIC</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=438</td>
<td>Modular design</td>
<td>Modular design</td>
</tr>
</tbody>
</table>
| **Design** | Monotherapy and combinations of divarasib with other anti-cancer therapies | Cohort G (KRAS G12C)  
- ARM A: divarasib  
- ARM B: Docetaxel | • ARM E (1L CRC): divarasib + cetuximab + FOLFOX  
• ARM F (2L CRC): divarasib + cetuximab |
| **Primary endpoint** | Safety | Progression-free survival | Safety |
| **Status** | • FPI Q3 2020  
• Data presented at WCLC 2022, ESMO 2022 | • BTD granted by FDA Q3 2022  
• FPI Q4 2022 | • FPI Q1 2023 |
| **CT Identifier** | NCT04449874 | NCT03178552 | NCT04929223 |

*Only cohorts with active recruitment shown; NSCLC=Non-small cell lung cancer; WCLC=World Conference on Lung Cancer; ESMO=European Society for Medical Oncology; BTD=Breakthrough therapy designation, CRC=Colorectal cancer*
**Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)**

A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein

<table>
<thead>
<tr>
<th>Indication</th>
<th>1L NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase Ib</td>
</tr>
<tr>
<td></td>
<td>KRASCENDO 170</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=60</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Combination of divarasib and pembrolizumab in 1L PD-L1+ metastatic NSCLC</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>Safety, tolerability</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>FPI Q2 2023</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT05789082</td>
</tr>
</tbody>
</table>

**NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand**
## Crovalimab (RG6107, SKY59)

**A humanized monoclonal antibody against complement C5**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Paroxysmal nocturnal hemoglobinuria (PNH)</th>
<th>Paroxysmal nocturnal hemoglobinuria (PNH) patients switching from a C5 inhibitor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase I/II COMPOSER</td>
<td>Phase III COMMODORE 1</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=59</td>
<td>N=89 (ARMs A/B)</td>
</tr>
</tbody>
</table>
| **Design** | Healthy volunteers and treatment naïve and pretreated patients with PNH:  
- **Part I:** Single ascending dose study in healthy subjects  
- **Part II:** Intra-patient single ascending dose study in PNH patients  
- **Part III:** Multiple-dose study in PNH patients  
- **Part IV:** Dose confirmation in PNH patients |  
- **ARM A:** Crovalimab  
- **ARM B:** Eculizumab  
- **ARM C:** Patients switching to crovalimab from ravulizumab, higher than labeled doses of eculizumab & C5 SNP patients (descriptive-arm) |
| **Primary endpoint** | Safety, PK, PD | Safety |
| **Status** | Nonclinical data published in Scientific Reports 2017 Apr; 7(1):1080  
Data presented for Part 2 and 3 at ASH 2018 and 2019 |  
- FPI Q3 2020  
- Study results in Q1 2023 supported the favorable benefit-risk profile of crovalimab, as seen in the pivotal COMMODORE 2 study  
- Data presented at EHA 2023  
- Filed in US and EU Q2 2023 |
| **CT Identifier** | NCT03157635 | NCT04432584 |

In collaboration with Chugai
ASH=American Society of Hematology; PNH=Paroxysmal nocturnal hemoglobinuria; PK/PD=Pharmacokinetics/Pharmacodynamics
# Crovalimab (RG6107, SKY59)

**A humanized monoclonal antibody against complement C5**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naïve patients</th>
<th>Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naïve patients (China only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase III COMMODORE 2</td>
<td>Phase III COMMODORE 3</td>
</tr>
<tr>
<td># of patients</td>
<td>N=204</td>
<td>N=51</td>
</tr>
<tr>
<td>Design</td>
<td><strong>ARM A:</strong> Crovalimab</td>
<td><strong>Crovalimab loading dose IV on Day 1, followed by weekly crovalimab SC doses for 4 weeks</strong></td>
</tr>
<tr>
<td></td>
<td><strong>ARM B:</strong> Eculizumab</td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Non-inferiority of crovalimab compared to eculizumab:</td>
<td>Percentage of patients with transfusion avoidance from baseline through week 25</td>
</tr>
<tr>
<td></td>
<td>• % patients with transfusion avoidance from baseline through week 25</td>
<td>• Mean percentage of participants with hemolysis control (week 5 through week 25)</td>
</tr>
<tr>
<td></td>
<td>• % patients with haemolysis control, as measured by LDH &lt;=1.5ULN from week 5-25</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>FPI Q4 2020</td>
<td>FPI Q1 2021; Recruitment completed Q3 2021</td>
</tr>
<tr>
<td></td>
<td>Recruitment completed Q2 2022</td>
<td>Study met its co-primary endpoints Q1 2021</td>
</tr>
<tr>
<td></td>
<td>Study met its primary endpoint Q1 2023</td>
<td>Filed in China (priority review) Q3 2022</td>
</tr>
<tr>
<td></td>
<td>Data presented at EHA 2023</td>
<td>Data presented at ASH 2022</td>
</tr>
<tr>
<td></td>
<td>Filed in US and EU Q2 2023</td>
<td></td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT04434092</td>
<td>NCT04654468</td>
</tr>
</tbody>
</table>

In collaboration with Chugai
LDH=Lactate Dehydrogenase; ULN=Upper Limit of Normal; IV=Intravenous; SC=Subcutaneous, ASH=American Society of Hematology
## Crovalimab (RG6107, SKY59)

**A humanized monoclonal antibody against complement C5**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Atypical hemolytic uremic syndrome (aHUS) study 1 - adults</th>
<th>Atypical hemolytic uremic syndrome (aHUS) study 2 - paediatrics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III COMMUTE-a</td>
<td>Phase III COMMUTE-p</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=90</td>
<td>N=35</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Single-arm study of aHUS patients  - <strong>Cohort 1</strong>: not previously treated with C5i  - <strong>Cohort 2</strong>: switching from C5i  - <strong>Cohort 3</strong>: known C5 polymorphism</td>
<td>Single-arm study of aHUS patients  - <strong>Cohort 1</strong>: not previously treated with C5i  - <strong>Cohort 2</strong>: switching from C5i ≤18y/o  - <strong>Cohort 3</strong>: previously treated with C5i (includes participants with known C5 polymorphism)</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>- <strong>Cohort 1+3</strong>: proportion of patients with complete TMA response anytime between baseline and week 25  - <strong>Cohort 2</strong>: proportion of patients with maintained TMA control from baseline through week 25</td>
<td>- <strong>Cohort 1</strong>: proportion of patients with complete TMA response anytime between baseline and week 25  - <strong>Cohort 2</strong>: proportion of patients with maintained TMA control from baseline through week 25</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>FPI Q4 2021</td>
<td>FPI Q4 2021</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT04861259</td>
<td>NCT04958265</td>
</tr>
</tbody>
</table>

In collaboration with Chugai
daHUS=Atypical Hemolytic Uremic Syndrome; C5i=C5 inhibitor; TMA=thrombotic microangiopathy
## Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

<table>
<thead>
<tr>
<th>Indication</th>
<th>Sickle cell disease (SCD) acute treatment</th>
<th>Sickle cell disease (SCD) chronic VOC prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase Ib CROSSWALK-a</td>
<td>Phase IIa CROSSWALK-c</td>
</tr>
<tr>
<td># of patients</td>
<td>N=30</td>
<td>N=90</td>
</tr>
<tr>
<td>Design</td>
<td>• ARM A: Crovalimab</td>
<td>• ARM A: Crovalimab</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Placebo</td>
<td>• ARM B: Placebo</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Safety</td>
<td>• VOC rate, up to 48 weeks</td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q1 2022</td>
<td>• FPI Q1 2022</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT04912869</td>
<td>NCT05075824</td>
</tr>
</tbody>
</table>

**VOC**= Vaso-occlusive crises
**Crovalimab (RG6107, SKY59)**

*A humanized monoclonal antibody against complement C5*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Lupus nephritis (LN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase I</td>
</tr>
<tr>
<td># of patients</td>
<td>N=15</td>
</tr>
<tr>
<td>Design</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Single-arm study of patients with active class III, IV, or V lupus nephritis and urine protein-to-creatinine ratio &gt;=1.5 g/g</td>
</tr>
<tr>
<td></td>
<td>• All patients to receive crovalimab IV loading dose and subsequent crovalimab SC q1w (Day 1, Week 1,2 and 3) followed by corvalimab SC q4w</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>PK, safety</td>
</tr>
<tr>
<td>Status</td>
<td>FPI Q1 2023</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>ISRCTN12809537</td>
</tr>
</tbody>
</table>

In collaboration with Chugai

IV=Intravenous, SC=Subcutaneous, PK=Pharmacokinetics
## Astegolimab (RG6149, Anti-ST2)

*A monoclonal antibody that selective binds to ST2*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Chronic obstructive pulmonary disease (COPD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II COPD-ST2OP</td>
</tr>
<tr>
<td># of patients</td>
<td>N=81</td>
</tr>
<tr>
<td>Design</td>
<td>Astegolimab SC 490mg q4w for 48 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>Number of moderate to severe exacerbation</td>
</tr>
<tr>
<td>Status</td>
<td>Published in Lancet Respir Med 2022;10(5):469-477. doi: 10.1016/S2213-2600(21)00556-7</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03615040</td>
</tr>
</tbody>
</table>

In collaboration with Amgen

COPD=Chronic obstructive pulmonary disease, SC=Subcutaneous
**Crenezumab (RG7412)**

*Humanized monoclonal antibody targeting all forms of Aβ*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Alzheimer’s prevention initiative (API) Colombia</th>
</tr>
</thead>
</table>

**Phase/study**

<table>
<thead>
<tr>
<th># of patients</th>
<th>N=252</th>
</tr>
</thead>
</table>

**Design**

- **ARM A**: PSEN1 E280A mutation carriers receive crenezumab SC or IV
- **ARM B**: PSEN1 E280A mutation carriers receive placebo
- **ARM C**: non-mutation carriers receive placebo

**Primary endpoint**

- Change on Alzheimer’s Prevention Initiative (API) Composite Cognitive Test total score at 260 weeks treatment
- Annualized rate of change in an Episodic Memory Measure: Free and Cued Selective Reminding Task (FCSRT)

**Status**

- Study did not meet its co-primary endpoints Q2 2022
- Data presented at AAIC 2022
- All carriers receive crenezumab

**CT Identifier**

| NCT01998841 |
**Tominersen (RG6042, HTT ASO)**

*Antisense oligonucleotide (ASO) targeting human HTT mRNA*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Huntington’s disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II GENERATION HD2</td>
</tr>
<tr>
<td># of patients</td>
<td>N=360</td>
</tr>
</tbody>
</table>
| Design | Patients aged 25 to 50 years with prodromal (very early subtle signs of HD) or early manifest HD
  - **ARM A:** Tominersen 60mg q16w via a lumbar puncture
  - **ARM B:** Tominersen 100mg q16w via a lumbar puncture
  - **ARM C:** Placebo q16w via a lumbar puncture |
| Primary endpoint | Safety, biomarkers and efficacy |
| Status | FPI Q1 2023 |
| CT Identifier | NCT05686551 |
# Fenebrutinib (RG7845, GCD-0853)

*Highly selective and reversible (noncovalent) bruton tyrosine kinase*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Primary progressive multiple sclerosis (PPMS)</th>
<th>Relapsing multiple sclerosis (RMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td>Phase III <strong>FENtrepid</strong></td>
<td>Phase III <strong>FENhance 1</strong></td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=946</td>
<td>N=736</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>• <strong>ARM A</strong>: Fenebrutinib twice daily oral</td>
<td>• <strong>ARM A</strong>: Fenebrutinib twice daily oral</td>
</tr>
<tr>
<td></td>
<td>• <strong>ARM B</strong>: Ocrevus 2x300mg IV q24w</td>
<td>• <strong>ARM B</strong>: Teriflunomide once daily oral</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td>• Time to onset of cCDP12</td>
<td>• Time to onset of cCDP12 and annualized relapse rate</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>• FPI Q4 2020</td>
<td>• FPI Q1 2021</td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT04544449</td>
<td>NCT04586023</td>
</tr>
</tbody>
</table>

**Note:** IV=Intravenous; cCDP12=Composite 12-week confirmed disability progression
# Fenebrutinib (RG7845, GCD-0853)

*Highly selective and reversible (noncovalent) bruton tyrosine kinase*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Relapsing multiple sclerosis (RMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II (Biomarker study) FENopta</td>
</tr>
<tr>
<td># of patients</td>
<td>N=109</td>
</tr>
</tbody>
</table>
| Design | • ARM A: Fenebrutinib  
• ARM B: Placebo |
| Primary endpoint | Total number of new gadolinium-enhancing T1 lesions observed on MRI scans of the brain at 12 weeks |
| Status | Data presented at EAN 2023 |
| CT Identifier | NCT05119569 |

MRI=Magnetic resonance imaging; EAN=European Academy of Neurology
**Balovaptan (RG7314)**

Small molecule antagonist of the V1A vasopressin receptor

<table>
<thead>
<tr>
<th>Indication</th>
<th>Post-traumatic stress disorder (PTSD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II</td>
</tr>
<tr>
<td># of patients</td>
<td>N=30</td>
</tr>
</tbody>
</table>
| Design | • **ARM A**: Balovaptan IV once a day for 12 weeks  
• **ARM B**: Placebo |
| Primary endpoint | • Change from baseline in the Clinician-Administered PTSD Total Symptom Severity Score |
| Status | • FPI Q3 2022 |
| CT Identifier | NCT05401565 |

PTSD=Post-traumatic stress disorder; IV=Intravenous
## Latent myostatin (RG6237, GYM329)

*Recycling and antigen-sweeping monoclonal anti-latent myostatin antibody*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Facioscapulohumeral Muscular Dystrophy (FSHD)</th>
<th>Spinal muscular atrophy (SMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase/study</td>
<td>Phase II <strong>MANOEUVRE</strong></td>
<td>Phase II/III <strong>MANATEE</strong>¹</td>
</tr>
<tr>
<td># of patients</td>
<td>N=48</td>
<td>N=180</td>
</tr>
<tr>
<td>Design</td>
<td>• <strong>ARM A</strong>: 4-week pre-treatment to collect baseline movement data with a wearable device, followed by latent myostatin&lt;br&gt;• <strong>ARM B</strong>: Placebo</td>
<td><strong>ARM A</strong>:&lt;br&gt;• <strong>Part I</strong>: GYM329 plus Evrysdi for 24 weeks, followed by GYM329 plus Evrysdi for 72 weeks&lt;br&gt;• <strong>Part II</strong>: GYM329 plus Evrysdi for 72 weeks&lt;br&gt;<strong>ARM B</strong>:&lt;br&gt;• Placebo plus Evrysdi</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Percent change in contractile muscle volume of quadriceps femoris muscles by MRI at week 52 and safety</td>
<td>• Change from baseline in RHS score after week 72 of treatment&lt;br&gt;• Safety, PK/PD and muscle biomarkers</td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q1 2023</td>
<td>• ODD granted by FDA in Q4 2021 for GYM329&lt;br&gt;• FPI Part I ambulatory cohort Q2 2022; non-ambulatory cohort July 2023</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT05548556</td>
<td>NCT05115110</td>
</tr>
</tbody>
</table>

¹ In collaboration with PTC Therapeutics and SMA Foundation

PK/PD=Pharmacokinetics/Pharmacodynamics; ODD=Orphan drug designation; RHS=Revised hammersmith scale; MRI=Magnetic Resonance Imaging
**Anti-IL-6 (RG6179)**

*A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Diabetic macular edema (DME) and Uveitic macular edema (UME)</th>
<th>Diabetic macular edema (DME)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td><strong>DOVETAIL</strong></td>
<td><strong>Phase II</strong></td>
</tr>
<tr>
<td>Phase II</td>
<td><strong>ALLUVIUM</strong></td>
<td></td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=90</td>
<td>N=210-230</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part I: Multiple ascending dose study of intravitreal monotherapy</td>
<td>ARM A: Anti-IL-6 plus ranibizumab</td>
<td>Arm A: 0.25 mg anti-IL-6 q8w</td>
</tr>
<tr>
<td>Part II: monotherapy and in combination with anti-VEGF</td>
<td>ARM B: Ranibizumab plus sham control</td>
<td>Arm B: 1.0 mg anti-IL-6 q8w</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm C: 1.0 mg anti-IL-6 q4w</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm D: 0.5 mg ranibizumab q4w</td>
</tr>
<tr>
<td><strong>Primary endpoint</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety, tolerability, PK</td>
<td>Mean change from baseline in BCVA averaged over week 44 and week 48</td>
<td>Mean change from baseline in BCVA averaged over week 44 and week 48</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FPI Q3 2019</td>
<td>FPI Q4 2021</td>
<td>FPI Q4 2021</td>
</tr>
<tr>
<td>Data presentation at ARVO 2023</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CT Identifier</strong></td>
<td>NCT05151744</td>
<td>NCT05151731</td>
</tr>
</tbody>
</table>

PK=Pharmacokinetics; BCVA=Best corrected visual acuity, ARVO=Association for Research in Vision & Ophthalmology
## Anti-IL-6 (RG6179)

**A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Uveitic macular edema (UME)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase/study</strong></td>
<td><strong>Phase III MEERKAT</strong></td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=225</td>
</tr>
</tbody>
</table>
| **Design** | - **ARM A:** Anti-IL-6 low-dose q4w to week 12, followed by PRN  
- **ARM B:** Anti-IL-6 high-dose q4w to week 12, followed by PRN  
- **ARM C:** Sham control q4w to week 12, followed by PRN | - **ARM A:** Anti-IL-6 low-dose q4w to week 12, followed by PRN  
- **ARM B:** Anti-IL-6 high-dose q4w to week 12, followed by PRN  
- **ARM C:** Sham control q4w to week 12, followed by PRN |
| **Primary endpoint** | - Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16 | - Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16 |
| **Status** | **FPI Q1 2023** | **FPI Q1 2023** |
| **CT Identifier** | NCT05642312 | NCT05642325 |

**BCVA=Best corrected visual acuity; PRN=Pro re nata**
Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
## pRED oncology development programs - 1

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Indication</th>
<th>Phase</th>
<th># of patients</th>
<th>Status</th>
<th>CT Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FAP-4-1BBL (RG7827)</strong></td>
<td>Solid tumors</td>
<td>I</td>
<td>~150</td>
<td>FPI Q2 2018 &lt;br&gt;Data presented at ESMO 2020 &lt;br&gt;Recruitment completed Q2 2021</td>
<td>FPI Q2 2018</td>
</tr>
<tr>
<td></td>
<td>3L+ MSS mCRC</td>
<td>Ib</td>
<td>80</td>
<td>FPI Q3 2021 &lt;br&gt;Combination study with cibisatamab</td>
<td>NCT04826003</td>
</tr>
<tr>
<td><strong>cibisatamab</strong>&lt;br&gt;(CEA x CD3, RG7802)</td>
<td>CEA-positive solid tumors</td>
<td>Ia</td>
<td>149</td>
<td>FPI Q4 2014 &lt;br&gt;Data presented at ASCO 2017</td>
<td>NCT02324257</td>
</tr>
<tr>
<td></td>
<td>3L+ MSS mCRC</td>
<td>Ib</td>
<td>228</td>
<td>FPI Q1 2016 &lt;br&gt;Data presented at ASCO 2017</td>
<td>NCT02650713</td>
</tr>
<tr>
<td><strong>tobemstomig</strong>&lt;br&gt;PD1-LAG3 (RG6139)</td>
<td>Solid tumors</td>
<td>I</td>
<td>320</td>
<td>FPI Q4 2019 &lt;br&gt;Data presented at ESMO 2022 &lt;br&gt;Recruitment completed Q4 2022</td>
<td>NCT04140500</td>
</tr>
<tr>
<td></td>
<td>advanced or metastatic esophageal squamous cell cancer</td>
<td>II</td>
<td>210</td>
<td>FPI Q2 2021 &lt;br&gt;Randomized trial, compared with nivolumab</td>
<td>NCT04785820</td>
</tr>
<tr>
<td></td>
<td>Untreated unresectable or metastatic melanoma</td>
<td>II</td>
<td>80</td>
<td>FPI Q3 2022</td>
<td>NCT05419388</td>
</tr>
<tr>
<td></td>
<td>Non-small cell lung cancer</td>
<td>II</td>
<td>180</td>
<td>FPI Q1 2023</td>
<td>NCT05775289</td>
</tr>
<tr>
<td></td>
<td>advanced and metastatic urothelial cancer</td>
<td>II</td>
<td>240</td>
<td>FPI Q2 2023</td>
<td>NCT05645692</td>
</tr>
<tr>
<td></td>
<td>Metastatic renal cell carcinoma</td>
<td>II</td>
<td>210</td>
<td>FPI Q2 2023</td>
<td>NCT05805501</td>
</tr>
</tbody>
</table>
# pRED oncology development programs -2

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Indication</th>
<th>Phase</th>
<th># of patients</th>
<th>Status</th>
<th>CT Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>englumafusp alfa (CD19–4-1BBL, RG6076)</td>
<td>R/R B cell non-Hodgkin’s lymphoma</td>
<td>I</td>
<td>362</td>
<td>Part I: FPI Q3 2019  Part II: FPI Q3 2020  Combination study with Columvi  Data presented at ASH 2022 and ICML 2023</td>
<td>NCT04077723</td>
</tr>
<tr>
<td>eciskafusp alfa (PD1-IL2v, RG6279)</td>
<td>Solid tumors</td>
<td>Ib</td>
<td>348</td>
<td>Part I: FPI Q2 2020; recruitment completed Q4 2021  Part II: FPI Q1 2022  Part III: FPI Q1 2023</td>
<td>NCT04303858</td>
</tr>
<tr>
<td>CD25 (RG6292)</td>
<td>Solid tumors</td>
<td>I</td>
<td>110</td>
<td>FPI Q4 2019  PK/PD data presented at AACR 2023</td>
<td>NCT04158583</td>
</tr>
<tr>
<td>forimtamig (Anti-GPRC5D, RG6234)</td>
<td>Multiple myeloma</td>
<td>I</td>
<td>400</td>
<td>FPI Q4 2020  Data presented at EHA 2022 and ASH 2022</td>
<td>NCT04557150</td>
</tr>
<tr>
<td>FAP-CD40 (RG6189)</td>
<td>Solid tumors</td>
<td>I</td>
<td>280</td>
<td>FPI Q2 2021</td>
<td>NCT04857138</td>
</tr>
<tr>
<td>BRAFi (3) (RG6344)</td>
<td>Solid tumors</td>
<td>I</td>
<td>292</td>
<td>FPI Q1 2022</td>
<td>ISRCTN13713551</td>
</tr>
<tr>
<td>CD19xCD28 (RG6333)</td>
<td>R/R B cell non-Hodgkin’s lymphoma</td>
<td>I</td>
<td>~200</td>
<td>FPI Q1 2022  Combination study with Columvi</td>
<td>NCT05219513</td>
</tr>
<tr>
<td>EGFRvIIIxCD3 (RG6156)</td>
<td>Glioblastoma</td>
<td>I</td>
<td>~200</td>
<td>FPI Q2 2022</td>
<td>NCT05187624</td>
</tr>
<tr>
<td>DLL3 trispecific (RG6524)</td>
<td>Solid tumors</td>
<td>I</td>
<td>168</td>
<td>FPI Q1 2023</td>
<td>NCT05619744</td>
</tr>
<tr>
<td>HLA-G CD3 TCB (RG6353)</td>
<td>Solid tumors</td>
<td>I</td>
<td>150</td>
<td>FPI Q2 2023</td>
<td>NCT05769959</td>
</tr>
</tbody>
</table>
# pRED neuroscience development programs

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Indication</th>
<th>Phase</th>
<th># of patients</th>
<th>Status</th>
<th>CT Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>trontinemab (BS-gantenerumab, RG6102)</td>
<td>Alzheimer's disease</td>
<td>IIa</td>
<td>~120</td>
<td>FPI Q1 2021</td>
<td>NCT04639050</td>
</tr>
<tr>
<td>Brain Shuttle-CD20 (BS-CD20, RG6035)</td>
<td>Multiple sclerosis</td>
<td>I</td>
<td>30-63</td>
<td>FPI Q3 2021</td>
<td>ISRCTN16295177</td>
</tr>
<tr>
<td>ralmitaront (partial TAAR1 agonist, RG7906)</td>
<td>Schizophrenia</td>
<td>II</td>
<td>36</td>
<td>FPI Q4 2018 Recruitment completed Q3 2019</td>
<td>NCT03669640 (TWAIN I)</td>
</tr>
<tr>
<td>prasinezumab (^1) (anti-αSynuclein, RG7935, PRX002)</td>
<td>Parkinson's disease</td>
<td>II</td>
<td>316</td>
<td>The study did not meet its primary endpoint, but showed a reduced clinical decline of core motor signs (MDS UPDRS partIII). Data presented at MDS &amp; ADPD 2020-22. The Open Label Extension is ongoing.</td>
<td>NCT03100149 (PASADENA)</td>
</tr>
<tr>
<td>alogabat (GABA-Aa5 PAM, RG7816)</td>
<td>Autism spectrum disorder</td>
<td>IIb</td>
<td>575</td>
<td>FPI Q2 2021 Recruitment completed Q1 2023</td>
<td>NCT04777331 (PADOVA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>105</td>
<td>FPI Q1 2021</td>
<td>NCT04299464 (Aurora)</td>
</tr>
</tbody>
</table>

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Partner: Prothena
BS=Brain Shuttle
pRED neuroscience development programs -2

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Indication</th>
<th>Phase</th>
<th># of patients</th>
<th>Status</th>
<th>CT Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>rugonersen (UBE3A LNA, RG6091)</td>
<td>Angelman syndrome</td>
<td>I</td>
<td>66</td>
<td>FPI Q3 2020</td>
<td>NCT04428281</td>
</tr>
<tr>
<td>MAGLi (RG6182)</td>
<td>Multiple sclerosis</td>
<td>I</td>
<td>Up to 36</td>
<td>FPI July 2023</td>
<td></td>
</tr>
<tr>
<td>NME (RG6289)</td>
<td>Alzheimer's disease</td>
<td>I</td>
<td>138</td>
<td>FPI Q4 2021</td>
<td></td>
</tr>
<tr>
<td>NME (RG6163)</td>
<td>Psychiatric disorders</td>
<td>I</td>
<td>84</td>
<td>FPI Q1 2022</td>
<td></td>
</tr>
<tr>
<td>selnoflast* (NLRP3i, RG6418)</td>
<td>Parkinson's disease</td>
<td>Ib</td>
<td>48</td>
<td>FPI Q3 2022</td>
<td></td>
</tr>
<tr>
<td>basmisanil (GABA-Aa5 NAM, RG1662)</td>
<td>Dup15q syndrome</td>
<td>II</td>
<td>90</td>
<td>FPI Q4 2022</td>
<td>NCT05307679</td>
</tr>
</tbody>
</table>

*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022
# pRED immunology and ophthalmology development programs

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Indication</th>
<th>Phase</th>
<th># of patients</th>
<th>Status</th>
<th>CT Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>selnoflast* (NLRP3i, RG618)</td>
<td>Chronic obstructive pulmonary disease</td>
<td>Ib</td>
<td>102</td>
<td>FPI Q2 2022 Study closed Q3 2022</td>
<td></td>
</tr>
<tr>
<td>zifibancimig (VEGF-Ang2 Dutafab, RG6120)</td>
<td>nAMD</td>
<td>I</td>
<td>251</td>
<td>FPI Q4 2020</td>
<td>NCT04567303 (BURGUNDY)</td>
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<td>vicasinabin (CB2 receptor agonist, RG7774)</td>
<td>DR</td>
<td>II</td>
<td>135</td>
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<td>NCT04265261 (CANBERRA)</td>
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<td>NME (RG6209)</td>
<td>retinal disease</td>
<td>I</td>
<td>~70 (Part I)</td>
<td>FPI Q4 2022</td>
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*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022*
# Infectious Diseases Development Programs

<table>
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<tr>
<th>Molecule</th>
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<th>Status</th>
<th>CT Identifier</th>
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<tbody>
<tr>
<td><strong>ruzotolimod (TLR7 agonist (3) RG7854)</strong></td>
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<td>I</td>
<td>150</td>
<td>FPI Q4 2016 Data presented at APASL 2019</td>
<td>NCT02956850</td>
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<td><strong>ruzotolimod/ xalnesiran/ PDL1 LNA (RG7854/RG6346/RG6084)</strong></td>
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<td>275</td>
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<td>35</td>
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<tr>
<td><strong>zosurabalpin (Abx MCP, RG6006)</strong></td>
<td>A. baumannii infections</td>
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<td>NCT04605718</td>
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<td>I</td>
<td>110</td>
<td>FPI Q2 2023</td>
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Abx MCP = antibiotic macrocyclic peptide
Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
# gRED oncology development programs - 1

<table>
<thead>
<tr>
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<th>CT Identifier</th>
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<td><strong>cevostamab</strong> (anti-FcRH5 x CD3; RG6160)</td>
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<td>BCMA-experienced R/R MM</td>
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<td><strong>runimotamab</strong> (HER2 x CD3, RG6194)</td>
<td>Metastatic HER2-expressing cancers</td>
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<td><strong>IL15/IL15Ra-Fc (RG6323)</strong></td>
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<td><strong>autogene cevumeran</strong> (Individualized Neoantigen-Specific Therapy (iNeST); RG6180)</td>
<td>Solid tumors</td>
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<td>1L advanced melanoma</td>
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### gRED oncology development programs -2

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<td>SHP2i (RG6433)$^1$</td>
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<td>KRAS-G12C mutant solid tumors</td>
<td>Ib</td>
<td>~500</td>
<td>FPI Q4 2021 Arm F of a combination study investigating divarasi monotherapy and combinations</td>
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<td>belvarafenib (RG6185)$^2$</td>
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<td>NME (RG6411)</td>
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<td>NCT05581004</td>
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<td>AR degrader (RG6537)$^3$</td>
<td>mCRPC</td>
<td>I</td>
<td>~160</td>
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<td>NCT05800665</td>
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Partner: $^1$Relay, $^2$Hanmi, $^3$Jemincare
## gRED immunology and ophthalmology development programs

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<td>NME (RG6287, GDC-8264)</td>
<td>Acute graft versus host disease</td>
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<td>40</td>
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<td>NME (RG6315, MTBT1466A)</td>
<td>Immunologic disorders</td>
<td>I</td>
<td>-24</td>
<td>FPI Q3 2020 Recruitment completed Q2 2022</td>
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<tr>
<td></td>
<td>Systemic sclerosis</td>
<td>Ib</td>
<td>100</td>
<td>FPI Q1 2023</td>
<td>NCT05462522</td>
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<td>NME (RG6341, GDC-6599)</td>
<td>Asthma</td>
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<td>84</td>
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<tr>
<td></td>
<td>Chronic cough</td>
<td>IIa</td>
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<td>NCT05660850</td>
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<td>TEMEM16A potentiator (RG6421, GDC-6988)</td>
<td>Cystic fibrosis</td>
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<td>30</td>
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<td>ISRCTN15406513</td>
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<tr>
<td>Vixarelimab (RG6536)¹</td>
<td>Idiopathic pulmonary fibrosis / Systemic sclerosis-ssociated interstitial lung disease</td>
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<td>~290</td>
<td>FPI Q2 2023</td>
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<td>DME</td>
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<td>42-78</td>
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<td>OpRegen (RG6501)²</td>
<td>Geographic atrophy</td>
<td>II</td>
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Partner: ¹Kiniksa Pharmaceuticals, ²Lineage Cell Therapeutics
### gRED neuroscience and infectious diseases development programs

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<th>Indication</th>
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<td><strong>Neuroscience</strong></td>
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</table>
| semorinemab (RG6100)\(^1\)      | Mild-to-moderate Alzheimer’s disease            | II    | 272           | FPI Q1 2019  
One of two co-primary endpoints met Q3 2021  
Data presented at CTAD 2021  
The Open Label Extension is ongoing | NCT03828747 (LAURIET) |
| **Infectious Diseases**         |                                                 |       |               |                                                                                                |                     |
| LepB inhibitor (RG6319)         | Complicated urinary tract infection             | I     | 32            | FPI Q1 2023                                                                                      |                     |

\(^1\) Partner: AC Immune
Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
Hemophilia A
Unique gene therapy platform

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Dirloctogene Samoparvovec (SPK-8011) (RG6357)</th>
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<tbody>
<tr>
<td>Indication</td>
<td>Hemophilia A</td>
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<tr>
<td>Phase/study</td>
<td>Phase I</td>
</tr>
<tr>
<td># of patients</td>
<td>N=100</td>
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<tr>
<td>Design</td>
<td>• Long term follow up study of patients who have received SPK-8011 in any prior Spark-sponsored SPK-8011 study</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Safety</td>
</tr>
<tr>
<td>Status</td>
<td>• Ongoing</td>
</tr>
<tr>
<td>CT Identifier</td>
<td>NCT03432520</td>
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</table>

ISTH=International Society on Thrombosis and Haemostasis; NEJM=New England Journal of Medicine
<table>
<thead>
<tr>
<th><strong>Molecule</strong></th>
<th>SPK-3006 (RG6359)</th>
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<tbody>
<tr>
<td><strong>Indication</strong></td>
<td>Pompe disease</td>
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<tr>
<td><strong>Phase/study</strong></td>
<td>Phase I/II RESOLUTE</td>
</tr>
<tr>
<td><strong># of patients</strong></td>
<td>N=20</td>
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<tr>
<td><strong>Design</strong></td>
<td>Gene transfer study for late-onset Pompe disease</td>
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<tr>
<td><strong>Primary endpoint</strong></td>
<td>Safety</td>
</tr>
<tr>
<td><strong>Status</strong></td>
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<td><strong>CT Identifier</strong></td>
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Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
# Geographical sales split by Divisions and Group

<table>
<thead>
<tr>
<th>Divisions</th>
<th>CHFm</th>
<th>HY 2022</th>
<th>HY 2023</th>
<th>% change CER</th>
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<tbody>
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<td>22,347</td>
<td>22,681</td>
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<tr>
<td>United States</td>
<td>11,363</td>
<td>11,743</td>
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<tr>
<td>Europe</td>
<td>4,104</td>
<td>4,105</td>
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<tr>
<td>Japan</td>
<td>2,202</td>
<td>2,210</td>
<td>+14</td>
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<tr>
<td>International</td>
<td>4,678</td>
<td>4,623</td>
<td>+9</td>
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<tr>
<td>Diagnostics Division</td>
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<td>-23</td>
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<tr>
<td>United States</td>
<td>2,511</td>
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<td>Europe</td>
<td>2,799</td>
<td>1,932</td>
<td>-27</td>
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<td>Japan</td>
<td>380</td>
<td>287</td>
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<td>Group</td>
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<td>Japan</td>
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<td>International</td>
<td>8,936</td>
<td>7,757</td>
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CER=Constant Exchange Rates; * Geographical sales split shown here does not represent operational organization
## Pharma Division sales HY 2023
### Top 20 products

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<th>CHFm</th>
<th>% CER</th>
<th>CHFm</th>
<th>% CER</th>
<th>CHFm</th>
<th>% CER</th>
<th>CHFm</th>
<th>% CER</th>
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| Pharma Division  | 22'681 | 8    | 11'743 | 7     | 4'105  | 5     | 2'210  | 14    | 4'623  | 9     |

CER=Constant Exchange Rates; *over 500%
## Pharma Division CER sales growth in %

### Global top 20 products

<table>
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<tr>
<th></th>
<th>Q1/22</th>
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<th>Q3/22</th>
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CER (Constant exchange Rates) of the respective year; *over 500%; ¹ Q1-Q4/22 vs Q1-Q4/21 at CER avg. full year 2021; Q1-Q2/23 vs Q1-Q2/22 at CER avg. full year 2022
Pharma Division CER sales growth¹ in %

**Top 20 products by region**

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CER (Constant exchange Rates) of the respective year; *over 500%; ¹ Q3-Q4/22 vs Q3-Q4/21 at CER avg. full year 2021; Q1-Q2/23 vs Q1-Q2/22 at CER avg. full year 2022
### CER sales growth (%)

**Quarterly development**

<table>
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<th>Division</th>
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CER (Constant exchange Rates) of the respective year
**HY 2023 sales of CHF 3,200m**

- US: Moving into earlier lines displacing orals; #1 in US for both dynamic and total share
- EU: Moving into earlier lines displacing orals; #1 in EU5 for both dynamic and total share
HY 2023 sales of CHF 2,087m

- US: Continued share gains in non-inhibitor patients
- EU: Continued share gains in non-inhibitor severe patients, label extension including moderate patients granted in Q1
- Japan: Strong uptake in non-inhibitor patients
- International: Accelerating momentum in all regions (LATAM, APAC, EEMEA)

CER=Constant Exchange Rates
**Perjeta**

**Global sales**

<table>
<thead>
<tr>
<th>Year</th>
<th>CHFbn</th>
</tr>
</thead>
<tbody>
<tr>
<td>HY 20</td>
<td>1.5</td>
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<td>HY 21</td>
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<td>HY 22</td>
<td>2.0</td>
</tr>
<tr>
<td>HY 23</td>
<td>2.5</td>
</tr>
</tbody>
</table>

**CER growth**

- **HY 2023**: +9%

**Regional sales**

- **US**: +7%
- **Europe**: -5%
- **Japan**: +3%
- **International**: +20%

**HY 2023 sales of CHF 2,082m**

- US: Growth driven by eBC; increasing conversion to Phesgo
- EU: Conversion to Phesgo
- International: Strong growth in all regions (LATAM, APAC, EEMEA)
**Tecentriq**

**Global sales**

- CER growth: +12%
- CHFbn:
  - HY 20: 1.2
  - HY 21: 1.6
  - HY 22: 2.0
  - HY 23: 2.0

**Regional sales**

- US: +9%
- Europe: +9%
- Japan: +11%
- International: +28%

**HY 2023 sales of CHF 1,853m**

- US: Growth driven by adj NSCLC; 1L HCC nearing peak penetration
- EU: Growth drive by adj NSCLC and 1L HCC
- Japan: Growing share in adj NSCLC

CER=Constant Exchange Rates
**Actemra / RoActemra**

**Global sales**

<table>
<thead>
<tr>
<th>HY 20</th>
<th>HY 21</th>
<th>HY 22</th>
<th>HY 23</th>
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<tr>
<td>CHFbn</td>
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<tr>
<td>1.2</td>
<td>1.5</td>
<td>1.2</td>
<td>0.9</td>
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</table>

**CER growth**

-6%

**Regional sales**

- **US**: -11%
- **Europe**: -4%
- **Japan**: +3%
- **International**: +1%

**HY 2023 sales of CHF 1,296m**

- US: Ongoing patient shift from Actemra IV to SC in RA; COVID-19 sales completely washed out as of Q2
- EU: Stable share of Actemra SC in RA; COVID-19 sales completely washed out as of Q2
HY 2023 sales of CHF 1,031m
- US: Growth driven by growth in CSU
HY 2023 sales of CHF 1,001m

- US: Share decline in metastatic BC due to competition
- EU: Share decline in metastatic BC due to competition
- Japan: Share decline in metastatic BC due to competition
- International: Growth driven by uptake in eBC all regions (LATAM, EEMEA, APAC)
Vabysmo

HY 2023 sales of CHF 957m

- US: Strong uptake with ~30% naïve patients, ~70% switches (mostly from aflibercept)
- EU: Similar uptake dynamics in first launch countries as seen in the US
- Japan: Double-digit market share with ~40% naïve patients
Rituxan / Mabthera

**Global sales**

<table>
<thead>
<tr>
<th>Year</th>
<th>CHFbn</th>
<th>CER growth</th>
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<tbody>
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<tr>
<td>HY 23</td>
<td>0.5</td>
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</table>

**Regional sales**

- **US**: -20%
- **Europe**: -4%
- **Japan**: -14%
- **International**: -13%

**HY 2023 sales of CHF 882m**

- US: Biosimilar erosion slowing
- EU: Biosimilar erosion bottoms out
- Japan: Biosimilar erosion slowing
- International: Biosimilar erosion slowing
**Herceptin**

**Global sales**

- **CHFbn**
  - HY 20: 2.5
  - HY 21: 2.0
  - HY 22: 1.5
  - HY 23: 1.0
- **CER growth -19%**

**Regional sales**

- **CER growth**
  - US: -31%
  - Europe: -17%
  - Japan: -32%
  - International: -14%

**HY 2023 sales of CHF 878m**

- US: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Conversion to Phesgo
- EU: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Conversion to Phesgo
- Japan: Decline due to biosimilars
- International: Decline due to biosimilars; Conversion to Phesgo

CER=Constant Exchange Rates
**Avastin**

**HY 2023 sales of CHF 837m**

- US: Biosimilar erosion slowing
- EU: Ongoing biosimilar erosion
- Japan: Ongoing biosimilar erosion
- International: Biosimilar erosion slowing
**Alecensa**

**Global sales**

<table>
<thead>
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<th>Year</th>
<th>CHFbn</th>
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**CER growth** +10%

**Regional sales**

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<td>Europe</td>
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<td>Japan</td>
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<tr>
<td>International</td>
<td>+14%</td>
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**HY 2023 sales of CHF 758m**

- US: Market leadership in 1L ALK+ NSCLC is maintained
- EU: Market leadership in 1L ALK+ NSCLC is maintained
- Japan: Market leadership in 1L ALK+ NSCLC is maintained
- International: Strong growth driven by all regions

CER=Constant Exchange Rates
Evrysdi

HY 2023 sales of CHF 705m

- US: Strong uptake across all patient segments; including treatment-naïve patients; leading market share with >25%
- EU: Continued strong growth and share gains, especially in Germany, UK and Italy
- Japan: Market leading position with >50%
- International: Strong growth in all regions
TNKase / Activase

HY 2023 sales of CHF 621m
- Spontaneous TNKase use in AIS early time window

CER=Constant Exchange Rates
**Phesgo**

**HY 2023 sales of CHF 517m**
- US: Strong growth driven by eBC, switching of patients from Perjeta+Herceptin to Phesgo
- EU: Strong growth in all regions, mainly UK, France, Germany and Italy
- International: Strong uptake in all regions

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**Global sales**

- CER growth: +69%

**Regional sales**

- US: +57%
- Europe: +57%
- International: +216%

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CER=Constant Exchange Rates
HY 2023 sales of CHF 402m

- US: Strong growth driven by combination therapies in 1L CLL
- EU: Strong growth driven by combination therapies in 1L CLL
- International: Continued growth in all key markets
**Polivy**

**Global sales**

<table>
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<th>CER growth</th>
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<td>+114%</td>
</tr>
</tbody>
</table>

**Regional sales**

- **US**: +65%
- **Europe**: +84%
- **Japan**: +182%
- **International**: +339%

**HY 2023 sales of CHF 353m**

- US: Strong growth following approval in 1L DLBCL and inclusion to the NCCN guidelines as Category I
- EU: Strong growth following approval in 1L DLBCL
- JP: Strong growth following approval in 1L DLBCL
- International: Strong growth following approval in 1L DLBCL
Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
## HY 2023: Diagnostics Division CER growth

**By Region and Customer Area (vs. 2022)**

<table>
<thead>
<tr>
<th></th>
<th>Global CHFm</th>
<th>% CER</th>
<th>EMEA¹ CHFm</th>
<th>% CER</th>
<th>North America CHFm</th>
<th>% CER</th>
<th>Asia-Pacific CHFm</th>
<th>% CER</th>
<th>Latin America CHFm</th>
<th>% CER</th>
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<tbody>
<tr>
<td>Core Lab²</td>
<td>3,935</td>
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<td>1,362</td>
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<td>Point of Care</td>
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<tr>
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<td><strong>7,098</strong></td>
<td><strong>-23</strong></td>
<td><strong>2,456</strong></td>
<td><strong>-22</strong></td>
<td><strong>1,940</strong></td>
<td><strong>-30</strong></td>
<td><strong>2,205</strong></td>
<td><strong>-23</strong></td>
<td><strong>497</strong></td>
<td><strong>0</strong></td>
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CER (Constant exchange Rates) of the respective year; ¹ Europe, Middle East and Africa; ² incl. Roche Information Solutions
Diagnostics Division quarterly sales and CER growth

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<tr>
<th></th>
<th>Q1 22</th>
<th>Q2 22</th>
<th>Q3 22</th>
<th>Q4 22</th>
<th>Q1 23</th>
<th>Q2 23</th>
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<tr>
<td></td>
<td>CHFm</td>
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<td>CHFm</td>
<td>% CER</td>
<td>CHFm</td>
<td>% CER</td>
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<td>7</td>
<td>323</td>
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<td>3,475</td>
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</tbody>
</table>

CER (Constant exchange Rates) of the respective year; \(^1\) versus same period of prior year; \(^2\) incl. Roche Information Solutions
HY 2023: Diagnostics Division regional sales

Decline in most regions

Sales YTD CHFm & % of total sales

Total YTD Sales = 7,098

2,456 / 35%
2,205 / 31%
1,940 / 27%
497 / 7%

Sales growth at CER

Diagnostics Division

EMEA* NOA APAC LAM

-23%
-22%
-30%
-23%
0%

GLOBAL

CER=Constant Exchange Rates; * Europe, Middle East and Africa
Core Lab¹

CER=Constant Exchange Rates; ¹ incl. Roche Information Solutions; underlying growth of Core Lab excluding Roche Information Solutions: +9%
Molecular Lab

2023 vs. 2022
CER growth
-40%

-5%
-50%
+24%
-2%
-39%
+13%
-60%

Virology  Blood Screening  MD Systems  Microbiology
Cervical Cancer  qPCR&NAP  Other

CER=Constant Exchange Rates
Diabetes Care

CER=Constant Exchange Rates
Pathology Lab

CHFbn

2023 vs. 2022
CER growth
+12%

CER=Constant Exchange Rates

HY 2021
HY 2022
HY 2023

Advanced Staining
Primary Staining
Companion Diagnostics

+20%
+17%
+10%
Point of Care

CER=Constant Exchange Rates
Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information
CHF/USD

Monthly averages

Year-To-Date averages
CHF/USD

HY 2023 -4%

avg full year 2022  avg full year 2023  monthly avg 2022  monthly avg 2023
CHF/EUR

Monthly averages

Year-To-Date averages
<table>
<thead>
<tr>
<th>Month</th>
<th>avg full year 2022</th>
<th>avg full year 2023</th>
<th>monthly avg 2022</th>
<th>monthly avg 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan</td>
<td>1.00</td>
<td>0.96</td>
<td>1.00</td>
<td>0.96</td>
</tr>
<tr>
<td>Feb</td>
<td>0.98</td>
<td>0.98</td>
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<td>0.98</td>
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<tr>
<td>May</td>
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<tr>
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<td>Jul</td>
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<td>1.10</td>
<td>1.10</td>
</tr>
<tr>
<td>Aug</td>
<td>1.12</td>
<td>1.12</td>
<td>1.12</td>
<td>1.12</td>
</tr>
<tr>
<td>Sep</td>
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<td>1.14</td>
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<td>Oct</td>
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<td>Nov</td>
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<td>Dec</td>
<td>1.20</td>
<td>1.20</td>
<td>1.20</td>
<td>1.20</td>
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</table>
## Average CHF Exchange Rates

<table>
<thead>
<tr>
<th>Currency</th>
<th>HY 2023</th>
<th>HY 2022</th>
<th>HY 2023 vs. HY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>0.91</td>
<td>0.94</td>
<td>-3%</td>
</tr>
<tr>
<td>EUR</td>
<td>0.99</td>
<td>1.03</td>
<td>-4%</td>
</tr>
<tr>
<td>JPY</td>
<td>0.68</td>
<td>0.77</td>
<td>-12%</td>
</tr>
</tbody>
</table>
Exchange rate impact on sales growth

Q2 2023: negative impact of JPY, USD and EUR

Development of average exchange rates versus prior year period

<table>
<thead>
<tr>
<th>Currency Pair</th>
<th>CHF / USD</th>
<th>CHF / EUR</th>
<th>CHF / JPY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exchange Rate Growth</td>
<td>0.2%</td>
<td>-4.3%</td>
<td>-12.1%</td>
</tr>
<tr>
<td>Prior Year Growth</td>
<td>-6.8%</td>
<td>-4.8%</td>
<td>-12.0%</td>
</tr>
</tbody>
</table>

Difference in CHF / CER growth

<table>
<thead>
<tr>
<th>CER Growth</th>
<th>CHF Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td>-3.1%</td>
<td>-6.8%</td>
</tr>
<tr>
<td>-0.2%</td>
<td>-8.8%</td>
</tr>
</tbody>
</table>

CHF growth vs. CER growth

CER=Constant Exchange Rates
Exchange rate impact on sales growth

HY 2023: negative impact of JPY, EUR and USD

Development of average exchange rates versus prior year period

<table>
<thead>
<tr>
<th>Currency Pair</th>
<th>CHF / USD</th>
<th>CHF / EUR</th>
<th>CHF / JPY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference</td>
<td>0.2%</td>
<td>-4.3%</td>
<td>-12.1%</td>
</tr>
<tr>
<td>Growth</td>
<td>-3.4%</td>
<td>-4.5%</td>
<td>-11.9%</td>
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</tbody>
</table>

Difference in CHF / CER growth:

| Growth          | -3.7%     | -6.1%     |

Sales growth 2023 vs. 2022:

<table>
<thead>
<tr>
<th>Quarter</th>
<th>CER growth</th>
<th>CHF growth</th>
<th>HY growth</th>
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</thead>
<tbody>
<tr>
<td>Q1</td>
<td>-3.1%</td>
<td>-6.8%</td>
<td>-7.8%</td>
</tr>
</tbody>
</table>
Doing now what patients need next