Roche

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.

Any statements regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche’s earnings or earnings per share for this year or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

For marketed products discussed in this presentation, please see full prescribing information on our website www.roche.com

Roche

Q1 2023 sales

Basel, 26 April 2023

Group

Thomas Schinecker
Chief Executive Officer

Q1 2023 performance

Outlook

Q1 2023: Strong underlying sales excluding COVID-19 decline

Roche

Group sales -3% driven by expected decline in COVID-19 testing

- Strong Pharma performance (+9%) driven by ongoing portfolio rejuvenation
- Good Diagnostics base business growth (+4%)
- COVID-19 sales decline in line with FY 2023 expectations

Growth supported by key products and strong launches

- Pharma key products Vabysmo, Ocrevus, Hemlibra, Evrysdi, Tecentriq, Perjeta, Phesgo and Polivy continuing to grow strongly
- Key Pharma approvals: Polivy in 1L DLBCL in the US, Hemlibra in moderate hem A in the EU, Columvi (glofitamab) in 3L+ DLBCL in Canada
- Diagnostics: launches of new tests in oncology, navify Algorithm Suite and navify Marketplace

Update on pipeline newsflow in 2023

- Positive Phase III results for Tecentriq + Avastin in adjuvant HCC and crovalimab in PNH achieved
- Pharma: 14 upcoming late-stage read-outs incl. 2 NMEs (tiragolumab, SRP-9001) and important line extensions for Ocrevus, Tecentriq, Venclexta, TNKase, Alecensa and Lunsumio
- Diagnostics: CCM Vertical, LightCycler Pro, Anti-HEV IgG/IgM, HBeAg Quant, and IL-6 Neonatal sepsis

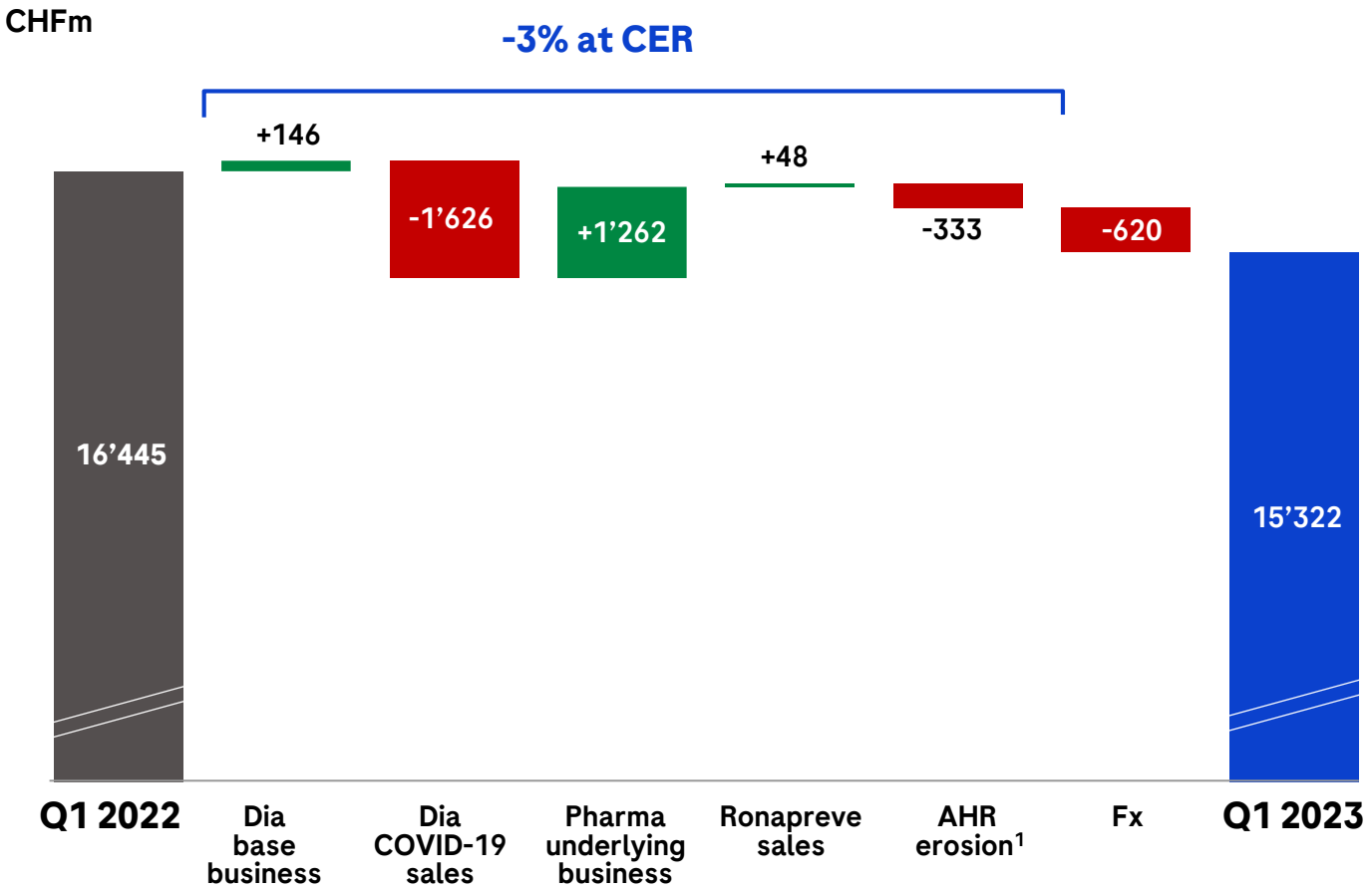
Growth rates at CER (Constant exchange Rates); DLBCL= diffuse large B-Cell lymphoma; NME=new molecular entity; HCC=hepatocellular carcinoma; PNH=paroxysmal nocturnal hemoglobinuria

Q1 2023: Group sales decline driven by COVID-19 sales erosion

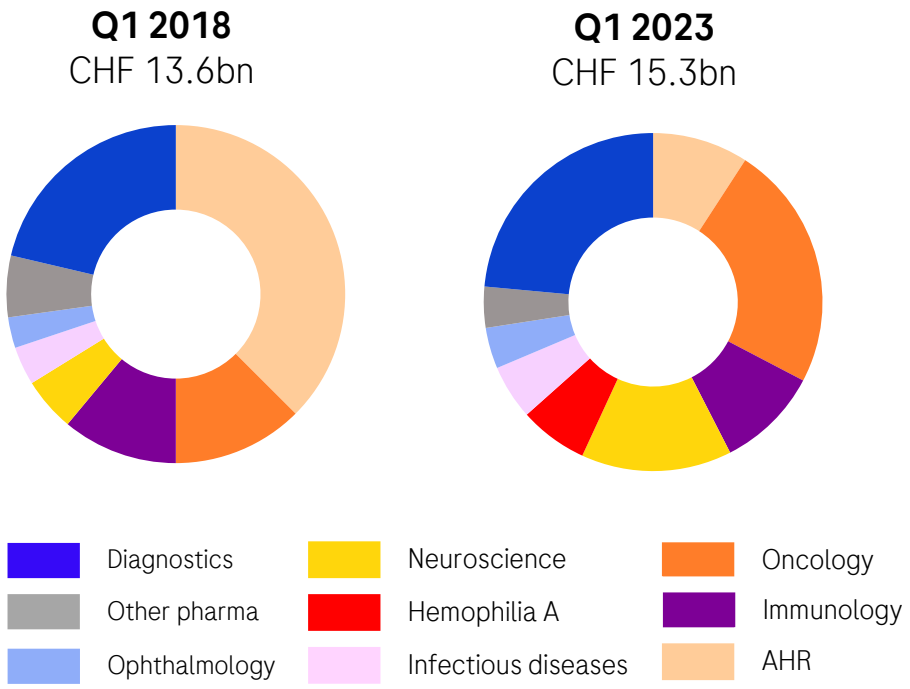
	2023 CHFbn	2022 CHFbn	Change in % CHF	Change in % CER	Excl. C19[1]
Pharmaceuticals Division	**11.7**	11.2	**5**	**9**	**9**
Diagnostics Division	**3.6**	5.3	**-31**	**-28**	**4**
Roche Group	**15.3**	16.4	**-7**	**-3**	**8**

CER=Constant Exchange Rates; totals may include differences due to rounding; [1] Pharmaceuticals Division sales excluding Ronapreve, Diagnostics Division base business

Q1 2023: Portfolio diversification ongoing



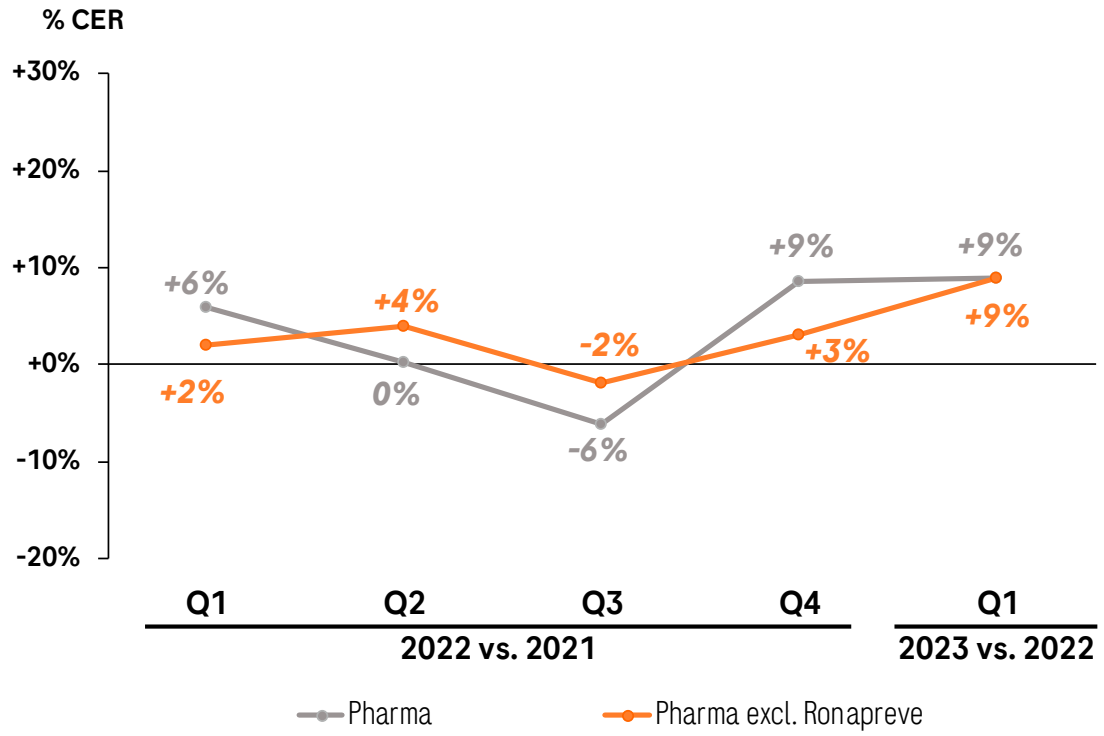
Diversification of Roche portfolio



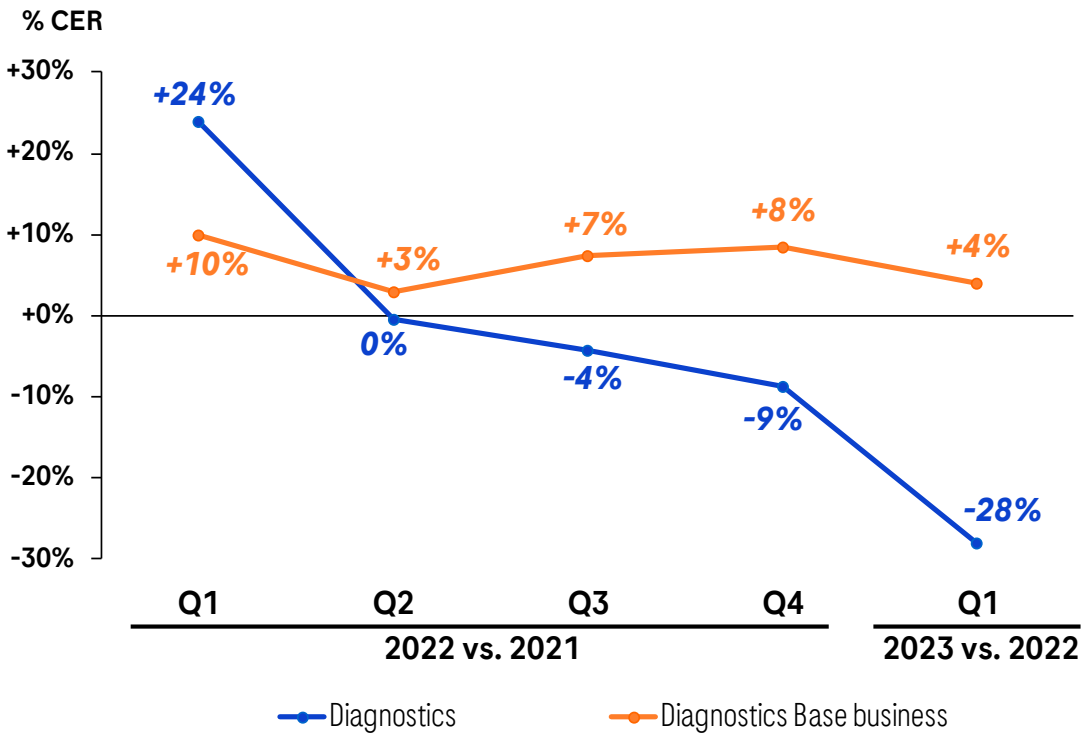
Values in reported CHFm, variances in CERm; [1] AHR: Avastin, Herceptin, Rituxan/MabThera sales erosion

Q1 2023: Strong underlying growth in Pharma and Diagnostics

Pharma
Quarterly sales evolution 2022-2023



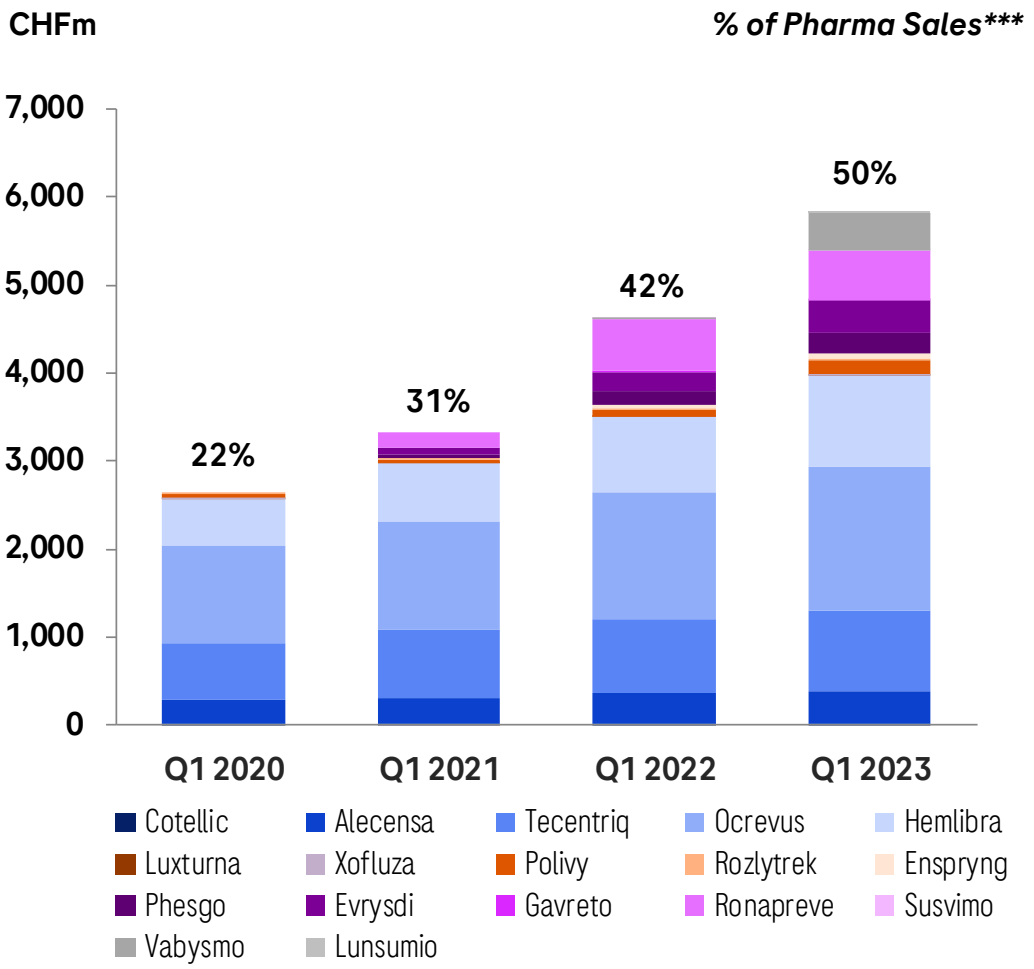
Diagnostics
Quarterly sales evolution 2022-2023



Growth rates at CER (Constant Exchange Rates)

Portfolio rejuvenation progressing; new launches with >50% of sales

*Columvi (glofitamab): first NME launch in 2023**



*First launch in Canada, PDUFA date in the US is July 1st; ** SRP-9001: Accelerated US-filing by partner company Sarepta; crovalimab: First filing in China; ***Venclexta sales booked by AbbVie and therefore not included

2023 performance

Outlook

2023: Upcoming newsflow

Pharma

Tiragolumab + Tecentriq in 1L PDL1+ NSCLC	**Glofitamab + GemOx** in 2L+ DLBCL
Tiragolumab + Tecentriq + chemo in 1L Esophageal	**Lunsumio + Polivy** in 2L+ DLBCL*
Tecentriq + Avastin in adjuvant HCC ✓	**Crovalimab** in PNH ✓
Tecentriq in adjuvant SCCHN	**Delandistrogene moxeparvovec (SRP-9001)** in DMD
Tecentriq + chemo in adjuvant TNBC ✗	**Ocrevus 6m SC** in RMS / PPMS
Tecentriq neoadjuvant/adjuvant TNBC	**TNKase** in Stroke
Phesgo OBI in HER2+ BC	**Susvimo** in DME ✓
Alecensa in adjuvant ALK+ NSCLC	**Susvimo** in DR ✓
Venclexta + azacitidine in 1L high risk MDS	**Xolair** in Food allergy
Venclexta + dexamethasone in R/R MM (t11;14)	

Diagnostics

CCM Vertical	Modular transportation system, integrated into existing cobas connection modules
LightCycler Pro	Flexible real-time PCR instrument with dual IVD and Research mode
Anti-HEV IgG and Anti-HEV IgM	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
HBeAg Quant	Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B
IL-6 Neonatal sepsis (claim extension)	Immunoassay with dedicated claim aiding in diagnosis of sepsis in neonates

Neuroscience
Oncology/Hematology
Ophthalmology
Immunology

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; *Results are event-driven, read-outs expected 2023/24

Corporate Executive Committee

Since April 2023

Thomas Schinecker
CEO Group

Pharma Division

Teresa Graham
Pharma CEO*

Levi Garraway
Head of Pharma Dev / CMO*

Hans Clevers
Head of pRED

Aviv Regev
Head of gRED

James Sabry
Head of Partnering

Diagnostics Division

Matt Sause
Diagnostics CEO

Group Functions

Alan Hippe
CFO / CIO

Cris Wilbur
Chief People Officer

Claudia Boeckstiegel
General Counsel

Barbara Schaedler
Head of Group Comms

Silke Hoernstein
Head of Strategy & Sustainability

*Co-chair late stage pipeline committee (LSPC); pRED=Pharma Research & Early Development; gRED=Genentech Research & Early Development

2023 sales outlook

Sales drivers[1]

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

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)

Pharmaceuticals Division

Teresa Graham
CEO Roche Pharmaceuticals

Q1 2023: Pharmaceuticals Division sales

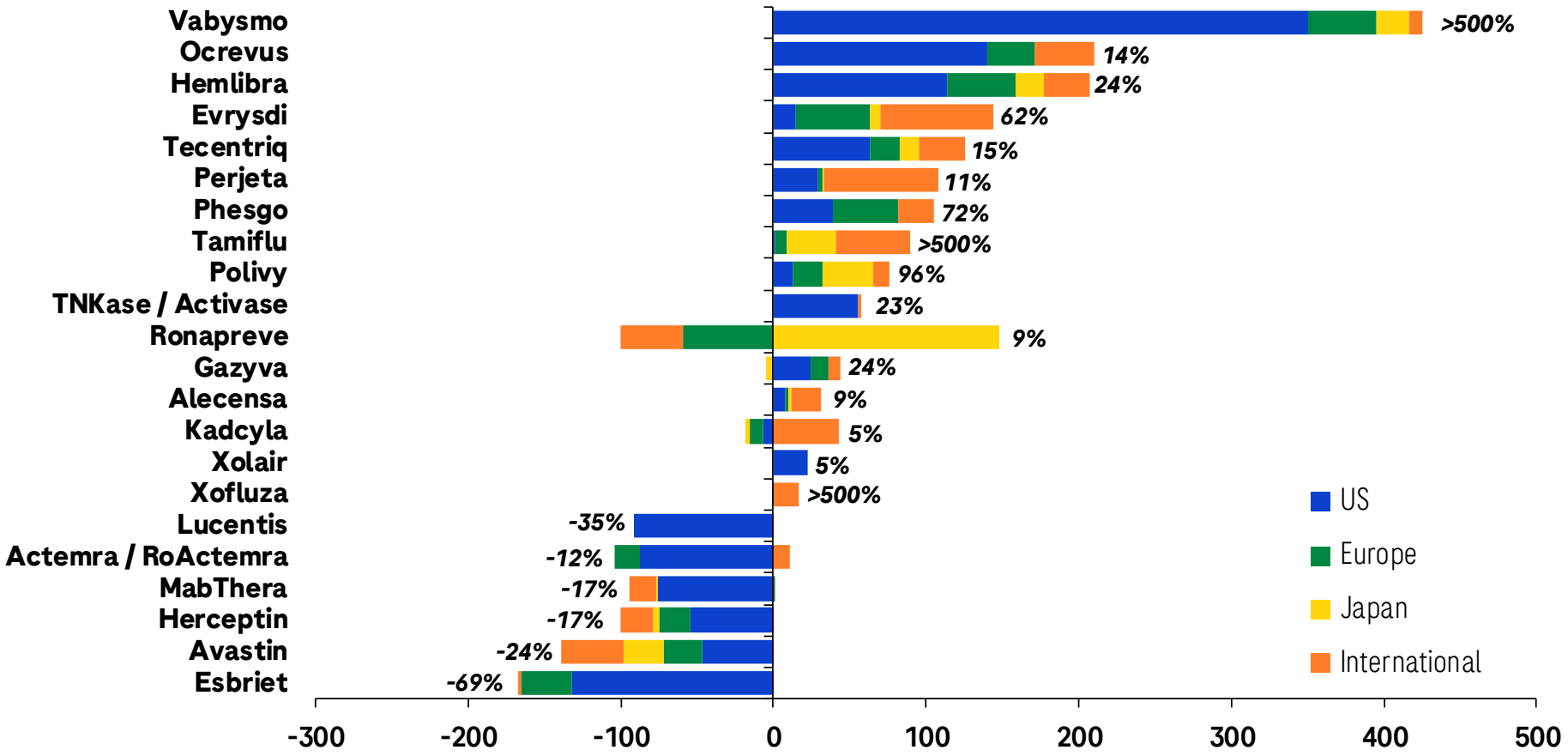
All regions delivering strong growth

	2023 CHFm	2022 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**11,699**	**11,159**	**5**	**9**
United States	5,853	5,489	7	6
Europe	2,071	2,072	0	5
Japan	1,390	1,337	4	18
International	2,385	2,261	5	13

CER=Constant Exchange Rates

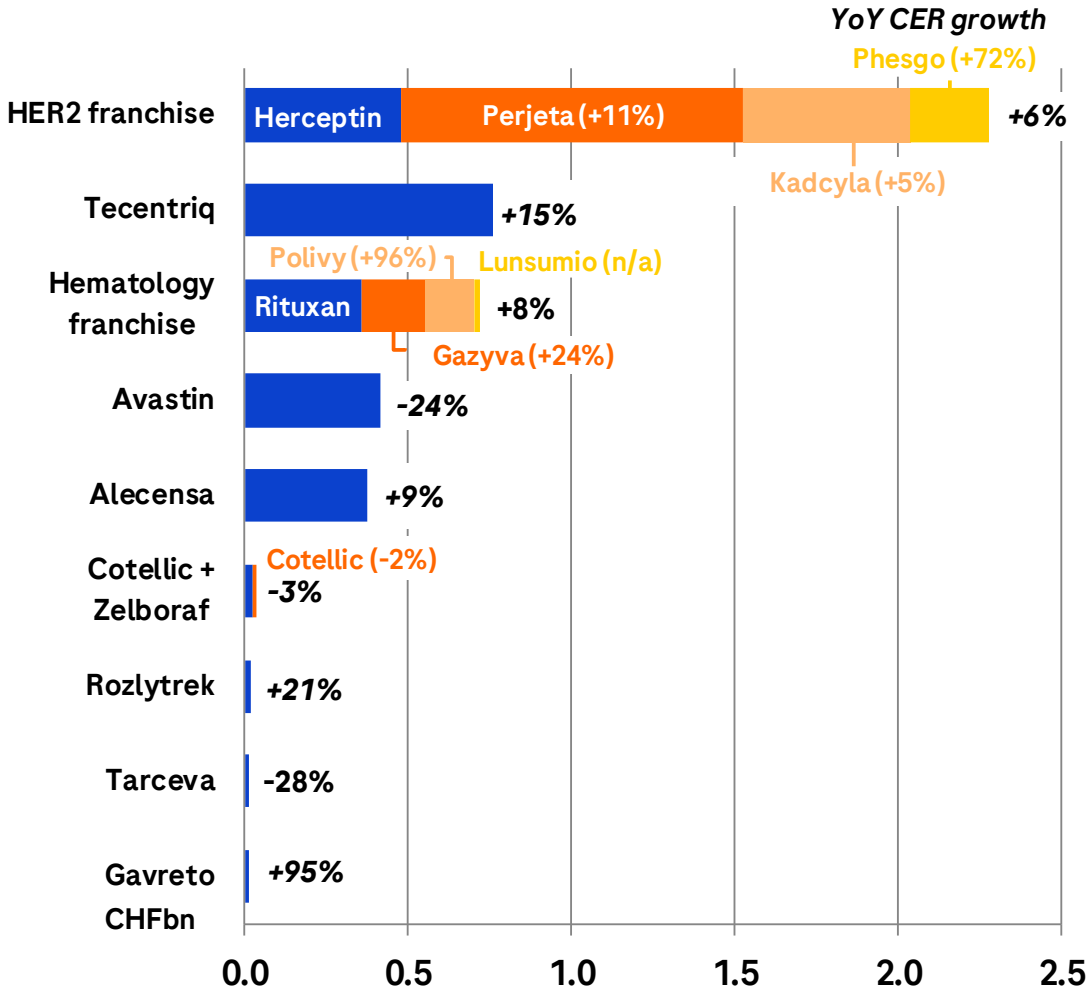
Q1 2023: Strong momentum for key growth drivers

Vabysmo leading growth contributor after only 5 quarters



Absolute values and growth rates at Constant Exchange Rates (CER)

Q1 2023: Oncology portfolio growing +4%



HER2 franchise

- Kadcyla (+5%) with growth ex-US in adj. BC; China NRDL listing granted
- Perjeta (+11%) driven by US & International
- Phesgo (+72%): 35% conversion in early launch countries*

Tecentriq

- Solid growth (+15%) driven by adjuvant NSCLC and 1L HCC

Hematology franchise

- Venclexta**: Expanding patient share in 1L AML & 1L CLL
- Gazyva (+24%): Growth driven by 1L FL and 1L CLL
- Polivy (+96%): Strong 1L DLBCL uptake ex-US; FDA approval in 1L DLBCL
- Lunsumio: Global 3L+ FL launch ongoing; NCCN guideline inclusion as category 2A granted

Alecensa

- Good growth (+9%) and 1L ALK+ NSCLC leadership in major markets
- Ph III (ALINA) in adjuvant ALK+ NSCLC expected in 2023

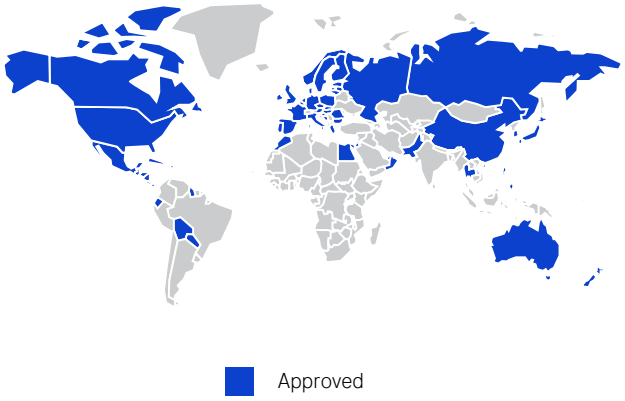
Q1 2023 Oncology sales: CHF 4.9bn, CER growth +4%; CER=Constant Exchange Rates; * Phesgo conversion rate is based on volumes (vials) and includes all launch countries after the 2nd quarter after the launch (30 countries); ** Venclexta sales booked by AbbVie and therefore not included; BC=breast cancer; NRDL=national reimbursement drug list; HCC=hepatocellular carcinoma; NSCLC=non-small cell lung cancer; AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; ALK=anaplastic lymphoma kinase; Polivy in collaboration with Seagen

Polivy in 1L DLBCL: FDA approval granted

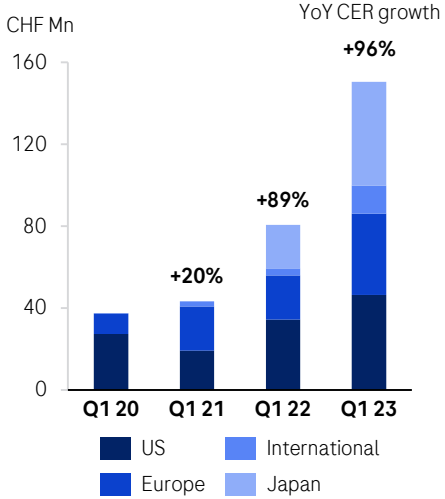
Comprehensive NHL development program ongoing

Uptake in 1L DLBCL accelerating

1L DLBCL approved in >70 countries



Polivy quarterly sales



- FDA ODAC voted 11-2 in favor of clinical benefit in 1L DLBCL
- US approval granted with label for 1L DLBCL with IPI score 2-5
- US: Included in NCCN guideline as category 1*
- UK: NICE reimbursement obtained**

NHL development program progressing

Indication	Regimen	Ph I	Ph II	Ph III
2L+ DLBCL *(SCT ineligible)*	Polivy + R-GemOx	POLARGO		
2L+ DLBCL *(SCT ineligible)*	Lunsumio + Polivy	SUNMO		
2L+ DLBCL *(SCT ineligible)*	Columvi + GemOx	STARGLO		
1L DLBCL	Columvi + Polivy + R-CHP			
1L DLBCL *(elderly unfit)*	Lunsumio + Polivy			
2L+ DLBCL *(SCT ineligible)*	Columvi + Polivy			
2L FL	Lunsumio + lenalidomide	CELESTIMO		

- Ph III Columvi + Polivy + R-CHP in 1L DLBCL to be initiated in 2023
- Ph III (SUNMO) Lunsumio + Polivy in 2L+ DLBCL to read out in 2023/24
- Ph III (STARGLO) Columvi + GemOx in 2L+ DLBCL to read out in H2 2023

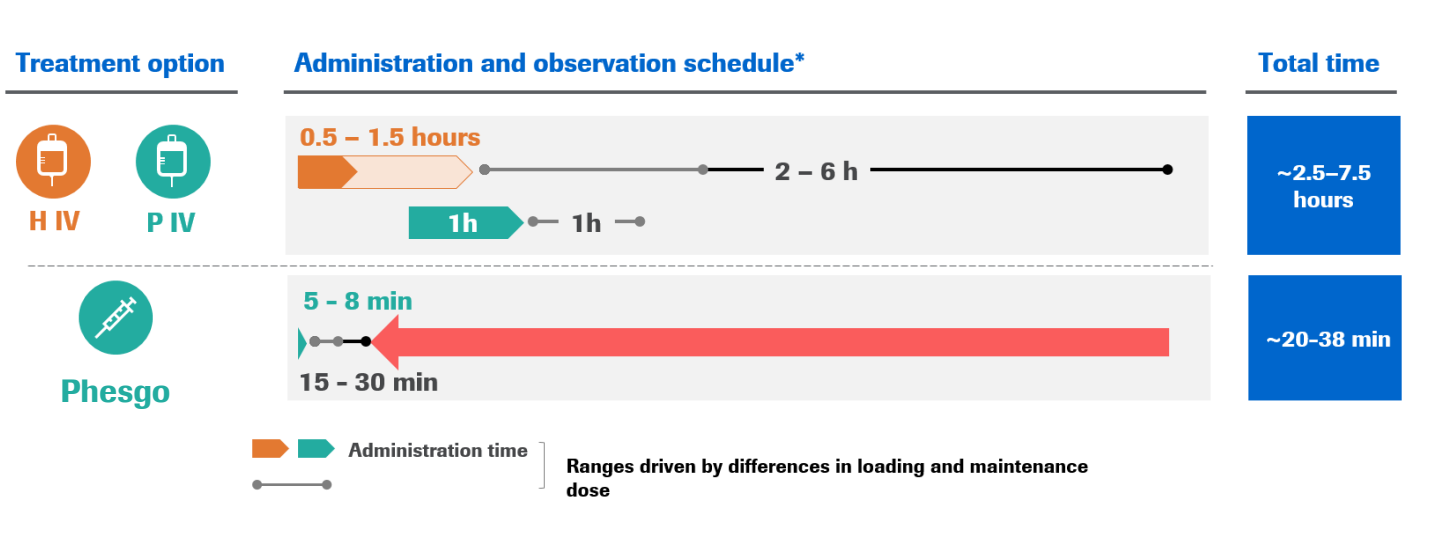
CER=constant exchange rates; NHL=Non-Hodgkin's lymphoma; DLBCL=diffuse large B-cell lymphoma; ODAC=oncologic drugs advisory committee; IPI=International prognostic index; FL=follicular lymphoma; R-GemOx=rituxan + gemcitabine + oxaliplatin; R-CH(O)P=rituxan + cyclophosphamide + doxorubicin + (vincristine) + prednisone; *NCCN guidelines for B-Cell Lymphomas (V1.2023); **NICE: Polatuzumab vedotin in combination for untreated diffuse large B-cell lymphoma [ID3901]; Polivy in collaboration with Seagen

Phesgo: Conversion rate in early launch countries climbing to 35%

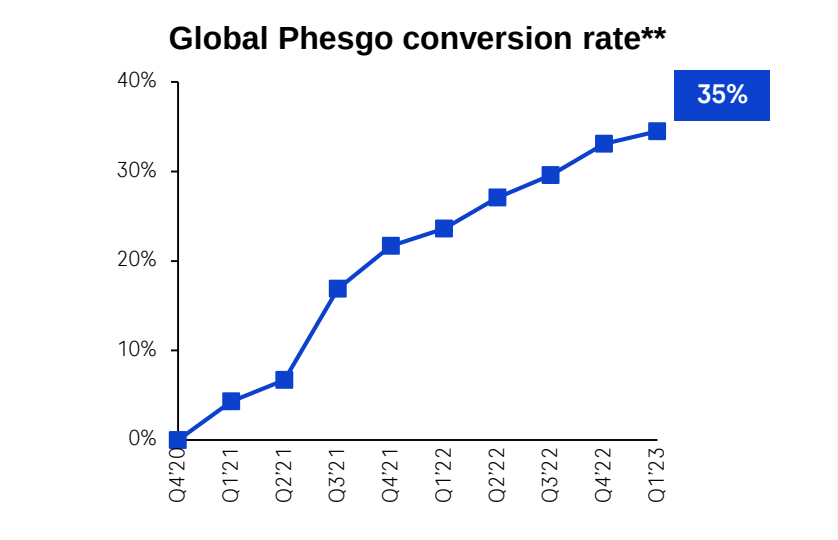
Roche

PHESGO®

Phesgo reduces administration time & costs



Phesgo with strong global launch



- 85% of patients preferred Phesgo for Subcutaneous administration over the intravenous formulation of Perjeta and Herceptin
- Phesgo conversion rate at 35% in early launch countries, including strong uptake in the US and Germany
- Pivotal Ph I results for Phesgo OBI (on body injector) to enable patient self-administration expected in H2

Source: O'Shaughnessy J, et al. ESMO 2020 (Abstract 165MO); H=Herceptin; P=Perjeta; IV=Intravenous; *Ranges driven by differences in loading and maintenance dose; **Phesgo conversion rate is based on volumes (vials) and includes all launch countries after the 2nd quarter after the launch (30 countries); Phesgo in collaboration with Halozyme

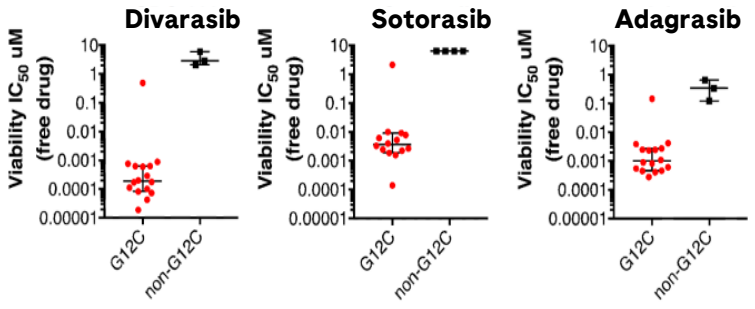
Divarasib in CRC: Positive early combination data at AACR

Potential for best-in-class profile

Divarasib (KRAS G12Ci)

FDA BTD

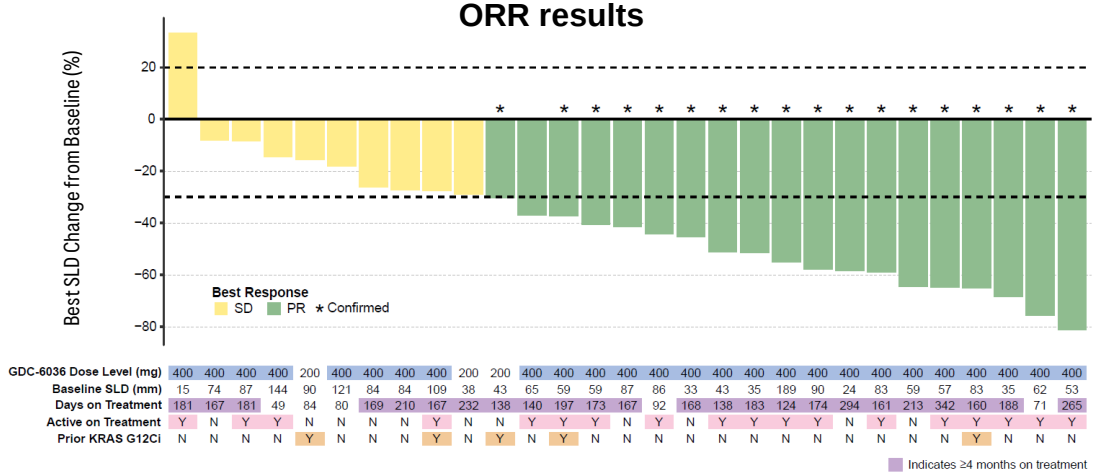
in vitro proliferation assay



- Irreversible covalent inhibitor of KRAS G12C
- More potent and selective *in vitro* than sotorasib and adagrasib
- Granted FDA BTD for 2L NSCLC
- KRAS is the most frequently mutated oncogene, occurring in more than 25% of all cancers

Ph Ib results for divarasib + cetuximab in advanced or metastatic CRC

ORR results

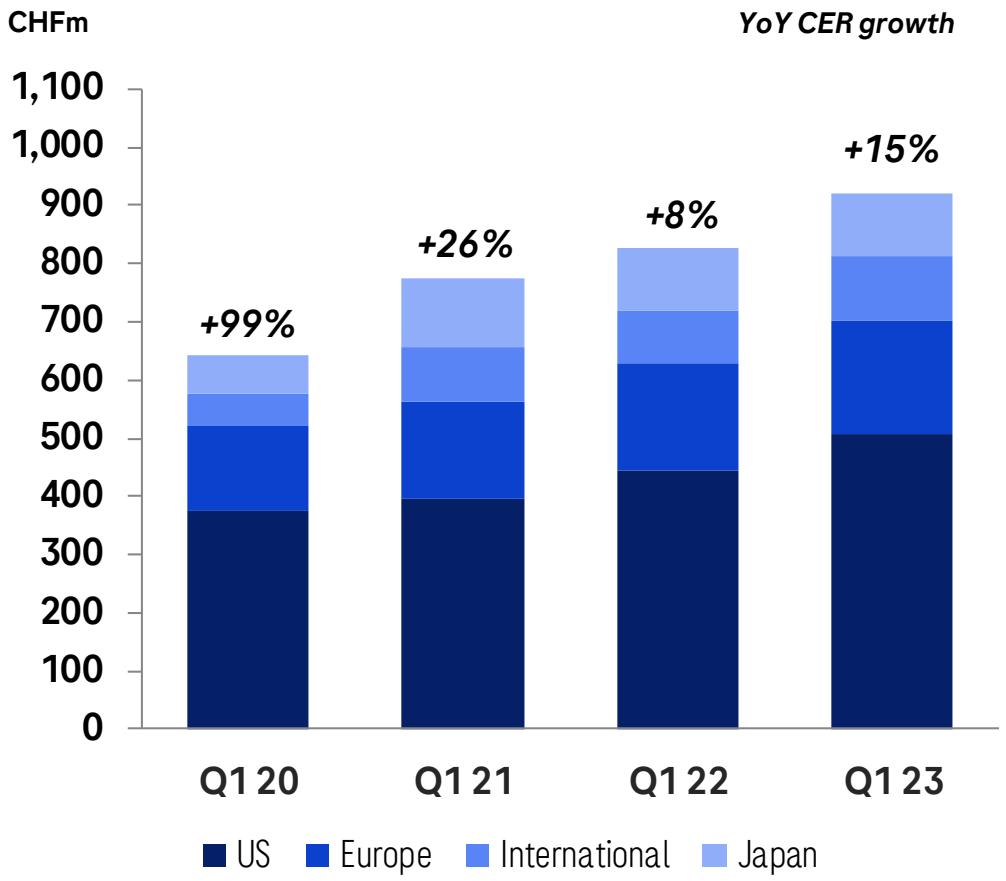


- Promising Ph Ib results in CRC with unconfirmed / confirmed ORR = 66 % / 62% and manageable safety profile
- Strong responses in several other indications, including 2L+ NSCLC
  - Confirmatory pivotal Ph III trial in 2L+ NSCLC initiated in Q4 2022
- Ph II/III (BFAST) with divarasib cohort in NSCLC ongoing

Source: Purkey et al. AACR 2022 ; Phase Ib study of GDC-6036 in combination with cetuximab in patients with colorectal cancer (CRC) with KRAS G12C mutation, Desai et al., AACR annual meeting 2023; KRAS=kirsten rat sarcoma; G12C=glycine-to-cysteine substitution at codon 12; IC_{50}=inhibitory concentration; BTD=breaktrough therapy designation; CRC=colorectal cancer; NSCLC=non-small cell lung cancer; ORR=overall response rate; SLD=sum of lesion diameter; SD=stable disease; PR=partial response; Lumakras (sotorasib) is a registered trademark/product of Amgen; Krazati (adagrasib) is a registered trademark/product of Mirati Therapeutics

Tecentriq: Solid growth across all regions

First PD-(L)1 with pivotal SC results filed and PDUFA set for September 15th



Q1 update

- Ph III (IMbrave050) results in adjuvant HCC presented at AACR; RFS primary endpoint met but OS immature
- Ph III (IMpassion030) in adjuvant TNBC to be discontinued

Lung franchise (NSCLC, SCLC)

- EU: Strong adjuvant NSCLC launch
- US: Growth in SCLC and adjuvant NSCLC

GI franchise (HCC)

- US/EU/Japan: Further growth in 1L HCC

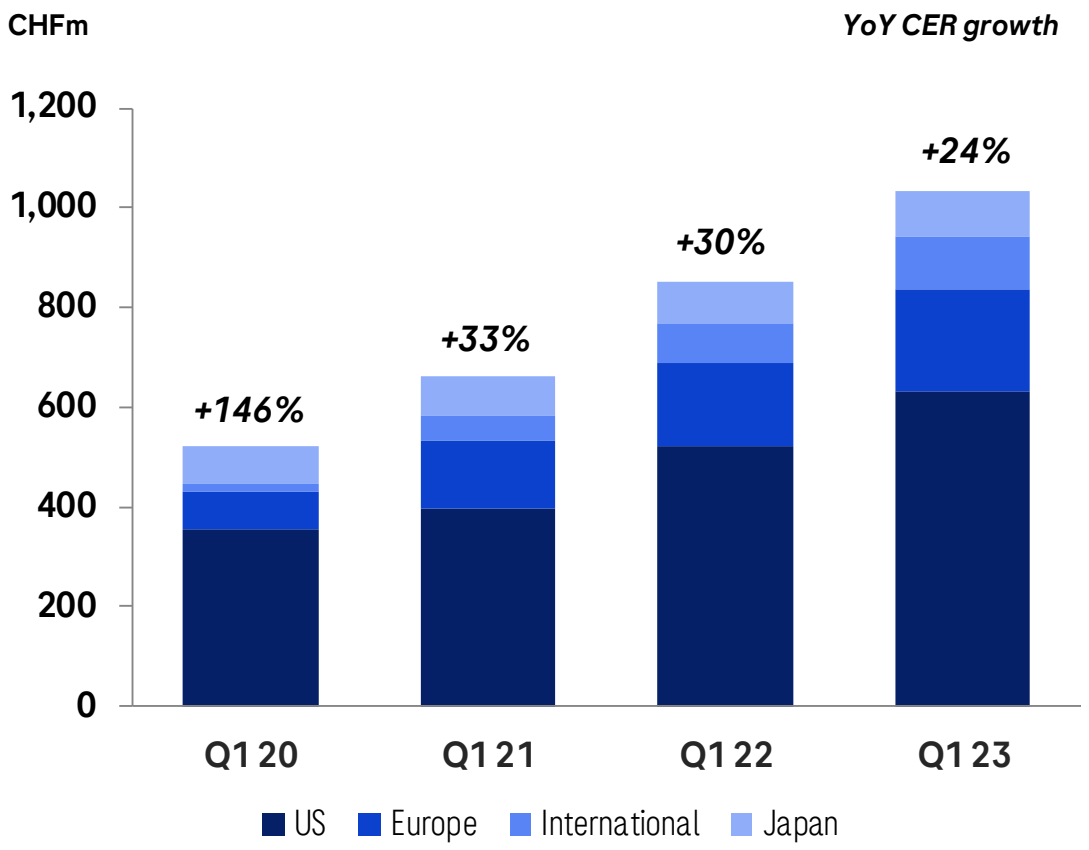
Outlook 2023

- Ph III (IMvoke010) results in adjuvant SCCHN expected in H2
- Ph III (SKYSCRAPER-01) Tecentriq + tiragolumab in 1L NSCLC to continue to final analysis, expected in Q3

CER=Constant Exchange Rates; SC=subcutaneous; NSCLC=non-small cell lung cancer; HCC=hepatocellular cancer; SCLC=small cell lung cancer; TNBC=triple-negative breast cancer; SCCHN=squamous cell carcinoma of head and neck; PDUFA=prescription drug user fee act; RFS=recurrence free survival; OS=overall survival

Hemophilia A: Hemlibra the global standard of care

37% US/EU-5 patient share reached



Q1 update

- ~20,000 patients treated globally
- Hemlibra continues to penetrate across all approved patient segments
- EU: Label extension to moderate patients (HAVEN 6) granted

Outlook 2023

- US/EU: Further patient share gains in non-inhibitors
- SPK-8011 (dirloctocogene samoparvovec) pivotal Ph III to be initiated

CER=Constant Exchange Rates

Crovalimab: Positive Ph III results in PNH

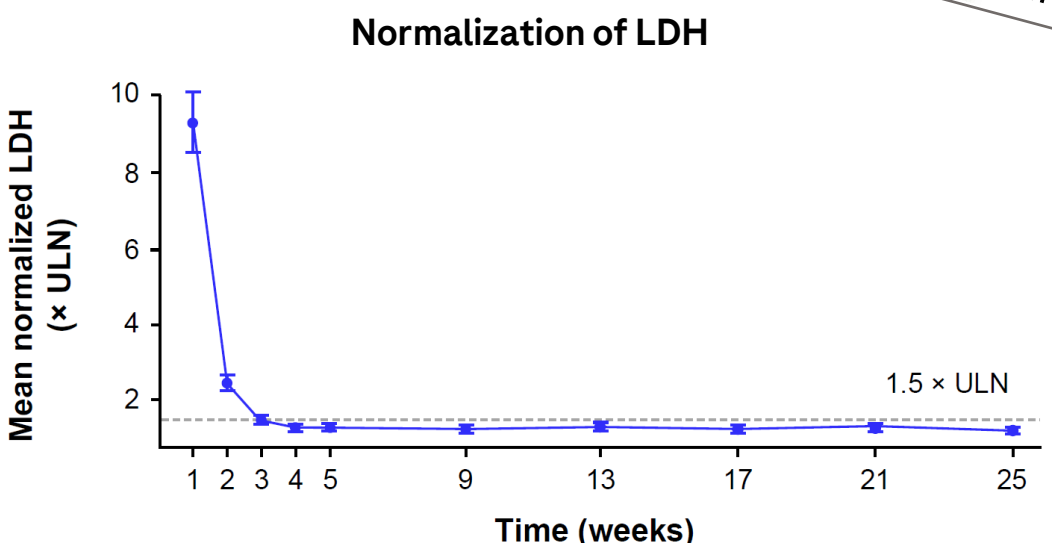
Expanding into additional diseases: Ph I in LN initiated

Roche

IR virtual event June 12th

Ph III (COMMODORE 3) results in PNH

ASH 2022



Crovalimab development program

Indication		Ph I	Ph II	Ph III	
PNH	*Paroxysmal nocturnal hemoglobinuria*	**COMPOSER**			✓
		COMMODORE 1 (switch)			✓
		COMMODORE 2 (naïve)			✓
		COMMODORE 3 (China)			✓
aHUS	*Atypical hemolytic uremic syndrome*	**COMMUTE-a** (adults)			
		COMMUTE-p (pediatric)			
SCD	*Sickle cell disease*	**CROSSWALK-c** (chronic)			
		CROSSWALK-a (acute)			
LN	*Lupus nephritis*				

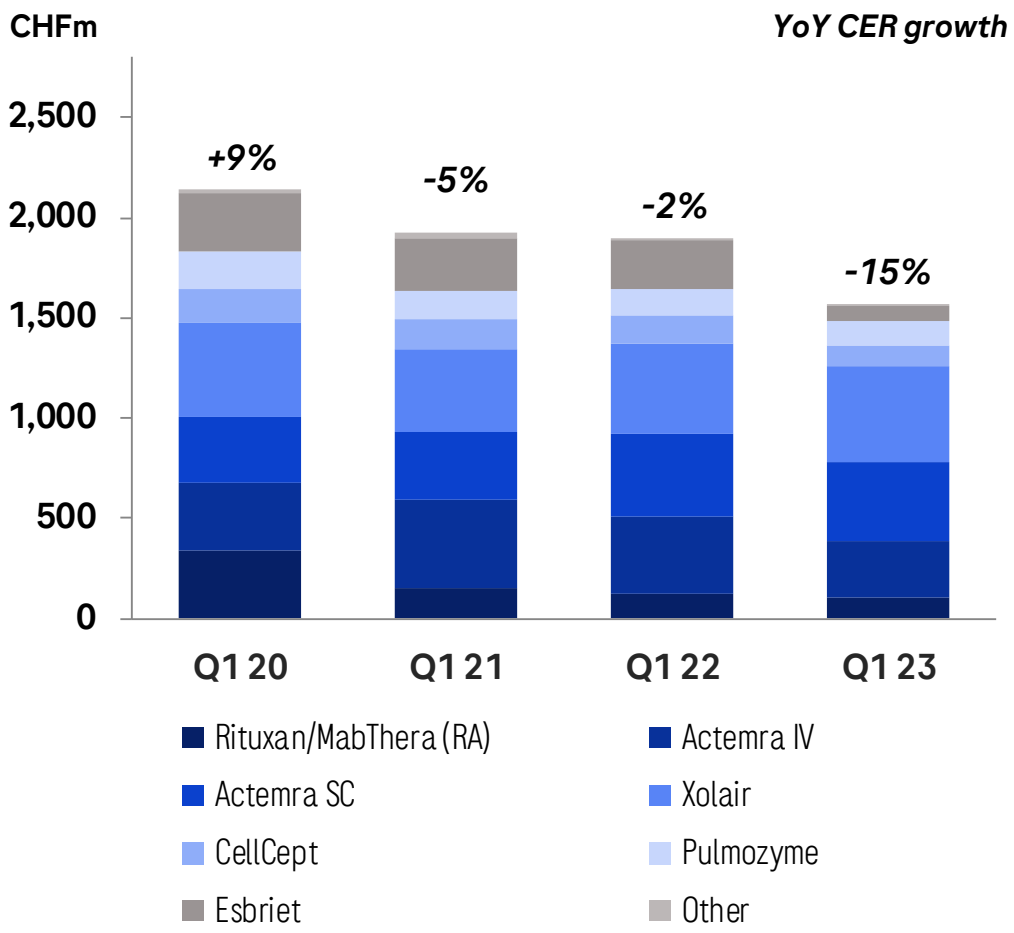
EHA 2023

- Ph III China (COMMODORE 3) results show that mean LDH ≤1.5 × ULN was reached by week 3 and maintained through week 25
- Ph III (COMMODORE 2/1) results show successful disease control in naïve patients, and a favorable benefit-risk profile for patients switching from other C5 inhibitors; Safety was consistent with the known safety profile of C5 inhibitors; Results to be presented at EHA 2023
- Filed in China (BTD, Priority Review) with approval expected in 2023; Global filing planned for H1 2023

Liu et al. ASH 2022; PNH=Paroxysmal nocturnal hemoglobinuria; LN=lupus nephritis; LDH=lactate dehydrogenase; ULN=upper limit of normal;; BTD=breakthrough therapy designation

Immunology: Actemra COVID-19 sales declining and Esbriet LOE

Xolair autoinjector approval and Ph III food allergy readout expected in 2023



Q1 updates

- Ph III (REGENCY) Gazyva in LN fully recruited; read out expected in 2024
- Ph III (INShore) Gazyva in PNS initiated

Actemra (-12%)

- COVID-19 related sales declining
- Shift from IV to SC ongoing, SC share at ~60%

Esbriet (-69%)

- Generic competition in US and EU

Xolair (+5%)

- Market leader in asthma biologics and strong growth in CSU

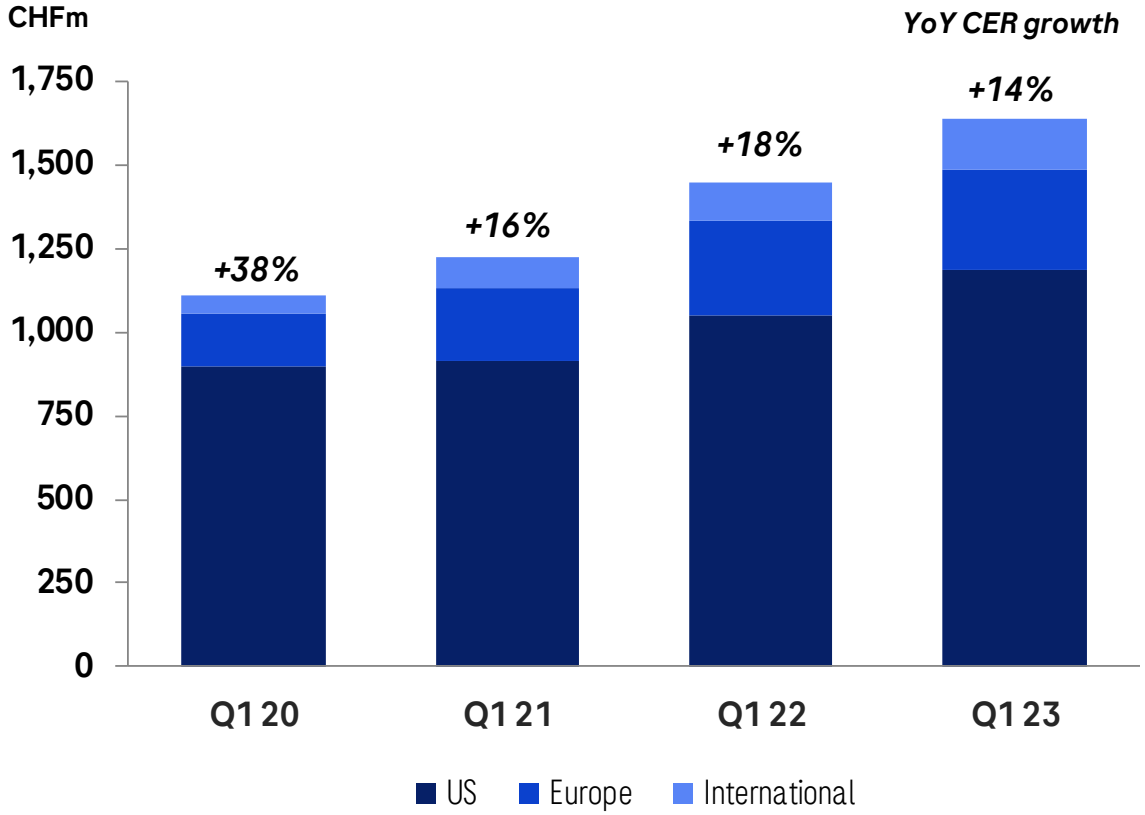
Outlook 2023

- US approval of Xolair autoinjector expected
- Ph III (OUtMATCH) in food allergy read out expected
- Ph III (IMAGINATION) ASO factor B in IgAN to be initiated

CER=Constant Exchange Rates; LOE=loss of exclusivity; RA=rheumatoid arthritis; IV=intravenous; SC=subcutaneous; LN=lupus nephritis; CSU=chronic spontaneous urticaria; ASO=antisense oligonucleotide; IgAN=immunoglobulin A nephropathy; PNS=pediatric nephrotic syndrome

Multiple Sclerosis: Ocrevus reaching 22% patient share

Ph III results for 6M SC Ocrevus expected in 2023



Q1 update

- >300k patients treated globally
- #1 treatment in US and EU-5, both in total share and new to brand share
- Higher retention rate than other MS medicines
- Ph III (GAVOTTE/MUSETTE) high-dose Ocrevus recruitment completion imminent

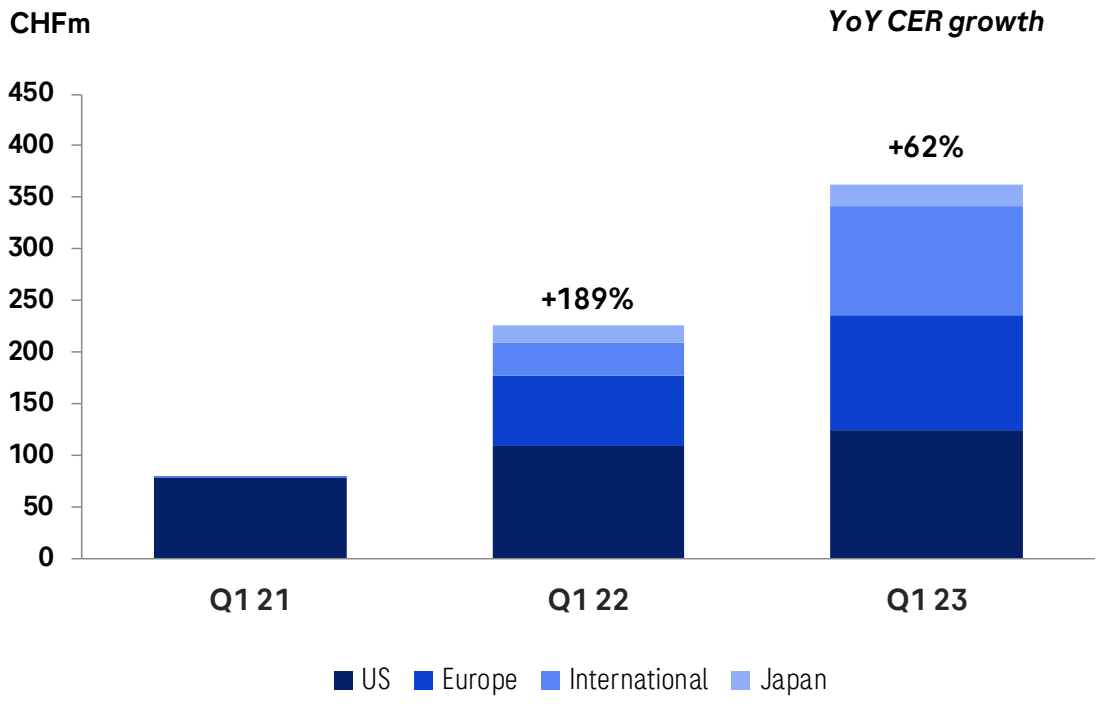
Outlook 2023

- US/EU: Further market share gains and growth expected
- Ph III (OCARINA II) Ocrevus SC with Q6M dosing in RMS & PPMS data read out expected
- First Ph II (FENopta) data for fenebrutinib in RMS expected

CER=Constant Exchange Rates; MS=multiple sclerosis; SC=subcutaneous; Q6M=every 6 months; RMS=relapsing MS; PPMS=primary progressive MS

Spinal Muscular Atrophy: Evrysdi market leader in US and Japan

Increasing penetration in treatment-naive patient segment



Q1 update

- >8,500 patients treated worldwide; retention rate in first 12 months of ~90% globally
- US: 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
- Ph II/III (SUNFISH) 4year data presented at MDA 2023

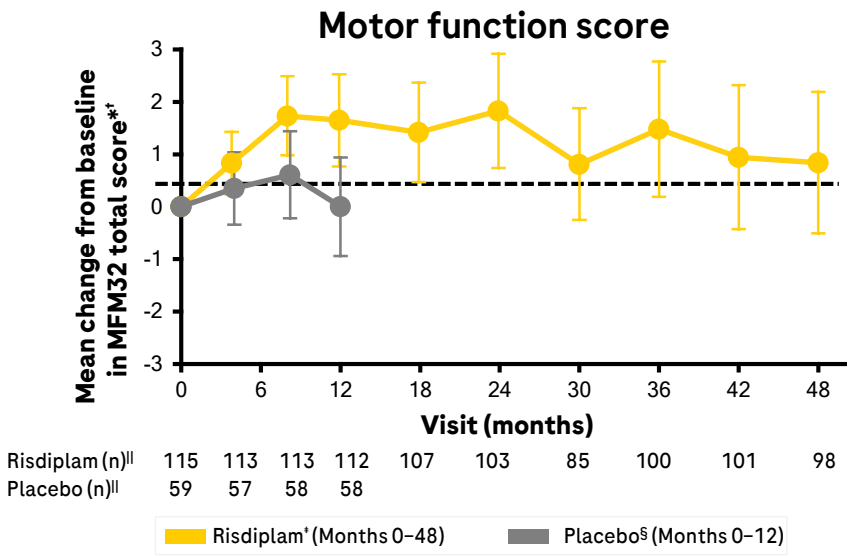
Outlook 2023

- Continued growth and market share gains
- EU: Label extension (<2 months old) based on Ph II (RAINBOWFISH) expected

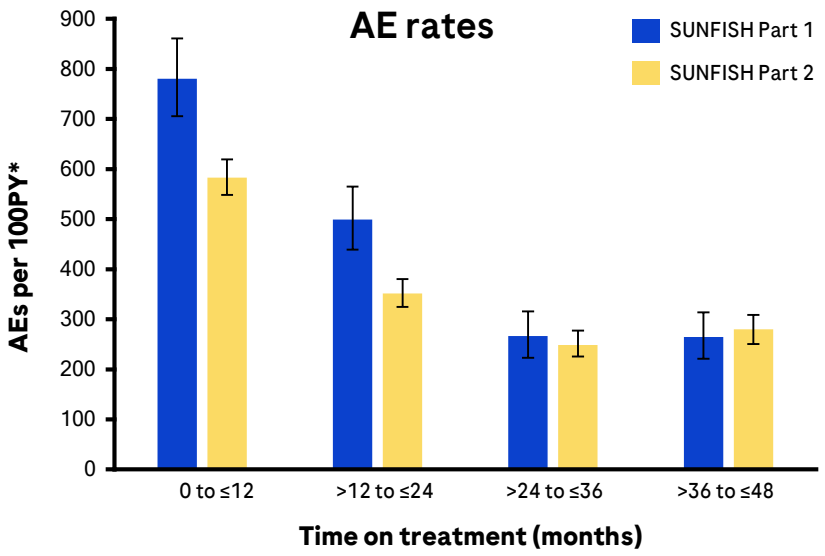
CER=Constant Exchange Rates

Evrysdi: 4 year data reinforce strong efficacy and safety profile

Ph II/III (SUNFISH) results in SMA



Ph II/III (SUNFISH) safety in SMA

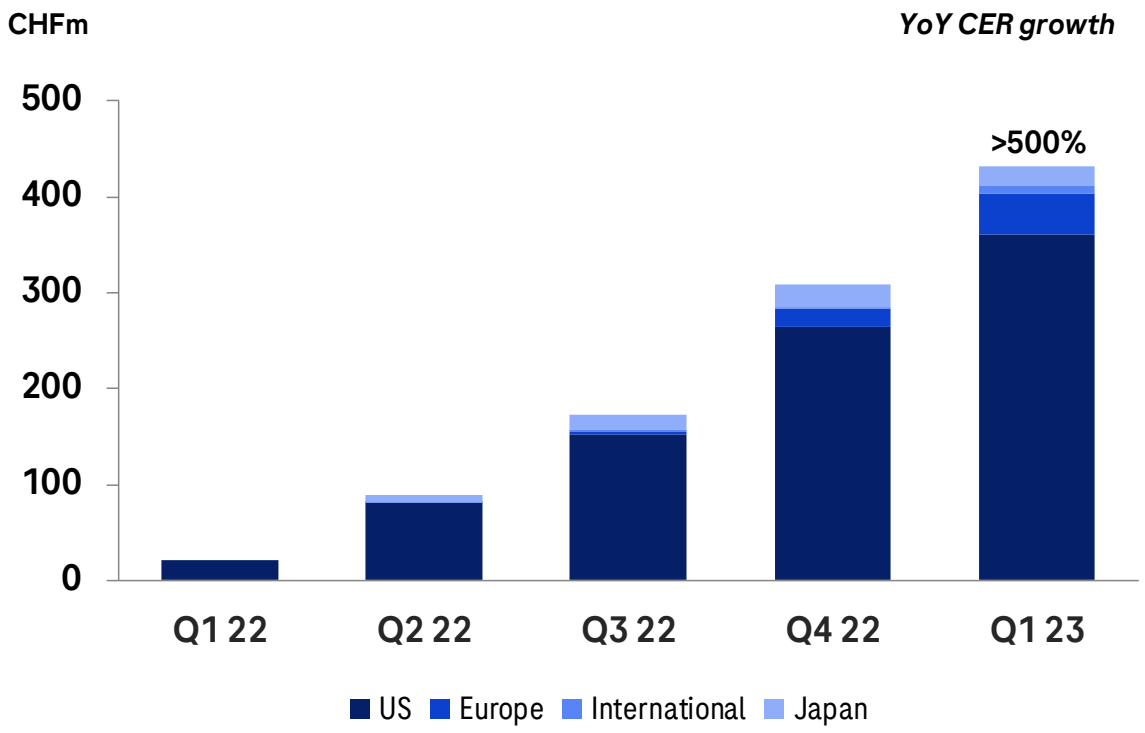


- Increase in motor function scores achieved in first year sustained after 4 years, compared to natural history data
- Overall AE rate decreased over 48 months, with AEs and SAEs reflective of underlying disease; treatment adherence at 99% and no treatment-related AEs leading to withdrawal or treatment discontinuation
- Diverse study population aged 2 to 25 years incl. more advanced disease (e.g. >65% of patients with scoliosis) reflecting a real-world population underserved in clinical trials

Source: Natural history cohort, Roche data on file; courtesy of Association Institut de Myology; first presented at MDA 2021. MFM32=32-item motor function measure; SMA=spinal muscular atrophy; PY=patient years; AE=adverse event; SAE=serious adverse event; *+/- 95% Confidence interval †Baseline is the last measurement prior to the first dose of risdiplam or placebo. ‡Data cut-off: 6 Sep 2022. §Data cut-off: 6 Sep 2019.; Number of patients with valid results = number of patients with an available total score (result) at respective time points

Ophthalmology: Excellent Vabysmo launch continues

*Double-digit US market share in nAMD and mid single-digit in DME**



Q1 update

Vabysmo

- US: Strong uptake with switches primarily from aflibercept; use in naive patients further accelerating
- >860k vials shipped globally in first 14 months of launch
- Positive Ph III (BALATON/COMINO) results for Vabysmo in RVO presented at Angiogenesis 2023
- Ph III post-hoc analyses in nAMD & DME indicating greater retinal drying for Vabysmo vs aflibercept presented at ARVO 2023 (23-27 April)

Susvimo

- Positive Ph III (PAGODA/PAVILLION) results for Susvimo in DME/DR presented at Angiogenesis 2023

Outlook 2023

- Vabysmo: Continued growth and market share gains in nAMD & DME

nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; RVO=retinal vein occlusion; DR=diabetic retinopathy; *Based on February 2023 patient claims data; Eylea (aflibercept) is a registered trademark/product of Regeneron

Vabysmo: Positive results in RVO presented at Angiogenesis 2023

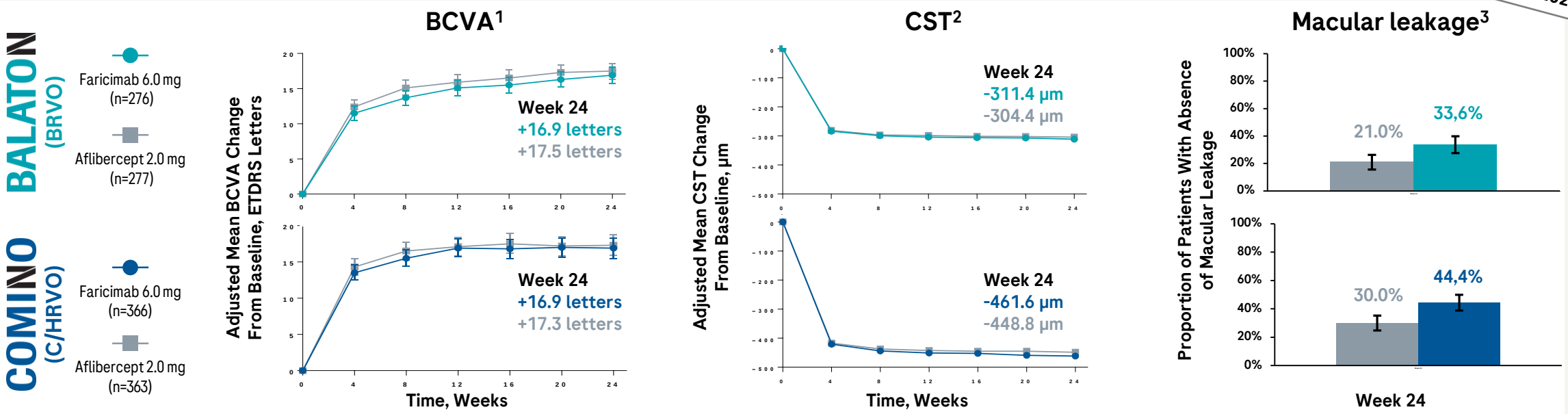
Improvement in macular leakage compared to aflibercept

Roche

VABYSMO

MIAMI Angiogenesis 2023

Ph III (BALATON/COMINO) results in RVO



- Vabysmo achieved robust BCVA gains and reductions in CST across both studies
- At week 24, more patients on Vabysmo achieved absence of macular leakage vs aflibercept
- Results to be filed globally with regulatory authorities

[1]BCVA was measured using the ETDRS visual acuity chart at a starting distance of 4 m; [2]CST is measured as ILM-BM, as graded by central reading center; [3]Macular leakage was a pre-specified exploratory endpoint in BALATON/COMINO. Macular leakage area within ETDRS grid was assessed by the reading center based on FA (fluorescein angiography) images obtained at baseline and predefined follow-up intervals, Absence is defined as area of leakage within the macula of 0 mm2 per FA; (B)RVO=(branch) retinal vein occlusion; CRVO=central retinal vein occlusion; HRVO=hemiretinal vein occlusion; BCVA=best-corrected visual acuity; ETDRS=early treatment diabetic retinopathy study; CST=central subfield thickness; BM=Bruch's membrane; Eylea (aflibercept) is a registered trademark/product of Regeneron

2023: Key late-stage news flow*

	Compound	Indication	Milestone	
Regulatory	**Hemlibra**	Moderate hemophilia A	EU approval	✓
	Polivy + R-CHP	1L DLBCL	US approval	✓
	Vabysmo	RVO	US approval/EU filing	
	Tecentriq	Subcutaneous administration	US approval/EU filing	✓ EU filing
	Columvi (glofitamab)	3L+ DLBCL	US/EU approval	
	Xofluza	Influenza (paediatric 1+ yrs.)	EU approval	✓
Phase III / pivotal readouts	**Tecentriq + Avastin**	Adjuvant HCC	Ph III IMbrave050	✓
	Tecentriq + chemo	Neoadjuvant / adjuvant TNBC	Ph III GeparDouze/NSABP B-59	
	Tecentriq	Adjuvant SCCHN	Ph III IMvoke010	
	Tecentriq + chemo	Adjuvant TNBC	Ph III IMpassion030	✗
	Tiragolumab + Tecentriq	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	
	Tiragolumab + Tecentriq + chemo	1L esophageal cancer	Ph III SKYSCRAPER-08 (China only)	
	Venclexta + dexamethasone	t(11;14) R/R MM	Ph III CANOVA	
	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA	
	Alecensa	Adjuvant ALK+ NSCLC	Ph III ALINA	
	Phesgo OBI (on body injector)	HER2+ BC	Ph I *(pivotal)*	
	Crovalimab	PNH	Ph III COMMODORE 1/2	✓
	Columvi + GemOx	2L+ DLBCL	Ph III STARGLO	
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO**	
	Delandistrogene moxeparvovec (SRP-9001)	DMD	Ph III EMBARK	
	Ocrevus 6m SC	RMS / PPMS	Ph III OCARINA II	
	TNKase	Stroke patients 4.5-24h	Ph III TIMELESS	
	Susvimo	DME	Ph III PAGODA	✓
	Susvimo	DR	Ph III PAVILION	✓
	Xolair	Food allergy	Ph III OUtMATCH	

* Outcome studies are event-driven: timelines may change; ** Results are event-driven; read-outs expected in 2023/24

Diagnostics Division

Matt Sause
CEO Roche Diagnostics

Q1 2023: Diagnostics Division sales

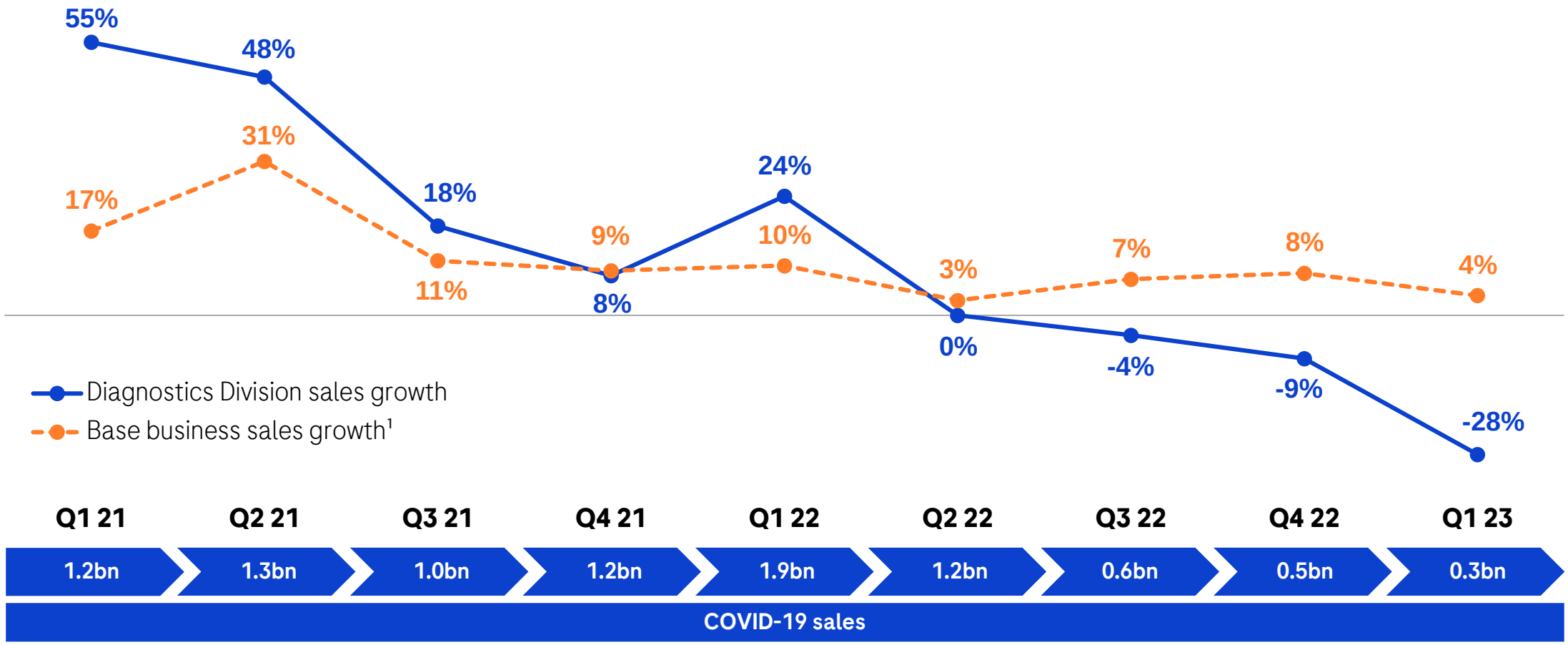
Good base business growth, partially offsetting COVID-19 sales decrease

	2023	2022	Change in %	
	CHFm	CHFm	CHF	CER
Diagnostics Division	**3,623**	**5,286**	**-31**	**-28**
Core Lab	1,928	1,896	2	7
Molecular Lab	593	1,189	-50	-48
Point of Care	397	1,466	-73	-72
Diabetes Care	376	417	-10	-5
Pathology Lab	329	318	3	7

CER=Constant Exchange Rates

Diagnostics Division sales growth by quarter

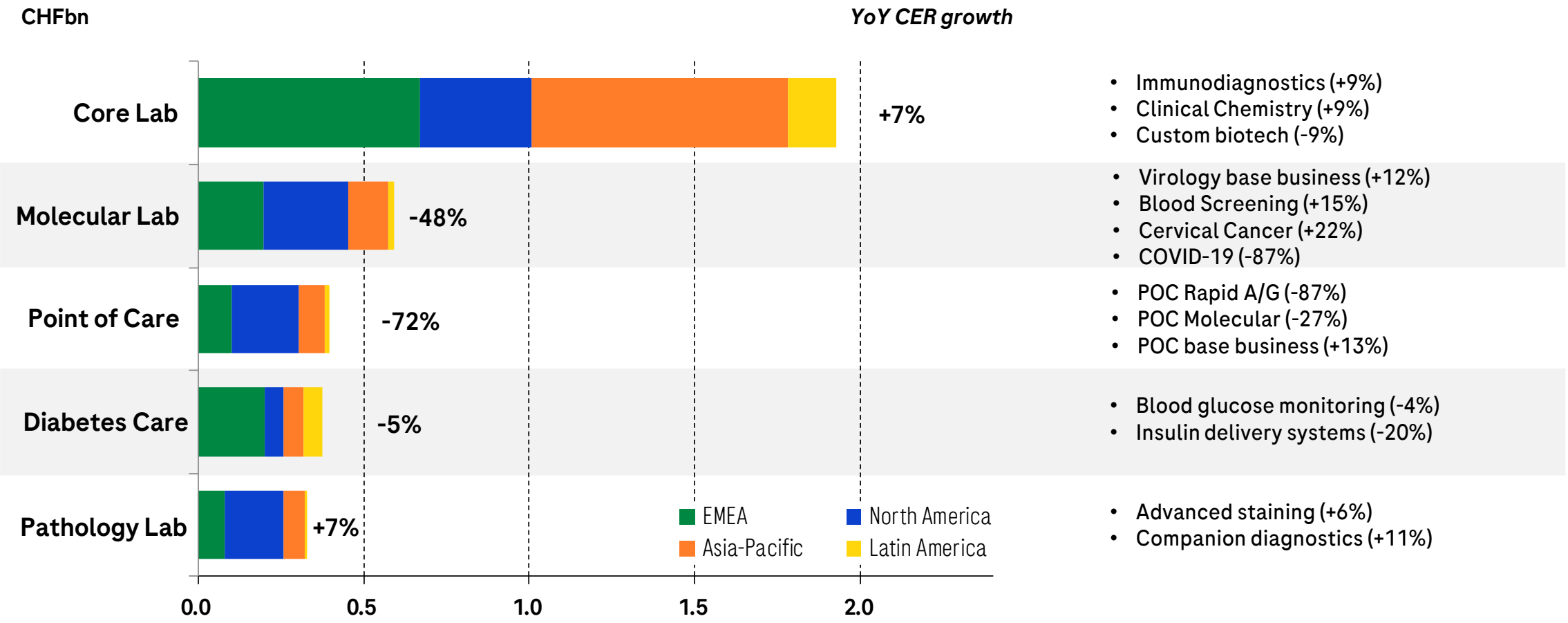
Good base business growth in Q1 2023



Growth rates and absolute values at CER (Constant exchange Rates); [1] Quarterly sales growth excluding COVID-19 sales

Q1 2023: Diagnostics Division highlights

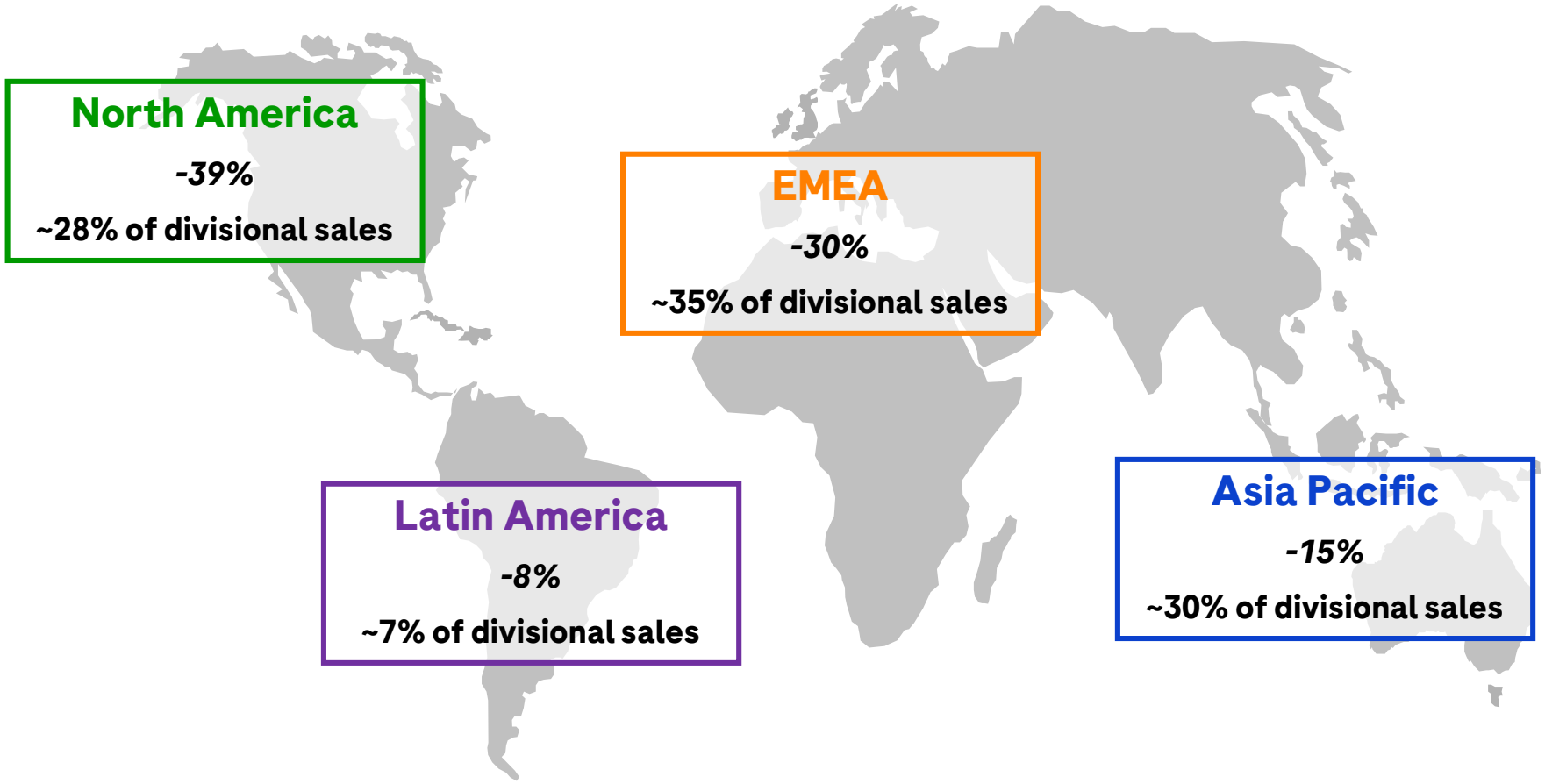
Good base business growth, partially offsetting COVID-19 sales decrease



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

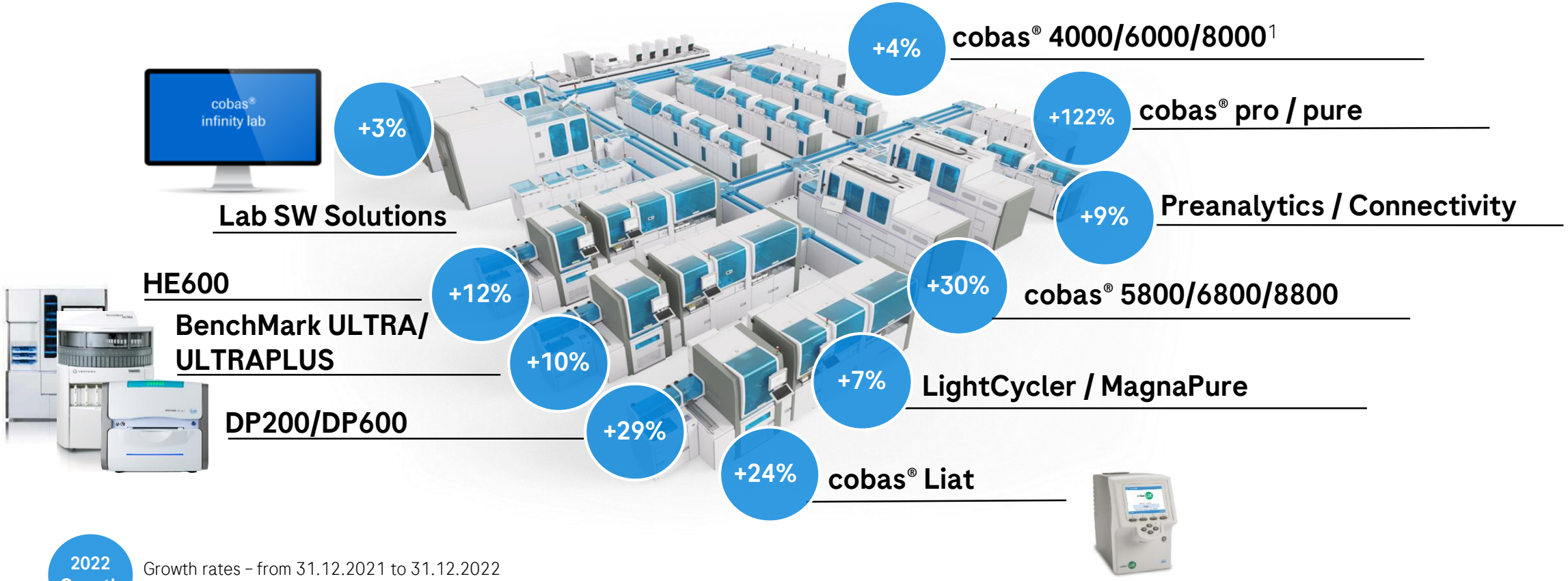
Q1 2023: Diagnostics Division regional sales

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



Growth rates at CER (Constant exchange Rates); EMEA=Europe, Middle East and Africa

Largest installed base worldwide with significant growth potential



2022 Growth

Growth rates – from 31.12.2021 to 31.12.2022
(Total installed modules as of 31.12.2022)

[1] cobas 6000 has been discontinued in CE mark countries and replaced with cobas pro / pure systems

Core Lab menu expansion driving future growth

>240 assays running on >100k installed cobas® serum work area instruments

Launches in 2021, 2022 and upcoming[4]

Immuno chemistry assays

- EBV EBNA IgG (CE)
- EBV VCA IgG (CE)
- EBV IgM (CE)
- Anti-p53 (CE)
- GAAD (CE)
- NT-proBNP claim extension[1] (CE)
- TnT-hs claim extension[1] (CE)
- PCT CE claim extension[1] (CE)
- Vit D total III[2] (CE & US)
- Anti-HBe (US)
- Sirolimus (CN)
- HBsAg Confirmatory[2] (CE)
- Alzh CSF biomarkers (CE)
- IGRA SARS-CoV-2 (CE)
- HCV Duo (CE)
- Anti-HAV II[2] (CN)
- HBsAg Confirmatory[2] (US)
- AFP-L3 (CE)
- FT4 IV[2] (CE)
- Alzh CSF biomarker (US)
- Anti-HEV IgG and Anti-HEV IgM (CE)
- GAAD[2] (CE)
- Maxi-Multipack RBSS (CE)
- HBeAg Quant (CE)
- Interferon Gamma (CE)
- NT-proBNP diagnosis ICON-RL[2] (US)
- NT-proBNP STRONG-HF (GL)
- Cortisol III urine application[2] (CE)
- tTAU CSF (Ver 2)
- Elecsys progesterone Diluent[2]
- FT4 IV[2] (US)
- IL6 - Claim extension neonatal (CE)
- Vitamin D total III[2] (CN)

Clinical chemistry assays

- Fentanyl[3] (CE, US)
- sTfR Gen 2[2] (CE)
- CRP4 (CN)
- Benz 2[2] (US)
- NH3L2 (CN)
- ASTP2/ALTP2 cobas 303[2] (CE/US)
- ASTP2/ALTP2 cobas c 503[2] (CE/US)
- BENZ2[2] (US)
- sTfR Gen.2[2] (CN)[2]
- free PHNY2

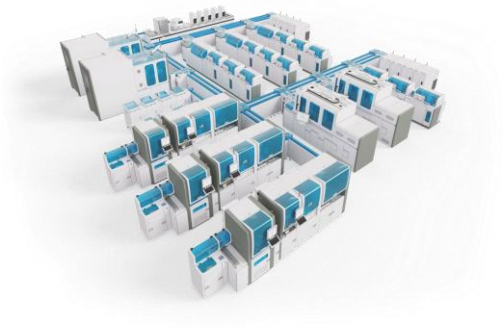
Launched in 2021 | Launched in 2022 | Upcoming Launches

[1] Claim extension, [2] Product update; [3] Partner Channel. EBV: Epstein-Barr-Virus; [4] non exhaustive, EBNA: Epstein-Barr virus nuclear antigen, VCA: viral capsid antigens, IgM: Immunoglobulin M, anti-p53: autoantibodies, GAAD: in-vitro diagnostic multivariate index assay, NT-proBNP: N-terminal prohormone of brain natriuretic peptide, TnT–hs: Troponin T-high sensitive, PCT: Procalcitonine, Vit D: vitamin D, Anti-HBe: hepatitis B e antigen (HBeAg), HBsAg: hepatitis B surface antigen, Alzh CSF: Alzheimer's disease Cerebrospinal Fluid, SARS-CoV-2: severe acute respiratory syndrome coronavirus 2, HCV: Hepatitis C virus, Anti-HAV: antibodies against Hepatitis A virus, AFP-L3: Lectin-reactive fraction of alpha-fetoprotein, FT4: Free Thyroxine (T4), HEV: Hepatitis E virus, RBSS: Roche Blood Safety Solution, NT-proBNP STRONG-HF Safety, Tolerability and Efficacy of Rapid Optimization, Helped by NT-proBNP testing of Heart Failure Therapies, tTau CSF: total tau protein concentration in human cerebrospinal fluid (CSF), IL6: Interleukin-6, sTfR Gen 2: Soluble Transferrin Receptor Generation 2, CRP4: C-reactive protein generation 4, BENZ: Benzodiazepines, NH3L2: Ammonia Gen.2, ASTP2: aspartate aminotransferase with pyridoxal phosphate activation Gen.2, ALTP2: alanine aminotransferase with pyridoxal phosphate Gen.2, free PHNY2: free phenytoin.

navify Marketplace and Algorithm Suite

Roll-out of two new digital solutions which will drive operational and clinical excellence

Customer base » **Customer access to Portal/Marketplace[2]** » **Access to applications[3]**



Roche instruments

3rd party devices

IT systems[1]

cobas infinity Central Lab

navify Portal/ Marketplace

NEW

navify Algorithm Suite

navify Inventory

navify Monitoring

navify Control

navify Analytics

navify Sample Tracking

Laboratories

Roche and 3rd party customers

navify Portal/ NEW Marketplace

digital store to directly connect to our and 3rd party's portfolio of innovative and certified applications

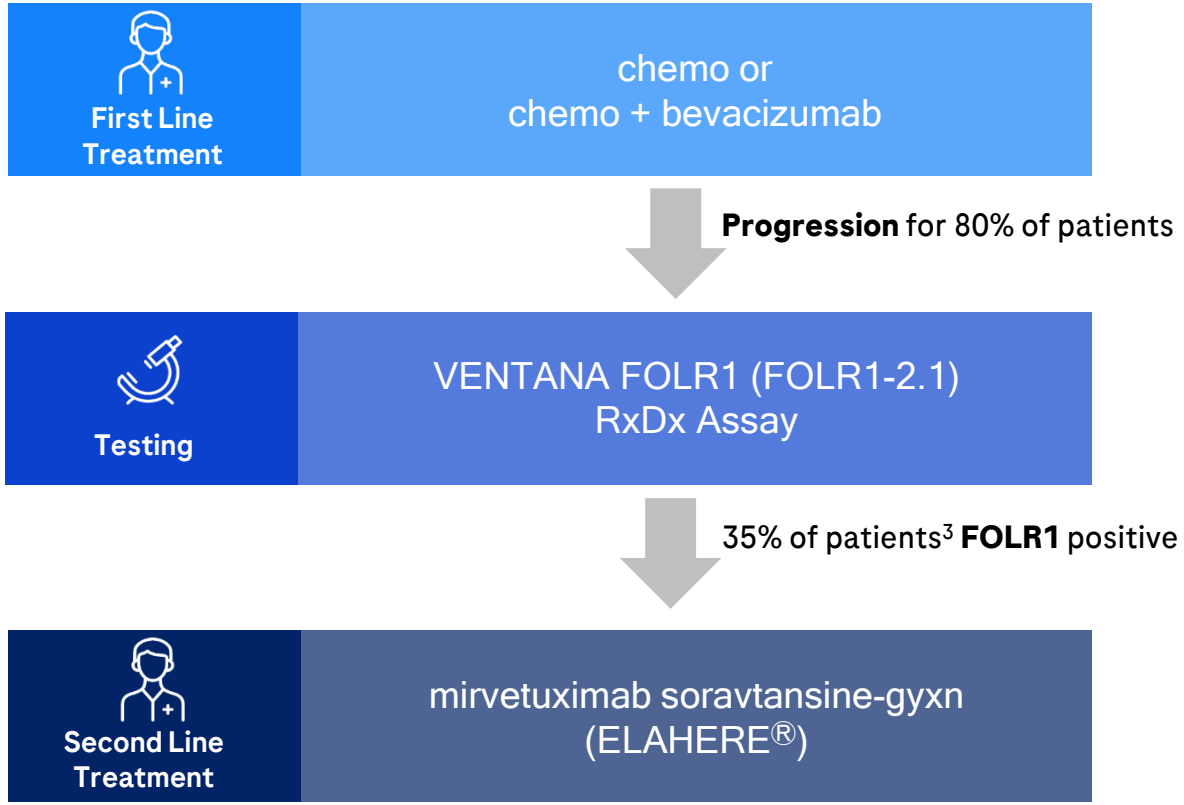
NEW **navify Algorithm Suite**

partnership with laboratories to provide trusted clinical diagnosis & decision support for clinicians

[1] Middle ware, [2] navify Portal for customers; navify Marketplace for non-customers, [3] Embedded in Network or with user-interface

VENTANA FOLR1 (FOLR1-2.1) RxDx assay

First FDA approved FOLR1 companion diagnostic test for ovarian cancer



- 322k estimated cases of ovarian cancer worldwide (2021)[1]
- First FDA-approved IHC companion diagnostic test for determining FRα protein expression in epithelial ovarian cancer (EOC)
- Enables pathologists to identify patients who may be eligible for a new therapy, ELAHERE ®[2]
- Runs on automated BenchMark series of instruments

[1] Clarivate Epidemiology Report: Ovarian Cancer, Clarivate Plc. Accessed 04/07/2023 ; [2] Results from the SORAYA clinical study demonstrated ~32 % of eligible patients showed a partial or complete response to ELAHERE therapy; [3] The VENTANA FOLR1 (FOLR-2.1) RxDx Assay was used as part of the SORAYA clinical study to identify patients whose tumors were positive for FRα protein (≥ 75% of viable tumor cells with moderate (2+) and/or strong (3+) membrane staining). In this study, approximately 35% of ovarian cancer patients expressed high levels of FRα (defined as ≥ 75% tumour cells staining with 2+/3+ intensity) and were considered FRα-positive by the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay. Roche. VENTANA FOLR1 (FOLR-2.1) RxDx Assay. US Package Insert. 2022. Matulonis UA, et al. Abstract LB4. Presented at Society of Gynecologic Oncology 2022 Annual Meeting on Women's Cancer. March 18-21, 2022.

Diagnostics key launches 2023

	Area	Product	Description	Markets	Status
Instruments Automation	Core Lab	CCM Vertical	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	Global	
		cobas pro integrated solutions	Scalable and modular serum work area analyzer for mid to high volume clinical chemistry and immunochemistry testing	China	
		cobas pure integrated solutions	Serum work area analyzer for low to mid volume clinical chemistry and immunochemistry testing on a footprint of two square meters	China	
	Molecular Lab	LightCycler Pro	Flexible real-time PCR instrument with dual IVD and research mode as well as enhanced system features	US & CE	
	Point of Care	cobas pulse	Handheld device combining professional glucose meter and a digital platform to host digital clinical decision support applications (from Roche and third parties)	US	
Tests	Pathology Lab	IDH1 R132H (IDH Glioma)	Neuropathology Immunohistochemistry (IHC) solution supporting the detection of tumor cells with the IDH1 R132H mutation aiding pathologists to render a diagnosis of gliomas	US	✓
	Core Lab	Anti-HEV IgG and Anti-HEV IgM	Anti-HEV IgM: Immunoassay aiding in the diagnosis of acute HEV infection in clinical settings; Anti-HEV IgG: 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	CE	
		HBeAg Quant	Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B viral infection	CE	
		IL-6 Neonatal sepsis (claim extension)	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	CE	
		RUO Amyloid Plasma Assays (pTau181 & ApoE4)	Two qualitative immunoassays measuring the phosphorylated Tau 181 protein and apolipoprotein E4 in human plasma for research use only	US	
Digital Solutions	Pathology Lab	RUO Digital Pathology Algorithm: PD-L1 SP142	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	Global	
	Lab Insights	navify Algorithm Suite	Digital solution providing access to an open library of certified IVD-based clinical algorithms	Selected markets[1]	✓
		Menu for navify Algorithm Suite	Certified clinical algorithms for oncology applications such as colon and liver cancers	Selected markets[1]	
		cobas infinity lab 3.05	Next-generation lab middleware enabling ecosystem of cloud-based solutions for quality control and instrument maintenance	Global	
		navify Marketplace	Digital marketplace offering lab customers full range of innovative applications (from Roche and third parties)	Selected markets[1]	✓
		navify Sample Tracking	Open digital solution offering sample tracking beyond the lab setting (from IVD-sample creation to lab reception) to improve testing traceability and quality	Selected markets[1]	

[1] Selected 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

Q1 2023: Highlights

Sales

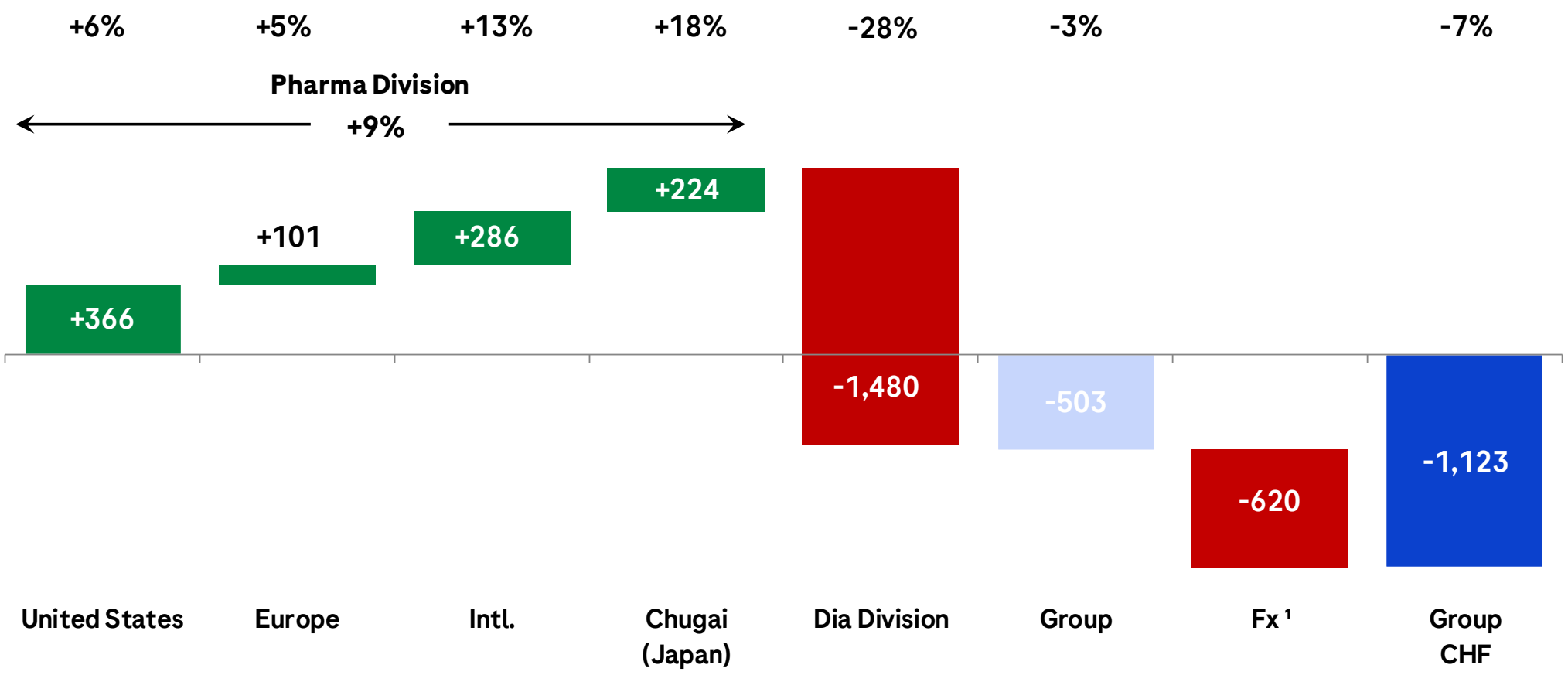
- Group sales decline of -3% resulting from erosion of COVID-19 related sales
- Solid Pharma and Diagnostics underlying business growth

Currency impact on sales

- Negative currency impact of -4%p primarily by the JPY, EUR and CNY

Growth rates at CER (Constant exchange Rates)

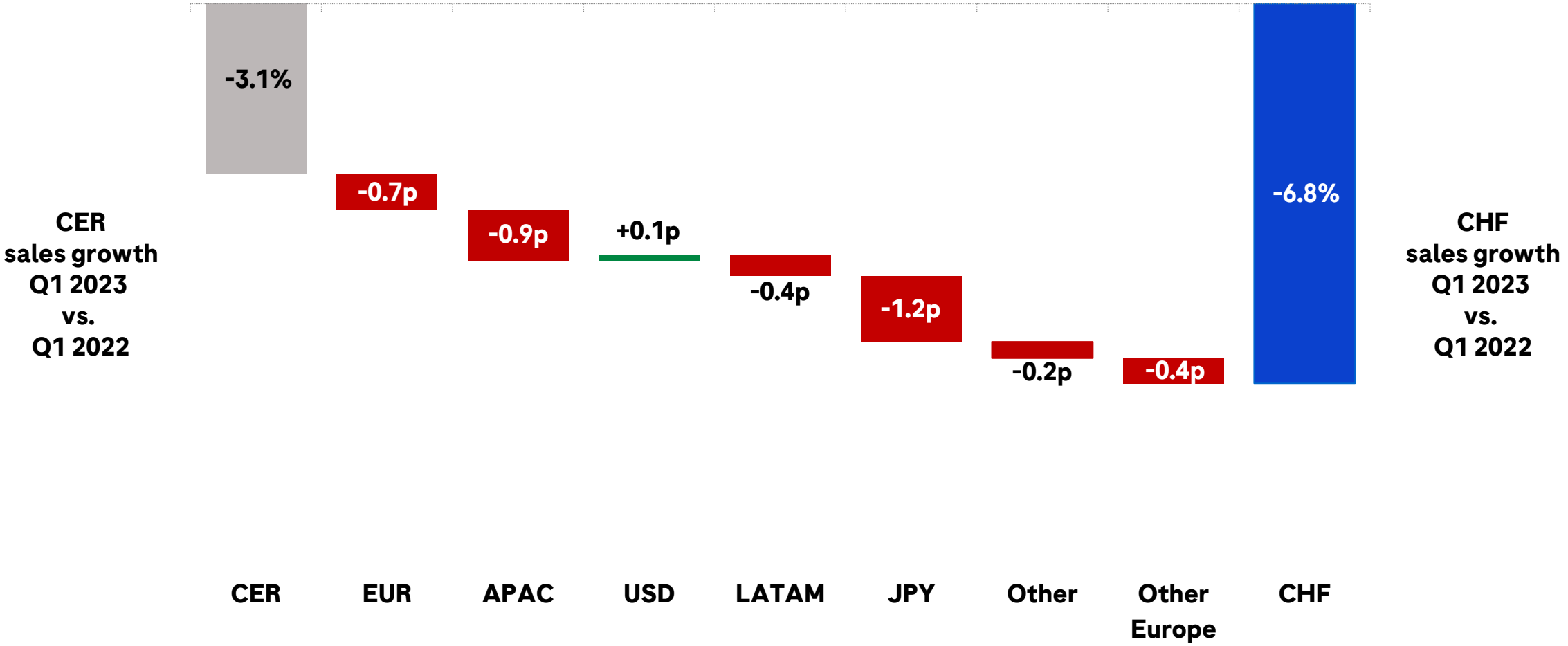
Q1 2023: Regional Pharma and Group sales bridge



Absolute values in CHFm at Constant Exchange Rates (avg full year 2022); [1] avg. full year 2022 to avg Q1 2023 fx impact

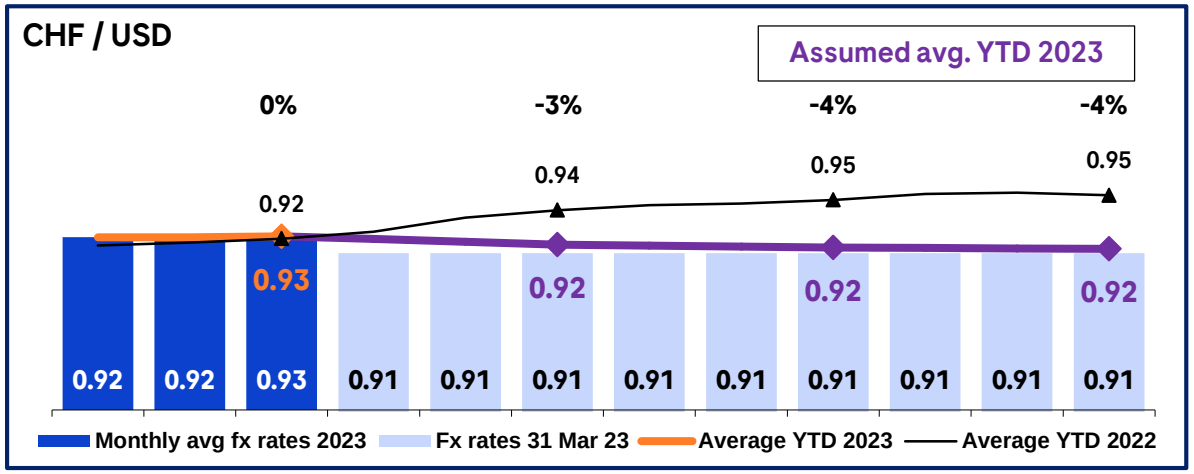
Exchange rate impact on sales growth

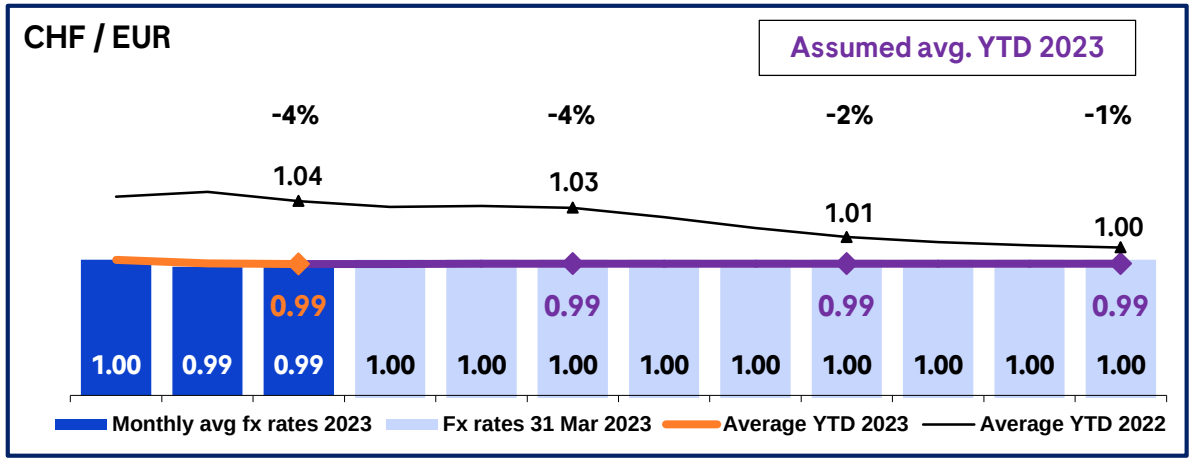
Negative impact driven by the JPY, EUR and CNY



CER = Constant Exchange Rates (avg full year 2022)

Expected 2023 currency impact





Assuming the 31 March 2023 exchange rates remain stable until end of 2023, 2023 impact[1] is expected to be (%p):

	Q1	HY	Sep YTD	FY
Sales	-4	-5	-5	-4
Core operating profit		-5		-4
Core EPS		-6		-5

[1] On group growth rates

2023 outlook

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)

Upcoming virtual ESG IR event on environmental sustainability

Roche ESG Event on May 23
Environmental Sustainability

15:30 - 17:00 CEST / 14:30 – 16:00 BST
09:30 – 11:00 am EDT / 6:30 – 8:00 am PDT

Why does ESG matter?

Alan Hippe, Chief Financial Officer

Environmental sustainability through operational and product innovation

Carbon emissions and the future of energy

Scott Hemphill, Global Expert in Environmental Sustainability

Sustainable construction

Georg Singewald, Head of Global Manufacturing Science, Technology and Engineering

Product stewardship in Pharma and Diagnostics

Ursina Kohler, Head of Product Stewardship

Water and waste management, and site remediation efforts

Richard Huerzeler, Chief Environment and Remediation Officer

Environmental sustainability in our supply chain

Marielle Beyer, Head of Global Procurement

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

Q1 2023 update

New to phase I

1AI:
RG6107 crovalimab - lupus nephritis

New to phase II

2 NMEs:
RG6501 OpRegen – geographic atrophy
RG6341 NME – chronic cough

1 AI:
RG6237 latent myostatin – FSHD

New to phase III

1 NME:
RG6149 astegolimab (Anti-ST2) – COPD

1 AI:
RG7159 Gazyva – pediatric nephrotic syndrome

New to registration

Removed from phase I

3 NMEs:
RG6129 HLA-A2-MAGE-A4 x CD3 – solid tumors
RG6290 MAGE-A4 ImmTAC – solid tumors
RG6312 NME – geographic atrophy

Removed from phase II

1 NME:
RG6354 zinpentraxin alfa (PRM-151) - myelofibrosis

Removed from phase III

2 AIs:
RG7446 Tecentriq + cabozantinib – RCC adv
RG7446 Tecentriq + paclitaxel – TNBC adj

Approvals

1 AI (US):
RG7596 Polivy – 1l DLBCL

NME approval in other territory than US and EU:
RG6026 Columvi (glofitamab) – 3L+ DLBCL (First approved in Canada)

Status as of April 26, 2023

Roche Group development pipeline

Phase I (50 NMEs + 12 AIs)

RG6007	HLA-A2-WT1 x CD3	AML
RG6026	Columvi (glofitamab) monotherapy + combos	heme tumors
RG6058	tiragolumab combos	heme & solid tumors
RG6076	englumafusp alfa (CD19-4-1BBL) combos	heme tumors
RG6114	inavolisib (mPI3K alpha inh)	solid tumors
RG6156	EGFRvIII x CD3	glioblastoma
RG6160	cevostamab (FcRH5 x CD3)	r/r multiple myeloma
RG6171	giredestrant (SERD)	solid tumors
RG6180	autogene cevumeran ± T	solid tumors
RG6185	belvarafenib (pan-RAF inh) + Cotellic ± T	solid tumors
RG6189	FAP-CD40 ± T	solid tumors
RG6194	runimotamab (HER2 x CD3)	BC
RG6234	forimtamig (GPRC5D x CD3)	multiple myeloma
RG6264	Phesgo OBI	HER2+ BC
RG6279	eciskafusp alfa (PD1-IL2v) ± T	solid tumors
RG6286	-	colorectal cancer
RG6292	CD25 MAb combos	heme & solid tumors
RG6323	IL15/IL15Ra-Fc ± T	solid tumors
RG6330	divarasib (KRAS G12C)	solid tumors
RG6333	CD19 x CD28 + Columvi (glofitamab)	r/r NHL
RG6344	BRAF inhibitor (3)	solid tumors
RG6392	-	oncology
RG6411	-	solid tumors
RG6433	SHP2i combos	solid tumors
RG6440	Anti-latent TGF-β1 (SOF10)	solid tumors
RG6512	FIXa x FX	hemophilia
RG6524	DLL3 x CD3 x CD137	solid tumors
RG6526[1]	camonsertib	solid tumors
RG6538[2]	P-BCMA-ALLO1	multiple myeloma
RG7446	Morpheus platform	solid tumors
RG7601	Venclexta ± azacitidine	r/r MDS

Status as of April 26, 2023

RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL monotherapy + combos	solid tumors
RG7828	Lunsumio monotheraphy + combos	heme tumors
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
CHU	CD137 switch antibody	solid tumors
CHU	RAS inhibitor	solid tumors
CHU	SPYK04	solid tumors
SQZ	PBMC vaccine	solid tumors
RG6107	crovalimab	lupus nephritis
RG6287	-	aGVHD
RG6315	-	immunologic disorders
RG6421	TMEM16A potentiator	cystic fibrosis
RG6536[3]	vixarelimab	immunology
RG7828	Lunsumio	SLE
CHU	anti-HLA-DQ2.5 x gluten peptides	celiac disease
CHU	RAY121	immunology
RG6006	zosurabalpin (Abx MCP)	bacterial infections
RG6319	LepB inhibitor	complicated urinary tract infection
RG6035	BS-CD20 MAb	multiple sclerosis
RG6091	rugonersen (UBE3A LNA)	Angelman syndrome
RG6163	-	psychiatric disorders
RG6182	MAGLi	multiple sclerosis
RG6289	-	Alzheimer´s
RG6418*	selnoflast	inflammation
RG7637	-	psychiatric disorders
RG6120	zifibancimig (VEGF-Ang2 DutaFab)	nAMD
RG6209	-	retinal disease
RG6351	-	retinal disease
RG7921	-	RVO
CHU	anti-IL-8 recycling antibody	endometriosis

RG-No - Roche/Genentech; CHU - Chugai managed; SQZ - SQZ Biotechnology managed; [1]Repare Therapeutics managed; [2]Poseida Therapeutics managed; [3]Kiniksa Pharmaceuticals managed; [4]IONIS managed; T=Tecentriq; BS=Brain Shuttle; OBI=On-Body Delivery System; *also developed in Immunology; **combination platform

Phase II (23 NMEs + 9 AIs)

RG6026	Columvi (glofitamab) + chemo	1L ctDNA high risk DLBCL
RG6058	tiragolumab + T	NSCLC
	tiragolumab + T + chemo	NSCLC neoadj-adj
	tiragolumab + T	cervical cancer
	tiragolumab + T	1L PD-L1+ mSCCHN
RG6107	crovalimab	sickle cell disease
RG6139	tobemstomig (PD1 x LAG3)	solid tumors
RG6180	autogene cevumeran + pembrolizumab	1L melanoma
RG6357	dirloctogene samoparvovec (SPK-8011)	hemophilia A
RG6358	SPK-8016	hemophilia A with inhibitors to factor VIII
RG6299[4]	ASO factor B	IgA nephropathy
RG6341	-	chronic cough
RG7854/ RG6346/ RG6084**	ruzotolimod (TLR7 ago[3])/ xalnesiran (siRNA)/ PDL1 LNA	HBV
RG6359	SPK-3006	Pompe disease
RG1662	basmisanil	Dup15q syndrome
RG6042	tominersen	Huntington's
RG6100	semorinemab	Alzheimer's
RG6102	trontinemab	Alzheimer's
RG6237	latent myostatin + Evrysdi	SMA
	latent myostatin	FSHD
RG6416	bepranemab	Alzheimer's
RG7314	balovaptan	post-traumatic stress disorder
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7816	alogabat (GABA Aa5 PAM)	ASD
RG7906	ralmitaront	schizophrenia
RG7935	prasinezumab	Parkinson's
RG6179	anti-IL-6	DME
RG6299[4]	ASO factor B	geographic atrophy
RG6501	OpRegen	geographic atrophy
RG7774	vicasinabin (CB2 receptor agonist)	DR

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

Roche Group development pipeline

Phase III (9 NMEs + 40 AIs)

RG3502	Kadcyla + T	HER-2+ eBC high-risk
RG6026	Columvi (glofitamab) + chemo	2L+ DLBCL
RG6058	tiragolumab + T	1L PD-L1+ NSCLC
	tiragolumab + T	1L esophageal cancer
	tiragolumab + T	locally advanced esophageal cancer
	tiragolumab + T	stage III unresectable 1L NSCLC
	tiragolumab + T	1L non-squamous NSCLC
RG6107	crovalimab*	PNH
	crovalimab	aHUS
RG6114	inavolisib (mPI3K alpha inh)	1L HR+ mBC
RG6171	giredestrant (SERD)	1L ER+/HER2- mBC
	giredestrant (SERD)	ER+ BC adj
	giredestrant (SERD) + Phesgo	1L ER+/HER2+ BC
RG6330	divarasib (KRAS G12C)	2L NSCLC
RG7446	Tecentriq + platinum chemo	NSCLC periadj
	Tecentriq	NMIBC, high-risk
	T ± chemo	SCCHN adj
	T + capecitabine or carbo/gem	1L TNBC
	T + Avastin	HCC adj
	Tecentriq	ctDNA+ high-risk MIBC
	T+ lurbinectedin	1L maintenance SCLC
RG7601	Venclexta	r/r MM t(11:14)
	Venclexta + azacitidine	1L MDS
RG7828	Lunsumio + lenalidomide	2L+ FL
	Lunsumio + Polivy	2L+ DLBCL
RG7853	Alecensa	ALK+ NSCLC adj

RG3648	Xolair	food allergy
RG6149	astegolimab (Anti-ST2)	COPD
RG7159	Gazyva	lupus nephritis
	Gazyva	membranous nephropathy
	Gazyva	systemic lupus erythematosus
	Gazyva	pediatric nephrotic syndrome
RG6152	Xofluza	influenza, pediatric (0-1 year)
	Xofluza	influenza direct transmission
RG1594	Ocrevus higher dose	RMS & PPMS
	Ocrevus SC	RMS & PPMS
RG3625	TNKase	stroke
RG6168	Enspryng	myasthenia gravis
	Enspryng	MOG-AD
	Enspryng	autoimmune encephalitis
RG6356	delandistrogene moxeparvovec (SRP-9001)	DMD
RG7845	fenebrutinib	RMS
	fenebrutinib	PPMS
RG6179	anti-IL-6	UME
RG6321	Susvimo (PDS)	DME
	Susvimo (PDS)	DR
	Susvimo (PDS)	wAMD, 36-week
RG7716	Vabysmo (faricimab)	BRVO
	Vabysmo (faricimab)	CRVO

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

Registration US & EU (1 NME + 3 AIs)

RG6026	Columvi (glofitamab)	3L+ DLBCL
RG7446	Tecentriq SC	all approved indications
RG6413+ RG6412	Ronapreve[1]	SARS-CoV-2 hospitalized
RG7916	Evrysdi[2]	SMA pediatric <2months

[1]Filed in EU
[2]Approved in US, filed in EU

T=Tecentriq
PDS=Port Delivery System with ranibizumab
*First filed in China in Q3 2022

Status as of April 26, 2023

NME submissions and their additional indications

Projects in phase II and III

- New Molecular Entity (NME)
- Additional Indication (AI)
- Oncology / Hematology
- Immunology
- Infectious Diseases
- Metabolism
- Neuroscience
- Ophthalmology
- Other

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
PDS=Port Delivery System with ranibizumab
*First filed in China
[1]IONIS managed

2023

RG6058	**tiragolumab + T** 1L PD-L1+ NSCLC
RG6058	**tiragolumab + T** 1L esophageal cancer (CN)
RG6107	**crovalimab*** PNH (EU, US)
RG6321	**Susvimo (PDS)** DME (US)
RG6321	**Susvimo (PDS)** DR (US)

2024

RG6026	**Columvi (glofitamab) + chemo** 2L DLBCL
RG6058	**tiragolumab + T** Stage III unresectable 1L NSCLC
RG6114	**inavolisib (mPI3K alpha inh)** 1L HR+ BC
RG6356	**delandistrogene moxeparvovec (SRP-9001)** DMD (EU)

2025

RG6107	**crovalimab** aHUS
RG6321	**Susvimo (PDS)** wAMD, DME, DR (EU)

2026 and beyond

RG6026	**Columvi (glofitamab) + chemo** 1L ctDNA+ high risk DLBCL
RG6058	**tiragolumab + T** 1L PD-L1+ cervical cancer
RG6058	**tiragolumab + T** locally adv esophageal cancer
RG6058	**tiragolumab + T** 1L non-sq NSCLC
RG6058	**tiragolumab + T** 1L PD-L1+ mSCCHN
RG6058	**tiragolumab+T+/- chemo** NSCLC neoadj/adj
RG6107	**crovalimab** sickle cell disease
RG6139	**tobemstomig (PD1xLAG3)** solid tumors
RG6171	**giredestrant (SERD)** 1L ER+/HER2- mBC
RG6171	**giredestrant (SERD)** ER+ BC adj
RG6171	**giredestrant (SERD) + Phesgo** 1L ER+/HER2+ BC
RG6180	**autogene cevumeran** 1L melanoma
RG6330	**divarasib (KRAS G12 C)** 2L NSCLC
RG6149	**astegolimab (anti-ST2)** COPD
RG6299[1]	**ASO factor B** IgA nephropathy
RG6341	**NME** chronic cough
RG7854/ RG6346/ RG6084	**ruzotolimod (TLR7 ago [3])/ xalnesiran (siRNA)/ PDL1 LNA** HBV
RG1662	**basmisanil** Dup15q syndrome
RG6042	**tominersen** Huntington's
RG6100	**semorinemab** Alzheimer's
RG6102	**trontinemab** Alzheimer's
RG6237	**latent myostatin + Evrysdi** SMA
RG6237	**latent myostatin** FSHD
RG6416	**bepranemab** Alzheimer's
RG7314	**balovaptan** post-traumatic stress disorder
RG7816	**alogabat (GABA Aa5 PAM)** ASD
RG7845	**fenebrutinib** RMS
RG7845	**fenebrutinib** PPMS
RG7906	**ralmitaront** schizophrenia
RG7935	**prasinezumab** Parkinson's
RG6179	**anti-IL-6** UME
RG6179	**anti-IL-6** DME
RG6299[1]	**ASO factor B** geographic atrophy
RG6321	**Susvimo (PDS)** wAMD, 36-week refill
RG6501	**OpRegen** geographic atrophy
RG7774	**vicasinabin (CB2 receptor agonist)** DR

Status as of April 26, 2023

AI submissions for existing products

Projects in phase II and III

- New Molecular Entity (NME)
- Additional Indication (AI)
- Oncology / Hematology
- Immunology
- Infectious Diseases
- Metabolism
- Neuroscience
- Ophthalmology
- Other

2023		2024				2025		2026 and beyond	
RG7446	**Tecentriq + Avastin** HCC adj							RG3502	**Kadcyla + Tecentriq** HER-2+ eBC high-risk
RG7601	**Venclexta** r/r MM t(11:14)	RG6264	**Phesgo OBI** HER2+ BC					RG7446	**Tecentriq** High-risk NMIBC
RG7853	**Alecensa** ALK+ NSCLC adj	RG7446	**Tecentriq**[1] NSCLC periadj					RG7446	**Tecentriq+ lurbinectedin** 1l maintenance SCLC
RG1594	**Ocrevus SC** RMS & PPMS	RG7446	**Tecentriq** SCCHN adj	RG7159	**Gazyva** lupus nephritis	RG7828	**Lunsumio (mosun) + lenalidomide** 2L FL	RG7159	**Gazyva** membranous nephropathy
RG3625	**TNKase** stroke	RG7446	**Tecentriq + capecitabine or carbo/gem** TNBC	RG6168	**Enspryng** myasthenia gravis	RG7828	**Lunsumio (mosun) + Polivy** 2L+ DLBCL (US)	RG7159	**Gazyva** systemic lupus erythematosus
RG3648	**Xolair** food allergy	RG7446	**Tecentriq** ctDNA+ high-risk MIBC	RG6152	**Xofluza** direct transmission	RG1594	**Ocrevus higher dose** RMS & PPMS	RG7159	**Gazyva** pediatric nephrotic syndrome
RG7716	**Vabysmo (faricimab)** BRVO/CRVO	RG7601	**Venclexta + azacitidine** 1L MDS	RG6152	**Xofluza** influenza, pediatric (0-1 year)	RG6168	**Enspryng** autoimmune encephalitis	RG6168	**Enspryng** MOG-AD

Status as of April 26, 2023

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
OBI=On-Body Delivery System, Mosun=mosunetuzumab
[1]filing timeline based on data from interim analysis

Major pending approvals 2023

Roche

US	
RG7446	**Tecentriq SC** all approved indications Filed Nov 2022
RG6026	**Columvi (glofitamab)** 3L+ DLBCL Filed Dec 2022

EU	
RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo Filed Nov 2021
RG6413+ RG6412	**Ronapreve*** SARS-CoV-2 hospitalized Filed Jan 2022
RG6026	**Columvi (glofitamab)** 3L+ DLBCL Filed April 2022
RG1569	**Actemra** SS-ILD Filed Aug 2022
RG7446	**Tecentriq SC** all approved indications Filed Nov 2022

China	
RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo Filed June 2022
RG6264	**Phesgo** HER-2+ BC Filed July 2022
RG6107	**crovalimab** PNH Filed Aug 2022
RG6026	**Columvi (glofitamab)** 3L+ DLBCL Filed Dec 2022

Japan-Chugai	
RG6264	**Phesgo** HER-2+ BC/CC Filed Sept 2022
RG1569	**Actemra** Cytokine release syndrome (CRS) Filed March 2023

Status as of April 26, 2023

- New Molecular Entity (NME)
- Additional Indication (AI)
- Oncology / Hematology
- Immunology
- Infectious Diseases
- Metabolism
- Neuroscience
- Ophthalmology
- Other

SC=Subcutaneous
*Ronapreve (casirivimab+imdevimab also known as REGEN-COV in the US) developed in collaboration with Regeneron Pharmaceuticals

Major granted approvals 2023

US	
RG7596	**Polivy** 1L DLBCL (US) April 2023

EU	
RG6152	**Xofluza** influenza pediatric Jan 2023
RG6013	**Hemlibra** moderate hemophilia A Jan 2023

China	
RG7596	**Polivy** 1L DLBCL Jan 2023
RG7596	**Polivy** r/r DLBCL Jan 2023
RG6152	**Xofluza** influenza pediatric 5 to <12 years March 2023

Japan-Chugai

Status as of April 26, 2023

- New Molecular Entity (NME)
- Additional Indication (AI)
- Oncology / Hematology
- Immunology
- Infectious Diseases
- Metabolism
- Neuroscience
- Ophthalmology
- Other

Roche

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

Indication	Hemophilia A patients without inhibitors to factor VIII	Hemophilia A patients with and without inhibitors to Factor VIII, dosing every 4 weeks
Phase/study	**Phase III** **HAVEN 3**	**Phase III** **HAVEN 4**
# of patients	N=135	N=46
Design	Patients on FVIII episodic treatment prior to study entry: ▪ **ARM A:** Hemlibra prophylaxis qw ▪ **ARM B:** Hemlibra prophylaxis q2w ▪ **ARM C:** Episodic FVIII treatment; switch to Hemlibra prophylaxis possible after 24 weeks Patients on FVIII prophylaxis prior to study entry: ▪ **ARM D:** Hemlibra prophylaxis qw	▪ **Part I:** Pharmacokinetic run-in part (N=6); Hemlibra q4w ▪ **Part II:** Expansion part (N=40); Hemlibra q4w
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 24 weeks
Status	▪ Study met primary and key secondary endpoints Q4 2017 ▪ FDA granted Breakthrough Therapy Designation April 2018 ▪ Data presented at WFH 2018 ▪ Filed in US (priority review) and EU in Q2 2018 ▪ Data published in *NEJM* 2018; 379: 811-822	▪ Pharmacokinetic run-in data at ASH 2017 ▪ Positive interim analysis outcome reported Q4 2017 ▪ Data presented at WFH 2018 ▪ Interim data filed in US and EU in Q2 2018 ▪ Data published in Lancet Haematology 2019 Jun;6(6):e295-e305
	▪ Approved in US Q4 2018 and EU Q1 2019	
CT Identifier	NCT02847637	NCT03020160

In collaboration with Chugai

ASH=American Society of Hematology; WFH=World Federation of Hemophilia; NEJM=New England Journal of Medicine

Hemlibra (emicizumab, RG6013)

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients with and without inhibitors to Factor VIII	Hemophilia A mild to moderate patients without inhibitors to Factor VIII
Phase/study	**Phase III** **HAVEN 5**	**Phase III** **HAVEN 6**
# of patients	N=85	N=70
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 Jan 2023
CT Identifier	NCT03315455	NCT04158648

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

Alecensa (alectinib, RG7853)

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK+ advanced NSCLC	Adjuvant ALK+ NSCLC
Phase/study	**Phase III ALEX**	**Phase III ALINA**
# of patients	N=286	N=255
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Progression-free survival	▪ Disease-free survival
Status	▪ Data presented at ASCO 2017, 2018, ESMO 2017, 2018 and 2019 (final PFS and updated OS) ▪ Data published in *NEJM* 2017; 377:829-838 ▪ Approved in US Q4 2017 (priority review) and in EU Q4 2017	▪ FPI Q3 2018 ▪ Recruitment completed Q4 2021
CT Identifier	NCT02075840	NCT03456076

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

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

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

Indication	HER2-positive early breast cancer (BC)		HER2-positive breast cancer (BC)
Phase/study	**Phase III** **FeDeriCa**	**Phase II** **PHranceSCa**	**Pivotal Phase I**[1]
# of patients	N=500	N=160	N=144
Design	Phesgo in combination with chemotherapy in neoadjuvant/adjuvant setting ▪ **ARM A:** Perjeta IV plus Herceptin IV plus chemotherapy ▪ **ARM B:** Phesgo plus chemotherapy	▪ **ARM A:** Perjeta and Herceptin IV followed by Phesgo ▪ **ARM B:** Phesgo followed by IV	▪ **ARM A:** Phesgo administered using a handheld syringe with hypodermic needle (SC) ▪ **ARM B:** Phesgo administered using the on-body delivery system (OBI)
Primary endpoint	▪ Trough Serum Concentration (Ctrough) of Perjeta during cycle 7	▪ Percentage of patients who preferred Phesgo	▪ AUC0-62*, Cmax**
Status	▪ Primary endpoint met Q3 2019 ▪ Data presented at SABCS 2019 ▪ Data published in Lancet Oncology 2021 Jan;22(1):85-97	▪ Final analysis completed, 85% patients preferred Phesgo ▪ Data presented at ESMO 2020 ▪ Data published in *Eur J Cancer* 2021 Jul;152:223-232	▪ FPI Q2 2022
	▪ Filed in US Q4 2019 & in EU Q1 2020; Approved in US Q2 2020 and EU Q4 2020		
CT Identifier	NCT03493854	NCT03674112	NCT05275010

[1]In collaboration with West Pharmaceuticals and Halozyme

*AUC0-62=comparability of area under the time-concentration curve from the start of dosing to 63 days; **Cmax=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

Indication	Adjuvant NSCLC	Periadjuvant NSCLC
Phase/study	**Phase III** **IMpower010**	**Phase III** **IMpower030**
# of patients	N=1,280	N=450
Design	Following adjuvant cisplatin-based chemotherapy ▪ **ARM A:** Tecentriq ▪ **ARM B:** Best supportive care	▪ **ARM A:** Tecentriq plus platinum-based chemotherapy ▪ **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 cell death-ligand 1; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; WCLC=World Conference on Lung Cancer

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L maintenance extensive-stage SCLC	Stage IV NSCLC
Phase/study	**Phase III** **IMforte**[1]	**Phase Ib/III** **IMscin001**[2]
# of patients	N=450	N=371
Design	▪ **ARM A:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin ▪ **ARM B:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq	**Phase Ib** ▪ Dose finding, Tecentriq SC followed by Tecentriq IV **Phase III** ▪ 2L NSCLC non inferiority of Tecentriq SC vs Tecentriq IV
Primary endpoint	▪ Progression-free survival and overall survival	▪ Observed concentration of Tecentriq in serum at cycle 1
Status	▪ FPI Q4 2021	▪ FPI Phase Ib Q4 2018 and FPI Phase III Q4 2020 ▪ Recruitment completed Q1 2022 ▪ Study met its primary end point Q3 2022 ▪ Data presented at ESMO-IO 2022 ▪ Filed in US and EU Q4 2022
CT Identifier	NCT05091567	NCT03735121

[1]In collaboration with Jazz Pharma, [2]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

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – SCCHN

Indication	Adjuvant squamous cell carcinoma of the head and neck (SCCHN)
Phase/study	**Phase III** **IMvoke010**
# of patients	N=406
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

Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – urothelial carcinoma

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

BCG=Bacille Calmette-Guérin; PD-L1=Programmed cell death-ligand 1

Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – renal cell cancer

Indication	Advanced renal cell carcinoma (RCC) after immune checkpoint inhibitor treatment
Phase/study	**Phase III** **Contact-03**
# of patients	N=500
Design	▪ **ARM A:** Tecentriq plus cabozantinib ▪ **ARM B:** Cabozantinib
Primary endpoint	▪ Progression-free survival and overall survival
Status	▪ FPI Q3 2020 ▪ Recruitment completed Q4 2021 ▪ Study did not meet it's primary endpoint (PFS) Q1 2023
CT Identifier	NCT04338269

In collaboration with Exelixis
PD-L1=Programmed cell death-ligand 1; PFS=Progression-free survival

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – hepatocellular carcinoma

Indication	Adjuvant hepatocellular carcinoma (HCC)
Phase/study	**Phase III** **IMbrave050**
# of patients	N=668
Design	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Active surveillance
Primary endpoint	▪ Recurrence-free survival
Status	▪ FPI Q4 2019 ▪ Recruitment completed Q4 2021 ▪ Study met its primary endpoint Q1 2023 ▪ Data presented at AACR 2023
CT Identifier	NCT04102098

PD-L1=Programmed cell death-ligand 1; AACR=American Association for Cancer Research

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Previously untreated metastatic triple negative breast cancer (TNBC)	
Phase/study	**Phase III** **IMpassion130**	**Phase III** **IMpassion132**
# of patients	N=902	N=572
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel	▪ **ARM A:** Tecentriq plus capecitabine or carbo/gem ▪ **ARM B:** Placebo plus capecitabine or carbo/gem
Primary endpoint	▪ Progression-free survival and overall survival (co-primary endpoint)	▪ Overall survival
Status	▪ Study met co-primary endpoint of PFS in both PD-L1+ and ITT populations Q3 2018 ▪ Primary PFS and interim OS data presented at ESMO 2018 and ASCO 2019 ▪ Data published in *NEJM* 2018; 379:2108-2121 ▪ US accelerated approval Q1 2019 – US indication voluntarily withdrawn Q3 2021 ▪ Approved in EU Q3 2019 ▪ Final OS presented at ESMO Asia 2020	▪ FPI Q1 2018
CT Identifier	NCT02425891	NCT03371017

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

Indication	Neoadjuvant triple negative breast cancer (TNBC)	Adjuvant triple negative breast cancer (TNBC)
Phase/study	**Phase III** **IMpassion031**	**Phase III** **IMpassion030**
# of patients	N=333	N=2,300
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel	▪ **ARM A:** Tecentriq plus paclitaxel followed by Tecentriq plus AC, followed by Tecentriq maintenance ▪ **ARM B:** Placebo plus paclitaxel followed by AC followed by placebo
Primary endpoint	▪ Percentage of participants with pathologic complete response	▪ Invasive disease-free survival
Status	▪ Study met primary endpoint Q2 2020 ▪ Data presented at ESMO 2020 ▪ Data published in Lancet 2020;396 (10257):1090-1100 ▪ Filed in EU Q4 2020 - application withdrawn Q3 2021	▪ FPI Q3 2018 ▪ Study discontinued Q1 2023 based on IDMC recommendation following a futility analysis as the study was deemed unlikely to meet it's primary endpoint
CT Identifier	NCT03197935	NCT03498716

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

Indication	Untreated chronic lymphocytic leukemia (CLL) patients with coexisting medical conditions	Relapsed or refractory chronic lymphocytic leukemia (CLL)	Untreated fit chronic lymphocytic leukemia (CLL) patients
Phase/study	**Phase III** **CLL14**	**Phase III** **MURANO**	**Phase III** **CristaLLo**
# of patients	N=445	N=389	N=165
Design	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Chlorambucil plus Gazyva	▪ **ARM A:** Venclexta plus Rituxan ▪ **ARM B:** Rituxan plus bendamustine	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Fludarabine plus cyclophosphamide plus Rituxan or bendamustine plus Rituxan
Primary endpoint	▪ Progression-free survival	▪ 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 ▪ Data published in *NEJM* 2019; 380:2225-2236 ▪ Approved US Q2 2019 and EU Q1 2020	▪ Study met primary endpoint at interim analysis ▪ Filed in US Q4 2017 and EU Q1 2018 ▪ Data published in *NEJM* 2018; 378:1107–20 ▪ Data presented at ASCO 2018 and ASH 2017, 2019, 2020 ▪ Approved in US Q2 2018 (priority review) and EU Q4 2018	▪ FPI Q2 2020 ▪ Recruitment completed Jan 2023
CT Identifier	NCT02242942	NCT02005471	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

Indication	Relapsed or refractory multiple myeloma (MM)	
Phase/study	Phase I	Phase III CANOVA
# of patients	N=117	N=244
Design	▪ **Dose escalation cohort:** Venclexta dose escalation ▪ **Safety expansion cohort (t11;14):** Venclexta expansion ▪ **Combination cohort:** Venclexta plus dexamethasone	▪ **ARM A:** Venclexta plus dexamethazone ▪ **ARM B:** Pomalidomide plus dexamethasone in t(11;14) positive r/r MM
Primary endpoint	▪ Safety and maximum tolerated dose	▪ Progression-free survival
Status	▪ Data presented at ASCO 2015, 2016 and ASH 2016 ▪ Data published in Blood 2017; 130(22):2401-2409 and Am *J Hematol* 2021 Apr 1;96(4):418-427	▪ FPI Q4 2018 ▪ Recruitment completed Q3 2022
CT Identifier	NCT01794520	NCT03539744

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
Bcl-2=B-cell lymphoma 2; MM=multiple myeloma; r/r=Relapsed or refractory ; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology

Venclexta (venetoclax, RG7601)

Novel small molecule Bcl-2 selective inhibitor – myelodysplastic syndromes

Indication	Relapsed or refractory myelodysplastic syndromes (MDS)	Treatment-naive myelodysplastic syndromes (MDS)	Newly diagnosed higher-risk myelodysplatic syndrome (MDS)
Phase/study	**Phase Ib**	**Phase Ib**	**Phase III VERONA**
# of patients	N=70	N=129	N=500
Design	**Cohort 1:** ▪ **ARM A:** Venclexta 400 mg ▪ **ARM B:** Venclexta 800 mg **Cohort 2:** ▪ Venclexta plus azacitidine **Study expansion:** ▪ Venclexta or 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	▪ Complete remission rate and 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 201 ▪ 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

Indication	1L DLBCL
Phase/study	**Phase III** **POLARIX**
# of patients	N=879
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 Jan 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

Indication	RET+ NSCLC, thyroid cancer and other advanced solid tumors	1L RET fusion-positive, metastatic NSCLC
Phase/study	**Phase I/II** **ARROW**	**Phase III** **AcceleRET Lung**
# of patients	N=647	N=250
Design	▪ **Part I:** Gavreto 30-600mg dose escalation ▪ **Part II:** Gavreto 400mg dose expansion	▪ **ARM A:** Gavreto 400mg ▪ **ARM B:** Platinum-based chemotherapy +/- pembrolizumab
Primary endpoint	▪ Safety and efficacy	▪ Progression-free survival
Status	▪ Filed in US and EU for RET fusion-positive NSCLC and US for RET-mutant MTC and RET fusion-positive thyroid cancer ▪ Approved in US Q3 2020 in RET fusion-positive NSCLC, in Q4 2020 in RET-mutant MTC and RET fusion-positive thyroid cancer ▪ Updated data presented at ASCO 2021 and 2022 ▪ Data published in Lancet Oncol 2021 Jul;22(7):959-969 and Lancet Diabetes & Endocrinology Aug 2021;9(8):491-501 ▪ Approved in EU for RET fusion-positive NSCLC Q4 2021 ▪ Filing withdrawn in EU Q4 2022 for RET-mutant MTC and RET fusion-positive thyroid cancer	▪ Study initiated in Q1 2020
CT Identifier	NCT03037385	NCT04222972

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

Indication	3L+ FL, 3L+ DLBCL & other relapsed or refractory NHL	1L DLBCL	Relapsed or refractory DLBCL
Phase/study	**Phase I/II**	**Phase Ib/II**	**Phase Ib/II**
# of patients	N=746	N=160	N=262
Design	▪ Dose escalation of Lunsumio monotheraphy 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
Primary endpoint	▪ Safety, tolerability, dose/schedule, PK and response rates	▪ Safety/tolerability and response	▪ Safety/tolerability and response
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 ▪ Data published in *J. Clin. Oncol.* 40(5)481-491 and in the *Lancet* July 2022: doi.org/10.1016/S1470-2045(22)00335-7	▪ 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

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

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

Indication	2L+ FL	Relapsed or refractory CLL
Phase/study	**Phase III** **CELESTIMO**	**Phase Ib/II**
# of patients	N=400	N=56
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

Indication	2L+ SCT ineligible DLBCL
Phase/study	**Phase III** **SUNMO**
# of patients	N=222
Design	▪ **ARM A:** Lunsumio plus Polivy ▪ **ARM B:** R + GemOx
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q2 2022
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

Indication	Relapsed or refractory Non-Hodgkin's lymphoma (NHL)		
Phase/study	**Phase I**	**Phase Ib**	**Phase I**
# of patients	N=700	N=140	N=18-36
Design	**Cohort 1:** Single-agent dose escalation study ▪ 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)	Dose escalation and expansion ▪ **ARM A:** Columvi plus Tecentriq ▪ **ARM B:** Columvi plus Polivy	Columvi SC ▪ Part 1 dose escalation
Primary endpoint	▪ Efficacy, safety, tolerability and pharmacokinetics	▪ Safety	▪ Safety
Status	▪ Data presented at ASH 2018, 2020, 2021, 2022, ICML 2019, 2021, EHA 2020, 2021, 2022 and ASCO 2021, 2022 ▪ Data published in *J Clin Oncology* 2021; 39:18:1959-1970 and *NEJM* 2022; 387:2220-2231 ▪ Filed in EU Q2 2022 and US Q4 2022 ▪ First approved in Canada Q1 2023	▪ ARM A: FPI Q2 2018 ▪ ARM B: FPI Q4 2020 ▪ Recruitment completed Q2 2022 ▪ Data presented at ASH 2019, 2021	▪ FPI Q3 2021
CT Identifier	NCT03075696	NCT03533283	ISRCTN17975931

DLBCL=diffuse large B cell lymphoma; FL=Follicular lymphoma; r/r=Relapsed or refractory; SC=subcutenous; 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

Indication	Non-Hodgkin's lymphoma (NHL)	2L+ SCT-ineligible DLBCL	1L ctDNA high risk DLBCL
Phase/study	**Phase Ib**	**Phase III** **STARGLO**	**Phase II**
# of patients	Part I: 15-60 Part II: ~66-104	N=270	N=40
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-CHP 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 and 2022	▪ 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

Indication	2L+ SCT-eligible DLBCL	2L+ SCT-ineligible DLBCL
Phase/study	**Phase Ib**	**Phase Ib**
# of patients	N=40	N=112
Design	▪ Columvi plus R-ICE (single-arm study)	▪ Columvi IV plus CELMoD (CC-220 and CC-99282) ▪ Lunsumio SC plus CELMoD (CC-220 and CC-99282)
Primary endpoint	▪ Objective response rate within 3 cycles	▪ Safety, DLT, RPTD
Status	▪ FPI Q4 2022	▪ FPI Q4 2022
CT Identifier	NCT05364424	NCT05169515

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

Indication	Relapsing multiple sclerosis (RMS)		Primary progressive multiple sclerosis (PPMS)
Phase/study	**Phase III OPERA I**	**Phase III OPERA II**	**Phase III ORATORIO**
# of patients	N=821	N=835	N=732
Design	96-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV followed by 600mg IV q24w ▪ **ARM B:** Interferon β-1a (Rebif)	96-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV followed by 600mg IV q24w ▪ **ARM B:** Interferon β-1a (Rebif)	120-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV q24w ▪ **ARM B:** Placebo
Primary endpoint	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Sustained disability progression versus placebo by EDSS
Status	▪ Primary endpoint met Q2 2015, OLE ongoing ▪ Data presented at ECTRIMS 2015, AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM* 2017; 376:221-234 ▪ Data published on COVID-19 in *Mult Scler Relat Disord* on Ocrevus treated people with MS, doi.org/10.1016/j.msard.2020.102725		▪ Primary endpoint met Q3 2015 ▪ Data presented at ECTRIMS 2015, AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM* 2017; 376:209-220
	▪ Approved in US Q1 2017 and EU Q1 2018		
CT Identifier	NCT01247324	NCT01412333	NCT01194570

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

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

IV=intravenous; IRR=Infusion Related Reaction

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple sclerosis (RMS)	PPMS & RMS
Phase/study	**Phase IIIb GAVOTTE**	**Phase IIIb MUSETTE**	**Phase III Ocarina II[1]**
# of patients	N ~ 699	N ~ 786	N ~ 232
Design	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV q24w ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg q24w	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV q24w ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg q24w	▪ **ARM A:** Ocrevus IV ▪ **ARM B:** Ocrevus SC
Primary endpoint	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Serum Ocrevus area under the concentration-time curve (AUCW1-12) at week 12
Status	▪ FPI Q4 2020	▪ FPI Q4 2020 ▪ Recruitment completed Q4 2021	▪ FPI Q2 2022 ▪ Recruitment completed Q4 2022
CT Identifier	NCT04548999	NCT04544436	NCT05232825

[1]SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase
cCDP=composite confirmed disability progression; IV=intravenous; SC=Subcutaneous

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)		
Phase/study	**Phase II/III** **FIREFISH**	**Phase II/III** **SUNFISH**	**Phase II** **JEWELFISH**
# of patients	N=21 (Part 1), 41 (Part 2)	N=51 (Part 1), 180 (Part 2)	N=174
Design	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
Primary endpoint	▪ Safety, tolerability, PK/PD and efficacy	▪ Safety, tolerability, PK/PD and efficacy	▪ Safety, tolerability, PK/PD
Status	▪ 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 ▪ 3-year data presented at EPNS 2022 and 4-year data presented at Cure SMA 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 SMA Europe 2020, 2-year data at MDA 2021, 3-year data at MDA 2022 and 4-year data at MDA 2023 ▪ Part II 1-year data published in Lancet Neurology, 2022; 21 (1) 42-52	▪ Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, WMS 2019, CureSMA 2020 and 2021 ▪ 2-year data presented at WMS 2022
	▪ ODD granted by FDA Q1 2017 and EU Q1 2019, PRIME designation in Q4 2018 ▪ Approved in US Q3 2020 and EU Q1 2021		
CT Identifier	NCT02913482	NCT02908685	NCT03032172

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

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)
Phase/study	**Phase II** **RAINBOWFISH**
# of patients	N=25
Design	▪ Infants aged from birth to 6 weeks who have been genetically diagnosed with SMA but are not yet presenting with symptoms
Primary endpoint	▪ Proportion of participants with two copies of the SMN2 gene and baseline CMAP>=1.5 millivolt who are sitting without support
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

Indication	Neuromyelitis optica spectrum disorder (NMOSD)	
Phase/study	**Phase III** **SAkuraStar**	**Phase III** **SAkuraSky**
# of patients	N=95	N=83
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

Indication	Generalised myasthenia gravis (MG)	Myelin oligodendrocyte glycoprotein antibody disease (MOG-AD)	Autoimmune encephalitis (AIE)
Phase/study	**Phase III** **Luminesce**	**Phase III** **METEOROID**	**Phase III** **CIELO**
# of patients	N=240	N=152	N=152
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

Gazyva (obinutuzumab, RG7159)

Immunology development program

Indication	Lupus nephritis		Membranous nephropathy
Phase/study	**Phase II** **NOBILITY**	**Phase III** **REGENCY**	**Phase III** **MAJESTY**
# of patients	N=126	N=252	N=140
Design	▪ **ARM A:** Gazyva 1000mg IV plus MFF / mycophenolic acid ▪ **ARM B:** Placebo IV plus MFF/ mycophenolic acid	▪ **ARM A:** Gazyva 1000mg IV (6 doses through Week 52) plus MFF ▪ **ARM B:** Gazyva1000 mg IV (5 doses through Week 52) plus MFF ▪ **ARM C:** Placebo IV plus MFF	▪ **ARM A:** Gazyva 1000mg IV on top of renin-angiotensin inhibitors ▪ **ARM B:** Tacrolimus treatment for 12 months
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of patients who achieve complete remission at week 104
Status	▪ Primary endpoint met Q2 2019 ▪ BTD granted by the FDA Q3 2019 ▪ Data presented at ASN and ACR 2019 ▪ Published in *Ann Rheum Dis* 2022 Jan;81(1):100-107	▪ FPI Q3 2020 ▪ Recruitment completed Q1 2023	▪ FPI Q2 2021
CT Identifier	NCT02550652	NCT04221477	NCT04629248

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

Indication	Systemic lupus erythematosus (SLE)	Pediatric nephrotic syndrome (PNS)
Phase/study	**Phase III** **ALLEGORY**	**Phase III** **INShore**
# of patients	N=200	N=80
Design	▪ **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
IV=Intravenous

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

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

Indication	Systemic lupus erythematosus (SLE)
Phase/study	**Phase I**
# of patients	N=50
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

In collaboration with Biogen
SC=subcutaneous

Xolair (omalizumab, RG3648)

Humanized monoclonal antibody that selectively binds to IgE

Indication	Food allergy
Phase/study	**Phase III** **OUtMATCH[1]**
# of patients	N=225
Design	▪ Xolair by SC injection either q2w or q4w for 16 to 20 weeks
Primary endpoint	▪ Number of participants who successfully consume ≥600mg of peanut protein without dose-limiting symptoms
Status	▪ FPI Q3 2019
CT Identifier	NCT03881696

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

Indication	Wet age-related macular degeneration (wAMD)		
Phase/study	**Phase III** **Archway**	**Phase II+III extension** **Portal**	**Phase IIIb** **Velodrome**
# of patients	N=418	N=1,000	N=442
Design	▪ **ARM A:** PDS q24w ▪ **ARM B:** Intravitreal ranibizumab q4w	▪ Patients from LADDER or Archway receive refills of ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)	▪ **ARM A:** PDS q36w ▪ **ARM B:** PDS q24w
Primary endpoint	▪ Change in BCVA from baseline at the average of week 36 and week 40	▪ Safety and long term efficacy	▪ Change in BCVA from baseline averaged over weeks 68 and 72
Status	▪ Study met primary endpoint Q2 2020 ▪ Data presented at ASRS 2020, 44/48 week data at Angiogenesis 2021 and 2-year data at Angiogenesis 2022 ▪ Filed in US (PRIME) and EU Q2 2021 ▪ Approved in US Q4 2021	▪ FPI Q3 2018	▪ FPI Q2 2021
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

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

Indication	Center-involving diabetic macular edema (CI-DME)	
Phase/study	**Phase III** **YOSEMITE**	**Phase III** **RHINE**
# of patients	N=940	N=951
Design	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab PTI up to q16w ▪ **ARM C:** Aflibercept, q8w	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab PTI up to q16w ▪ **ARM C:** Aflibercept, q8w
Primary endpoint	▪ Change from baseline in BCVA at 1 year	▪ Change from baseline in BCVA at 1 year
Status	▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021	▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021
	▪ Filed in US and EU Q2 2021 ▪ Published in the Lancet 2022 Feb 19;399(10326):741-755. ▪ 2-year data presented at Angiogenesis 2022 ▪ Approved in US Q1 2022 and EU Q3 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03622580	NCT03622593

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

Indication	Wet age related macular degeneration (wAMD)	
Phase/study	**Phase III** **TENAYA**	**Phase III** **LUCERNE**
# of patients	N=671	N=658
Design	▪ **ARM A:** Faricimab 6.0mg q16w flexible after 4 IDs ▪ **ARM B:** Aflibercept 2.0mg q8w after 3 IDs	▪ **ARM A:** Faricimab 6.0mg q16w flexible after 4 IDs ▪ **ARM B:** Aflibercept 2.0mg q8w after 3 IDs
Primary endpoint	▪ Change from baseline in BCVA week 40, 44 & 48	▪ Change from baseline in BCVA week 40, 44 & 48
Status	▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021	▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021
	▪ Filed in US and EU Q2 2021 ▪ Published in Lancet 2022 Feb 19;399(10326):729-740 ▪ Approved in US Q1 2022 and EU Q3 2022 ▪ 2-year data presented at ASRS 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03823287	NCT03823300

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

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

PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity; Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza		
Phase/study	**Phase III** **miniSTONE 1 (0-1 year old)**	**Phase III** **miniSTONE 2 (1- <12 years old)**	**Phase IIIb** **CENTERSTONE**
# of patients	N=30	N=176	N=3,160
Design	Healthy pediatric patients from birth to <1 year with influenza-like symptoms receive Xofluza on Day 1	Healthy pediatric patients 1 to <12 years of age with influenza-like symptoms ▪ **ARM A:** Xofluza ▪ **ARM B:** Tamiflu	Reduction of direct transmission of influenza from otherwise healthy patients to household contacts ▪ **ARM A:** Xofluza ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety	▪ Safety	▪ Percentage of household contacts who are PCR-positive for influenza by day 5 post randomization of index patients
Status	▪ FPI Q1 2019	▪ Primary endpoint met Q2 2019 ▪ Data presented at OPTIONS X 2019 ▪ Filed in US Q1 2020 and EU Q4 2021 ▪ Data published in *Pediatric Infectious Disease* 2020 Aug;39(8):700-705 ▪ Approved in the US (age 5 years and older) Q3 2022 , EU Jan 2023 and China (age 5 years and older) Q1 2023	▪ FPI Q4 2019
CT Identifier	NCT03653364	NCT03629184	NCT03969212

In collaboration with Shionogi & Co., Ltd.
CAP=Catabolite Activating Protein

Roche

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

Indication	1L NSCLC PD-L1 TPS>50%	Stage III unresectable 1L NSCLC
Phase/study	**Phase III** **SKYSCRAPER-01**	**Phase III** **SKYSCRAPER-03**
# of patients	N=500-560	N=800
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
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

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

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

Indication	Locally advanced esophageal cancer (EC)	1L esophageal cancer (EC)	1L recurrent/metastatic PD-L1 positive squamous cell head and neck carcinoma (SCCHN)
Phase/study	**Phase III** **SKYSCRAPER-07**	**Phase III** **SKYSCRAPER-08**	**Phase II** **SKYSCRAPER-09**
# of patients	N=750	N=500	N=120
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

Indication	Solid tumors	NSCLC	Relapsed or refractory multiple myeloma (MM) or r/r B-cell NHL
Phase/study	Phase I	Phase II CITYSCAPE	Phase I
# of patients	N=540	N=135	N=52
Design	▪ **Phase Ia:** Dose escalation and expansion of tiragolumab ▪ **Phase Ib:** Dose escalation and expansion of tiragolumab in combination with Tecentriq and/or other anti-cancer therapies	▪ **ARM A:** Tecentriq plus tiragolumab ▪ **ARM B:** Tecentriq monotherapy	▪ **Phase Ia:** Tiragolumab monotherapy ▪ **Phase Ib:** Tiragolumab plus daratumumab (r/r MM) or rituximab (r/r NHL)
Primary endpoint	▪ Safety, tolerability, PK variability and preliminary efficacy	▪ Overall response rate and progression-free survival	▪ Safety, tolerability, PK/PD and preliminary efficacy
Status	▪ Data presented at AACR 2020	▪ Data presented at ASCO 2020 and WCLC and ESMO IO 2021 ▪ BTD granted by FDA Q4 2020 ▪ Data published in *Lancet Oncol* 2022 Jun;23(6):781-792	▪ FPI Q2 2019
CT Identifier	NCT02794571	NCT03563716	NCT04045028

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 PI3Kα inhibitor

Indication	PIK3CA-mutant HR+ metastatic breast cancer (mBC)	PIK3CA mutant solid tumors and metastatic ER+ HER2-neg breast cancer
Phase/study	**Phase III** **INAVO120**	**Phase I**
# of patients	N=400	N=256
Design	▪ **ARM A:** Inavolisib plus palbociclib plus fulvestrant ▪ **ARM B:** Placebo plus palbociclib plus fulvestrant	Monotherapy and in combination with standard of care (letrozole; letrozole plus palbociclib; fulvestrant) ▪ **Stage 1:** Dose escalation ▪ **Stage 2:** Dose expansion
Primary endpoint	▪ Progression-free survival	▪ Safety, tolerability and pharmacokinetics
Status	▪ FPI Q1 2020	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017 ▪ Data presented at SABCS 2019, 2020 and 2021
CT Identifier	NCT04191499	NCT03006172

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

Giredestrant (SERD (3),RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

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

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

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

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor

Giredestrant (SERD (3),RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

Indication	1L ER+/HER2-positive breast cancer (BC)
Phase/study	**Phase III** **heredERA**
# of patients	N=812
Design	Induction Phesgo plus taxane followed by maintenance with either: ▪ **ARM A:** Giredestrant plus Phesgo ▪ **ARM B:** Phesgo
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q2 2022
CT Identifier	NCT05296798

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

Indication	Advanced or metastatic solid tumors with a KRAS G12C mutation	2L NSCLC	2L, 1L metastatic colorectal cancer (mCRC)
Phase/study	**Phase I**	**Phase II/III** **B-FAST***	**Phase Ib** **INTRINSIC**
# of patients	N=438	Modular design	Modular design
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

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH)	Paroxysmal nocturnal hemoglobinuria (PNH) patients switching from a C5 inhibitor
Phase/study	**Phase I/II** **COMPOSER**	**Phase III** **COMMODORE 1**
# of patients	N=59	N=89 (ARMs A/B)
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
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

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

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

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

In collaboration with Chugai
aHUS=Atypical Hemolytic Uremic Syndrome; C5i=C5 inhibitor; TMA=thrombotic microangiopathy

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

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

VOC=Vaso-occlusive crises

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Lupus nephritis (LN)
Phase/study	**Phase I**
# of patients	N=15
Design	▪ Single-arm study of patients with active class III, IV, or V lupus nephritis and urine protein-to-creatinine ratio >=1.5 g/g ▪ All patients to receive crovalimab IV loading dose and subsequent crovalimab SC q1w
Primary endpoint	▪ PK, safety
Status	▪ FPI Q1 2023
CT Identifier	ISRCTN12809537

In collaboration with Chugai
IV=Intravenous, SC=Subcutaneous, PK=Pharmacokinetics

Astegolimab (RG6149, Anti-ST2)

A monoclonal antibody that selective binds to ST2

Indication	Chronic obstructive pulmonary disease (COPD)		
Phase/study	**Phase II** **COPD-ST2OP**	**Phase IIb** **ALIENTO**	**Phase III** **ARNASA**
# of patients	N=81	N=930	N=1,290
Design	▪ Astegolimab SC 490mg q4w for 48 weeks	▪ **ARM A:** SC astegolimab q2w ▪ **ARM B:** SC astegolimab q4w ▪ **ARM C:** SC placebo q2w	▪ **ARM A:** SC astegolimab q2w ▪ **ARM B:** SC astegolimab q4w ▪ **ARM C:** SC placebo q2w
Primary endpoint	▪ Number of moderate to severe exacerbation	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period
Status	▪ Published in Lancet Respir Med 2022;10(5):469-477. doi: 10.1016/S2213-2600(21)00556-7	▪ FPI Q4 2021	▪ FPI Q1 2023
CT Identifier	NCT03615040	NCT05037929	NCT05595642

In collaboration with Amgen
COPD=Chronic obstructive pulmonary disease, SC=Subcutaneous

Crenezumab (RG7412)

Humanized monoclonal antibody targeting all forms of Aß

Indication	Alzheimer's prevention initiative (API) Colombia
Phase/study	**Phase II** **Cognition study**
# of patients	N=252
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

In collaboration with AC Immune
Ab=amyloid-beta; SC=Subcutaneous; IV=Intravenous

Tominersen (RG6042, HTT ASO)

Antisense oligonucleotide (ASO) targeting human HTT mRNA

Indication	Huntington's disease
Phase/study	**Phase II** **GENERATION HD2**
# of patients	N=360
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

In collaboration with Ionis Pharmaceuticals
HD=Huntington's Disease; HTT=Huntingtin

Fenebrutinib (RG7845, GCD-0853)

Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple sclerosis (RMS)	
Phase/study	**Phase III** **FENtrepid**	**Phase III** **FENhance 1**	**Phase III** **FENhance 2**
# of patients	N=946	N=736	N=736
Design	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Ocrevus 2x300mg IV q24w	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Teriflunomide once daily oral	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Teriflunomide once daily oral
Primary endpoint	▪ Time to onset of cCDP12	▪ Time to onset of cCDP12 and annualized relapse rate	▪ Time to onset of cCDP12 and annualized relapse rate
Status	▪ FPI Q4 2020	▪ FPI Q1 2021	▪ FPI Q1 2021
CT Identifier	NCT04544449	NCT04586023	NCT04586010

IV=Intravenous; cCDP12=Composite 12-week confirmed disability progression

Balovaptan (RG7314)

Small molecule antagonist of the V1A vasopressin receptor

Indication	Post-traumatic stress disorder (PTSD)
Phase/study	**Phase II**
# of patients	N=30
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

TNKase (RG3625, tenecteplase)

Small molecule tissue plasminogen activator

Indication	Stroke patients between 4.5 and 24 hours
Phase/study	**Phase III** **TIMELESS**
# of patients	N=456
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
CT Identifier	NCT03785678

Neuroscience

Latent myostatin (RG6237, GYM329)

Recycling and antigen-sweeping monoclonal anti-latent myostatin antibody

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

[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

Indication	Diabetic macular edema (DME) and Uveitic macular edema (UME)	Diabetic macular edema (DME)	
Phase/study	**Phase I** **DOVETAIL**	**Phase II** **BARDENAS**	**Phase II** **ALLUVIUM**
# of patients	N=90	N=210-230	N=360-400
Design	▪ Part I: Multiple ascending dose study of intravitreal monotherapy ▪ Part II: monotherapy and in combination with anti-VEGF	▪ **ARM A:** Anti-IL-6 plus ranibizumab ▪ **ARM B:** Ranibizumab plus sham control	▪ **Arm A:** 0.25 mg anti-IL-6 q8w ▪ **Arm B:** 1.0 mg anti-IL-6 q8w ▪ **Arm C:** 1.0 mg anti-IL-6 q4w ▪ **Arm D**: 0.5 mg ranibizumab q4w
Primary endpoint	▪ Safety, tolerability, PK	▪ Mean change from baseline in BCVA averaged over week 44 and week 48	▪ Mean change from baseline in BCVA averaged over week 44 and week 48
Status	▪ FPI Q3 2019 ▪ Data presentation at ARVO 2023	▪ FPI Q4 2021	▪ FPI Q4 2021
CT Identifier		NCT05151744	NCT05151731

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

Indication	Uveitic macular edema (UME)	
Phase/study	**Phase III** **MEERKAT**	**Phase III** **SANDCAT**
# of patients	N=225	N=225
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 Jan 2023	▪ FPI Q1 2023
CT Identifier	NCT05642312	NCT05642325

BCVA=Best corrected visual acuity; PRN= Pro re nata

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pRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
FAP-4-1BBL (RG7827)	Solid tumors	I	~150	FPI Q2 2018 Data presented at ESMO 2020 Recruitment completed Q2 2021	
	3L+ MSS mCRC	Ib	80	FPI Q3 2021 Combination study with cibisatamab	NCT04826003
cibisatamab (CEA x CD3, RG7802)	CEA-positive solid tumors	Ia	149	FPI Q4 2014 Data presented at ASCO 2017	NCT02324257
		Ib	228	FPI Q1 2016 Data presented at ASCO 2017	NCT02650713
	3L+ MSS mCRC	Ib	46	FPI Q1 2019	NCT03866239
tobemstomig PD1-LAG3 (RG6139)	Solid tumors	I	320	FPI Q4 2019 Data presented at ESMO 2022 Recruitment completed Q4 2022	NCT04140500
	advanced or metastatic esophageal squamous cell cancer	II	210	FPI Q2 2021 Randomized trial, compared with nivolumab	NCT04785820 TALIOS
	Untreated unresectable or metastatic melanoma	II	80	FPI Q3 2022	NCT05419388
	Non-small cell lung cancer	II	180	FPI Q1 2023	NCT05775289
	advanced and metastatic urothelial cancer	II	240	FPI April 2023	NCT05645692

pRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
englumafusp alfa (CD19-4-1BBL, RG6076)	R/R B cell non-Hodgkin's lymphoma	I	362	Part I: FPI Q3 2019 Part II: FPI Q3 2020 Data presented at ASH 2022	NCT04077723
eciskafusp alfa (PD1-IL2v, RG6279)	Solid tumors	Ib	348	Part I: FPI Q2 2020; recruitment completed Q4 2021 Part II: FPI Q1 2022 Part III: FPI Q1 2023	NCT04303858
CD25 (RG6292)	Solid tumors	I	110	FPI Q4 2019	NCT04158583
forimtamig (Anti-GPRC5D, RG6234)	Multiple myeloma	I	400	FPI Q4 2020 Data presented at EHA 2022 and ASH 2022	NCT04557150
HLA-A2-WT1 x CD3 (RG6007)	AML	I	220	FPI Q4 2020	NCT04580121
FAP-CD40 (RG6189)	Solid tumors	I	280	FPI Q2 2021	NCT04857138
BRAFi (3) (RG6344)	Solid tumors	I	292	FPI Q1 2022	ISRCTN13713551
CD19xCD28 (RG6333)	R/R B cell non-Hodgkin's lymphoma	I	~200	FPI Q1 2022 Combination study with Columvi	NCT05219513
EGFRvIIIxCD3 (RG6156)	Glioblastoma	I	~200	FPI Q2 2022	NCT05187624
DLL3 x CD3 x CD137 (RG6524)	Solid tumors	I	168	FPI Q1 2023	NCT05619744

pRED neuroscience development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
trontinemab (BS-gantenerumab, RG6102)	Alzheimer's disease	IIa	~120	FPI Q1 2021	NCT04639050
Brain Shuttle-CD20 (BS-CD20, RG6035)	Multiple sclerosis	I	30-63	FPI Q3 2021	ISRCTN16295 177 NCT05704361
ralmitaront (partial TAAR1 agonist, RG7906)	Schizophrenia	II	36	FPI Q4 2018 Recruitment completed Q3 2019	
		II	247	FPI Q4 2019	NCT03669640 (TWAIN I)
prasinezumab[1] (anti-αSynuclein, RG7935, PRX002)	Parkinson's disease	II	316	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 & ADPD 2020-22. The Open Label Extension is ongoing.	NCT03100149 (PASADENA)
		IIb	575	FPI Q2 2021 Recruitment completed Q1 2023	NCT04777331 (PADOVA)
alogabat (GABA-Aa5 PAM, RG7816)	Autism spectrum disorder	II	105	FPI Q1 2021	NCT04299464 (Aurora)
NME (RG7637)	Psychiatric disorders	I	80	FPI Q3 2020	NCT04475848
rugonersen (UBE3A LNA, RG6091)	Angelman syndrome	I	66	FPI Q3 2020	NCT04428281
MAGLi (RG6182)	Multiple sclerosis	I	30	FPI Q4 2020	

Partner: [1]Prothena
BS=Brain Shuttle

pRED neuroscience development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
NME (RG6289)	Alzheimer's disease	I	138	FPI Q4 2021	
NME (RG6163)	Psychiatric disorders	I	84	FPI Q1 2022	
selnoflast* (NLRP3i, RG6418)	Parkinson's disease	Ib	48	FPI Q3 2022	
basmisanil (GABA-Aa5 NAM, RG1662)	Dup15q syndrome	II	90	FPI Q4 2022	NCT05307679

*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022

pRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
selnoflast* (NLRP3i, RG6418)	Chronic obstructive pulmonary disease	Ib	102	FPI Q2 2022 Study closed Q3 2022	
Ophthalmology					
zifibancimig (VEGF-Ang2 DutaFab, RG6120)	nAMD	I	200	FPI Q4 2020	NCT04567303
vicasinabin (CB2 receptor agonist, RG7774)	DR	II	135	FPI Q2 2020	NCT04265261 (CANBERRA)
NME (RG6209)	retinal disease	I	~70 (Part I)	FPI Q4 2022	

*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022

pRED infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Infectious Diseases					
ruzotolimod (TLR7 agonist (3) RG7854)	Chronic hepatitis B	I	150	FPI Q4 2016 Data presented at APASL 2019	NCT02956850
ruzotolimod/ xalnesiran/ PDL1 LNA (RG7854/RG6346/RG6084)	Chronic hepatitis B	II	275	FPI Q3 2020	NCT04225715 (PIRANGA)
PDL1 LNA (RG6084)	Chronic hepatitis B	I	35	FPI Q1 2019 Part Ia: completed Part Ib: initiated	
zosurabalpin (Abx MCP, RG6006)	A. baumannii infections	I	204	FPI Q4 2020	NCT04605718

Abx MCP=antibiotic macrocyclic peptide

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gRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
cevostamab (anti-FcRH5 x CD3; RG6160)	R/R multiple myeloma	I	300	FPI Q3 2017 Data presented at ASH 2020, 2021 & 2022	NCT03275103
	R/R multiple myeloma	I	120	FPI Q2 2021	NCT04910568
	BCMA-experienced R/R MM	I/II	140	FPI Q4 2022	NCT05535244
runimotamab (HER2 x CD3, RG6194)	Metastatic HER2-expressing cancers	I	440	FPI Q2 2018	NCT03448042
NME (RG6286)	Locally advanced or metastatic colorectal cancer	I	67	FPI Q3 2020	NCT04468607
IL15/IL15Ra-Fc (RG6323)[1]	Solid tumors	Ia/Ib	250	FPI Q1 2020	NCT04250155
	R/R multiple myeloma	I	60	FPI Q2 2022	NCT05243342
	R/R multiple myeloma	I	90	FPI Q1 2023 Combination study with cevostamab	NCT05646836
autogene cevumeran (Individualized Neoantigen-Specific Therapy (iNeST); RG6180)[2]	Solid tumors	Ia/IIb	271	FPI Q4 2017 Data presented at AACR 2020 Recruitment completed Q1 2022	NCT03289962
	1L advanced melanoma	II	132	FPI Q1 2019	NCT03815058 (IMcode001)

Partner: [1]Xencor, [2]BioNTech

gRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
SHP2i (RG6344)[1]	Solid tumors	Ia	~50	FPI Q1 2020	NCT04252339
	Solid tumors	Ib	~125	FPI Q3 2022	NCT05487235
	KRAS-G12C mutant solid tumors	Ib	~500	FPI Q4 2021 Arm F of a combination study investigating divarasib monotheraphy and combinations	NCT04449874
belvarafenib (RG6185)[2]	nRASmt CPI-experienced melanoma	Ib	83	FPI Q2 2021 Data presented at ESMO 2021	NCT04835805
NME (RG6392)	Oncology	I	60	FPI Q4 2021	ISRCTN92655801
NME (RG6411)	Solid tumors	I	110	FPI Q4 2022	NCT05581004

Partner: [1]Relay, [2]Hanmi

gRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
NME (RG6287, GDC-8264)	Inflammatory bowel disease	I	68	FPI Q1 2020 Recruitment completed Q3 2021	EUDRACT2019-002613-19
	Inflammatory diseases	I	16	FPI Q4 2021 Recruitment completed Q1 2022	
	Acute graft versus host disease	Ib	40	FPI April 2023	NCT05673876
NME (RG6315, MTBT1466A)	Immunologic disorders	I	~24	FPI Q3 2020	
	Systemic sclerosis	Ib	100	FPI Q1 2023	NCT05462522
NME (RG6341, GDC-6599)	Asthma	Ia/Ib	84	FPI Q4 2021	
	Chronic cough	IIa	80	FPI Q1 2023	NCT05660850
TMEM16A potentiator (RG6421, GDC-6988)	Cystic fibrosis	Ib	30	FPI Q3 2022	ISRCTN15406513
Ophthalmology					
NME (RG6351)	DME	I	42-78	FPI Q2 2022	ISRCTN14152148
OpRegen (RG6501)[1]	Geographic atrophy	II	60	FPI Q1 2023	NCT05626114

Partner: [1]Lineage Cell Therapeutics

gRED neuroscience and infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
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	

Partner: [1]AC Immune

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Hemophilia A

Unique gene therapy platform

Molecule	Dirloctogene Samoparvovec (SPK-8011) (RG6357)		SPK-8016 (RG6358)
Indication	Hemophilia A		Hemophilia A with inhibitors to Factor VIII
Phase/study	Phase I	Phase I/II	Phase I/II
# of patients	N=100	N=30	N=30
Design	▪ Long term follow up study of patients who have received SPK-8011 in any prior Spark-sponsored SPK-8011 study	▪ Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8011	▪ Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8016 in individuals with FVIII inhibitors
Primary endpoint	▪ Safety	▪ Safety and changes from baseline in FVIII activity levels at week 52	▪ Safety; peak and steady state FVIII activity levels at week 52
Status	▪ Ongoing	▪ Updated data presented at ISTH 2020 and 2021 ▪ Recruitment completed Q1 2021 ▪ Data published in *NEJM* 2021; 385:1961-1973 ▪ 5-year data published at ASH 2022	▪ FPI Q1 2019
CT Identifier	NCT03432520	NCT03003533	NCT03734588

ISTH=International Society on Thrombosis and Haemostasis; NEJM=New England Journal of Medicine

Pompe disease

Unique gene therapy platform

Molecule	SPK-3006 (RG6359)
Indication	Pompe disease
Phase/study	Phase I/II RESOLUTE
# of patients	N=20
Design	▪ Gene transfer study for late-onset Pompe disease
Primary endpoint	▪ Safety
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2022
CT Identifier	NCT04093349

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Foreign exchange rates information

Geographical sales split by Divisions and Group*

CHFm	Q1 2022	Q1 2023	% change CER
Pharmaceuticals Division	**11,159**	**11,699**	**+9**
United States	5,489	5,853	+6
Europe	2,072	2,071	+5
Japan	1,337	1,390	+18
International	2,261	2,385	+13
Diagnostics Division	**5,286**	**3,623**	**-28**
United States	1,465	936	-36
Europe	1,600	995	-34
Japan	223	156	-21
International	1,998	1,536	-18
Group	**16,445**	**15,322**	**-3**
United States	6,954	6,789	-3
Europe	3,672	3,066	-12
Japan	1,560	1,546	+13
International	4,259	3,921	-2

CER=Constant Exchange Rates; * Geographical sales split shown here does not represent operational organization

Pharma Division sales Q1 2023

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	1,636	14	1,188	13	298	11	-	-	150	32
Perjeta	1,049	11	392	8	220	1	53	2	384	22
Hemlibra	1,034	24	631	21	206	27	92	24	105	38
Tecentriq	920	15	507	14	195	11	105	12	113	34
Actemra / RoActemra	676	-12	296	-22	193	-8	77	0	110	10
Ronapreve	567	9	-	-	-	-100	567	33	-	-100
Kadcyla	509	5	198	-3	154	-6	26	-8	131	42
Xolair	479	5	479	5	-	-	-	-	-	-
Herceptin	477	-17	91	-37	97	-17	9	-30	280	-7
MabThera	459	-17	274	-21	51	0	6	-13	128	-12
Vabysmo	432	*	360	*	44	-	21	-	7	-
Avastin	416	-24	133	-25	30	-45	91	-21	162	-19
Alecensa	372	9	106	7	73	3	50	5	143	14
Evrysdi	363	62	124	13	113	74	21	47	105	189
TNKase / Activase	302	23	288	23	-	-	-	-	14	17
Phesgo	241	72	98	62	114	59	-	-	29	232
Gazyva	197	24	99	32	55	25	8	-35	35	27
Lucentis	167	-35	167	-35	-	-	-	-	-	-
Polivy	150	96	46	35	40	93	51	169	13	340
Pulmozyme	127	-5	83	-5	20	-16	-	-	24	10
Pharma Division	**11,699**	**9**	**5,853**	**6**	**2,071**	**5**	**1,390**	**18**	**2,385**	**13**

CER=Constant Exchange Rates; *over 500%

Pharma Division sales Q1 2023

Products launched since 2015

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Cotellic	12	-2	5	21	3	-17	-	-	4	-9
Alecensa	372	9	106	7	73	3	50	5	143	14
Tecentriq	920	15	507	14	195	11	105	12	113	34
Ocrevus	1,636	14	1,188	13	298	11	-	-	150	32
Hemlibra	1,034	24	631	21	206	27	92	24	105	38
Luxturna	4	-23	4	-23	-	-	-	-	-	-
Xofluza	18	*	1	-10	-	*	-	-	17	*
Polivy	150	96	46	35	40	93	51	169	13	340
Rozlytrek	19	21	10	-6	4	80	2	5	3	144
Phesgo	241	72	98	62	114	59	-	-	29	232
Enspryng	54	42	15	16	4	96	33	44	2	246
Evrysdi	363	62	124	13	113	74	21	47	105	189
Gavreto	10	95	6	48	2	83	-	-	2	*
Ronapreve	567	9	-	-	-	-100	567	33	-	-100
Susvimo	1	-33	1	-33	-	-	-	-	-	-
Vabysmo	432	*	360	*	44	-	21	-	7	-
Lunsumio	14	-	12	-	2	-	-	-	-	-
Total	**5,847**	**31**	**3,115**	**31**	**1,098**	**22**	**942**	**35**	**692**	**41**

CER=Constant Exchange Rates; *over 500%

Pharma Division sales Q1 2023

Product sales Pharmaceuticals Division

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	1,636	14	1,188	13	298	11	-	-	150	32
Perjeta	1,049	11	392	8	220	1	53	2	384	22
Hemlibra	1,034	24	631	21	206	27	92	24	105	38
Tecentriq	920	15	507	14	195	11	105	12	113	34
Actemra / RoActemra	676	-12	296	-22	193	-8	77	0	110	10
Ronapreve	567	9	-	-	-	-100	567	33	-	-100
Kadcyla	509	5	198	-3	154	-6	26	-8	131	42
Xolair	479	5	479	5	-	-	-	-	-	-
Herceptin	477	-17	91	-37	97	-17	9	-30	280	-7
MabThera	459	-17	274	-21	51	0	6	-13	128	-12
Vabysmo	432	*	360	*	44	-	21	-	7	-
Avastin	416	-24	133	-25	30	-45	91	-21	162	-19
Alecensa	372	9	106	7	73	3	50	5	143	14
Evrysdi	363	62	124	13	113	74	21	47	105	189
TNKase / Activase	302	23	288	23	-	-	-	-	14	17
Phesgo	241	72	98	62	114	59	-	-	29	232
Gazyva	197	24	99	32	55	25	8	-35	35	27
Lucentis	167	-35	167	-35	-	-	-	-	-	-
Polivy	150	96	46	35	40	93	51	169	13	340
Pulmozyme	127	-5	83	-5	20	-16	-	-	24	10
Enspryng	54	42	15	16	4	96	33	44	2	246
Rozlytrek	19	21	10	-6	4	80	2	5	3	144
Xofluza	18	*	1	-10	-	*	-	-	17	*
Lunsumio	14	-	12	-	2	-	-	-	-	-
Cotellic	12	-2	5	21	3	-17	-	-	4	-9
Gavreto	10	95	6	48	2	83	-	-	2	*
Luxturna	4	-23	4	-23	-	-	-	-	-	-
Susvimo	1	-33	1	-33	-	-	-	-	-	-
Other Products	994	-15	239	-38	153	-20	178	4	424	2
Pharma Division	**11,699**	**9**	**5,853**	**6**	**2,071**	**5**	**1,390**	**18**	**2,385**	**13**

CER=Constant Exchange Rates; *over 500%

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q1/22	Q2/22	Q3/22	Q4/22	Q1/23
Ocrevus	18	17	16	18	14
Perjeta	1	9	5	4	11
Hemlibra	30	31	23	24	24
Tecentriq	8	13	9	24	15
Actemra / RoActemra	3	-23	-42	-22	-12
Ronapreve	272	-91	-92	118	9
Kadcyla	9	18	6	-3	5
Xolair	9	13	8	6	5
Herceptin	-19	-11	-23	-22	-17
MabThera	-21	-20	-19	-20	-17
Vabysmo	-	-	-	-	*
Avastin	-32	-27	-28	-25	-24
Alecensa	23	16	11	10	9
Evrysdi	189	65	93	59	62
TNKase / Activase	-20	1	-5	-27	23
Phesgo	410	168	76	73	72
Gazyva	7	9	9	9	24
Lucentis	-26	-9	-39	-40	-35
Polivy	1	9	5	4	96
Pulmozyme	-3	2	-3	-15	-5

CER=Constant Exchange Rates; * over 500%; [1] Q1-Q4/22 vs Q1-Q4/21; Q1/23 vs Q1/22

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Ocrevus	10	17	15	13	34	11	26	11	-	-	-	-	62	26	29	32
Perjeta	4	0	13	8	-12	-15	-15	1	-1	-1	3	2	37	30	13	22
Hemlibra	24	16	21	21	29	36	27	27	24	22	14	24	115	53	45	38
Tecentriq	15	3	20	14	24	17	23	11	-9	0	6	12	17	30	70	34
Actemra / RoActemra	-31	-61	-42	-22	-2	-3	-14	-8	-2	-4	6	0	-44	-44	51	10
Ronapreve	-	-	-	-	-99	-54	-100	-100	-	-100	313	33	-68	-99	-81	-100
Kadcyla	-1	-8	-4	-3	12	3	-2	-6	20	16	2	-8	81	46	-3	42
Xolair	13	8	6	5	-	-	-	-	-	-	-	-	-	-	-	-
Herceptin	-29	-29	-29	-37	-9	-18	-27	-17	-27	-28	-28	-30	-3	-22	-17	-7
MabThera	-24	-14	-15	-21	-16	-18	-21	0	-2	-13	-23	-13	-13	-32	-28	-12
Vabysmo	-	-	-	*	-	-	-	-	-	-	-	-	-	-	-	-
Avastin	-36	-31	-26	-25	-49	-47	-56	-45	-13	-19	-21	-21	-17	-23	-16	-19
Alecensa	14	22	13	7	8	5	3	3	5	4	7	5	29	9	13	14
Evrysdi	28	13	20	13	227	216	116	74	-	776	83	47	-5	231	73	189
TNKase / Activase	1	-6	-29	23	-	-	-	-	-	-	-	-	4	12	20	17
Phesgo	134	62	58	62	188	107	61	59	-	-	-	-	278	20	531	232
Gazyva	3	7	11	32	-8	-9	-8	25	-10	-17	-12	-35	101	91	62	27
Lucentis	-9	-39	-40	-35	-	-	-	-	-	-	-	-	-	-	-	-
Polivy	4	0	13	35	-12	-15	-15	93	-1	-1	3	169	37	30	13	340
Pulmozyme	5	2	-17	-5	-12	-12	-13	-16	44	-1	38	18	14	-16	-9	10

CER=Constant Exchange Rates; * over 500%; [1] Q2-Q4/22 vs Q2-Q4/21; Q1/23 vs Q1/22

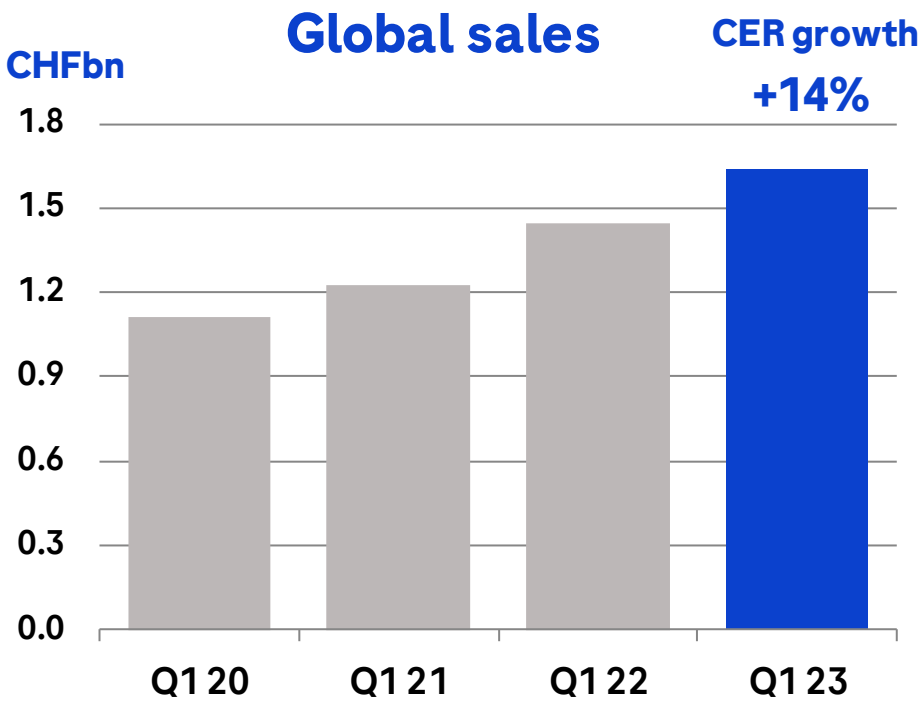
CER sales growth (%)

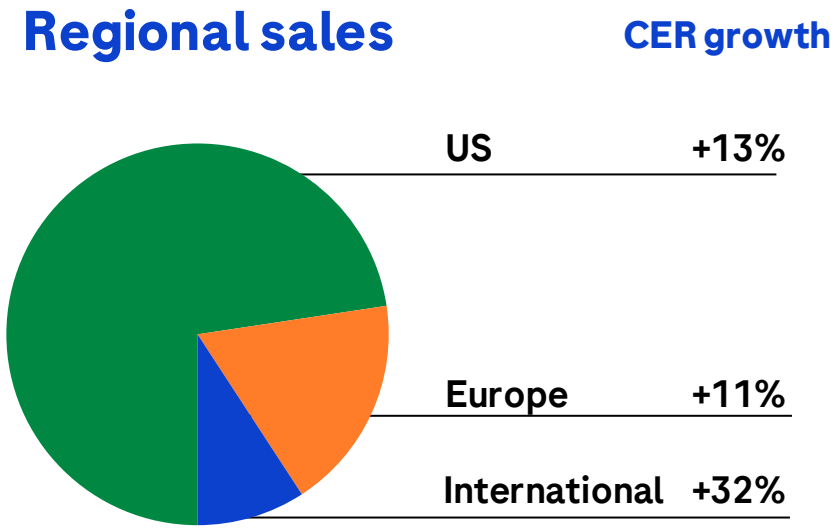
Quarterly development

	2022 vs. 2021				2023 vs. 2022
	Q1	Q2	Q3	Q4	Q1
Pharmaceuticals Division	**6**	**0**	**-6**	**9**	**9**
United States	2	1	-6	1	6
Europe	-1	-6	4	-3	5
Japan	69	3	-27	69	18
International	0	4	-3	4	13
Diagnostics Division	**24**	**0**	**-4**	**-9**	**-28**
Roche Group	**11**	**0**	**-6**	**4**	**-3**

CER=Constant Exchange Rates

Ocrevus



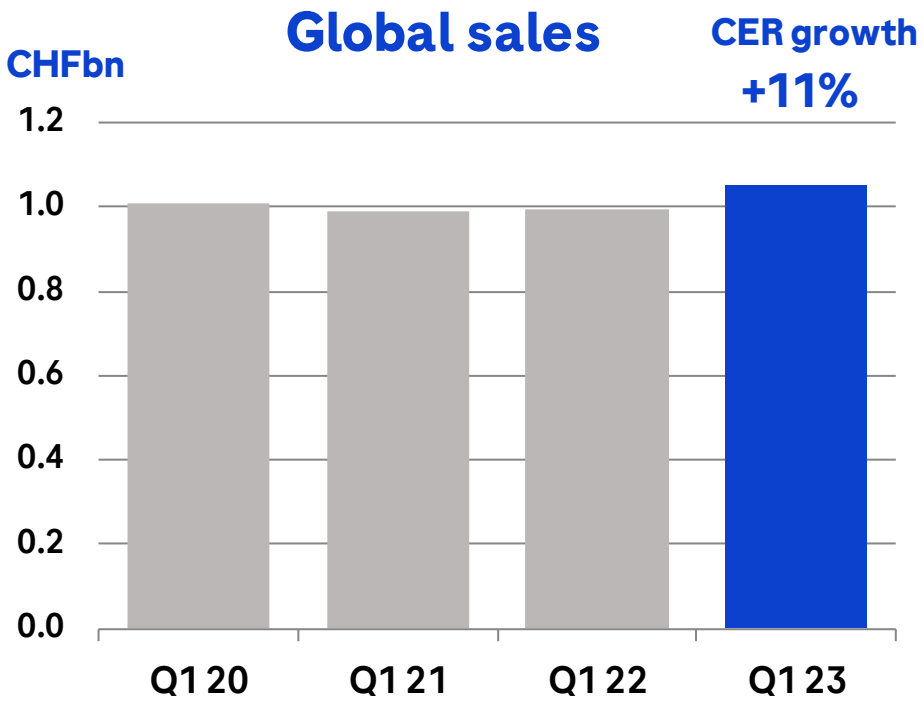


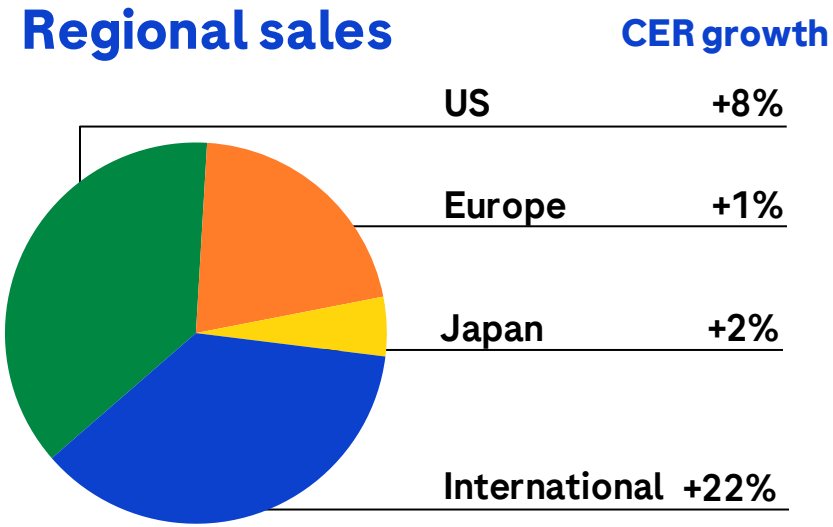
Q1 2023 sales of CHF 1,636m

- US: Moving into earlier lines displacing orals; #1 in US for both total share and NTB
- EU: Moving into earlier lines displacing orals; #1 in EU5 for both total share and NTB

CER=Constant Exchange Rates; NTB=New to brand

Perjeta



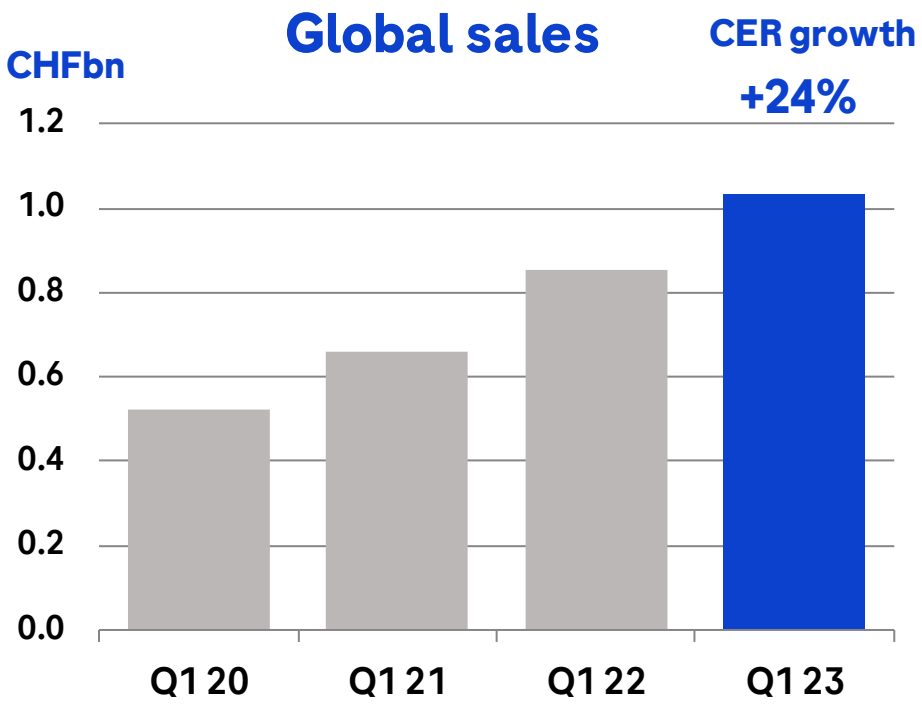


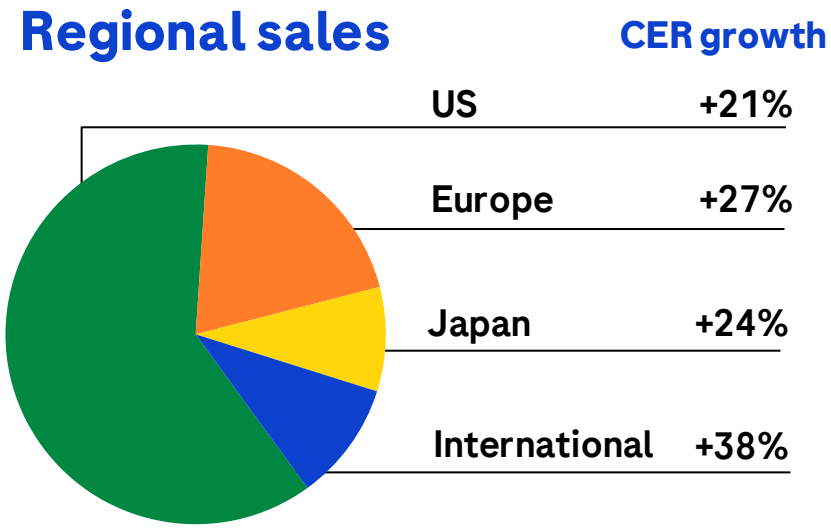
Q1 2023 sales of CHF 1,049m

- US: Growth driven by eBC; increasing cannibalization from Phesgo
- EU: Cannibalization from Phesgo
- International: Accelerated growth in all regions (LATAM, APAC, EEMEA)

CER=Constant Exchange Rates

Hemlibra



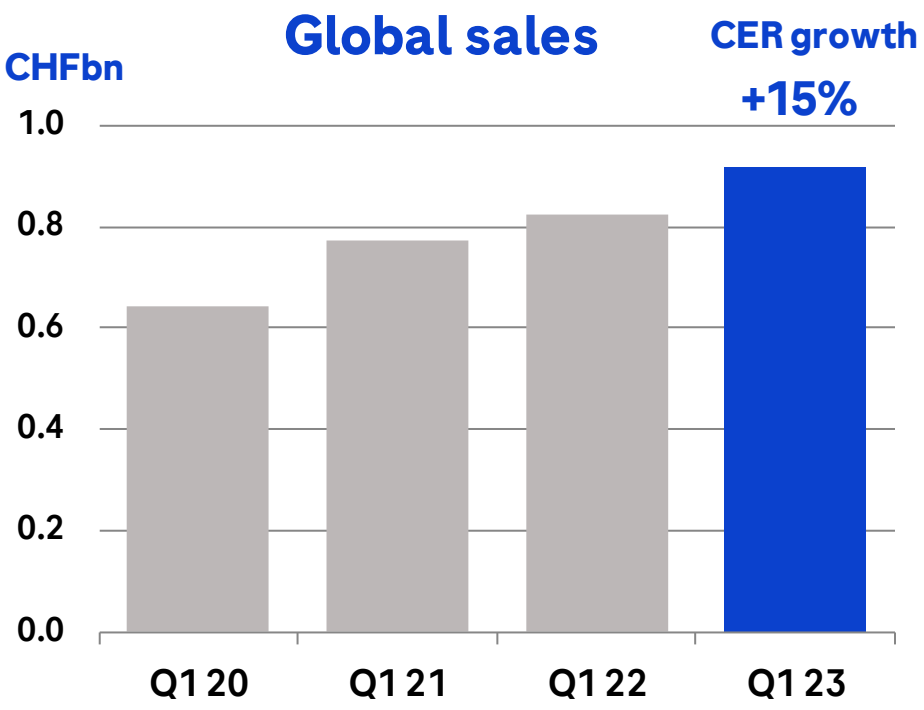


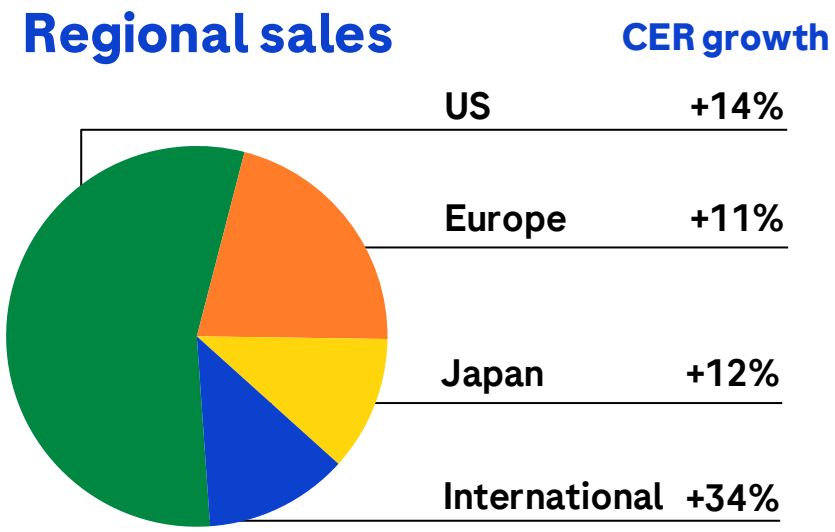
Q1 2023 sales of CHF 1,034m

- 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; SoC=Standard of care

Tecentriq



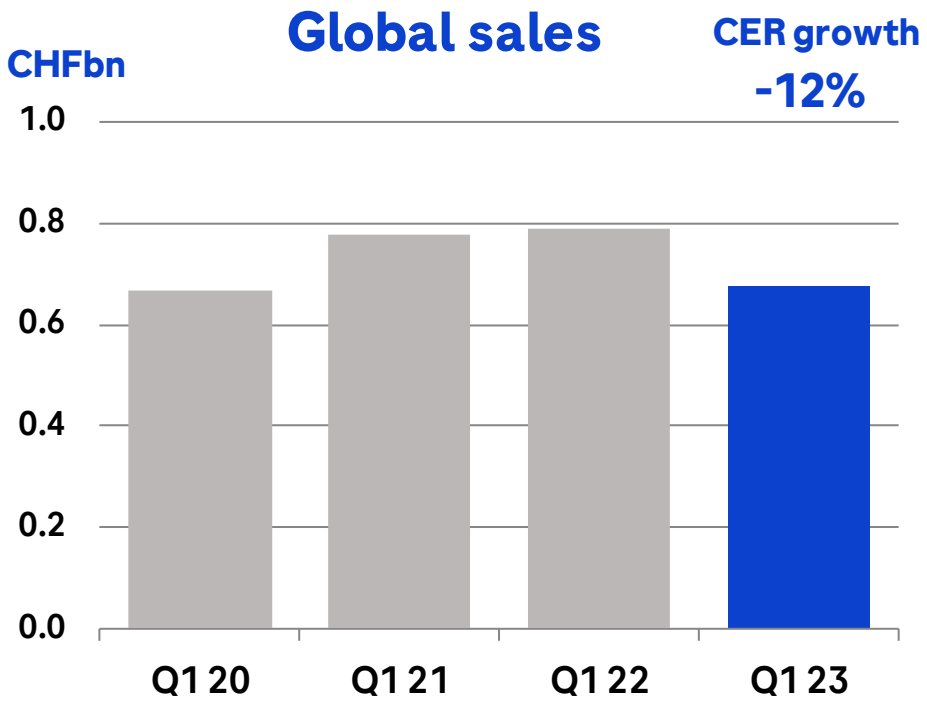


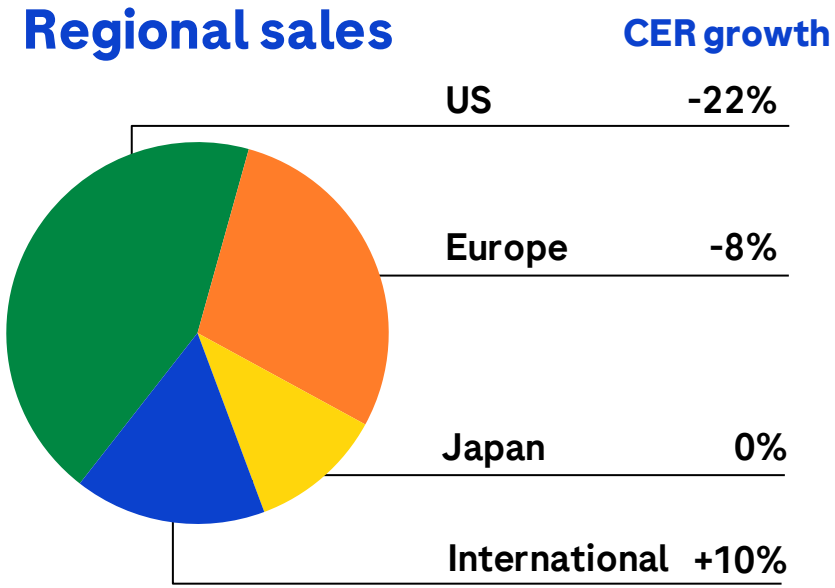
Q1 2023 sales of CHF 920m

- US: Growth driven by SCLC and adj NSCLC, continued growth in 1L HCC
- EU: Strong adj NSCLC launch, further growth in 1L HCC
- Japan: Growing share in adj NSCLC

CER=Constant Exchange Rates; HCC=Hepatocellular carcinoma; NSCLC=Non-small cell lung cancer; SCLC=Small cell lung cancer

Actemra / RoActemra



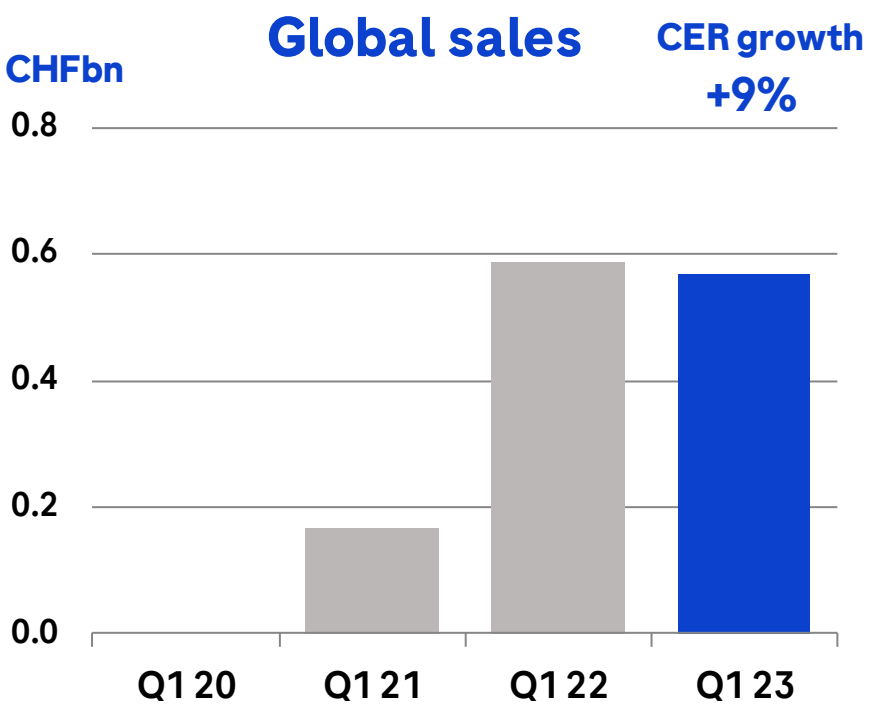


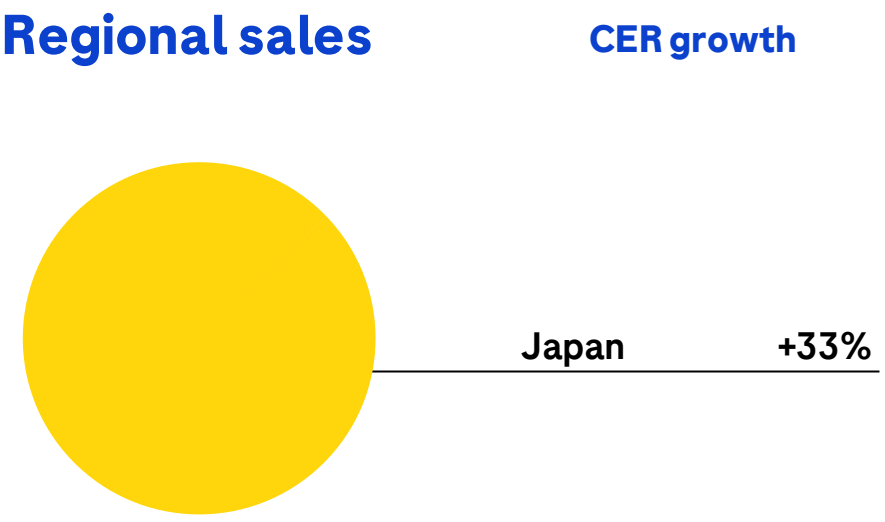
Q1 2023 sales of CHF 676m

- US: Ongoing patient shift from Actemra IV to SC in RA; continued COVID-19 washout
- EU: Stable share of Actemra SC in RA; continued COVID-19 washout
- International: Significant uplift from COVID-related sales in China

CER=Constant Exchange Rates; RA=Rheumatoid arthritis

Ronapreve



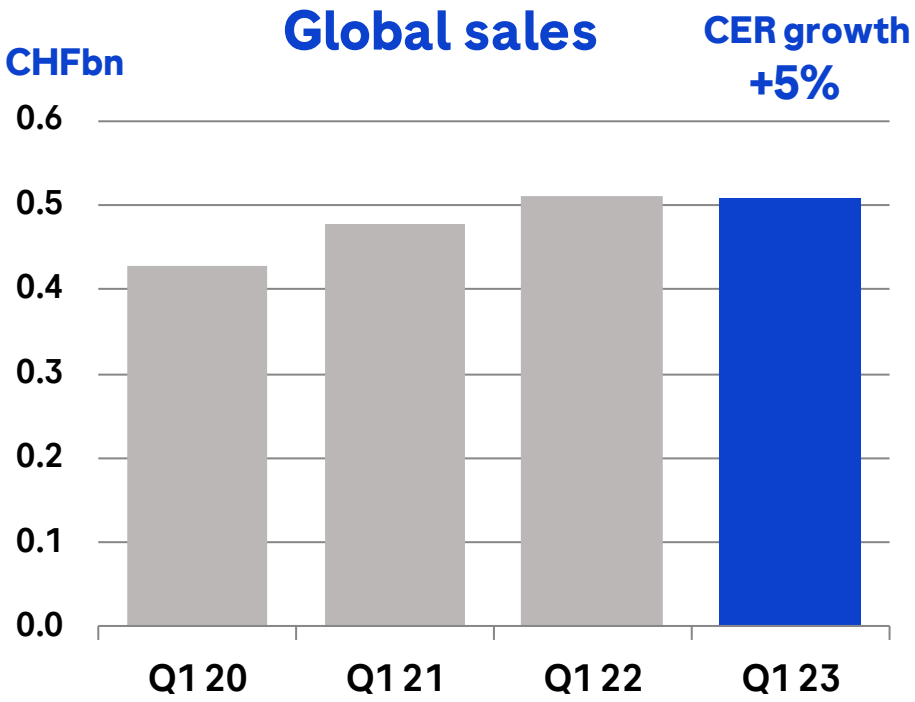


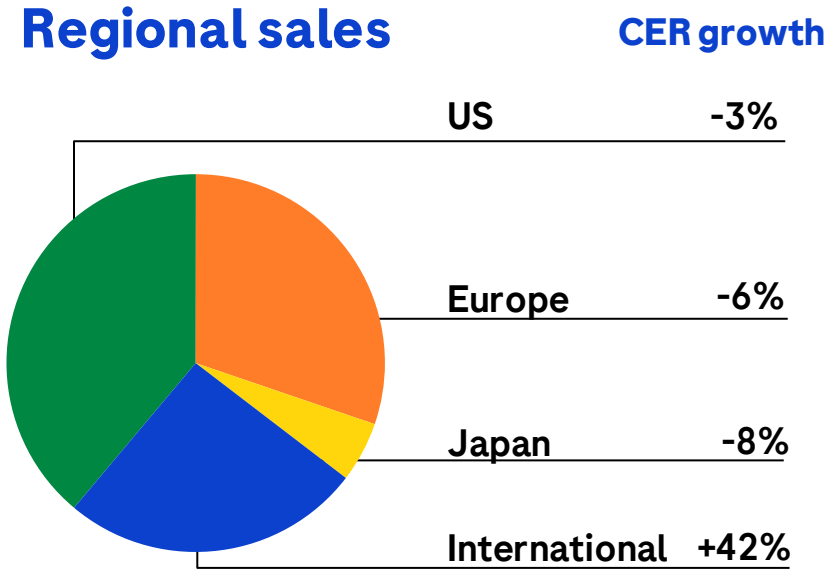
Q1 2023 sales of CHF 567m

- Japan: Final sales from governmental order booked in Q1
- No sales outside of Japan

CER=Constant Exchange Rates

Kadcyla



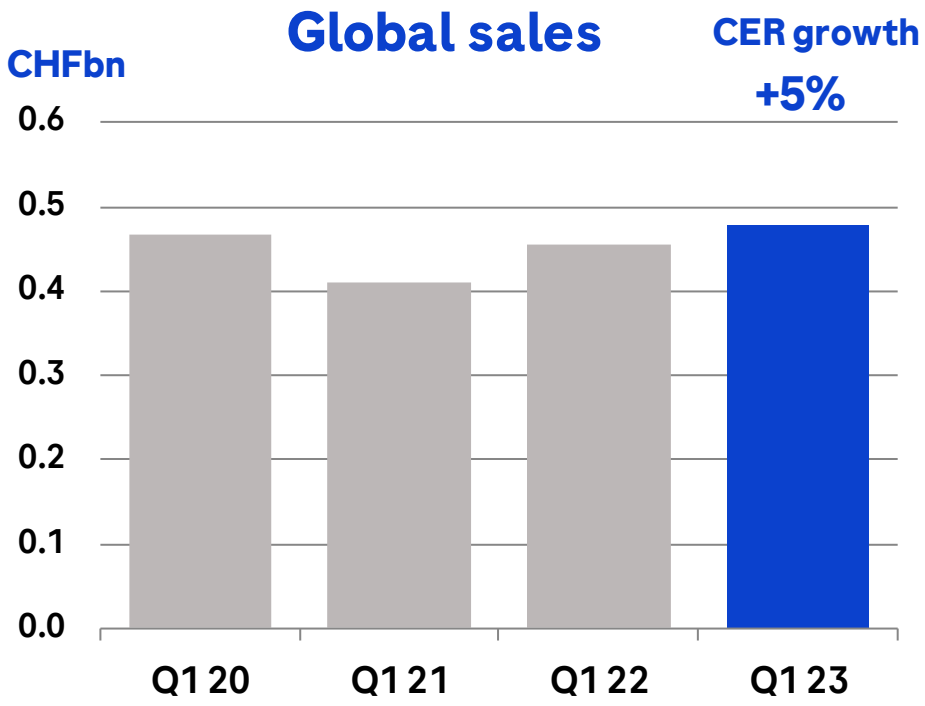


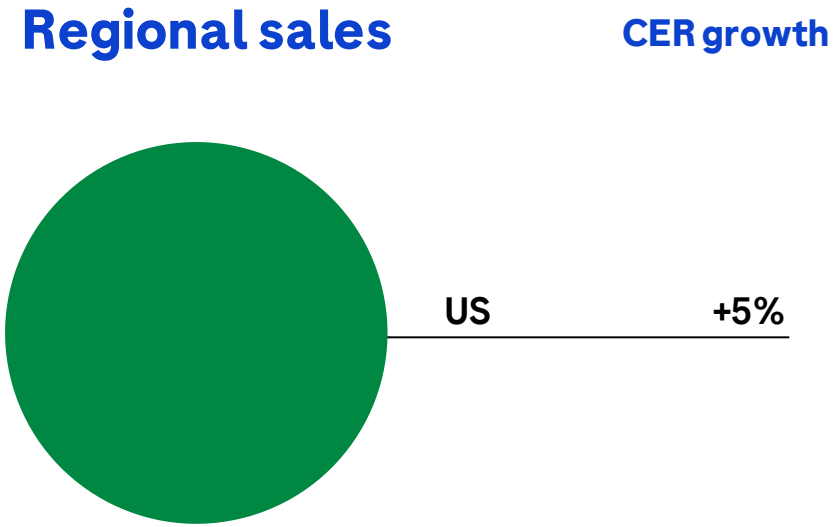
Q1 2023 sales of CHF 509m

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

CER=Constant Exchange Rates; mBC=metastatic breast cancer; eBC=early breast cancer

Xolair



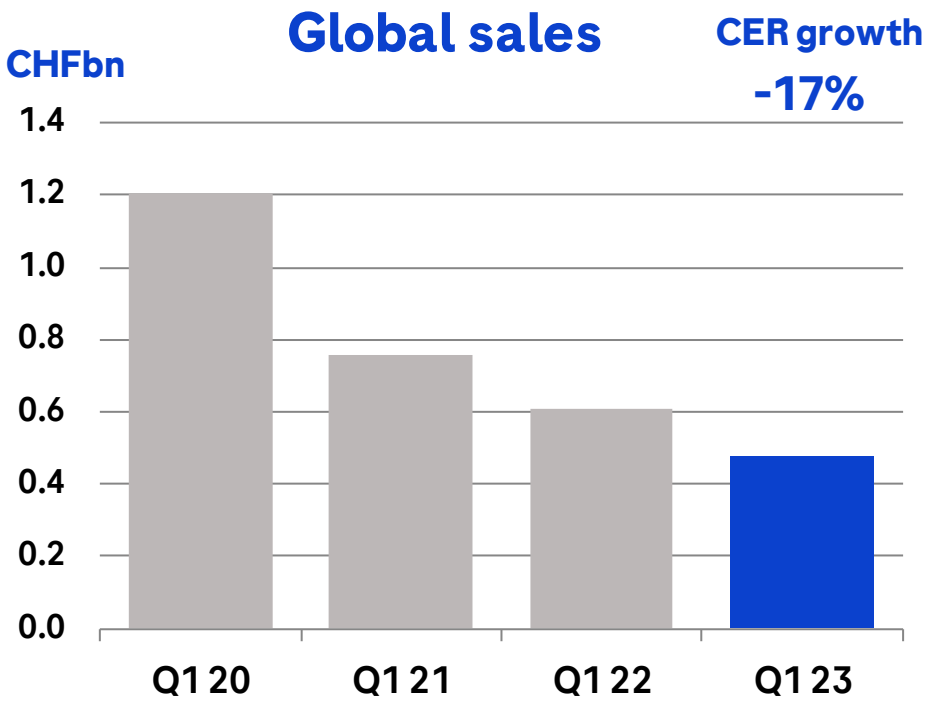


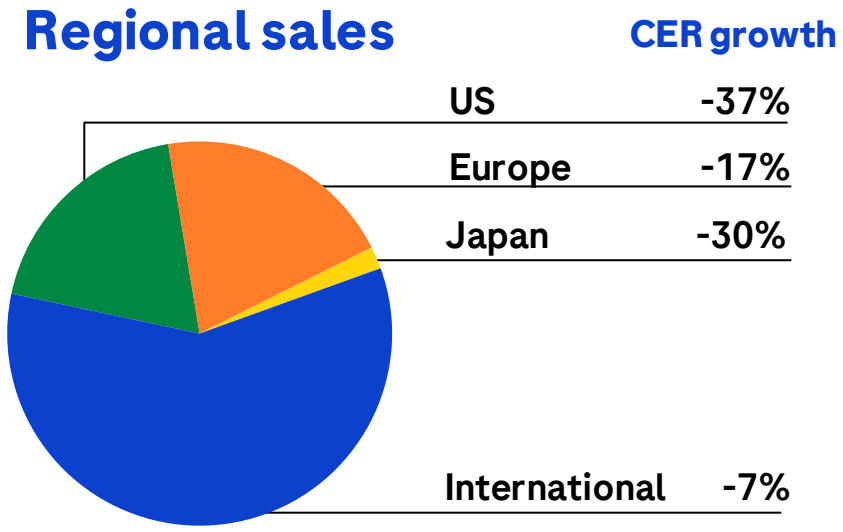
Q1 2023 sales of CHF 479m

- US: Growth driven by growth in CSU

CER=Constant Exchange Rates; CSU=Chronic spontaneous urticaria

Herceptin



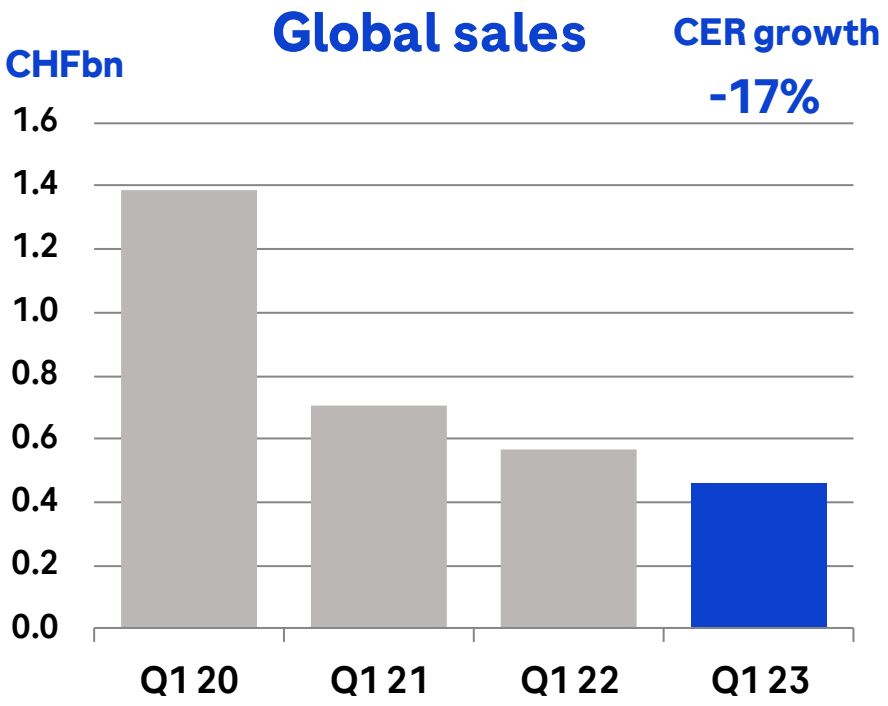


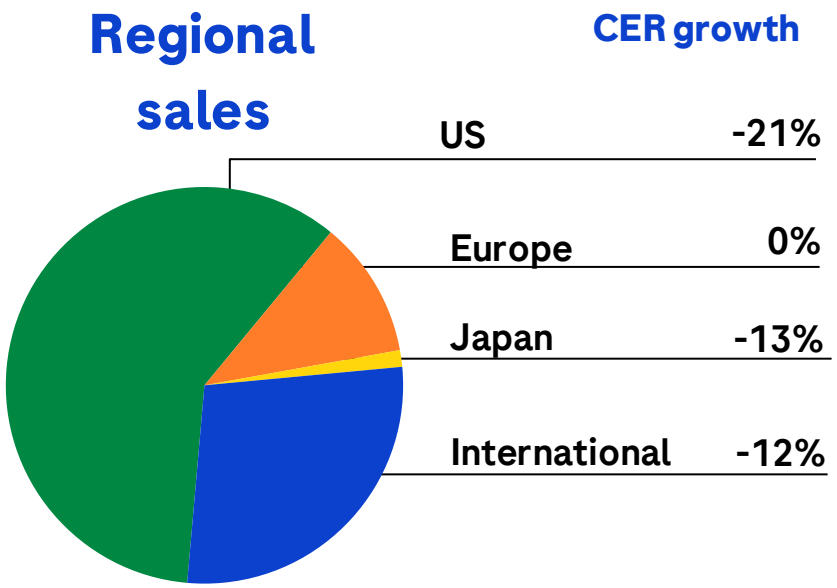
Q1 2023 sales of CHF 477m

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

CER=Constant Exchange Rates

Rituxan / Mabthera



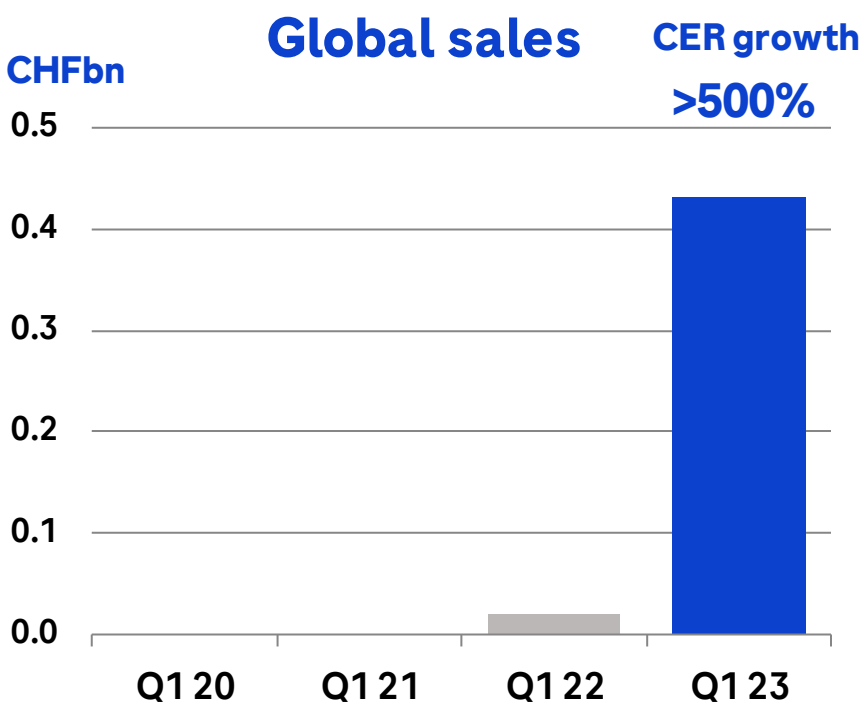


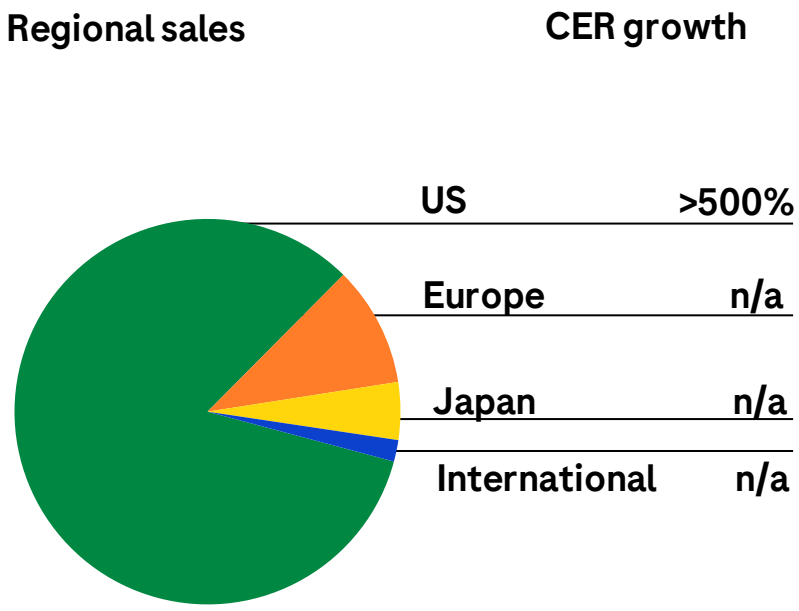
Q1 2023 sales of CHF 459m

- US: Biosimilar erosion slowing
- EU: Biosimilar erosion slowing
- Japan: Biosimilar erosion slowing
- International: Biosimilar erosion slowing

CER=Constant Exchange Rates; SC=Subcutaneous

Vabysmo



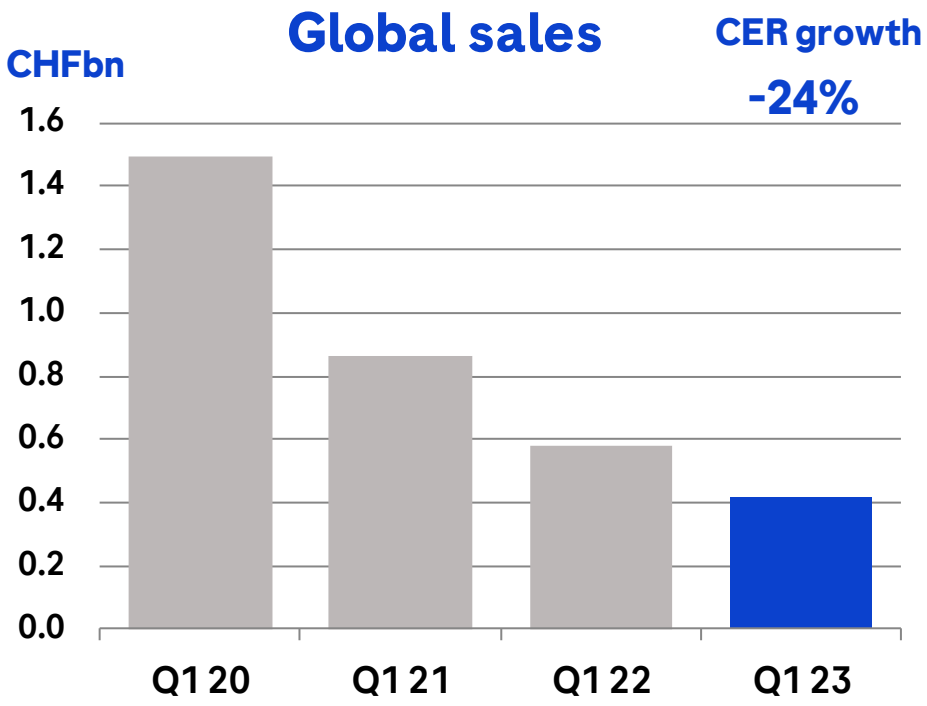


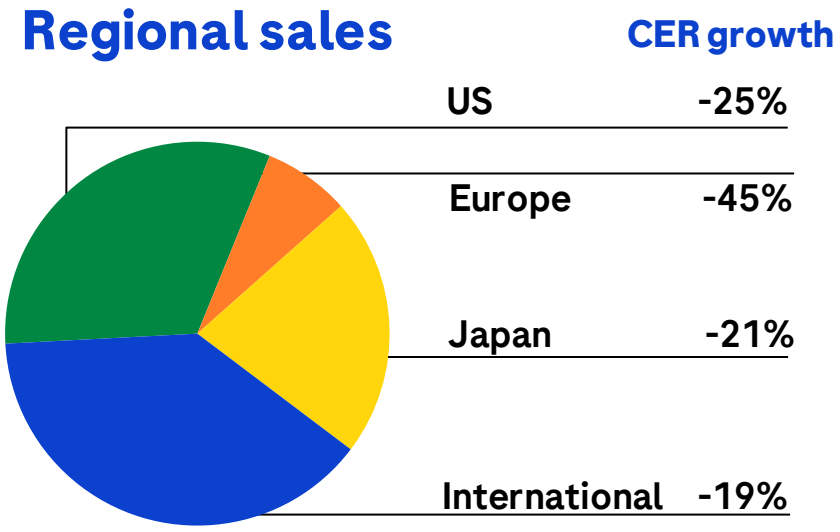
Q1 2023 sales of CHF 432m

- US: Strong uptake with switches primarily from aflibercept; use in naive patients further accelerating
- EU: Strong uptake in first launch countries
- Japan: Strong uptake with switches primarily from aflibercept; use in naive patients further accelerating

CER=Constant Exchange Rates

Avastin



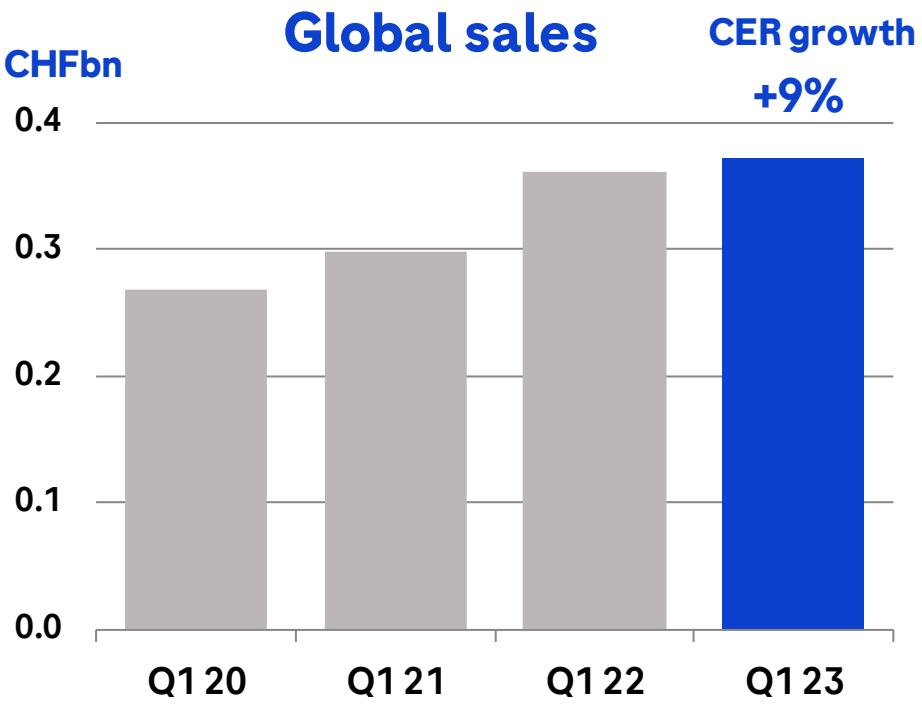


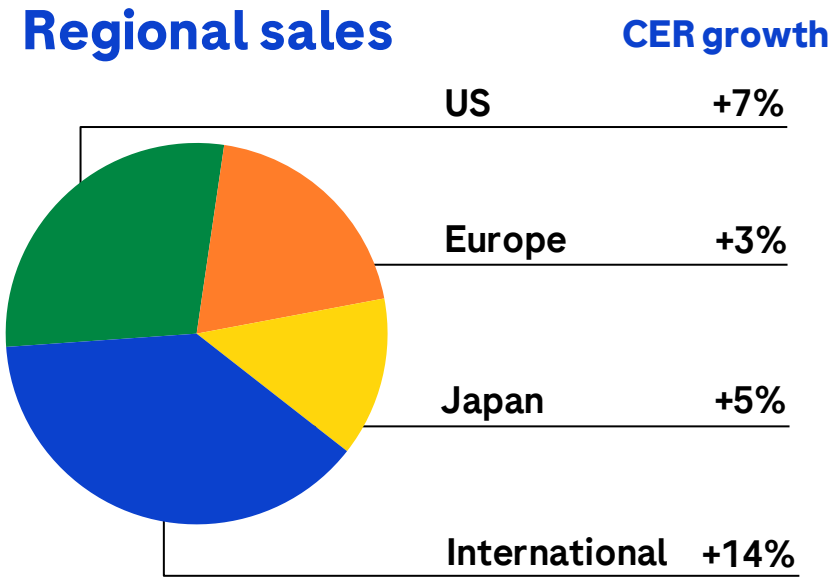
Q1 2023 sales of CHF 416m

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

CER=Constant Exchange Rates

Alecensa



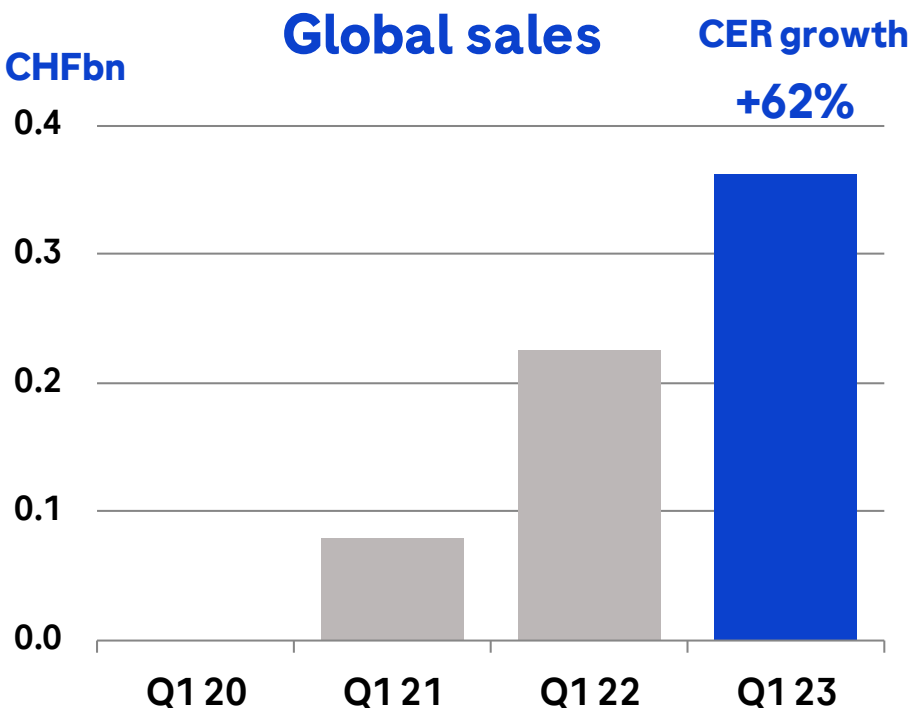


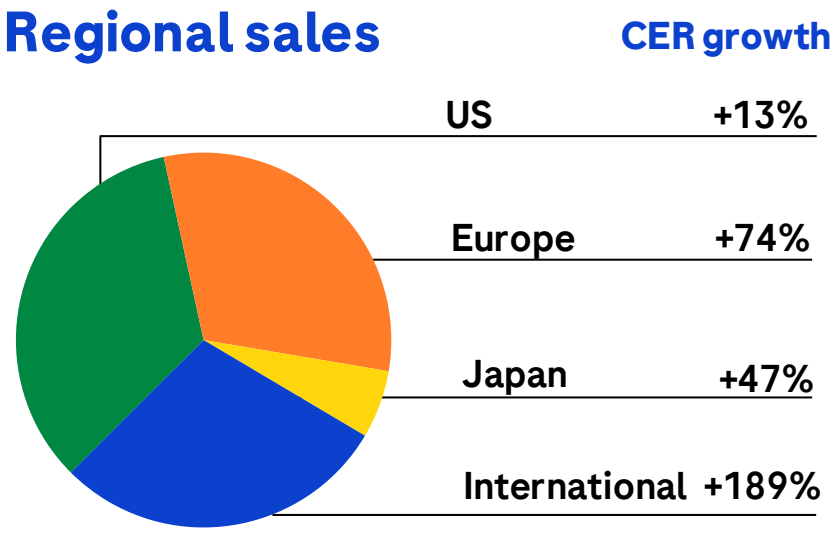
Q1 2023 sales of CHF 372m

- 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; NSCLC=Non-small cell lung cancer

Evrysdi



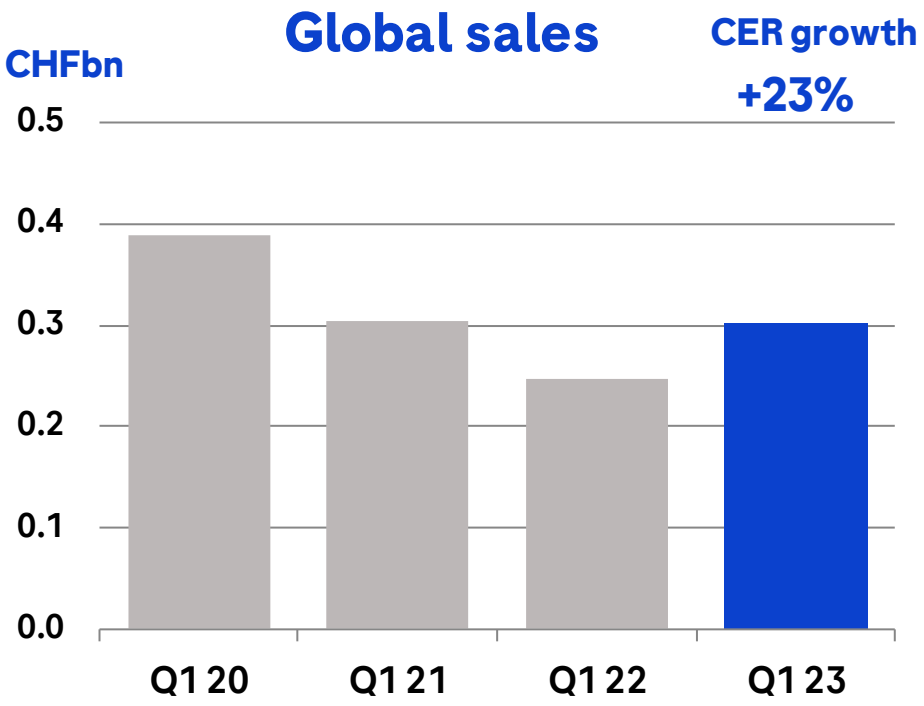


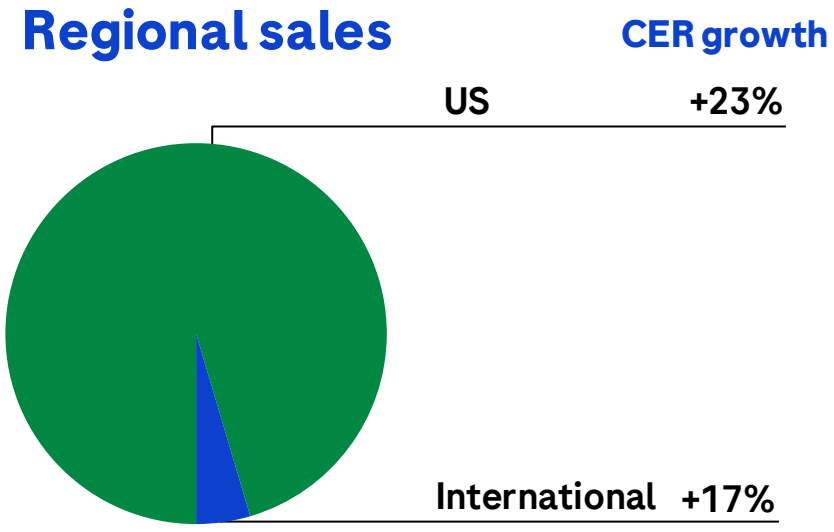
Q1 2023 sales of CHF 363m

- US: Strong uptake across all patient segments; including treatment-naive 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

CER=Constant Exchange Rates

TNKase / Activase



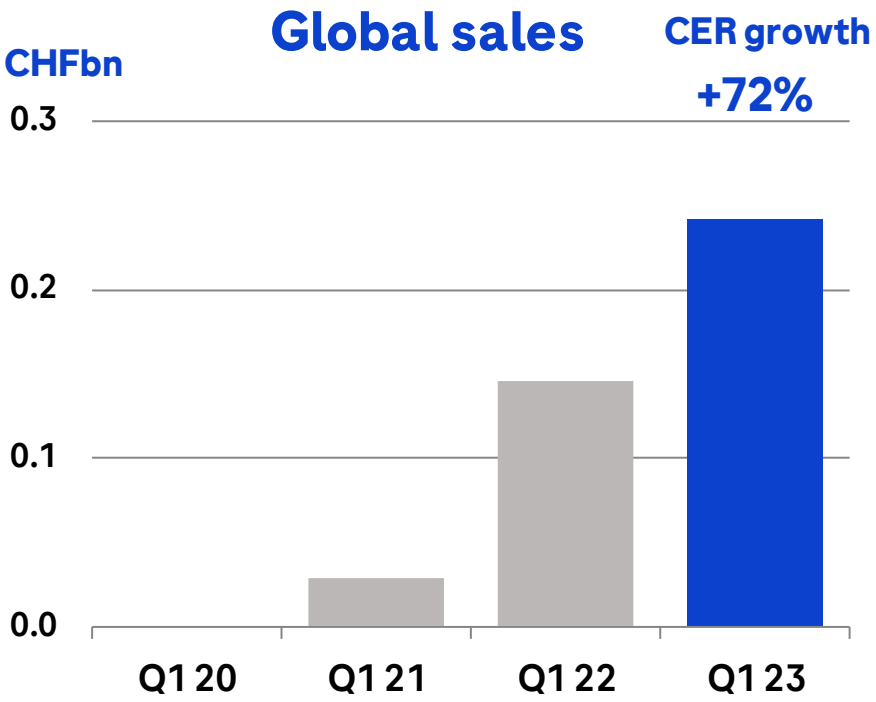


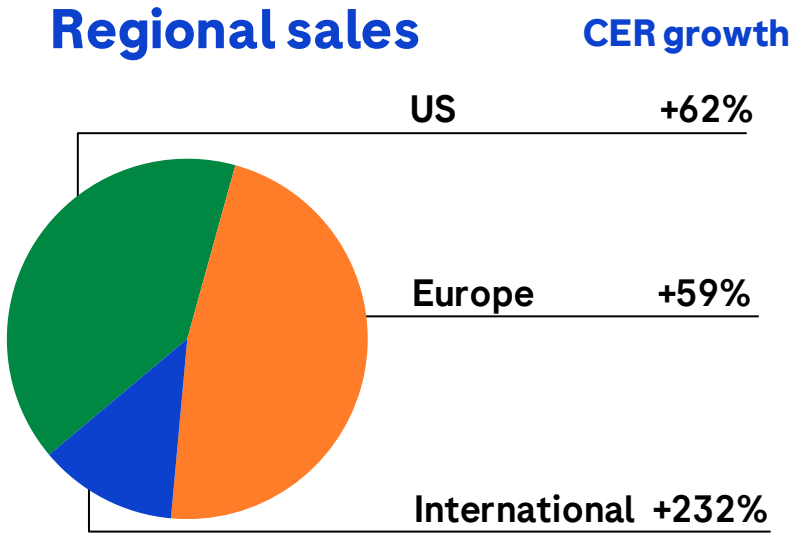
Q1 2023 sales of CHF 302m

- Topline data from Ph III (TIMELESS) trial expected in May 2023

CER=Constant Exchange Rates

Phesgo



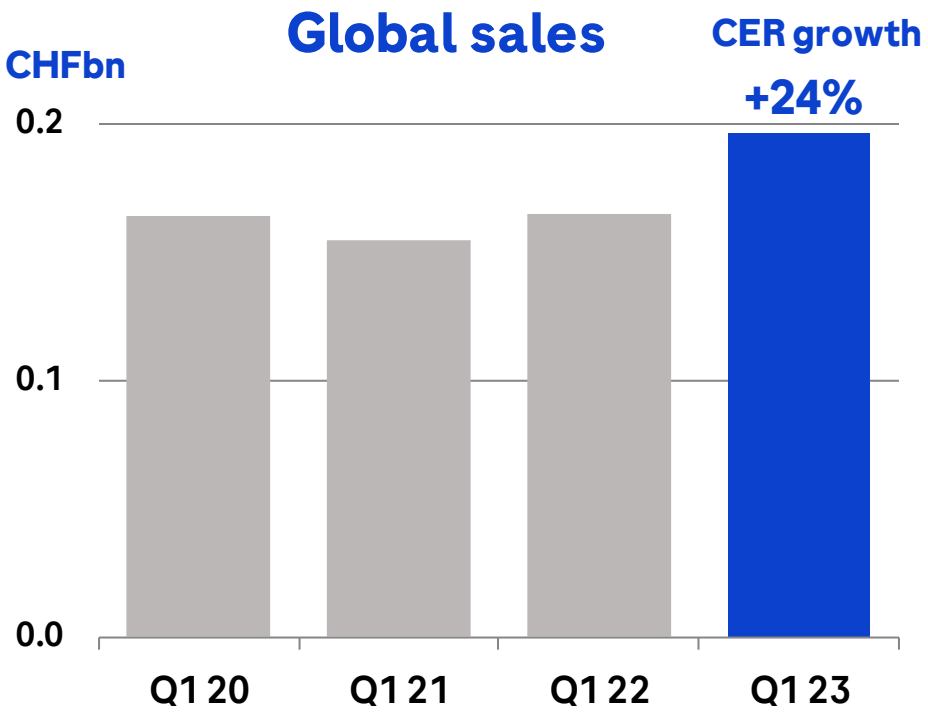


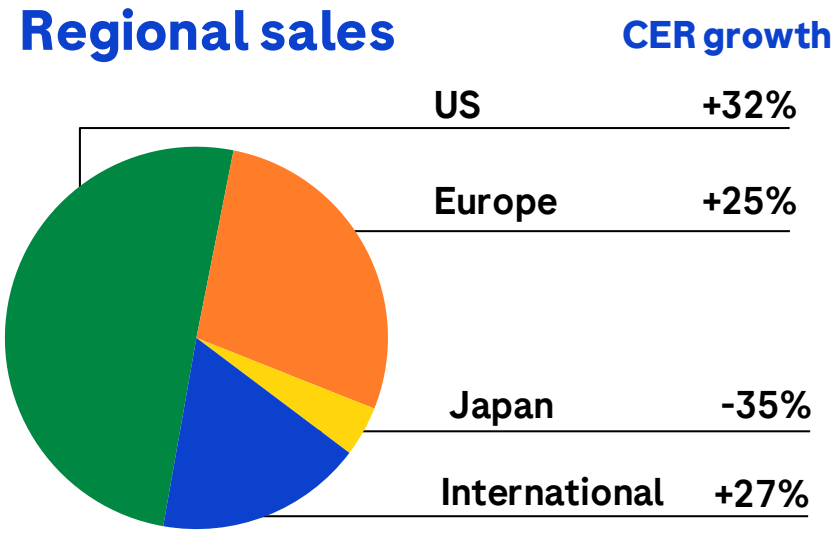
Q1 2023 sales of CHF 241m

- 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

CER=Constant Exchange Rates; eBC=early breast cancer

Gazyva





Q1 2023 sales of CHF 197m

- US: Very strong growth driven by 1L FL and 1L CLL (in combination with Venclexta)
- EU: Very strong growth driven by 1L FL and 1L CLL (in combination with Venclexta)
- International: Continued growth in all key markets

CER=Constant Exchange Rates; FL=Follicular lymphoma; CLL=Chronic lymphocytic leukemia

Roche

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

Q1 2023: Diagnostics Division CER growth

By Region and Customer Area (vs. 2022)

	Global		EMEA[1]		North America		Asia-Pacific		Latin America	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Core Lab	1,928	7	669	4	337	-3	774	13	148	15
Molecular Lab	593	-48	198	-54	256	-36	120	-55	19	-48
Point of Care	397	-72	102	-76	203	-72	79	-64	13	-74
Diabetes Care	376	-5	202	-11	55	-4	63	-4	56	21
Pathology Lab	329	7	82	12	178	6	62	0	7	35
Diagnostics Division	**3,623**	**-28**	**1,253**	**-30**	**1,029**	**-39**	**1,098**	**-15**	**243**	**-8**

CER=Constant Exchange Rates; [1] Europe, Middle East and Africa

Diagnostics Division quarterly sales and CER growth[1]

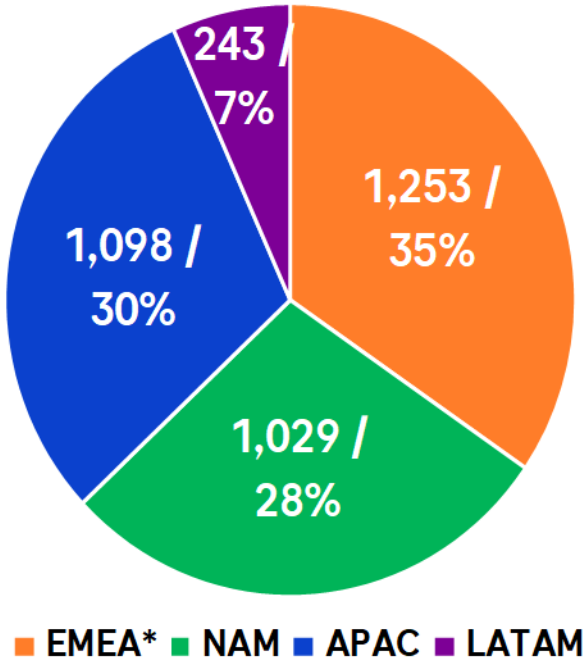
	Q1 22		Q2 22		Q3 22		Q4 22		Q1 23	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Core Lab	1,896	8	1,979	1	1,958	7	1,942	9	1,928	7
Molecular Lab	1,189	21	791	-20	755	-24	715	-35	593	-48
Point of Care	1,466	84	1,143	15	477	-16	503	-26	397	-72
Diabetes Care	417	-7	415	-3	387	2	379	1	376	-5
Pathology Lab	318	14	334	7	323	10	343	12	329	7
Diagnostics Division	**5,286**	**24**	**4,662**	**0**	**3,900**	**-4**	**3,882**	**-9**	**3,623**	**-28**

CER=Constant Exchange Rates; [1] versus same period of prior year

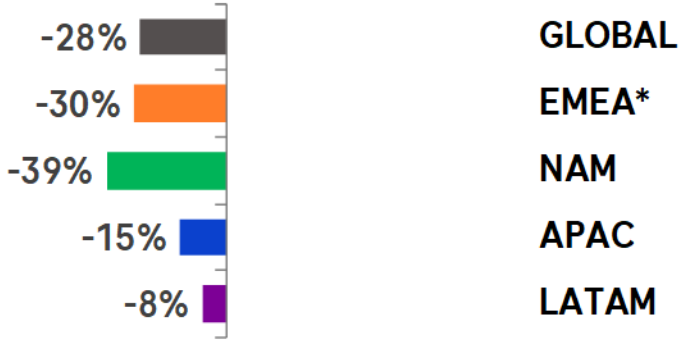
Q1 2023: Diagnostics Division regional sales

Decline in all regions

Sales YTD CHFm & % of total sales
Total YTD Sales = 3,623

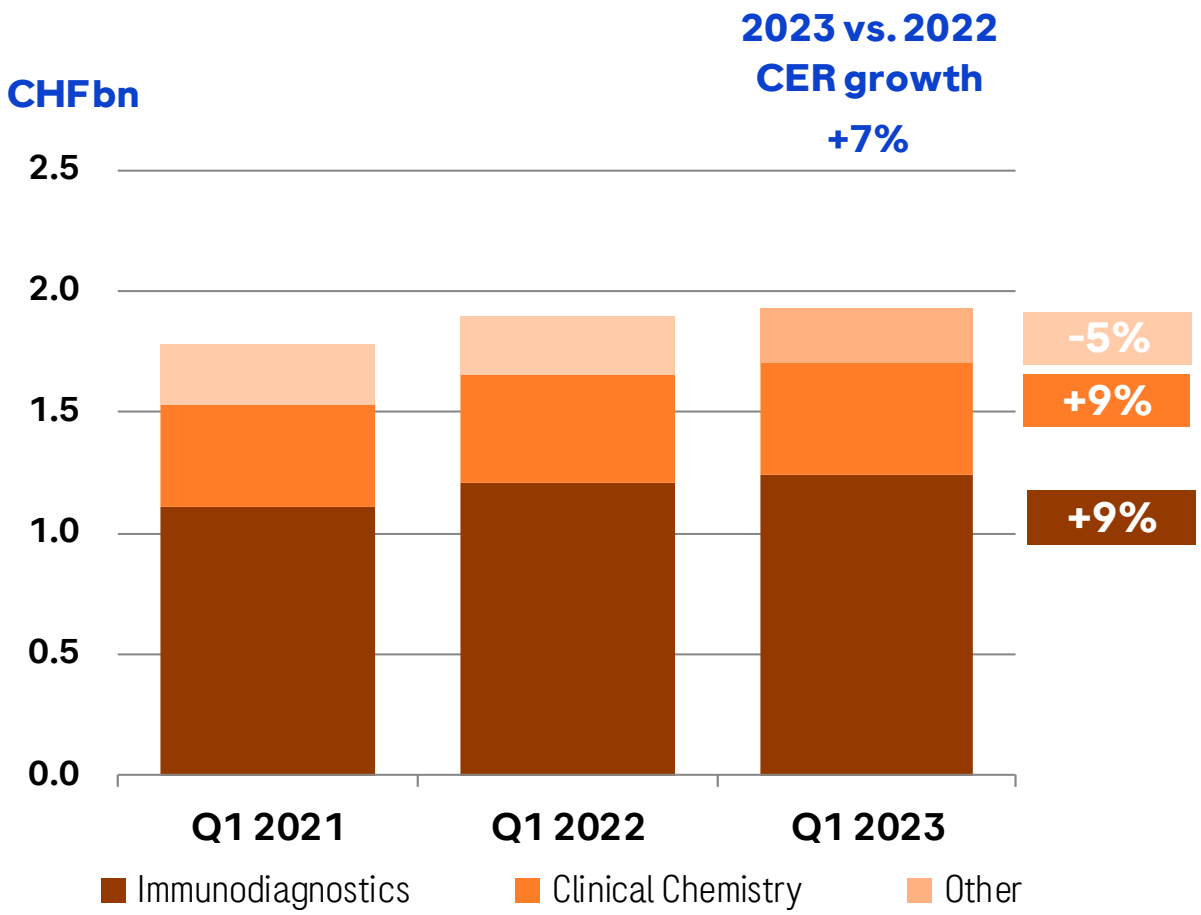


Sales growth at CER
Diagnostics Division



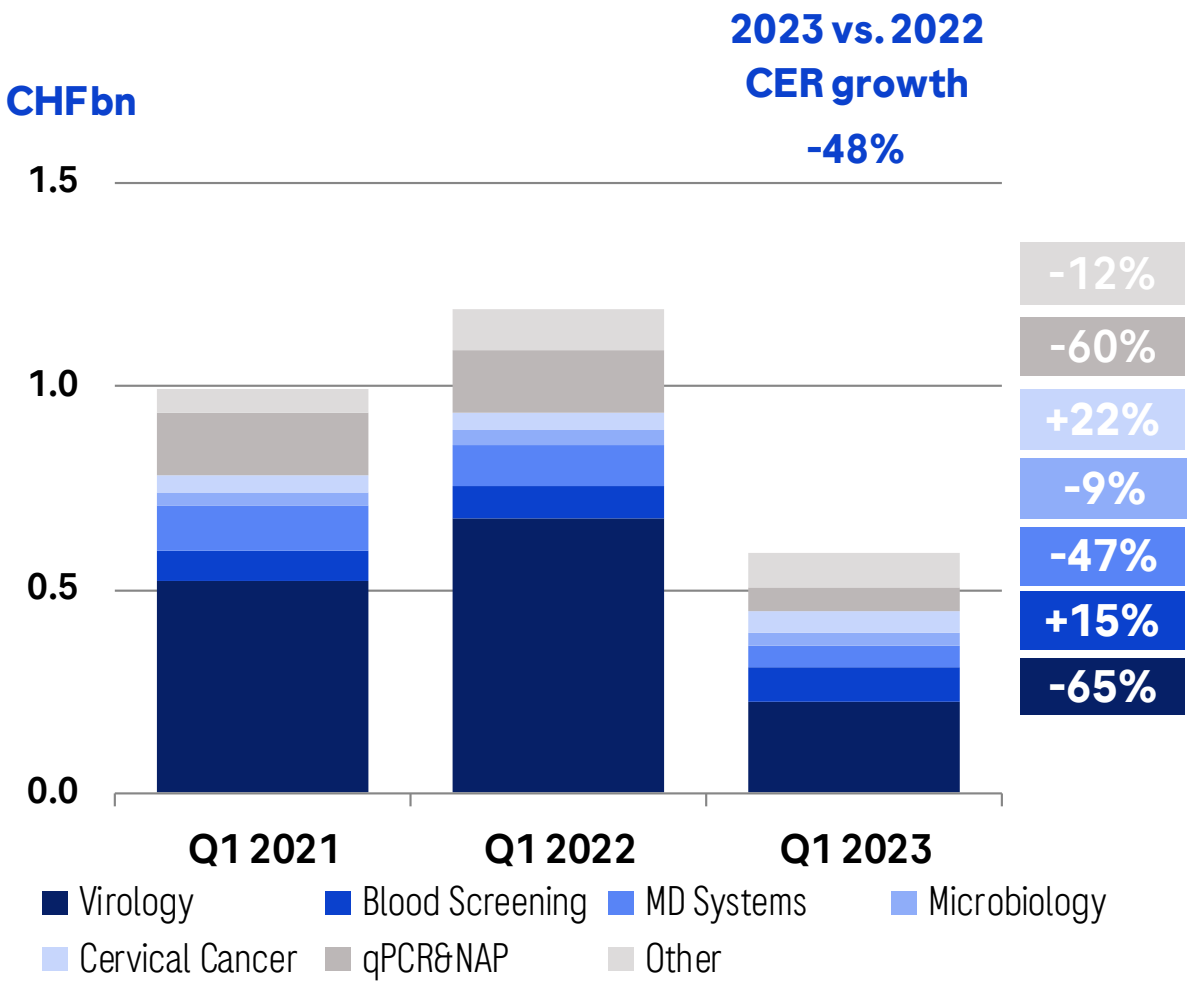
CER=Constant Exchange Rates; * Europe, Middle East and Africa

Core Lab



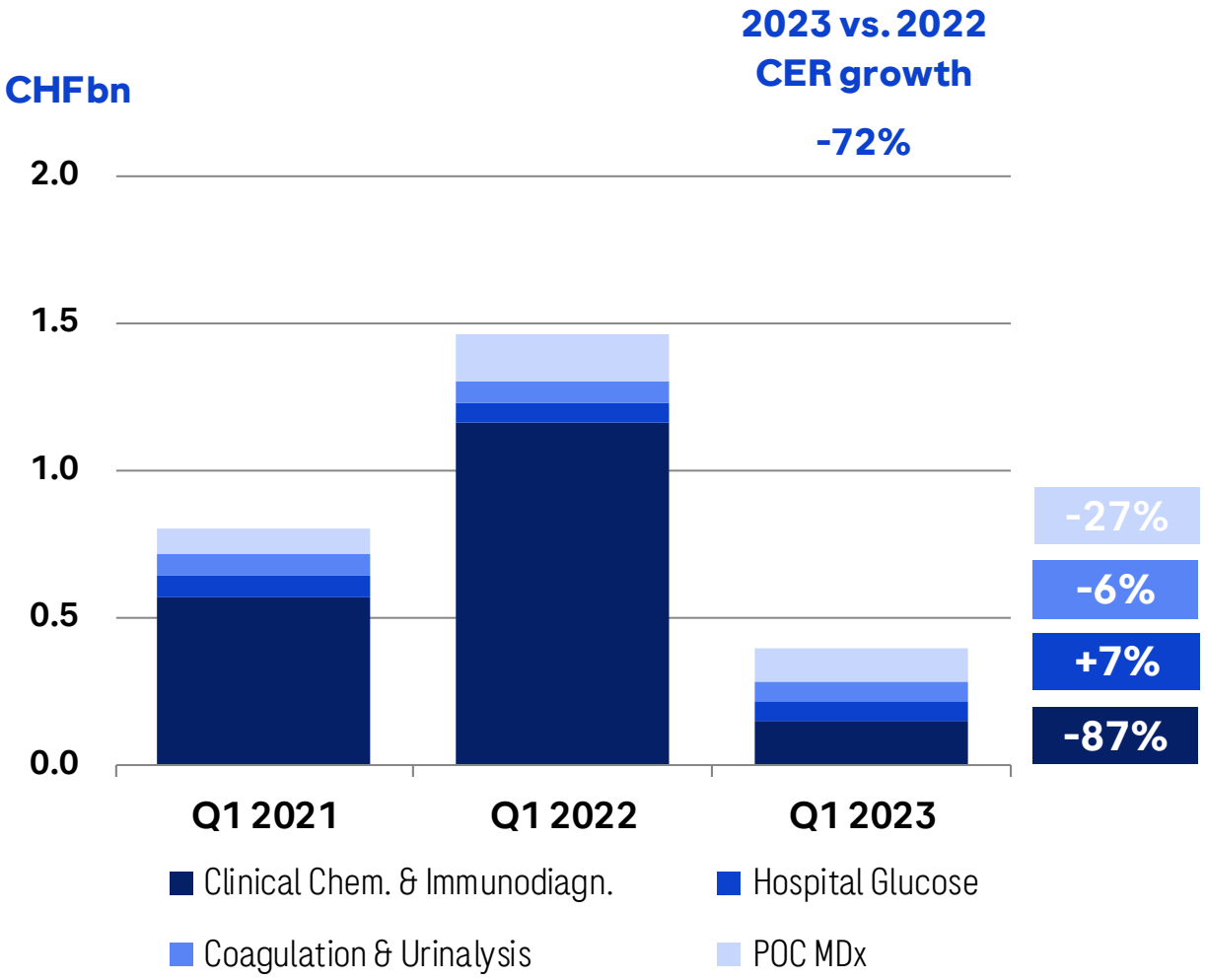
CER=Constant Exchange Rates

Molecular Lab



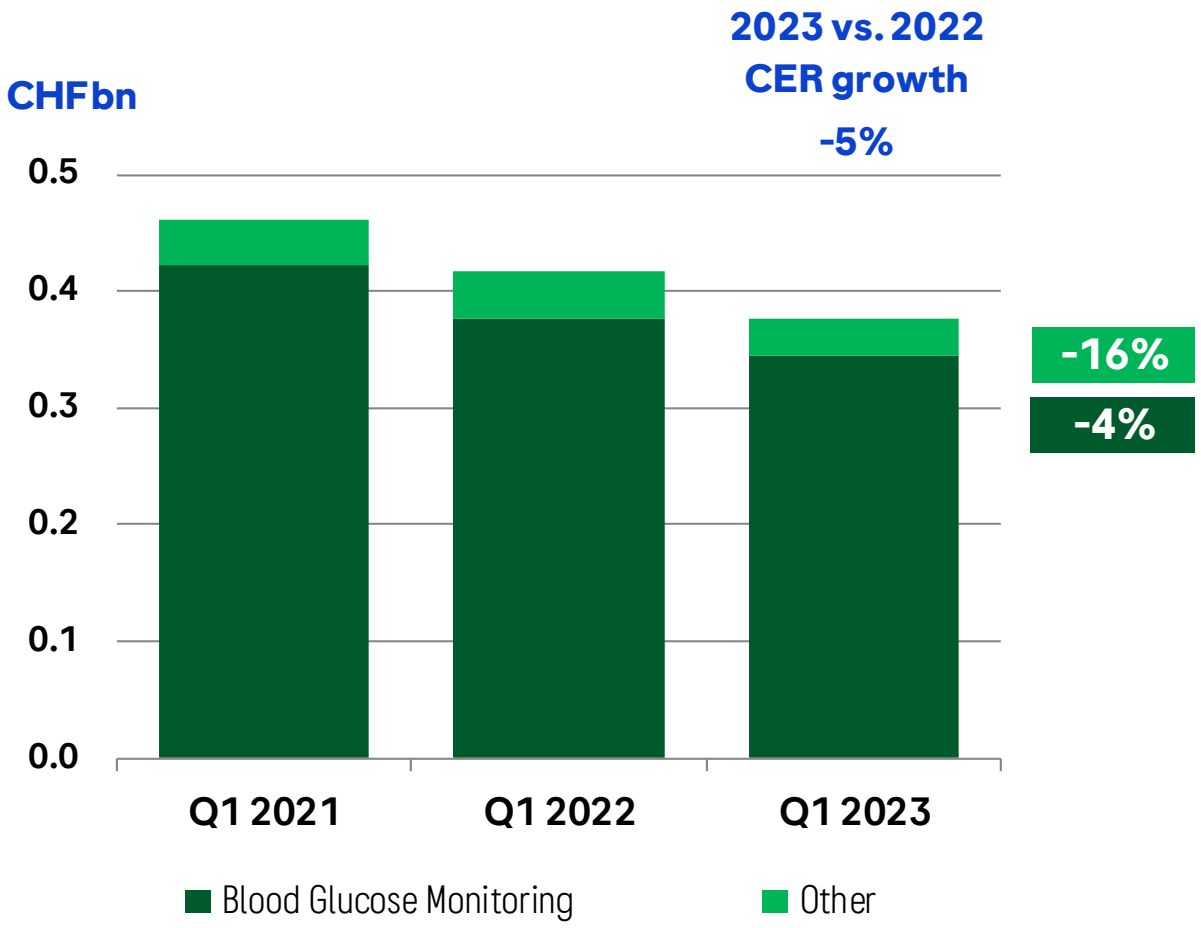
CER=Constant Exchange Rates

Point of Care



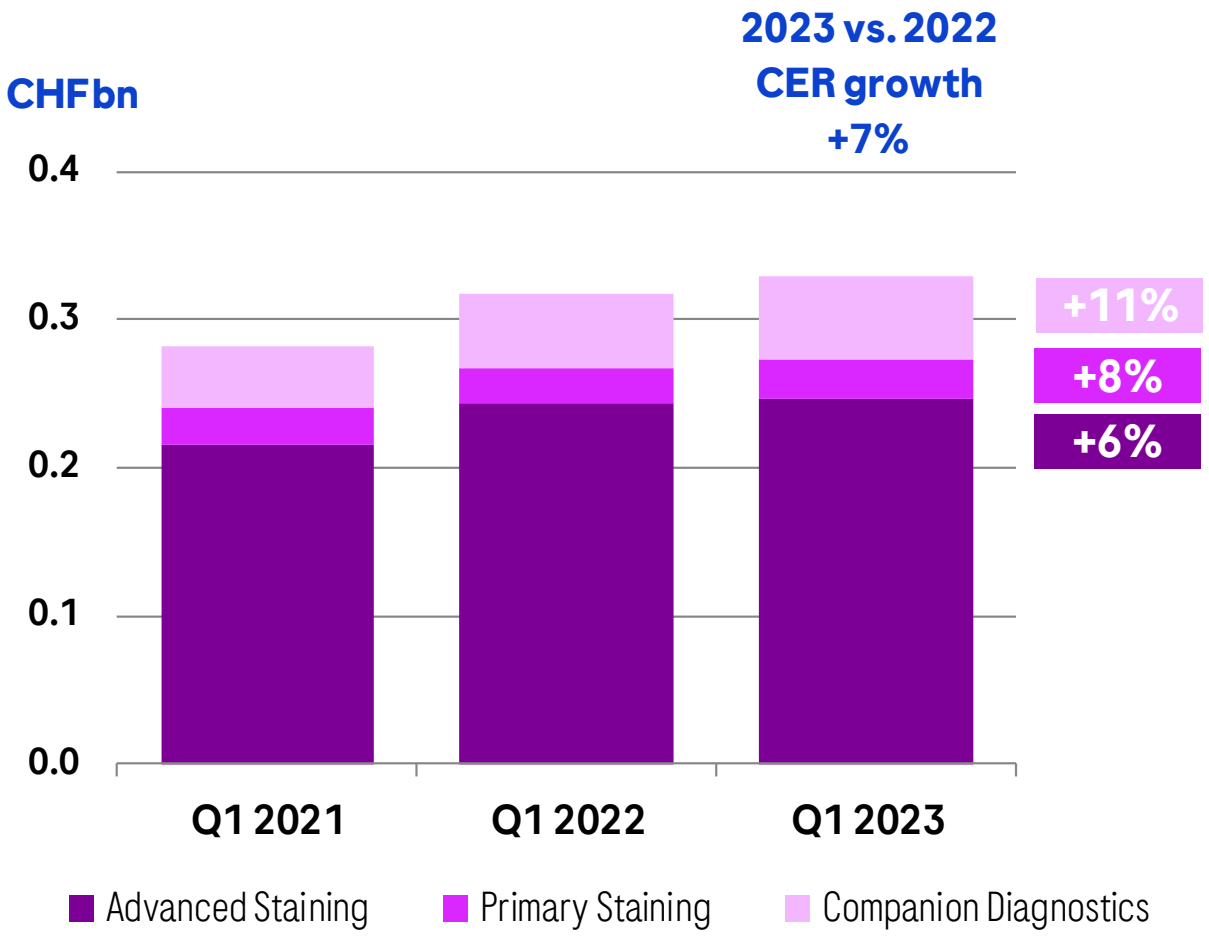
CER=Constant Exchange Rates

Diabetes Care



CER=Constant Exchange Rates

Pathology Lab



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)

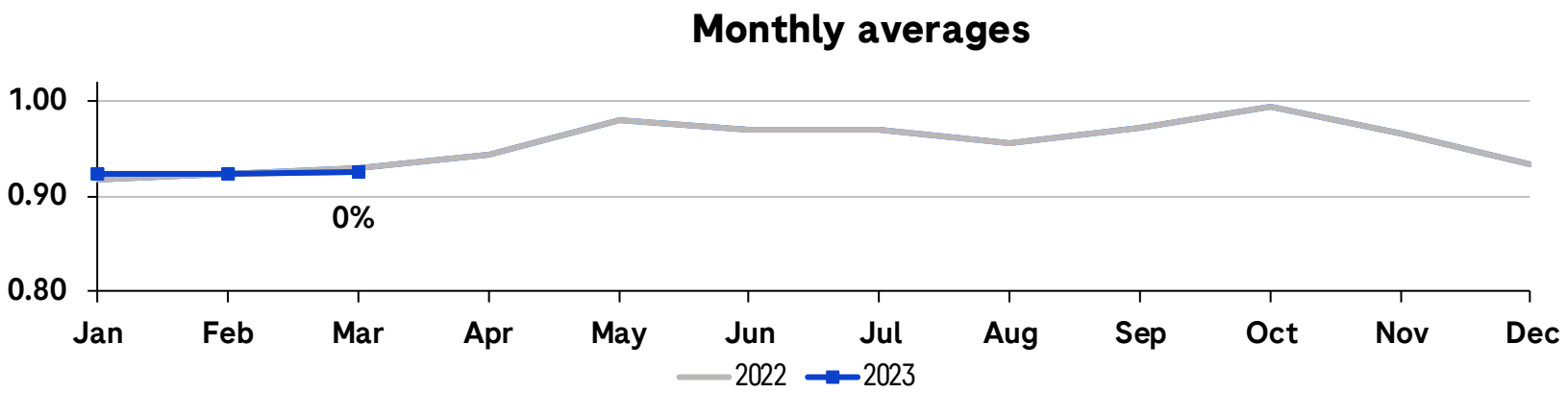
Spark

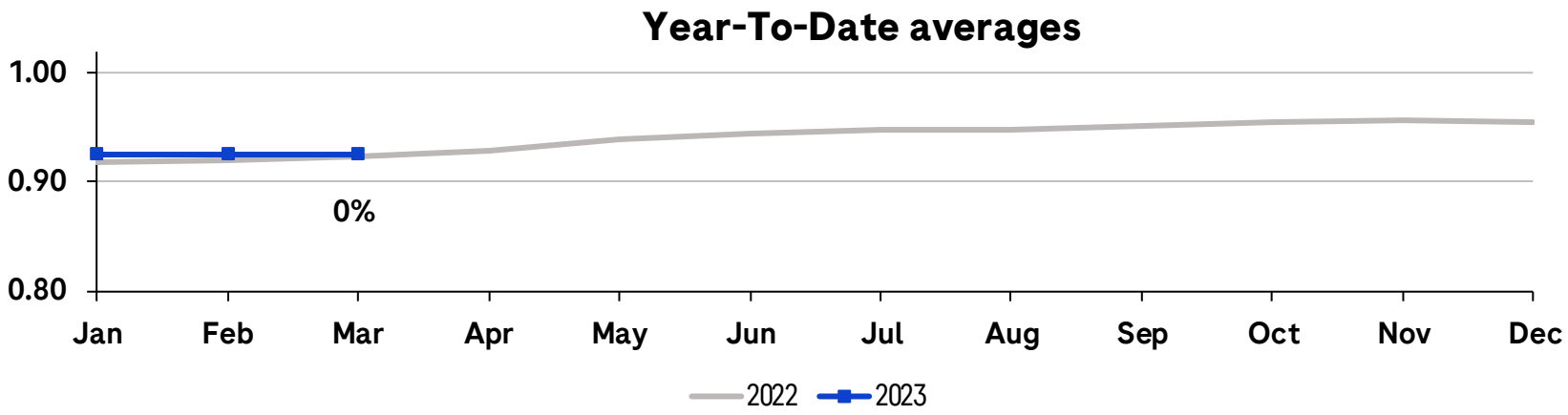
Pharma sales appendix

Diagnostics sales appendix

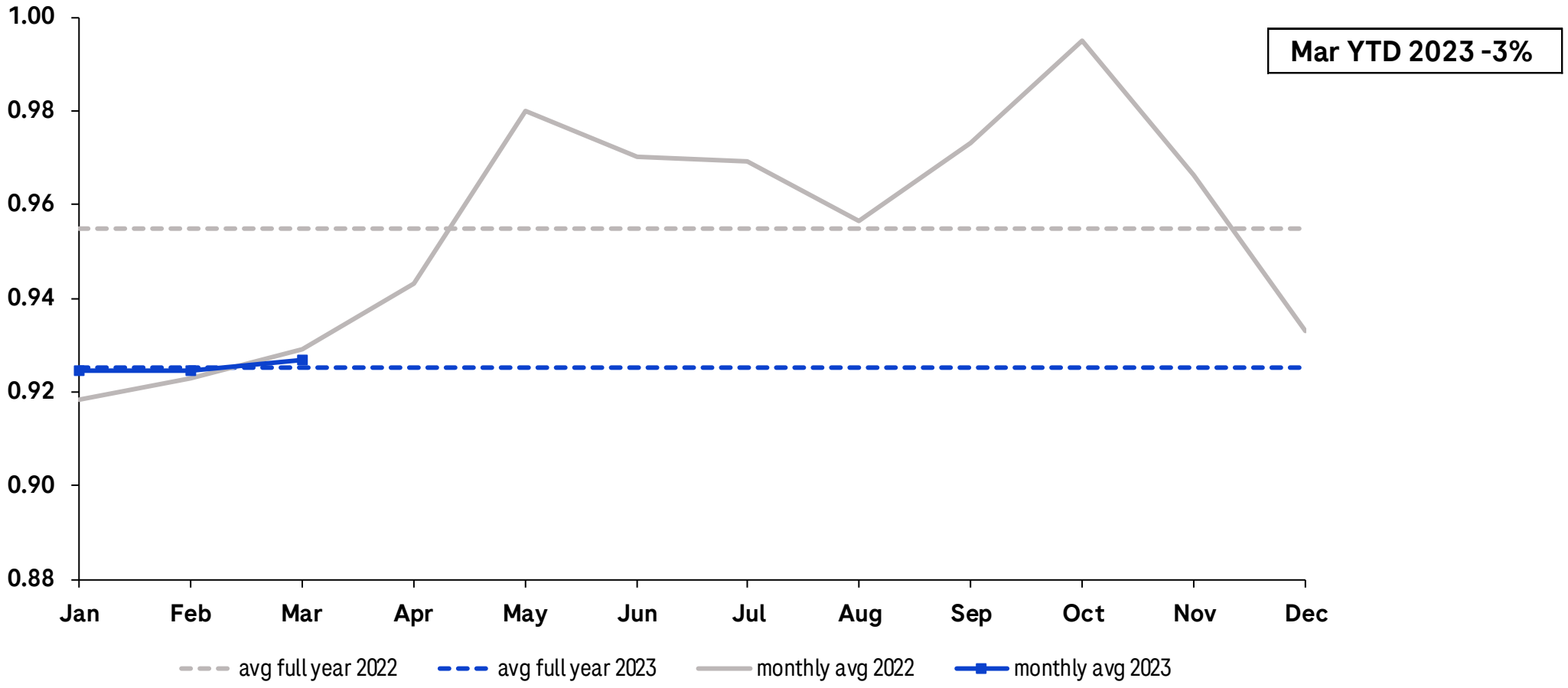
Foreign exchange rates information

CHF/USD

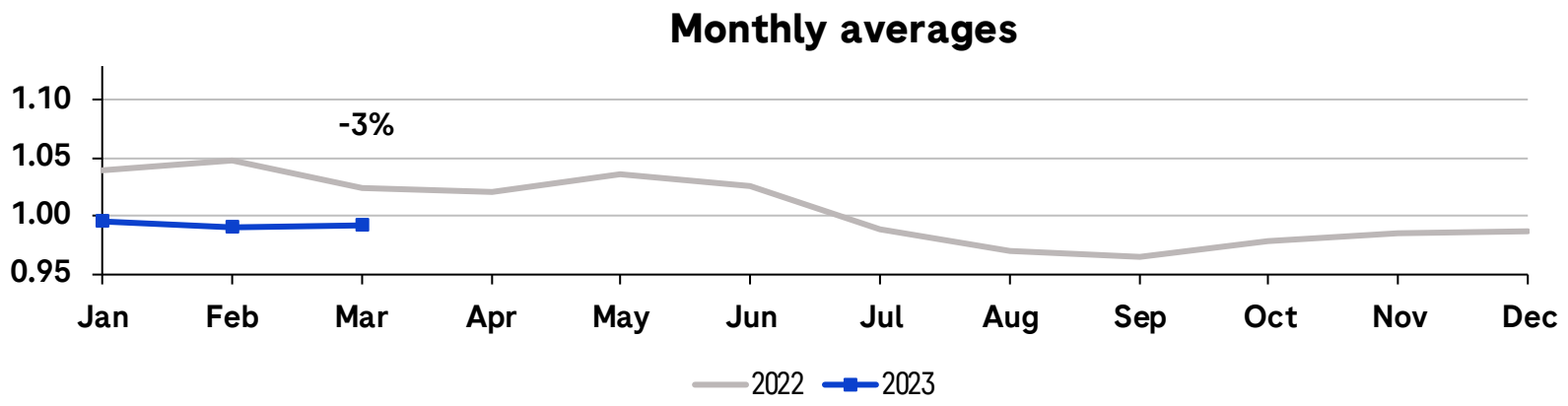

Monthly averages
1.00
0.90
0.80
0%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

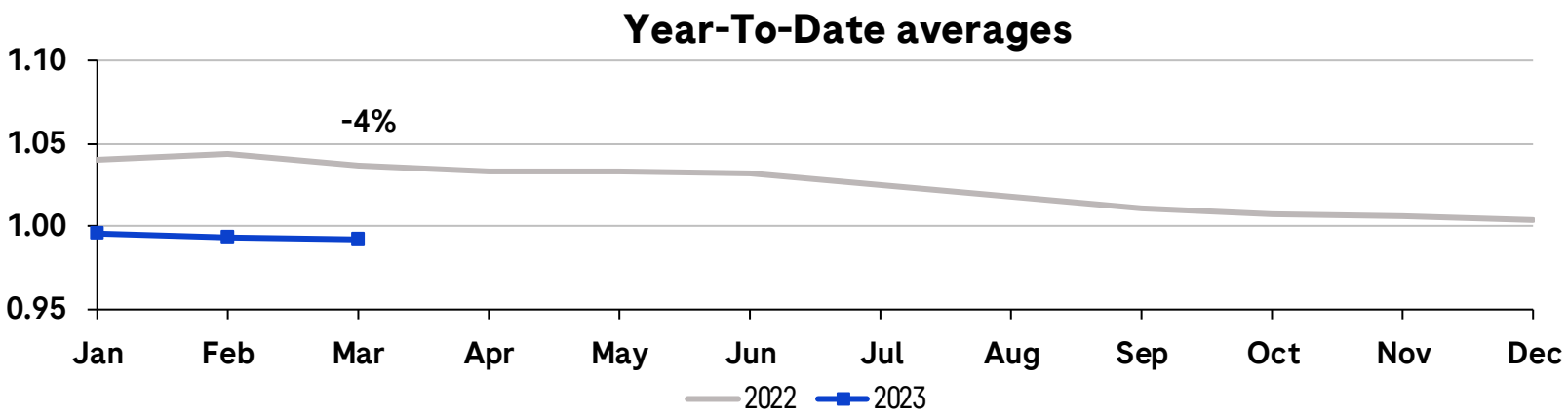

Year-To-Date averages
1.00
0.90
0.80
0%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

CHF/USD

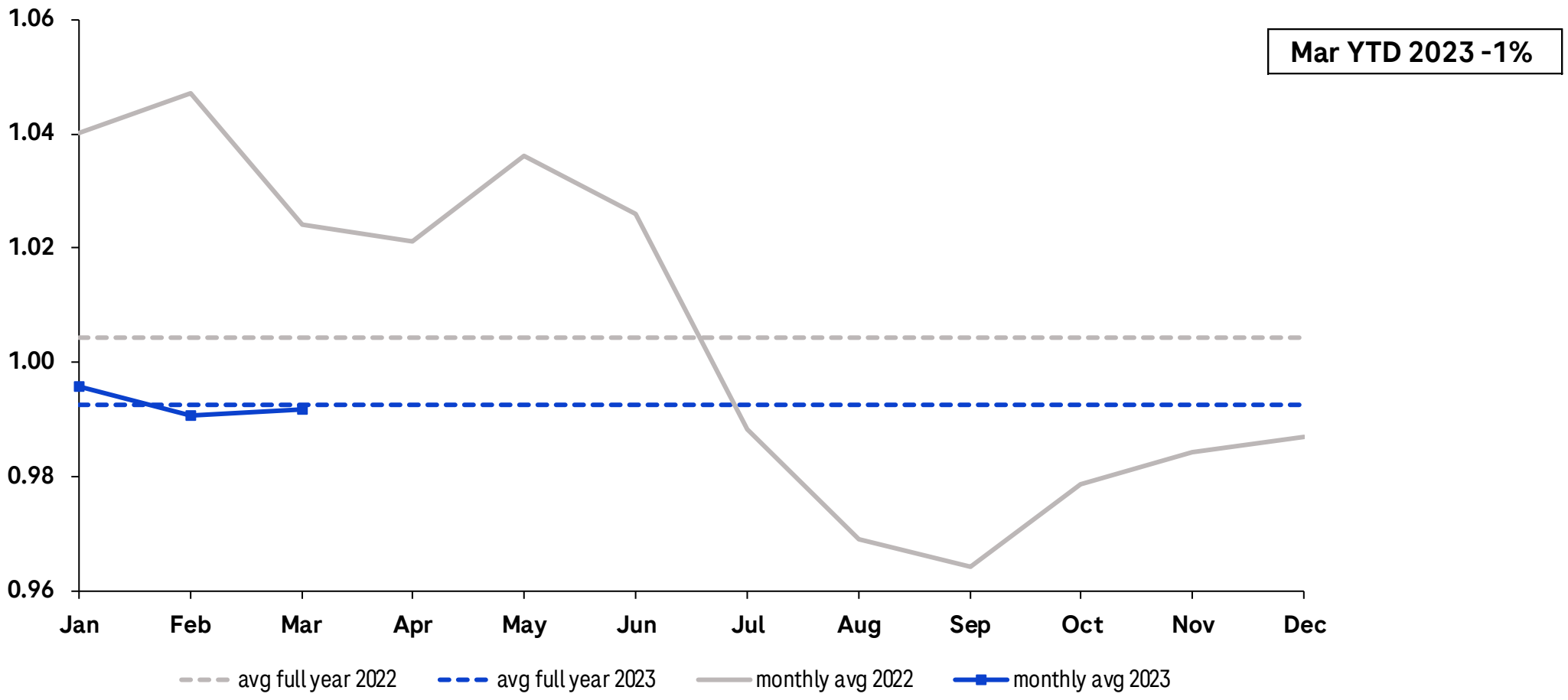

1.00
0.98
0.96
0.94
0.92
0.90
0.88
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Mar YTD 2023 -3%
avg full year 2022
avg full year 2023
monthly avg 2022
monthly avg 2023

CHF/EUR


Monthly averages
1.10
1.05
1.00
0.95
-3%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

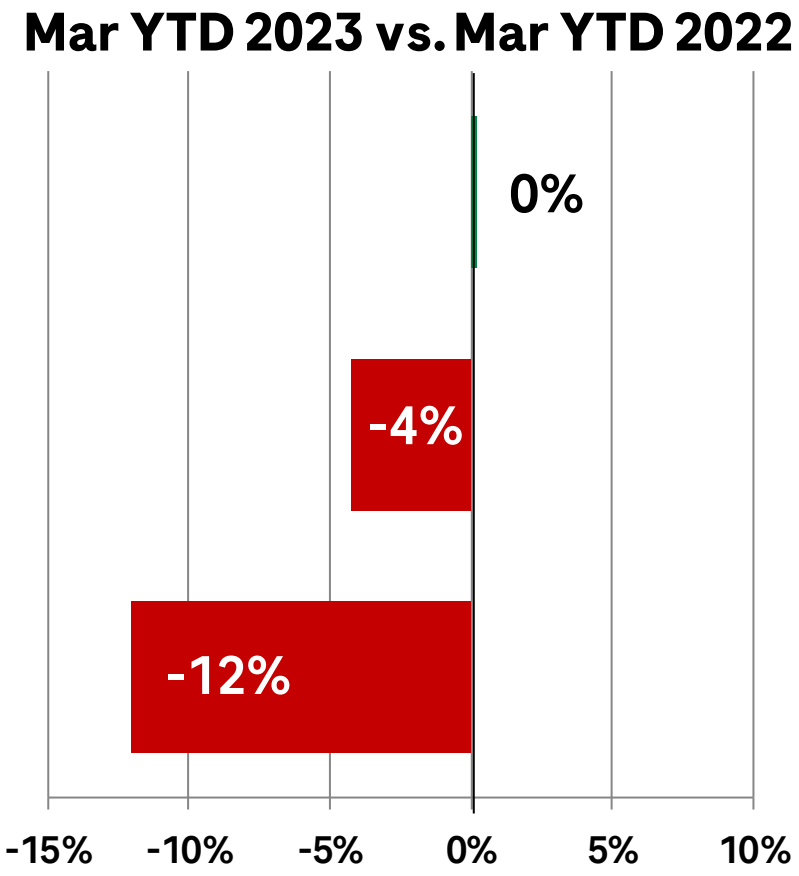

Year-To-Date averages
1.10
1.05
1.00
0.95
-4%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

CHF/EUR


Mar YTD 2023 -1%
1.06
1.04
1.02
1.00
0.98
0.96
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
avg full year 2022
avg full year 2023
monthly avg 2022
monthly avg 2023

Average CHF Exchange Rates

	Mar YTD 2023	Mar YTD 2022
USD	0.93	0.92
EUR	0.99	1.04
JPY	0.70	0.80

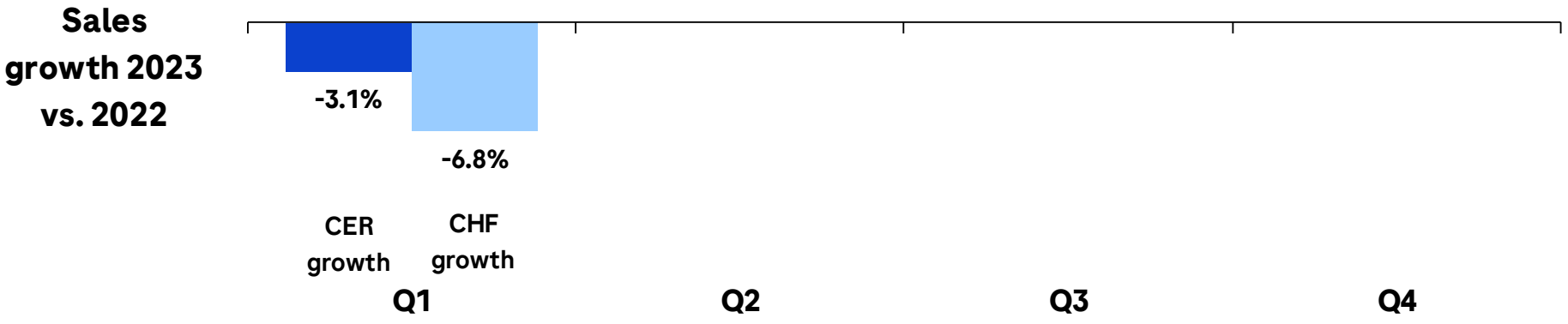


Exchange rate impact on sales growth

Q1 2023: negative impact of JPY and EUR

Development of average exchange rates versus prior year period

CHF / USD	0.2%
CHF / EUR	-4.3%
CHF / JPY	-12.1%
Difference in CHF / CER growth	-3.7%



CER=Constant Exchange Rates

Doing now what patients need next