Roche Late Stage Oncology Pipeline Update

Virtual IR event

31 May 2024
Opening remarks

Bruno Eschli
Head of Investor Relations
Agenda

**Opening remarks**
15:00 – 15:05 CET
Bruno Eschli, Head of Investor Relations

**Late-stage pipeline Oncology**
15:05 – 15:40 CET
Charles Fuchs, SVP Global Head of Oncology and Hematology, Product Development

**Q&A**
15:40 – 16:00 CET
Young portfolio to drive growth in the near- to mid-term
Two NME approvals expected for 2024: PiaSky (crovalimab) in PNH¹ and inavolisib in HR+ breast cancer

Potential NME launches:
- crovalimab
- inavolisib

Young portfolio defined as all launches since end of 2015; ¹PiaSky (crovalimab) in PNH approved in Japan and China with US/EU approvals expected in 2024; ²Elevidys: Accelerated US approval by partner company Sarepta; ³Venclexta sales booked by AbbVie and therefore not included; NME=new molecular entity; PNH=Paroxysmal Nocturnal Hemoglobinuria; HR=hormone receptor
Roche’s key oncology products

**Q1 2024 sales (YoY CER growth)**

- **TECENTRIQ**
  - CHF 3.9bn (+1%)
  - Growth driven ex-US by adjuvant NSCLC and 1L HCC
  - EU launch of SC formulation ongoing

- **PHESGO**
  - CHF 1.8bn (+12%)
  - 0.9bn (+1%)
  - Growth driven ex-US by adjuvant NSCLC and 1L HCC
  - EU launch of SC formulation ongoing

- **ALECENSA**
  - CHF 14.4bn
  - 0.4bn (+4%)
  - Global market leader in 1L ALK+ mNSCLC
  - Adj. ALK+ NSCLC (ALINA): US approval & CHMP positive opinion

- **POLIVY**
  - CHF 1.8bn (+12%)
  - 0.4bn (+4%)
  - Global market leader in 1L ALK+ mNSCLC
  - Adj. ALK+ NSCLC (ALINA): US approval & CHMP positive opinion

- **Lunsumio**
  - CHF 1.8bn (+12%)
  - 0.3bn (+81%)
  - Strong 1L DLBCL uptake in all major markets
  - US patient share in 1L DLBCL (IPI 0-5) climbing to 23%

- **Columvi**
  - CHF 1.8bn (+12%)
  - 25mn (N/A)
  - Growth driven by strong 3L+ DLBCL launch
  - Ph III (STARGLO) in 2L+ DLBCL met primary endpoint of OS

- **Anti-CD20 Fab’ drug conjugate**
  - CHF 1.8bn (+12%)
  - 16mn (+21%)
  - Growth driven by strong 3L+ FL launch
  - Ph III (SUNMO) in 2L+ DLBCL to read out in 2025

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*Perjeta/Phesgo conversion rate calculated using volumes, currently taking 46 launch countries into account; CER=constant exchange rate; mNSCLC=metastatic non-small cell lung cancer; HCC=hepatocellular cancer; SC=subcutaneous; ALK=anaplastic lymphoma kinase; DLBCL=diffuse large B-cell lymphoma; OS=overall survival; FL=follicular lymphoma*
HER2+ franchise outlook

HER2+ BC treatment landscape

**Phesgo**
- Strong launch uptake and ongoing geographic expansion with conversion rate reaching 41%*
- Phesgo leading to increased market penetration
- Phesgo conversion to exceed 50% by 2026

**Kadcyla**
- Continued growth in the adjuvant setting with established iDFS and OS benefit in this setting
- 2L: Kadcyla maintains stable ~20% market share despite competition

**Continuing to develop in HER2+ BC**

1. Phesgo inavolisib (INAVO122)
   - 1L PIK3CA-mut HER2+ BC
2. Phesgo + giredestrtant (heredERA)
   - 1L HER2+/HR+ BC
3. HER2 TKI
   - HER2+ BC with brain metastases

*Perjeta/Phesgo conversion rate calculated using volumes, currently taking 46 launch countries into account; HR+=hormone receptor positive; BC = breast cancer; neoadj = neoadjuvant; adj = adjuvant; iDFS=invasive disease-free survival
Key growth drivers beyond 2025
Many opportunities with significant market potential in both divisions

### Pharmaceuticals

<table>
<thead>
<tr>
<th>NME</th>
<th>Indication</th>
<th>Newsflow</th>
<th>Timing</th>
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<tr>
<td>tiragolumab</td>
<td>NSCLC</td>
<td>Final Ph III data</td>
<td>H2 2024</td>
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<tr>
<td>inavolisib</td>
<td>BC</td>
<td>US/EU filing</td>
<td>2024</td>
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<tr>
<td>divarasib</td>
<td>NSCLC</td>
<td>Ph I/II readout</td>
<td>2024/25</td>
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<tr>
<td>giredestrant</td>
<td>BC</td>
<td>Ph III readout</td>
<td>2025</td>
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<tr>
<td>Elevidys</td>
<td>DMD</td>
<td>Ph III readout</td>
<td>2024/25</td>
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<tr>
<td>prasinezumab</td>
<td>PD</td>
<td>Ph I/II readout</td>
<td>2024</td>
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<tr>
<td>Evrysi + GYM329</td>
<td>SMA</td>
<td>Ph II readout</td>
<td>2024</td>
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<tr>
<td>trontinemab</td>
<td>AD</td>
<td>Ph I/II readout</td>
<td>2024</td>
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<tr>
<td>fenebrutinib</td>
<td>MS</td>
<td>Ph III readout</td>
<td>2025</td>
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<td>Gazyva</td>
<td>LN</td>
<td>Ph III readout</td>
<td>2024</td>
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<tr>
<td>anti-TL1A</td>
<td>IBD</td>
<td>Ph III initiation</td>
<td>2024</td>
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<tr>
<td>astegolimab</td>
<td>COPD</td>
<td>Ph III readout</td>
<td>2025</td>
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<tr>
<td>vamikibart (anti-IL6)</td>
<td>DME/UME</td>
<td>Ph II/III readout</td>
<td>2024/25</td>
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<td>ASO factor B</td>
<td>GA</td>
<td>Ph II readout</td>
<td>2024</td>
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<tr>
<td>zilebesiran</td>
<td>HT</td>
<td>Ph II readout</td>
<td>2024</td>
</tr>
<tr>
<td>CT-388/868/996 (GLP-1/GIP)</td>
<td>Obesity</td>
<td>Ph I/II readout</td>
<td>2024</td>
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### Diagnostics

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Launch</th>
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<tbody>
<tr>
<td>i601 mass spec</td>
<td>Total solution for clinical mass spectrometry and first reagent ipack</td>
<td>2024</td>
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<tr>
<td>cobas pro serology solution</td>
<td>Roche blood safety solution for the US donor screening market</td>
<td>2024</td>
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<tr>
<td>cobas c703 &amp; ISE neo</td>
<td>High-throughput clinical chemistry and ISE testing on cobas pro</td>
<td>2024</td>
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<tr>
<td>Elecsys Amyloid Plasma Panel</td>
<td>Rule-out blood-based test for amyloid pathology detection in AD</td>
<td>2025</td>
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<tr>
<td>cobas 6800/8800 v2.0</td>
<td>Upgrade with increased testing flexibility, throughput and automation</td>
<td>2024</td>
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<tr>
<td>cobas Respiratory flex</td>
<td>Novel TAGS® multiplex technology for respiratory testing on cobas x800</td>
<td>2024</td>
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<tr>
<td>Next generation sequencing</td>
<td>Nanopore sequencer with unique sequencing by expansion technology</td>
<td>2025+</td>
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<tr>
<td>Accu-Chek SmartGuide</td>
<td>Roche’s first generation continuous glucose monitoring solution</td>
<td>2024</td>
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<tr>
<td>cobas Liat Resp. panel</td>
<td>Detection &amp; differentiation of four most prevalent respiratory targets</td>
<td>2024</td>
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Upcoming Roche IR events 2024
Additional events driven by readouts

**Diagnostics Day**
- May 22
- Deep-dive into the current product portfolio
- Updates on key development projects and upcoming launches, including mass spectrometry, CGM, NGS

**Oncology/ASCO**
- May 31
- Oncology solid tumors pipeline update (tiragolumab, giredestrant, inavolisib, divarasib)
- Malignant hematology portfolio and pipeline update

**Hematology/EHA**
- June 16
- Ph III (STARGLO) results for Columvi + GemOx in 2L+ DLBCL
- Update on non-malignant hematology

**Ophthalmology/ASRS**
- Jul 23
- Ophthalmology franchise update
- Ophthalmology pipeline (early- and late-stage)
- Data presented at ASRS

**Pharma Day**
- Sep 30
- Update on Group & Pharma strategy
- Update on R&D excellence
- Deep-dive into the current product portfolio
- Building blocks for future growth: Late stage pipeline update

**Neurology Update**
- Virtual
- Mon, 11 Mar 15:00-16:30 CET

**Diagnostics Day**
- London & virtual
- Wed, 22 May 13:00-15:30 BST

**Oncology/ASCO**
- Virtual
- Fri, 31 May 16:00-17:30 CEST

**Hematology/EHA**
- Virtual
- Sun, 16 June 13:00-14:00 CEST

**Ophthalmology/ASRS**
- Virtual
- Tue, 23 Jul 16:30-17:30 CEST

**Pharma Day**
- London & virtual
- Mon, 30 Sep tbd

CGM=continuous glucose monitoring; NGS=next generation sequencing; ASCO=American Society of Clinical Oncology; ASRS=American Society of Retina Specialists; EHA=European Hematology Association
Late stage pipeline Oncology

Charles Fuchs
SVP Global Head of Oncology and Hematology, Product Development
### Strategic pillars of oncology and hematology

<table>
<thead>
<tr>
<th><strong>Precision medicine</strong></th>
<th><strong>Early disease</strong></th>
<th><strong>Novel immunotherapy</strong></th>
<th><strong>Rational combinations</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Right medicines for the right patient</td>
<td>Early diagnosis and treatment increases the chance for cure</td>
<td>Need more options for patients who have progressed on prior treatment</td>
<td>Leverage breadth of oncology portfolio to explore new combinations</td>
</tr>
</tbody>
</table>

**Recent examples**

- **inavolisib**
  - INAVO120 (1L HR+ PI3Km BC)
  - US filing completed

- **divarasib**
  - Ph III in 2L NSCLC H2H vs sotorasib/adagrasib to initiate in H2 2024

- **Alecensa**
  - ALINA (adj ALK+ NSCLC)
  - US approval / EU filing

- **tiragolumab + Tecentriq**
  - Ph III in 1L NSCLC final OS results expected in H2

- **Columvi + Polivy + R-CHP**
  - Ph III in 1L DLBCL ongoing

- **giredestrant**
  - Potential to replace ET in eBC (and mBC)

- **tobemstomig**
  - Multiple Ph II trials in mUC, NSCLC, RCC ongoing

- **giredestrant + Phesgo**
  - Ph III in 1L HER2+/HR+ BC ongoing

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NSCLC=Non-Small Cell Lung Cancer; H2H=head-to-head; R-CHP=Rituxan + cyclophosphamide + hydroxydaunorubicin + prednisone; DLBCL=Diffuse large B-cell lymphoma; PI3K=Phosphoinositide 3-Kinase; ET=Endocrine therapy; eBC=Early breast cancer; mBC=Metastatic breast cancer; HR=Hormone receptor; adj+adjvant; mUC=Metastatic urothelial carcinoma; RCC=Renal cell carcinoma; HER2=Human Epidermal growth factor Receptor
Advancing new modalities across key oncology pathways
A pioneer in bispecific antibodies and antibody drug conjugates (ADC)

Explore biology of early disease and transform treatment of cancer
### Oncology solid tumor pipeline

A broad portfolio differentiated on targets and modalities

<table>
<thead>
<tr>
<th>Ph I (22 NMEs)</th>
<th>Ph II</th>
<th>Ph III</th>
<th>Launched</th>
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<tbody>
<tr>
<td><strong>RG6194</strong> runinotamab (HER2 x CD3)</td>
<td><strong>RG6058</strong> tiragolumab Multiple indications</td>
<td><strong>RG6058</strong> tiragolumab Multiple indications</td>
<td><strong>RG6058</strong> Alecensa ALK+ NSCLC</td>
</tr>
<tr>
<td><strong>RG6279</strong> eciskafusp alfa (PD1-IL2v)</td>
<td><strong>RG6139</strong> tolbequstomig Solid tumors</td>
<td><strong>RG6114</strong> inavolisib HR+ mBC</td>
<td><strong>RG3502</strong> Kadcyla HER2+ BC</td>
</tr>
<tr>
<td><strong>RG6292</strong> vopikitung</td>
<td><strong>RG6180</strong> autogene cevumeran 1L melanoma</td>
<td><strong>RG6171</strong> giredestrant HR+ BC</td>
<td><strong>RG1273</strong> Perjeta HER2+ BC</td>
</tr>
<tr>
<td><strong>RG6323</strong> efbalopodecin alfa (IL15/IL15Rα-Fc)</td>
<td><strong>RG6292</strong> vopikitung</td>
<td><strong>RG6330</strong> divarsib 2L NSCLC</td>
<td><strong>RG6264</strong> Phesgo HER2+ BC</td>
</tr>
<tr>
<td><strong>RG6344</strong> BRAF inhibitor (3)</td>
<td><strong>RG6411</strong> undisclosed</td>
<td><strong>RG6302</strong> Kadcyla HER2+ eBC high risk</td>
<td><strong>RG7446</strong> Tecentriq Multiple indications</td>
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<tr>
<td><strong>RG6433</strong> undisclosed</td>
<td><strong>RG6468</strong> undisclosed</td>
<td><strong>RG6268</strong> Tecentriq Multiple indications</td>
<td><strong>RG6268</strong> Rozlytrek ROS1+ &amp; NTRK+ NSCLC</td>
</tr>
<tr>
<td><strong>RG6440</strong> Anti-latent TGF-β1 (SOF10)</td>
<td><strong>RG6524</strong> DLL3 trispecific</td>
<td><strong>RG7446</strong> Tecentriq Multiple indications</td>
<td><strong>RG6264</strong> Phesgo HER2+ BC</td>
</tr>
<tr>
<td><strong>RG6457</strong> WRN covalent inhibitor</td>
<td><strong>RG6587</strong> AR Degrader</td>
<td><strong>RG6330</strong> divarsib 2L NSCLC</td>
<td><strong>RG6268</strong> Tecentriq Multiple indications</td>
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<tr>
<td><strong>RG6484</strong> undisclosed</td>
<td><strong>RG6596</strong> ZN-1041 (HER2 TKI)</td>
<td><strong>RG6302</strong> Kadcyla HER2+ eBC high risk</td>
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<td><strong>RG6614</strong> KSO-4279 (USP1 inh)</td>
<td><strong>RG6268</strong> Tecentriq Multiple indications</td>
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<tr>
<td><strong>RG6537</strong> FAP-4-18BL</td>
<td><strong>RG7827</strong> CHU glypican-3 x CD3</td>
<td><strong>RG7446</strong> Tecentriq Multiple indications</td>
<td><strong>RG6268</strong> Tecentriq Multiple indications</td>
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<td><strong>RG6640</strong> Anti-latent TGF-β1 (SOF10)</td>
<td><strong>RG6640</strong> CHU CD137 switch antibody</td>
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<td><strong>RG6268</strong> Tecentriq Multiple indications</td>
</tr>
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1. managed by Zion Pharma; 2. managed by KSQ Therapeutics; NME=new molecular entities
### Hematology pipeline

A broad portfolio enabling novel combinations

#### Ph I (7 NMEs)
- **RG6076**
  - **englumafusp alfa**
  - Heme tumors
- **RG6160**
  - **cevostamab**
  - r/r MM
- **RG6234**
  - **forimtamig**
  - MM
- **RG6333**
  - **CD19 x CD28**
  - r/r NHL
- **RG6512**
  - **FiXa x FX**
  - Hemophilia
- **RG6538**
  - **P-BCMA-ALLO1**
  - MM
- **RG6026**
  - **Columvi**
  - Heme tumors
- **RG7828**
  - **Lunsumio**
  - Heme tumors

#### Ph II
- **RG6107**
  - PiaSky (crovalimab)
  - SCD
- **RG6357**
  - diriocloctogene samoparvovec
  - Hemophilia A

#### Ph III
- **RG6026**
  - Columvi
  - 1L & 2L+ DLBCL, r/r MCL
- **RG7828**
  - Lunsumio
  - 2L+ FL & 2L+ DLBCL
- **RG6107**
  - PiaSky (crovalimab)
  - aHUS
- **RG7601**
  - Venclexta
  - 1L MDS

#### Registration
- **RG6107**
  - PiaSky (crovalimab)²
  - PNH

#### Launched
- **RG6026**
  - Columvi
  - 3L+ DLBCL
- **RG7828**
  - Lunsumio
  - 3L+ FL
- **RG7596**
  - Polivy
  - 1L & r/r DLBCL
- **RG7601**
  - Venclexta
  - CLL & AML
- **RG7159**
  - Gazyva
  - CLL & FL
- **RG105**
  - MabThera
  - DLBCL, FL & CLL
- **RG6013**
  - Hemlibra
  - Hemophilia A

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1. managed by Poseida Therapeutics; ²PiaSky (crovalimab) in PNH approved in Japan and China with US/EU approvals expected in 2024; NME=new molecular entities; CAR-T=chimeric antigen receptor T-cell
Despite a variety of treatment options, high unmet medical need remains...
HR+/HER2- BC treatment pathway

HR+ BC treatment landscape

1. **Low risk (~55%)**
2. **Medium risk (~25%)**
3. **High risk (~20%)**

**Endocrine Therapy (ET)**
Endocrine therapy is backbone treatment for ER+ breast cancer; however, there are limitations with current ET options

**CDK4/6i**
ET+CDK4/6i established as backbone in HR+ mBC, and emerging in high-risk eBC

**Targeted therapies**
Targeted therapies to-date have been limited to late lines

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1. Risk definitions vary according to guidelines and tools used: stage at diagnosis based on internal estimates using SEER data.
2. AI sensitive defined as patients who relapse >1yr after completion of adjuvant therapy.
3. HR=Hormone receptor, ET = Endocrine Therapy, BC = breast cancer, eBC = early breast cancer, mBC = metastatic breast cancer, neoadj = neoadjuvant, adj = adjuvant
Giredestrant has the potential to overcome the limitations of current ET options and improve patient outcomes

Current standard of care* – Remaining unmet needs1-15

- Tolerability and AEs leading to low adherence
- Relapse rate
- Development of ESR1 mutation / limited efficacy in ESR1m BC
- Limited applicability in eBC
- Quality of life impacts

Giredestrant (SERD)

- Highest preclinical potency vs. other oral SERDs in development
- Combinable with all CDKis including: palbociclib, abemaciclib, ribociclib
- Well tolerated at all doses, with no dose-limiting toxicity

AE = adverse event; eBC = early breast cancer; ER = estrogen receptor; ET = endocrine therapy; SERD = selective estrogen receptor degrader; SERM = selective oestrogen receptor modulator.


Adapted from: Brufsky AM & Dickler MN. Oncologist 2018.
Giredestrant data support potential in 1L and adjuvant HR+ BC

**Ki67 suppression in the neoadjuvant setting can predict benefit of ET in adjuvant trials**

- Ph II (coopERA) in neoadjuvant setting: Final analysis confirmed greater suppression of Ki67 and rates of complete cycle arrest with giredestrant vs. anastrozole at time of surgery
- Ki67 is a biomarker of proliferation associated with improved long-term efficacy outcomes in early stage disease. Ki67 results in the neoadjuvant setting have been predictive of benefit in subsequent adjuvant trials (letrozole, anastrozole)

**Giredestrant drives benefit where ER dependency persists**

- In 2L/3L, only ESR1m patients' tumors appear to be sensitive to endocrine inhibition. In this population, giredestrant benefit vs. fulvestrant was more pronounced (PFS HR: 0.61)
- In eBC and 1L mBC, tumors are still ER dependent, with ER activity comparable to that of 2L+ ESR1m patients. Hence, in earlier lines, giredestrant has potential to drive meaningful benefit in all patients, regardless of ESR1m status

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1Exploratory biomarker analysis from aceiERA: Collier A. et al., ASCO 2023; Fasching P. et al., ASCO 2022; Martin M. et al., ESMO 2022; adj=adjuvant; ORR=objective response rate; PFS=progression-free survival; HR=hazard ratio; HR+=Hormone receptor positive; ER=estrogen receptor; eBC=early breast cancer; m=months; CI=confidence interval; ESR1=estrogen receptor 1
Giredestrant: Potential new best-in-class endocrine backbone

Giredestrant aims to replace standard of care ET across eBC and mBC

- First results from Ph III persevERA (1L mBC) expected 2025
- Initiated additional Ph III (pionERA) trial in 1L mBC with giredestrant + CDK4/6i of choice (abema, ribo, palbo)
- Leading SERD with head-to-head adjuvant trial vs. AI
- Evaluating combination with abemaciclib in eBC with single arm substudy as part of Ph 3 lidERA

Ph 3 development program

1. gire + palbo (persevERA) → 1L ER+/HER2- mBC (endocrine sensitive)
2. gire + any CDK4/6i (pionERA) → 1L ER+/HER2- mBC (endocrine resistant)
3. giredestrant (lidERA) → Adjuvant ER+/HER2- mBC
4. gire + Phesgo (heredERA) → 1L maintenance ER+/HER2+ mBC

1 Risk definitions vary according to guidelines and tools used: stage at diagnosis based on internal estimates using SEER data *giredestrant + CDK4/6i in adjuvant HR+ BC being evaluated as single arm substudy as part of Ph 3 lidERA **giredestrant + everolimus in 2L+ HR+ BC is being investigated as Medical Affairs study

AI = aromatase inhibitor, ET = Endocrine Therapy, eBC = early breast cancer, mBC = metastatic breast cancer, neoadj = neoadjuvant, adj = adjuvant, SERD = selective estrogen receptor degrader
Inavolisib in PiK3CAm HR+ BC

**Best-in-class PI3Kα inhibitor**

<table>
<thead>
<tr>
<th>Potency/selectivity (inavolisib vs. alpelisib)</th>
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<tbody>
<tr>
<td>PI3Kα potency</td>
</tr>
<tr>
<td>58x</td>
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<tr>
<td>PI3Kα selectivity vs. β</td>
</tr>
<tr>
<td>6x</td>
</tr>
<tr>
<td>PI3Kα selectivity vs. δ</td>
</tr>
<tr>
<td>26x</td>
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<tr>
<td>PI3Kα selectivity vs. γ</td>
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<tr>
<td>32x</td>
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Fold change (inavolisib vs. alpelisib)

- **Inavolisib**
- **Alpelisib**

Differentiated from alpelisib:
- More potent and selective for PI3Kα subunit
- Better *in vivo* efficacy
- Greater safety margins allow for combination with ET and palbociclib at standard doses

**PIK3CA is one of the most frequently mutated oncogenes in cancers**

- ~40% of HR+ BC patients and ~17% of all cancer patients harbor PIK3CA mutations
- Current PI3K inhibitors have been limited to late line therapy, due to issues with tolerability and lack of combinability with CDK4/6i
- Combinations to achieve maximal inhibition of ER, PI3K, CDK4/6 pathways anticipated to deliver greatest clinical benefit

**Tumor type** | **PIK3CA mut prevalence**
--- | ---
HR+ BC | 40%
HER2+ BC | 30%
Ovarian Clear Cell | ~33%
Endometrial | 22-31%
Colorectal | 13-20%
Bladder | 14-20%
Cervical | 11-24%
HNSCC | 11-16%
Gastric | 5-9%

---

Jhaveri KL et al., SABCS 2023; PFS=progression-free survival; PIK3CA-mut=phosphatidylinositol 3-kinase, catalytic alpha polypeptide mutated; HR+=hormone-receptor positive; ER+=estrogen receptor positive; HER2+=human epidermal growth factor receptor 2; (m)BC=(metastatic) breast cancer; CDK=cyclin-dependent kinase; inavo=inavolisib; Palbo=palbociclib; fulv=fulvestrant; Pbo=placebo; mo=months; HR=hazard ratio; CI=confidence interval; OS=overall survival
Inavolisib has potential to expand broadly in PIK3CAm BC

**Potential for inavolisib based regimen in PIK3CA mutated HR+ BC**

- **Low risk (~55%)**
  - Neoad
    - ET
  - Adj
    - ET
  - 1L
    - ET
    - ET+CDKi

- **Medium risk (~25%)**
  - Neoad
    - ET
  - Adj
    - ET
  - 1L
    - ET+CDKi
    - ET+CDKi/6i inavo

- **High risk (~20%)**
  - Neoad
    - ET
  - Adj
    - ET
  - 1L
    - ET+CDKi
    - ET+CDKi/6i inavo

- **De novo (30%)**
  - Al-sensitive (30%)
    - ET+CDKi
    - ET+CDKi/6i inavo
  - Al-resistant (40%)
    - ET

- **SURGERY**
  - Potential future trial

- **Visceral crisis**
  - Chemo +/- bev
  - ADC

**Ongoing study**  **Future development plan**

**Future development plan**
- Ph III (INAVO123) to be initiated in 1L ET sensitive patients
- Ph III (INAVO121) head-to-head trial vs. alpelisib ongoing in CDKi experienced patients
- Potential to initiate additional trials in eBC
- Potential to expand into other PIK3CA-mut tumors: 12 Ph lb/lII signal seeking studies ongoing to establish proof of concept across multiple tumors

**Risk definitions vary according to guidelines and tools used**: stage at diagnosis based on internal estimates using SEER data; AI = aromatase inhibitor, ET = Endocrine Therapy, eBC = early breast cancer, mBC = metastatic breast cancer, neoadj = neoadjuvant, adj = adjuvant, BTD = breakthrough therapy designation, PR = priority review, PDUFA = prescription drug user fee act
**INAVO120: Strong PFS supported by TTNT analysis, interim OS**

Data submitted to FDA, EMA and granted FDA BTD and Priority Review (PDUFA date Nov 2024)

*Oncology solid tumors*

**Inavolisib more than doubles PFS in 1L PIK3CAm HR+ BC**

- **PFS (investigator assessed)**
  - Inavo+Palbo+Fulv (n=161)
  - Pbo+Palbo+Fulv (n=164)
  - Median, mo: 15.0 vs 7.3
  - Stratified HR: 0.43
  - p=0.0001
  - Median follow up = 21.3 mo

- **Time to Next Treatment (TTNT) Analysis**
  - Time from randomization to end or discontinuation of next-line treatment, or death from any cause
  - Inavo+Palbo+Fulv (n=161)
  - Pbo+Palbo+Fulv (n=164)
  - Median, mo: 24.0 vs 15.1
  - Stratified HR: 0.54 (0.38, 0.77)

- **Δ 8.9 months**

**• Inavolisib with palbociclib and fulvestrant was associated with sustained benefit beyond disease progression, demonstrating a delayed need for subsequent therapy (Δ 8.9m), including chemotherapy (NE vs 15.0 m)**

- **• Fewer patients on inavo + palbo + fulv went on to receive subsequent therapies: 40% vs. 50%**

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1. Jhaveri KL et al., SABCS 2023; PFS=progression-free survival; PIK3CA-mut=phosphatidylinositol 3-kinase, catalytic, alpha polypeptide mutated; HR+=hormone-receptor positive; ER+=estrogen receptor positive; HER2=human epidermal growth factor receptor 2; (m)BC=(metastatic) breast cancer; CDK=cyclin-dependent kinase; inavo=inavolisib; Palbo=palbociclib; fulv=fulvestrant; Pbo=placebo; mo=months; HR=hazard ratio; CI=confidence interval
Tiragolumab with a comprehensive development program
Mode of action indicates potentially improved and durable tumor control\(^1\)

**Key insights from Guan et al.\(^1\)**

- Nature publication on tiragolumab mode of action indicates potentially improved and durable tumor control\(^1\)
- Ph III (SKYSCRAPER-01) tiragolumab + Tecentriq in 1L PD-L1 high NSCLC final OS results expected in H2 2024
- Phase III trials ongoing, read-outs are event-driven; signal seeking studies ongoing across solid tumors

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**Clinical development program**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Ph I</th>
<th>Ph II</th>
<th>Ph III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L NSCLC: PD-L1 high</td>
<td>SKYSCRAPER-01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage II unresectable NSCLC</td>
<td>SKYSCRAPER-03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neoadjuvant / Adj NSCLC</td>
<td>SKYSCRAPER-05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L non-squamous NSCLC</td>
<td>SKYSCRAPER-06</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjuvant NSCLC</td>
<td>SKYSCRAPER-07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locally advanced ESCC</td>
<td>SKYSCRAPER-08</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L ESCC (China)</td>
<td>SKYSCRAPER-07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L uHCC</td>
<td>SKYSCRAPER-14/IMbrave152</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1L SCCHN</td>
<td>SKYSCRAPER-09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI Cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixed-dose combination</td>
<td>SKYSCRAPER-10</td>
<td></td>
<td>SKYSCRAPER-11</td>
</tr>
<tr>
<td>Others</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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1Guan et al., Nature 2024; NSCLC=non-small cell lung cancer; PD-L=programmed death ligand; (Neo)Adj=(neo) adjuvant; ESCC=esophageal squamous cell carcinoma; uHCC=unresectable hepatocellular cancer; SCCHN=squamous cell cancer of the head and neck; OS=overall survival
**Divarasib in KRAS G12C-mutant tumors**

Building on best-in-class potential and strong previous clinical results

**KRAS G12C inhibitor**

- Divarasib is an irreversible covalent inhibitor of mutant KRAS G12C protein resulting in a locked inactive conformation
- Best-in-class potential being more potent and selective in vitro than sotorasib/adagrasib

**Ph I results in 2L+ mNSCLC**

- Robust clinical benefit in KRAS G12C+ mNSCLC as monotherapy in both mPFS and cORR
- Manageable safety with reversible adverse events across tumor types

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1 Purkey H. et al., AACR 2022; 2Sacher et al., NEJM 2023; *Note: This analysis is not intended as a cross trial comparison; mNSCLC= metastatic non-small cell lung cancer; KRAS=Kirsten rat sarcoma; (m)PFS=(median) progression free survival; cORR=confirmed objective response rate; QD=once daily; BID=twice daily
Ph III H2H vs. sotarasib/adagrasib in 2L NSCLC to initiate in H2 2024
Potential to establish divarasib as the superior KRAS G12C inhibitor

Clinical development program

<table>
<thead>
<tr>
<th>Indication</th>
<th>Regimen</th>
<th>Ph I</th>
<th>Ph II</th>
<th>Ph III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1L mNSCLC</td>
<td>divarasib + X*</td>
<td>(to initiate in 2025)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2L+ mNSCLC</td>
<td>divarasib vs sotorasib/adagrasib</td>
<td>Krascendo 1 (to initiate in H2 ’24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2L+ mNSCLC</td>
<td>divarasib</td>
<td>BFAST</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Key inclusion criteria
- 2L+ mNSCLC
- KRAS G12C+
- PD-L1 All Comers
- ECOG PS 0-1

Primary endpoints
- PFS and OS

Ph III (Krascendo 1) divarasib in 2L mNSCLC

- Ph Ib/II (Krascendo-170) in 1L mNSCLC with divarasib + pembrolizumab +/- chemo ongoing
- Ph III in 1L NSCLC to initiate in 2025
- Ph II (BFAST) in 2L+ mNSCLC with divarasib dose finding cohort ongoing

*Ph III 1L NSCLC regimen to be disclosed at a later stage; mNSCLC= metastatic non-small cell lung cancer; H2H=head-to-head; OS=overall survival; PFS=progression free survival; PD-L1=programmed death ligand 1; KRAS=Kirsten rat sarcoma; ECOG PS=eastern cooperative oncology group performance status
Roche keeps shifting the standard of care in NHL

Hematology

NHL: accounting for ~ 50% of hematological malignancies\(^1\)

- aNHL (incl. DLBCL, MCL)
- iNHL (incl. FL)
- Leukemia (incl. CLL)
- Hodgkin Lymphoma
- Myeloma
- MPNs
- MDS

chemotherapy

**Diffuse Large B cell Lymphoma (DLBCL)**

- 1L
  - CHOP
  - R-CHOP
  - Polivy+ R-CHP\(^*\)
- R/R
  - benda
  - R+benda
- 3L+
  - Polivy+ R+benda
  - Polivy+ Lunnsmio
  - Polivy+ Lunnsmio + GemOx

**Follicular Lymphoma (FL)**

- 1L
  - chemo
  - R+chemo
  - G+chemo
- 2L+
  - benda
  - R+benda
  - G+benda
- 3L+
  - Lunnsmio + lenalidomide
  - Lunnsmio + lenalidomide + Lunnsmio

\(^1\)The Leukemia & Lymphoma Society. Facts 2022-2023. Updated Data on Blood Cancers. Published August 2023. Accessed [date]. https://www.lls.org/booklet/facts-updated-data-blood-cancers; NHL, Non-hodgkin lymphoma; aNHL, iNHL, aggressive, indolent Non-hodgkin lymphoma, 1L, first line; 2L+, second line or later; 3L+, third line or later; R/R, relapsed/refractory; FL, follicular lymphoma; DLBCL, diffuse large B-cell lymphoma; MCL, mantle cell lymphoma; MPNs, myeloproliferative neoplasms; MDS, Myelodysplastic syndrome; R-CHOP, Rituxan + cyclophosphamide + doxorubicin + vincristine + prednisone; R-CHP, Rituxan + cyclophosphamide + hydroxydaunorubicin + prednisone; R+benda, rituxinab+bendamustine; G+benda, Gazyva+bendamustine; GemOx, gemcitabine+oxaliplatin

\(\sqrt{\text{= approved}}\)
**NHL development program progressing**
Fixed duration, off the shelf, high CR rates with durable responses & manageable safety

**Comprehensive clinical trial program**

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Indication</th>
<th>Ph I</th>
<th>Ph II</th>
<th>Ph III</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polivy + R-CHP</td>
<td>1L DLBCL</td>
<td></td>
<td></td>
<td>✔️</td>
<td>US/EU approved</td>
</tr>
<tr>
<td>Lunsumio</td>
<td>3L+ FL</td>
<td></td>
<td></td>
<td>✔️</td>
<td>US/EU approved</td>
</tr>
<tr>
<td>Lunsumio + Polivy</td>
<td>2L+ DLBCL (SCT-ineligible)</td>
<td></td>
<td></td>
<td>✔️ ✔️</td>
<td>Readout 2025</td>
</tr>
<tr>
<td>Lunsumio + lenalidomide</td>
<td>2L+ FL</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Lunsumio + lenalidomide</td>
<td>1L FL</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Lunsumio + Polivy</td>
<td>1L DLBCL (elderly/unfit)</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Columvi</td>
<td>3L+ DLBCL</td>
<td></td>
<td></td>
<td>✔️</td>
<td>US/EU approved</td>
</tr>
<tr>
<td>Columvi + GemOx</td>
<td>2L+ DLBCL (SCT-ineligible)</td>
<td></td>
<td></td>
<td>✔️ ✔️</td>
<td>OS met</td>
</tr>
<tr>
<td>Columvi + Polivy + R-CHP</td>
<td>1L DLBCL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Columvi</td>
<td>R/R MCL (post-BTKi)</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Columvi + CD19x4-1BBL</td>
<td>r/r NHL</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Columvi + CD19xCD28</td>
<td>r/r NHL</td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>P-CD19xCD20-ALLO1</td>
<td>r/r B-cell malignancies</td>
<td></td>
<td></td>
<td>✔️</td>
<td>FPI achieved Q2 2024</td>
</tr>
</tbody>
</table>

NHL=Non-hodgkin lymphoma; 1L=first line; 2L=second line; 3L+ =third line or later; FL=follicular lymphoma; DLBCL=diffuse large B-cell lymphoma; MCL=mantle cell lymphoma; CRS=cytokine release syndrome; CR=complete response; CAR=chimeric antigen receptor; P-CD19xCD20-ALLO1 in collaboration with Poseida Therapeutics
**Ph III STARGLO: Primary endpoint of OS in 2L DLBCL met**

Late Breaking Abstract accepted at EHA 2024

### Progressing patients

- ~30-40% of DLBCL patients progress; ~50% of R/R patients are ASCT ineligible\(^1\)
- Need efficacious and cost effective 2L options

### Ph III (STARGLO) Columvi + GemOx in 2L R/R DLBCL

- Patients (N=274)
  - Age ≥18 years
  - R/R DLBCL
  - ECOG PS 0–2
  - ≥1 prior systemic anti-lymphoma therapy
  - Ineligible for ASCT

- Primary endpoint: Overall Survival

- Columvi + GemOx (N=183)

- Rituximab + GemOx (N=91)

**Ph III STARGLO** met its primary endpoint of OS

- Safety was consistent with the known safety profiles of the individual drugs

- Results to be presented at EHA 2024

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**Columvi is the first CD20xCD3 bispecific to demonstrate an OS benefit in DLBCL**

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\(^1\) Budde et al. 2024; Nature Medicine 30, 229–239; OS=Overall survival; 2L=second line; DLBCL=diffuse large B cell lymphoma; GemOx= Gemcitabine + oxaliplatin; ASCT= Autologous stem cell transplant; R/R=Relapsed/refractory; ECOG PS=Eastern Cooperative Oncology Group Performance Status; , CAR-T=chimeric antigen receptor T-cells; EHA=European Hematology Association
Ph III SUNMO: Chemo-free combo of two unique MoAs in 2L DLBCL
High activity and durable responses for patients unable to tolerate chemo

Ph Ib/II (GO40516): Lunsumio + Polivy with durable ORR and CR rates in R/R LBCL

<table>
<thead>
<tr>
<th>Efficacy endpoints</th>
<th>Refractory* (n=45)</th>
<th>Relapse* (n=27)</th>
<th>Overall population (N=98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORR, %</td>
<td>49%</td>
<td>74%</td>
<td>59%</td>
</tr>
<tr>
<td>CR, %</td>
<td>36%</td>
<td>59%</td>
<td>46%</td>
</tr>
<tr>
<td>Median DOR, months</td>
<td>20.5 (14.0–NE)</td>
<td>20.8 (8.8–NE)</td>
<td>20.8 (14.2–NE)</td>
</tr>
<tr>
<td>Median PFS, months</td>
<td>8.1 (4.8–NE)</td>
<td>12.7 (8.8–NE)</td>
<td>11.4 (6.2–18.7)</td>
</tr>
<tr>
<td>Median OS, months</td>
<td>13.3 (8.5–NE)</td>
<td>NR (12.7–NE)</td>
<td>23.3 (14.8–NE)</td>
</tr>
</tbody>
</table>

- Durable ORR and CR benefits despite poor response to first line therapy for relapsed and refractory patients
- Potential synergistic effects via different mechanisms of action and cell-surface targets

Lunsumio + Polivy could offer benefit for R/R DLBCL patients who cannot tolerate, or do not want chemotherapy

Ph III (SUNMO) Lunsumio + Polivy in 2L+ R/R aggressive LBCL

- CD20+ aggressive lymphoma, including: DLBCL, NOS, HGBCL or double/ triple hit, transformed FL, and Grade 3b FL
- ECOG PS 0–2
- ≥1 prior systemic anti-lymphoma therapy
- Ineligible for ASCT

Hematology

1Budde et al. 2024; Nature Medicine 30, 229–239; 2Assouline et al., ASCO 2024; 3Pavlovsky et al., ICML 2023. *Refractory was defined as SD, PD, PR, or CR with relapse <3 months after first-line therapy. Relapse was defined as CR with relapse ≥3 and ≤12 months after 1L therapy. CR=complete response; ORR=Overall response rate; DOR=Duration of Response; PFS=Progression free survival; OS=Overall survival; NE=not evaluable; LBCL=Large B-cell lymphomas; DLBCL=diffuse large B cell lymphoma; NOS=not otherwise specified; HGBCL=high grade B-cell lymphoma; FL=Follicular lymphoma; GemOx= Gemcitabine + oxaliplatin; ASCT= Autologous stem cell transplant; R/R=Relapsed/refractory; SC=Subcutaneous; ECOG PS=Eastern Cooperative Oncology Group Performance Status
**Polivy+R-CHP: New SoC with >23k pts treated to date in 1L DLBCL**

**Ph III (POLARIX): Polivy+R-CHP with a PFS HR of 0.76 at 36 months**

- At 36mo, +7.7% with Pola+R-CHP
- mFU 39.7 months
- HR 0.76$^1$ (CI: 0.60-0.97)

**Reducing DLBCL progression results in cost savings**

- Treating DLBCL progression increases adjusted PPPM costs by over 8000 USD compared with patients who do not progress$^2$

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**Treating progression with CAR-Ts is associated with an 18-fold increase in PPPM cost vs no progression**

- Polivy+R-CHP as 1L DLBCL SoC therapy in guidelines of 18 countries including USA (NCCN category 1), Ger and Japan
Ph III SKYGLO: Adding Columvi to Polivy + R-CHP in 1L DLBCL

Early data support the potential for Columvi in combination with current SoC

- Rapid enrollment as Polivy R-CHP is SoC; addition of Columvi represents a potential improvement, with minimal safety concerns
- SKYGLO began enrollment in 2023; 500+ patients enrolled to date

Ph III (SKYGLO) Columvi + Polivy-R-CHP in 1L DLBCL

Primary endpoint: PFS with 2yr FU by IRC

Pts (N=1130)

*CD20+ LBCL, incl. DLBCL, NOS, HGBCL
*IPI 2-5
*Age 18-80 years
*ECOG 0-2

Columvi + R-CHOP (N=56)

Columvi + Pola-R-CHP (N=24)

Best ORR 93% 100%
CMR 84% 92%
12 m PFS 80% 92%

Ph Ib (NP40126): Columvi + R-CHOP or Pola-R-CHP with high ORR and promising PFS

Progression-free survival (PFS)

- Columvi + R-CHOP/Pola-R-CHP demonstrates durable responses with high ORR and CMR rates, alongside manageable safety profile

SKYGLO is Roche’s ambition to further enhance cure rates in 1L DLBCL

Topp M et al, ASH 2023; DLBCL=diffuse large B cell lymphoma; ORR=overall response rate; CMR=complete metabolic response; R-CHOP=Rituxan + cyclophosphamide + doxorubicin + vincristine + prednisone; Pola-R-CHP=Polivy + Rituxan + cyclophosphamide + hydroxydaunorubicin + prednisone; PFS=progression free survival; SoC=standard of care; NOS=not otherwise specified; HGBCL=high grade B-cell lymphoma; IPI=International prognostic index; ECOG=Eastern Cooperative Oncology Group; IRC=independent review committee; FU= follow-up; yr=year
Ph III GLOBRYTE: Columvi monotherapy in R/R MCL
Updated Ph Ib/II data for Columvi in R/R MCL presented at ASCO 2024

Ph Ib/II (NP30179): Columvi in R/R MCL, incl. post-BTKi, with compelling and durable response rates

<table>
<thead>
<tr>
<th>Overall Pop (n=60)</th>
<th>post-BTKi (n=31)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ORR</strong></td>
<td>85%</td>
</tr>
<tr>
<td></td>
<td>74%</td>
</tr>
<tr>
<td><strong>CR</strong></td>
<td>78%</td>
</tr>
<tr>
<td></td>
<td>71%</td>
</tr>
<tr>
<td><strong>Median DOCR, months</strong></td>
<td>15.4</td>
</tr>
<tr>
<td></td>
<td>12.6</td>
</tr>
<tr>
<td><strong>Median PFS, months</strong></td>
<td>16.8</td>
</tr>
<tr>
<td></td>
<td>8.6</td>
</tr>
<tr>
<td><strong>Median PFS FU, months</strong></td>
<td>17.2</td>
</tr>
<tr>
<td></td>
<td>26.1</td>
</tr>
</tbody>
</table>

Median duration of Columvi therapy was 7.4 months; median number of cycles was 12

- Columvi maintains response rates beyond end of treatment
- Long-term durability of response in heavily pre-treated patients, including those with prior BTKi therapy
- Safety profile manageable and CRS mostly low grade

Ph III (GLOBRYTE) Columvi monotherapy in R/R MCL

Patients (N=182)
- R/R MCL
- ≥1 prior Tx including BTKi

Primary Endpoint: PFS by IRC

Columvi monotherapy
- Rituximab + bendamustine
- Rituximab + lenalidomide

- MCL accounts for 5% of NHL cases with mean OS of only 3-4 years
- There is currently no standard of care for patients with R/R MCL
- Patients with R/R MCL have a poor prognosis, especially those who progress after BTKi therapy

GLOBRYTE currently enrolling R/R MCL patients

1Phillips et al. ASCO 2024; 2Phillips et al.; ASH 2023; 3Inamdar et al. Oncotarget. 2016;7:48692-48731. MCL=Mantle cell lymphoma; ORR=overall response rate; CR=complete response; DOCR=Duration of complete response; PFS=progression free survival; FU=follow-up; BTKi=Bruton’s tyrosine kinase inhibitor; R/R=relapsed or refractory; SCT=stem cell transplant
Lunsumio adds to Roche’s strong presence in FL
Fixed duration treatment that can be given as outpatient regimen

Follicular lymphoma treatment landscape¹,²

<table>
<thead>
<tr>
<th>Stage</th>
<th>Lyphoma Status</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1L</td>
<td>Asymptomatic</td>
<td>Monitor, start Tx as needed</td>
</tr>
<tr>
<td>2L</td>
<td>Low Tumor Burden</td>
<td>Monitor, start Tx as needed</td>
</tr>
<tr>
<td>3L</td>
<td>High Tumor Burden</td>
<td>Lunsumio</td>
</tr>
</tbody>
</table>

Lunsumio is approved for use in 3L+ FL

- Lunsumio delivers high rates of durable CRs in 3L+ FL patients, including those with high-risk disease
- Lunsumio offers patient convenience and health care system efficiencies and cost savings vs CAR-Ts
- Subcutaneous Lunsumio will bring further benefit to FL patients
- Lunsumio is under investigation for use in earlier lines of FL therapy

Lunsumio adds to Roche’s strong presence in FL
Fixed duration treatment that can be given as outpatient regimen

Follicular lymphoma treatment landscape¹,²

<table>
<thead>
<tr>
<th>Stage</th>
<th>Lyphoma Status</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1L</td>
<td>Asymptomatic</td>
<td>Monitor, start Tx as needed</td>
</tr>
<tr>
<td>2L</td>
<td>Low Tumor Burden</td>
<td>Monitor, start Tx as needed</td>
</tr>
<tr>
<td>3L</td>
<td>High Tumor Burden</td>
<td>Lunsumio</td>
</tr>
</tbody>
</table>

Lunsumio is approved for use in 3L+ FL

- Lunsumio delivers high rates of durable CRs in 3L+ FL patients, including those with high-risk disease
- Lunsumio offers patient convenience and health care system efficiencies and cost savings vs CAR-Ts
- Subcutaneous Lunsumio will bring further benefit to FL patients
- Lunsumio is under investigation for use in earlier lines of FL therapy

Lunsumio is the first bispecific antibody approved for R/R FL

DOI:10.1200/CCI.23.00067
Lunsumio + lenalidomide as a chemo-free options in 1/2L FL
Ph III program building on encouraging early results

Ph Ib/II (CO41942): High ORR and CMR rates with durable responses using Lunsumio IV + Len in R/R FL

Duration of response

- CMR
- ORR 90%
- N=29

Main endpoint:
- Age ≥18 years
- Grade 1–3a CD20+ FL
- ECOG PS 0–2
- ≥1 prior systemic anti-lymphoma therapy
- Target enrolment: 400

Ph III (CELESTIMO) Lunsumio IV + Len in R/R FL

Primary endpoint: PFS by IRC

Ph III (MorningLyte, LYSARC led*) Lunsumio SC+ Len in 1L FL

Duration of response

- CR 89%
- N= 37

Main endpoint:
- Age ≥18 years
- Previously untreated
- Grade 1–3a CD20+ FL
- FLIPI 2–5
- ECOG PS 0–2
- Target enrolment: 790

Chemo-free Lunsumio-lenalidomide may be an attractive outpatient regimen for the future management of FL

1Morschhauser et al ASH 2021; 2Nastoupil et al. ASCO 2022 3; 3Morschhauser F, et al ASH 2023; 4The Lymphoma Academic Research Organisation. (2024). MorningLyte (Clinicaltrials.gov Identifier NCT06284122); SC=subcutaneous; FL=follicular lymphoma; ORR=overall response rate; CMR=complete metabolic response; PMR=partial metabolic response; CR=complete response; PET=position emission tomography; *For more information on MorningLyte please contact Franck Morschhauser: franck.morschhauser@chu-lille.fr or Christian Buske: christian.buske@uni-ulm.de
Doing now what patients need next