



Click below to navigate through the document

Company overview

Financial review

Conclusions

Appendix

References

# Q12025 Results

**Investor presentation** April 29, 2025







Click below to navigate through the document

Company overview

Financial review

Conclusions

Appendix

References

### Disclaimer

This presentation contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as "potential," "expected," "will," "planned," "pipeline," "outlook," "confident, or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, potential product launches, or regarding potential future revenues from any such products; or regarding results of ongoing clinical trials; or regarding potential future, pending or announced transactions; regarding potential future sales or earnings; or by discussions of strategy, plans, expectations or intentions, including discussions regarding our continued investment into new R&D capabilities and manufacturing; or regarding our capital structure. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. You should not place undue reliance on these statements. There can be no guarantee that the investigational or approved products described in this presentation will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. Neither can there be any guarantee that the expected benefits or synergies from the transactions described in this presentation will be achieved in the expected timeframe, or at all. In particular, our expectations could be affected by, among other things: uncertainties concerning global healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties regarding the success of key products, commercial priorities and strategy; uncertainties in the research and development of new products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; uncertainties regarding our ability to realize the strategic benefits, operational efficiencies or opportunities expected from our external business opportunities; uncertainties in the development or adoption of potentially transformational digital technologies, including artificial intelligence, and business models; uncertainties surrounding the implementation of our new IT projects and systems; uncertainties regarding potential significant breaches of information security or disruptions of our information technology systems; uncertainties regarding actual or potential legal proceedings, including regulatory actions or delays or government regulation related to the products and pipeline products described in this presentation; safety, quality, data integrity, or manufacturing issues; our performance on and ability to comply with environmental, social and governance measures and requirements; major macroeconomic and geo- and socio-political developments, including the impact of any potential tariffs on our products or the impact of war in certain parts of the world; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and other risks and factors referred to in Novartis AG's most recently filed Form 20-F and in subsequent reports filed with, or furnished to, the US Securities and Exchange Commission. Novartis is providing the information in this presentation as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

All product names appearing in italics are trademarks owned by or licensed to Novartis.

This presentation includes non-IFRS financial measures, including Constant currencies (cc), core results and free cash flow. An explanation of non-IFRS measures can be found on page 31 of the Novartis First Quarter 2025 Condensed Interim Financial Report.







Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

References

## Company overview

Vas Narasimhan, M.D.
Chief Executive Officer







Click below to navigate through the document

**Company overview** 

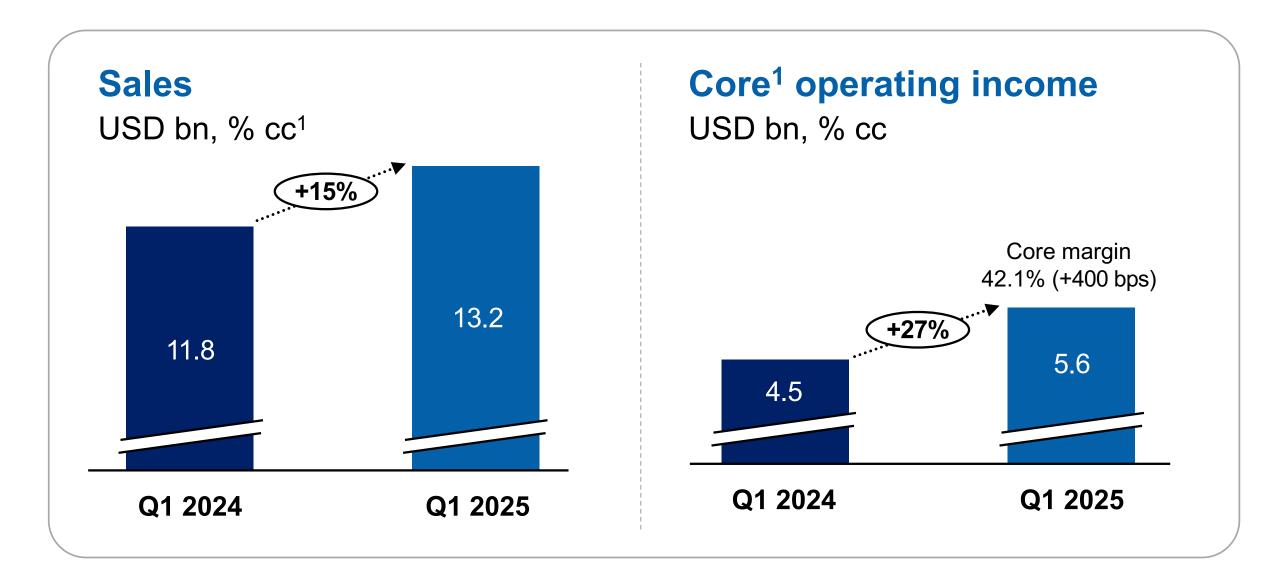
Financial review

Conclusions

**Appendix** 

References

# Novartis delivered double-digit sales growth and robust margin expansion in Q1, supporting upgrade to FY 2025 guidance



### **Innovation highlights**

Pluvicto® FDA approval for pre-taxane mCRPC

Vanrafia® FDA accelerated approval for IgAN

Fabhalta® FDA, EC and NMPA approvals for C3G

Remibrutinib global submissions for CSU

**OAV101 IT** Ph3 STEER study positive readout in SMA

FY 2025 guidance upgraded<sup>2</sup>: Sales expected to grow high single-digit, and core operating income to grow low double-digit



<sup>1.</sup> Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

<sup>2.</sup> Please see detailed guidance assumptions on slide 22.



Click below to navigate through the document

**Company overview** 

Financial review

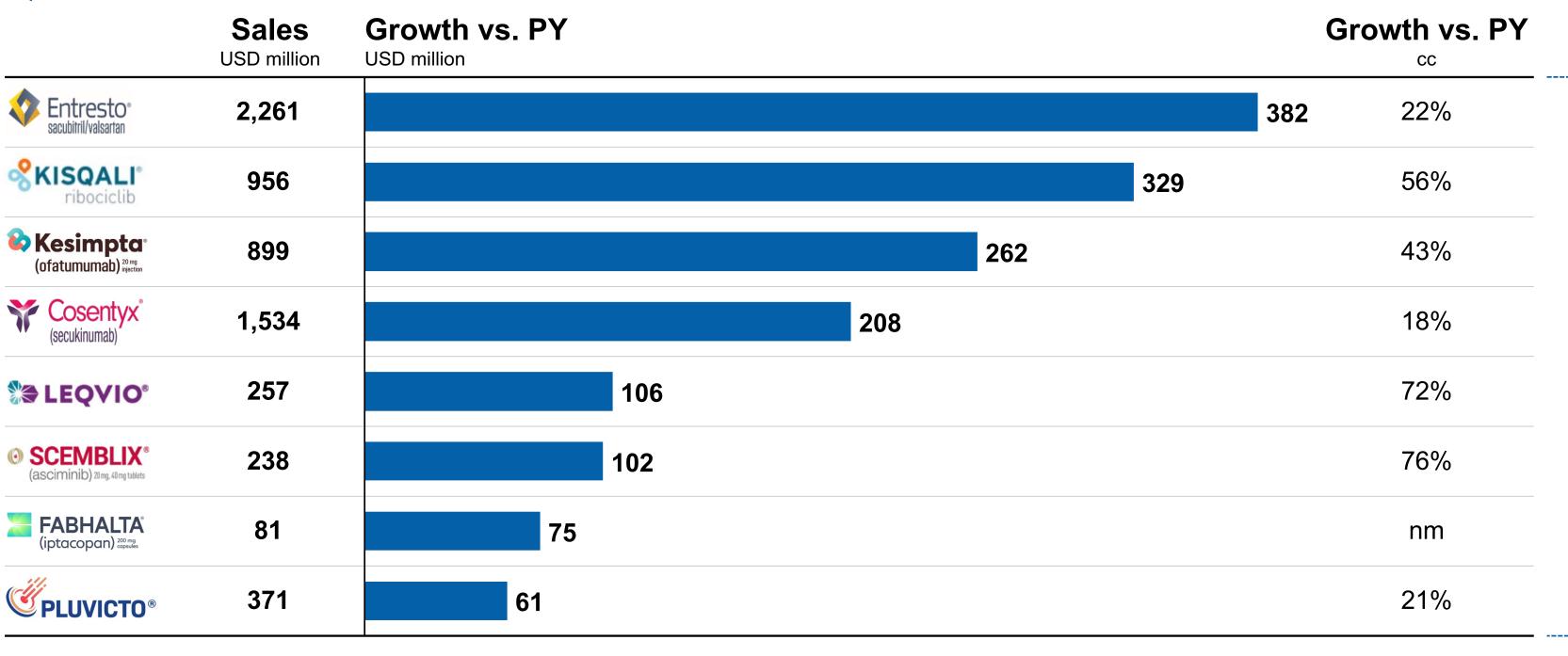
Conclusions

**Appendix** 

References

# Strong momentum from priority brands continued to drive robust growth, demonstrating our replacement power

### Q1 sales



Strong growth
+32% cc
excl. Entresto +38% cc

Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

**Appendix** 

References

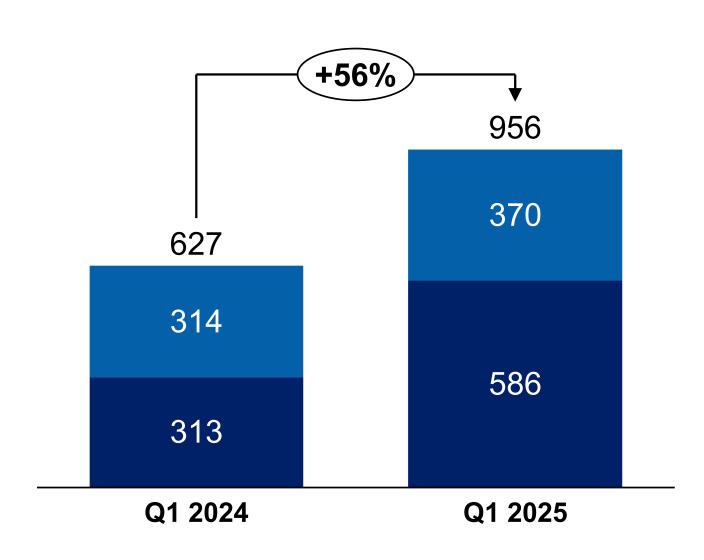
## Kisqali® grew +56% cc, reflecting positioning as CDK4/6 inhibitor of choice across mBC and eBC



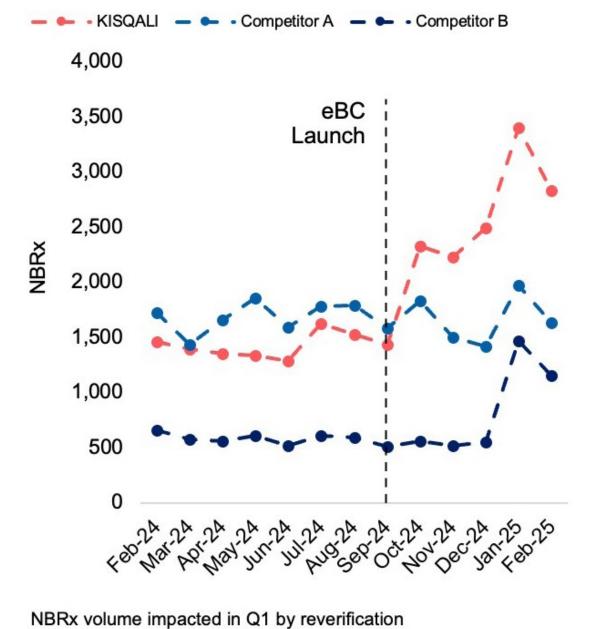
### Sales evolution

USD m, % cc

US Ex-US







### US: +87% in Q1

- Leading share in mBC NBRx at 48%<sup>2</sup>; now tied for TRx leadership
- eBC NBRx grew 65% with share reaching 60%<sup>2</sup>;
   56% of volume from exclusive population

### Ex-US: +24% cc in Q1

- mBC leader in top 10 countries with 46%<sup>3</sup>
   NBRx share and 35%<sup>3</sup> TRx share
- eBC now approved in EU + 9 countries;
   Germany eBC NBRx share at 67%<sup>4</sup>

### Strong guidelines support

- Category 1 Preferred NCCN Guidelines recommendation in both mBC and eBC
- Only CDK4/6i with highest ESMO magnitude of benefit score for mBC and eBC

See page 72 for references (footnotes 1-4). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

References

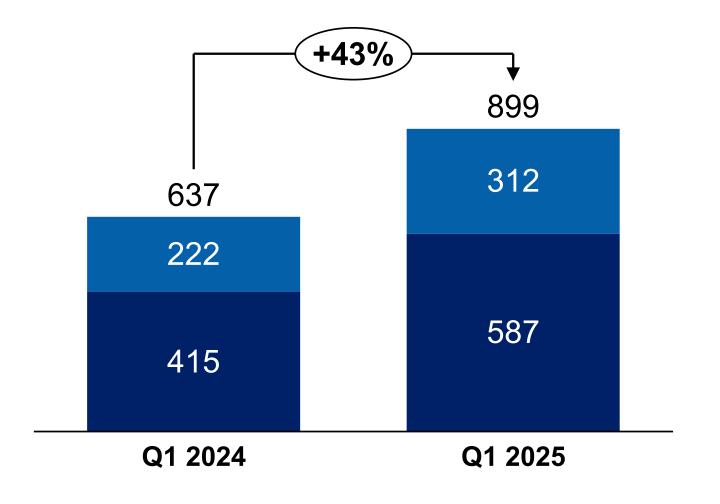
### Kesimpta® grew +43% cc, outpacing both B-cell and MS market

Kesimpta®

### Sales evolution

USD m, % cc





### **Continued robust demand growth**

- US: +41%, with TRx growth (+29% vs. PY) outpacing B-cell (+12%) and MS (+3%) markets; highest quarterly NBRx volume since launch
- Ex-US: +45% cc, with leading NBRx share in patients in 8/10 major markets<sup>1</sup>

### 7-year data at AAN reinforce favorable benefit/risk profile

• ALITHIOS OLE: ~9/10 recently diagnosed and treatment naive RMS patients showed delays in disability progression based on 6-month PIRA at year 7<sup>2,3</sup>

### Convenience of at-home self-administration

- First and only B-cell treatment option intentionally designed for self-administration
- One dose delivers consistent treatment benefits across BMI subgroups<sup>4</sup>
- One minute, once a month, at home or on the go, no pre-medications<sup>5</sup>

See page 72 for references (footnotes 1-5). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. OLE: Open-label extension study.



Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

**Appendix** 

References

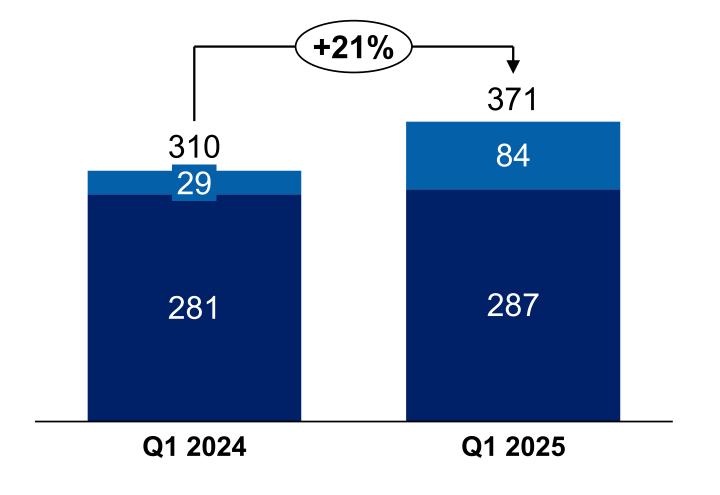
# Pluvicto® grew +21% cc in Q1, laying the foundation for mCRPC pre-taxane launch in US



### Sales evolution

USD m, % cc





### Market leader in mCRPC post-taxane setting

- Leading NBRx in VISION 1L setting (~40%), closest to PSMAfore population
- Encouraging momentum in VISION NBRx (>1.9k NBRx, +9% vs. PQ)
- Gaining traction in community setting (~4k TRx, +11% vs. PY)
- Ex-US: Continuous growth driven by Europe and expansion into 20+ countries

### March FDA approval in pre-taxane setting based on PSMAfore

- Pluvicto more than doubled median rPFS with favorable safety and tolerability vs. daily oral ARPI
- Final OS analysis unadjusted for crossover numerically favored Pluvicto with HR 0.91; crossover-adjusted<sup>1</sup> HR 0.59
- NCCN Guidelines already updated to recommend Pluvicto in the PSMAfore setting

### **Continuing to advance Pluvicto LCM**

PSMAddition readout in mHSPC expected H2 2025; incidence similar to mCRPC population

See page 72 for references (footnote 1). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

**Appendix** 

References

### Confident in growth acceleration with PSMAfore launch in US



### **Strong foundation in place**

- PSMAfore population ~2x VISION
- **~620 sites opened** (+5% vs. PQ)
- Pre-filled syringe national launch enabling broad adoption
- ~50% of PSMAfore patients
   treated by key HCPs who have
   prescribed in VISION
- Increased promotional spend (doubled FF, DTC)

### **Launch dynamics**

- for new patients to be treated
- Initial uptake driven by depth in established accounts with high VISION 1L share
- Expanding breadth in community and urology over time
- Favorable NCCN Guidelines recommendation supporting access and reimbursement confidence



Infusion







Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

Appendix

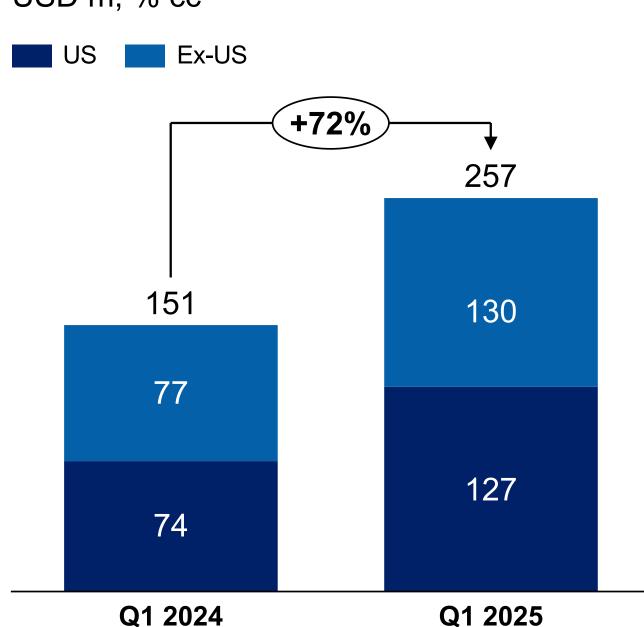
References

### Leqvio® grew +72% cc in Q1, on track to achieve blockbuster status in 2025



### Sales evolution

USD m, % cc



### US: +72%, outpacing advanced lipid-lowering market<sup>1,2</sup>

- Steady climb in MOTRx, +70% vs. PY (vs. market +37%), with growth across all channels
- Increasing depth in priority systems, +10% vs. PQ and +51% vs. PY
- Evolved field operating model to support continued growth and customer impact

### Ex-US: +74% cc, with robust growth in all markets

- Solid pricing and access secured in Japan
- Continued out-of-pocket market expansion in China

### Significant runway to expand the market

- 2025 ACC/AHA ACS Guidelines now recommend use of non-statin LLT
- Only 2% of secondary prevention patients in US receive aLLT within 12 months of event

See page 72 for references (footnotes 1-2). Constant currencies (cc) is a non-IFRS measure. An explanation can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. Novartis obtained global rights to develop, manufacture, and commercialize Leqvio under license/collaboration agreement with Alnylam Pharmaceuticals.







Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

Appendix

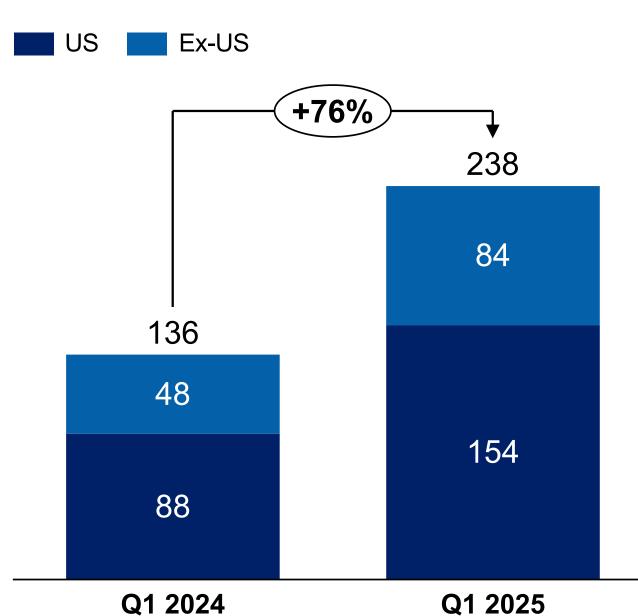
References

# Scemblix® market leadership continues globally in 3L+, with early lines launch driving momentum in the US



### Sales evolution

USD m, % cc



### Consistent leadership in 3L+ CML

- US: NBRx share of 54%, >3x higher than next competitor<sup>1</sup>
- Ex-US: NBRx leadership (68% in JP, 47% in DE)<sup>2</sup> and 47% total share in key markets<sup>3</sup>

### Continued momentum in early lines launch in US

- Strong start driven by clinical profile (including NCCN Guidelines Category 1 Preferred recommendation) and expanded payer coverage (54% of Commercial lives PA to label)
- Expanding prescriber breadth, +16% vs. PQ
- Strong uptake in 2L, with NBRx leadership (40% share)<sup>1</sup>
- Making inroads in 1L with 10% NBRx share<sup>1</sup>

### Early line approvals on track globally

- Early lines indication approved in 10 countries
- Regulatory submission to EMA completed

See page 73 for references (footnotes 1-3). Constant currencies (cc) is a non-IFRS measure. An explanation can be found on page 31 of Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

**Appendix** 

References

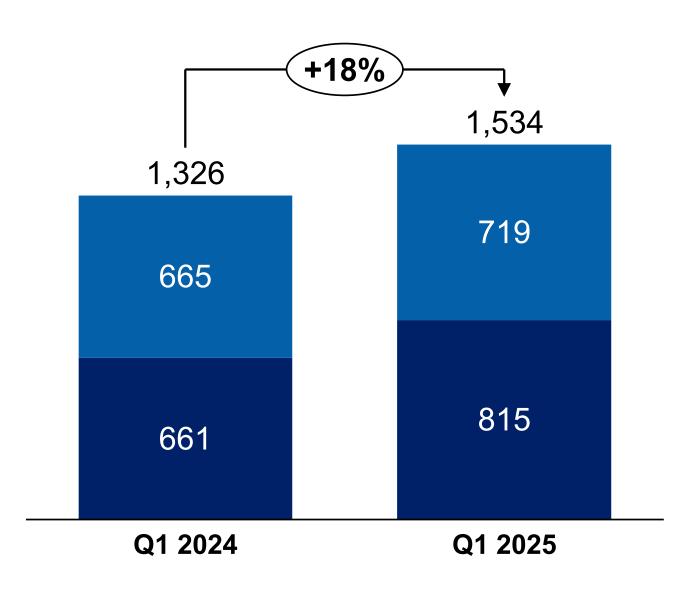
# Cosentyx® grew +18% cc, with ongoing launches in HS and IV and expansion in core indications



### Sales evolution

USD m, % cc





### **US** continued strong growth (+23%)

- Strong demand growth (+29%) more than offsetting Medicare Part D redesign impact
- NBRx volume outperforming the market in core indications QoQ (+15% vs. market in PsO, +12% SpA)<sup>1</sup>
- Continued NBRx leadership in HS (~53%)<sup>1</sup>
- Accelerated adoption in IV (>1,900 accounts, +13% QoQ)<sup>2</sup>

### Ex-US growth (+12% cc) driven by demand

- Delivered +15% volume growth, mainly in core indications
- Leading originator biologic in EU<sup>3</sup> and China<sup>4</sup>
- HS reimbursed in key markets<sup>5</sup>; approved by China NMPA in Q1

### **Confident in continued growth**

Anticipating two Ph3 readouts in 2025: GCA and PMR

See page 73 for references (footnotes 1-5). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. SpA refers to the Cosentyx indications in psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA), and ankylosing spondylitis (AS).





Click below to navigate through the document

**Company overview** 

Financial review

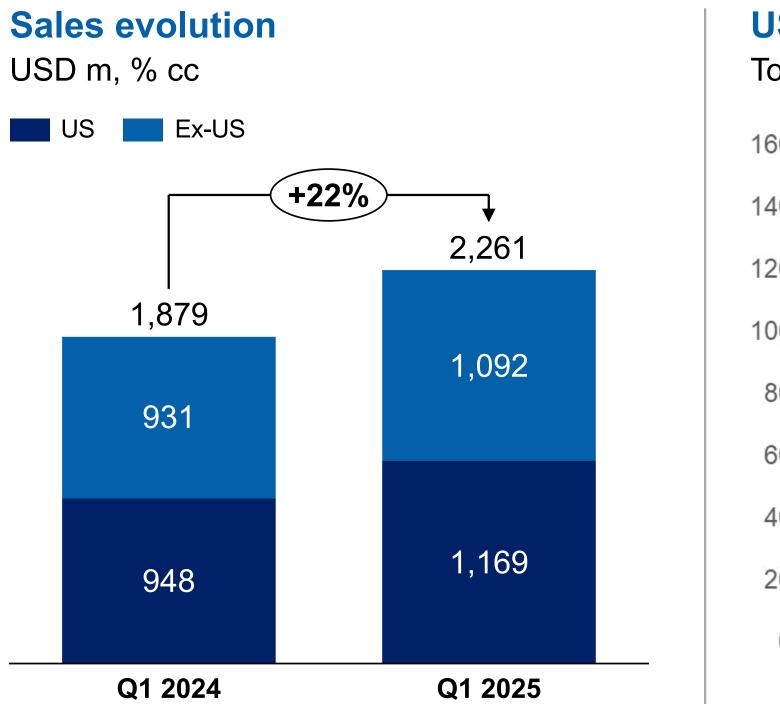
Conclusions

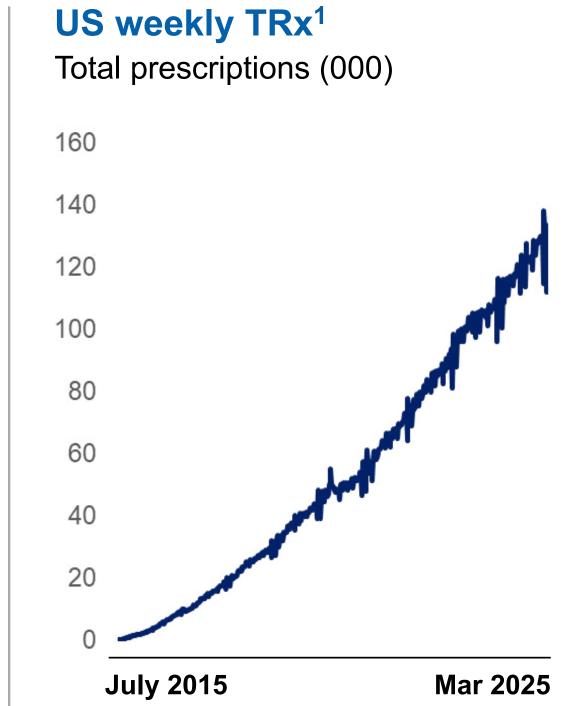
Appendix

References

### Entresto® delivered consistent performance, growing +22% cc in Q1







## **Expect continued growth ex-US post US LoE**

- Strong guideline position<sup>2</sup> (US/EU)
- Balanced geographic sales<sup>3</sup>: US ~50%,
   Europe ~20%, China ~10%, Japan ~5%
- Ex-US: RDP to Nov 2026<sup>4</sup> in EU, Jun 2030 in Japan, with possible additional protection
- US: For forecasting purposes, we assume Entresto® LoE in mid-2025<sup>5</sup>

See page 73 for references (footnotes 1-5). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

**Appendix** 

References

## Renal portfolio continues to expand, with ongoing US Fabhalta<sup>®</sup> launches and Vanrafia<sup>®</sup> FDA accelerated approval

### **Fabhalta**



### **IgAN**

>100% volume growth, >60% increase in writers vs. PQ<sup>1</sup>

>90% patients remaining on treatment after 5 months<sup>2</sup>

68% commercial PA to label coverage in <9 months post-launch

### C3G

Approved by FDA in March; first patient treated within 5 days

>2K HCPs REMS certified applicable to IgAN and C3G

**Approved in EU** in Q1, **China** in April

### Vanrafia



### **IgAN**

Approved by FDA in April based on Ph3 ALIGN study

Once-daily, non-steroidal, oral treatment

Seamless add-on to supportive care with **no dosing adjustment or discontinuation needed**for RAS inhibitors<sup>3</sup>

First and only ETA receptor antagonist approved with **no REMS** for hepatotoxicity or pregnancy<sup>3,4</sup>

Strong commercial synergies across portfolio >>>

See page 74 for references (footnotes 1-4). 5. Use of Vanrafia is contraindicated in patients who are pregnant and patients with hypersensitivity. Serious warnings associated with Vanrafia include embryo-fetal toxicity, hepatotoxicity, fluid retention, and decreased sperm counts.





Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

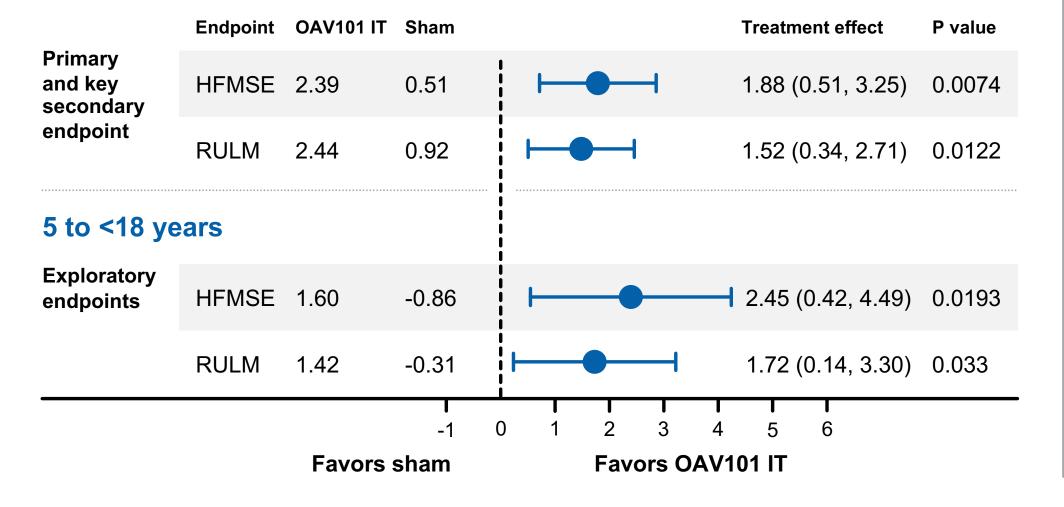
**Appendix** 

References

# OAV101 IT: STEER & STRENGTH studies underscore positive benefit/risk profile of one-time treatment in broad SMA population

### Ph3 STEER study in treatment-naive SMA patients

### 2 to <18 years



### Clinical benefit in broad population

### > STEER study

Primary endpoint met with 2.39-point improvement in HFMSE, a gold standard in SMA, vs. 0.51 sham

Robust treatment effect in patients over 5 years of age

### STRENGTH study

Treatment-experienced patients stabilized motor function over 52 weeks, a key goal for patients on chronic therapies

### Favorable safety profile

Consistent across all studies to date (STRONG, STEER & STRENGTH), with data in treated patients extending >5 years

Next steps > Global regulatory submissions planned in H1 2025





Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

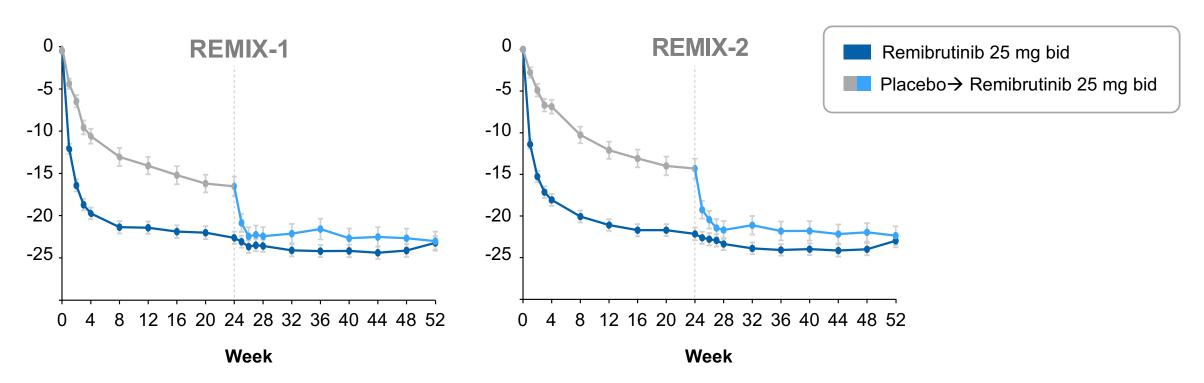
**Appendix** 

References

# Remibrutinib: Long-term data in CSU support differentiated profile of this potential pipeline-in-a-pill; FDA decision expected H2 2025

### **REMIX** studies: Strong efficacy<sup>1,2</sup> with oral convenience

Change from baseline in UAS7 (mean ± SE)



- Meaningful improvement in symptom control across all measures<sup>3</sup> as early as week 1 and sustained to week 52
- Favorable safety profile<sup>4</sup> up to 52 weeks, including balanced LFTs

### **Achieving key milestones in CSU**

- NEJM publication of REMIX 24-week results
- Completed submissions in US with PRV, EU and China
- Initiated HTH study vs. dupilumab; readout exp. 2027<sup>5</sup>

### **Advancing indications beyond CSU**

- CINDU: Ph3 ongoing, targeting 2026 submission
- HS: Ph3 studies started in Q1
- **FA**: Ph2a/b ongoing, readout expected H2 2025
- **RMS:** Ph3 ongoing, readout expected in 2026
- **gMG**: Ph3 ongoing, readout expected in 2028

Next steps > FDA decision on CSU indication expected H2 2025

See page 74 for references (footnotes 1-5).





Click below to navigate through the document

**Company overview** 

Financial review

Conclusions

Appendix

References

### Key innovation milestones in 2025

2025 selected key events (expected)		H1 2025	H2 2025	Status as of end Q1
Regulatory	Atrasentan IgAN	US		US approval in April
decisions	Fabhalta® (iptacopan) C3G	US, JP	EU	US, EU approvals in Q1, China approval in April
uccisions	Pluvicto® mCRPC, pre-taxane	US		US approval in Q1
	Scemblix® 1L CML		JP	
Submissions	Remibrutinib CSU	US, EU, CN		US, EU and China submissions in Q1, China priority review granted
	Zolgensma® SMA IT	US, EU	JP	Ph3 STEER & STRENGH data presented at MDA 2025
	Scemblix® CML 1L	EU		EU submission in Q1
	Pluvicto® mHSPC		US	
	Cosentyx® GCA		US, EU	
Readouts	Cosentyx® GCA	Ph3 (GCAPTAIN)		
	Cosentyx® PMR		Ph3 (REPLENISH)	
	lanalumab SjS		Ph3s (NEPTUNUS-1 and -2)	
	Ianalumab 2L ITP		Ph3 (VAYHIT2)	
	Pluvicto® mHSPC		Ph3 (PSMAddition)	
	Remibrutinib FA		Ph2	
	lanalumab HS	Ph2		
	Votoplam (PTC518) HD <sup>1</sup>	Ph2		
Key study	Remibrutinib HS	Ph3		Ph3 trials RECHARGE-1 and -2 started in Q1
starts	Remibrutinib gMG	Ph3		Ph3 trial RELIEVE started in Q1
Starts	Ac-PSMA-617 PC	Ph3		
	YTB323 AAV	Ph2		Ph2 trial started in Q1
	JSB462 (AR degrader) PC		Ph2	
	GIA632 (IL-15 mAb)		Ph2	
	QCZ484 rHTN		Ph2	Ph2 trial started in Q1
	VHB937 (TREM2) AD		Ph2	

<sup>1.</sup> Ongoing study shown is sponsored by PTC Therapeutics. Novartis has obtained global rights to develop, manufacture, and commercialize votoplam under License & Collaboration agreement with PTC Therapeutics.







Click below to navigate through the document

Company overview

**Financial review** 

Conclusions

Appendix

References

## Financial review and 2025 guidance

**Harry Kirsch** 

**Chief Financial Officer** 





Click below to navigate through the document

Company overview

**Financial review** 

Conclusions

**Appendix** 

References

### Q1 net sales increased +15% cc, with strong core<sup>1</sup> margin expansion

Key figures <sup>1</sup>	Q1	Q1	Change	e vs. PY
USD million	2024	2025	% USD	% cc
Total net sales	11,829	13,233	12	15
Core operating income	4,537	5,575	23	27
Core margin	38.4%	42.1%	+3.7% pts	+4.0% pts
Operating income	3,373	4,663	38	44
Net income	2,688	3,609	34	37
Core EPS	1.80	2.28	27	31
EPS	1.31	1.83	40	42
Free cash flow	2,038	3,391	66	



<sup>1.</sup> Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



Click below to navigate through the document

Company overview

**Financial review** 

Conclusions

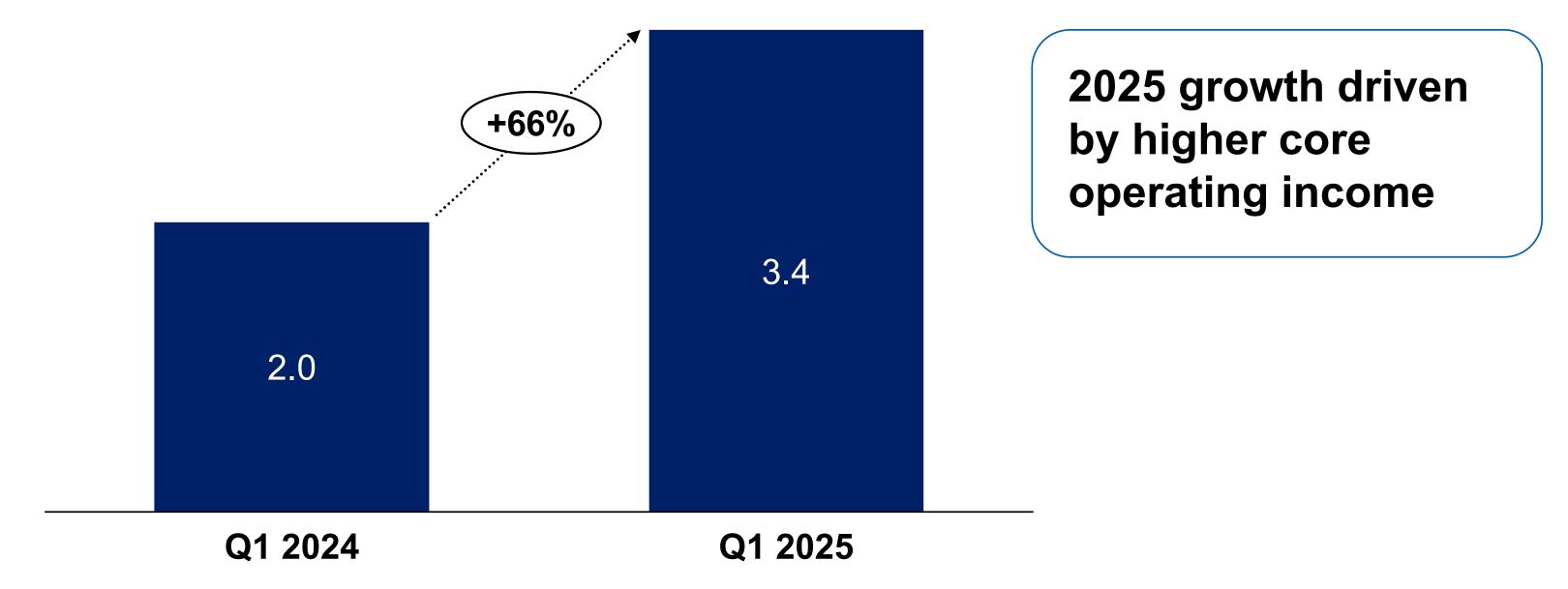
Appendix

References

### Continued focus on Free Cash Flow generation

### Free Cash Flow<sup>1</sup>

USD bn, period rates



1. Free Cash Flow and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





Click below to navigate through the document

Company overview

**Financial review** 

Conclusions

**Appendix** 

References

### Continuing our shareholder-friendly capital allocation strategy

### **Investing in the business**

### **Investments in organic business**

Ongoing investment in R&D and CapEx, e.g., five-year USD 23bn investment in the US

### **Value-creating bolt-ons**

Acquisition of Anthos Therapeutics (closed in April)

### Returning capital to shareholders

### Consistently growing annual dividend<sup>1</sup>

USD 7.8bn dividend paid in March/April 2025<sup>2</sup>

### **Share buybacks**

Up-to USD 15bn share buyback continuing, with up to USD 2.7bn still to be executed<sup>3</sup>

**Substantial** 

cash

generation



<sup>1.</sup> In CHF. 2. USD 5.3 billion annual net dividend payment in March, which is the gross dividend of USD 7.8 billion reduced by the USD 2.5 billion Swiss withholding tax that was paid in April 2025, according to its due date. 3. As of March 31, 2025.



Click below to navigate through the document

Company overview

**Financial review** 

Conclusions

**Appendix** 

References

### Raising Novartis 2025 full year guidance

Expected, barring unforeseen events; growth vs. PY in cc<sup>1</sup>

### **Net sales**

expected to grow high single-digit

(from mid- to high single-digit)

### **Core operating income**

expected to grow low double-digit

(from high single to low double-digit)

### **Key assumptions<sup>2</sup>**

• We assume Tasigna®, Promacta® and Entresto® US generic entry mid-2025 for forecasting purposes²

### FY guidance on other financial KPIs

- Core net financial result: Expenses expected to be around USD 1bn
- Core tax rate: Expected to be around 16-16.5%



<sup>1.</sup> Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.
2. Timing of Entresto US generic entry is subject to ongoing patent and regulatory litigation.



Click below to navigate through the document

Company overview

Financial review

Conclusions

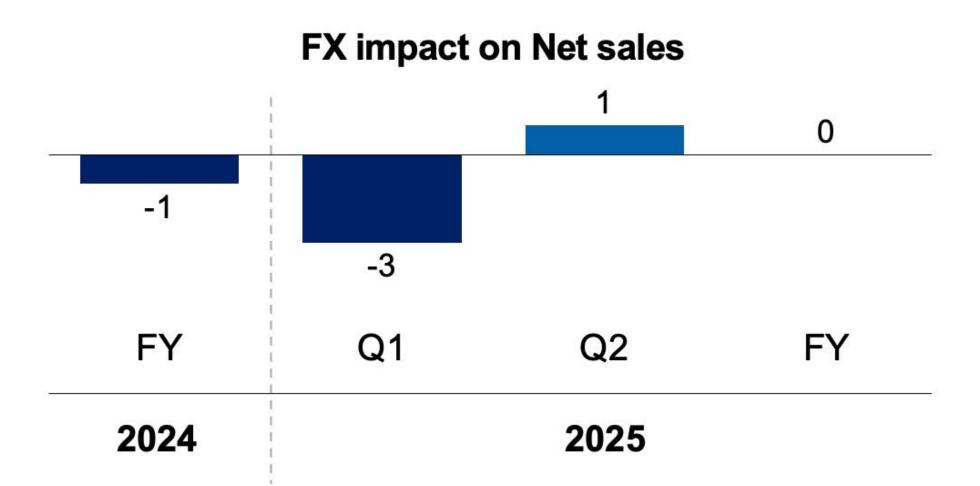
Appendix

References

### **Expected currency impact for Q2 and full year 2025**

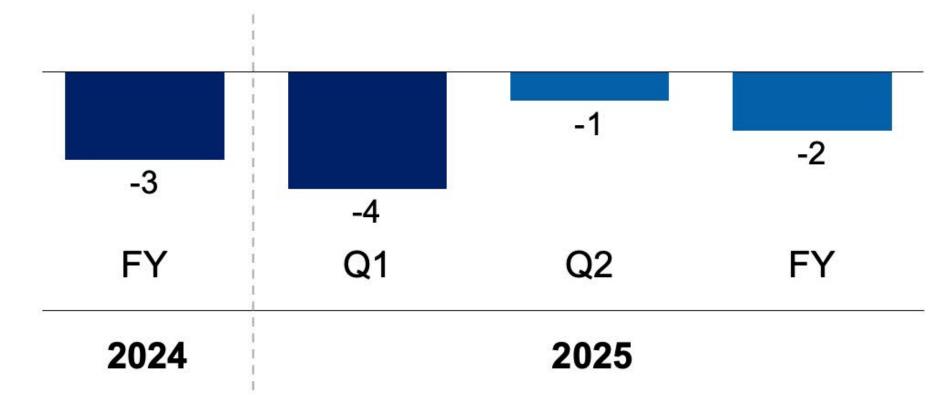
### **Currency impact vs. PY**

%pts, assuming late-April exchange rates prevail in 2025





### **FX** impact on Core operating income







Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

References

## Conclusions

Vas Narasimhan, M.D. **Chief Executive Officer** 







Click below to navigate through the document

Company overview

Financial review

**Conclusions** 

**Appendix** 

References



Strong start to
the year, with
double-digit sales
growth and robust
core margin
expansion



Upgraded guidance for FY 2025



Significant
pipeline progress,
including three new
product approvals



Confident in achieving our mid- to long-term growth outlook

Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview Financial performance Innovation: Clinical trials **Abbreviations** 

References

## Appendix







Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

**Innovation: Pipeline overview** 

Financial performance Innovation: Clinical trials **Abbreviations** 

References

### Our pipeline projects at a glance

	Phase I/II	Phase III	Registration	Total
Oncology	23	9	1	33
Solid tumors Hematology	18 5	<b>4 5</b>	1	23 10
Immunology	14	8	1	23
Neuroscience	8	7	0	15
Cardiovascular, Renal and Metabolic	7	8	0	15
Others (thereof IB&GH)	10 (9)	3 (3)	2 (2)	15
	62	35	4	101

IB&GH: In-market Brands and Global Health.





Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

**Innovation: Pipeline overview** 

Financial performance Innovation: Clinical trials **Abbreviations** 

References

### Novartis pipeline in Phase I

Oncology				
Code	Name	Mechanism	Indication(s)	
Solid to	umors			
AAA603	<sup>177</sup> Lu-NeoB	Radioligand therapy target GRPR	Breast cancer	
			Glioblastoma multiforme	
AAA617	Pluvicto <sup>®</sup>	Radioligand therapy target PSMA	Metastatic neuroendocrine prostate cancer	
AAA802	<sup>225</sup> Ac-PSMA-R2	Radioligand therapy target PSMA	Prostate cancer	
AAA817	<sup>225</sup> Ac-PSMA-617	Radioligand therapy target PSMA	Metastatic castration-resistant prostate cancer	
ECI830	ECI830	CDK2 inhibitor	Breast cancer	
FXX489	<sup>177</sup> Lu-NNS309	Radioligand therapy	Solid tumors	
HRO761	HRO761	Werner inhibitor	Solid tumors	
IAG933	IAG933	-	Mesothelioma	
KFA115	KFA115	Novel immunomodulatory Agent	Solid tumors	
MGY825	MGY825	-	NSCLC	
Hematology				
DFV890	DFV890	NLRP3 inhibitor	Low risk myelodysplastic syndrome	
PIT565	PIT565	-	B-cell malignancies	
YTB323	rapcabtagene autoleucel	CD19 CAR-T	Adult ALL	

Cardio	Cardiovascular, Renal and Metabolic				
Code	Name	Mechanism	Indication(s)		
DFV890	DFV890	NLRP3 inhibitor	Cardiovascular risk reduction		

### 16 lead indications

Lead indication

Neuroscience					
Code	Name	Mechanism	Indication(s)		
DFT383	DFT383	CTNS gene delivery	Cystinosis		
NIO752	NIO752	Tau antisense oligonucleotide	Alzheimer's disease		
			Progressive supranuclear palsy		
YTB323	rapcabtagene autoleucel	CD19 CAR-T	Relapsing multiple sclerosis		
			Primary progressive multiple sclerosis		
			Generalized Myasthenia Gravis		

Immunology				
Code	Name	Mechanism	Indication(s)	
IPX643	IPX643	-	Inflammation-driven diseases	
PIT565	PIT565	-	Systemic lupus erythematosus	
YMI024	YMI024	-	Inflammation-driven diseases	

Others					
Code	Name	Mechanism	Indication(s)		
IB&GH					
EDI048	EDI048	CpPI(4)K inhibitor	Cryptosporidiosis		
ITU512	ITU512	HbF inducing agent	Sickle cell disease		





Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

**Innovation: Pipeline overview** 

Financial performance Innovation: Clinical trials **Abbreviations** 

References

### Novartis pipeline in Phase II

Oncol	Oncology					
Code	Name	Mechanism	Indication(s)			
Solid to	umors					
AAA601	Lutathera <sup>®</sup>	Radioligand therapy target SSTR	GEPNET, pediatrics			
			1L ES-SCLC			
			Glioblastoma			
AAA603	<sup>177</sup> Lu-NeoB	Radioligand therapy target GRPR	Multiple solid tumors			
AAA614	AAA614	Radioligand therapy target FAP	Solid tumors			
DZR123	tulmimetostat	EZH1, EZH2 inhibitor	Solid tumors & lymphomas			
JSB462	luxdegalutamide	Androgen receptor protein degrader	Prostate cancer			
Hematology						
ABL001	Scemblix <sup>®</sup>	BCR-ABL inhibitor	Chronic myeloid leukemia, pediatrics			
YTB323	rapcabtagene autoleucel	CD19 CAR-T	1L high-risk large B-cell lymphoma			

Neuro	science		
Code	Name	Mechanism	Indication(s)
HTT227	votoplam	Huntingtin Modulator	Huntington's disease
VHB937	VHB937	TREM2 stabilizer and activator	Amyotrophic lateral sclerosis

Cardiovascular, Renal and Metabolic				
Code	Name	Mechanism	Indication(s)	
LNP023	Fabhalta <sup>®</sup>	CFB inhibitor	Lupus nephritis	
			ANCA associated vasculitis	
LTP001	LTP001	SMURF1 inhibitor	Pulmonary arterial hypertension <sup>1</sup>	
			Idiopathic pulmonary fibrosis	
QCZ484	QCZ484	-	Hypertension	
TIN816	TIN816	ATP modulator	Acute kidney injury	

1. Phase I / II.

### 17 lead indications

Lead indication

Immui	lmmunology					
Code	Name	Mechanism	Indication(s)			
DFV890	DFV890	NLRP3 inhibitor	Osteoarthritis			
LOU064	remibrutinib	BTK inhibitor	Food allergy			
MAS825	MAS825	IL1B, IL18 Inhibitor	NLRC4-GOF indications			
NGI226	NGI226	-	Tendinopathy			
RHH646	RHH646	-	Osteoarthritis			
VAY736		BAFF-R inhibitor, ADCC-	Hidradenitis suppurativa			
		mediated B-cell depletor	Systemic scleroderma			
YTB323	rapcabtagene autoleucel	CD19 CAR-T	srSLE/LN			
			Systemic scleroderma			
			Myositis			
			ANCA associated vasculitis			

Others				
Code	Name	Mechanism	Indication(s)	
IB&GH				
EYU688	EYU688	NS4B inhibitor	Dengue fever	
INE963	INE963	Plasmodium falciparum inhibitor	Malaria, uncomplicated	
KAE609	cipargamin	PfATP4 inhibitor	Malaria, severe	
			Malaria, uncomplicated	
LXE408	LXE408	Proteasome inhibitor	Visceral leishmaniasis	
PKC412	Rydapt <sup>®</sup>	Multi-targeted kinase inhibitor	Acute myeloid leukemia, pediatrics	
SEG101	Adakveo <sup>®</sup>	P-selectin inhibitor	Sickle cell disease, pediatrics	
Others				
LNP023	Fabhalta <sup>®</sup>	CFB inhibitor	iAMD	





Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

**Innovation: Pipeline overview** 

Financial performance Innovation: Clinical trials **Abbreviations** 

References

### Novartis pipeline in Phase III

Oncology				
Code	Name	Mechanism	Indication(s)	
Solid to	umors			
AAA601	Lutathera®	Radioligand therapy target SSTR	Gastroenteropancreatic neuroendocrine tumors	
AAA617	Pluvicto <sup>®</sup>	Radioligand therapy target PSMA	Metastatic hormone sensitive prostate cancer (mHSPC)	
			Oligometastatic prostate cancer	
BYL719	Vijoice <sup>®</sup>	PI3K-alpha inhibitor	Lymphatic malformations	
Hemato	ology			
DAK539	pelabresib	BET inhibitor	Myelofibrosis	
LNP023	Fabhalta <sup>®</sup>	CFB inhibitor	Atypical hemolytic uraemic syndrome	
VAY736	ianalumab	BAFF-R inhibitor, ADCC- mediated B-cell depletor	1L Immune Thrombocytopenia	
			2L Immune Thrombocytopenia	
			warm Autoimmune Hemolytic Anemia	

Cardiovascular, Renal and Metabolic				
Code	Name	Mechanism	Indication(s)	
FUB523	zigakibart	Anti-APRIL	IgA nephropathy	
KJX839	Leqvio <sup>®</sup>	siRNA (regulation of LDL-C)	CVRR (secondary prevention)	
			CVRR (primary prevention)	
			Hyperlipidemia, pediatrics	
LNP023	Fabhalta <sup>®</sup>	CFB inhibitor	C3 glomerulopathy, pediatrics	
			IC-MPGN	
MAA868	abelacimab	FXI inhibitor	Atrial fibrillation	
TQJ230	pelacarsen	ASO targeting Lp(a)	Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein (a) (CVRR-Lp(a))	

### 6 lead indications

Lead indication

Neuroscience			
Code	Name	Mechanism	Indication(s)
BAF312	Mayzent®	S1P1,5 receptor modulator	Multiple sclerosis, pediatrics
LNP023	Fabhalta <sup>®</sup>	CFB inhibitor	Myasthenia gravis
LOU064	remibrutinib	BTK inhibitor	Multiple sclerosis
			Myasthenia gravis
OAV101	onasemnogene abeparvovec	SMN1 gene replacement therapy	SMA IT administration
OMB157	Kesimpta <sup>®</sup>	CD20 Antagonist	Multiple sclerosis, pediatrics
			Multiple sclerosis, new dosing regimen

Immunology				
Code	Name	Mechanism	Indication(s)	
AIN457	Cosentyx®	IL17A inhibitor	Giant cell arteritis	
			Polymyalgia rheumatica	
LOU064	remibrutinib	BTK inhibitor	Chronic spontaneous urticaria, pediatrics	
			Chronic inducible urticaria	
			Hidradenitis suppurativa	
VAY736	ianalumab	BAFF-R inhibitor, ADCC-	Sjögren's	
		mediated B-cell depletor	Lupus Nephritis	
			Systemic lupus erythematosus	

Others				
Code	Name	Mechanism	Indication(s)	
IB&GH				
AMG334	Aimovig <sup>®</sup>	CGRPR antagonist	Migraine, pediatrics	
KLU156	Ganaplacide + lumefantrine	Non-artemisinin plasmodium falciparum inhibitor	Malaria, uncomplicated	
QMF149	Atectura <sup>®</sup>	LABA + ICS	Asthma, pediatrics	





Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

Innovation: Pipeline overview

Financial performance
Innovation: Clinical trials
Abbreviations

References

### Novartis pipeline in registration

Oncology				
Code	Name	Mechanism	Indication(s)	
Solid tu	ımors			
AAA601 <sup>1</sup>	Lutathera <sup>®</sup>	Radioligand therapy target SSTR	Gastroenteropancreatic neuroendocrine tumors (GEP-NET), 1st line in G2/3 tumors	

Others				
Code	Name	Mechanism	Indication(s)	
IB&GH				
COA566	Coartem®	Artemisinin combination therapy	Malaria, uncomplicated (<5kg patients)	
RTH258	Beovu <sup>®</sup>	VEGF Inhibitor	Diabetic retinopathy	

### 1 lead indication

Immunology				
Code	Name	Mechanism	Indication(s)	
LOU064	remibrutinib	BTK inhibitor	Chronic spontaneous urticaria	



<sup>1. 177</sup>Lu-dotatate in US.



Click below to navigate through the document

Company overview

Financial review

Conclusions

#### **Appendix**

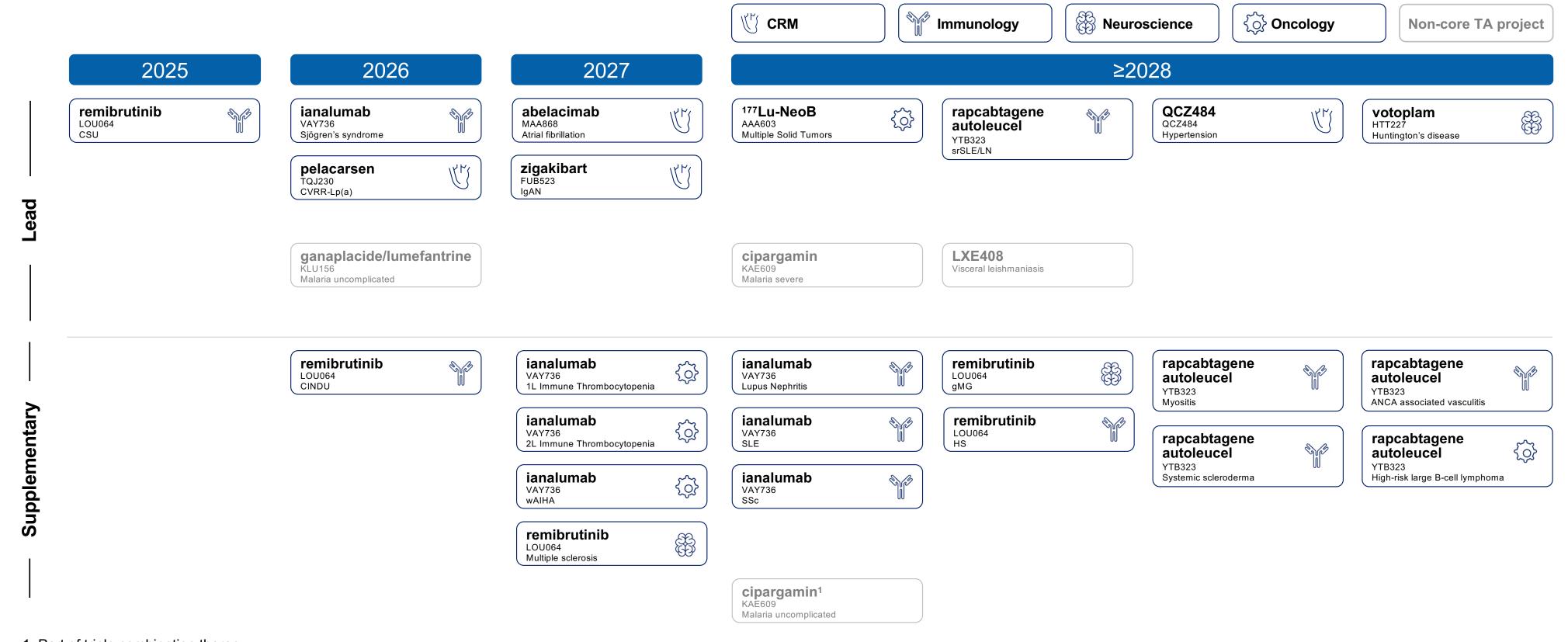
**Innovation: Pipeline overview** 

Financial performance
Innovation: Clinical trials
Abbreviations

References

### Novartis submission schedule

New Molecular Entities: Lead and supplementary indications



1. Part of triple combination therapy.





Click below to navigate through the document

Company overview

Financial review

Conclusions

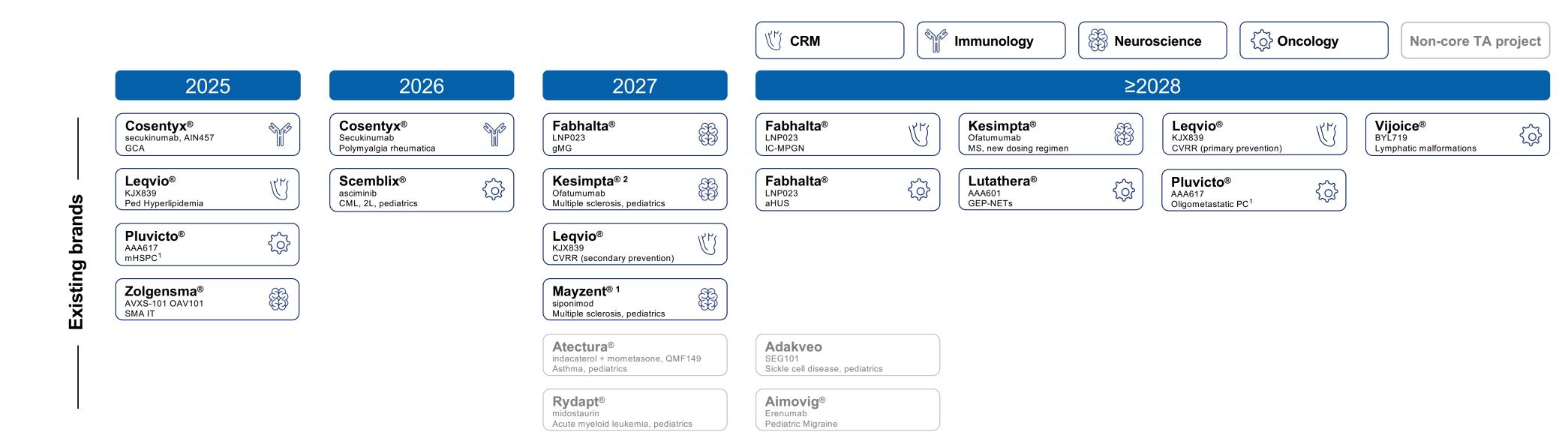
### **Appendix**

**Innovation: Pipeline overview** 

Financial performance
Innovation: Clinical trials
Abbreviations

References

## Novartis submission schedule Supplementary indications for existing brands





<sup>1.</sup> Event-driven trial endpoint. 2. Kesimpta and Mayzent: Pediatric trial in multiple sclerosis run in conjunction (NEOS).



Click below to navigate through the document

Company overview

Financial review

Conclusions

**Appendix** 

Innovation: Pipeline overview

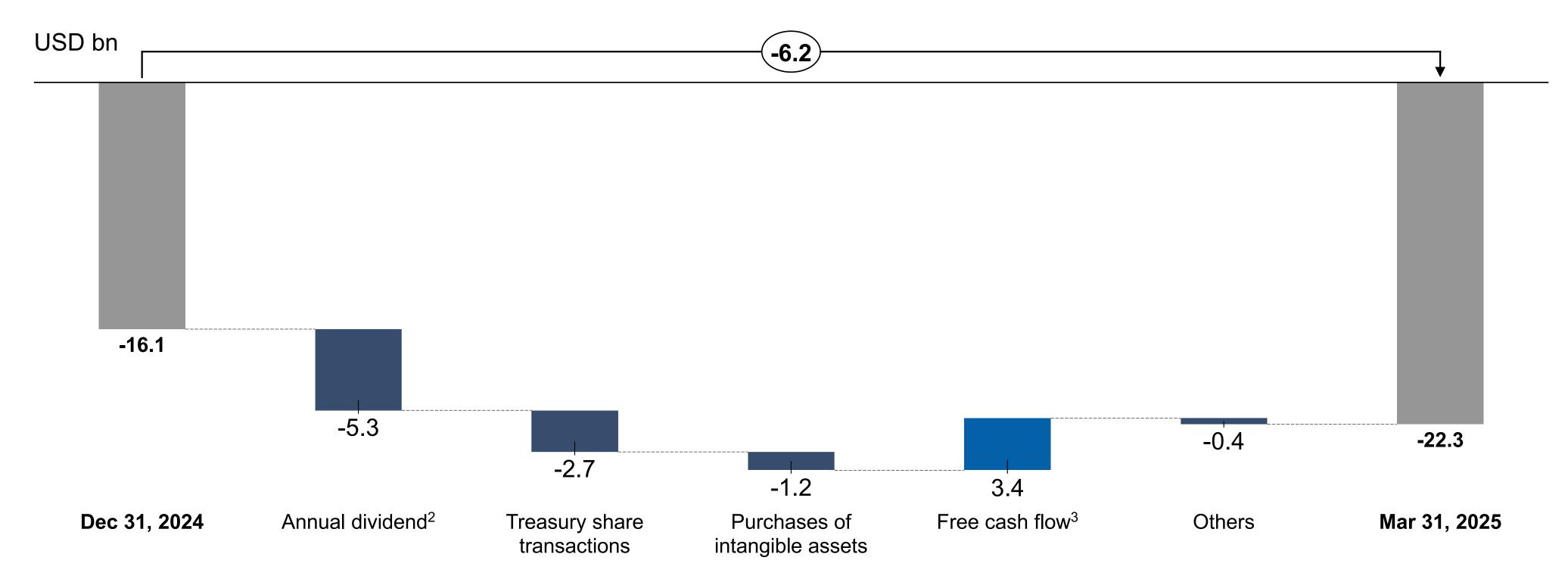
Financial performance

Innovation: Clinical trials

Abbreviations

References

# Net debt<sup>1</sup> increased by USD 6.2bn as strong FCF was more than offset by annual dividend, share buybacks and intangibles



<sup>1.</sup> Net debt is presented as additional information. An explanation of additional information can be found on page 32 of the Condensed Interim Financial Report 2. Annual net dividend payment in March (which is the gross dividend of USD 7.8 billion reduced by the USD 2.5 billion Swiss withholding tax that was paid in April 2025, according to its due date). 3. Free cash flow is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 31 of the Condensed Interim Financial Report.







Click below to navigate through the document

Company overview

Financial review

Conclusions

#### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

Immunology

Neuroscience

Oncology

In-market Brands & Global Health

**Abbreviations** 

References

## **Clinical Trials Update**

Includes selected ongoing or recently concluded global trials of Novartis development programs/products which are in confirmatory development or marketed (typically Phase 2b or later).

For further information on all Novartis clinical trials, please visit: www.novartisclinicaltrials.com







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic

Immunology

Neuroscience

Oncology

In-market Brands & Global Health

Abbreviations

References

## Cardiovascular, **Renal and Metabolic**







Click below to navigate through the document

### Company overview

Financial review

### Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic Immunology

Neuroscience

Oncology In-market Brands

& Global Health

Abbreviations

References

# atrasentan - ETA receptor antagonist

### NCT04573478 ALIGN (CHK01-01)

Indication	IgA nephropathy
Phase	Phase 3
Patients	380
Primary	Change in proteinuria Time Frame: Up to Week 24 or approximately 6 months
Outcome Measures	Annualized total estimated Glomerular Filtration Rate (eGFR) slope estimated over 24 months
Arms Intervention	Arm 1 Experimental: Atrasentan, once daily oral administration of 0.75 mg atrasentan for 132 weeks
	Arm 2 Placebo comparator: Placebo once daily oral administration of placebo for 132 weeks
Target Patients	Patients with IgA nephropathy (IgAN) at risk of progressive loss of renal function
Readout Milestone(s)	2023 (primary endpoint for US initial submission) 2026 (24 months)
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic

Immunology

Neuroscience

Oncology

In-market Brands & Global Health

**Abbreviations** 

References

# Fabhalta® - CFB inhibitor

### **NCT04578834 APPLAUSE-IgAN (CLNP023A2301)**

Indication	IgA nephropathy
Phase	Phase 3
Patients	450
Primary Outcome Measures	Ratio to baseline in urine protein to creatinine ratio (sampled from 24h urine collection) at 9 months Annualized total estimated Glomerular Filtration Rate (eGFR) slope estimated over 24 months
Arms Intervention	Arm 1 - LNP023 200mg BID Arm 2 - Placebo BID
<b>Target Patients</b>	Primary IgA Nephropathy patients
Readout Milestone(s)	2023 (primary endpoint for US initial submission, 9 months UPCR) 2025 (24 months)
Publication	TBD

# Fabhalta® - CFB inhibitor

### NCT05755386 APPARENT (CLNP023B12302)

Indication	Immune complex-mediated membranoproliferative glomerulonephritis
Phase	Phase 3
Patients	106
Primary Outcome Measures	Log-transformed ratio to baseline in UPCR (sampled from a 24 hour urine collection)
Arms Intervention	Arm 1 experimental: Drug: iptacopan 200 mg b.i.d. (Adults 200mg b.i.d; Adolescents 2x 100mg b.i.d) Arm 2 placebo to iptacopan 200mg b.i.d. (both on top of SoC)
Target Patients	Patients (adults and adolescents aged 12-17 years) with idiopathic IC-MPGN
Readout Milestone(s)	2028
Publication	Vivarelli M, et al., Kidney International Reports (2023), Iptacopan in idiopathic immune complex-mediated membranoproliferative glomerulonephritis: Protocol of the APPARENT multicenter, randomized Phase III study







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic

Immunology

Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

References

# Leqvio® - siRNA (regulation of LDL-C)

### NCT03705234 ORION-4 (CKJX839B12301)

Indication	Hypercholesterolemia inc. Heterozygous Familial Hypercholesterolaemia (HeFH)
Phase	Phase 3
Patients	16124
Primary Outcome Measures	A composite of major adverse cardiovascular events, defined as: Coronary heart disease (CHD) death; Myocardial infarction; Fatal or non-fatal ischaemic stroke; or Urgent coronary revascularization procedure
Arms Intervention	Arm 1: every 6 months treatment Inclisiran sodium 300mg (given by subcutaneous injection on the day of randomization, at 3 months and then every 6-months) for a planned median duration of about 5 years  Arm 2: matching placebo (given bysubcutaneous injection on the day of randomization, at 3 months and then every 6 months) for a planned median duration of about 5 years.
Target Patients	Patient population with mean baseline LDL-C ≥ 100mg/dL
Readout Milestone(s)	2026
Publication	TBD

# Leqvio® - siRNA (regulation of LDL-C)

### NCT05030428 VICTORION-2P (CKJX839B12302)

Indication	Secondary prevention of cardiovascular events in patients with elevated levels of LDL-C
Phase	Phase 3
Patients	16970
Primary Outcome Measures	Time to First Occurrence of 3P-MACE (3-Point Major Adverse Cardiovascular Events)
Arms Intervention	Arm 1: Experimental Inclisiran sodium, Subcutaneous injection Arm 2: Placebo Comparator, Placebo Subcutaneous injection
Target Patients	Participants with established cardiovascular disease (CVD)
Readout Milestone(s)	2027
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic

Immunology

Neuroscience

Oncology

In-market Brands & Global Health

Abbreviations

References

# Leqvio® - siRNA (regulation of LDL-C)

### NCT04652726 ORION-16 (CKJX839C12301)

Indication	Hyperlipidemia, pediatrics
Phase	Phase 3
Patients	141
Primary Outcome Measures	Percentage (%) change in low-density lipoprotein cholesterol (LDL-C) from baseline to Day 330
Arms Intervention	Group 1: Inclisiran sodium 300mg on Days 1, 90, 270, placebo on Day 360, inclisiran sodium 300mg on Days 450 and 630 Group 2: Placebo on Days 1, 90, 270, inclisiran sodium 300mg on Days 360, 450 and 630.
Target Patients	Adolescents (12 to less than 18 years) with heterozygous familial hypercholesterolemia (HeFH) and elevated low density lipoprotein cholesterol (LDL-C)
Readout Milestone(s)	2025
Publication	Publication Design publication (O-16/-13) in Eur. J. Prev. Cardiol. Vol. 29, Feb. 2022 Presentation at EAS May-2022 on O-13/-16 study design

# Leqvio® - siRNA (regulation of LDL-C)

### NCT04659863 ORION-13 (CKJX839C12302)

Indication	Hyperlipidemia, pediatrics
Phase	Phase 3
Patients	13
Primary Outcome Measures	Percentage (%) change in low-density lipoprotein cholesterol (LDL-C) from baseline to day 330
Arms Intervention	Group 1: Inclisiran sodium 300mg on Days 1, 90, 270, placebo on Day 360, inclisiran sodium 300mg on Days 450 and 630.  Group 2: Placebo on Days 1, 90, 270, inclisiran sodium 300mg on Days 360, 450 and 630.
Target Patients	Adolescents (12 to less than 18 years) with homozygous familial hypercholesterolemia (HoFH) and elevated low density lipoprotein cholesterol (LDL-C)
Readout Milestone(s)	2025
Publication	Publication Design publication (O-16/-13) in Eur. J. Prev. Cardiol. Vol. 29, Feb. 2022 Presentation at EAS May-2022 on O-13/-16 study design







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic Immunology Neuroscience

Oncology In-market Brands

& Global Health

Abbreviations

References

# Leqvio® - siRNA (regulation of LDL-C)

### NCT05739383 VICTORION-1P (CKJX839D12302)

Indication	CVRR (Primary prevention)
Phase	Phase 3
Patients	14000
Primary Outcome Measures	Time to the first occurrence of 4P-MACE 4-Point-Major Adverse Cardiovascular Events (4P-MACE): composite of cardiovascular death, non-fatal myocardial infarction, non-fatal ischemic stroke, and urgent coronary revascularization
Arms Intervention	Arm 1 Experimental: Inclisiran Sodium 300mg, subcutaneous injection in pre-filled syringe Arm 2 Placebo
Target Patients	High-risk primary prevention patients
Readout Milestone(s)	2029
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic

Immunology Neuroscience

Oncology In-market Brands

& Global Health

Abbreviations

References

# pelacarsen - Antisense oligonucleotide (ASO) targeting Lp(a)

# NCT04023552 Lp(a)HORIZON (CTQJ230A12301)

Indication	Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein(a)
Phase	Phase 3
Patients	8323
Primary Outcome Measures	Time to the first occurrence of MACE (cardiovascular death, non-fatal MI, non-fatal stroke and urgent coronary re-vascularization)
Arms Intervention	TQJ230 80 mg injected monthly subcutaneously or matched placebo
Target Patients	Patients with a history of Myocardial infarction or Ischemic Stroke, or a clinically significant symptomatic Peripheral Artery Disease, and Lp(a) ≥ 70 mg/dL
Readout Milestone(s)	2026 (Event driven)
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic Immunology

Neuroscience

Oncology In-market Brands

& Global Health

Abbreviations

References

# **QCZ484**

## NCT06857955 (CQCZ484A12201)

Indication	Hypertension
Phase	Phase 2
Patients	380
Primary Outcome Measures	Change from baseline at Month 3 in mean 24hr systolic blood pressure (SBP) by ambulatory blood pressure measurement (ABPM)
Arms Intervention	Placebo Comparator: Placebo Control Arm 1: QCZ484 Dose 1 solution for injection Arm 2: QCZ484 Dose 2 solution for injection Arm 3: QCZ484 Dose 3 solution for injection Arm 4: QCZ484 Dose 4 solution for injection Arm 5: QCZ484 Dose 5 solution for injection
Target Patients	Mild to moderate hypertensive patients
Readout Milestone(s)	2027
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

> Cardiovascular, Renal and Metabolic Immunology Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

References

# zigakibart - Anti-APRIL

### NCT05852938 BEYOND (CFUB523A12301)

Indication	IgA nephropathy
Phase	Phase 3
Patients	292
Primary Outcome Measures	Change in proteinuria [ Time Frame: 40 weeks or approximately 9 months ]
Arms Intervention	Arm 1 Experimental: BION-1301 (Zigakibart) 600mg subcutaneous administration every 2 weeks for 104 weeks Arm 2 Placebo Comparator: Placebo subcutaneous administration every 2 weeks for 104 weeks
<b>Target Patients</b>	Adults with IgA Nephropathy
Readout Milestone(s)	2026
Publication	WCN Poster April 2024: BEYOND: A Phase 3, Randomized, Double-Blind, Placebo- controlled Trial of Zigakibart in Adults with IgA Nephropathy. Trimarchi H., et. al.







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

> Immunology

Neuroscience

Oncology

In-market Brands & Global Health

**Abbreviations** 

References

# Immunology







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

#### > Immunology

Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

References

# Cosentyx® - IL-17A inhibitor

### NCT05767034 REPLENISH (CAIN457C22301)

Indication	Polymyalgia rheumatica
Phase	Phase 3
Patients	360
Primary Outcome Measures	Proportion of participants achieving sustained remission
Arms Intervention	Arm 1 Experimental: Secukinumab 300 mg, randomized in 1:1:1 ratio every 4 weeks
	Arm 2 Experimental: Secukinumab 150 mg, randomized in 1:1:1 ratio every 4 weeks
	Arm 3 Placebo : randomized in 1:1:1 ratio every 4 weeks
<b>Target Patients</b>	Adult patients with PMR who have recently relapsed
Readout Milestone(s)	2025
Publication	TBD

# Cosentyx® - IL-17A inhibitor

### NCT04930094 GCAPTAIN (CAIN457R12301)

Indication	Giant cell arteritis
Phase	Phase 3
Patients	349
Primary Outcome Measures	Number of participants with sustained remission
Arms Intervention	Experimental: Secukinumab 150 and 300 mg Placebo Comparator: Placebo
<b>Target Patients</b>	Patients with Giant Cell Arteritis (GCA)
Readout Milestone(s)	Primary 2025
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

### > Immunology

Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

References

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05126277 SIRIUS-LN (CVAY736K12301)

Indication	Lupus Nephritis
Phase	Phase 3
Patients	420
Primary Outcome Measures	Frequency and percentage of participants achieving complete renal response (CRR) [ Time Frame: week 72 ]
Arms Intervention	Arm 1: Experimental - ianalumab s.c. q4w in addition to standard of care (SoC) Arm 2: Experiemental - ianalumab s.c. q12w in addition to SoC Arm 3: Placebo comparator - Placebo s.c. q4w in addition to SoC
Target Patients	Patients with active Lupus Nephritis
Readout Milestone(s)	Primary 2027
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

#### > Immunology

Neuroscience Oncology

In-market Brands

& Global Health

Abbreviations

References

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05349214 NEPTUNUS-2 (CVAY736A2302)

Indication	Sjögren's syndrome
Phase	Phase 3
Patients	506
Primary Outcome Measures	Change from baseline in EULAR Sjögren Syndrome Disease Activity Index (ESSDAI) score at Week 48 as compared to placebo
Arms Intervention	Arm 1: Experimental - ianalumab exposure level 1 Arm 2: Experimental - ianalumab exposure level 2 Arm 3: Placebo comparator
Target Patients	Patients with active Sjogren's syndrome
Readout Milestone(s)	Primary 2025
Publication	TBD

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05350072 NEPTUNUS-1 (CVAY736A2301)

	·
Indication	Sjögren's syndrome
Phase	Phase 3
Patients	276
Primary Outcome Measures	Change from baseline in EULAR Sjögren Syndrome Disease Activity Index (ESSDAI) score at Week 48 as compared to placebo
Arms	Arm 1: Experimental - ianalumab
Intervention	Arm 2: Placebo comparator
<b>Target Patients</b>	Patients with active Sjogren's syndrome
Readout Milestone(s)	Primary 2025
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

#### > Immunology

Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

References

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05639114 SIRIUS-SLE 1 (CVAY736F12301)

Indication	Systemic lupus erythematosus
Phase	Phase 3
Patients	406
Primary Outcome Measures	Proportion of participants on monthly ianalumab achieving Systemic Lupus Erythematosus Responder Index -4 (SRI-4) [ Time Frame: Week 60 ]
Arms Intervention	Experimental: lanalumab s.c. monthly Experimental: lanalumab s.c. quarterly Placebo Comparator: Placebo s.c. monthly
Target Patients	Patients with active systemic lupus erythematosus (SLE)
Readout Milestone(s)	2027
Publication	TBD

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05624749 SIRIUS-SLE 2 (CVAY736F12302)

	,
Indication	Systemic lupus erythematosus
Phase	Phase 3
Patients	280
Primary Outcome Measures	Proportion of participants achieving Systemic Lupus Erythematosus Responder Index -4 (SRI-4) [ Time Frame: Week 60 ]
Arms Intervention	Experimental: ianalumab s.c. monthly Placebo Comparator: placebo s.c. monthly
Target Patients	Patients with active systemic lupus erythematosus (SLE)
Readout Milestone(s)	2027
Publication	TBD







Click below to navigate through the document

### Company overview

Financial review

### Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

#### > Immunology

Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

### References

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT06470048 (CVAY736S12201)

Indication	Systemic scleroderma
Phase	Phase 2
Patients	200
Primary Outcome Measures	3/5 Revised Composite Response Index in Systemic Sclerosis 25 (rCRISS25) response at Week 52
Arms	Arm 1 Experimental VAY736 (Ianalumab)
Intervention	- Treatment Period 1: Ianalumab subcutaneous (s.c.) injection as defined in the protocol
	- Treatment Period 2: Open-label (OL) lanalumab subcutaneous (s.c.) injection as defined in the protocol
	Arm 2 Placebo Comparator: Placebo
	- Treatment Period 1: Placebo to Ianalumab subcutaneous (s.c.) injection as defined in the protocol
	- Treatment Period 2: Open-label (OL) lanalumab subcutaneous (s.c.) injection as defined in the protocol
<b>Target Patients</b>	Patients with diffuse cutaneous systemic sclerosis
Readout Milestone(s)	2028
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

#### > Immunology

Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

References

# remibrutinib - BTK inhibitor

### NCT05976243 (CLOU064M12301)

Indication	Chronic inducible urticaria
Phase	Phase 3
Patients	348
Primary Outcome Measures	<ol> <li>Proportion of participants with complete response in Total Fric Score; symptomatic dermographism [ Time Frame: Week 12 ]</li> <li>Proportion of participants with complete response in critical temperature threshold; cold urticaria [ Time Frame: Week 12 ]</li> <li>Proportion of participants with itch numerical rating scale =0; cholinergic urticaria [ Time Frame: Week 12 ]</li> </ol>
Arms Intervention	All arms oral, twice daily: Arm 1 Experimental Remibrutinib, symptomatic dermographism group Arm 2 Placebo symptomatic dermographism group Arm 3 Experimental Remibrutinib, cold urticaria group Arm 4 Placebo cold urticaria group Arm 5 Experimental Remibrutinib, cholinergic urticaria group Arm 6 Placebo cholinergic urticaria group
Target Patients	Adults suffering from CINDU inadequately controlled by H1-antihistamines
Readout Milestone(s)	2026
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

#### > Immunology

Neuroscience Oncology

In-market Brands & Global Health

**Abbreviations** 

References

# remibrutinib - BTK inhibitor

### NCT06799000 RECHARGE1 (CLOU064J12301)

Indication	Hidradenitis suppurativa
Phase	Phase 3
Patients	555
Primary Outcome Measures	Proportion of participants with Hidradenitis Suppurativa clinical response 50 (HiSCR50) at Week 16
Arms Intervention	Arm 1: Experimental Participants randomized to receive remibrutinib Dose A during Treatment Period 1 and 2
	Arm 2: Experimental Participants randomized to receive remibrutinib Dose B during Treatment Period 1 and 2
	Arm 3: Placebo comparator Participants randomized to receive placebo during Treatment Period 1 followed by remibrutinib dose B during Treatment Period 2
<b>Target Patients</b>	Adult patients With moderate to severe Hidradenitis Suppurativa
Readout Milestone(s)	2028
Publication	TBD

# remibrutinib - BTK inhibitor

### NCT06840392 RECHARGE2 (CLOU064J12302)

Indication	Hidradenitis suppurativa
Phase	Phase 3
Patients	555
Primary Outcome Measures	Proportion of participants with Hidradenitis Suppurativa clinical response 50 (HiSCR50) at Week 16
Arms Intervention	Arm 1: Experimental Participants randomized to receive remibrutinib Dose A during Treatment Period 1 and 2
	Arm 2: Experimental Participants randomized to receive remibrutinib Dose B during Treatment Period 1 and 2
	Arm 3: Participants randomized to receive placebo during Treatment Period 1 followed by remibrutinib dose B during Treatment Period 2
<b>Target Patients</b>	Adult patients With moderate to severe Hidradenitis Suppurativa
Readout Milestone(s)	2028
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

Immunology

> Neuroscience

Oncology

In-market Brands & Global Health

**Abbreviations** 

References

# Neuroscience







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

> Neuroscience

Oncology In-market Brands & Global Health

Abbreviations

References

# Fabhalta® - CFB inhibitor

### **NCT123456 APPRAISE (CLNP023Q12301)**

Indication	Generalized Myasthenia Gravis
Phase	Phase 3
Patients	146
Primary Outcome Measures	Change from baseline to Month 6 in Myasthenia Gravis Activity of Daily Living (MG-ADL) total score
Arms Intervention	Participants who meet the eligibility criteria will be randomized in a ratio of 1:1, to receive either iptacopan at a dose of 200 mg orally b.i.d or matching placebo
Target Patients	Patients with generalized MG who anti-AchR-positive and are not adequately responding to 2/3rd line SoC.
Readout Milestone(s)	2027
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

#### > Neuroscience

Oncology In-market Brands

& Global Health

Abbreviations

References

# Kesimpta® - anti-CD20

## NCT06869785 FILIOS (COMB157Q12301)

Indication	Multiple sclerosis new dosing regimen
Phase	Phase 3
Patients	180
Primary Outcome Measures	Ofatumumab plasma pharmacokinetics - area under the curve, up to 12 weeks
Arms Intervention	Arm 1: Active Comparator Ofatumumab dose 1, Approved dosage
	Arm 2: Experimental Ofatumumab dose 2, New dosage
<b>Target Patients</b>	Patients with relapsing multiple sclerosis
Readout Milestone(s)	2028
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

#### > Neuroscience

Oncology In-market Brands

& Global Health Abbreviations

References

# Mayzent® - S1P1,5 receptor modulator

### NCT04926818 NEOS (CBAF312D2301)

Indication	Multiple sclerosis, pediatrics
Phase	Phase 3
Patients	120
Primary Outcome Measures	Annualized relapse rate (ARR) in target pediatric participants
Arms Intervention	Arm 1: Experimental ofatumumab - 20 mg injection/ placebo Arm 2: Experimental siponimod - 0.5 mg, 1 mg or 2 mg/ placebo Arm 3: Active Comparator fingolimod - 0.5 mg or 0.25 mg/ placebo
Target Patients	Children/adolescent patients aged 10-17 years old with Multiple Sclerosis (MS). The targeted enrollment is 120 participants with multiple sclerosis which will include at least 5 participants with body weight (BW) ≤40 kg and at least 5 participants with age 10 to 12 years in each of the ofatumumab and siponimod arms. There is a minimum 6 month follow up period for all participants (core and extension). Total duration of the study could be up to 7 years.
Readout Milestone(s)	2027
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

#### > Neuroscience

Oncology

In-market Brands & Global Health

Abbreviations

References

# remibrutinib - BTK inhibitor

### NCT05147220 REMODEL-1 (CLOU064C12301)

Indication	Multiple sclerosis
Phase	Phase 3
Patients	800
Primary Outcome Measures	Annualized relapse rate (ARR) of confirmed relapses [Core Part]. ARR is the average number of confirmed MS relapses in a year
Arms Intervention	Arm 1: Experimental; Remibrutinib - Core (Remibrutinib tablet and matching placebo of teriflunomide capsule) Arm 2: Active Comparator; Teriflunomide - Core (Teriflunomide capsule and matching placebo remibrutinib tablet)
	Arm 3: Experimental; Remibrutinib - Extension (Participants on remibrutinib in Core will continue on remibrutinib tablet)
	Arm 4: Experimental; Remibrutinib - Extension (on teriflunomide in Core) (Participants on teriflunomide in Core will switch to remibrutinib tablet)
<b>Target Patients</b>	Patients with relapsing Multiple Sclerosis
Readout Milestone(s)	Estimated primary completion 2026
Publication	TBD

# remibrutinib - BTK inhibitor

### NCT05156281 REMODEL-2 (CLOU064C12302)

	,
Indication	Multiple sclerosis
Phase	Phase 3
Patients	800
Primary Outcome Measures	Annualized relapse rate (ARR) of confirmed relapses
Arms Intervention	Arm 1: Experimental; Remibrutinib – Core Remibrutinib tablet and matching placebo of teriflunomide capsule Arm 2: Active Comparator; Teriflunomide – Core Teriflunomide capsule and matching placebo remibrutinib tablet Arm 3: Experimental: Remibrutinib – Extension Participants on remibrutinib in Core will continue on remibrutinib tablet Arm 4: Experimental: Remibrutinib - Extension (on teriflunomide in Core) Participants on teriflunomide in Core will switch to remibrutinib tablet
<b>Target Patients</b>	Patients with relapsing Multiple Sclerosis
Readout Milestone(s)	Estimated primary completion 2026
Publication	TBD







Click below to navigate through the document

### Company overview

Financial review

### Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

> Neuroscience Oncology

In-market Brands & Global Health

Abbreviations

References

# remibrutinib - BTK inhibitor

## NCT06744920 RELIEVE (CLOU064O12301)

Indication	Myasthenia Gravis
Phase	Phase 3
Patients	180
Primary Outcome Measures	Change from baseline to Month 6 in Myasthenia Gravis Activity of Daily Living (MG-ADL) total score
Arms Intervention	Arm 1 experimental: remibrutinib tablet taken orally Arm 2 placebo comparator: placebo tablet taken orally
<b>Target Patients</b>	Patients with generalized Myasthenia Gravis
Readout Milestone(s)	2028
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

Immunology

Neuroscience

#### > Oncology

In-market Brands & Global Health

Abbreviations

References

# Oncology







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

Neuroscience

> Oncology In-market Brands

& Global Health

Abbreviations

References

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05653349 VAYHIT1 (CVAY736I12301)

Indication	1L Immune Thrombocytopenia
Phase	Phase 3
Patients	225
Primary Outcome Measures	Time from randomization to treatment failure (TTF)
Arms Intervention	Arm 1: Experimental: lanalumab Lower dose administered intravenously with corticosteroids oral or parentally (if clinically justified)  Arm 2: lanalumab Higher dose administered intravenously with corticosteroids oral or parentally (if clinically justified)  Arm 3: Placebo Comparator administered intravenously with corticosteroids oral or parentally (if clinically justified)
Target Patients	Adult patients with primary ITP
Readout Milestone(s)	2026
Publication	TBD

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05653219 VAYHIT2 (CVAY736Q12301)

	(6 1111166 412661)
Indication	2L Immune Thrombocytopenia
Phase	Phase 3
Patients	150
Primary Outcome Measures	Time from randomization to treatment failure (TTF)
Arms Intervention	Arm 1: Experimental: eltrombopag and ianalumab lower dose Arm 2: Experimental: eltrombopag and ianalumab higher dose Arm 3: eltrombopag and placebo
Target Patients	Primary ITP patients who failed steroids
Readout Milestone(s)	2025
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

Neuroscience

> Oncology

In-market Brands & Global Health

Abbreviations

References

# ianalumab - BAFF-R inhibitor, ADCC-mediated B-cell depletor

### NCT05648968 VAYHIA (CVAY736O12301)

Indication	Warm autoimmune hemolytic anemia
Phase	Phase 3
Patients	90
Primary Outcome Measures	Binary variable indicating whether a patient achieves a durable response Durable response: hemoglobin level ≥10 g/dL and ≥2 g/dL increase from baseline, for a period of at least eight consecutive weeks between W9 and W25, in the absence of rescue medication or prohibited treatment
Arms Intervention	Arm 1: experimental lanalumab low dose (intravenously) Arm 2: experimental lanalumab high dose (intravenously) Arm 3: placebo Comparator (intravenously)
Target Patients	Previously treated patients with warm Autoimmune Hemolytic Anemia
Readout Milestone(s)	2026
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

> Oncology

In-market Brands & Global Health

Neuroscience

Abbreviations

References

# iptacopan - CFB inhibitor

### NCT04889430 APPELHUS (CLNP023F12301)

Indication	Atypical haemolytic uraemic syndrome
Phase	Phase 3
Patients	75
Primary Outcome Measures	Percentage of participants with complete TMA response without the use of PE/PI and anti-C5 antibody
Arms Intervention	Single arm open-label with 50 adult patients receiving 200mg oral twice daily doses of iptacopan
Target Patients	Adult patients with aHUS who are treatment naive to complement inhibitor therapy (including anti-C5 antibody)
Readout Milestone(s)	2028
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

Neuroscience

> Oncology In-market Brands

& Global Health

Abbreviations

References

# Lutathera® - Radioligand therapy target SSTR

### NCT06784752 NETTER-3 (CAAA601A62301)

Indication	Gastroenteropancreatic neuroendocrine tumors
Phase	Phase 3
Patients	240
Primary Outcome Measures	Progression Free Survival (PFS) centrally assessed by Blinded Independent Review Committee (BIRC)
Arms Intervention	Arm 1: Experimental: [177Lu]Lu-DOTA-TATE + Octreotide LAR Participants in this arm will receive [177Lu]Lu-DOTA-TATE plus Octreotide longacting release (LAR).
	Arm 2: Active Comparator: Octreotide LAR Participants in this arm will receive Octreotide LAR only.
<b>Target Patients</b>	Patients newly diagnosed with Grade 1 and Grade 2 (Ki-67 <10%) advanced GEP-NET with high disease burden
Readout Milestone(s)	2028
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

Neuroscience

> Oncology In-market Brands

& Global Health

Abbreviations

References

# Pluvicto® - Radioligand therapy target PSMA

### **NCT04720157 PSMAddition (CAAA617C12301)**

Indication	Metastatic hormone sensitive prostate cancer
Phase	Phase 3
Patients	1126
Primary Outcome Measures	Radiographic Progression Free Survival (rPFS)
Arms Intervention	Arm 1: <sup>177</sup> Lu-PSMA-617 Participant will receive 7.4 GBq (+/- 10%) <sup>177</sup> Lu-PSMA-617, once every 6 weeks for a planned 6 cycles, in addition to the Standard of Care (SOC); ARDT +ADT is considered as SOC and treatment will be administered per the physician's order
	Arm 2: For participants randomized to Standard of Care arm, ARDT +ADT is considered as SOC and treatment will be administered per the physician's order
Target Patients	Patients with metastatic Hormone Sensitive Prostate Cancer (mHSPC)
Readout Milestone(s)	Primary Analysis: 2025 (event driven)
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology

Neuroscience

> Oncology In-market Brands & Global Health

Abbreviations

References

# Vijoice® - PI3Ki

### NCT05948943 EPIK-L1 (CBYL719P12201)

Indication	Lymphatic Malformation
Phase	Phase 2/3
Patients	230
Primary Outcome Measures	Stage 2: Radiological response rate at Week 24 of Stage 2 (adult and pediatric (6 - 17 years o age) participants) Time Frame: Baseline, Week 24
Arms Intervention	Arm 1: Experimental. Adult participants, alpelisib dose 1 (Stage 1)
	Arm 2: Experimental. Adult participants, alpelisib dose 2 (Stage 1)
	Arm 3: Experimental. Pediatric participants (6-17 years of age), alpelisib dose 2 (Stage 1)
	Arm 4: Experimental. Pediatric participants (6-17 years of age), alpelisib dose 3 (Stage 1)
	Arm 5: Experimental. Adult participants, alpelisib (Stage 2)
	Arm 6: Placebo comparator. Adult participants, placebo (Stage 2)
	Arm 7: Experimental. Pediatric participants (6-17 years of age), alpelisib (Stage 2)
	Arm 8: Placebo Comparator. Pediatric participants (6-17 years of age), placebo (Stage 2)
	Arm 9: Experimental. Pediatric participants (2-5 years of age), alpelisib (Stage 2)
Target Patients	Pediatric and adult patients with lymphatic malformations associated with a PIK3CA mutation
Readout Milestone(s)	2030
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic

Immunology

Neuroscience

Oncology

> In-market Brands & Global Health

Abbreviations

References

# **In-market Brands** & Global Health







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology Neuroscience

> In-market Brands & Global Health

Abbreviations

Oncology

References

# cipargamin - PfATP4 inhibitor

### NCT04675931 KARISMA (CKAE609B12201)

Indication	Malaria severe
Phase	Phase 2
Patients	252
Primary Outcome Measures	Percentage of participants achieving at least 90% reduction in Plasmodium falciparum (P. falciparum) at 12 hours [Time Frame: Day 1 (12 Hours)]
Arms Intervention	Age descending treatment evaluating IV KAE609 doses versus active comparator, IV Artesunate. Follow on therapy for all arms: Coartem, Standard of care
Target Patients	Patients with Malaria, severe
Readout Milestone(s)	2025
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

#### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology Neuroscience

Oncology > In-market Brands & Global Health

Abbreviations

References

# ganaplacide/lumefantrine - Non-artemisinin plasmodium falciparum inhibitor

### NCT05842954 KALUMA (CKLU156A12301)

Indication	Malaria, uncomplicated
Phase	Phase 3
Patients	1500
Primary Outcome Measures	PCR-corrected adequate clinical and parasitological response (ACPR) at day 29
Arms Intervention	Arm 1 experimental: KLU156 oral; 400/480 mg (ganaplacide/ lumefantrine) is the fixed dose combination for patients with a bodyweight ≥ 35kg. Patients < 35kg will take a fraction of the dose according to weight group as defined in the protocol. Arm 2 active comparator: Coartem, oral, dosing will be selected based on patient's body weight as per product's label.
<b>Target Patients</b>	Adults and children ≥ 5 kg Body Weight with uncomplicated P. Falciparum Malaria
Readout Milestone(s)	2025
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview

Financial performance

### **Innovation: Clinical trials**

Cardiovascular, Renal and Metabolic Immunology Neuroscience Oncology

> In-market Brands & Global Health

Abbreviations

References

# Rydapt® - Multi-targeted kinase inhibitor

### NCT03591510 (CPKC412A2218)

Indication	Acute myeloid leukemia, pediatrics
Phase	Phase 2
Patients	20
Primary	Occurrence of dose limiting toxicities
Outcome Measures	Safety and Tolerability
Arms Intervention	Chemotherapy followed by Midostaurin
Target Patients	Newly diagnosed pediatric patients with FLT3 mutated acute myeloid leukemia (AML)
Readout Milestone(s)	2026
Publication	TBD







Click below to navigate through the document

Company overview

Financial review

Conclusions

### **Appendix**

Innovation: Pipeline overview Financial performance Innovation: Clinical trials

References

**Abbreviations** 

# **Abbreviations**

<b>Abbreviation</b>	Full Form
AAV	Adeno-Associated Virus
ACC	American College of Cardiology
ACS	Acute Coronary Syndrome
AD	Alzheimer's Disease
AHA	American Heart Association
aLLT	Advanced Lipid Lowering Therapy
AS	Ankylosing Spondylitis
C3G	Complement 3 Glomerulopathy
CIndU	Chronic Inducible Urticaria
CML	Chronic Myeloid Leukemia
CSU	Chronic Spontaneous Urticaria
DTC	Direct to Consumer
eBC	Early Breast Cancer
FA	Food Allergy
FF	Field Force
GCA	Giant Cell Arteritis
GEP-NET	Gastroenteropancreatic Neuroendocrine Tumors
gMG	Generalized Myasthenia Gravis
Hb	Hemoglobin
HCP	Health Care Provider
HD	Huntington's Disease
HF	Heart Failure
HFMSE	Hammersmith Functional Motor Scale Expanded
HR	Hazard Ratio
HS	Hidradenitis Suppurativa
HTN	Hypertension
IB&GH	In-market Brands and Global Health
IgAN	Immunoglobin A Nephropathy
ITP	Immune Thrombocytopenia
IV	Intravenous
LFT	Liver Function Test
LoE	Loss of Exclusivity

Abbreviation	Full Form
mBC	Metastatic Breast Cancer
mCRPC	Metastatic Castration-Resistant Prostate Cancer
mHSPC	Metastatic Hormone-Sensitive Prostate Cancer
MOTRx	Units Normalized to Month-on-Therapy
MS	Multiple Sclerosis
NBRx	New to Brand Prescription
NCCN	National Comprehensive Cancer Network
NEJM	The New England Journal of Medicine
nr-axSpA	Non-Radiographic Axial Spondyloarthritis
NSCLC	Non-Small Cell Lung Cancer
OLE	Open Label Extension
OS	Overall Survival
PA	Prior Authorization
PC	Prostate Cancer
PIRA	Progression Independent of Relapse Activity
PMA	Polymyalgia Arteritica
PMR	Polymyalgia Rheumatica
PNH	Paroxysmal Nocturnal Hemoglobinuria
PRV	Priority Review Voucher
PsA	Psoriatic Arthritis
PSMA	Prostate-Specific Membrane Antigen
PsO	Psoriasis
RDP	Regulatory Data Protection
REMS	Risk Evaluation and Mitigation Strategy
rHTN	Resistant Hypertension
RMS	Relapsing Multiple Sclerosis
rPFS	Radiographic Progression-Free Survival
RULM	Revised Upper Limb Module
SMA	Spinal Muscular Atrophy
SjS	Sjögren's Syndrome
SpA	Spondyloarthritis
TRx	Total Prescriptions
UAS7	Weekly Urticaria Activity Score







Click below to navigate through the document

Company overview

Financial review

Conclusions

Appendix

References

# References 1/3

### Kisqali<sup>®</sup> (slide 6 references)

- 1 IQVIA Market Sizing Monthly Report, February 2025; Data lag: ~ 2 months.
- 2 Of CDK4/6 market, US rolling 3 months ending February 2025, IQVIA Breast Cancer Market Sizing report.
- 3 Ex-US data ending December 2024 based on country specific IQVIA or local PMR data.
- 4 Monthly NBRx. BEST International New to Brand (Dynamic Patients), Feb 2025.

### Kesimpta® (slide 7 references)

- 1 The 8 markets include Germany, Japan, China, Australia, Canada, France, Italy, and UK.
- 2 Pardo et al. Continuous Ofatumumab Treatment Up to 7 Years Shows a Consistent Safety Profile and Delays Disability Progression in People With Relapsing Multiple Sclerosis (P7.016 AAN 2025).
- 3 Limitations include a potential for attrition bias and the open-label nature of the extension study.
- Coyle et al. B-Cell Depletion and EfficacyOutcomes of Ofatumumab Are Consistent Across Different Body Mass Index Categories: Insights From ASCLEPIOS I and II Trials (P09.002 AAN 2024).
- 5 As per stability technical specification data, when the patient is ready to inject, it typically takes less than 1 minute a month to administer. Once-monthly dosing begins after the initial dosing period, which consists of 20 mg subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA. Patient must take pen out of the refrigerator 15-30 minutes before self-administering.

### Pluvicto® (slide 8 references)

1 With the inverse probability of censoring weighting (IPCW) method.

### Leqvio<sup>®</sup> (slide 10 references)

- 1 Includes PCSK9 monoclonal antibodies and bempedoic acid.
- 2 Depth: complete Q1 '25 data; MOTRx Q1 QTD ending 3/28.







Click below to navigate through the document

Company overview

Financial review

Conclusions

Appendix

References

# References 2/3

### Scemblix® (slide 11 references)

- Source: US January rolling 3-months US IQVIA CML market sizing report (April 2025).
- 2-3 Source and Q1 Patient Share Projection Assumptions: For Q1'25 International Patient share calculation considered individual markets patient shares as follows, EU4: IQVIA OD until Feb'25 (Preliminary data), Germany: LRx until Jan'25 and Japan: MDV until Q4'24 and assumed same shares for Q1'25 as in Q4'24.

### Cosentyx® (slide 12 references)

- 1 IQVIA National Source of Business (NSOB) data. NBRx volume has been adjusted by excluding the volume of Cordavis Humira since Mar 8, 2024.
- 2 IV formulation indication: PsA, AS, nr-axSpA. Source: IQVIA mastered 867 data.
- 3 Refers to EU5. Indications: Pso, PsA, axSpA. Source: DE: IQVIA LRx; FR: IQVIA Ltd; UK: IQVIA Analyzer, Stethos; IT: Stethos, Elma (September 2024); ES: IQVIA, Amber Market Research (June 2024 data extrapolated to September).
- 4 Hospital value share. Market definition includes all approved immunology brands with at least one indication overlapping with Cosentyx" Source: IQVIA China Immunology Market Value Share (November 2024).
- 5 US, DE, UK, FR, ES, AU.

### Entresto® (slide 13 references)

- 1 IQVIA National Prescription Audit.
- 2 Approved indications differ by geography. Examples include "indicated to reduce the risk of cardiovascular death and hospitalization for HF in adult patients with CHF. Benefits are most clearly evident in patients with LVEF below normal" (US), HFrEF (EU), HFrEF and HTN (China) and CHF and HTN (JP). HTN is not an approved indication in the US and EU.
- 3 Based on 2024 sales.
- Extension of regulatory data protection to November 2026 in EU based on approval of pediatric indication.
- 5 Timing of Entresto US generic entry is subject to ongoing IP and regulatory litigation.







Click below to navigate through the document

Company overview

Financial review

Conclusions

Appendix

References

# References 3/3

### Fabhalta® (slide 14 references)

- 1 Based on Novartis internal data as of March 2025.
- 2 UBC; data through March 21, 2025.

### Vanrafia® (slide 14 references)

- 3 Vanrafia prescribing information. April 2025.
- 4 Heerspink HJL, Jardine M, Kohan DE, et al. Atrasentan in Patients with IgA Nephropathy. N Engl J Med. 2025;392(6):544-554. doi:10.1056/NEJMoa2409415.

### Remibrutinib (slide 16 references)

- 1 Originally 24-week data was presented at the American College of Allergy, Asthma, and Immunology (ACAAI) 2023 with 52-week data presented at European Academy of Allergy and Clinical Immunology (EAACI) 2024.
- 2 Full analysis set; data from the REMIX-1 and REMIX-2 studies presented at EAACI 2024.
- 3 Weekly Urticaria Activity Score (UAS7) comprised of the Weekly Itch Severity Score (ISS7) and the Weekly Hives Severity Score (HSS7).
- 4 Full analysis set; data from the REMIX-1 and REMIX-2 studies presented at European Academy of Dermatology and Venereology (EADV) 2024.
- 5 Anticipating approval of remibrutinib in CSU H2 2025.

