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# Q4 2024 Results

Investor presentation  
January 31, 2025







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# Company overview

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







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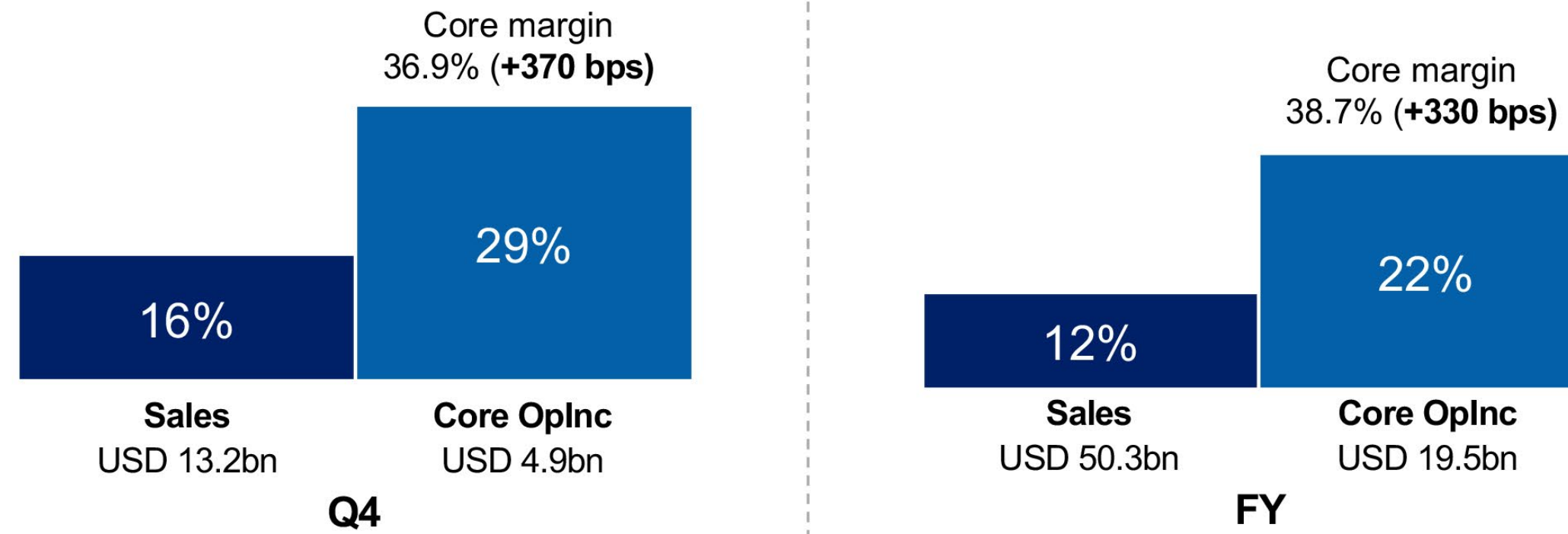
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# Novartis delivered one of the strongest performances in our history in 2024

## Robust growth on top and bottom line in Q4 and FY<sup>1</sup>

Growth vs. PY, cc



## Q4 pipeline highlights

**Scemblix<sup>®</sup>** FDA accelerated approval for 1L Ph+ CML-CP

**Kisqali<sup>®</sup>** EC approval for HR+/HER2-stage II and III eBC

**Fabhalta<sup>®</sup>** (iptacopan) FDA submission for C3G; priority review granted

**OAV101** IT Phase III STEER study positive readout in SMA

**Met and exceeded FY guidance<sup>2</sup> in 2024; confident in continued growth in sales and core OpInc in 2025**

1. Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. 2. Please see detailed guidance assumptions on slide 27.

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# Priority brands continued to drive robust growth, demonstrating our replacement power

## FY sales

	Sales USD million	Growth vs. PY USD million	Growth vs. PY cc
 Entresto <sup>®</sup> <small>secubitril/valsartan</small>	7,822	1,787	31%
 Cosentyx <sup>®</sup> <small>(secukinumab)</small>	6,141	1,161	25%
 Kesimpta <sup>®</sup> <small>(ofatumumab) 20 mg injection</small>	3,224	1,053	49%
 KISQALI <sup>®</sup> <small>ribociclib</small>	3,033	953	49%
 PLUVICTO <sup>®</sup>	1,392	412	42%
 LEQVIO <sup>®</sup>	754	399	114%
 SCEMBLIX <sup>®</sup> <small>(asciminib) 20 mg, 40 mg tablets</small>	689	276	68%
 FABHALTA <sup>®</sup> <small>(iptacopan) 200 mg capsules</small>	129	128	nm

**Strong growth**  
**+38% cc**  
excl. Entresto +41% cc

Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 47 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

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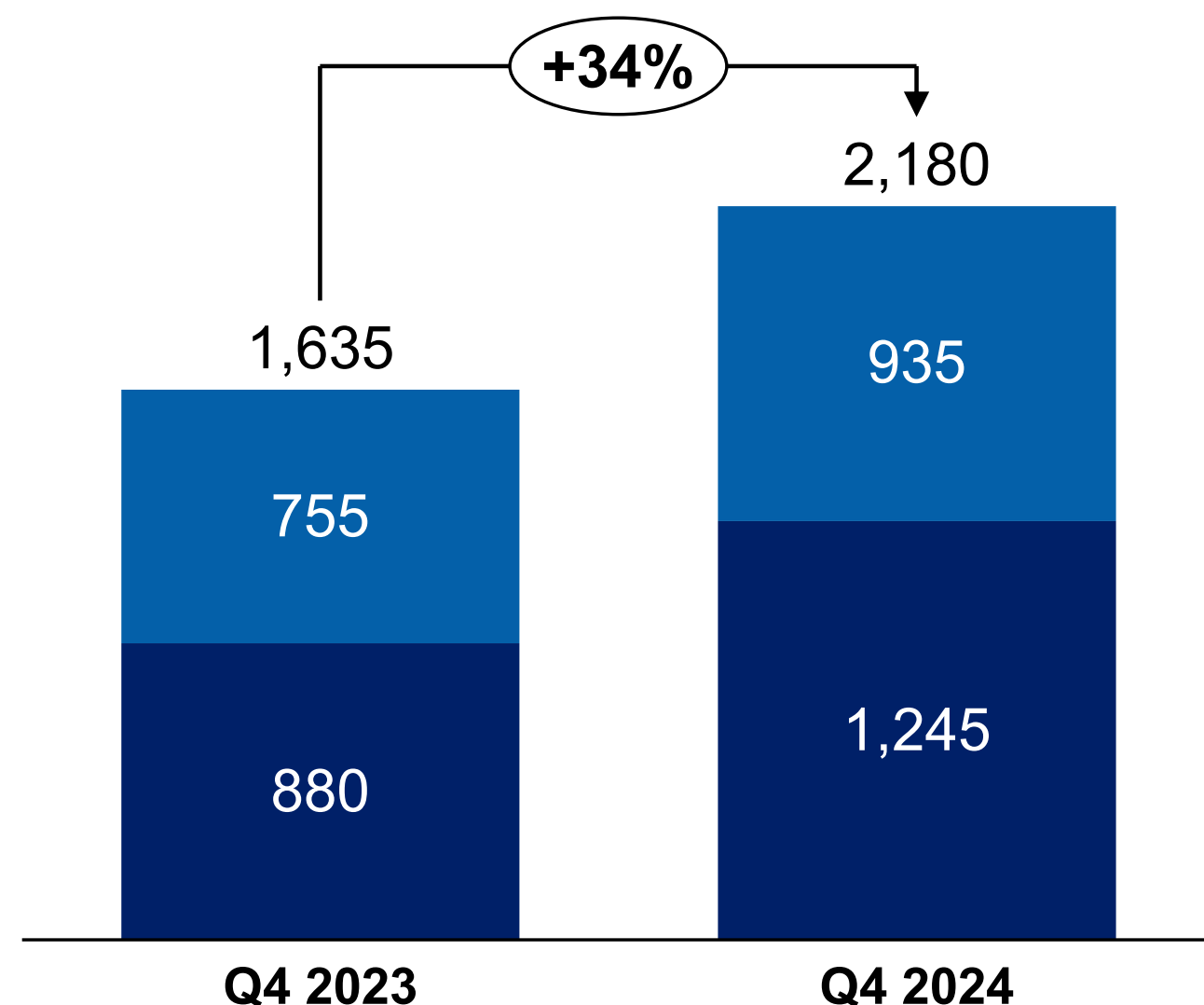
# Entresto® achieved FY sales of USD 7.8bn, +31% cc vs. PY



## Sales evolution

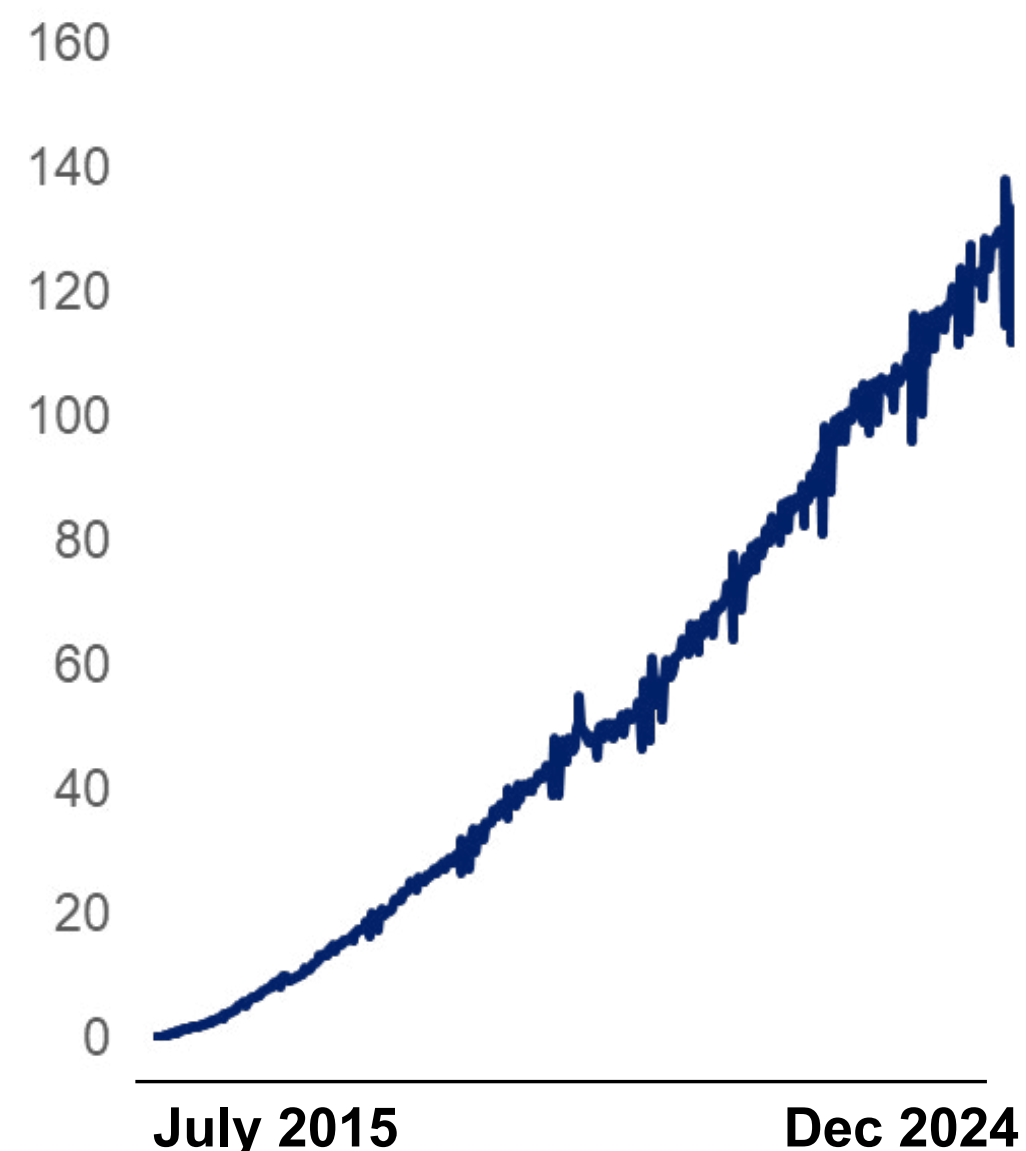
USD m, % cc

■ US ■ Ex-US



## US weekly TRx<sup>1</sup>

Total prescriptions (000)



## Continued strong momentum in Q4

- US: +41% with ~9k NBRx per week
- Ex-US: +26% cc, with continued penetration in HF as well as HTN in China/Japan<sup>2</sup>

## Expect continued growth ex-US post US LoE

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

See page 75 for references (footnotes 1-5). Constant currencies (cc) is a non-IFRS measure. Explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report.

# Cosentyx<sup>®</sup> FY sales topped USD 6bn, +25% cc, fueled by new launches and expansion in core indications

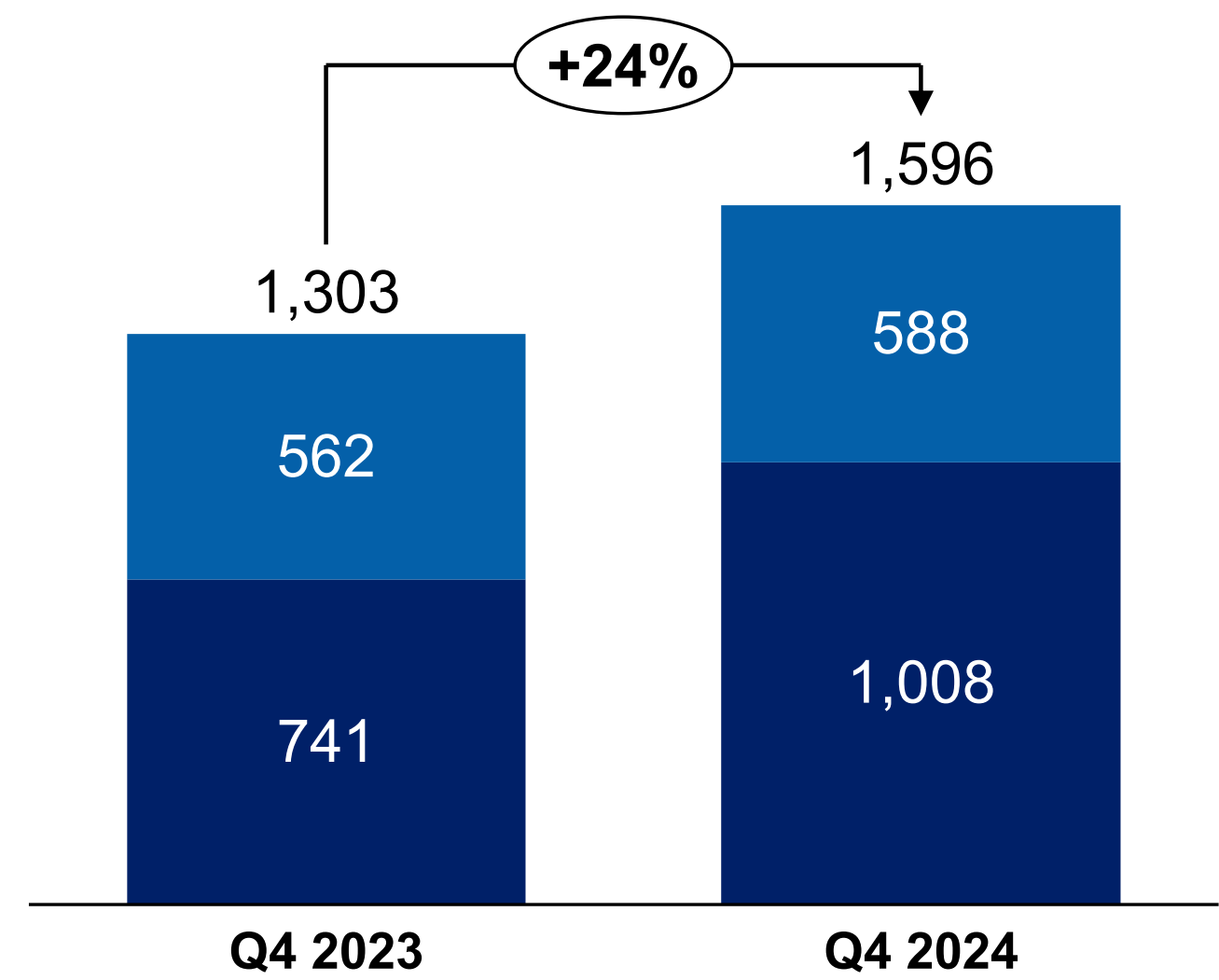


## Sales evolution

USD m, % cc

■ US ■ Ex-US

**FY USD 6.1bn**  
**+25% cc**



## Strong demand-driven growth in Q4

- US: +36%, driven by HS and IV launches
- Ex-US: +7% cc, driven by volume growth (+14%), mainly core indications

## Competitive in core indications (PsO, PsA, AS, nr-axSpA)

- #1 IL-17 in US dynamic market<sup>1</sup>
- Leading originator biologic in EU<sup>2</sup> and China<sup>3</sup>

## New launches continue to accelerate growth

- HS: NBRx leadership in US (~60% share); reimbursed in key markets<sup>4</sup>
- IV: accelerated adoption in US (>1,625 accounts, +22% QoQ)<sup>5</sup>
- Anticipating two Ph3 readouts in 2025: GCA and PMR

See page 75 for references (footnotes 1-5). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



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# Kesimpta® FY sales grew +49% cc to USD 3.2bn, outpacing both B-cell and MS market growth

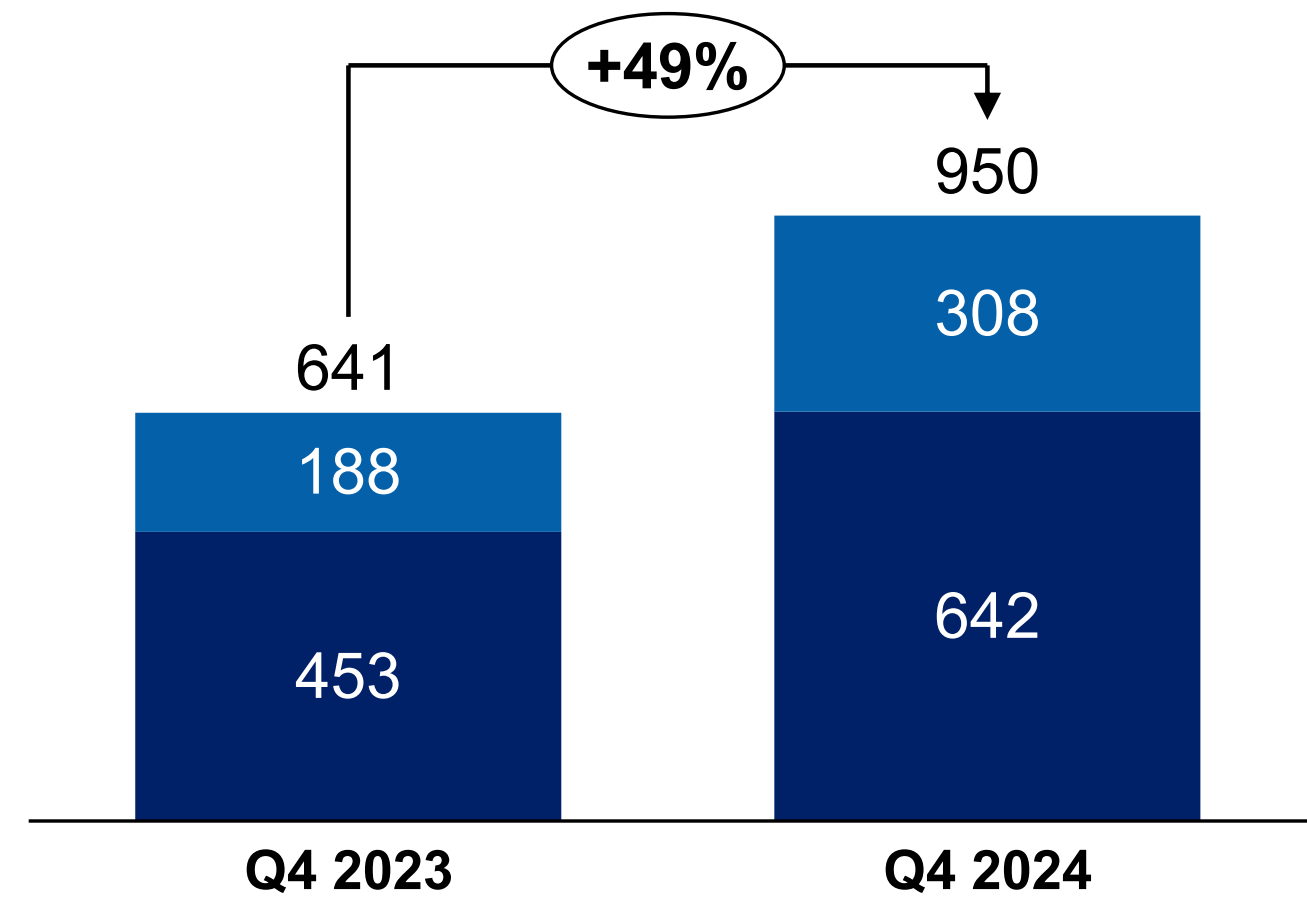


## Sales evolution

USD m, % cc

■ US ■ Ex-US

**FY USD 3.2bn  
+49% cc**



## Solid volume and market share gains in Q4

- US: +42%, with TRx growth (+29%) outpacing B-cell segment (+12%)<sup>1</sup>
- Ex-US: +67% cc, reaching blockbuster status for FY

## Prescribed earlier in therapy

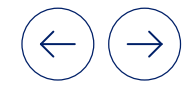
- Over 70% of new US patients are first-line (naive) or first switch<sup>2</sup>
- Over 80% of US commercial lives have first-line coverage<sup>3</sup>
- #1 in NBRx naive in 7 of top 10 ex-US markets<sup>4</sup>

## First and only self-administered B-cell treatment option

- One minute, once a month, at home or on the go<sup>5</sup>

See page 75 for references (footnotes 1-5). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





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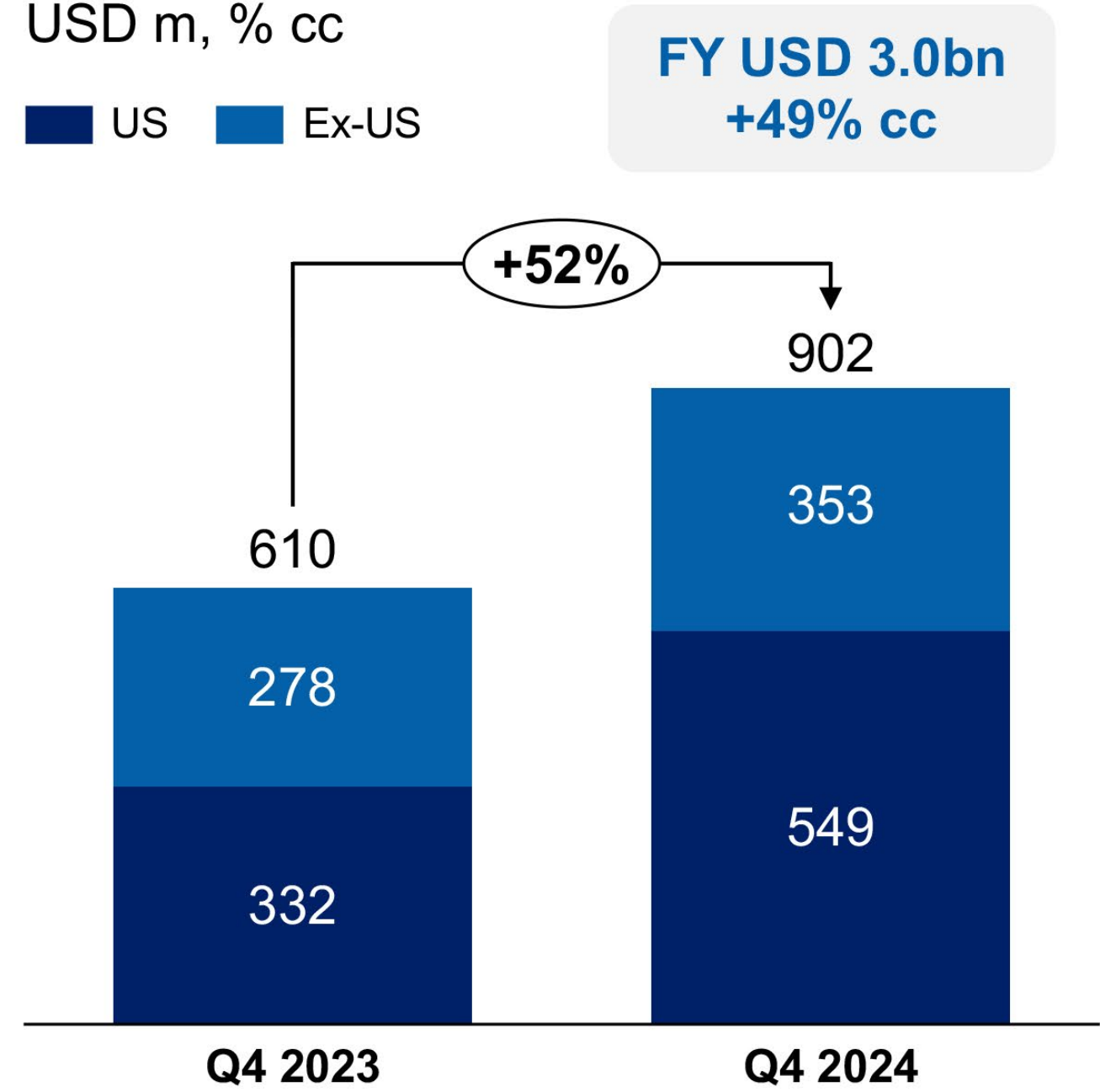
# Kisqali® FY sales grew +49% cc to USD 3.0bn, reflecting market leadership in mBC NBRx and strong early launch uptake in eBC



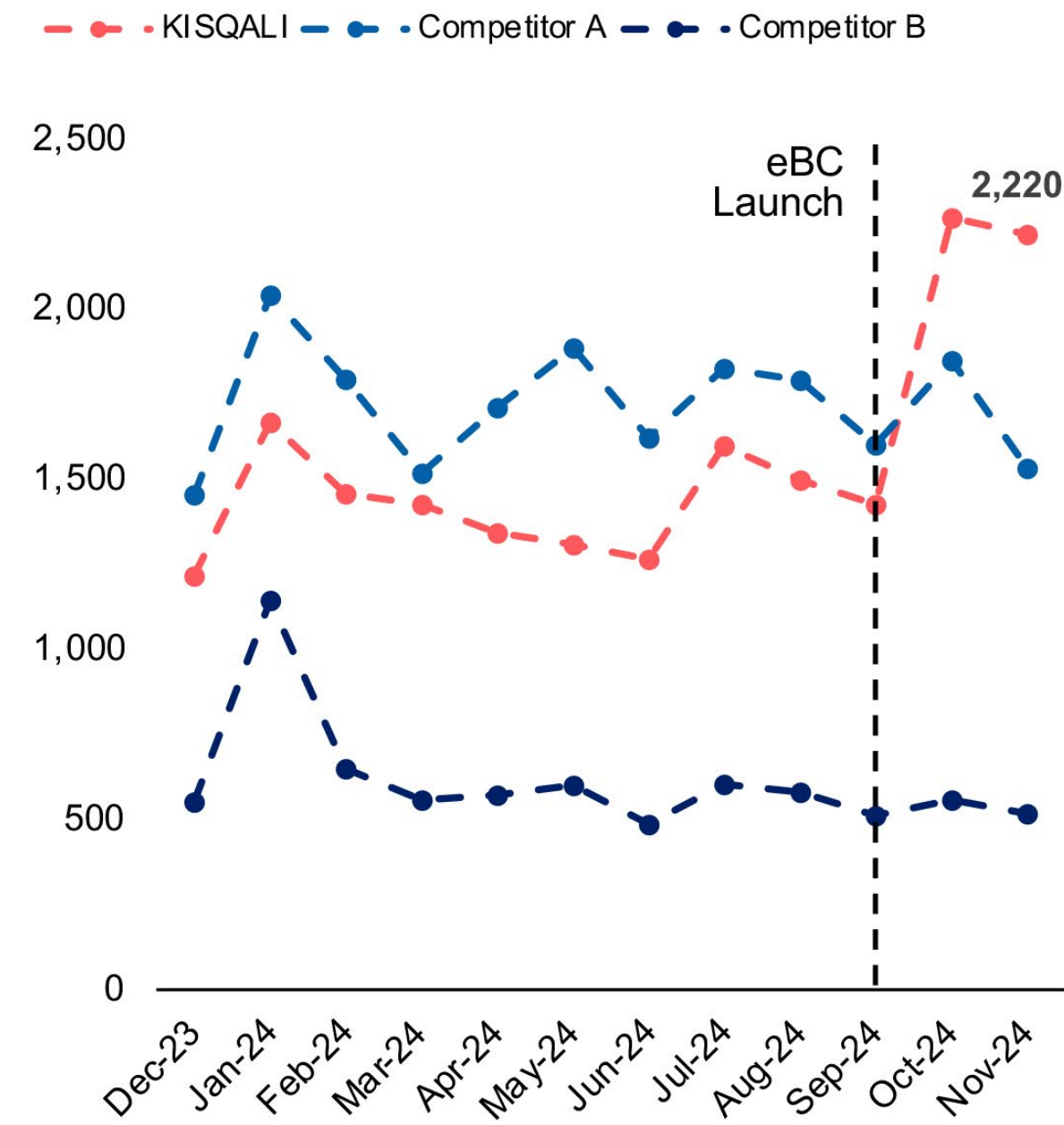
## Sales evolution

USD m, % cc

■ US ■ Ex-US



## US Total Brand NBRx<sup>1</sup>



## US: +65% in Q4

- Leading share in mBC NBRx at 50%; second in TRx share with 33%<sup>2</sup>
- Leading share in eBC NBRx reaching 52% within 3 months of launch
- Category 1 Preferred NCCN Guidelines recommendation in both mBC and eBC
- In January 2025, Novartis settled compound patent litigation with a generic manufacturer, supporting Kisqali US patent protection until at least Q1 2031

## Ex-US: +34% cc in Q4

- Leading share in mBC NBRx at 42%<sup>3</sup>, highest total patient share to date of 33%
- eBC indication approved by EC in Q4

See page 76 for references (footnotes 1-3). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

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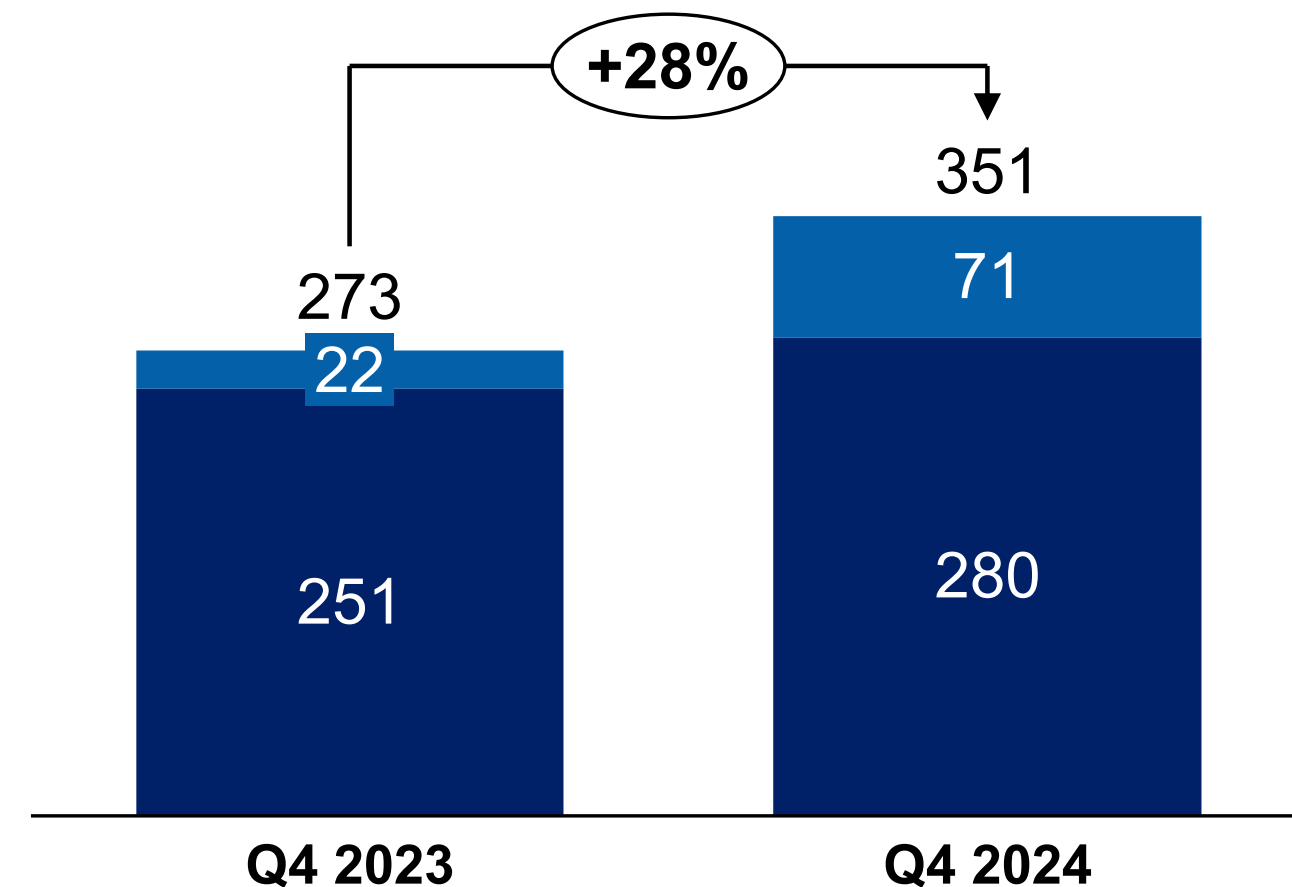
# Pluvicto<sup>®</sup> delivered FY sales of USD 1.4bn (+42% cc) in post-taxane setting, while laying foundation for anticipated pre-taxane launch in H1 2025



## Sales evolution

USD m, % cc

■ US ■ Ex-US



## Sustained growth in post-taxane setting in Q4

- US: +12%, reaching blockbuster status
- Achieved 40% VISION 1L mCRPC NBRx share with gains in community segment, in line with push towards earlier use within indication
- Ex-US: Pluvicto now available in 20+ countries

## Confident in accelerated growth with PSMAfore launch in 2025

- Completed final OS analysis, unadjusted HR 0.91 (95% CI: 0.72-1.14); submitted to FDA as part of ongoing review
- ~590 sites opened (+12% vs. PQ, ~2x vs. PY), ~350 sites actively ordering
- Expect initial uptake to come from depth in existing sites

## Preparing for further Pluvicto and RLT expansion

- Pluvicto PSMAddition readout in mHSPC expected H2 2025
- Pluvicto filings in China (post-taxane) and Japan (pre/post-taxane) accepted
- Ac-PSMA-617 Ph3 study start planned in 2025

Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



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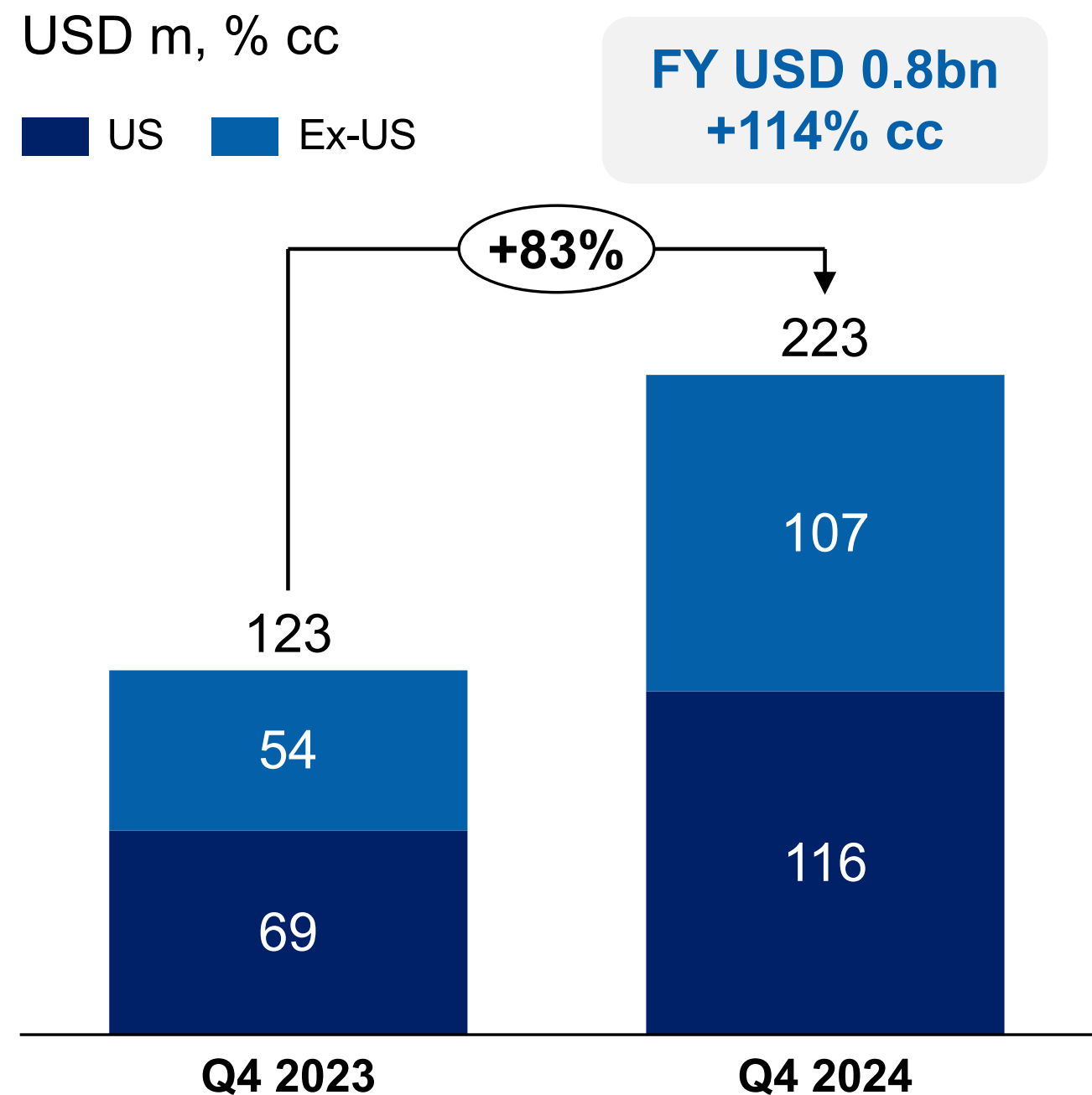
# Leqvio<sup>®</sup> continued steady trajectory, delivering +114% cc FY growth



## Sales evolution

USD m, % cc

■ US ■ Ex-US



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

- 3,230 health systems, representing 68% of aLLT market volume, have ordered Leqvio<sup>®</sup>, with depth increasing +42% vs. PY
- Demand growth in all channels (ASOCs, hospitals, outpatient groups)

### Ex-US: Robust growth in all markets

- Leqvio now registered in >100 countries
- China out-of-pocket growth makes it the top-ranked market ex-US

### Multiple Ph3 studies expected to be presented in 2025

- V-MONO: Superiority of Leqvio vs. both placebo and ezetimibe in LDL-C reduction<sup>3</sup>
- V-INCEPTION: First study evaluating the effectiveness of Leqvio initiated in real-world ASCVD population with ACS ≤ 5 weeks prior to study screening
- ORION-13: Evaluating Leqvio in adolescents with HoFH, first completed study in pediatric program

See page 76 for references (footnotes 1-3). Constant currencies (cc) is a non-IFRS measure. An explanation can be found on page 47 of the Condensed 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.

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# Scemblix® FY sales grew +68% cc, with continued momentum in 3L+ CML and promising early lines launch in US

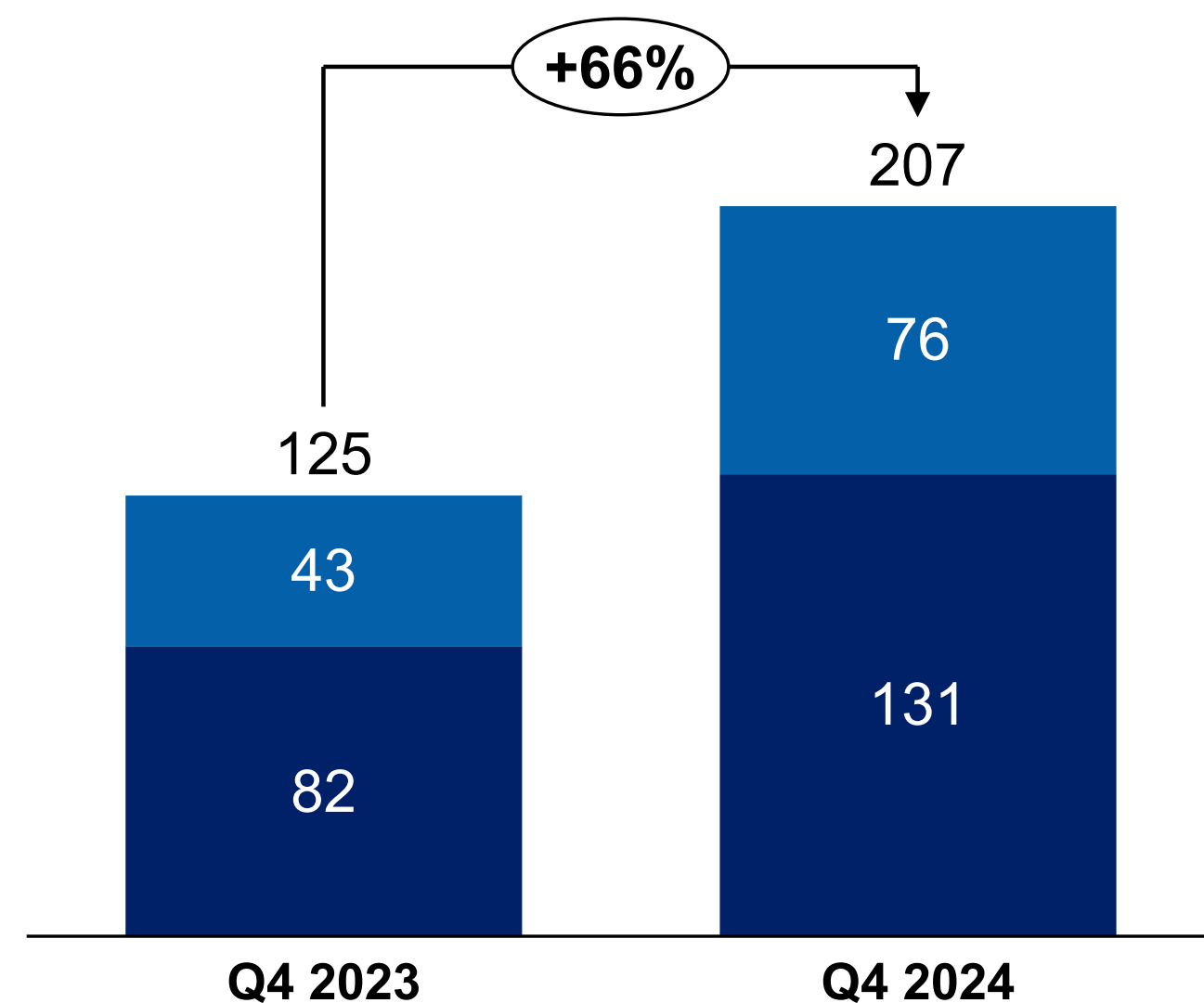


## Sales evolution

USD m, % cc

■ US ■ Ex-US

FY USD 0.7bn  
+68% cc



## Market leader in 3L+ CML

- US: NBRx share of 49%, 3x higher than next competitor<sup>1</sup>
- Ex-US: leadership in NBRx (66%)<sup>2</sup> and total patient share in key markets<sup>3</sup>

## Solid start to early lines launch in US

- NCCN Category 1 Preferred recommendation received Nov 2024
- Scemblix fastest growing TKI by NBRx share across lines
- Already market leader in 2L NBRx share at 29%

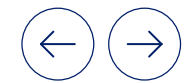
## Confident in global 1L opportunity

- Ph3 ASC4FIRST 96-week data reinforce superior efficacy vs. all SOC TKIs, with favorable safety and tolerability profile
- Ph3b ASC4START trial comparing TTDAE vs nilotinib met primary endpoint at IA

See page 76 for references (footnotes 1-3). Constant currencies (cc) is a non-IFRS measure. An explanation can be found on page 47 of Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



# Phase 3 ASC4FIRST 96-week data reinforce Scemblix<sup>®</sup> superior efficacy with favorable safety and tolerability profile



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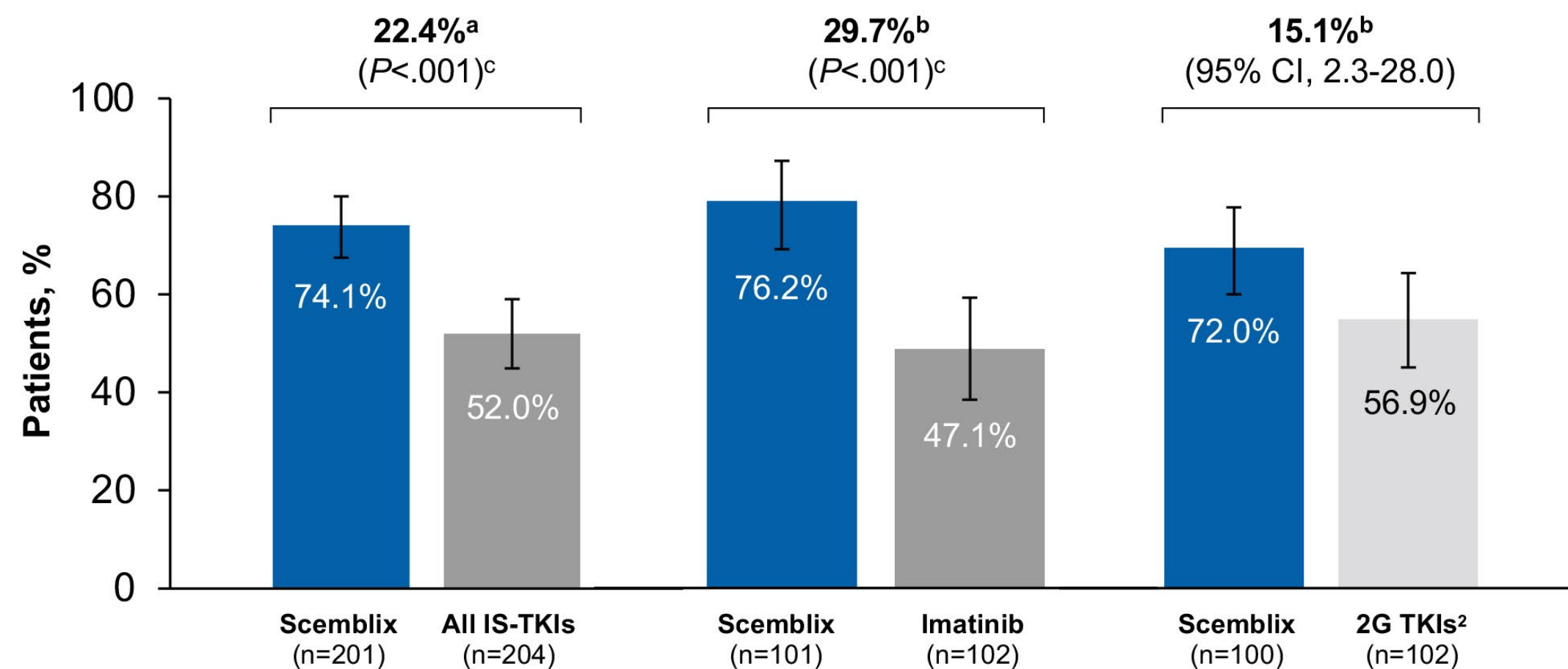
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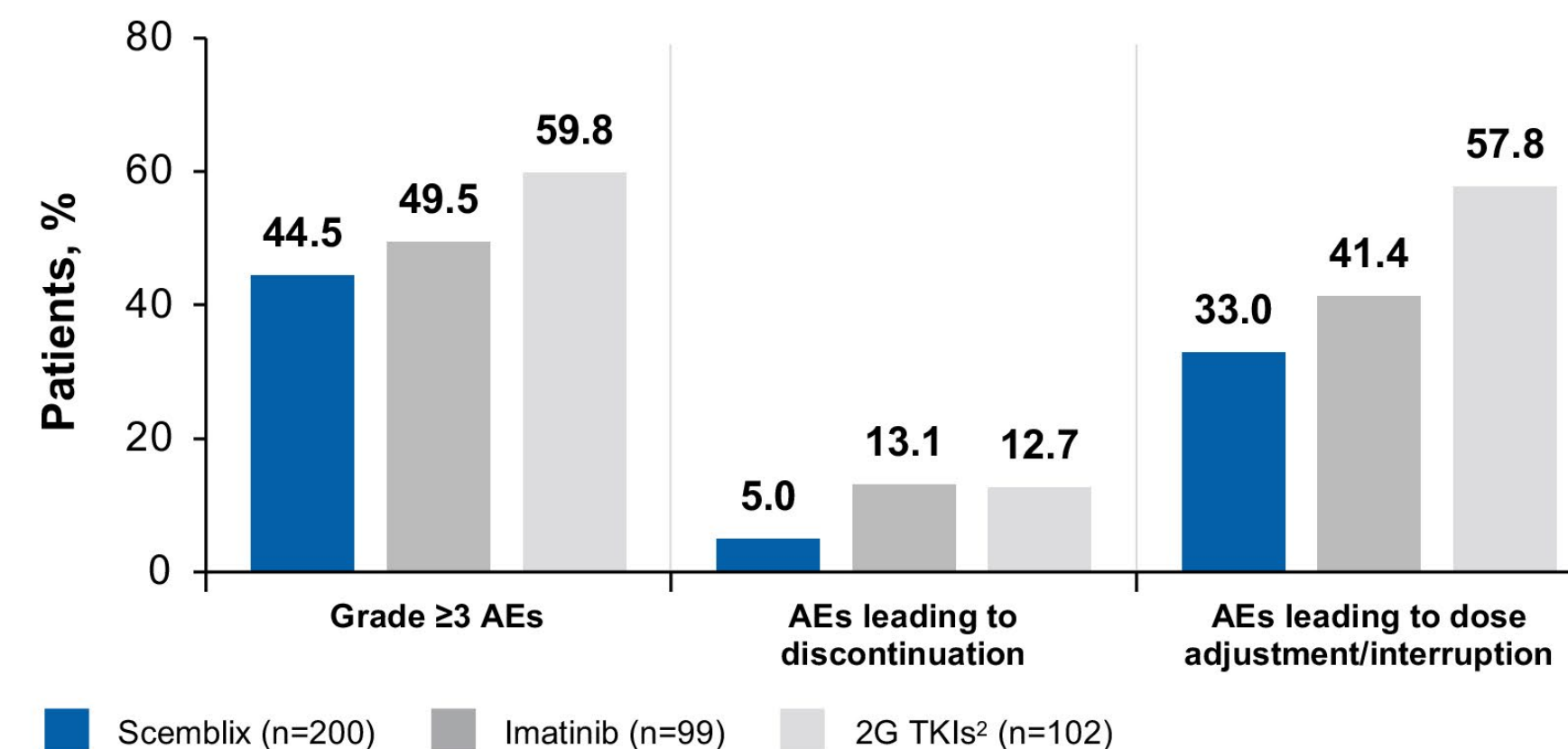
## Efficacy

- **Sustained MMR** vs. all investigator-selected TKIs and vs. imatinib alone, meeting both key secondary endpoints
- **Clinically relevant 15.1% higher MMR rate vs. 2G TKIs**



## Safety

- **Fewer grade ≥3 AEs**
- **Less than half the discontinuation rate due to AEs**
- **Fewer dose adjustment/interruption needed to manage AEs**



Error bars represent 95% CIs. The common treatment difference and its 95% CI were estimated using the Mantel-Haenszel method after stratifying for a prerandomization-selected TKI and baseline ELTS risk groups (both IRT data) or b baseline ELTS risk groups (IRT data). c Adjusted 1-sided P value was calculated based on the graphical gatekeeping procedure. The null hypothesis is rejected if the adjusted P value is ≤.025.



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# Fabhalta<sup>®</sup> on track across first three core indications



## PNH

Continued strong uptake in rare disease setting

### US

**+23% volume growth** vs. PQ, with uptake across all Hb levels

**~75% switch** patients

**Strong persistency** with >90% of patients continuing after first refill

**~80% Commercial coverage** to label

### Ex-US

**Approved in 40+ countries**

**Early uptake** led by Germany, China and Japan

**~95% switch** patients<sup>1</sup>

## IgAN

Encouraging early launch signals in US



**Strong access pull-through** resulting in 67% Commercial coverage to label



**REMS certifications and new writers** ahead of internal goals



**High interest in Fabhalta MOA** as only approved complement inhibitor for IgAN

> **C3G** FDA filing completed in Q4, priority review granted; FDA confirmed no AdCom; preparing for US launch in H1 2025

See page 76 for references (footnote 1).





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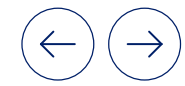
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# We continued to advance our pipeline in Q4

## 2024 selected key events (expected)

		H1 2024	H2 2024	Status as of end Q4
<b>Regulatory decisions</b>	Fabhalta® PNH		EU, JP	EU, JP and China approval in Q2
	Kisqali® HR+/HER2- adj.BC		US, EU	US approval in Q3; <b>EU approval in Q4</b>
<b>Submissions</b>	Atrasentan IgAN	US		US submission in Q2; <b>China submission in Q4</b>
	Fabhalta® (iptacopan) C3G		US, EU	EU, JP and China submissions in Q3; <b>US submission in Q4</b>
	Fabhalta® (iptacopan) IgAN	US		US accelerated approval and China submission in Q3
	Pluvicto® mCRPC, pre-taxane		US	US submission in Q3
	Remibrutinib CSU			Ph3 REMIX-1 and -2 52-week readout in Q1; submissions expected 2025
	Scemblix® CML 1L	US	JP	China and Japan submissions in Q3; <b>US approval in Q4</b>
	Lutathera® GEP-NET 1L G2/G3	EU		EU submission in Q2
<b>Readouts</b>	Scemblix® CML 1L	Ph3 (ASC4FIRST)		Ph3 ASC4FIRST readout in Q1; <b>96-week data at ASH in Q4</b>
	Zolgensma® SMA IT		Ph3 (STEER)	<b>Positive readout in Q4</b>
	XXB750 Hypertension		Ph2	Development will not be advanced following review of available data
<b>Ph3 starts</b>	Pluvicto® oligometastatic PC	Ph3		Ph3 PSMA-DC started in Q1
	Opnurasib 1L NSCLC (combo) <sup>1</sup>	Ph2/3		Program discontinued to prioritize other key programs in portfolio

See page 76 for references (footnote 1).



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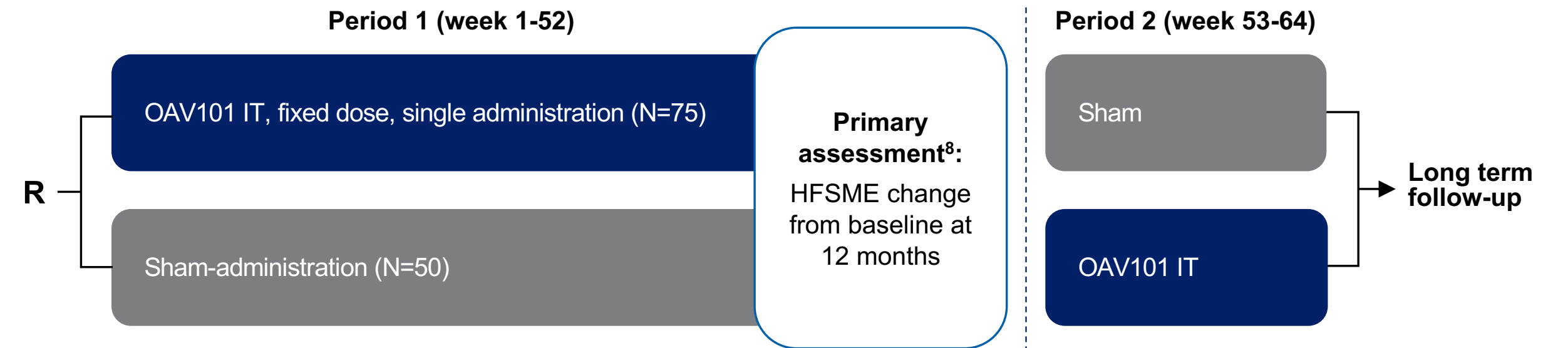
# Phase 3 STEER study of OAV101 IT met primary endpoint in children and young adults with spinal muscular atrophy

First investigational gene therapy to provide clinical benefit in treatment-naive patients with SMA aged two and above<sup>6</sup>

## Primary endpoint met

- **Increase from baseline in HFMSE**, a gold standard for SMA-specific assessment of motor ability and disease progression<sup>1-5</sup>, vs. sham controls
- **Favorable safety profile** with adverse events similar between arms<sup>7</sup>
- Data will be presented at an **upcoming medical congress**

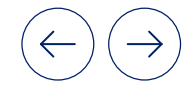
## Study design



**Broad patient population:** Treatment-naive patients with SMA Type 2, ≥ 2 to < 18 years of age, treatment naive, sitting, and never ambulatory

> **Global regulatory submissions expected in 2025**

See page 77 for references (footnotes 1-8).



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# Bolstered Neuroscience pipeline with in-licensing of voptoplam (PTC518), potential first oral disease-modifying therapy for Huntington’s Disease

## Significant unmet need in HD

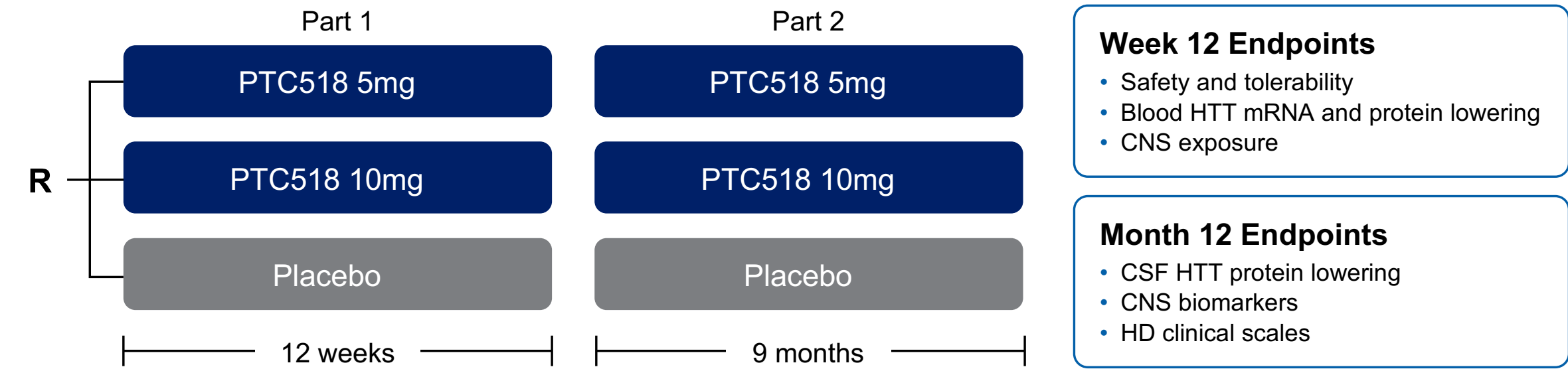
- Fatal neurodegenerative disease caused by an inherited genetic mutation in the HTT gene
- No existing disease-modifying therapies
- Prevalence: ~37k (US) and ~28k (EU5) “manifest” symptomatic patients, ~2x “pre-manifest” patients<sup>1</sup>

## Potential first oral disease-modifying therapy

- Voptoplam is an HTT splicing modifier, which reduces HTT expression
- LMW approach has favorable biodistribution for mHTT reduction

## Ph2 PIVOT-HD study ongoing

### Study design



### Interim results from 32 patients at 12 months

- Dose-dependent mHTT protein reductions in blood and CSF, and promising trends in clinical measures with no evidence of treatment-related spikes in NfL

> Ph2 PIVOT-HD study readout expected in H1 2025

See page 77 for references (footnote 1). Novartis obtained global rights to develop, manufacture, and commercialize voptoplam under license/collaboration agreement with PTC Therapeutics.





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# Expect to continue our innovation momentum in 2025

## 2025 selected key events (expected)

**15+** Key approvals or submissions

- Atrasentan IgAN (US approval)
- Fabhalta® C3G (US, JP, EU approvals)
- Pluvicto® mCRPC, pre-taxane (US approval)
- Scemblix® 1L CML (JP approval, EU submission)
- Pluvicto® mHSPC (US submission)
- Cosentyx® GCA (US, EU submissions)
- Remibrutinib CSU (US, EU, CN submissions)
- Zolgensma® SMA IT (US, EU, JP submissions)

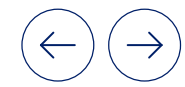
**10+** Key readouts (six pivotal)

- Cosentyx® GCA Ph3
- Cosentyx® PMR Ph3
- lanalumab SjS Ph3s
- lanalumab 2L ITP Ph3
- Pluvicto® mHSPC Ph3
- KLU156 Malaria Ph3
- Remibrutinib FA Ph2
- lanalumab HS Ph2
- Votoplam (PTC518) HD Ph2<sup>1</sup>
- NIO752 (tau ASO) (AD, PSP) Ph1

**10+** Key study initiations

- Remibrutinib HS Ph3
- Remibrutinib gMG Ph3
- Ac-PSMA-617 PC Ph3
- Kisqali + oral SERD Ph3<sup>2</sup>
- YTB323 AAV Ph2
- JSB462 (AR degrader) PC Ph2
- GIA632 (IL-15 mAb) Ph2
- QCZ484 rHTN Ph2
- VHB937 (TREM2) AD Ph2
- YTB323 gMG Ph1

1. Ongoing study shown is sponsored by PTC Therapeutics. 2. Ongoing combination study shown is sponsored by Olema Pharmaceuticals.



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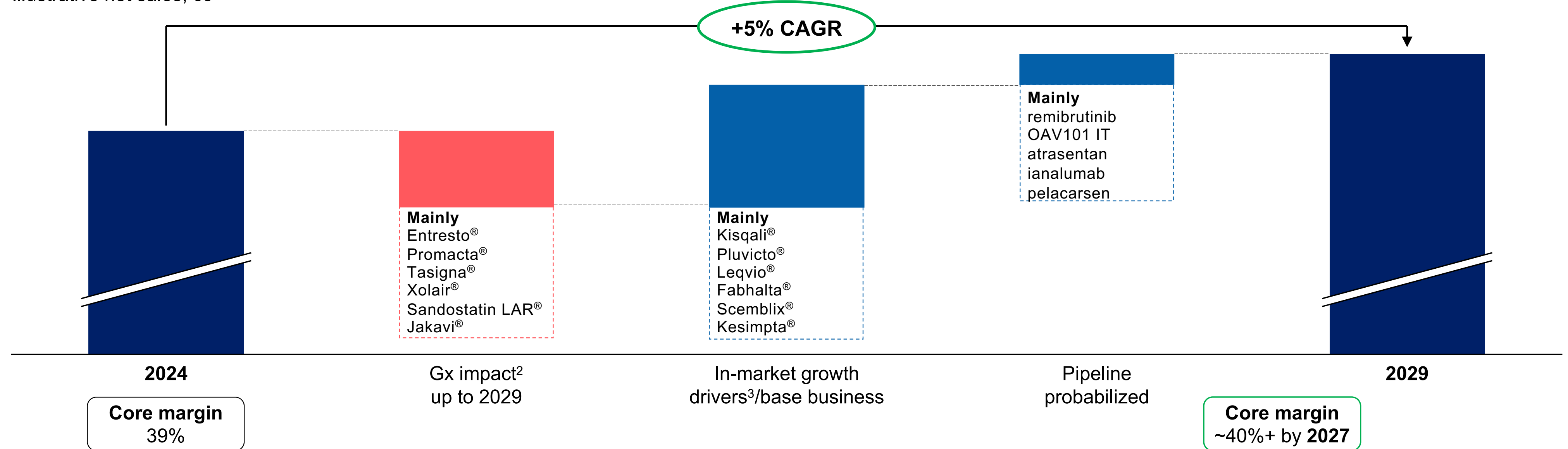
References

# Confident in our mid-term guidance of +5% cc sales CAGR 2024-2029 and 40%+ core margin by 2027

## Mid-term guidance

2024-2029 +5% (cc) expected sales CAGR (previous guidance 2023-2028)

Illustrative net sales, cc<sup>1</sup>



Note: All figures reflecting Continuing Operations. 1. Core results and constant currencies (cc) are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report  
2. For forecasting purposes, we assume Entresto US LoE in mid-2025. 3. Including indication expansion. Leqvio – licensed from Alnylam Pharmaceuticals, Inc. Pelacarsen – licensed from Ionis Pharmaceuticals, Inc.





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# Financial review and 2025 guidance

**Harry Kirsch**

Chief Financial Officer



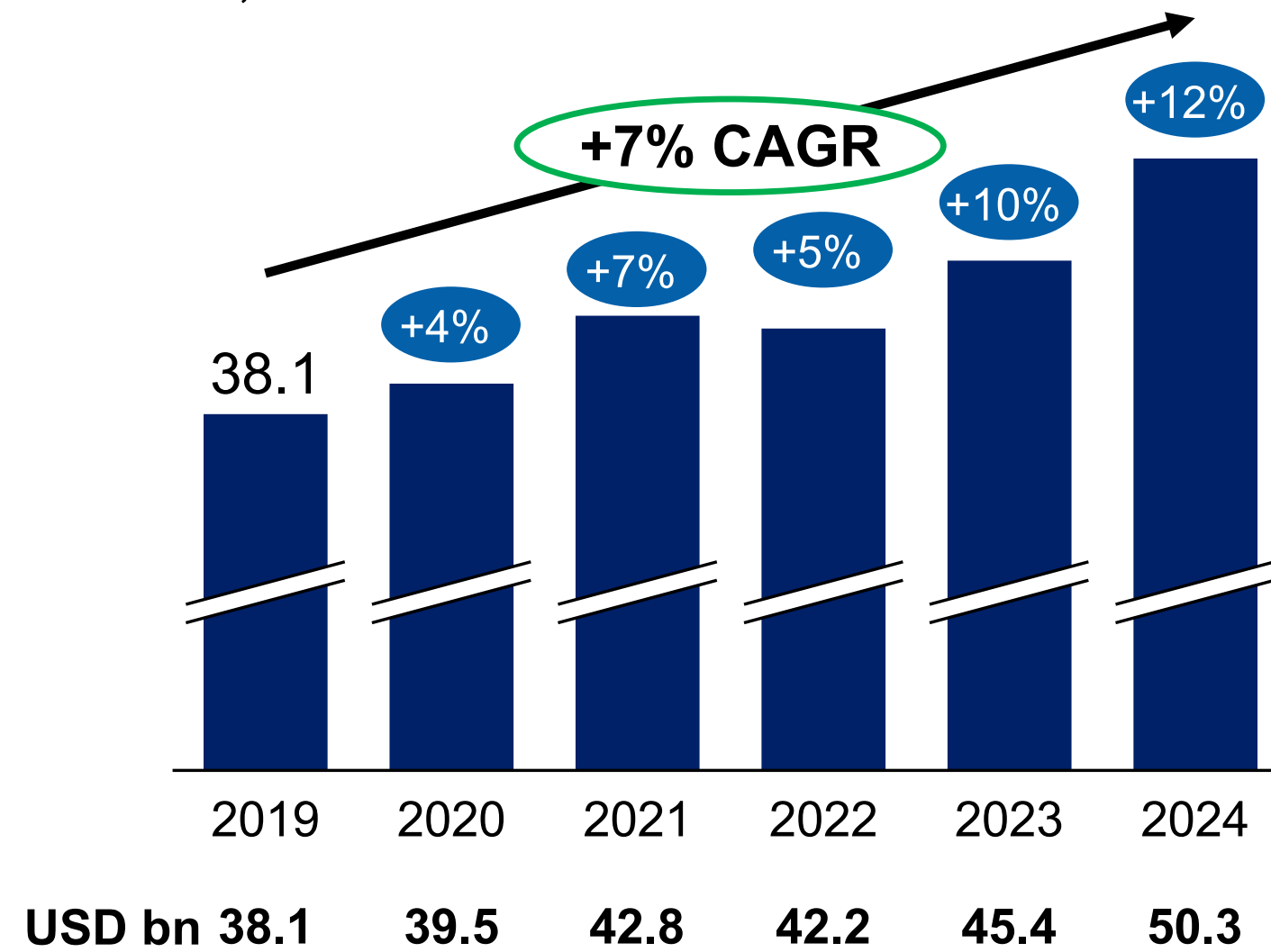


# Novartis continues strong track record of sales growth with margin expansion in 2024

Continuing operations<sup>1</sup> performance, *numbers restated post-Sandoz spin-off*

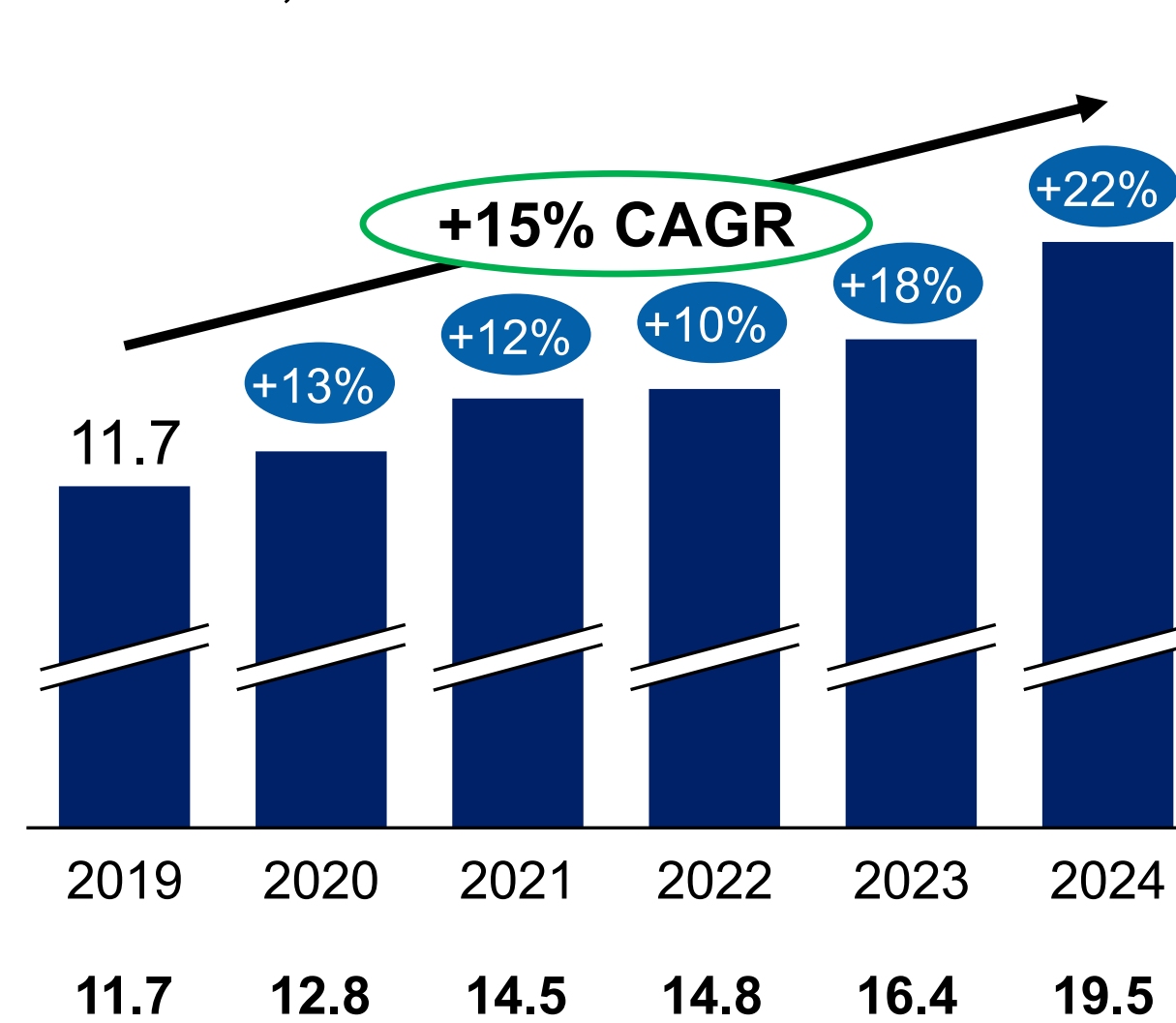
## Net sales

USD bn, % cc



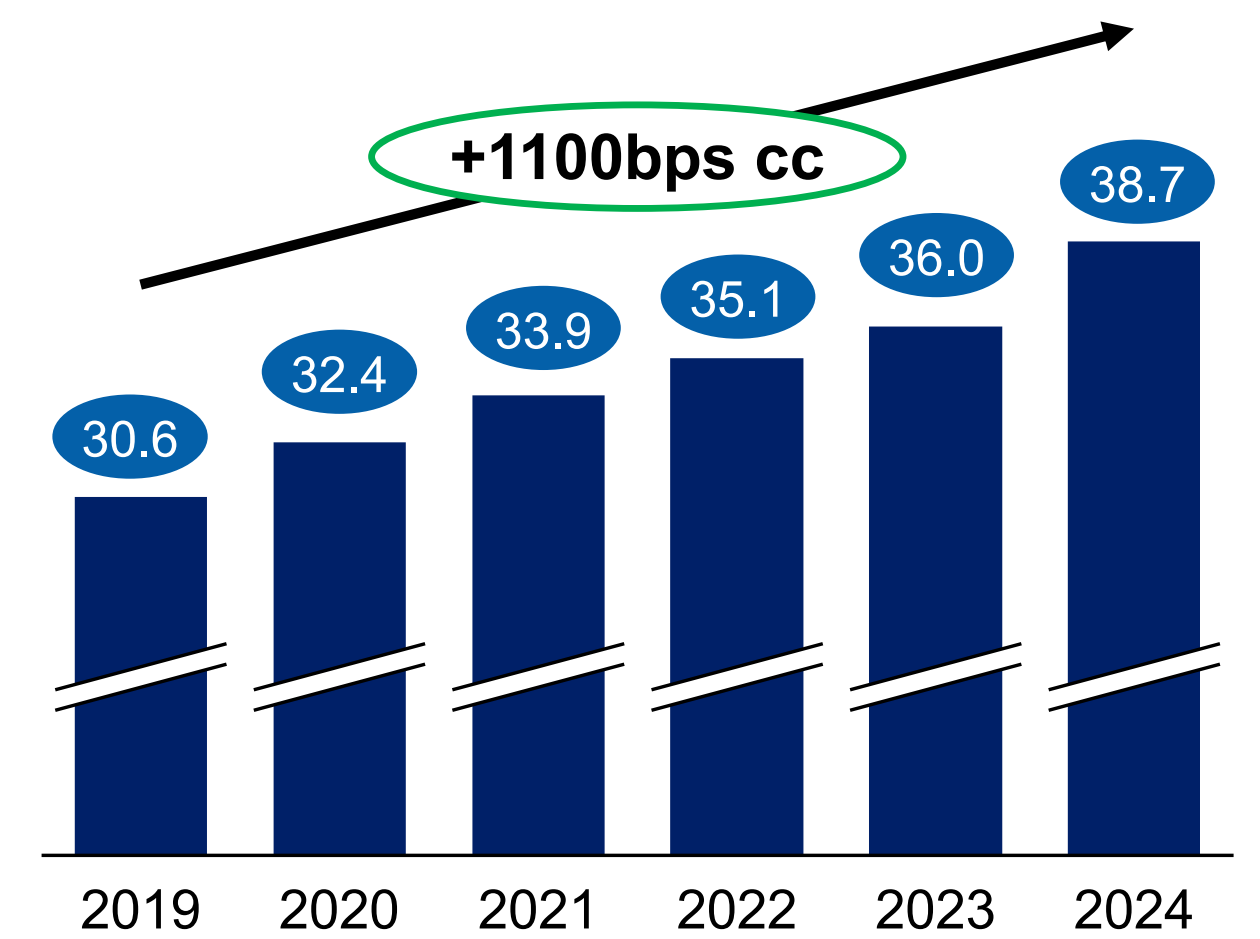
## Core OpInc<sup>2</sup>

USD bn, % cc



## Core margin<sup>2</sup>

%



1. As defined on page 35 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities. 2. Core results and constant currencies are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



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# In 2024, we met and exceeded our full-year guidance

## Continuing operations<sup>1</sup>

In cc<sup>2</sup>

**FY guidance**  
(as per Q3 2024)

**Actual results**  
FY 2024 vs. PY

Sales	Core OpInc
Expected to grow low double-digit	Expected to grow high-teens
<b>+12%</b>	<b>+22%</b>

1. As defined on page 35 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities. 2. Core results and constant currencies are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report.

# Robust top and bottom-line growth during Q4 and FY, with record margin and free cash flow in 2024

Continuing Operations <sup>1,2</sup> USD million	Q4 2023	Q4 2024	Change vs. PY		FY 2023	FY 2024	Change vs. PY	
			% USD	% cc			% USD	% cc
Total Net Sales	11,423	13,153	15	16	45,440	50,317	11	12
Core operating income	3,821	4,859	27	29	16,372	19,494	19	22
Core margin	33.5%	36.9%	+3.4%pts	+3.7%pts	36.0%	38.7%	+2.7%pts	+3.3%pts
Operating income	2,582	3,530	37	39	9,769	14,544	49	55
Net Income	2,638	2,820	7	6	8,572	11,939	39	45
Core EPS	1.53	1.98	29	33	6.47	7.81	21	24
EPS	1.29	1.42	10	10	4.13	5.92	43	49
Free cash flow	2,141	3,635	70		13,160	16,253	24	

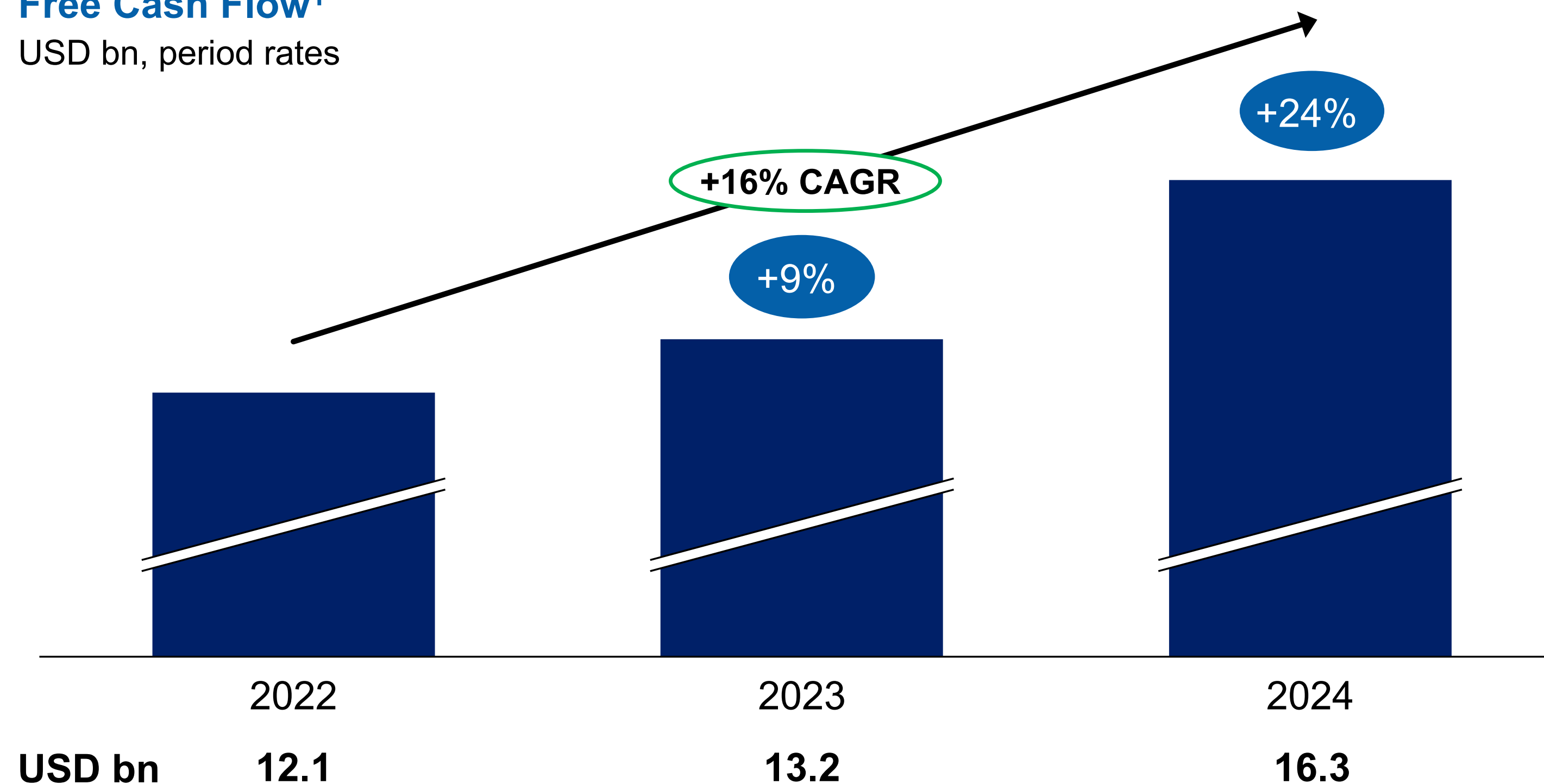
1. Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. 2. As defined on page 35 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the innovative medicines business and the continuing Corporate activities and Discontinued operations include operational results from the Sandoz business.



# Continued focus on Free Cash Flow generation

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

USD bn, period rates



**2024 growth driven by higher core operating income**

1. Free cash flow and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



# Continuing our shareholder-friendly capital allocation strategy

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## Investing in the business

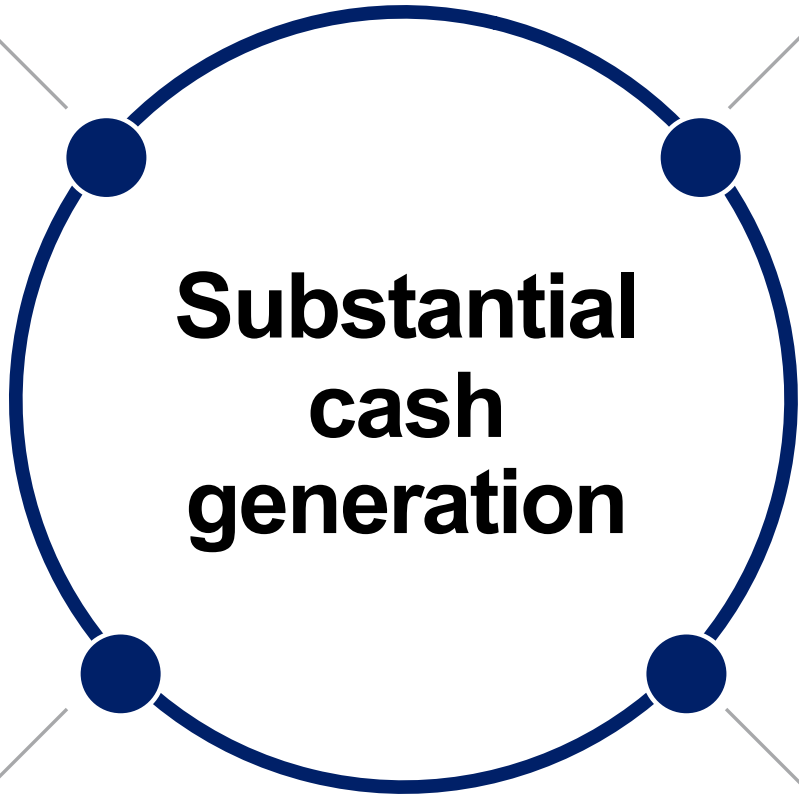
## Returning capital to shareholders

### Investments in organic business

Ongoing investment in R&D (USD 9.3bn in 2024<sup>1</sup>) and CapEx (USD 1.4bn in 2024)

### Value-creating bolt-ons

>30 strategic deals in the last 2 years to strengthen our pipeline, including in NS, RLT and Renal



### Consistently growing annual dividend<sup>2</sup>

Dividend of CHF 3.50 per share, increase of 6.1%, proposed for 2024

### Share buybacks

Up-to USD 15bn share buyback continuing, with up to USD 5.4bn still to be executed<sup>3</sup>

1. Refers to Core R&D expenses. Core results and constant currencies are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. 2. In CHF. 3. As of December 31, 2024.



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# Novartis proposes 3.50 CHF/share<sup>1</sup> dividend at the AGM; 28<sup>th</sup> consecutive dividend increase in CHF since 1996

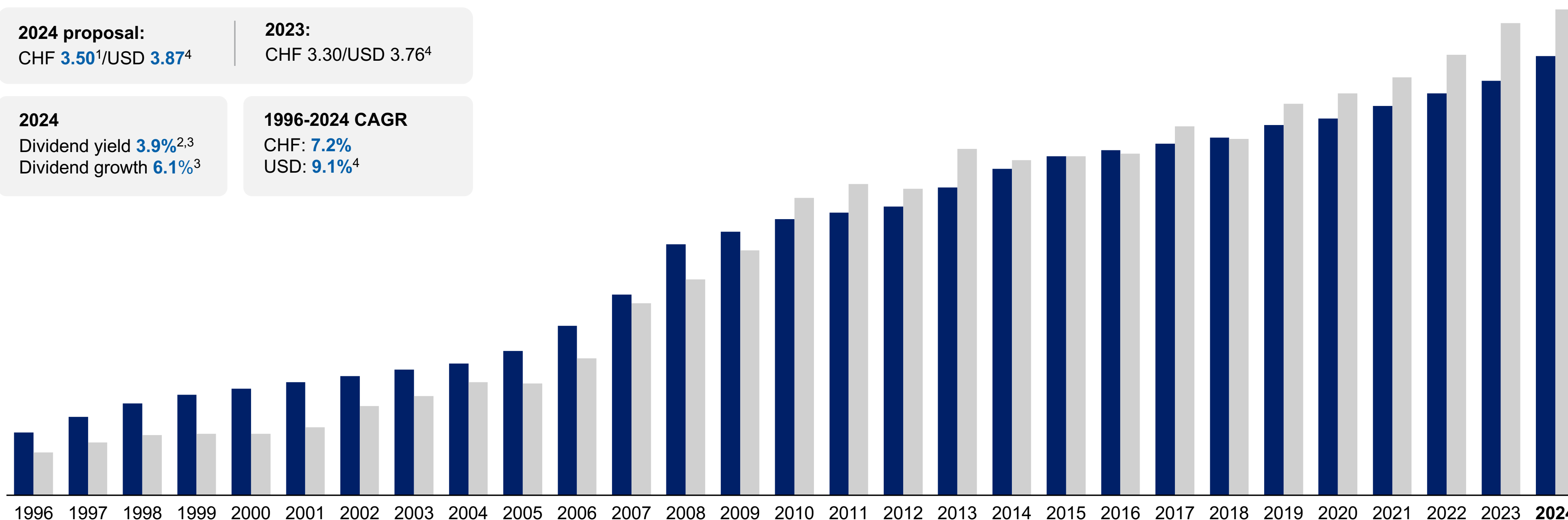
■ CHF dividend ■ USD dividend

**2024 proposal:**  
CHF 3.50<sup>1</sup>/USD 3.87<sup>4</sup>

**2023:**  
CHF 3.30/USD 3.76<sup>4</sup>

**2024**  
Dividend yield 3.9%<sup>2,3</sup>  
Dividend growth 6.1%<sup>3</sup>

**1996-2024 CAGR**  
CHF: 7.2%  
USD: 9.1%<sup>4</sup>



1. Proposal to shareholders at the 2025 Annual General Meeting, taking place on March 7, 2025. 2. Based on the NOVN closing share price of CHF 88.70, as of December 31, 2024. 3. In CHF.  
4. Historical dividends per share converted at historical exchange rates at the dividend payment dates as per Bloomberg; for 2024, translated into US dollars at the FX rate of CHF/USD of 1.107, as of December 31, 2024.



# Novartis 2025 full year guidance

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

## Net sales

expected to grow

**mid- to high single-digit**

## Core operating income

expected to grow

**high single to low double-digit**

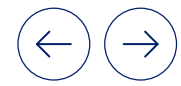
## Key assumptions<sup>2</sup>

- We assume Tassigna<sup>®</sup>, Promacta<sup>®</sup> and Entresto<sup>®</sup> US generic entry mid-2025 for forecasting purposes<sup>2</sup>

## 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%

1. Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed 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.



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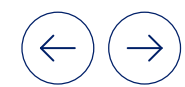
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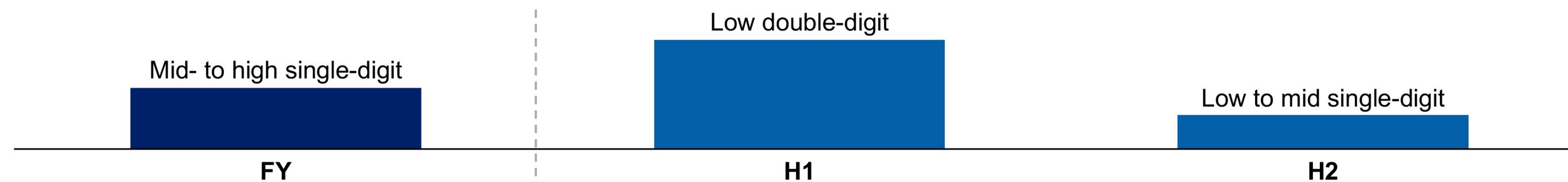
References

# Expect continued strong volume growth from priority brands in 2025; H2 impacted by potential Tasigna<sup>®</sup>, Promacta<sup>®</sup> and Entresto<sup>®</sup> US Gx entry<sup>2</sup>

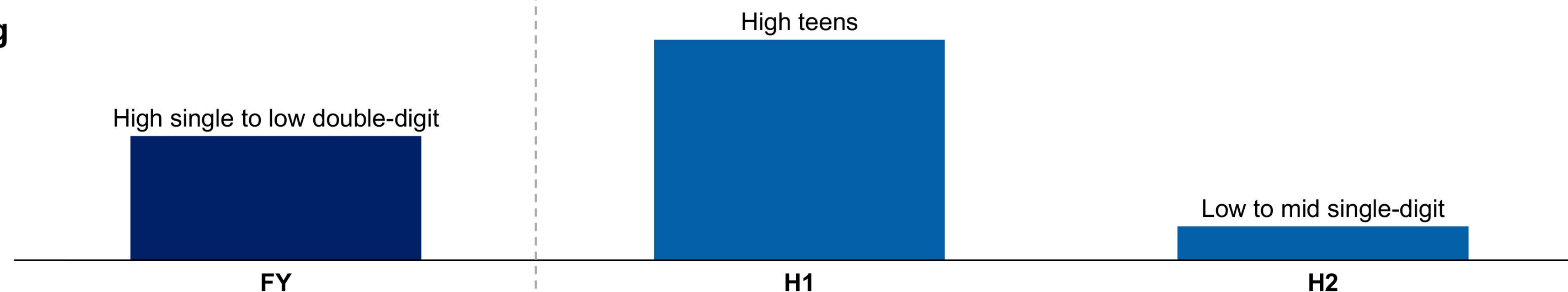
## 2025 growth vs. PY (cc)

Illustrative

### Net Sales



### Core operating Income



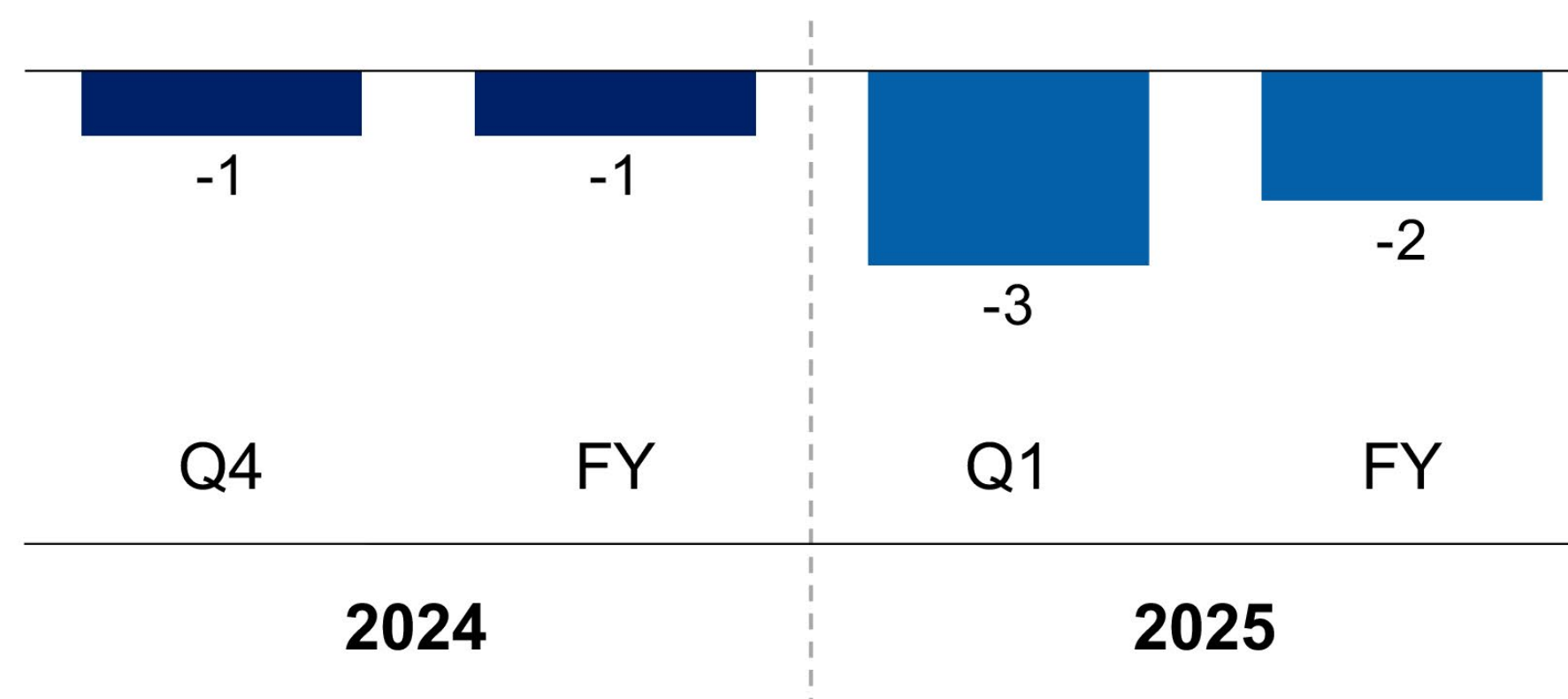
1. Core results and constant currencies are non-IFRS measures. Details regarding non-IFRS measures can be found starting on page 47 of the Condensed Financial Report. 2. We assume Tasigna<sup>®</sup>, Promacta<sup>®</sup> and Entresto<sup>®</sup> US generic entry mid-2025 for forecasting purposes.

# Expected currency impact for Q1 and full year 2025

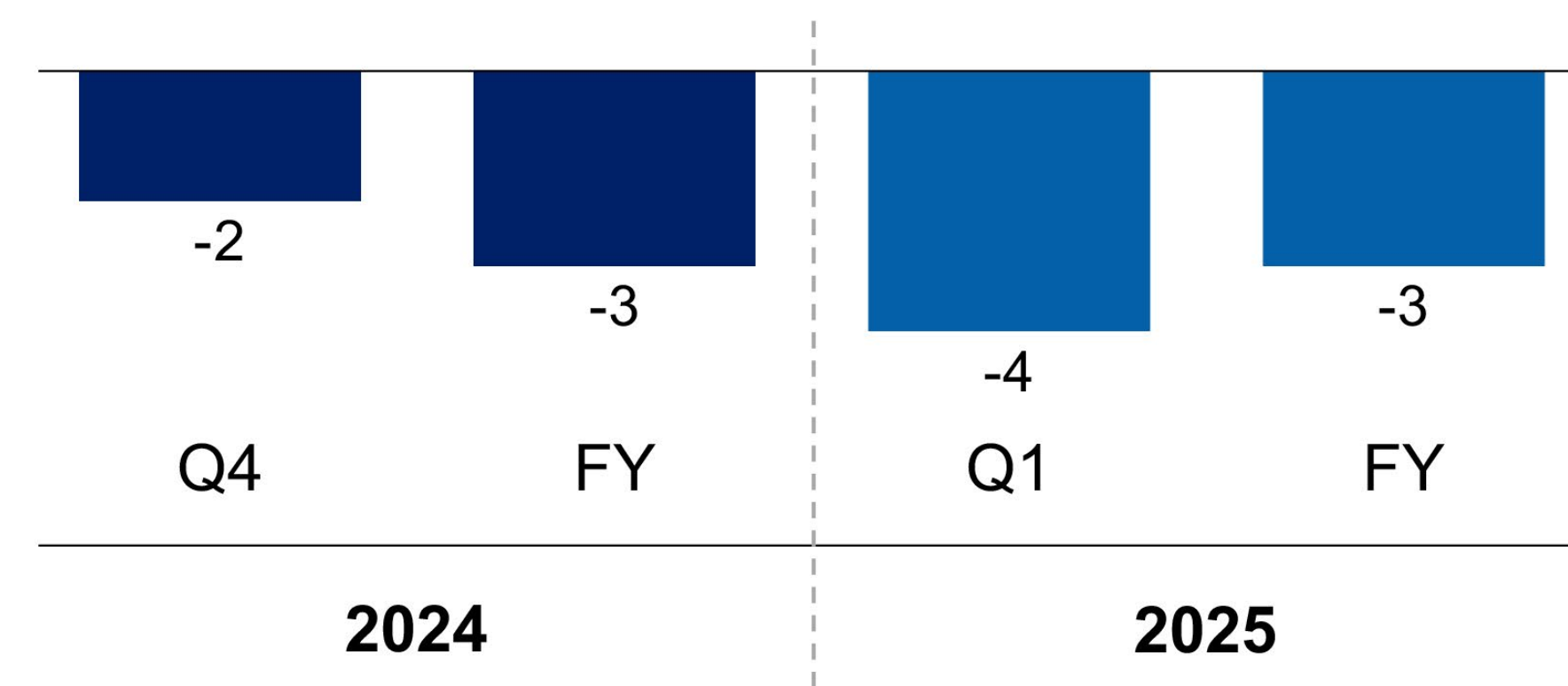
## Currency impact vs. PY

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

### FX impact on Net sales

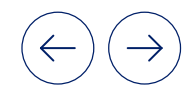


### FX impact on Core operating income



Actual Simulation

1. Core results are non-IFRS measures as defined on page 47 of Condensed Financial Report.



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







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**Continued strong business momentum in Q4**, delivering one of the best financial performances in our history



**Met and exceeded our full-year guidance**



**Continued to advance our pipeline**, including new approvals and readouts for assets that will fuel our mid-to long-term growth



**Expect to continue strong sales growth with margin expansion in 2025**, and remain on track to deliver our mid-term guidance

Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



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# Key innovation milestones in 2025

## 2025 selected key events (expected)

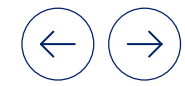
		H1 2025	H2 2025
<b>Regulatory decisions</b>	Atrasentan IgAN	US	
	Fabhalta® (iptacopan) C3G	US, JP	EU
	Pluvicto® mCRPC, pre-taxane	US	
	Scemblix® 1L CML		JP
<b>Submissions</b>	Remibrutinib CSU	US, EU, CN	
	Zolgensma® SMA IT	US, EU	JP
	Scemblix® CML 1L	EU	
	Pluvicto® mHSPC		US
	Cosentyx® GCA		US, EU
<b>Readouts</b>	Cosentyx® GCA	Ph3 (GCAPTAIN)	
	Cosentyx® PMR		Ph3 (REPLENISH)
	Ianalumab SjS		Ph3s (NEPTUNUS-1 and -2)
	Ianalumab 2L ITP		Ph3 (VAYHIT2)
	Pluvicto® mHSPC		Ph3 (PSMAddition)
	Remibrutinib FA		Ph2
	Ianalumab HS	Ph2	
	Votoplam (PTC518) HD <sup>1</sup>	Ph2	
	Remibrutinib HS	Ph3	
	Remibrutinib gMG	Ph3	
<b>Key study starts</b>	Ac-PSMA-617 PC	Ph3	
	YTB323 AAV	Ph2	
	JSB462 (AR degrader) PC		Ph2
	GIA632 (IL-15 mAb)		Ph2
	QCZ484 rHTN		Ph2
	VHB937 (TREM2) AD		Ph2

1. Ongoing study shown is sponsored by PTC Therapeutics.

# Our pipeline projects at a glance

	Phase 1/2	Phase 3	Registration	Total
<b>Oncology</b>	23	8	4	35
Solid tumors	18	3	4	25
Hematology	5	5	0	10
<b>Immunology</b>	15	8	0	23
<b>Neuroscience</b>	7	6	0	13
<b>Cardiovascular, Renal and Metabolic</b>	4	7	2	13
<b>Others</b> (thereof IB&GH)	12 (9)	3 (3)	2 (2)	17
	<b>61</b>	<b>32</b>	<b>8</b>	<b>101</b>

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



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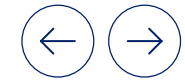
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# Novartis pipeline in Phase 1

16 lead indications

Lead indication



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## Oncology

Code	Name	Mechanism	Indication(s)
<b>Solid tumors</b>			
AAA603	<sup>177</sup> Lu-NeoB	Radioligand therapy target GRPR	Breast cancer Glioblastoma multiforme
AAA617	Pluvicto®	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
FXX489	<sup>177</sup> Lu-NNS309	Radioligand therapy	Solid tumors
GIZ943	GIZ943	-	Solid tumors
HRO761	HRO761	Werner inhibitor	Solid tumors
IAG933	IAG933	-	Mesothelioma
KFA115	KFA115	Novel immunomodulatory Agent	Solid tumors
MGY825	MGY825	-	NSCLC
<b>Hematology</b>			
DFV890	DFV890	NLRP3 inhibitor	Low risk myelodysplastic syndrome
PIT565	PIT565	-	B-cell malignancies
YTB323	rapcabtagene autoleucel	CD19 CAR-T	Adult ALL

## Cardiovascular, Renal and Metabolic

Code	Name	Mechanism	Indication(s)
DFV890	DFV890	NLRP3 inhibitor	Cardiovascular risk reduction

## 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

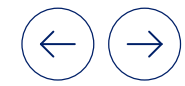
Code	Name	Mechanism	Indication(s)
<b>IB&amp;GH</b>			
EDI048	EDI048	CpPI(4)K inhibitor	Cryptosporidiosis
ITU512	ITU512	HbF inducing agent	Sickle cell disease



# Novartis pipeline in Phase 2

16 lead indications

  Lead indication



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## Oncology

Code	Name	Mechanism	Indication(s)
<b>Solid tumors</b>			
AAA601	Lutathera®	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	JSB462	Androgen receptor protein degrader	Prostate cancer
<b>Hematology</b>			
ABL001	Scemblix®	BCR-ABL inhibitor	Chronic myeloid leukemia, pediatrics
YTB323	rapcabtagene autoleucl	CD19 CAR-T	1L high-risk large B-cell lymphoma

## Neuroscience

Code	Name	Mechanism	Indication(s)
VHB937	VHB937	TREM2 stabilizer and activator	Amyotrophic lateral sclerosis

## Cardiovascular, Renal and Metabolic

Code	Name	Mechanism	Indication(s)
LNP023	Fabhalta®	CFB inhibitor	Lupus nephritis ANCA associated vasculitis
TIN816	TIN816	ATP modulator	Acute kidney injury

## Immunology

Code	Name	Mechanism	Indication(s)
DFV890	DFV890	NLRP3 inhibitor	Osteoarthritis
LOU064	remibrutinib	BTK inhibitor	Food allergy Hidradenitis suppurativa
LRX712	LRX712	-	Osteoarthritis
MAS825	MAS825	IL1B, IL18 Inhibitor	NLRC4-GOF indications
NGI226	NGI226	-	Tendinopathy
RHH646	RHH646	-	Osteoarthritis
VAY736	ianalumab	BAFF-R inhibitor, ADCC-mediated B-cell depletor	Hidradenitis suppurativa Systemic sclerosis
YTB323	rapcabtagene autoleucl	CD19 CAR-T	srSLE/LN Systemic sclerosis Myositis

## Others

Code	Name	Mechanism	Indication(s)
<b>IB&amp;GH</b>			
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®	Multi-targeted kinase inhibitor	Acute myeloid leukemia, pediatrics
SEG101	Adakveo®	P-selectin inhibitor	Sickle cell disease, pediatrics
<b>Others</b>			
LNP023	Fabhalta®	CFB inhibitor	iAMD
LTP001	LTP001	SMURF1 inhibitor	Pulmonary arterial hypertension Idiopathic pulmonary fibrosis



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# Novartis pipeline in Phase 3

## 6 lead indications

  Lead indication

### Oncology

Code	Name	Mechanism	Indication(s)
<b>Solid tumors</b>			
AAA617	Pluvicto®	Radioligand therapy target PSMA	Metastatic hormone sensitive prostate cancer (mHSPC) Oligometastatic prostate cancer
BYL719	Vijoice®	PI3K-alpha inhibitor	Lymphatic malformations
<b>Hematology</b>			
DAK539	pelabresib	BET inhibitor	Myelofibrosis
LNP023	Fabhalta®	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®	siRNA (regulation of LDL-C)	CVRR (secondary prevention) CVRR (primary prevention) Hyperlipidemia, pediatrics
LNP023	Fabhalta®	CFB inhibitor	C3 glomerulopathy, pediatrics IC-MPGN
TQJ230	pelacarsen	ASO targeting Lp(a)	Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein (a) (CVRR-Lp(a))

### Neuroscience

Code	Name	Mechanism	Indication(s)
BAF312	Mayzent®	S1P1,5 receptor modulator	Multiple sclerosis, pediatrics
LNP023	Fabhalta®	CFB inhibitor	Myasthenia gravis
LOU064	remibrutinib	BTK inhibitor	Multiple sclerosis Myasthenia gravis
OAV101	AVXS-101	SMN1 gene replacement therapy	SMA IT administration
OMB157	Kesimpta®	CD20 Antagonist	Multiple sclerosis, pediatrics

### Immunology

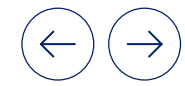
Code	Name	Mechanism	Indication(s)
AIN457	Cosentyx®	IL17A inhibitor	Giant cell arteritis Polymyalgia rheumatica
LOU064	remibrutinib	BTK inhibitor	Chronic spontaneous urticaria Chronic spontaneous urticaria, pediatrics Chronic inducible urticaria
VAY736	ianalumab	BAFF-R inhibitor, ADCC-mediated B-cell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

### Others

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

1 lead indication

# Novartis pipeline in registration



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## Oncology

Code	Name	Mechanism	Indication(s)
------	------	-----------	---------------

**Solid tumors**

AAA601 <sup>1</sup>	Lutathera®	Radioligand therapy target SSTR	Gastroenteropancreatic neuroendocrine tumors (GEP-NET), 1st line in G2/3 tumors
AAA617	Pluvicto®	Radioligand therapy target PSMA	Metastatic castration-resistant prostate cancer (mCRPC), pre-taxane
INC424	Jakavi®	JAK1/2 inhibitor	Acute GVHD, pediatrics Chronic GVHD, pediatrics

## Cardiovascular, Renal and Metabolic

Code	Name	Mechanism	Indication(s)
------	------	-----------	---------------

EXV811	atrasentan	ET <sub>A</sub> receptor antagonist	IgA nephropathy
LNP023	Fabhalta®	CFB inhibitor	C3 glomerulopathy

## Others

Code	Name	Mechanism	Indication(s)
------	------	-----------	---------------

**IB&GH**

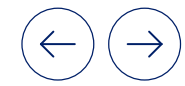
COA566	Coartem®	Artemisinin combination therapy	Malaria, uncomplicated (<5kg patients)
RTH258	Beovu®	VEGF Inhibitor	Diabetic retinopathy

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



# Novartis submission schedule

## New Molecular Entities: Lead and supplementary indications



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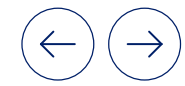
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- CRM
- Immunology
- Neuroscience
- Oncology
- Non-core TA project



1. Part of triple combination therapy.



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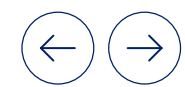
# Novartis submission schedule

## Supplementary indications for existing brands



Existing brands

1. <sup>177</sup>Lu-dotatate in US. 2. Event-driven trial endpoint. 3. Kesimpta and Mayzent: Pediatric trial in multiple sclerosis run in conjunction (NEOS).



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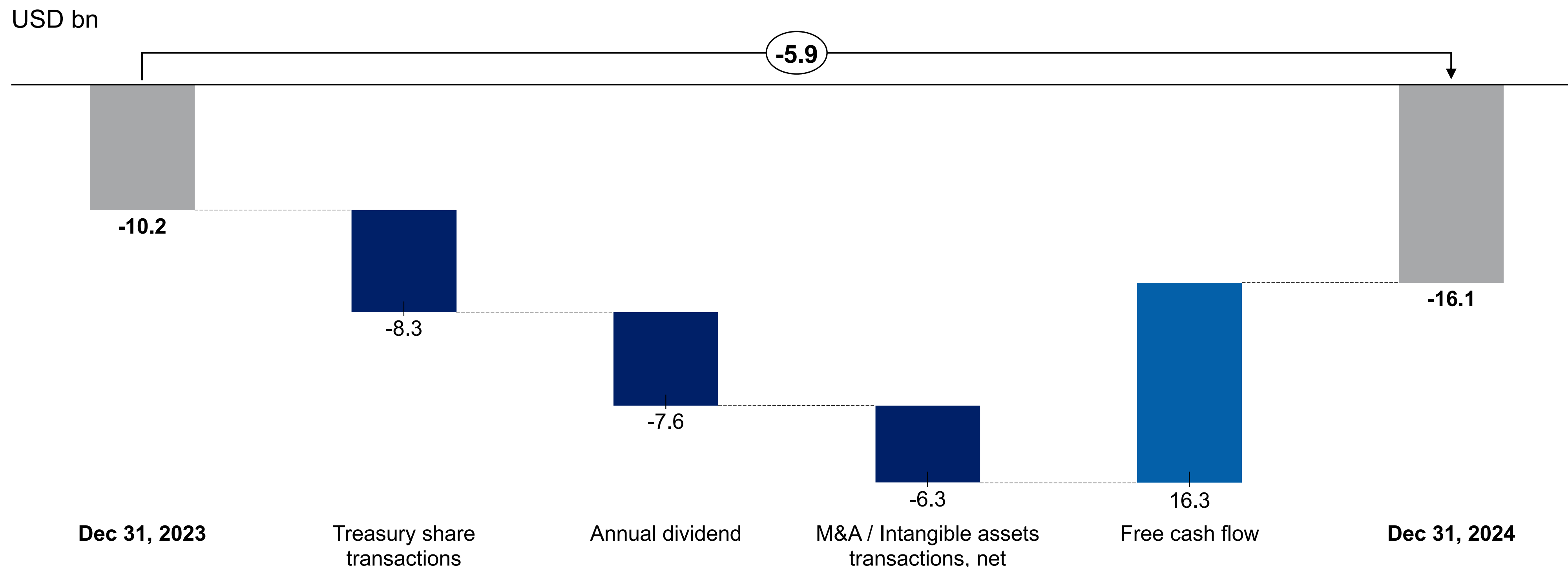
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# Net debt increased by USD 5.9bn due to share buybacks, the annual dividend and M&A, partially offset by FCF



Free cash flow is a non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.





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# 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](http://www.novartisclinicaltrials.com)



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# Cardiovascular, Renal and Metabolic



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# atrasentan - ETA receptor antagonist

## NCT04573478 ALIGN (CHK01-01)

<b>Indication</b>	IgA nephropathy
<b>Phase</b>	Phase 3
<b>Patients</b>	380
<b>Primary Outcome Measures</b>	Change in proteinuria Time Frame: Up to Week 24 or approximately 6 months Annualized total estimated Glomerular Filtration Rate (eGFR) slope estimated over 24 months
<b>Arms Intervention</b>	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
<b>Target Patients</b>	Patients with IgA nephropathy (IgAN) at risk of progressive loss of renal function
<b>Readout Milestone(s)</b>	2023 (primary endpoint for US initial submission) 2026 (24 months)
<b>Publication</b>	TBD





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# Fabhalta<sup>®</sup> - CFB inhibitor

## NCT04578834 APPLAUSE-IgAN (CLNP023A2301)

<b>Indication</b>	IgA nephropathy
<b>Phase</b>	Phase 3
<b>Patients</b>	450
<b>Primary Outcome Measures</b>	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
<b>Arms Intervention</b>	Arm 1 - LNP023 200mg BID Arm 2 - Placebo BID
<b>Target Patients</b>	Primary IgA Nephropathy patients
<b>Readout Milestone(s)</b>	2023 (primary endpoint for US initial submission, 9 months UPCR) 2025 (24 months)
<b>Publication</b>	TBD

# Fabhalta<sup>®</sup> - CFB inhibitor

## NCT05755386 APPARENT (CLNP023B12302)

<b>Indication</b>	Immune complex-mediated membranoproliferative glomerulonephritis
<b>Phase</b>	Phase 3
<b>Patients</b>	68
<b>Primary Outcome Measures</b>	Log-transformed ratio to baseline in UPCR (sampled from a 24-hour urine collection) at 6 months. [ Time Frame: 6 months (double-blind) ] <i>To demonstrate the superiority of iptacopan compared to placebo in reducing proteinuria at 6 months.</i> Log-transformed ratio to baseline in UPCR at the 12-month visit (both study treatment arms) [ Time Frame: 12 months ] <i>To evaluate the effect of iptacopan on proteinuria at 12 months.</i> Log-transformed ratio to 6-month visit in UPCR at the 12-month visit in the placebo arm. [ Time Frame: 12 months ] <i>To evaluate the effect of iptacopan on proteinuria at 12 months.</i>
<b>Arms Intervention</b>	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)
<b>Target Patients</b>	Patients (adults and adolescents aged 12-17 years) with idiopathic IC-MPGN
<b>Readout Milestone(s)</b>	2028
<b>Publication</b>	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



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# Leqvio<sup>®</sup> - siRNA (regulation of LDL-C)

## NCT03705234 ORION-4 (CKJX839B12301)

<b>Indication</b>	Hypercholesterolemia inc. Heterozygous Familial Hypercholesterolaemia (HeFH)
<b>Phase</b>	Phase 3
<b>Patients</b>	16124
<b>Primary Outcome Measures</b>	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
<b>Arms Intervention</b>	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 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.
<b>Target Patients</b>	Patient population with mean baseline LDL-C $\geq$ 100mg/dL
<b>Readout Milestone(s)</b>	2026
<b>Publication</b>	TBD

# Leqvio<sup>®</sup> - siRNA (regulation of LDL-C)

## NCT05030428 VICTORION-2P (CKJX839B12302)

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



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## Leqvio<sup>®</sup> - siRNA (regulation of LDL-C)

### NCT04652726 ORION-16 (CKJX839C12301)

<b>Indication</b>	Hyperlipidemia, pediatrics
<b>Phase</b>	Phase 3
<b>Patients</b>	141
<b>Primary Outcome Measures</b>	Percentage (%) change in low-density lipoprotein cholesterol (LDL-C) from baseline to Day 330
<b>Arms Intervention</b>	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.
<b>Target Patients</b>	Adolescents (12 to less than 18 years) with heterozygous familial hypercholesterolemia (HeFH) and elevated low density lipoprotein cholesterol (LDL-C)
<b>Readout Milestone(s)</b>	2025
<b>Publication</b>	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<sup>®</sup> - siRNA (regulation of LDL-C)

### NCT04659863 ORION-13 (CKJX839C12302)

<b>Indication</b>	Hyperlipidemia, pediatrics
<b>Phase</b>	Phase 3
<b>Patients</b>	13
<b>Primary Outcome Measures</b>	Percentage (%) change in low-density lipoprotein cholesterol (LDL-C) from baseline to day 330
<b>Arms Intervention</b>	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.
<b>Target Patients</b>	Adolescents (12 to less than 18 years) with homozygous familial hypercholesterolemia (HoFH) and elevated low density lipoprotein cholesterol (LDL-C)
<b>Readout Milestone(s)</b>	2025
<b>Publication</b>	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





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## Leqvio<sup>®</sup> - siRNA (regulation of LDL-C)

### NCT05739383 VICTORION-1P (CKJX839D12302)

<b>Indication</b>	CVRR (Primary prevention)
<b>Phase</b>	Phase 3
<b>Patients</b>	14000
<b>Primary Outcome Measures</b>	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
<b>Arms Intervention</b>	Arm 1 Experimental: Inclisiran Sodium 300mg, subcutaneous injection in pre-filled syringe Arm 2 Placebo
<b>Target Patients</b>	High-risk primary prevention patients
<b>Readout Milestone(s)</b>	2029
<b>Publication</b>	TBD

## Leqvio<sup>®</sup> - siRNA (regulation of LDL-C)

### NCT05763875 V-Mono (CKJX839D12304)

<b>Indication</b>	CVRR (Primary prevention)
<b>Phase</b>	Phase 3
<b>Patients</b>	350
<b>Primary Outcome Measures</b>	1. Percentage change in Low-density Lipoprotein Cholesterol (LDL-C) from baseline to day 150 compared with placebo [ Time Frame: Baseline, Day 150 ]  2. Percentage change in LDL-C from baseline to day 150 compared with ezetimibe [ Time Frame: Baseline, Day 150 ]
<b>Arms Intervention</b>	Arm 1 Experimental: Inclisiran s.c and Placebo p.o Arm 2 Active Comparator: Placebo s.c. and Ezetimibe p.o. Arm 3 Placebo Comparator: Placebo s.c. and Placebo p.o.
<b>Target Patients</b>	Adult patients with primary hypercholesterolemia not receiving any lipid-lowering therapy (LLT), with a 10-year Atherosclerotic Cardiovascular Disease (ASCVD) risk of less than 7.
<b>Readout Milestone(s)</b>	2024
<b>Publication</b>	TBD



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

## NCT04023552 Lp(a)HORIZON (CTQJ230A12301)

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



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# zigakibart - Anti-APRIL

## NCT05852938 BEYOND (CFUB523A12301)

<b>Indication</b>	IgA nephropathy
<b>Phase</b>	Phase 3
<b>Patients</b>	292
<b>Primary Outcome Measures</b>	Change in proteinuria [ Time Frame: 40 weeks or approximately 9 months ]
<b>Arms Intervention</b>	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
<b>Readout Milestone(s)</b>	2026
<b>Publication</b>	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.





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# Immunology



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# Cosentyx® - IL-17A inhibitor

## NCT05767034 REPLENISH (CAIN457C22301)

<b>Indication</b>	Polymyalgia rheumatica
<b>Phase</b>	Phase 3
<b>Patients</b>	360
<b>Primary Outcome Measures</b>	Proportion of participants achieving sustained remission
<b>Arms Intervention</b>	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
<b>Readout Milestone(s)</b>	2025
<b>Publication</b>	TBD

# Cosentyx® - IL-17A inhibitor

## NCT04930094 GCAPTAIN (CAIN457R12301)

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



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

## NCT05126277 SIRIUS-LN (CVAY736K12301)

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



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

## NCT05349214 NEPTUNUS-2 (CVAY736A2302)

<b>Indication</b>	Sjögren's syndrome
<b>Phase</b>	Phase 3
<b>Patients</b>	505
<b>Primary Outcome Measures</b>	Change from baseline in EULAR Sjögren Syndrome Disease Activity Index (ESSDAI) score at Week 48 as compared to placebo
<b>Arms Intervention</b>	Arm 1: Experimental - ianalumab exposure level 1 Arm 2: Experimental - ianalumab exposure level 2 Arm 3: Placebo comparator
<b>Target Patients</b>	Patients with active Sjogren's syndrome
<b>Readout Milestone(s)</b>	Primary 2025
<b>Publication</b>	TBD

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

## NCT05350072 NEPTUNUS-1 (CVAY736A2301)

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





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

## NCT05639114 SIRIUS-SLE 1 (CVAY736F12301)

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

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

## NCT05624749 SIRIUS-SLE 2 (CVAY736F12302)

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



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

## NCT06470048 (CVAY736S12201)

<b>Indication</b>	Systemic scleroderma
<b>Phase</b>	Phase 2
<b>Patients</b>	200
<b>Primary Outcome Measures</b>	3/5 Revised Composite Response Index in Systemic Sclerosis 25 (rCRISS25) response at Week 52
<b>Arms Intervention</b>	<p>Arm 1 Experimental VAY736 (lanalumab)</p> <ul style="list-style-type: none"> <li>- Treatment Period 1: lanalumab subcutaneous (s.c.) injection as defined in the protocol</li> <li>- Treatment Period 2: Open-label (OL) lanalumab subcutaneous (s.c.) injection as defined in the protocol</li> </ul> <p>Arm 2 Placebo Comparator: Placebo</p> <ul style="list-style-type: none"> <li>- Treatment Period 1: Placebo to lanalumab subcutaneous (s.c.) injection as defined in the protocol</li> <li>- Treatment Period 2: Open-label (OL) lanalumab subcutaneous (s.c.) injection as defined in the protocol</li> </ul>
<b>Target Patients</b>	Patients with diffuse cutaneous systemic sclerosis
<b>Readout Milestone(s)</b>	2028
<b>Publication</b>	TBD



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# remibrutinib - BTK inhibitor

## NCT05976243 (CLOU064M12301)

<b>Indication</b>	Chronic inducible urticaria
<b>Phase</b>	Phase 3
<b>Patients</b>	348
<b>Primary Outcome Measures</b>	<ol style="list-style-type: none"> <li>1. Proportion of participants with complete response in Total Fric Score; symptomatic dermographism [ Time Frame: Week 12 ]</li> <li>2. Proportion of participants with complete response in critical temperature threshold; cold urticaria [ Time Frame: Week 12 ]</li> <li>3. Proportion of participants with itch numerical rating scale =0; cholinergic urticaria [ Time Frame: Week 12 ]</li> </ol>
<b>Arms Intervention</b>	<p>All arms oral, twice daily:</p> <p>Arm 1 Experimental Remibrutinib, symptomatic dermographism group</p> <p>Arm 2 Placebo symptomatic dermographism group</p> <p>Arm 3 Experimental Remibrutinib, cold urticaria group</p> <p>Arm 4 Placebo cold urticaria group</p> <p>Arm 5 Experimental Remibrutinib, cholinergic urticaria group</p> <p>Arm 6 Placebo cholinergic urticaria group</p>
<b>Target Patients</b>	Adults suffering from CINDU inadequately controlled by H1-antihistamines
<b>Readout Milestone(s)</b>	2026
<b>Publication</b>	TBD



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# Fabhalta<sup>®</sup> - CFB inhibitor

## NCT123456 APPRAISE (CLNP023Q12301)

<b>Indication</b>	Generalized Myasthenia Gravis
<b>Phase</b>	Phase 3
<b>Patients</b>	146
<b>Primary Outcome Measures</b>	Change from baseline to Month 6 in Myasthenia Gravis Activity of Daily Living (MG-ADL) total score
<b>Arms Intervention</b>	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
<b>Target Patients</b>	Patients with generalized MG who anti-AchR-positive and are not adequately responding to 2/3rd line SoC.
<b>Readout Milestone(s)</b>	2027
<b>Publication</b>	TBD



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# Mayzent® - S1P1,5 receptor modulator

## NCT04926818 NEOS (CBAF312D2301)

<b>Indication</b>	Multiple sclerosis, pediatrics
<b>Phase</b>	Phase 3
<b>Patients</b>	120
<b>Primary Outcome Measures</b>	Annualized relapse rate (ARR) in target pediatric participants
<b>Arms Intervention</b>	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
<b>Target Patients</b>	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.
<b>Readout Milestone(s)</b>	2027
<b>Publication</b>	TBD



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## remibrutinib - BTK inhibitor

### NCT05147220 REMODEL-1 (CLOU064C12301)

<b>Indication</b>	Multiple sclerosis
<b>Phase</b>	Phase 3
<b>Patients</b>	800
<b>Primary Outcome Measures</b>	Annualized relapse rate (ARR) of confirmed relapses [Core Part]. ARR is the average number of confirmed MS relapses in a year
<b>Arms Intervention</b>	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
<b>Readout Milestone(s)</b>	Estimated primary completion 2026
<b>Publication</b>	TBD

## remibrutinib - BTK inhibitor

### NCT05156281 REMODEL-2 (CLOU064C12302)

<b>Indication</b>	Multiple sclerosis
<b>Phase</b>	Phase 3
<b>Patients</b>	800
<b>Primary Outcome Measures</b>	Annualized relapse rate (ARR) of confirmed relapses
<b>Arms Intervention</b>	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
<b>Readout Milestone(s)</b>	Estimated primary completion 2026
<b>Publication</b>	TBD



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# remibrutinib - BTK inhibitor

## NCT06744920 RELIEVE (CLOU064O12301)

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





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# Zolgensma® - SMN1 gene replacement therapy

## NCT05089656 STEER (COAV101B12301)

<b>Indication</b>	Spinal muscular atrophy (IT administration)
<b>Phase</b>	Phase 3
<b>Patients</b>	125
<b>Primary Outcome Measures</b>	1. Change from baseline in Hammersmith functional motor scale - Expanded (HFMSE) total score at the end of follow-up period 1 in treated patients compared to sham controls in the ≥ 2 to < 18 years age group
<b>Arms Intervention</b>	Arm 1: Experimental OAV101. Administered as a single, one-time intrathecal dose Arm 2: Sham Comparator: Sham control. A skin prick in the lumbar region without any medication.
<b>Target Patients</b>	Patients Type 2 Spinal Muscular Atrophy (SMA) who are ≥ 2 to < 18 years of age, treatment naive, sitting, and never ambulatory
<b>Readout Milestone(s)</b>	2024 (actual, positive readout)
<b>Publication</b>	TBD

# Zolgensma® - SMN1 gene replacement therapy

## NCT05386680 STRENGTH (COAV101B12302)

<b>Indication</b>	Spinal muscular atrophy (IT administration)
<b>Phase</b>	Phase 3B
<b>Patients</b>	28
<b>Primary Outcome Measures</b>	Number and percentage of participants reporting AEs, related AEs, SAEs, and AESIs [ Time Frame: 52 weeks ]
<b>Arms Intervention</b>	Experimental: OAV-101 Single intrathecal administration of OAV101 at a dose of 1.2 x 10 <sup>14</sup> vector genomes
<b>Target Patients</b>	Participants with SMA who discontinued treatment With Nusinersen or Risdiplam (STRENGTH)
<b>Readout Milestone(s)</b>	2024 (actual, positive readout)
<b>Publication</b>	TBD



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

## NCT05653349 VAYHIT1 (CVAY736I12301)

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

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

## NCT05653219 VAYHIT2 (CVAY736Q12301)

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



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

## NCT05648968 VAYHIA (CVAY736O12301)

<b>Indication</b>	Warm autoimmune hemolytic anemia
<b>Phase</b>	Phase 3
<b>Patients</b>	90
<b>Primary Outcome Measures</b>	Binary variable indicating whether a patient achieves a durable response Durable response: hemoglobin level $\geq 10$ g/dL and $\geq 2$ 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
<b>Arms Intervention</b>	Arm 1: experimental lanalumab low dose (intravenously) Arm 2: experimental lanalumab high dose (intravenously) Arm 3: placebo Comparator (intravenously)
<b>Target Patients</b>	Previously treated patients with warm Autoimmune Hemolytic Anemia
<b>Readout Milestone(s)</b>	2026
<b>Publication</b>	TBD





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# iptacopan - CFB inhibitor

## NCT04889430 APPELHUS (CLNP023F12301)

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



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# Pluvicto® - Radioligand therapy target PSMA

## NCT04689828 PSMAfore (CAAA617B12302)

<b>Indication</b>	Metastatic castration-resistant prostate cancer, pre-taxane
<b>Phase</b>	Phase 3
<b>Patients</b>	450
<b>Primary Outcome Measures</b>	Radiographic Progression Free Survival (rPFS)
<b>Arms Intervention</b>	Arm 1: Participants will receive 7.4 GBq (200 mCi) +/- 10% <sup>177</sup> Lu-PSMA-617 once every 6 weeks for 6 cycles. Best supportive care, including ADT may be used Arm 2: For participants randomized to the ARDT arm, the change of ARDT treatment will be administered per the physician's orders. Best supportive care, including ADT may be used
<b>Target Patients</b>	mCRPC patients that were previously treated with an alternate ARDT and not exposed to a taxane-containing regimen in the CRPC or mHSPC settings
<b>Readout Milestone(s)</b>	Primary Analysis: 2022 (actual) Final Analysis: 2025
<b>Publication</b>	6 June 2024: SNMMI Abstract of the Year: [177Lu]Lu-PSMA-617 Extends Progression-Free Survival with Manageable Safety Profile in Taxane-Naïve Advanced Prostate Cancer Patients

# Pluvicto® - Radioligand therapy target PSMA

## NCT04720157 PSMAddition (CAAA617C12301)

<b>Indication</b>	Metastatic hormone sensitive prostate cancer
<b>Phase</b>	Phase 3
<b>Patients</b>	1126
<b>Primary Outcome Measures</b>	Radiographic Progression Free Survival (rPFS)
<b>Arms Intervention</b>	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
<b>Target Patients</b>	Patients with metastatic Hormone Sensitive Prostate Cancer (mHSPC)
<b>Readout Milestone(s)</b>	Primary Analysis: 2025 (event driven)
<b>Publication</b>	TBD



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# Vioice® - PI3Ki

## NCT05948943 EPIK-L1 (CBYL719P12201)

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



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# cipargamin - PfATP4 inhibitor

## NCT04675931 KARISMA (CKAE609B12201)

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



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# ganaplacide/lumefantrine - Non-artemisinin plasmodium falciparum inhibitor

## NCT05842954 KALUMA (CKLU156A12301 )

<b>Indication</b>	Malaria, uncomplicated
<b>Phase</b>	Phase 3
<b>Patients</b>	1500
<b>Primary Outcome Measures</b>	PCR-corrected adequate clinical and parasitological response (ACPR) at day 29
<b>Arms Intervention</b>	Arm 1 experimental: KLU156 oral; 400/480 mg (ganaplacide/ lumefantrine) is the fixed dose combination for patients with a bodyweight $\geq$ 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 $\geq$ 5 kg Body Weight with uncomplicated P. Falciparum Malaria
<b>Readout Milestone(s)</b>	2025
<b>Publication</b>	TBD



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# Rydapt® - Multi-targeted kinase inhibitor

## NCT03591510 (CPKC412A2218)

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



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# Abbreviations

Abbreviation	Full Form
ACS	Acute Coronary Syndrome
Adj.BC	Adjuvant Breast Cancer
aLLT	Advanced Lipid Lowering Therapy
AS	Ankylosing Spondylitis
ASH	American Society of Hematology
ASOC	Alternate Site of Care
C3G	Complement 3 Glomerulopathy
CML	Chronic Myeloid Leukemia
CSU	Chronic Spontaneous Urticaria
DDFS	Distant Disease-Free Survival
eBC	Early Breast Cancer
EVH	Extravascular Hemolysis
GEP-NET	Gastroenteropancreatic Neuroendocrine Tumors
HD	Huntington's Disease
HF	Heart Failure
HS	Hidradenitis Suppurativa
HTN	Hypertension
HTT	Huntingtin
IA	Interim Analysis
IB&GH	In-market Brands and Global Health
IgAN	Immunoglobulin A Nephropathy

Abbreviation	Full Form
IL	Interleukin
IV	Intravenous
IVH	Intravascular Hemolysis
LoE	Loss of Exclusivity
mBC	Metastatic Breast Cancer
mCRPC	Metastatic Castration-Resistant Prostate Cancer
mHSPC	Metastatic Hormone-Sensitive Prostate Cancer
MoA	Method of Action
mRNA	Messenger Ribonucleic Acid
NBRx	New to Brand Prescription
nr-axSpA	Non-Radiographic Axial Spondyloarthritis
NSCLC	Non-small Cell Lung Cancer
PNH	Paroxysmal Nocturnal Hemoglobinuria
PsA	Psoriatic Arthritis
PsO	Psoriasis
RDP	Regulatory Data Protection
REMS	Risk Evaluation and Mitigation Strategy
SMA	Spinal Muscular Atrophy
TRx	Total Prescriptions
TTDAE	Time to Treatment Discontinuation due to Adverse Events





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## Entresto® (slide 6 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 Timing of Entresto US generic entry is subject to ongoing patent and regulatory litigation.
- 4 Extension of regulatory data protection to November 2026 in EU based on approval of pediatric indication.
- 5 Based on 2024 sales.

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## Cosentyx® (slide 7 references)

- 1 Refers to NBRx. Indications: Derm (PsO+HS) and Rheum (SpA) combined. Source: IQVIA National Source of Business (NSOB) YTD January 2025.
- 2 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).
- 3 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).
- 4 US, DE, UK, FR, ES, AU.
- 5 IV formulation indication: PsA, AS, nr-axSpA. Source: IQVIA mastered 867 data.

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## Kesimpta® (slide 8 references)

- 1 NBRx (adjusted) data. Source: Contracted SP data + Access card and IQVIA NPA adjusted by NSP. Based on data availability, December actuals through Dec 6, 2024, and projected for remaining 3 weeks of December 2024.
- 2 IQVIA LAAD adjusted by contracted SP data + Access card and IQVIA NPA adjusted by NSP, through October 2024.
- 3 MMIT, LLC database as of December 2024 and Data on File. First line coverage defined as no step therapy/previous treatment failure required. PA is often required.
- 4 Top 10 ex-US markets include Germany, Japan, China, UK, France, Spain, Italy, Canada, Brazil, Australia.
- 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.



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## Kisqali® (slide 9 references)

- 1 IQVIA Market Sizing Monthly Report, November 2024; Data lag: ~ 2 months.
- 2 Of CDK4/6 mBC market, US rolling 3 months ending November 2024, IQVIA Breast Cancer Market Sizing report.
- 3 Of CDK4/6 mBC market, ex-US 3 months ending October 2024, IQVIA Breast Cancer Market Sizing report.

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## Leqvio® (slide 11 references)

- 1 Includes PCSK9 monoclonal antibodies and bempedoic acid.
- 2 12 months ended December 2024.
- 3 Data on file. Study NCT05763875. Novartis Pharmaceuticals Corp; 2024.

---

## Scemblix® (slide 12 references)

- 1 October rolling 3-months US IQVIA CML market sizing report, January 2025.
- 2 Average calculated considering Germany (IQVIA LRx October 24) and Japan (MDV Q3'24).
- 3 Average projected considering EU4 (OD November 2024), DE (LRX Oct 2024) and JP (MDV Q3'24).

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## Fabhalta® (slide 14 reference)

- 1 International markets average ~95% except China where Fabhalta is approved only for naive patients.

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## Pipeline (slide 15 references)

- 1 This is a seamless Ph2/3 trial.



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## OAV101 IT (slide 16 references)

- 1 Oskoui M, et al. SUNFISH Parts 1 and 2: 4-year efficacy and safety data of risdiplam in types 2 and 3 Spinal Muscular Atrophy (SMA). Available at: <https://medically.roche.com/global/en/neuroscience/wcn-2023/medical-material/WCN-2023-presentation-oskoui-sunfish-parts-1-and-2-4-year-efficacy-pdf.html>.
- 2 Fainmesser Y, et al. Longer-term follow-up of nusinersen efficacy and safety in adult patients with spinal muscular atrophy types 2 and 3. *Neuromuscular Disorders*. 2022;32(6): 451-459.
- 3 Weber C, et al. *Brain and Development*. 2024;46(5):89-198.
- 4 Coratti G, et al. *Eur J Neurol*. 2024;31:e16309.
- 5 Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool - PMC.
- 6 O'Hagen JM, et al. *Neuromuscular disorders: NMD*. 2007;17(9-10):693-7. Epub 2007/07/31.
- 7 The most common adverse events were upper respiratory tract infection, pyrexia and vomiting.
- 8 Secondary objectives included evaluating safety and efficacy of OAV101 IT using the Revised Upper Limb Module (RULM) scale.

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## PTC518 (slide 17 reference)

- 1 Epidemiology values reflective of 2024 prevalence.