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Q4 2023 Results

Investor presentation
January 31, 2024



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Vas Narasimhan, M.D.
Chief Executive Officer





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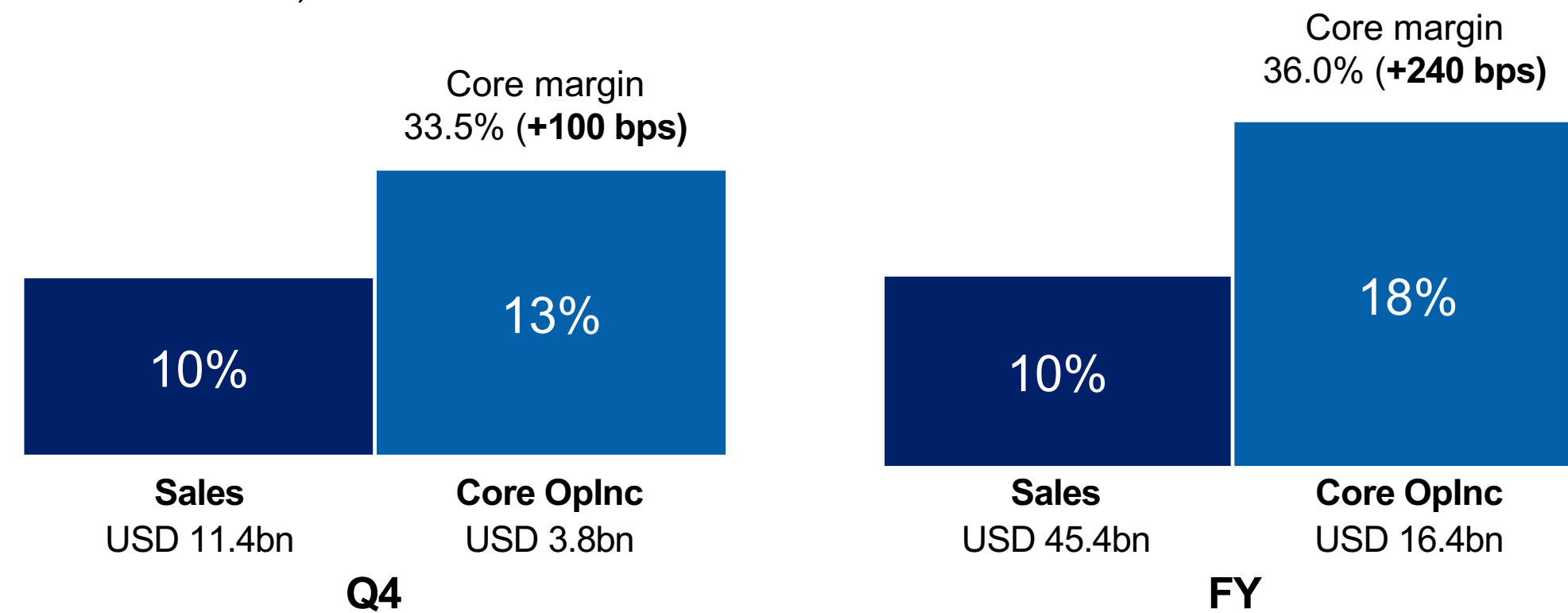
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Novartis delivers strong full year performance with margin expansion. Continuing innovation momentum with multiple positive Ph3 readouts

Double-digit growth for sales and Core OpInc for the quarter and full year¹

Growth vs. PY, cc



Several major innovation milestones in Q4

Fabhalta® (iptacopan) US approval in PNH

Cosentyx® US approval in HS

Cosentyx® US approval of IV formulation (PsA, AS, nr-axSpA)

Iptacopan Ph3 APPLAUSE study met its primary endpoint in IgAN

Atrasentan Ph3 ALIGN study met its primary endpoint in IgAN

Iptacopan Ph3 APPEAR-C3G met its primary endpoint in C3G

Scemblix® Ph3 ASC4FIRST met primary endpoints in 1L Ph+ CML-CP (Jan)

Successful spin-off of Sandoz

FY 2024 guidance¹: Sales expected to grow mid single digit; Core OpInc expected to grow high single digit

Mid-term guidance¹ updated: Sales expected to grow +5% cc CAGR 2023-28; core operating income margin ~40%+ by 2027

OpInc – operating income. 1. As defined on page 37 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



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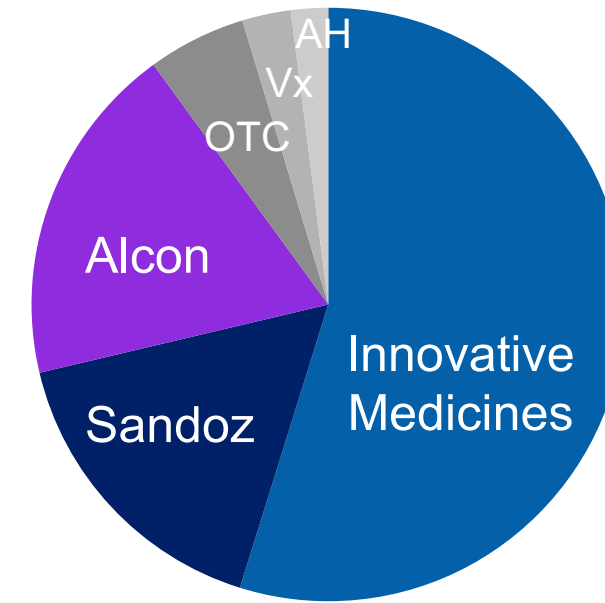
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Completed the transformation; laying the foundation for our future growth

Strategy

FY 2014
Pre-portfolio transformation



FY 2023
Focused company



Operations

Core margin

25.2%

36.0%

FCF (USD)
as % of sales

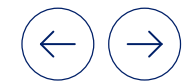
11.1bn
19.1%

13.2bn
29.0%

Innovation

10 positive Ph3 readouts on assets
with significant sales potential

2014 figures reflecting revised free cash flow definition, 2023 figures reflect Continuing Operations. As defined on page 37 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities.



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Strong Q4 growth driven by performance from Entresto[®], Kesimpta[®], Kisqali[®] and Cosentyx[®]

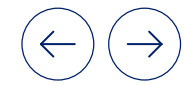
Q4 sales

| | Sales USD million | Growth vs. PY USD million | Growth vs. PY cc |
|--|----------------------|------------------------------|---------------------|
| Entresto [®] <small>sacubitril/valsartan</small> | 1,635 | 344 | 26% |
| Kesimpta [®] <small>(ofatumumab) 20mg/500mg</small> | 641 | 272 | 73% |
| KISQALI [®] <small>ribociclib</small> | 610 | 253 | 76% |
| Cosentyx [®] <small>(secukinumab)</small> | 1,303 | 223 | 21%* |
| PLUVICTO [™] | 273 | 94 | 53% |
| LEQVIO [®] | 123 | 81 | 190% |
| SCEMBLIX [®] <small>(asciminib) 400mg, 800mg tablets</small> | 125 | 73 | 143% |
| ILARIS [®] <small>(canakinumab) 300mg, 150mg, 75mg, 37.5mg</small> | 376 | 75 | 29% |
| JAKAVI [®] <small>ruxolitinib</small> | 444 | 56 | 14% |
| Xolair [®] <small>Omalizumab</small> | 378 | 55 | 16% |
| PROMACTA [®] <small>(eltrombopag)</small> | 563 | 23 | 4% |

Strong growth (+40% cc); expected to continue

* Benefitting from lower prior year base.

Constant currencies (cc) is a non-IFRS measure; explanation of non-IFRS measures can be found on page 49 of Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



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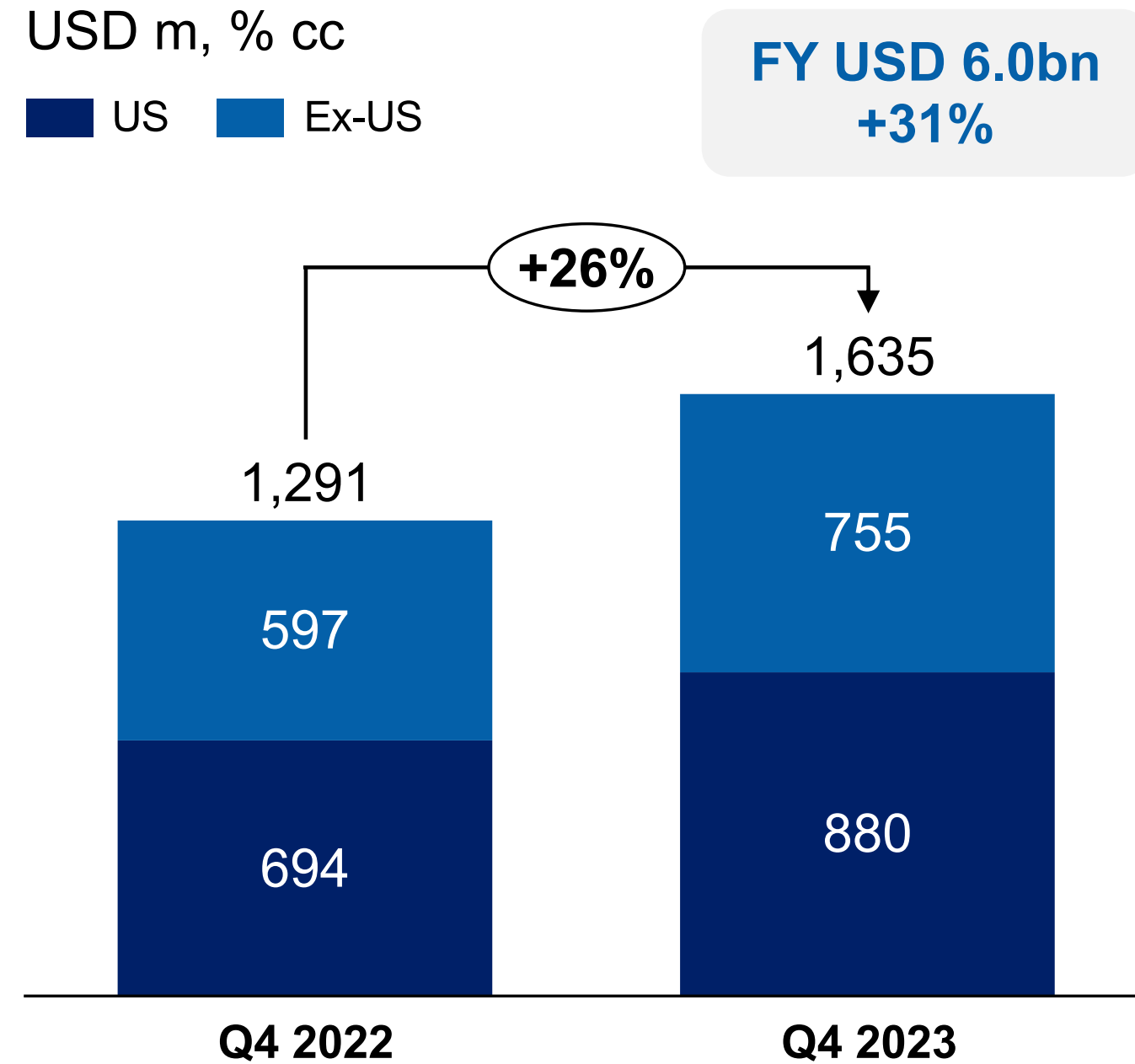
Entresto® delivers 31% FY growth with sales reaching USD 6bn. Expecting USD 7bn peak sales



Sales evolution

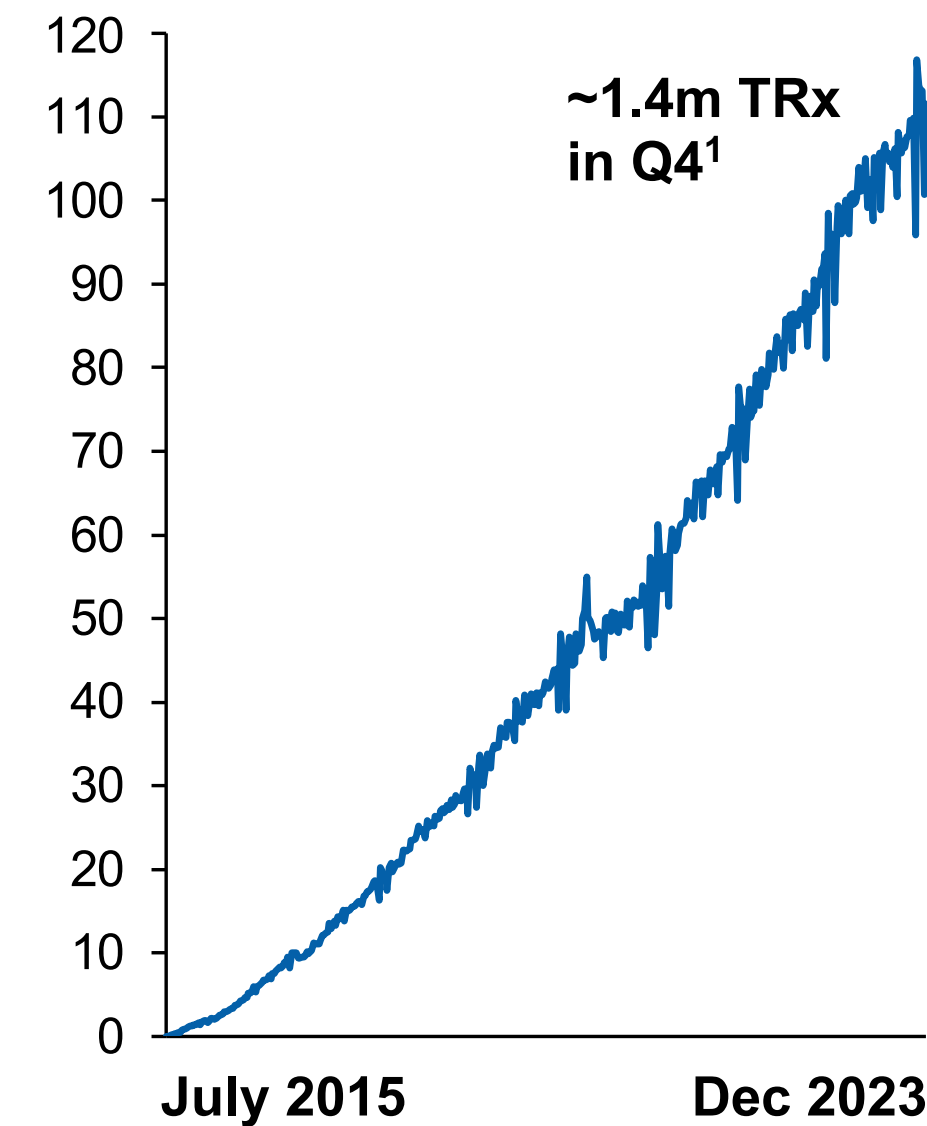
USD m, % cc

■ US ■ Ex-US



US weekly TRx¹

Total prescriptions (000)



Continues strong momentum in Q4

- US: **+27%** cc
- Ex-US: **+26%** cc
- China/Japan: Contribution from HTN²

Confidence in future growth

- Strong guidelines position³ (US/EU)
- Further penetration in HF and HTN
- US: Forecasting purposes, we assume Entresto® LoE in 2025
- EU: RDP to Nov 2026⁴

See last page for references (footnotes 1-4). Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report. TRx – total prescriptions. HF – heart failure. HTN – hypertension. LoE – loss of exclusivity. RDP – Regulatory data protection.

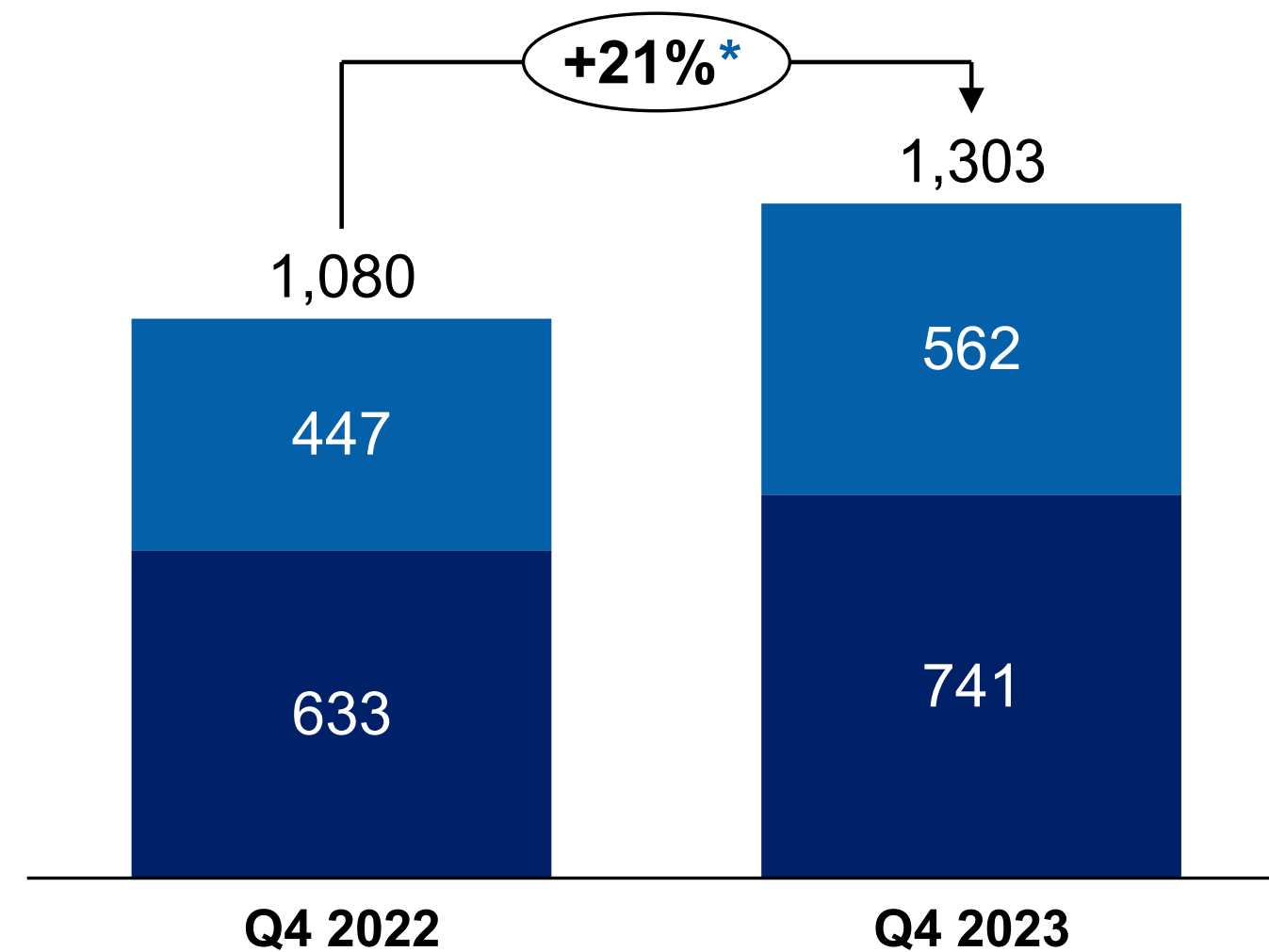
Cosentyx[®] FY sales reached USD 5bn¹. Expect mid to high single-digit growth in 2024 and USD 7bn peak sales



Sales evolution

USD m, % cc

■ US ■ Ex-US



Q4 performance benefitted from lower PY base

- US +17% cc; Ex-US sales +26% cc
- Lower PY base in US due to revenue deduction adjustments
- Launched IV and HS in US

FY 2024: Expect mid to high single-digit growth

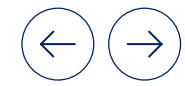
- US/EU: HS launch
- US: IV launch in adult PsA, AS and nr-axSpA
- China: PsA approved January 2024

Further Cosentyx[®] innovation

- 3 Ph3 studies ongoing: Giant Cell Arteritis, Polymyalgia Rheumatica, Rotator Cuff Tendinopathy

* Benefitting from lower prior year base

HS – moderate to severe hidradenitis suppurativa in adult population. IV – intravenous. PsA – psoriatic arthritis. AS – ankylosing spondylitis. nr-axSpA – non-radiographic axial spondyloarthritis. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report. 1. Rounded from USD 4.98bn.



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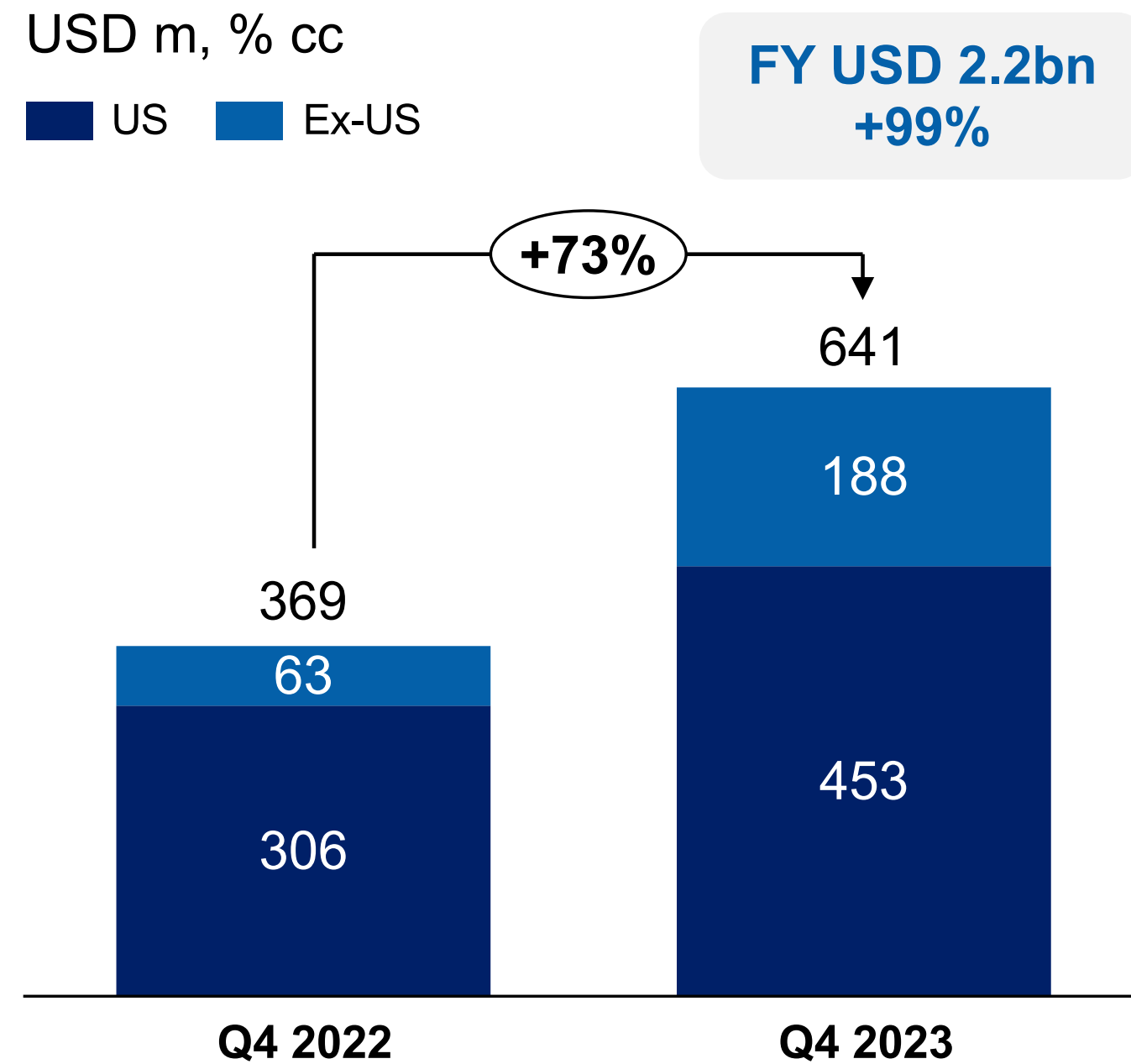
Kesimpta® FY sales doubled (USD 2.2bn) and on track for USD 4bn peak based on compelling product profile



Sales evolution

USD m, % cc

■ US ■ Ex-US



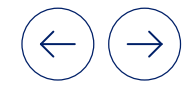
Launch momentum continues across all regions

- >85k patients treated, majority naive or first switch¹
- US (+48% cc in Q4): Demand-driven growth
- Ex-US (+193% cc in Q4): NBRx leadership in 7/10 major markets²

Compelling product profile

- Clinically meaningful efficacy superiority over teriflunomide³
- 1 minute a month dosing at home/anywhere⁴
- ~90% find Kesimpta Sensoready® pen easy and simple to use (US RWE study)^{5,6}
- 5-year efficacy⁷, safety and tolerability data^{8,9}

See last page for references (footnotes 1-9). NBRx – new to brand prescription. MS – Multiple Sclerosis. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report.



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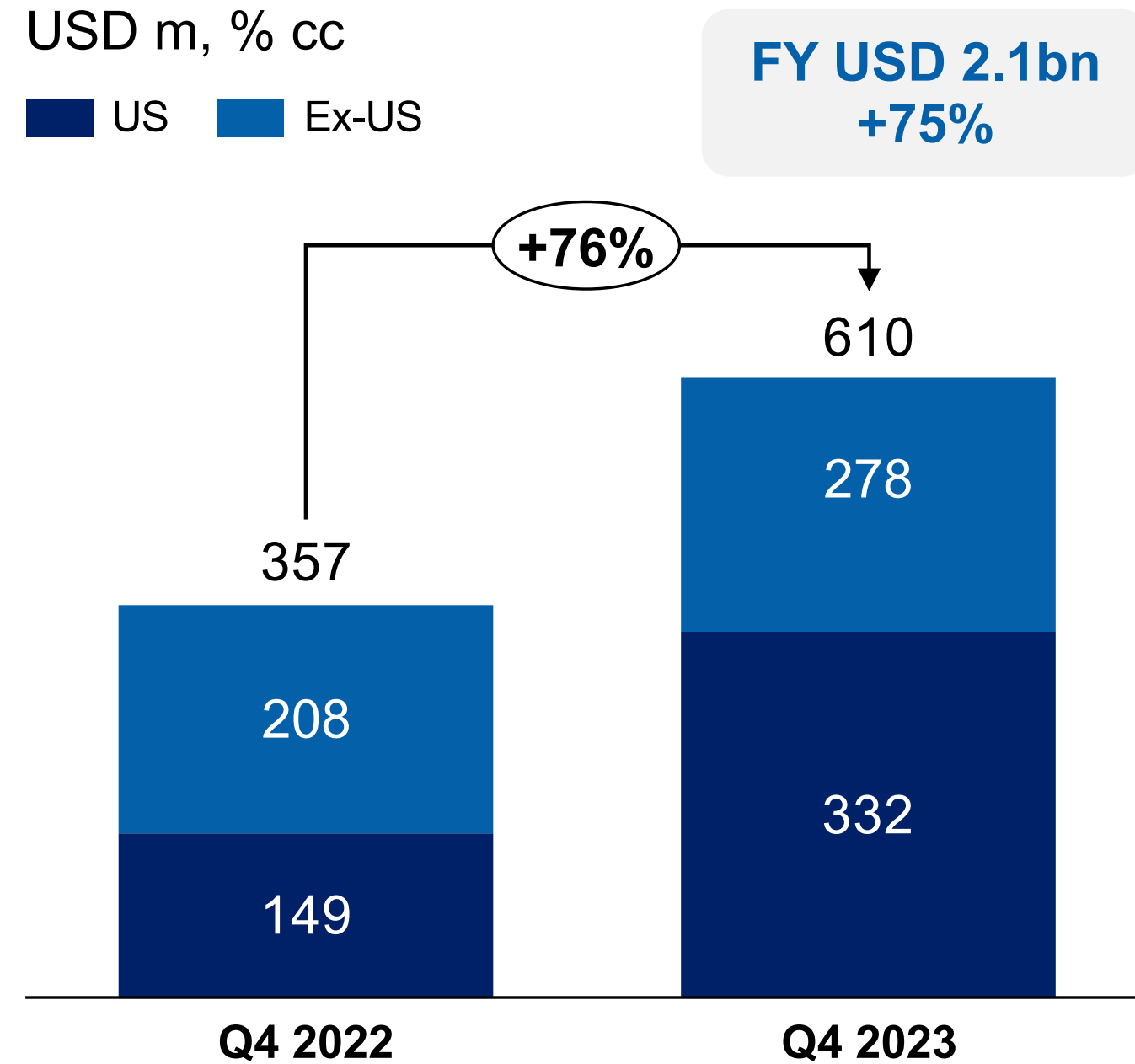
Kisqali® FY sales reached USD 2.1bn in metastatic breast cancer (mBC). Maintain USD 4bn peak sales guidance for mBC



Sales evolution

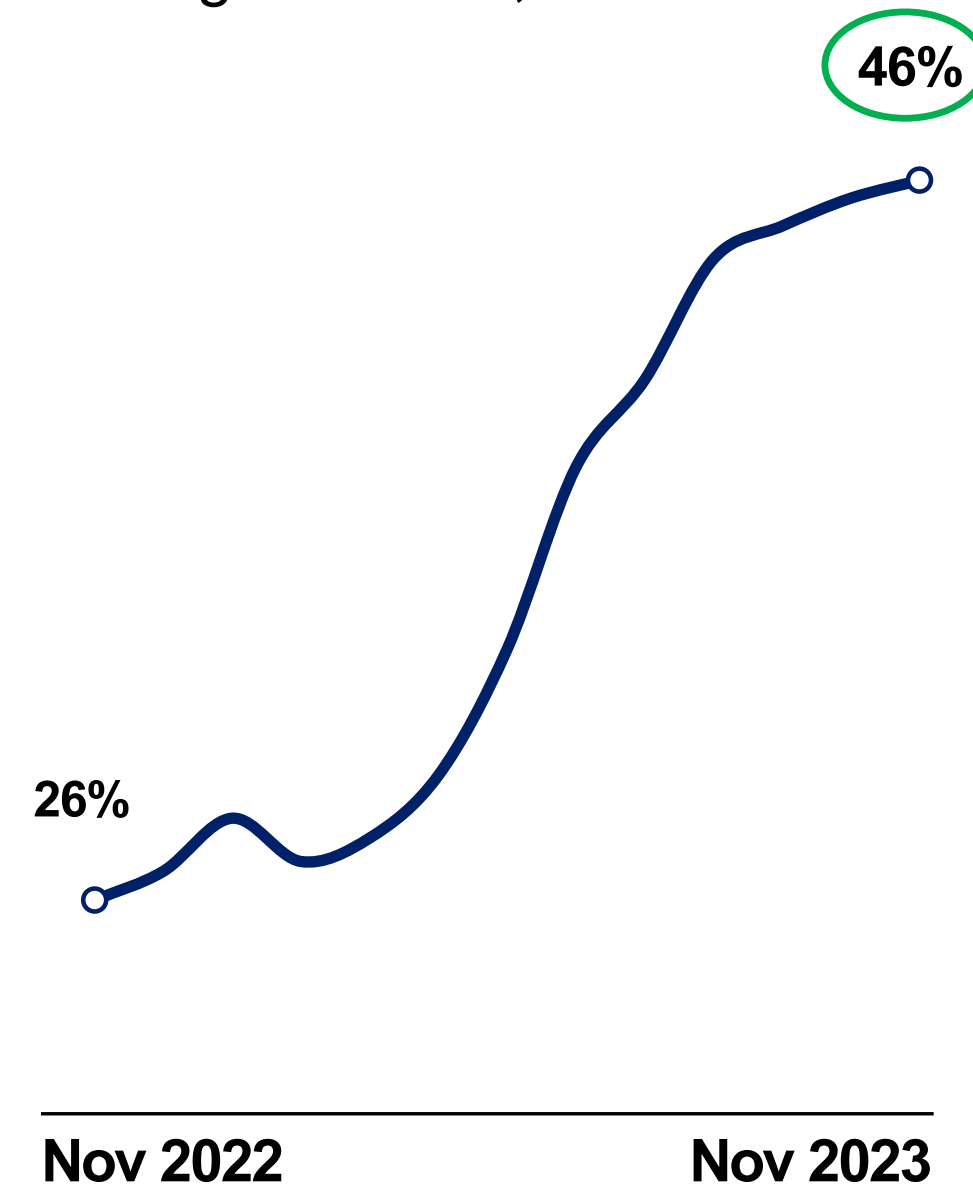
USD m, % cc

■ US ■ Ex-US



US mBC NBRx share¹

Rolling 3 months, %



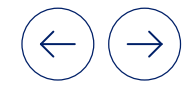
Expect continued strong sales momentum in mBC

- **Statistically significant OS benefit** proven across all 3 Ph3 pivotal trials²
- Recognized by **NCCN** guidelines with **Category 1 designation** for 1L and **highest score by ESMO-MCBS³**
- **Median OS of ~5 years** across all 3 pivotal trials when combined with letrozole or fulvestrant in 1L mBC

Adjuvant indication

- Filed in EU, US and China

mBC – metastatic breast cancer. NBRx – new to brand prescription. NCCN – national comprehensive cancer network. AI – aromatase inhibitor. 1. Of CDK4/6 mBC market, US 3 months ending Nov 2023, IQVIA Breast Cancer Market Sizing report. 2. MONALEESA-2: Hortobagyi et al, NEJM 2022; MONALEESA-7: Lu et al, Clin Cancer Res 2022; MONALEESA-3: Neven et al, ESMO Breast 2022. 3. NCCN Guidelines updated as of 27-Jan-2023. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report.



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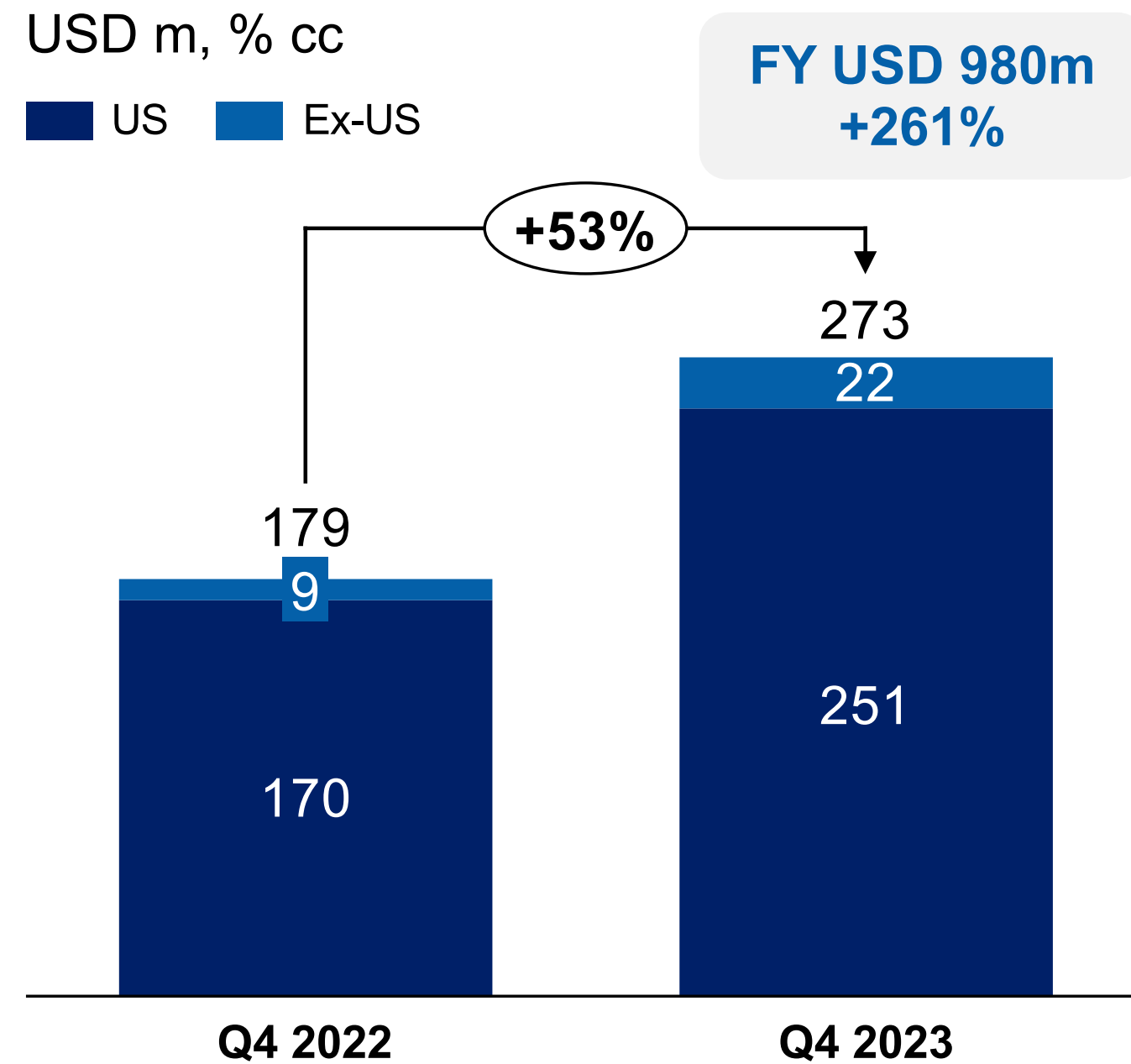
Pluvicto[®] FY sales close to blockbuster. Supply now unconstrained. Maintain multi-bn peak sales guidance for current indication (post-taxane)



Sales evolution

USD m, % cc

■ US ■ Ex-US

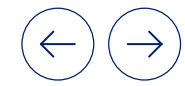


- Q4 sales grew YoY (+53% cc) and QoQ (+7% USD) driven by demand
- **Treatment sites:** 300+ US sites, vast majority active and regularly ordering
- **Unconstrained supply:** 99.9% of doses injected on planned day in Q4 in US: approval of Indianapolis site to increase capacity to 250k RLT doses in 2024
- **Global network expansion:** RLT facility investment in China and Japan
- **Confident in 2024:** Expect return to stronger QoQ growth following earlier supply disruption

Additional indications

- PSMAfore (pre-taxane) expect US submission in H2 2024
- Additional studies in earlier stages of disease (PSMAddition in mHSPC, PSMA-DC in localized oligometastatic disease)

Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report.



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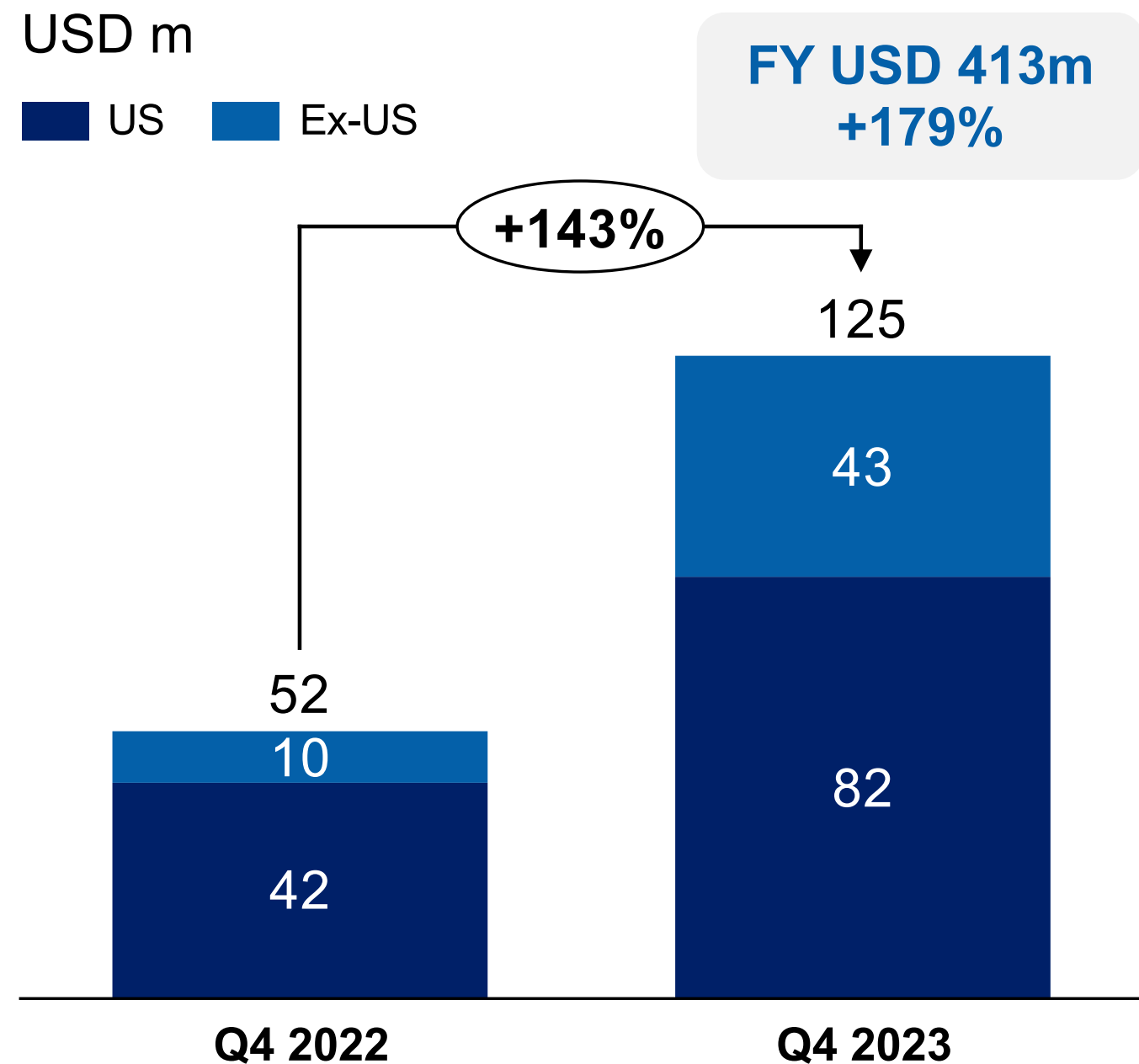
Scemblix® continues strong launch trajectory, driven by increasing recognition of its differentiated profile and high unmet need in CML



Sales evolution

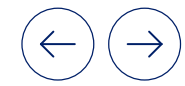
USD m

■ US ■ Ex-US



- FY and Q4 sales more than doubled driven by highly differentiated profile
- Leading 3L+ market share in US (NBRx 43%, TRx 22%) and ex-US (TRx 28%)¹
- **High unmet need** in 3L patients: >50% of hematologists aim to improve quality of life and management of side effects²
- ASCEMBL Ph3 data 3L with nearly **4 years of follow-up** reinforces **differentiated profile** vs. alternative TKIs; with sustained efficacy and safety benefit³
- Global rollout in 3L ongoing with approval in 60+ countries; access pathways in 25+, with consistently positive feedback from payers on **added clinical benefit**

Ph+ CML-CP – Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase. 1. US: October rolling 3-months US IQVIA CML market sizing report (Jan 2024). Ex-US: IPSOS & IQVIA Oncology Dynamics, EU5 and JP, MAT October 2023). 2. Survey on unmet needs in CML at EHA: reveals the need for treatment decisions that balance quality of life, efficacy, and tolerability goals; Chronic Myeloid Leukemia Survey on Unmet Needs (CML SUN). 3. Mauro M.J. et al., ASH 2023, Poster 4536 (median follow-up of 3.7 years). Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report.



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Scemblix®: ASC4FIRST trial met both primary endpoints with clinically meaningful and statistically significant results

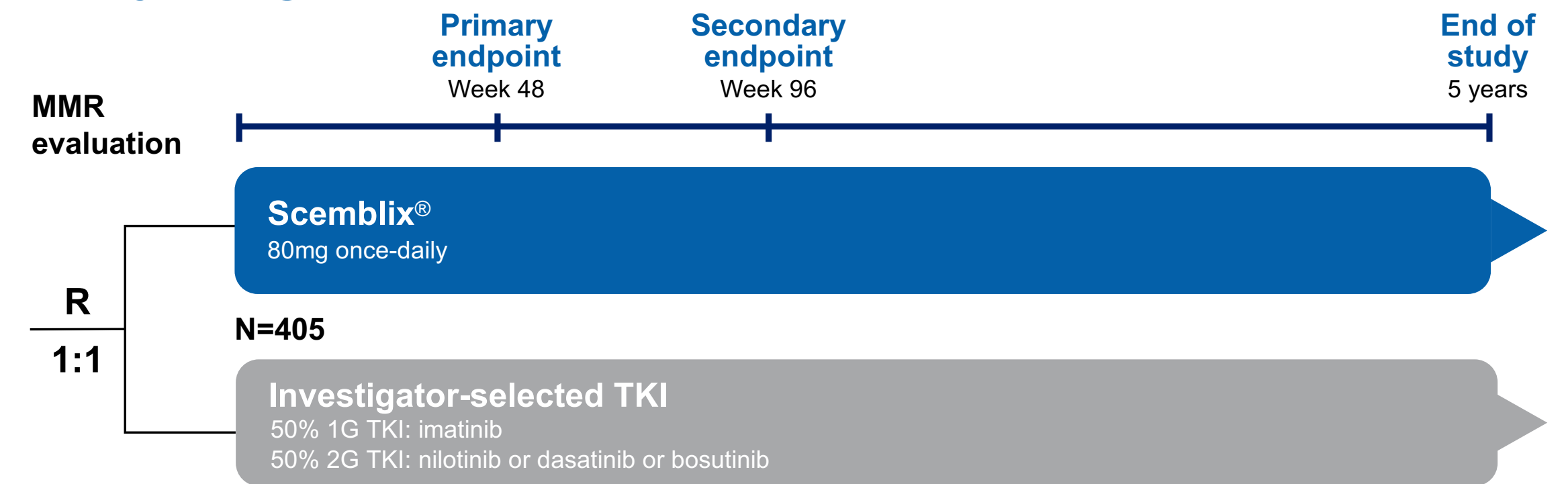
Both primary endpoints met

- Scemblix shows **superior MMR rates** at week 48 vs. SoC TKIs in newly diagnosed Ph+ CML-CP patients
- **Favorable safety and tolerability profile** with fewer AEs and treatment discontinuations vs. SoC TKIs and no new safety signals were observed

Achievement of MMR

- BCR-ABL1 ≤ 0.1% is associated with higher rates of EFS, PFS and OS¹

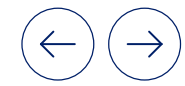
Study design



Population: Newly diagnosed adult patients with CML-CP with no prior TKI
Primary endpoints as assessed by MMR at 48 weeks: Superiority of Scemblix® vs. 1) investigator choice TKI and/or 2) imatinib subgroup alone

Data will be presented at an upcoming medical congress | CML-CP 1L FDA submission anticipated in H1 2024

CML-CP – chronic myeloid leukemia in chronic phase. MMR – major molecular response (BCR-ABL 1IS ≤0.1%). SoC – Standard of care. TKI – tyrosine kinase inhibitor. 1. Saussele S et al. Leukemia; 32(5):1222-8; 2018; Hochhaus et al., Leukemia; 34:966-84, 2020.



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Leqvio[®] adoption continues to expand across regions

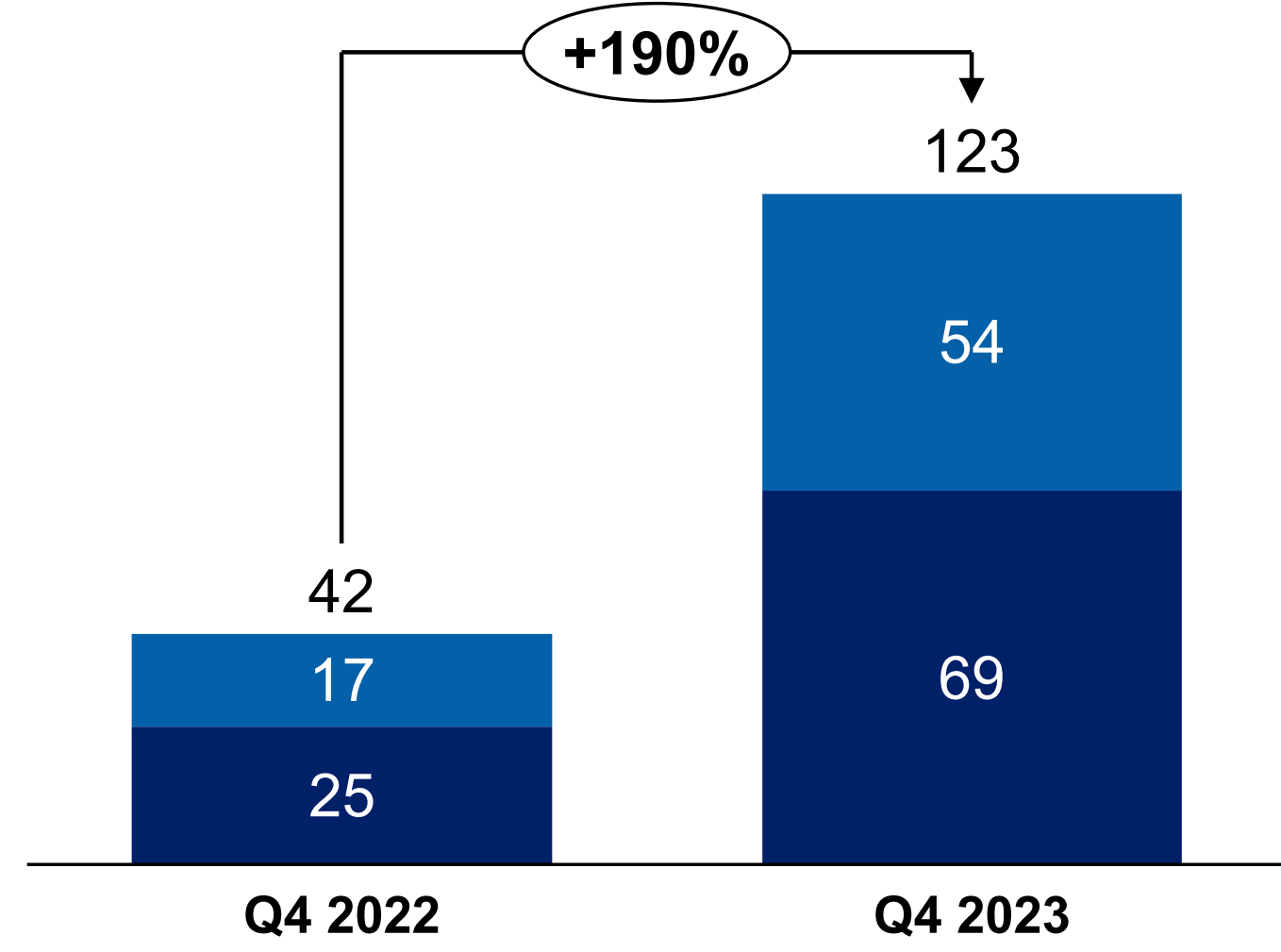


Sales evolution

USD m, % cc

■ US ■ Ex-US

FY USD 355m
+217%



US: Steady growth, ahead of advanced lipid lowering market¹

Adoption

- 3,500 facilities have ordered Leqvio[®] (+13% vs. Q3)
- ~55% of business is from in-office buy & bill

Continued execution on growth enablers

- Depth is increasing in key accounts
- Buy & bill is fastest growing acquisition channel
- Improved HCP targeting driving increase in breadth and depth

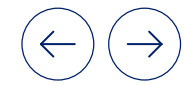
Ex-US: Rollout continues

- 29 countries with public reimbursement
- 39 countries have private (commercial) coverage
- Solid early uptake in China self-pay market

Outcomes trials

- On track for readout 2026+

HCP – healthcare professional. 1. Includes PCSK9 mAbs and bempedoic acid. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report.



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Fabhalta^{®1}: FDA approved with compelling label in PNH

Positive early launch signals, expect modest ramp



Strong product profile reflected in label

Compelling data


- Hb improvement vs. C5i in patients with residual anemia
- Transfusion avoidance
- Comprehensive IVH and EVH control
- Demonstrated safety profile

Broad population

- Adults with PNH
- Naive and switch

Oral administration

- First oral monotherapy
- REMS requirements similar to other complement inhibitors



Positive early launch signals, expect modest ramp

Launch execution

- Promotion started early Dec incl. at ASH
- REMS and patient support programs live
- First patients initiated shortly after approval

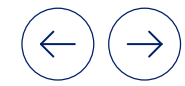
Sentiment

- Positive HCP sentiment on efficacy, safety and oral profile
- Strong interest from patients/patient groups

Access

- Distribution with two national specialty pharmacies
- Bridge support in place pending payer coverage

PNH – paroxysmal nocturnal hemoglobinuria. C5i – complement 5 inhibitor. IVH – intravascular hemolysis. EVH – extravascular hemolysis. REMS – risk evaluation and mitigation strategies. ASH – American Society of Hematology. HCP – healthcare professional. 1. Iptacopan is the generic name for unapproved indications.



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Achieved our innovation milestones in 2023

10 positive Ph3 readouts for medicines with significant sales potential¹

Status update – as of end Q4

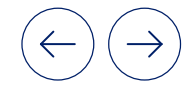
| | | Status update – as of end Q4 |
|-----------------------------|--|--|
| Regulatory decisions | Cosentyx® HS | EU approval (Q2), US approval (Q4) |
| | Cosentyx® 2ml AI | US approval (Q2) |
| | Cosentyx® IV | US approval (Q4) |
| | Fabhalta® (iptacopan) PNH | US approval (Q4) |
| | Leqvio® Hypercholesterolemia | Japan and China approval in Q3 |
| Submissions | Iptacopan PNH (US/EU/JP) | Filed in US, EU (Q2), JP (Q3) |
| | Kisqali® HR+/HER2- BC (adj) | Filed in EU in Q3, in US in Q4 |
| | Pluvicto® mCRPC, pre-taxane (US) | US submission expected in 2024 |
| Readouts | Atrasentan IgAN | Met pre-specified interim analysis primary endpoint in Q4 |
| | Kisqali® HR+/HER2- BC (adj) | Primary endpoint met at interim analysis; 500 iDFS event milestone reached; data consistent with interim analysis (March 2023 ²) |
| | Iptacopan IgAN | Met pre-specified interim analysis primary endpoint in Q3 |
| | Iptacopan C3G | Met primary endpoint in Q4 |
| | Lutathera® GEP-NETs | Met primary endpoint in Q3 |
| | Remibrutinib CSU | Met primary endpoint in Q4 |
| Ph3 starts | Iptacopan in IC-MPGN | APPARENT trial (Q2) |
| | Leqvio® CVRR primary prevention | VICTORION-1P (Q1) |
| | Ianalumab in immune thrombocytopenia | 1L (VAYHIT1) and 2L (VAYHIT2) (H1) |
| | Ianalumab in systemic lupus erythematosus | SIRIUS-SLE 1 and 2 (Q1) |

10 positive Ph3 readouts

- 1 Kisqali® eBC NATALEE
- 2 Iptacopan PNH APPOINT
- 3 Remibrutinib CSU REMIX-1
- 4 Remibrutinib CSU REMIX-2
- 5 Lutathera® GEP-NETs NETTER-2
- 6 Iptacopan IgAN APPLAUSE
- 7 Pluvicto® mCRPC pre-taxane PSMAfore
- 8 Atrasentan IgAN ALIGN
- 9 Iptacopan C3G APPEAR
- 10 Scemblix® 1L CML ASC4FIRST (Jan 2024)

HS – hidradenitis suppurativa. PNH – paroxysmal nocturnal hemoglobinuria. mCRPC – metastatic castration-resistant prostate cancer. FIR – first interpretable results. IgAN – immunoglobulin A nephropathy. C3G – complement 3 Glomerulopathy. IC-MPGN – immune complex membranoproliferative glomerulonephritis. 1. Readout or presentations 2. Interim analysis in March 2023, data presented at ASCO 2023.

Iptacopan: Ph3 APPEAR study demonstrates clinically meaningful and statistically significant proteinuria reduction in patients with C3G



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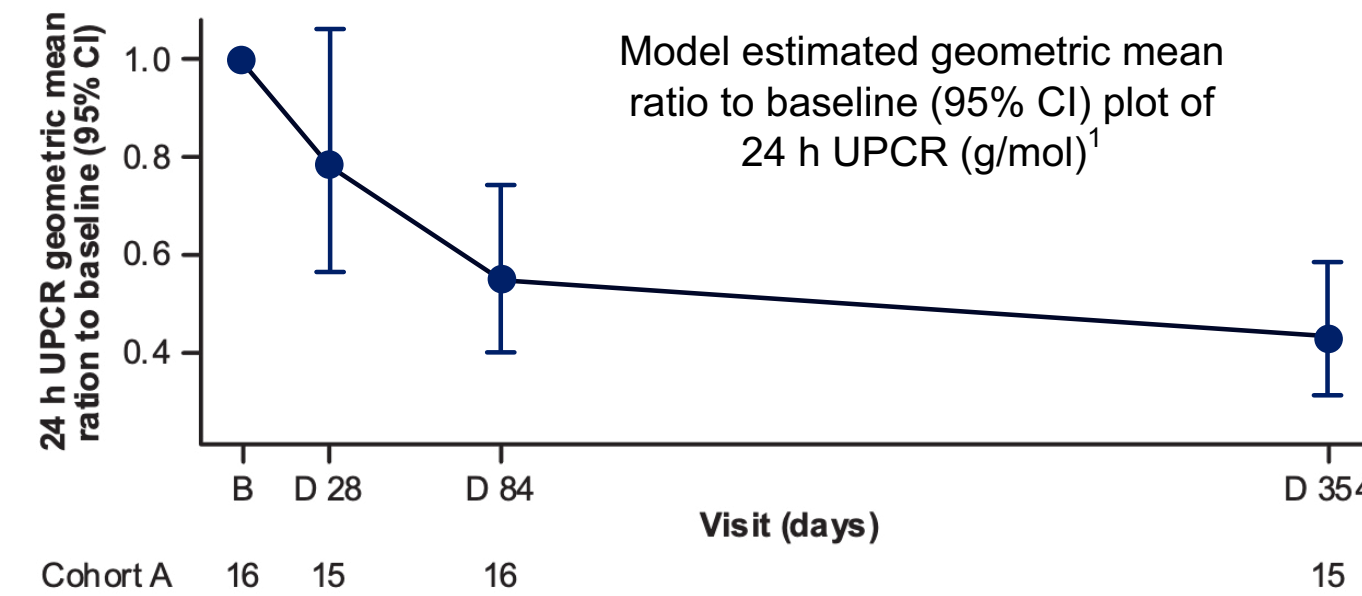
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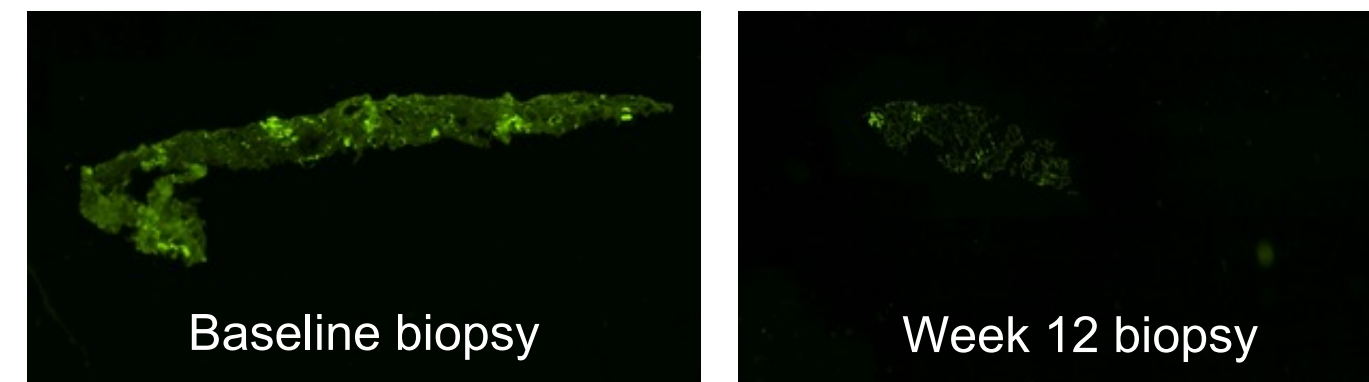
References

Ph2 showed sustained benefits up to 1 year

Primary endpoint native kidney



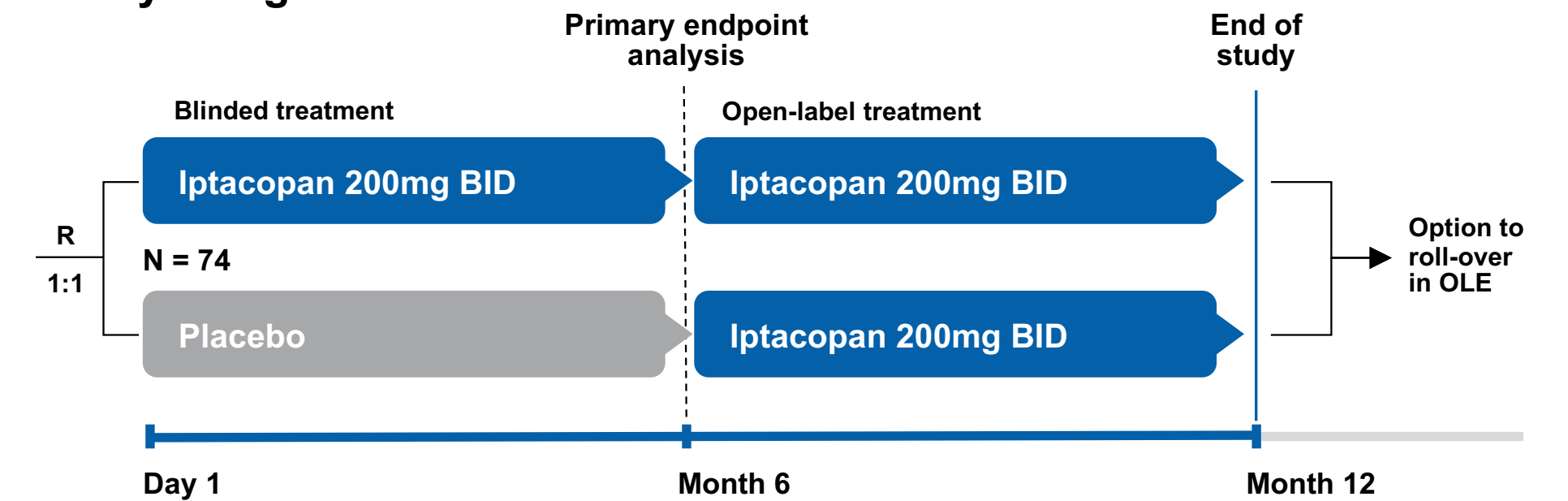
Primary endpoint transplanted kidney²



Ph3 met primary endpoint³

- Clinically meaningful and statistically significant proteinuria reduction at six-month analysis
- Safety profile consistent with previously reported data
- Simple administration: Oral

Study design



Review results with health authorities for potential submissions in 2024

RoE – Roll-over extension. UPCR – urine protein creatinine ratio. CI – confidence interval. 1. ASN 2022 poster. 2. Kidney biopsy baseline → Week 12 C3 Deposit Score. Wong EK, et al. ePoster ASN 2021. 3. December 2023.

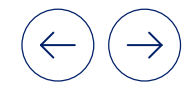
Iptacopan and atrasentan: Positive Ph3 readouts demonstrating clinically meaningful proteinuria reduction in IgAN

| Assets | 2021 | 2022 | 2023 | 2024 | 2025 | 2026+ | Comments |
|------------|----------------|------|------|---------------------------|------|-------|---|
| Iptacopan | Ph3 - APPLAUSE | | | * | | | Positive clinically meaningful IA ¹ (primary endpoint) |
| Atrasentan | Ph3 - ALIGN | | | * | | | Positive clinically meaningful IA ¹ (primary endpoint) |
| Zigakibart | | | | Ph3 – BEYOND ² | | | UPCR submission-enabling readout expected 2026 |

* US submission for accelerated approval

Iptacopan and atrasentan FDA submissions expected in H1 2024, based on proteinuria reduction
 Studies continue to confirmatory endpoint (eGFR) in 2025

UPCR – urine protein creatinine ratio. 1. October 2023, 9 months readout may support US submission for accelerated approval. 2. Global, randomized, multicenter, double-blind, placebo-controlled Ph3 comparing safety and efficacy of zigakibart (600mg Q2W) vs. placebo in patients (N~272) with IgAN at risk of progressive loss of kidney function.



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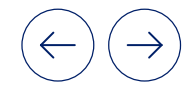
References

Expect to continue our innovation momentum in 2024...

2024 selected key events (expected)

| | | H1 2024 | H2 2024 |
|-----------------------------|---|-----------------|-------------|
| Regulatory decisions | Fabhalta® PNH | | EU, JP |
| | Kisqali® HR+/HER2- adj.BC | | US, EU |
| Submissions | Atrasentan IgAN | US | |
| | Iptacopan C3G | US | EU |
| | Iptacopan IgAN | US | |
| | Pluvicto® mCRPC, pre-taxane | | US |
| | Remibrutinib CSU | | US, EU, JP |
| | Scemblix® CML 1L | US | JP |
| | Lutathera® GEP-NET 1L G2/G3 | EU | |
| Readouts | Scemblix® CML 1L | Ph3 (ASC4FIRST) | |
| | Zolgensma® SMA IT | | Ph3 (STEER) |
| | XXB750 Hypertension | | Ph2 |
| Ph3 starts | Pluvicto® Oligometastatic prostate cancer | Ph3 | |
| | Opnurasib 1L NSCLC (combo) ¹ | Ph2/3 | |

PNH – paroxysmal nocturnal hemoglobinuria. mCRPC – metastatic castration-resistant prostate cancer. FIR – first interpretable results. IgAN – immunoglobulin A nephropathy. C3G – complement 3 Glomerulopathy. cCSU – Chronic spontaneous urticaria. CML – Chronic myeloid leukemia. SMA – Spinal muscular atrophy. NSCLC – Non-small cell lung cancer. 1. This is a seamless Ph2/3 trial.



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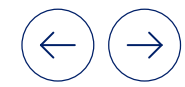
References

... and to deliver >20 key submissions in core therapeutic areas by 2028

Select key assets submission schedule

| Core therapeutic areas | 2024 | 2025 | 2026-2028 | | |
|------------------------|---|---|---|--|---|
| | <ul style="list-style-type: none"> CRM Immunology Neuroscience Oncology | <ul style="list-style-type: none"> atrasentan IgAN¹ iptacopan IgAN¹ iptacopan C3G remibrutinib CSU Pluvicto® mCRPC, pre-taxane Scemblix® CML 1L | <ul style="list-style-type: none"> pelacarsen CVRR-Lp(a) Pluvicto® mHSPC² Zolgensma® SMA IT Cosentyx® GCA Leqvio® Hyperlipidemia ped | <ul style="list-style-type: none"> Cosentyx® Tendinopathy Cosentyx® Polymyalgia rheumatica ianalumab 2L ITP ianalumab 1L ITP ianalumab wAIHA | <ul style="list-style-type: none"> ianalumab Sjögren's syndrome ianalumab Lupus Nephritis ianalumab SLE iptacopan IC-MPGN Leqvio® CVRR-LDLC |

1. US submission for accelerated approval. 2. Event-driven trial endpoint.



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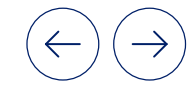
We have signed >15 strategic deals during the last year, totaling >6bn USD, to enhance our pipeline across core therapeutic areas and technology platforms

Select recent examples

| | | |
|--|---|--|
|    |   |    |
|    |    |    |
|    |    |    |
|   |    |  |

-  CRM
-  Immunology
-  Neuroscience
-  Oncology

Note: Number of strategic M&A and BD&L transactions announced, value reflecting upfront payments.



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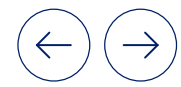
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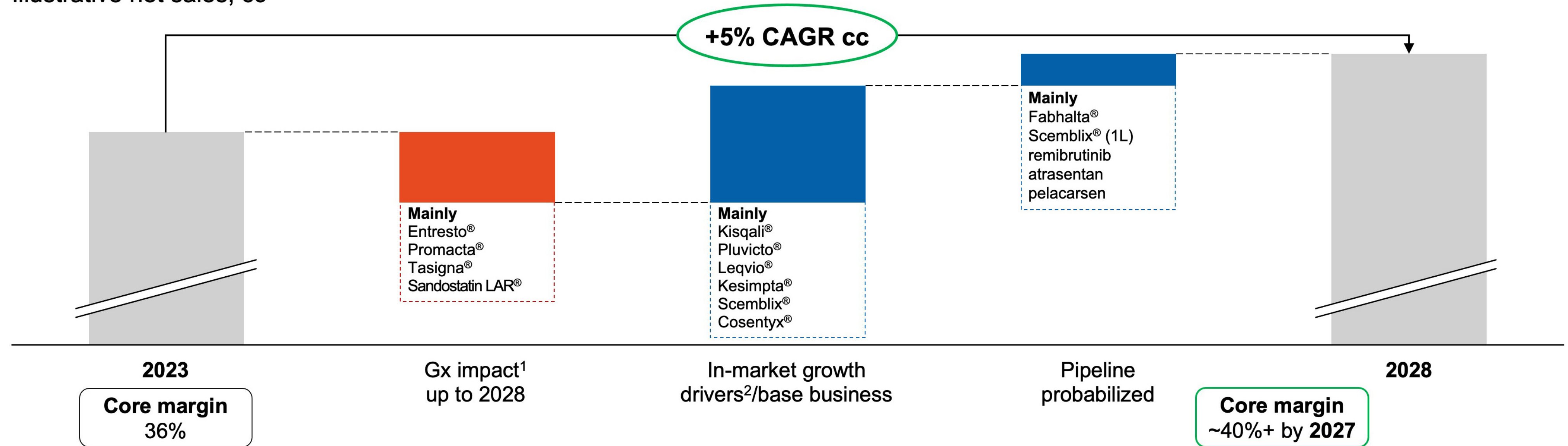
References

Updating mid-term sales guidance: Expect to grow +5% CAGR 2023-2028 and maintaining core margin of ~40%+ by 2027

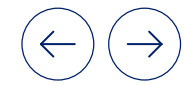
Updated mid-term guidance

2023-2028 +5% (cc) expected sales CAGR (previous guidance 2022-27)

Illustrative net sales, cc



Note: All figures reflecting Continuing Operations. 1. For forecasting purposes, we assume Entresto US LoE in 2025. 2. Including indication expansion. Leqvio – licensed from Alnylam Pharmaceuticals, Inc. Pelacarsen – licensed from Ionis Pharmaceuticals, Inc.



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We continue to focus on material environmental, social and governance factors alongside our pursuit of sustainable shareholder value creation

Value creation

Innovation and access to medicines

Future-proof pipeline addressing unmet need

Broad access to medicines

Human Capital

Diversity, Equity & Inclusion

Culture

Risk mitigation

Environmental Sustainability

Climate

Water

Waste

Ethical Standards

Ethics

Compliance

Human rights

Enablers

Governance, transparency, non-financial reporting

Right thing to do

Creating sustainable social and economic impact

Consistent industry-leading performance across priority ESG ratings

#1 in Sustainalytics¹

Leaders group in MSCI

Industry leader group in ISS ESG

Leadership group in ATMI

AA in CDP climate and water



ATMI – Access to Medicines Index. 1. Pharmaceuticals subindustry group. Copyright Morningstar Sustainalytics. All rights reserved.



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Financial review and 2024 guidance

Harry Kirsch

Chief Financial Officer



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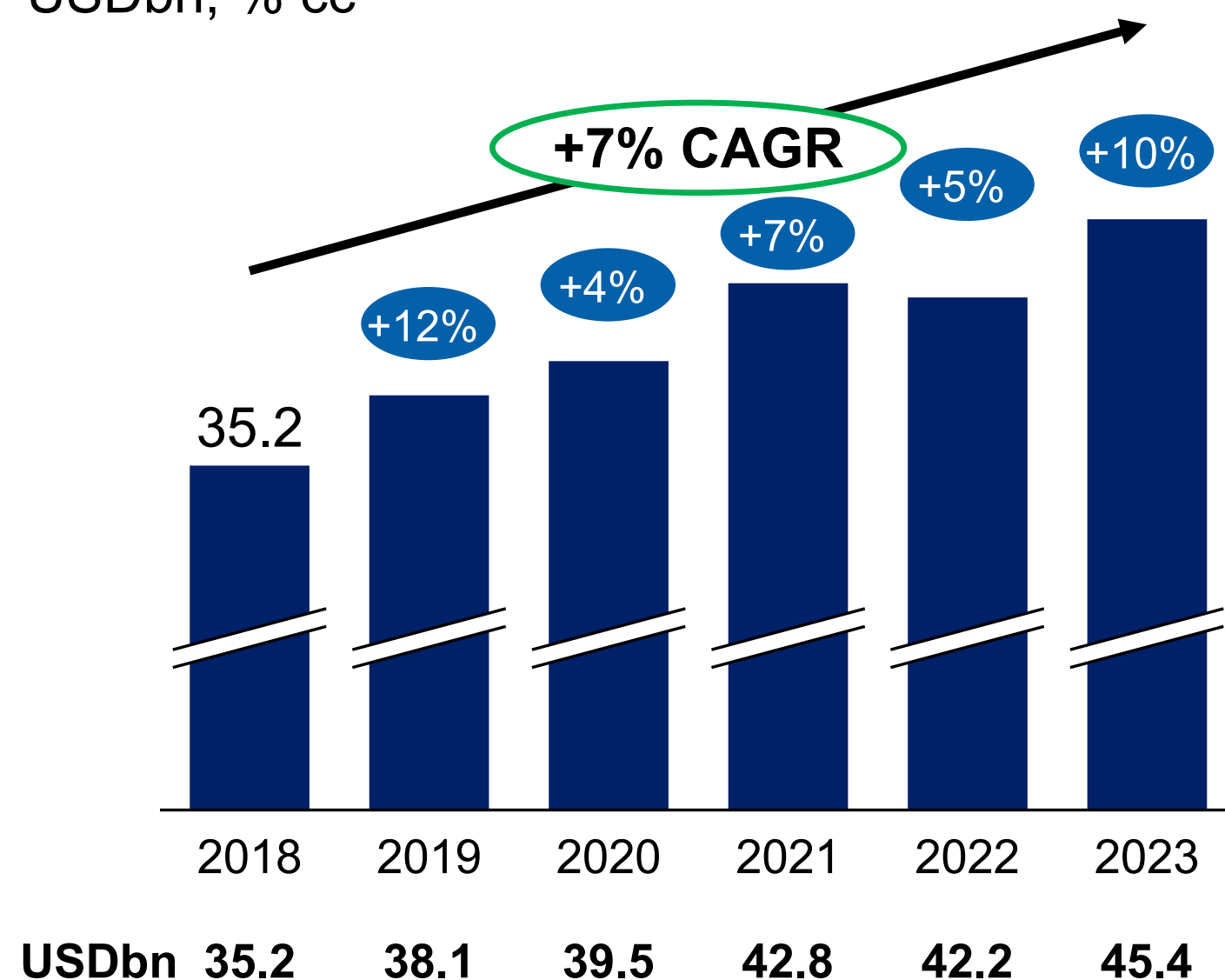
References

Novartis continues to deliver strong operational performance over a number of years...

Continuing operations¹ performance, *numbers restated post-Sandoz spin-off*

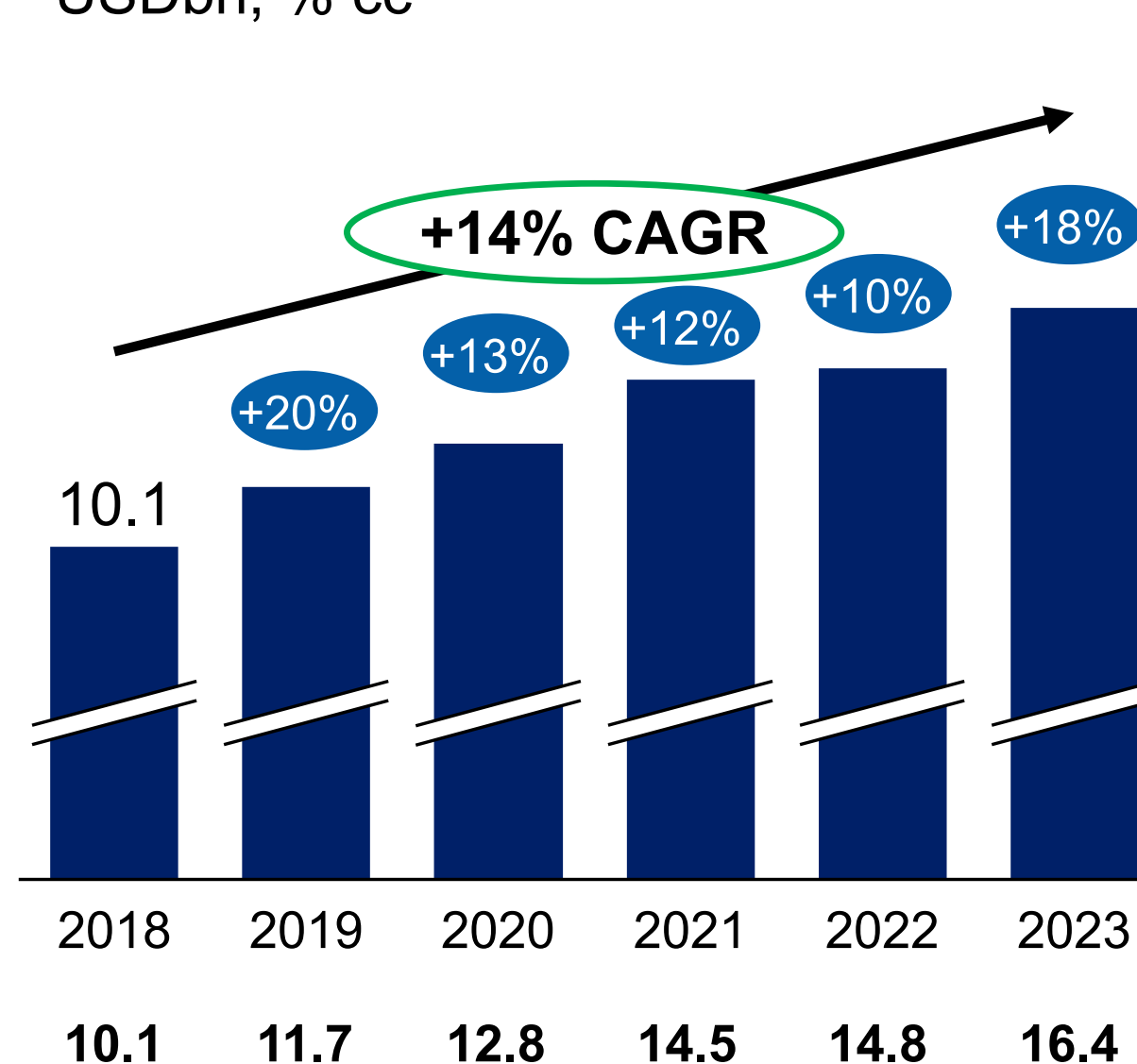
Net sales

USDbn, % cc



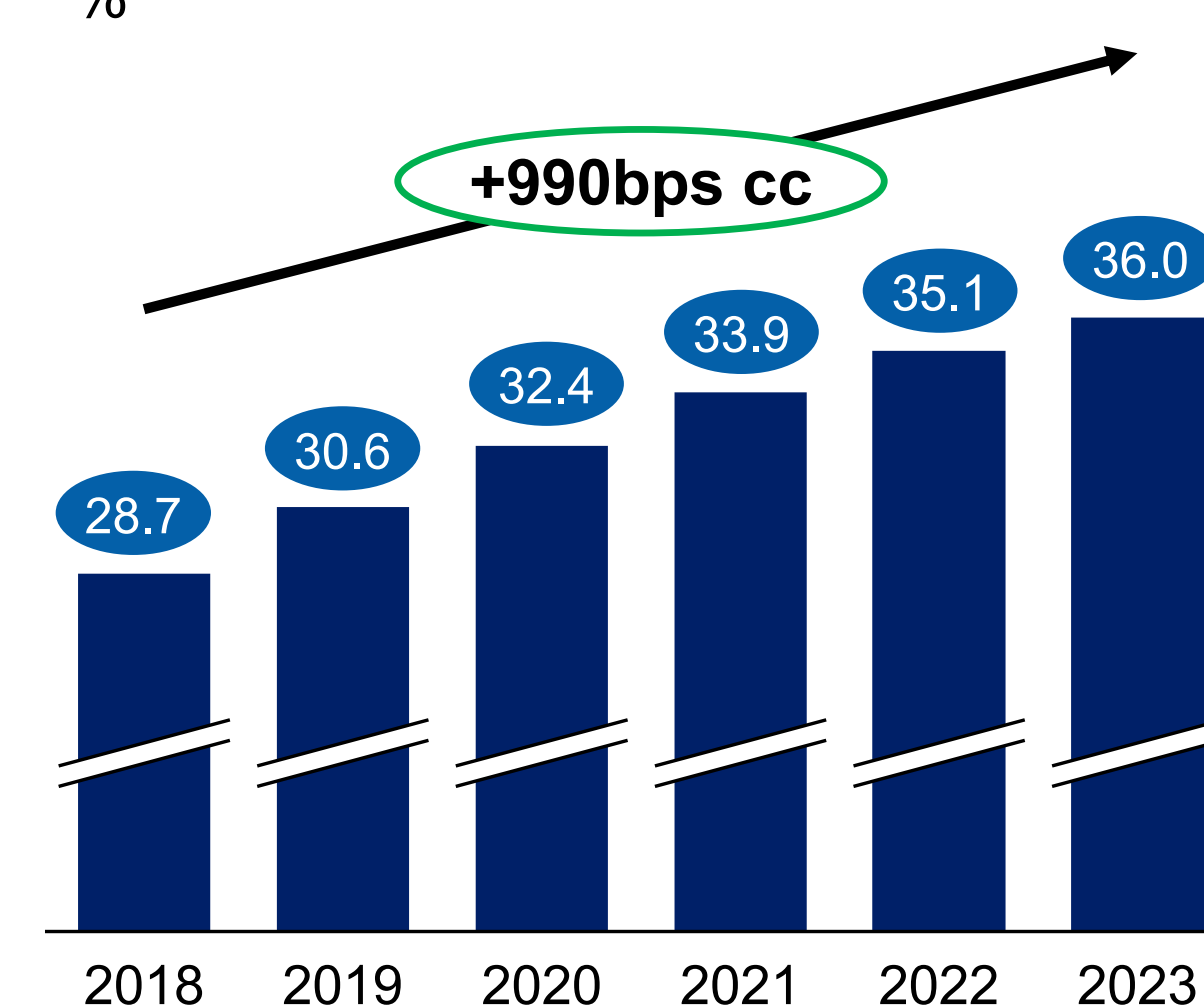
Core OpInc²

USDbn, % cc



Core margin²

%



1. As defined on page 37 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. Details regarding non-IFRS measures can be found starting on page 49 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.



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... and in 2023, met/exceeded our upgraded FY guidance

Continuing operations¹

In cc

FY guidance (Q3 earnings Oct 2023)

Actual results
FY 2023 vs. PY

Prior guidance
before upgrades
(Q4 2022)

Sales expected to grow high single-digit

+10%

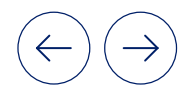
Guidance as per Q4 2022 earnings
Sales expected to grow low to mid single-digit

Core operating income expected to grow mid to high-teens

+18%

Guidance as per Q4 2022 earnings
Core operating income expected to grow mid to high single-digit

1. As defined on page 37 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 49 of Condensed Financial Report.



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Robust top and bottom-line growth during the quarter and FY

| Continuing operations ¹ USD million | Q4 2023 | Change vs. PY | | FY 2023 | Change vs. PY | |
|---|------------|---------------|--------|------------|---------------|----------|
| | | % USD | % cc | | % USD | % cc |
| Net sales | 11,423 | 8 | 10 | 45,440 | 8 | 10 |
| Core operating income | 3,821 | 5 | 13 | 16,372 | 11 | 18 |
| Core margin | 33.5% | | 1% pts | 36.0% | | 2.4% pts |
| Operating income | 2,582 | 47 | 68 | 9,769 | 23 | 39 |
| Net Income | 2,638 | 101 | 130 | 8,572 | 42 | 62 |
| Core EPS (USD) | 1.53 | 10 | 16 | 6.47 | 18 | 25 |
| EPS (USD) | 1.29 | 108 | 140 | 4.13 | 49 | 70 |
| Free cash flow | 2,141 | -38 | | 13,160 | 9 | |

1. As defined on page 37 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities. Core results and constant currencies are non-IFRS measures. Details regarding non-IFRS measures can be found starting on page 49 of the Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Continuing to create significant shareholder value



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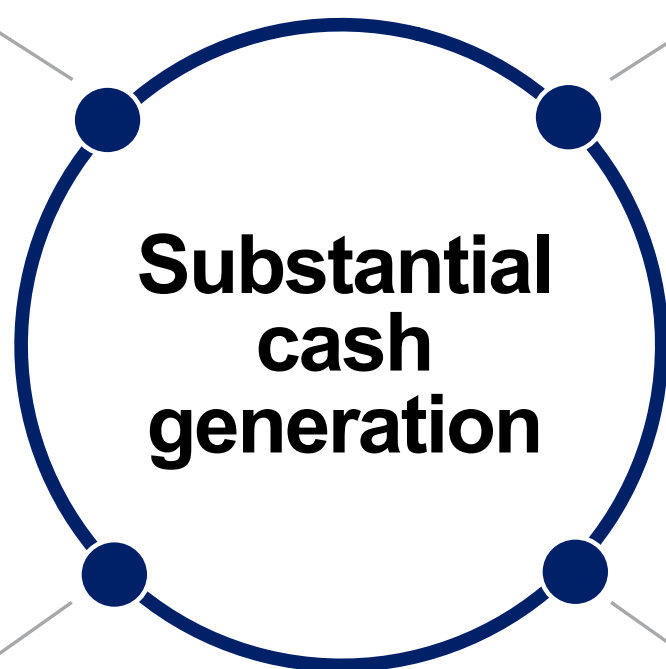
Investing in the business

Investments in organic business

R&D >USD 47bn, CAPEX >USD 6bn 2018-2023¹

Value-creating bolt-ons

>USD 33bn 2018-2023



Returning capital to shareholders

Consistently growing annual dividend²

>USD 42bn of dividends 2018-2023
No rebasing post Alcon and Sandoz spin-off

Share buybacks

>USD 32bn 2018-2023
New USD 15bn SBB commenced in Jul 2023

Whilst also creating shareholder value via numerous strategic actions

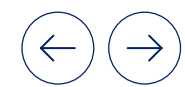
Jun 2018
Divested consumer health JV

Apr 2019
Spun Alcon

Nov 2021
Exited Roche stake

Oct 2023
Spun Sandoz

1. Core R&D and CAPEX actuals. 2. In CHF.



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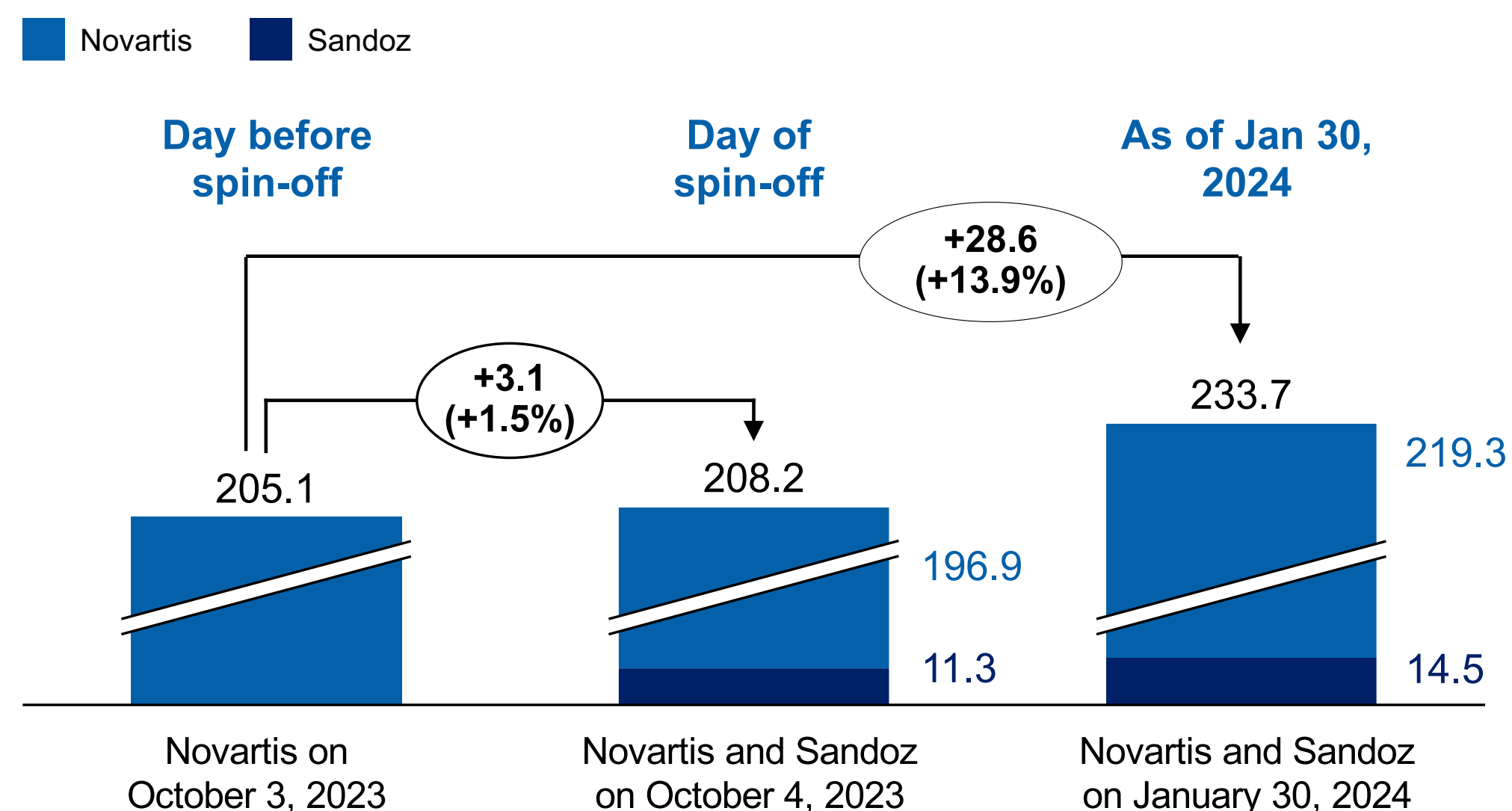
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For Novartis and Sandoz shareholders since October 3, 2023, USD 28.6bn (+13.9%) of value has been created

Market capitalization growth since the Sandoz spin-off

Total market capitalization^{1,2} (in USD bn)



Sandoz spin-off highlights

- Completed the separation of Sandoz to create an independent company by way of 100% spin-off (Oct 4, 2023)
- Shares of Sandoz are listed on the SIX Swiss Exchange and traded OTC in the US
- Novartis continues with its consistently growing annual dividend with no re-basing post the Sandoz spin-off

1. Market capitalization of Novartis on October 3, 2023 is based on closing share price and outstanding shares of 2,055,060,483 (as per October 3); market capitalization for Novartis and Sandoz on October 4, 2023 are based on opening share prices on October 4, outstanding shares of 2,055,060,483 for Novartis and 431,000,000 shares for Sandoz; market capitalization for Novartis and Sandoz on January 30, 2024 are based on closing share prices on January 30, outstanding shares as of December 31, 2023 of 2,044,033,986 for Novartis and 431,000,000 shares for Sandoz. 2. USD values based on USD/CHF exchange rates as per the respective days; source: Bloomberg.

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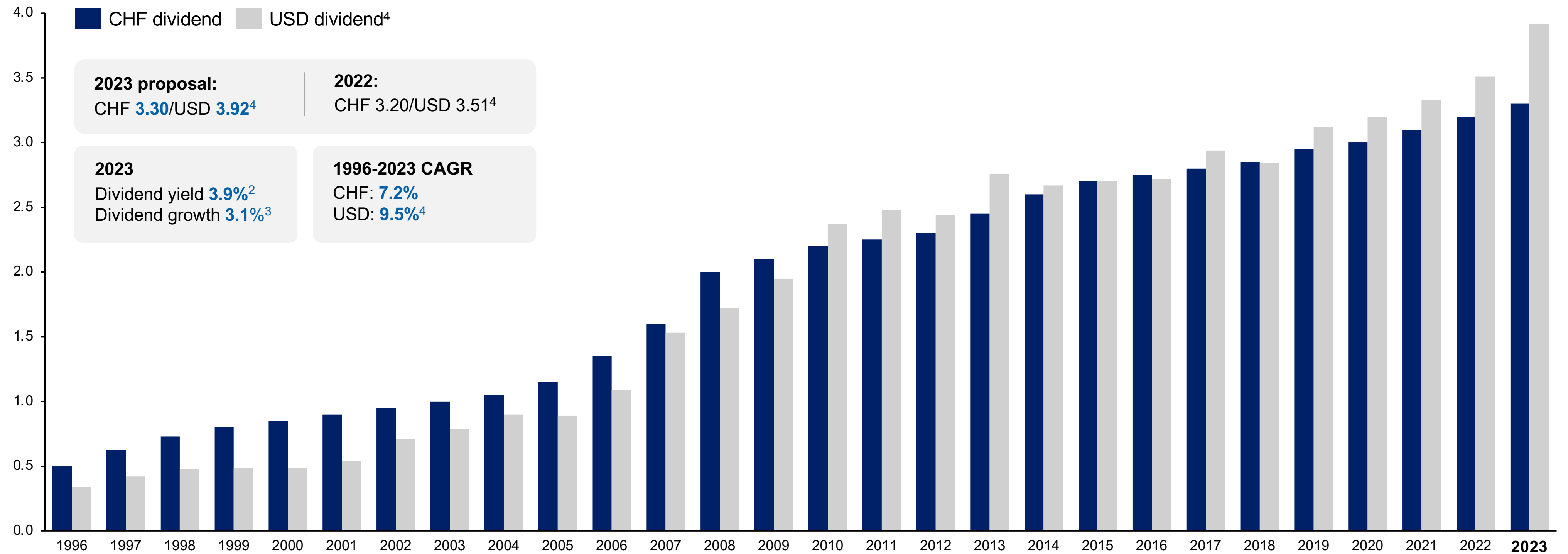
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Novartis proposes 3.30 CHF/share¹ dividend at the AGM; 27th consecutive dividend increase (no rebasing post Sandoz spin-off)



1. Proposal to shareholders at the 2024 Annual General Meeting, taking place on March 5, 2024. 2. Based on the NOVN closing share price of CHF 84.87, as of December 29, 2023. 3. In CHF. 4. Historical dividends per share converted at historical exchange rates at the dividend payment dates as per Bloomberg; for 2023, translated into US dollars at the FX rate of CHF/USD of 1.189, as of December 31, 2023.



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Novartis (continuing operations¹) 2024 full year guidance

Expected, barring unforeseen events; growth vs. PY in cc

Net sales expected to grow

mid-single-digit

Core operating income expected to grow

high single-digit

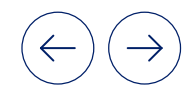
Key assumptions

- No US Entresto[®] Gx launch in 2024

FY 2024 guidance on other financial KPIs

- **Core net financial result:**
Expenses expected to be around USD 0.6bn to 0.7bn
- **Core tax rate:**
Expected to be around 16-16.5%

1. As defined on page 37 of the Condensed Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities. Core results and constant currencies are non-IFRS measures. Further details regarding non-IFRS measures can be found starting on page 49 of the Condensed Financial Report.



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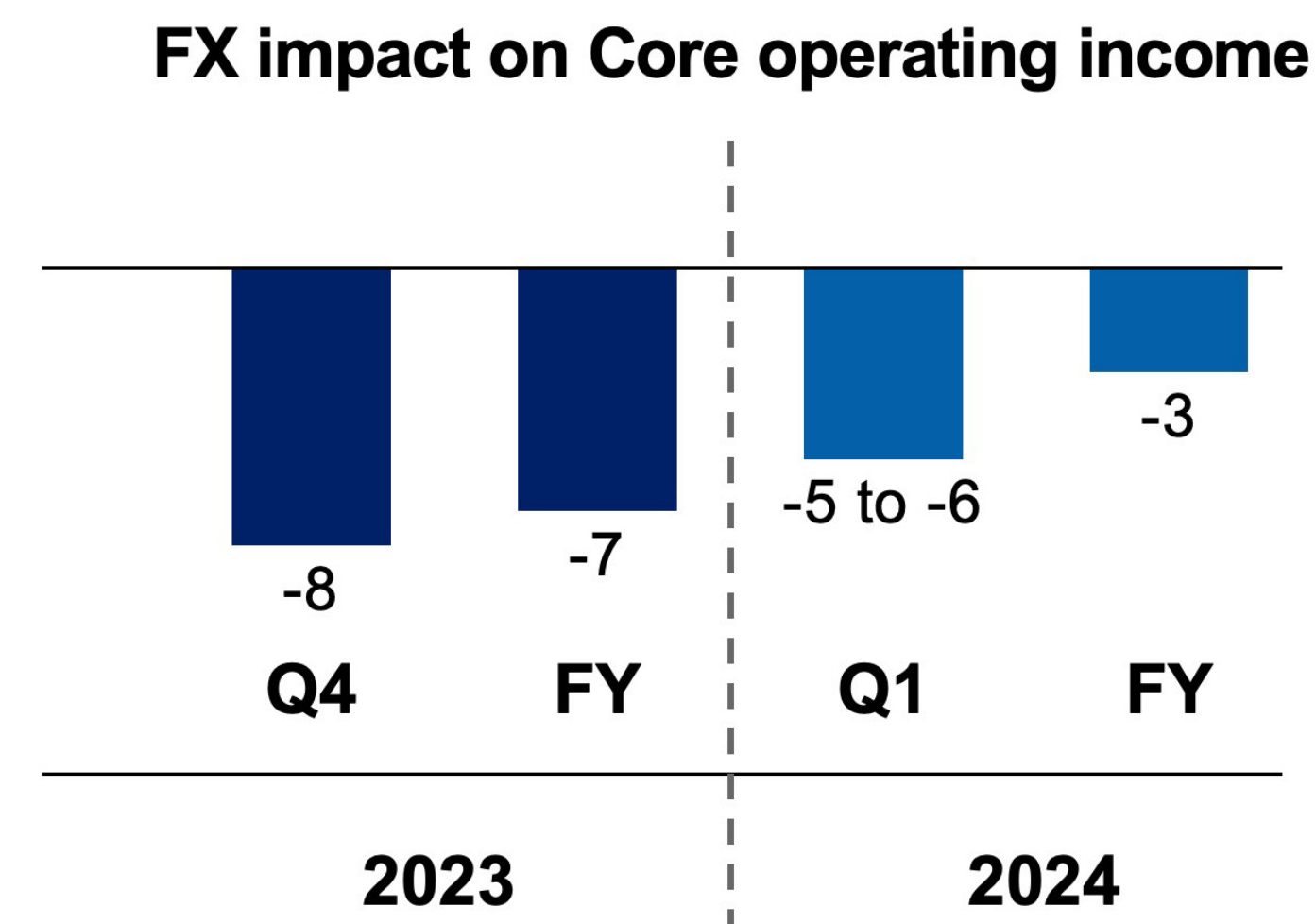
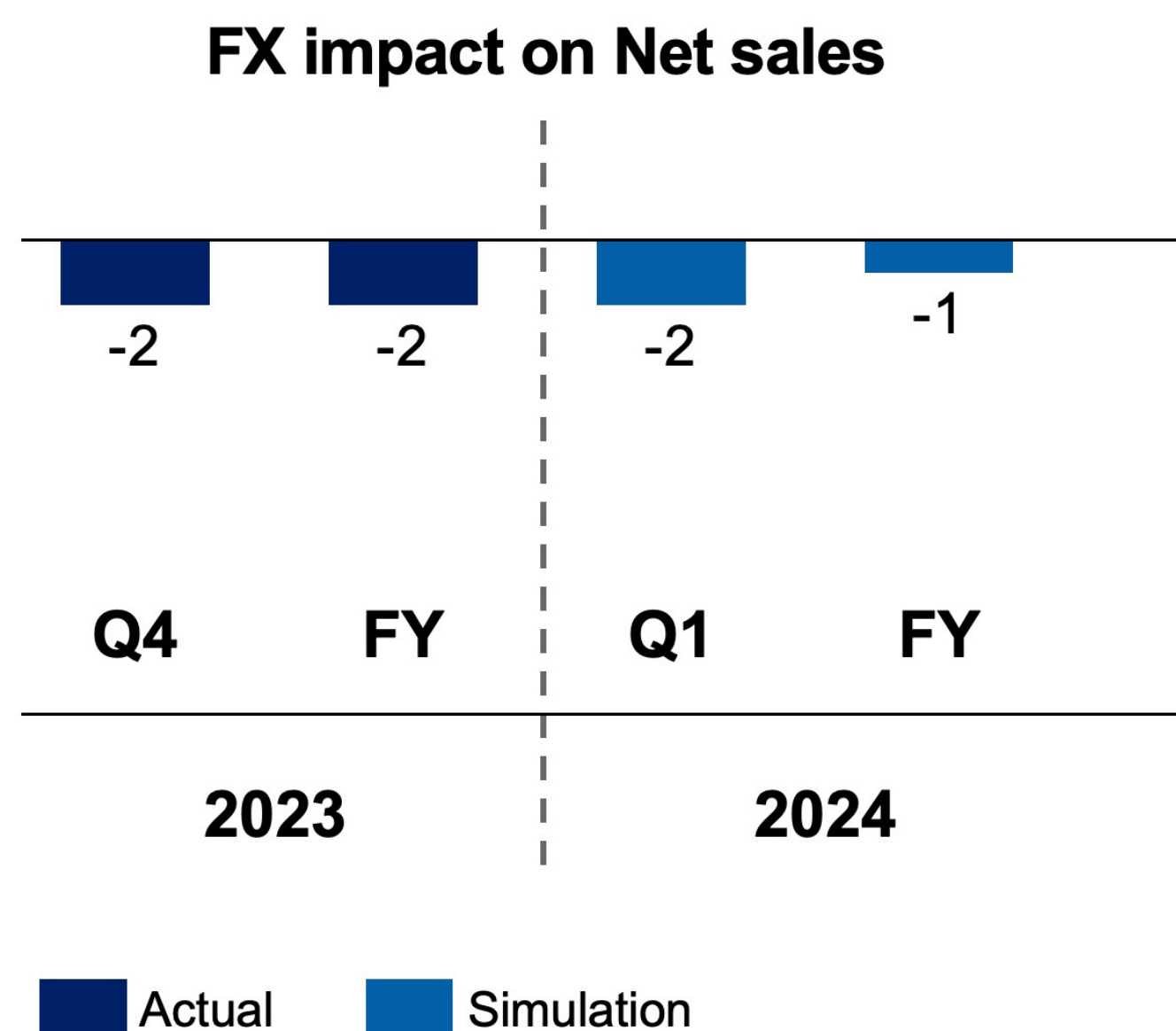
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Expected currency impact for Q1 and full year 2024

Currency impact vs. PY

%pts, assuming late-January exchange rates prevail in 2024



Q4 Core OpInc FX impact includes app. -2%pts from the effect of mid Dec Argentina ARS devaluation¹

1. Core results are non-IFRS measures as defined on page 49 of Condensed Financial Report. 2. IFRS requires for our Argentina subsidiary, as it operates in a hyperinflation economy, to translate for consolidation purposes their full year income statement to our USD presentation currency using the ARS closing rate, and not using the average exchange rate for the period. This results in the 9-months and the Q4 devaluation impact being recognized in Q4.



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Vas Narasimhan, M.D.
Chief Executive Officer





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Very strong 2023: Double-digit growth for sales and Core OpInc for the quarter and full year

Met/exceeded all strategic, operational and innovation targets: Including successful Sandoz spin-off; 10 positive Ph3 readouts with significant sales potential

Confident for 2024 and mid-term guidance of 5% cc sales CAGR 2023-28, ~40%+ margin by 2027



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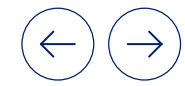
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Strong FY growth driven by performance from Entresto®, Kesimpta®, Kisqali® and Pluvicto®

FY sales

| | Sales USD million | Growth vs. PY USD million USD growth @ Period | Growth vs. PY cc |
|--|----------------------|---|---------------------|
| Entresto® <small>secubitril/valsartan</small> | 6,035 | 1,391 | 31% |
| Kesimpta® <small>(ofatumumab) 100mg</small> | 2,171 | 1,079 | 99% |
| KISQALI® <small>ribociclib</small> | 2,080 | 849 | 75% |
| PLUVICTO™ | 980 | 709 | 261% |
| SCEMBLIX® <small>(asciminib) 20mg, 40mg tablets</small> | 413 | 264 | 179% |
| LEQVIO® | 355 | 243 | 217% |
| Cosentyx® <small>(secukinumab)</small> | 4,980 | 192 | 5% |
| ILARIS® <small>(canakinumab)</small> | 1,355 | 222 | 22% |
| PROMACTA® <small>(eltrombopag)</small> | 2,269 | 181 | 10% |
| JAKAVI® <small>ruxolitinib</small> | 1,720 | 159 | 12% |
| Tafinlar® + Mekinist® | 1,922 | 152 | 11% |

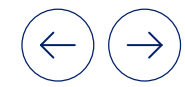
Strong growth (+40% cc); expected to continue

Constant currencies (cc) is a non-IFRS measure; explanation of non-IFRS measures can be found on page 49 of Condensed Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Our pipeline projects at a glance

| | Phase 1/2 | Phase 3 | Registration | Total |
|--|-----------|-----------|--------------|------------|
| Oncology | 25 | 12 | 3 | 40 |
| Solid tumors | 18 | 6 | 3 | 27 |
| Hematology | 7 | 6 | 0 | 13 |
| Immunology | 17 | 10 | 1 | 28 |
| Neuroscience | 5 | 5 | 0 | 10 |
| Cardiovascular, Renal and Metabolic | 6 | 10 | 0 | 16 |
| Others (thereof IB&GH) | 11 (7) | 4 (3) | 0 | 15 |
| | 64 | 41 | 4 | 109 |

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



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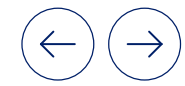
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Novartis pipeline in Phase 1

17 lead indications

Lead indication



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Oncology

| Code | Name | Mechanism | Indication(s) |
|---------------------|----------------------------|---|---|
| Solid tumors | | | |
| AAA603 | ¹⁷⁷ Lu-NeoB | Radioligand therapy target GRPR | Multiple solid tumors Breast cancer Glioblastoma multiforme |
| AAA604 | AAA604 | Radioligand therapy target integrin beta-3/beta-5 | Pancreatic cancer |
| AAA614 | AAA614 | Radioligand therapy target FAP | Solid tumors |
| AAA802 | ²²⁵ Ac-PSMA-R2 | Radioligand therapy target PSMA | Prostate cancer |
| AAA817 | ²²⁵ Ac-PSMA-617 | Radioligand therapy target PSMA | Metastatic castration-resistant prostate cancer |
| HRO761 | HRO761 | Werner inhibitor | Solid tumors |
| IAG933 | IAG933 | - | Mesothelioma |
| KFA115 | KFA115 | Novel immunomodulatory Agent | Solid tumors |
| MGY825 | MGY825 | - | NSCLC |
| NZV930 | NZV930 | CD73 antagonist | Solid tumors |
| QEQ278 | QEQ278 | NKG2D/-L pathway modulator | Solid tumors |

Hematology

| Code | Name | Mechanism | Indication(s) |
|--------|-------------------------|-----------------|-----------------------------------|
| 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 pre/post kidney transplant |
| NIO752 | NIO752 | Tau antisense oligonucleotide | Alzheimer's disease Progressive supranuclear palsy |

Immunology

| Code | Name | Mechanism | Indication(s) |
|--------|--------|-----------------------|------------------------------|
| MHV370 | MHV370 | TLR7, TLR8 Antagonist | Systemic lupus erythematosus |

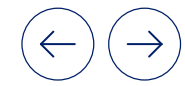
Others

| Code | Name | Mechanism | Indication(s) |
|------------------|--------|--------------------|------------------------|
| IB&GH | | | |
| EDI048 | EDI048 | CpPI(4)K inhibitor | Cryptosporidiosis |
| EYU688 | EYU688 | NS4B inhibitor | Dengue |
| INE963 | INE963 | - | Malaria, uncomplicated |

Novartis pipeline in Phase 2

20 lead indications

 Lead indication



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Oncology

| Code | Name | Mechanism | Indication(s) |
|---------------------|------------------------|---------------------------------|--|
| Solid tumors | | | |
| AAA601 | Lutathera® | Radioligand therapy target SSTR | GEPNET, pediatrics 1L ES-SCLC Glioblastoma |
| JDQ443 | opnurasib | KRAS inhibitor | NSCLC and CRC (mono and/or combo) |
| TNO155 | TNO155 | SHP2 inhibitor | Solid tumors |
| Hematology | | | |
| ABL001 | Scemblix® | BCR-ABL inhibitor | Chronic myeloid leukemia, 2L, pediatrics |
| PHE885 | durcabtagene autoleucl | BCMA cell therapy | 4L multiple myeloma |
| PKC412 | Rydapt® | Multi-targeted kinase inhibitor | Acute myeloid leukemia, pediatrics |
| YTB323 | rapcabtagene autoleucl | CD19 CAR-T | 1L high-risk large B-cell lymphoma |

Neuroscience

| Code | Name | Mechanism | Indication(s) |
|---------------------|-------------|--------------------------------------|-------------------------------|
| BLZ945 | sotuletinib | CSF-1R inhibitor | Amyotrophic lateral sclerosis |
| DLX313 ¹ | minzasolmin | Alpha-synuclein misfolding inhibitor | Parkinson's disease |

Cardiovascular, Renal and Metabolic

| Code | Name | Mechanism | Indication(s) |
|--------|-----------|----------------|-------------------------------|
| CFZ533 | iscalimab | CD40 inhibitor | Lupus nephritis |
| LNP023 | iptacopan | CFB inhibitor | Lupus nephritis |
| TIN816 | TIN816 | ATP modulator | Acute kidney injury |
| XXB750 | XXB750 | NPR1 agonist | Hypertension Heart failure |

Immunology

| Code | Name | Mechanism | Indication(s) |
|--------|------------------------|---|--|
| CFZ533 | iscalimab | CD40 inhibitor | Sjögren's |
| DFV890 | DFV890 | NLRP3 inhibitor | Osteoarthritis Familial cold auto-inflammatory syndrome |
| LNA043 | LNA043 | ANGPTL3 agonist | Osteoarthritis Osteoarthritis (combos) |
| LOU064 | remibrutinib | BTK inhibitor | Food allergy Hidradenitis suppurativa |
| LRX712 | LRX712 | - | Osteoarthritis |
| MAS825 | MAS825 | - | NLRC4-GOF indications |
| MHV370 | MHV370 | TLR7, TLR8 Antagonist | Sjögren's Mixed connective tissue disease |
| NGI226 | NGI226 | - | Tendinopathy |
| QUC398 | QUC398 | ADAMTS5 inhibitor | Osteoarthritis |
| RHH646 | RHH646 | - | Osteoarthritis |
| VAY736 | ianalumab | BAFF-R inhibitor, ADCC-mediated B-cell depletor | Autoimmune hepatitis |
| YTB323 | rapcabtagene autoleucl | CD19 CAR-T | srSLE/LN |

Others

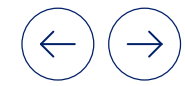
| Code | Name | Mechanism | Indication(s) |
|------------------|------------|----------------------|--|
| IB&GH | | | |
| KAE609 | cipargamin | PfATP4 inhibitor | Malaria, severe Malaria, uncomplicated |
| LXE408 | LXE408 | Proteasome inhibitor | Visceral leishmaniasis |
| SEG101 | Adakveo® | P-selectin inhibitor | Sickle cell disease, pediatrics |
| Others | | | |
| CMK389 | CMK389 | IL-18 inhibitor | Pulmonary sarcoidosis |
| LNP023 | iptacopan | CFB inhibitor | iAMD |
| LTP001 | LTP001 | SMURF1 inhibitor | Pulmonary arterial hypertension Idiopathic pulmonary fibrosis |

1. DLX313 is the Novartis compound code for UCB0599.

Novartis pipeline in Phase 3

8 lead indications

 Lead indication



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|---------------------|-------------------|---|--|
| Code | Name | Mechanism | Indication(s) |
| Solid tumors | | | |
| AAA617 | Pluvicto® | Radioligand therapy target PSMA | Metastatic castration-resistant prostate cancer (mCRPC), pre-taxane Metastatic hormone sensitive prostate cancer (mHSPC) Oligometastatic prostate cancer |
| AAA601 ¹ | Lutathera® | Radioligand therapy target SSTR | Gastroenteropancreatic neuroendocrine tumors, 1st line in G2/3 tumors (GEP-NET 1L G3) |
| BYL719 | Piqray®, Vijoyce® | PI3K-alpha inhibitor | Lymphatic malformations |
| JDQ443 | opnurasib | KRAS inhibitor | 2/3L Non-small cell lung cancer |
| Hematology | | | |
| ABL001 | Scemblix® | BCR-ABL inhibitor | Chronic myeloid leukemia, 1st line |
| ETB115 | Promacta® | Thrombopoietin receptor (TPO-R) agonist | Radiation sickness syndrome |
| LNP023 | iptacopan | 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) |
| EXV811 | atrasentan | ET _A receptor antagonist | IgA nephropathy |
| FUB523 | zigakibart | Anti-APRIL | IgA nephropathy |
| KJX839 | Leqvio® | siRNA (regulation of LDL-C) | CVRR-LDLC Primary prevention Hyperlipidemia, pediatrics |
| LNP023 | iptacopan | CFB inhibitor | IgA nephropathy C3 glomerulopathy 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)) |

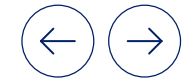
1. ¹⁷⁷Lu-dotatate in US.

| Neuroscience | | | |
|--------------|--------------|---------------------------------------|--------------------------------|
| Code | Name | Mechanism | Indication(s) |
| AMG334 | Aimovig® | CGRPR antagonist | Migraine, pediatrics |
| BAF312 | Mayzent® | S1P _{1,5} receptor modulator | Multiple sclerosis, pediatrics |
| LOU064 | remibrutinib | BTK inhibitor | Multiple sclerosis |
| 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 Rotator cuff tendinopathy |
| LOU064 | remibrutinib | BTK inhibitor | Chronic spontaneous urticaria Chronic spontaneous urticaria, pediatrics CINDU |
| QGE031 | ligelizumab | IgE inhibitor | Food allergy |
| VAY736 | ianalumab | BAFF-R inhibitor, ADCC-mediated B-cell depletor | Sjögren's Lupus Nephritis Systemic lupus erythematosus |

| Others | | | |
|------------------|----------------------------|---|--|
| Code | Name | Mechanism | Indication(s) |
| IB&GH | | | |
| COA566 | Coartem® | PGH-1 (artemisinin combination therapy) | Malaria, uncomplicated (<5kg patients) |
| KLU156 | Ganaplacide + lumefantrine | Non-artemisinin plasmodium falciparum inhibitor | Malaria, uncomplicated |
| QMF149 | Atecura® | LABA + ICS | Asthma, pediatrics |
| Others | | | |
| RTH258 | Beovu® | VEGF Inhibitor | Diabetic retinopathy |

Novartis pipeline in registration



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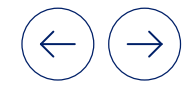
| Code | Name | Mechanism | Indication(s) |
|---------------------|----------|------------------|--------------------------|
| Solid tumors | | | |
| LEE011 | Kisqali® | CDK4/6 Inhibitor | HR+/HER2- BC (adj) |
| INC424 | Jakavi® | JAK1/2 inhibitor | Acute GVHD, pediatrics |
| | | | Chronic GVHD, pediatrics |

Immunology

| Code | Name | Mechanism | Indication(s) |
|--------|---------|---------------|---------------|
| IGE025 | Xolair® | IgE inhibitor | Food Allergy |

Novartis submission schedule

New Molecular Entities: Lead and supplementary indications



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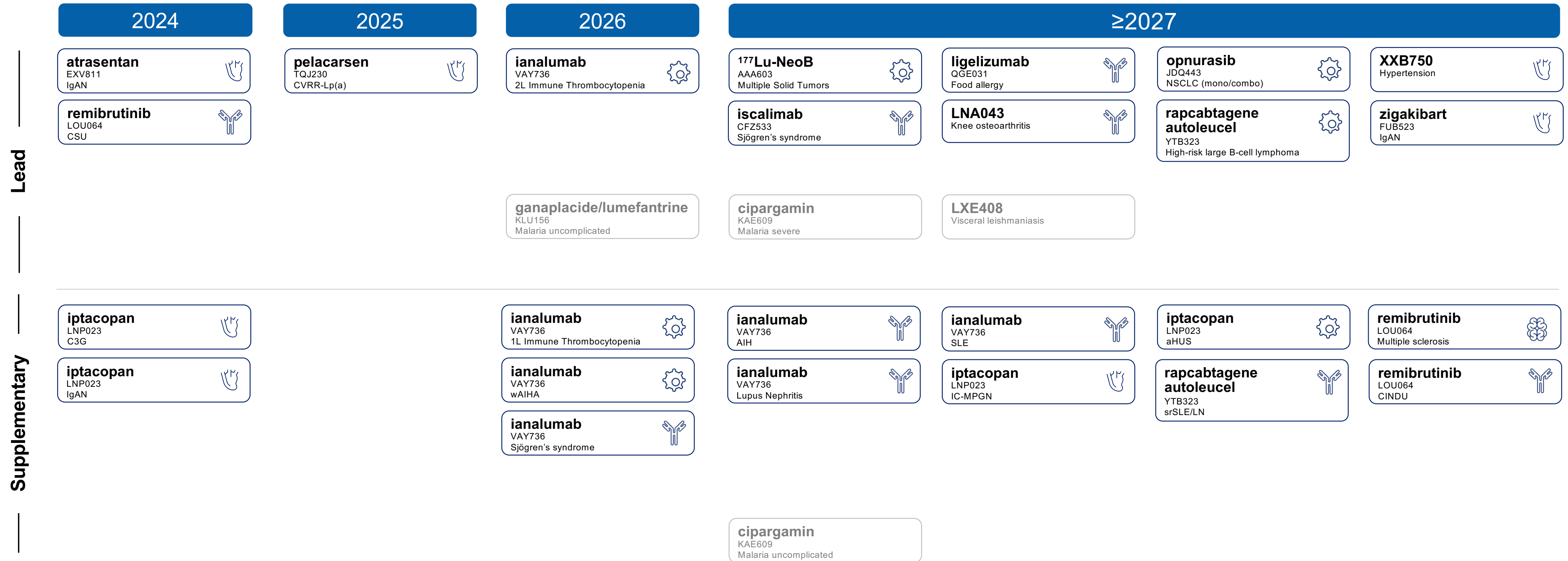
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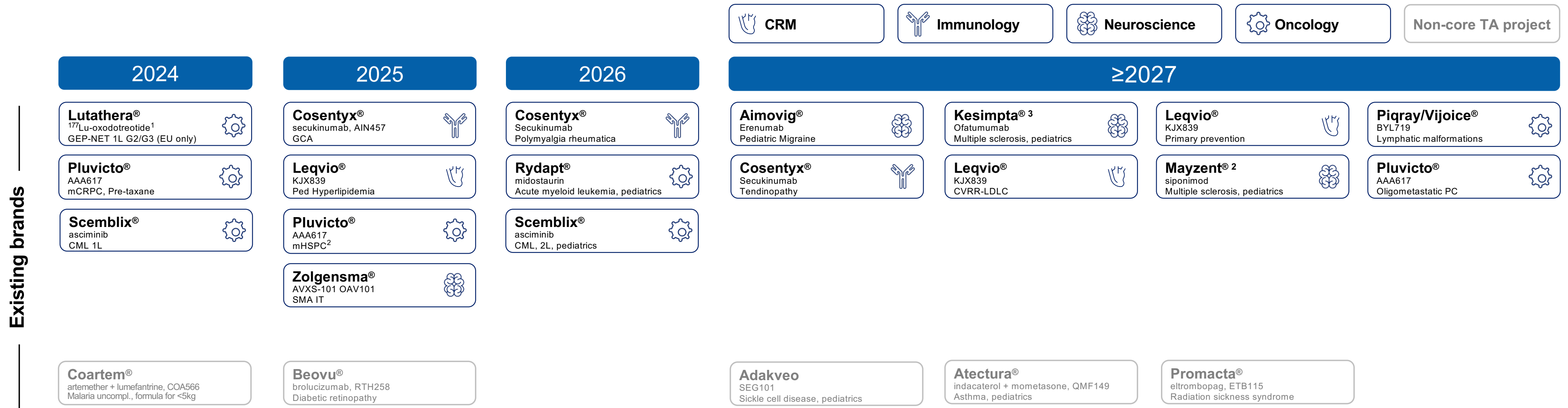
References

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

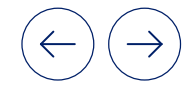


Novartis submission schedule

Supplementary indications for existing brands



1. ¹⁷⁷Lu-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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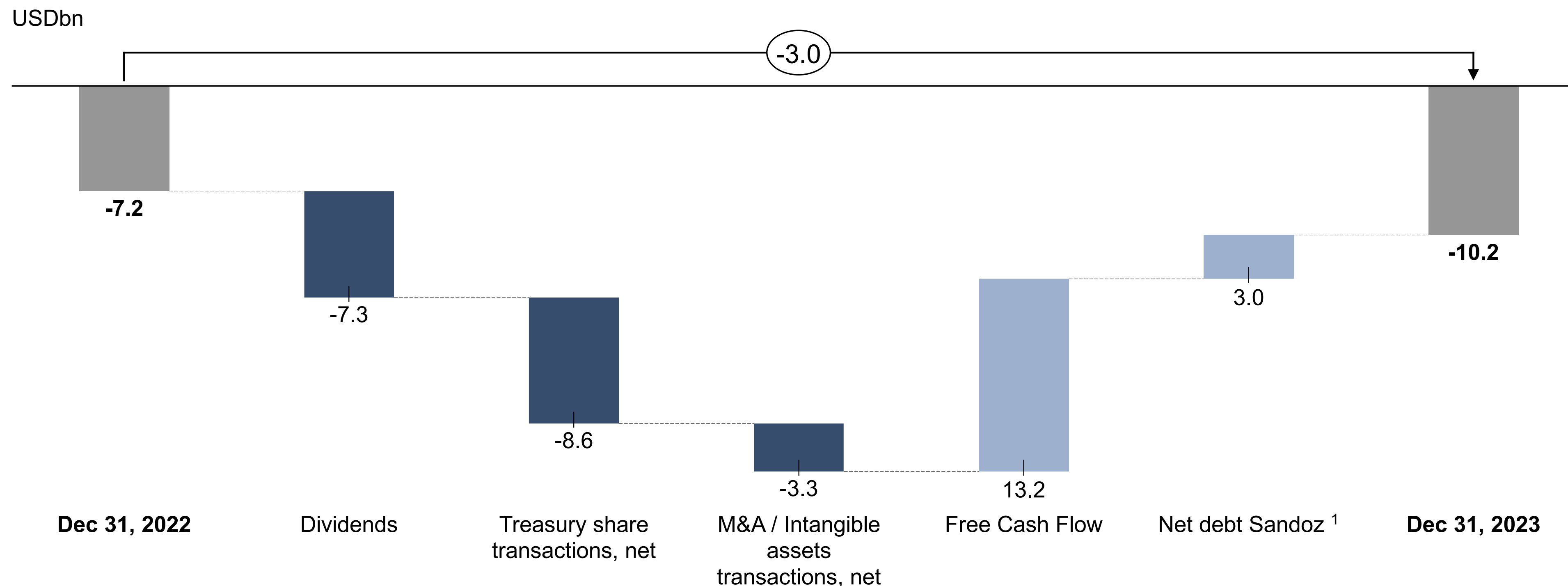
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Net debt increased by USD 3.0bn mainly due to dividends and share buybacks, partly offset by FCF



¹ Reflects USD 0.7bn cash and cash equivalents, and USD 3.7bn of financial debts of Sandoz at the time of the spin-off.



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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



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Cardiovascular, Renal and Metabolic



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atrasentan - ETA receptor antagonist

NCT04573478 ALIGN (CHK01-01)

| | |
|---------------------------------|---|
| Indication | IgA nephropathy |
| Phase | Phase 3 |
| Patients | 380 |
| Primary Outcome Measures | 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 |
| 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 |



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iptacopan - 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 |
| Target Patients | Primary IgA Nephropathy patients |
| Readout Milestone(s) | 2023 (primary endpoint for US initial submission, 9 months UPCR) 2025 (24 months) |
| Publication | TBD |

iptacopan - CFB inhibitor

NCT05755386 APPARENT (CLNP023B12302)

| | |
|---------------------------------|--|
| Indication | Immune complex-mediated membranoproliferative glomerulonephritis |
| Phase | Phase 3 |
| Patients | 68 |
| Primary Outcome Measures | 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> |
| 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) | 2026 |
| 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 |



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iptacopan - CFB inhibitor

NCT03955445 (CLNP023B12001B)

| | |
|---------------------------------|---|
| Indication | C3 glomerulopathy (C3G) |
| Phase | Phase 2 |
| Patients | 27 patients from ongoing Ph2 (sample size from Ph3 pending HA discussions Q1 2021), total patients for this study will increase |
| Primary Outcome Measures | Characterize the effect of LNP023 treatment on a composite renal response endpoint at 9 months (1. a stable or improved eGFR and, 2. a reduction in proteinuria and 3. an increase in C3 compared to the CLNP023X2202 baseline visit) |
| Arms Intervention | Open-label LNP023 200mg bid |
| Target Patients | Patients with C3 glomerulopathy |
| Readout Milestone(s) | 2025 |
| Publication | TBD |

iptacopan - CFB inhibitor

NCT04817618 APPEAR-C3G (CLNP023B12301)

| | |
|---------------------------------|---|
| Indication | C3 glomerulopathy |
| Phase | Phase 3 |
| Patients | 83 |
| Primary Outcome Measures | Log-transformed ratio to baseline in UPCR (sampled from a 24 hour urine collection) |
| Arms Intervention | Experimental: iptacopan 200mg b.i.d. Placebo Comparator: Placebo to iptacopan 200mg b.i.d. |
| Target Patients | Patients with native C3G |
| Readout Milestone(s) | 2023 |
| Publication | TBD |



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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 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. |
| Target Patients | Patient population with mean baseline LDL-C \geq 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 | 1. 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 |



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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 | TBD |

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 | TBD |



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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 |

Leqvio® - siRNA (regulation of LDL-C)

NCT05763875 V-Mono (CKJX839D12304)

| | |
|---------------------------------|--|
| Indication | CVRR (Primary prevention) |
| Phase | Phase 3 |
| Patients | 300 |
| Primary Outcome Measures | 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] |
| Arms Intervention | 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. |
| Target Patients | 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. |
| Readout Milestone(s) | 2024 |
| Publication | TBD |



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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) \geq 70 mg/dL |
| Readout Milestone(s) | 2025 |
| Publication | TBD |



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XXB750 - NPR1 agonist

NCT05562934 (CXXB750B12201)

| | |
|---------------------------------|--|
| Indication | Hypertension |
| Phase | Phase 2b |
| Patients | 170 |
| Primary Outcome Measures | Change from baseline in mean 24hr ambulatory systolic blood pressure at week 12 |
| Arms Intervention | Arm 1 experimental: Dose 1 Arm 2 experimental: Dose 2 Arm 3 experimental: Dose 3 Arm 4 experimental: Dose 4 Arm 5 placebo comparator |
| Target Patients | Resistant Hypertension Patients |
| Readout Milestone(s) | 2024 |
| Publication | TBD |

XXB750 - NPR1 agonist

NCT06142383 (CXXB750A12201)

| | |
|---------------------------------|---|
| Indication | Heart failure |
| Phase | Phase 2 |
| Patients | 720 |
| Primary Outcome Measures | Change in log NT-proBNP from baseline to Week 16 [Time Frame: Baseline to Week 16] |
| Arms Intervention | Arm 1 Placebo Comparator Arm 2 Experimental: XXB750 Low Dose Arm 3 Experimental: XXB750 Medium Dose Arm 4 Experimental: XXB750 High Dose Arm 5 Active Comparator: Sacubitril/valsartan, open label tablet |
| Target Patients | Patients with heart failure |
| Readout Milestone(s) | 2026 |
| Publication | TBD |



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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 |
| Target Patients | Adults with IgA Nephropathy |
| Readout Milestone(s) | 2026 |
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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 |
| Target Patients | 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 | 348 |
| Primary Outcome Measures | Number of participants with sustained remission |
| Arms Intervention | Experimental: Secukinumab 300 mg Placebo Comparator: Placebo |
| Target Patients | Patients with Giant Cell Arteritis (GCA) |
| Readout Milestone(s) | Primary 2025 Final 2026 |
| Publication | TBD |



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Cosentyx® - IL-17A inhibitor

NCT05722522 (CAIN457O12301)

| | |
|---------------------------------|--|
| Indication | Rotator cuff tendinopathy |
| Phase | Phase 3 |
| Patients | 234 |
| Primary Outcome Measures | Change from BSL in in the Western Ontario Rotator Cuff Index (WORC) Physical Symptom Domain (PSD) score [Time Frame: At Week 16]: - Improving physical shoulder symptoms in participants with moderate to severe RCT at Week 16 |
| Arms Intervention | Arm 1: Secukinumab 2 X 150 mg / 1 mL, subcutaneous (s.c.) injection, randomized in a 1:1 ratio Arm 2: Placebo 2X 1 mL, subcutaneous (s.c.) injection, randomized in a 1:1 ratio |
| Target Patients | Patients with moderate-severe Rotator Cuff Tendinopathy |
| Readout Milestone(s) | 2025 |
| Publication | TBD |

Cosentyx® - IL-17A inhibitor

NCT05758415 (CAIN457O12302)

| | |
|---------------------------------|--|
| Indication | Rotator cuff tendinopathy |
| Phase | Phase 3 |
| Patients | 234 |
| Primary Outcome Measures | Change from BSL in in the Western Ontario Rotator Cuff Index (WORC) Physical Symptom Domain (PSD) score [Time Frame: At Week 16]: - Change in physical shoulder symptoms in participants with moderate to severe RCT at Week 16 |
| Arms Intervention | Arm 1 experimental: Secukinumab 2 X 150 mg / 1 mL, subcutaneous (s.c.) injection, randomized in a 1:1 ratio Arm 2 placebo: 2 X 1 mL, subcutaneous (s.c.) injection, randomized in a 1:1 ratio |
| Target Patients | Patients with moderate-severe Rotator Cuff Tendinopathy |
| Readout Milestone(s) | 2025 |
| Publication | TBD |



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ianalumab - BAFF-R inhibitor

NCT03217422 AMBER (CVAY736B2201)

| | |
|---------------------------------|--|
| Indication | Autoimmune hepatitis |
| Phase | Phase 2 |
| Patients | 68 |
| Primary Outcome Measures | Alanine aminotransferase (ALT) normalization |
| Arms Intervention | VAY736 Placebo control with conversion to active VAY736 |
| Target Patients | Autoimmune hepatitis patients with incomplete response or intolerant to standard treatment of care |
| Readout Milestone(s) | 2024 |
| Publication | TBD |

ianalumab - BAFF-R inhibitor

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: Experimental - 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 |



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ianalumab - BAFF-R inhibitor

NCT05349214 NEPTUNUS-2 (CVAY736A2302)

| | |
|---------------------------------|---|
| Indication | Sjögren's syndrome |
| Phase | Phase 3 |
| Patients | 489 |
| 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 2026 |
| Publication | TBD |

ianalumab - BAFF-R inhibitor

NCT05350072 NEPTUNUS-1 (CVAY736A2301)

| | |
|---------------------------------|--|
| Indication | Sjögren's syndrome |
| Phase | Phase 3 |
| Patients | 268 |
| 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 Arm 2: Placebo comparator |
| Target Patients | Patients with active Sjogren's syndrome |
| Readout Milestone(s) | Primary 2026 |
| Publication | TBD |



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ianalumab - BAFF-R inhibitor

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: ianalumab s.c. monthly Experimental: ianalumab 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

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 |



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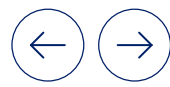
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LNA043 - ANGPTL3 agonist

NCT04864392 ONWARDS (CLNA043A12202)

| | |
|---------------------------------|---|
| Indication | Knee osteoarthritis |
| Phase | Phase 2 |
| Patients | 550 |
| Primary Outcome Measures | Change from baseline in the cartilage thickness of the medial compartment of the knee as assessed by imaging |
| Arms Intervention | LNA043 injection to the knee with dosing regimen A LNA043 injection to the knee with dosing regimen B LNA043 injection to the knee with dosing regimen C LNA043 injection to the knee with dosing regimen D Placebo injection to the knee |
| Target Patients | Patients with Symptomatic knee osteoarthritis |
| Readout Milestone(s) | Primary 2024 |
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remibrutinib - BTK inhibitor

NCT05030311 REMIX-1 (CLOU064A2301)

| | |
|---------------------------------|---|
| Indication | Chronic spontaneous urticaria |
| Phase | Phase 3 |
| Patients | 470 |
| Primary Outcome Measures | Change from baseline in UAS7 (Scenario 1 with UAS7 as primary efficacy endpoint) |
| Arms Intervention | Arm 1: LOU064 (blinded) LOU064 (blinded) taken orally for 24 weeks, followed by LOU064 (open-label) taken orally open label for 28 weeks. Randomized in a 2:1 ratio (arm 1:arm 2) Arm 2: LOU064 placebo (blinded) LOU064 placebo (blinded) taken orally for 24 weeks, followed by LOU064 (open-label) taken orally for 28 weeks. Randomized in a 2:1 ratio (arm 1:arm 2) |
| Target Patients | Adult Chronic Spontaneous Urticaria (CSU) patients inadequately controlled by H1-antihistamines |
| Readout Milestone(s) | 2024 (Final) |
| Publication | TBD |

remibrutinib - BTK inhibitor

NCT05032157 REMIX-2 (CLOU064A2302)

| | |
|---------------------------------|---|
| Indication | Chronic spontaneous urticaria |
| Phase | Phase 3 |
| Patients | 455 |
| Primary Outcome Measures | 1. Change from baseline in UAS7 (Scenario 1 with UAS7 as primary efficacy endpoint) 2. Absolute change in ISS7 an absolute change in HSS7 (Scenario 2 with ISS7 and HSS7 as co-primary efficacy endpoints) |
| Arms Intervention | Arm 1: LOU064 (blinded) LOU064A (blinded) taken orally b.i.d. for 24 weeks, followed by LOU064 (open-label) taken orally open label for 28 weeks Arm 2: LOU064 placebo (blinded) LOU064A placebo (blinded) taken orally for 24 weeks, followed by LOU064 (open-label) taken orally open label for 28 weeks Eligible participants randomized to the treatment arms in a 2:1 ratio (arm 1: arm 2) |
| Target Patients | Adult participants suffering from chronic spontaneous urticaria (CSU) inadequately controlled by H1-antihistamines in comparison to placebo |
| Readout Milestone(s) | 2024 (Final) |
| Publication | TBD |



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remibrutinib - BTK inhibitor

NCT05976243 (CLOU064M12301)

| | |
|---------------------------------|---|
| Indication | Chronic inducible urticaria |
| Phase | Phase 3 |
| Patients | 348 |
| Primary Outcome Measures | <ol style="list-style-type: none"> 1. Proportion of participants with complete response in Total Fric Score; symptomatic dermographism [Time Frame: Week 12] 2. Proportion of participants with complete response in critical temperature threshold; cold urticaria [Time Frame: Week 12] 3. Proportion of participants with itch numerical rating scale =0; cholinergic urticaria [Time Frame: Week 12] |
| Arms Intervention | <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> |
| Target Patients | Adults suffering from CINDU inadequately controlled by H1-antihistamines |
| Readout Milestone(s) | 2026 |
| Publication | TBD |



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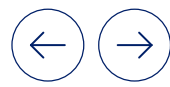
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Mayzent® - S1P1,5 receptor modulator

NCT04926818 NEOS (CBAF312D2301)

| | |
|---------------------------------|--|
| Indication | Multiple sclerosis, pediatrics |
| Phase | Phase 3 |
| Patients | 180 |
| 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 180 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) | 2026 |
| Publication | TBD |



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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) |
| Target Patients | 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 |
| Target Patients | Patients with relapsing Multiple Sclerosis |
| Readout Milestone(s) | Estimated primary completion 2026 |
| Publication | TBD |



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Zolgensma® - SMN1 gene replacement therapy

NCT05089656 STEER (COAV101B12301)

| | |
|---------------------------------|---|
| Indication | Spinal muscular atrophy (IT administration) |
| Phase | Phase 3 |
| Patients | 125 |
| Primary Outcome Measures | 1. Change from baseline in Hammersmith functional motor scale - Expanded (HFMSSE) 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 |
| Arms Intervention | 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. |
| Target Patients | Patients Type 2 Spinal Muscular Atrophy (SMA) who are ≥ 2 to < 18 years of age, treatment naive, sitting, and never ambulatory |
| Readout Milestone(s) | 2024 |
| Publication | TBD |

Zolgensma® - SMN1 gene replacement therapy

NCT05386680 STRENGTH (COAV101B12302)

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



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ianalumab - BAFF-R inhibitor

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: 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) |
| Target Patients | Adult patients with primary ITP |
| Readout Milestone(s) | 2025 |
| Publication | TBD |

ianalumab - BAFF-R inhibitor

NCT05653219 VAYHIT2 (CVAY736Q12301)

| | |
|---------------------------------|---|
| 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 |
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lanalumab - BAFF-R inhibitor

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 |
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iptacopan - CFB inhibitor

NCT04889430 APPELHUS (CLNP023F12301)

| | |
|---------------------------------|---|
| Indication | Atypical haemolytic uraemic syndrome |
| Phase | Phase 3 |
| Patients | 50 |
| 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) |
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opnurasib - KRAS inhibitor

NCT05132075 KontRASt-02 (CJDQ443B12301)

| | |
|---------------------------------|--|
| Indication | Non-small cell lung cancer, 2/3L |
| Phase | Phase 3 |
| Patients | 360 |
| Primary Outcome Measures | Progression free survival (PFS) |
| Arms Intervention | Arm 1 Experimental: JDQ443 Arm 2 Active Comparator: Participant will be treated with docetaxel following local guidelines as per standard of care and product labels |
| Target Patients | Patients with advanced non-small cell lung cancer (NSCLC) harboring a KRAS G12C mutation who have been previously treated with a platinum-based chemotherapy and immune checkpoint inhibitor therapy either in sequence or in combination. |
| Readout Milestone(s) | 2025 |
| Publication | NA |



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Pluvicto® - Radioligand therapy target PSMA

NCT04689828 PSMAfore (CAAA617B12302)

| | |
|---------------------------------|---|
| Indication | Metastatic castration-resistant prostate cancer, pre-taxane |
| Phase | Phase 3 |
| Patients | 450 |
| Primary Outcome Measures | Radiographic Progression Free Survival (rPFS) |
| Arms Intervention | Arm 1: Participants will receive 7.4 GBq (200 mCi) +/- 10% ¹⁷⁷ 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 |
| Target Patients | mCRPC patients that were previously treated with an alternate ARDT and not exposed to a taxane-containing regimen in the CRPC or mHSPC settings |
| Readout Milestone(s) | Primary Analysis: 2022 (actual) Final Analysis: 2025 |
| Publication | H2 2023 |

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: ¹⁷⁷ Lu-PSMA-617 Participant will receive 7.4 GBq (+/- 10%) ¹⁷⁷ 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 |
| Publication | TBD |



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Rydapt® - Multi-targeted kinase inhibitor

NCT03591510 (CPKC412A2218)

| | |
|---------------------------------|---|
| Indication | Acute myeloid leukemia, pediatrics |
| Phase | Phase 2 |
| Patients | 20 |
| Primary Outcome Measures | Occurrence of dose limiting toxicities 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 |



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Scemblix® - BCR-ABL inhibitor

NCT04971226 ASC4FIRST (CABL001J12301)

| | |
|---------------------------------|--|
| Indication | Chronic myeloid leukemia, 1st line |
| Phase | Phase 3 |
| Patients | 402 |
| Primary Outcome Measures | Major Molecular Response (MMR) at week 48 |
| Arms Intervention | Arm 1: asciminib 80 mg QD Arm 2: Investigator selected TKI including one of the below treatments: - Imatinib 400 mg QD - Nilotinib 300 mg BID - Dasatinib 100 mg QD - Bosutinib 400 mg QD |
| Target Patients | Patients with newly diagnosed philadelphia chromosome positive chronic myelogenous leukemia in chronic phase |
| Readout Milestone(s) | 2024 (actual) |
| Publication | TBD |



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TNO155 - SHP2 inhibitor

NCT03114319 (CTNO155X2101)

| | |
|---------------------------------|--|
| Indication | Solid tumors (single agent) |
| Phase | Phase 1 |
| Patients | 255 |
| Primary Outcome Measures | Number of participants with adverse events Number of participants with dose limiting toxicities |
| Arms Intervention | Drug: TNO155 Drug: TNO155 in combination with EGF816 (nazartinib) |
| Target Patients | Adult patients with advanced solid tumors in selected indications |
| Readout Milestone(s) | 2025 |
| Publication | TBD |



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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 of age) participants) Time Frame: Baseline, Week 24 |
| Arms Intervention | <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> |
| Target Patients | Pediatric and adult patients with lymphatic malformations associated with a PIK3CA mutation |
| Readout Milestone(s) | 2030 |
| Publication | TBD |



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Beovu® - VEGF Inhibitor

NCT04278417 CONDOR (CRTH258D2301)

| | |
|---------------------------------|---|
| Indication | Diabetic retinopathy |
| Phase | Phase 3 |
| Patients | 694 |
| Primary Outcome Measures | Change from Baseline in BCVA |
| Arms Intervention | Arm 1: RTH258 (brolucizumab) 6 mg/50uL Arm 2: Panretinal photocoagulation laser initial treatment followed with additional PRP treatment as needed |
| Target Patients | Patients with proliferative diabetic retinopathy |
| Readout Milestone(s) | 2024 |
| Publication | TBD |



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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 | Arm 1: experimental, IV KAE609 Dose regimen 1 Arm 2: experimental, IV KAE609 Dose regimen 2 Arm 3: experimental, IV KAE609 Dose regimen 3 Arm 4: active comparator, IV Artesunate Arm 5: Coartem, Standard of care |
| Target Patients | Patients with Malaria, severe |
| Readout Milestone(s) | 2025 |
| Publication | TBD |



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Coartem® - PGH-1 (artemisinin combination therapy)

NCT04300309 CALINA (CCOA566B2307)

| | |
|---------------------------------|---|
| Indication | Malaria, uncomplicated (<5kg patients) |
| Phase | Phase 3 |
| Patients | 44 |
| Primary Outcome Measures | Artemether Cmax |
| Arms Intervention | Experimental: artemether lumefantrine (2.5 mg:30 mg) artemether lumefantrine (2.5 mg:30 mg) bid over 3 days, from 1-4 tablets per dose |
| Target Patients | Infants and Neonates <5 kg body weight with acute uncomplicated plasmodium falciparum malaria |
| Readout Milestone(s) | Primary (actual) 2024 (final) |
| Publication | TBD |



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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 is the dose 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. |
| Target Patients | Adults and children \geq 5 kg Body Weight with uncomplicated P. Falciparum Malaria |
| Readout Milestone(s) | 2025 |
| Publication | TBD |



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| AI | Auto-injector | IgAN | IgA nephropathy |
| AIH | Autoimmune hepatitis | IPF | Idiopathic pulmonary fibrosis |
| aHUS | atypical Hemolytic Uremic Syndrome | ITP | Immune thrombocytopenia |
| ALL | Acute lymphoblastic leukemia | LBCL | Large B-cell lymphoma |
| ALS | Amyotrophic lateral sclerosis | LN | Lupus nephritis |
| AML | Acute myeloid leukemia | mCRPC | Metastatic castration-resistant prostate cancer |
| BC | Breast cancer | MDS | Myelodysplastic syndrome |
| C3G | C3 glomerulopathy | mHSPC | Metastatic hormone sensitive prostate cancer |
| CART | Chimeric androgen receptor T | mPDAC | Metastatic pancreatic ductal adenocarcinoma |
| CLL | Chronic lymphocytic leukemia | MS | Multiple sclerosis |
| CML | Chronic myeloid leukemia | NASH | Non-alcoholic steatohepatitis |
| CRC | Colorectal cancer | nmCRPC | Non-metastatic castration-resistant prostate cancer |
| COPD | Chronic obstructive pulmonary disease | NPR1 | Natriuretic peptide receptor 1 |
| COSP | Chronic ocular surface pain | nr-axSpA | Non-radiographic axial spondyloarthritis |
| CSU | Chronic spontaneous urticaria | NSAI | Non-steroidal aromatase inhibitor |
| CVRR-Lp(a) | Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein (a) | NSCLC | Non-small cell lung cancer |
| CVRR-LDL | Secondary prevention of cardiovascular events in patients with elevated levels of LDL | OS | Overall survival |
| DME | Diabetic macular edema | PFS | Prefilled syringe |
| DLBCL | Diffuse large B-cell lymphoma refractory | PNH | Paroxysmal nocturnal haemoglobinuria |
| ESCC | Esophageal squamous-cell carcinoma | PsA | Psoriatic arthritis |
| FL | Follicular lymphoma | rHR | Resistant hypertension |
| GCA | Giant cell arteritis | rMS | Relapsing multiple sclerosis |
| GVHD | Graft-versus-host disease | rPFS | Radiographic progression free survival |
| GRPR | Gastrin releasing peptide receptor | SLE | Systemic lupus erythematosus |
| HCC | Hepatocellular carcinoma | SMA Type 1 | Spinal muscular atrophy (IV formulation) |
| HD | Huntington's disease | SMA Type 2/3 | Spinal muscular atrophy (IT formulation) |
| HR LBCL | High risk large B-cell lymphoma | SpA | Spondyloarthritis |
| IA | Interim analysis | T1DM | Type 1 Diabetes mellitus |
| iAMD | Intermediate age-related macular degeneration | wAIHA | Warm autoimmune hemolytic anemia |
| IC-MPGN | Immune complex membranoproliferative glomerulonephritis | | |



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Entresto® (slide 7 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 AHA/ACC/HFSA/ESC.
- 4 Extension of regulatory data protection to November 2026 in EU based on approval of pediatric indication.

Kesimpta® (slide 9 references)

- 1 Data on file. Global data as of Nov 2023.
- 2 Data on file.
- 3 Kappos et al., AAN 2020, Ofatumumab Versus Teriflunomide in Patients with Relapsing Multiple Sclerosis: Phase 3 ASCLEPIOS I and II Trials.
- 4 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. Patient must take pen out of the refrigerator 15-30 minutes before self-administering.. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA.
- 5 Ross AP, Nicholas J, Tai MH, et al. US Real-world satisfaction and experience with injection and autoinjector device for ofatumumab indicated for multiple sclerosis. LB09. Presented at: Consortium of Multiple Sclerosis Centers Annual Meeting; May 31-June 3, 2023; Aurora, CO.
- 6 Novartis KESIMPTA Sensoready® Pen survey HEORUSV201392 in US. June 2022.
- 7 Efficacy outcomes as measured by disability progression and brain volume change.
- 8 Cohen et al, Poster presented at American Academy of Neurology, Boston, 22-27 April 23.
- 9 Cohen et al, oral presentation at American Academy of Neurology, Boston, 22-27 April 23.