Q3 2023 Results
Investor presentation

NOVARTIS | Reimagining Medicine

Disclaimer

This presentation contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as “potential,” “expected,” “will,” “planned,” “pipeline,” “outlook,” or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, potential product launches, or regarding potential future revenues from any such products; or regarding potential future, pending or announced transactions; or regarding potential future sales or earnings of Novartis; or regarding discussions of strategy, priorities, plans, expectations or intentions, including our transformation into a “pure-play” innovative medicines business; or regarding our liquidity or cash flow positions and our ability to meet our ongoing financial obligations and operational needs; or regarding our USD 15 billion share buyback; or regarding our appeal of the negative decision of the US District Court for the District of Delaware on the validity of our patent covering Entresto and combinations of sacubitril and valsartan. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. You should not place undue reliance on these statements. There can be no guarantee that the investigational or approved products described in this presentation will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. Neither can there be any guarantee expected benefits or synergies from the transactions described in this presentation will be achieved in the expected timeframe, or at all. In particular, our expectations could be affected by, among other things: liquidity or cash flow disruptions affecting our ability to meet our ongoing financial obligations and to support our ongoing business activities; the impact of a partial or complete failure of the return to normal global healthcare systems including prescription dynamics; global trends toward healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the development of the products described in this presentation; the potential that the benefits and opportunities expected from our planned spin-off of Sandoz may not be realized or may be more difficult or take longer to realize than expected; the uncertainties in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; safety, quality, data integrity, or manufacturing issues; uncertainties involved in the development or adoption of potentially transformational technologies and business models; uncertainties regarding actual or potential legal proceedings, investigations or disputes; our performance on environmental, social and governance measures; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this presentation as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

Supent® is a registered trademark of C.P. Pharmaceuticals International C.V.

Vas Narasimhan, M.D.

Chief Executive Officer

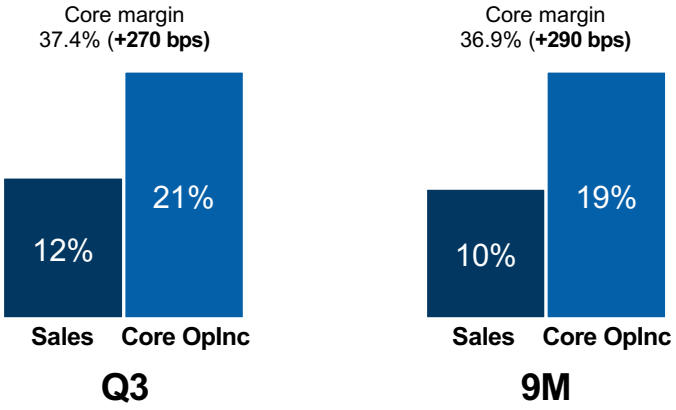
Company overview

SUMMARY

Novartis delivers strong sales growth, robust margin expansion and raises guidance. Successfully spun Sandoz

Growth and productivity[1]

% cc



FY 2023 guidance raised[1]

Sales expected to grow high single digit; Core OpInc expected to grow mid to high teens (from low double digit to mid teens)

Successful spin-off of Sandoz

Completed October 4, 2023

Several major innovation milestones in Q3

- **Cosentyx®** IV formulation approved in US (PsA, AS, nr-axSpA)
- **Leqvio®** approved in China and Japan
- **Kisqali®** submitted in EU; US submission planned in Q4 2023

Clinically meaningful and statistically significant Ph3 data for multiple assets with blockbuster potential

- **Pluvicto®** mCRPC pre-taxane
- **Iptacopan** IgAN
- **Remibrutinib** CSU
- **Lutathera®** GEP-NETs

1. Continuing operations. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. OpInc – operating income.

GROWTH

Strong Q3 growth driven by performance from Kesimpta®, Entresto®, Kisqali® and Pluvicto®. Cosentyx® returns to growth

Q3 sales

	Sales USD million	Growth vs. PY USD million	Growth vs. PY cc
Kesimpta (ofatumumab)	657	368	124%
Entresto sacubitril/valsartan	1,485	350	31%
KISQALI ribociclib	562	235	76%
PLUVICTO	256	176	217%
SCEMBLIX (asciminib)	106	65	157%
LEQVIO	90	56	165%
Cosentyx (secukinumab)	1,329	55	4%
ILARIS (canakinumab)	335	63	24%
PROMACTA (eltrombopag)	576	53	10%
Xolair (omalizumab)	369	47	13%
JAKAVI ruxolitinib	427	41	9%

Strong growth (+41% cc); expected to continue

Constant currencies (cc) is a non-IFRS measure; explanation of non-IFRS measures can be found on page 48 of Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

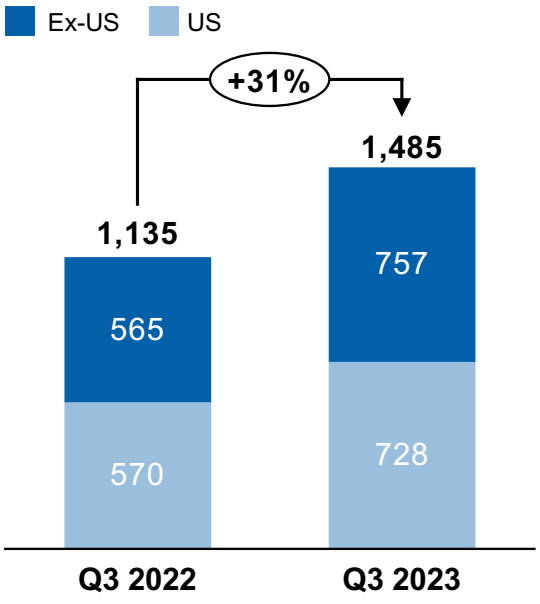
GROWTH

Entresto® delivers 31% growth with sales approaching USD 1.5bn in the quarter

Entresto®

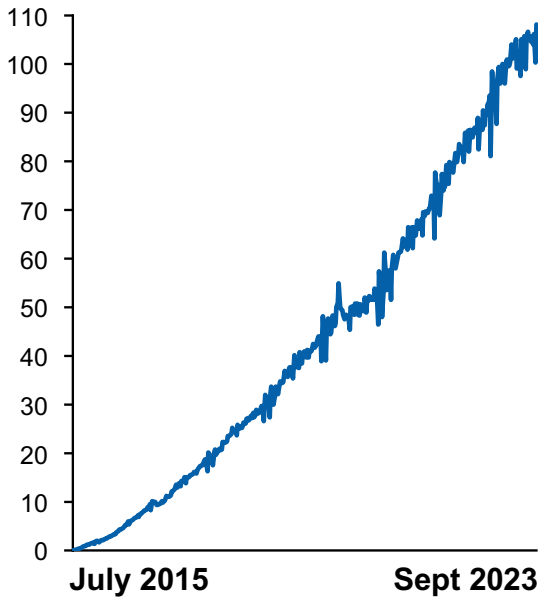
Sales evolution

USD m, % cc



US weekly TRx[1]

Total prescriptions (000)



Strong Q3 momentum

- US: robust growth outpacing market, sales **+28%** cc, ~1.4m TRx in Q3[1]
- Ex-US: sales **+34%** cc
- China/Japan: significant contribution from HTN[2]

Confidence in future growth

- Strong guidelines position[3] (US/EU)
- Expect further penetration in HF (2/3 eligible patients still on prior SoC) and HTN (China/Japan)
- EU: paediatric approval confirms RDP to Nov 2026[4]
- US: appeal filed to uphold validity of combination patent; other patent litigation ongoing and no generics have FDA approval[5]

See last page for references. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report. TRx – total prescriptions. HF – heart failure. HTN – hypertension. RDP – Regulatory data protection. SOC – standard of care.

NOVARTIS | Reimagining Medicine

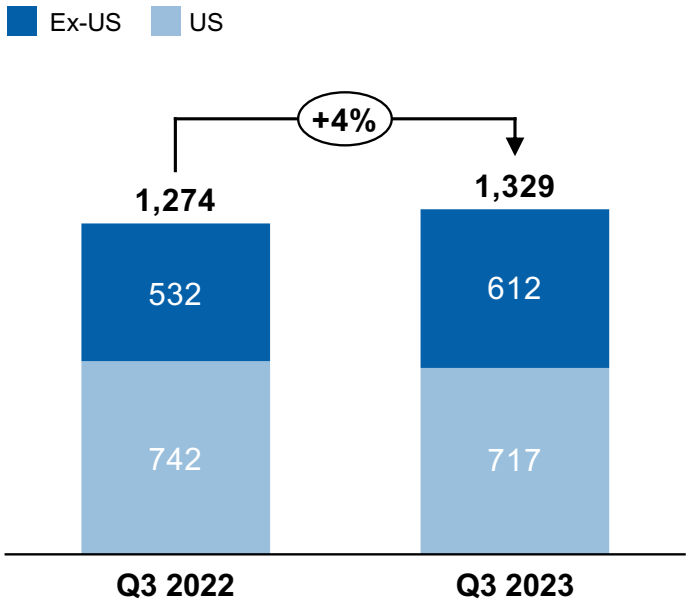
GROWTH

Cosentyx® returns to growth; expecting stronger Q4

Cosentyx®

Sales evolution

USD m, % cc



Q3 performance

- US sales (-3%): supported by volume growth, offset by PY base effects
- Ex-US sales (+15%): growth in core indications

Q4 expect stronger sales growth

- US: continuing volume growth; lower PY base due to Q4 2022 RD true-up
- EU: HS approved in Q2, launch on track

Life cycle management

- US: ☑ IV formulation[1] approved, HS approval expected Q4
- 3 Ph3 studies ongoing: GCA, Polymyalgia Rheumatica, Rotator Cuff Tendinopathy

GCA – Giant Cell Arteritis. HS – hidradenitis suppurativa. IV – intravenous. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report. 1. for adult AS, PsA and nr-axSpA.

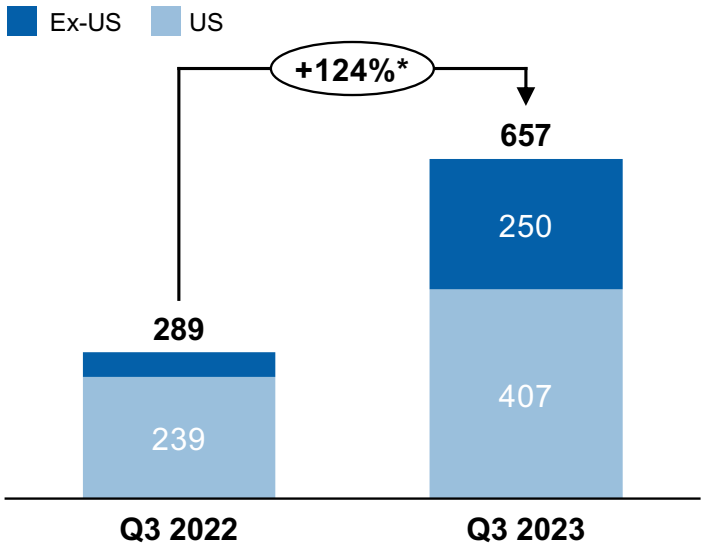
GROWTH

Kesimpta® continues strong launch trajectory across regions

Kesimpta

Sales evolution

USD m, % cc



*Without the one-time revenue deduction adjustment, sales growth **+86% cc**

US: growing faster than market[1,2]

- TRx +75% Q3 vs. PY (market +3%)
- NBRx +30% Q3 vs. PY (market +18%)
- B-cell NBRx share ~56% of MS market

Europe: launch momentum progressing

- >29k patients treated, majority naive or first switch
- Q3 sales includes one-time revenue deduction adjustment*

Confident in future growth

- Only about 1/3 of MS patients on B-cell therapy
- NBRx leadership in key markets including Germany
- Compelling product profile: 1 minute a month dosing from home/anywhere[3]; 5-year efficacy[4], safety and tolerability data[5,6]

See last page for references. TRx – total prescriptions. NBRx – new to brand prescription. MS - Multiple Sclerosis. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report.

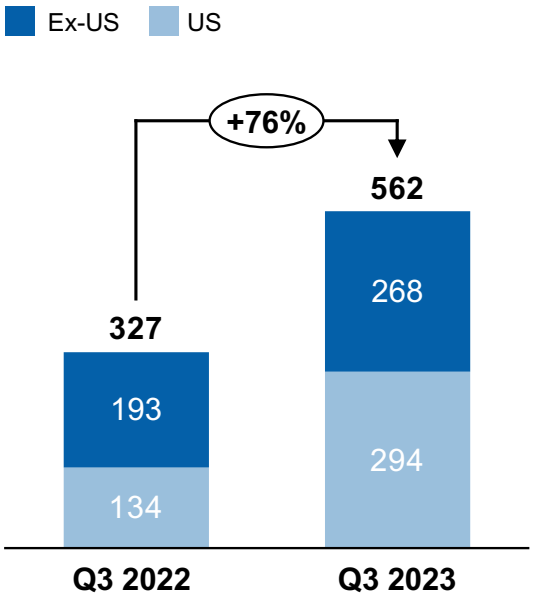
GROWTH

Kisqali® sales grew 76% to USD 562m, with increasing recognition of its differentiated benefit-risk profile

KISQALI®

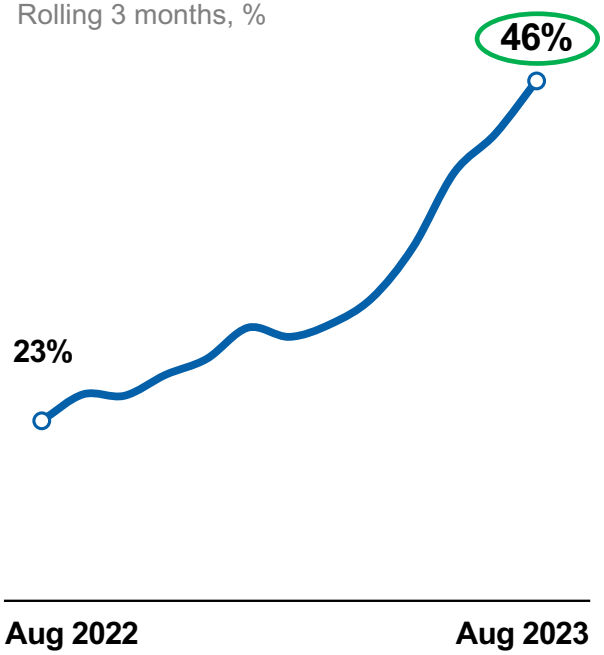
Sales evolution

USD m, % cc



US mBC NBRx share[1]

Rolling 3 months, %



Consistent efficacy

Kisqali Ph3 OS results in 1L mBC[2]

Stage IV	HR	95% CI
☑ MONALEESA-2	**0.76**	(0.63, 0.93)
☑ MONALEESA-7	**0.76**	(0.61, 0.96)
☑ MONALEESA-3	**0.67**	(0.50, 0.90)

Consistent OS benefit across 3 Ph3 studies

NCCN guideline support as only Category 1 treatment for 1L mBC with AI[3]

Right Choice data showing benefit vs. doublet chemo in aggressive HR+/HER2- mBC

Most adverse events asymptomatic

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 Aug 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 48 of Condensed Interim Financial Report.

INNOVATION

Kisqali® Ph3 NATALEE iDFS 500 event analysis complete, US submission planned for Q4 2023; file submitted in EU

KISQALI®

Ph3 NATALEE results as presented at ASCO 2023[1]

Second interim efficacy analysis at 426 iDFS events

	HR	95% CI
iDFS – total population	**0.75**	(0.62, 0.91)
iDFS – stage II	**0.76**	(0.53, 1.10)
iDFS – stage III	**0.74**	(0.59, 0.92)
iDFS – node negative	**0.63**	(0.34, 1.16)
iDFS – node positive	**0.77**	(0.63, 0.94)
RFS	**0.72**	(0.58, 0.88)
DDFS	**0.74**	(0.60, 0.91)
OS	**0.76**	(0.54, 1.07)

ESMO 2023 updates

Consistent iDFS benefit[2] across subgroups: stage, menopausal status, age, nodal status

Good tolerability profile[3]**:** addition of Kisqali® to ET did not compromise patients' QoL on any of the scales evaluated

Regulatory status / next steps

☑ Filed in Europe

500 iDFS event milestone reached; data consistent with interim analysis (March 2023[4])

US submission planned for Q4 2023

1. Interim analysis. Slamon D, Stroyakovskiy D, Yardley D, et al. Ribociclib and endocrine therapy as adjuvant treatment in patients with HR+/HER2- early breast cancer. 2. Slamon D, et al. ASCO 2023. LBA500 [Oral].
3. Fasching PA, et al. ESMO 2023 Virtual Plenary. Oral VP3-2023. 4. Interim analysis in March 2023, data presented at ASCO 2023.

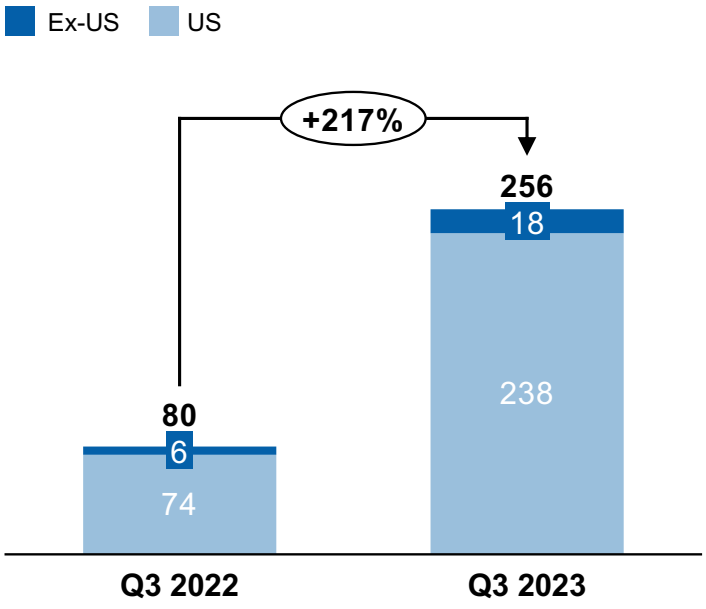
GROWTH

Pluvicto® grew to USD 256m; supply now unconstrained, focusing on initiating new patients

PLUVICTO™

Sales evolution

USD m, % cc



Continued progress in Q3

- Growth rates slowed in the quarter given supply challenges earlier in the year
- >200 active centers ordering in US and onboarding another approximately 130
- Ex-US reimbursement discussions ongoing

Supply capacity now unconstrained; maintaining reliability

- Millburn capacity expanded with FDA approval of two additional lines
- Indianapolis site submitted for FDA approval

INNOVATION

PSMAfore study showed robust efficacy with favorable safety of Pluvicto® in PSMA+ mCRPC patients in the pre-taxane setting

Robust efficacy	Pluvicto® vs. ARPI arm
☑ rPFS[1]	HR **0.41** (0.29, 0.56)
☑ Median rPFS[2]	**12.0** vs. 5.6 months
☑ PSA50 response	**57.6%** vs. 20.4%
☑ Time to SSE[3]	HR **0.35** (0.22, 0.57)
☑ ORR[4]	**50.7%** vs. 14.9%
☑ Time to worsening (FACT-P[5])	HR **0.59** (0.47, 0.72)
☑ Time to worsening (BPI-SF[6])	HR **0.69** (0.56, 0.85)
Crossover-adjusted OS	HR **0.80** (0.48, 1.33)
Unadjusted OS **(84% crossover)**	HR 1.16 (0.83, 1.64)

Favorable safety
☑ Vast majority of AEs low-grade
☑ Grade 3-4 AEs: 33.9% Pluvicto® vs. 43.1% ARPI
☑ SAEs: 20.3% Pluvicto® vs. 28.0% ARPI
☑ AEs leading to discontinuation[7]: 5.7% vs. 5.2%
☑ AEs leading to dose adjustment[7]: 3.5% vs. 15.1%

Overall exposure to Pluvicto® ~2,000 patient-years
(incl. VISION, PSMAfore and post-marketing experience)

Presented at ESMO; submission to FDA now planned in 2024

1. Primary rPFS analysis based on 166 rPFS events per BICR assessment (or centrally confirmed rPFS events); 1-sided p-value: <0.0001. Updated analysis of rPFS (at time of 2nd interim OS analysis) was consistent, with HR 0.43 (0.33, 0.54). All other data points from updated analysis with more mature data. 2. (95% CI): 12.0 (9.3, 14.4) vs. 5.6 (4.2, 5.95). 3. SSE = symptomatic skeletal event. 4. ORR in soft tissue per RECIST 1.1 for pts with measurable disease at baseline; (95% CI): 50.7% (38.6, 62.8) vs. 14.9% (7.7, 25.0). 5. FACT-P: prostate cancer-specific quality of life. 6. BPI-SF: severity of pain and impact of pain on daily functions. 7. Comparisons for Pluvicto® vs. ARPI arm.

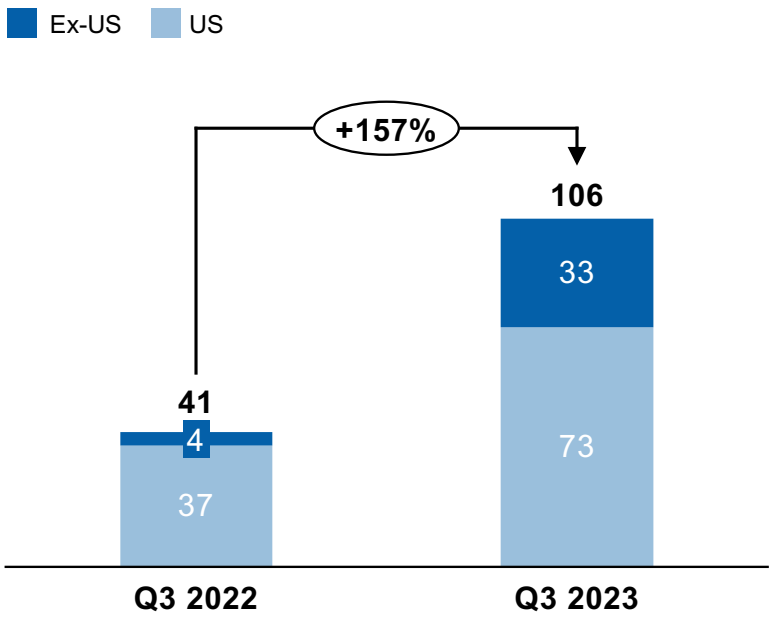
GROWTH

Scemblix® sales grew across all regions, demonstrating the high unmet need in CML

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Sales evolution

USD m



- Q3 sales reflect continued demand from patients with Ph+ CML-CP resistant or intolerant to 2 or more prior TKIs
- Leading market share 3L+ in US (NBRx 34%, TRx 20%)
- Global rollout ongoing with strong performance in Japan and France
- >40% of patients not satisfied with side effect profile of 1st and 2nd generation TKIs, highlighting need for more tolerable treatments[1]
- ASC4FIRST (1L registrational study) readout and filing expected 2024

Ph+ CML-CP – Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase.

1. 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).

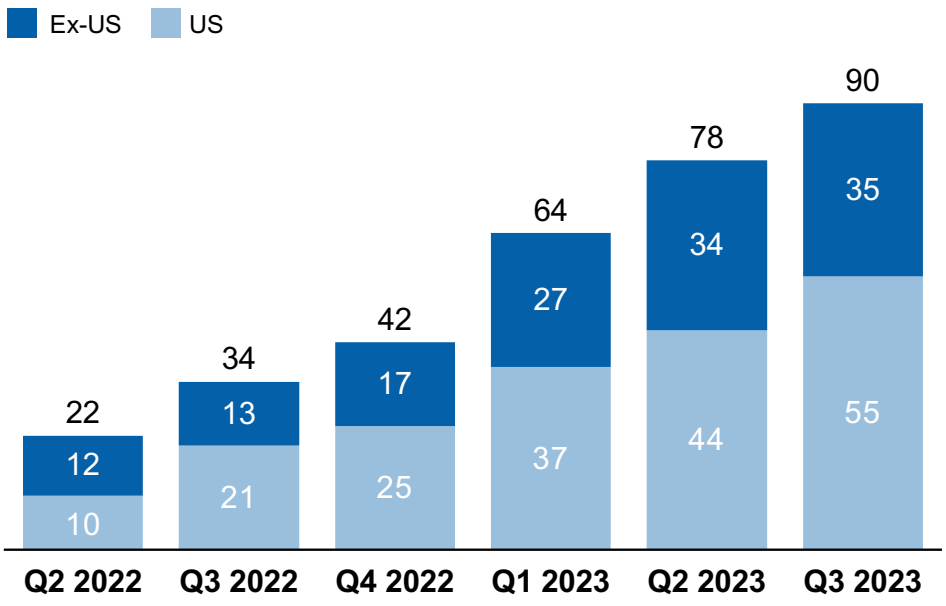
GROWTH

Leqvio® adoption continues to expand steadily

LEQVIO®

Sales evolution

USD m



US: Building foundation for acceleration

Adoption

- 3,100 facilities have ordered Leqvio® (+16% vs. Q2)
- >55% of business is from buy and bill

Enablers for future growth

- Drive depth in key accounts with high utilization
- Increase confidence in buy and bill
- Improve HCP targeting

Ex-US rollout continues

☑ Approved in China and Japan

B&B – Buy and Bill. Leqvio® is administered initially, again at 3 months, and then once every 6 months. Novartis has obtained global rights to develop, manufacture and commercialize Leqvio® under a license agreement with Alnylam Pharmaceuticals, Inc.

INNOVATION

Key 2023 readouts for high-value medicines on track

Key assets* with submission enabling readouts in 2023

Kisqali®

●●●

Ph3 NATALEE trial in adjuvant breast cancer testing broad patient population (anatomical stage II and III[1]).

500 iDFS event milestone reached; data consistent with interim analysis (March 2023[2])

Filed in EMA in **Q3**

FDA regulatory submission planned in **Q4 2023**

Pluvicto®

●●

PSMAfore trial in mCRPC (post-ARDT, pre-taxane) positive readout

Detailed data presented at **ESMO 2023**

FDA regulatory submission now planned in **2024**

Iptacopan

●●●

PNH filed with FDA and EMA in **Q2 2023**

APPLAUSE-IgAN Ph3 met its pre-specified interim analysis primary endpoint[3] in **Q3 2023**

APPEAR-C3G Ph3 readout expected in **Q4 2023**

Atrasentan

IgAN readout expected in **Q4 2023**

*Unprobabilized estimated peak sales of all asset indications in late-stage development: ● > USD 1bn ●● > USD 2bn ●●● > USD 3bn

mCRPC – metastatic castration resistant prostate cancer. ARDT – androgen receptor directed therapy. 1. Based on AJCC prognostic staging. 2. Interim analysis in March 2023, data presented at ASCO 2023. 3. 9 months readout may support US submission for accelerated approval.

INNOVATION

Submission enabling readouts expected to increase in 2024-2025 timeframe

Selected key assets* with submission enabling readouts in 2024-2025

Remibrutinib ●●●

CSU

Positive readout for primary analysis[1]; data to be presented at ACAAI 2023

Final (52 weeks) readout and submission expected in **2024**

Scemblix® ●●

1L CML-CP

Readout and submission expected in **2024**

Pluvicto® ●●

mHSPC

Readout and submission planned in **2024**[2]

OAV-101 ●●

SMA IT

Readout expected in **2024**; submission planned in **2025**

Pelacarsen ●●●

CVRR

Readout and submission expected in **2025**

Ianalumab ●●●

1L and 2L ITP readouts expected in **2025** with submission planned in **2026**

Additional hematology and immunology indications **2026+**

Iptacopan ●●●

Additional readouts/submissions expected in **2025/2026+**

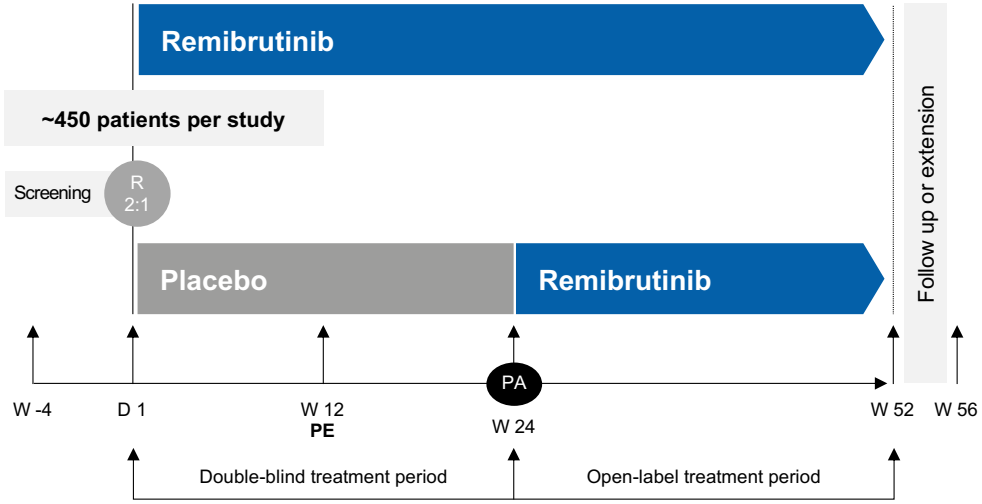
*Unprobabilized estimated peak sales of all asset indications in late-stage development: ● > USD 1bn ●● > USD 2bn ●●● > USD 3bn

CSU – chronic spontaneous urticaria. CML-CP – chronic myeloid leukemia in chronic phase. mHSPC – metastatic hormone-sensitive prostate cancer. SMA IT – spinal muscular atrophy intrathecal. CVRR – cardiovascular risk reduction. ITP – immune thrombocytopenia. 1. Double blind treatment period of 24 weeks with primary analysis at 12 weeks. 2. Event-driven trial endpoint.

INNOVATION

Remibrutinib demonstrated clinically meaningful and statistically significant benefit in Ph3 CSU trials

Ph3 REMIX 1 & 2 studies



All participants on a stable, locally label approved dose of a second generation H_1-AH ("background therapy") throughout the entire study

Remibrutinib met ALL primary and secondary endpoints at 12 weeks

- ☑ **Clinically meaningful and statistically significant** reduction in urticaria activity
- ☑ **Fast symptom improvement** as early as 2 weeks[1]
- ☑ **Well tolerated** and favorable safety profile (incl. balanced liver function tests)
- ☑ **Oral**

Next steps

Presentation at ACAAI 2023; final 52 week readout and filing expected in 2024

CSU - Chronic spontaneous urticaria. PA – Primary analysis. 1. As illustrated by a higher proportion of patients achieving UAS7≤6 at Week 2 in the REMIX-1 and REMIX-2 studies when treated with remibrutinib compared to placebo.

INNOVATION

Remibrutinib – opportunity for efficacious oral therapy with fast onset of action[1] after antihistamines

Remibrutinib, a highly selective oral BTKi

WW: 40m CSU patients[2]; US: ~1.1m treated adults with CSU[3]

Antihistamines	CSU treatment gap	Biologics
~600k[3] patients controlled with SoC[4]	**~400k[3] patients not controlled** with SoC[4] **High unmet need** after antihistamines	**Only ~80k[3] patients** treated with biologics

Opportunity for Remibrutinib

CSU - Chronic spontaneous urticaria. HCP - Healthcare professional. SOC – Standard of care. 1. As illustrated by a higher proportion of patients achieving UAS7≤6 at Week 2 in the REMIX-1 and REMIX-2 studies when treated with remibrutinib compared to placebo. 2. Maurer M, Weller K, Bindslev-Jensen C, et al. Unmet clinical needs in chronic spontaneous urticaria. A GA2LEN task force report. Allergy. 2011;66:317-330 and The World Bank. Population, total. Available from: https://data.worldbank.org/indicator/SP.POP.TOTL [Last accessed: July 2023]. 3. US only Novartis internal analysis. 4. H1, H2 antihistamines and antihistamines escalation.

INNOVATION

Iptacopan is a potential first-in-class, oral, selective factor B inhibitor, targeting complement system proximally via alternative pathway[1]

Indication	2021	2022	2023	2024	2025	2026+	Key updates	US prevalence Thousands
PNH	Ph3 - APPLY						☑ Superior to SoC for both primary endpoints in patients with residual anemia despite SoC ☑ Achieved clinically meaningful increases in Hb levels in treatment-naive patients with PNH	<10
	Ph3 - APPOINT							
IgA nephropathy	Ph3 - APPLAUSE *						☑ Clinically meaningful and highly statistically significant proteinuria reduction at 9 months	185[2]
C3G	Ph3 - APPEAR						▶ Submission enabling readout Q4 2023	<10
aHUS		Ph3 - APPELHUS					▶ Submission enabling readout in 2025	<10
IC-MPGN			Ph3				▶ Ph3 started	<10

Additional ongoing early-stage (Ph2) activities in Lupus Nephritis, iAMD

* 9 months readout may support US submission for accelerated approval

PNH – paroxysmal nocturnal hemoglobinuria. IgAN – immunoglobulin A nephropathy. C3G – complement 3 glomerulopathy. aHUS – atypical hemolytic uremic syndrome. iAMD – intermediate age-related macular degeneration. IC-MPGN – immune complex membranoproliferative Glomerulonephritis. 1. Phase 3 studies initiated; additional indications are being explored. 2. Estimated ~46-55k number of US patients at high risk of progression with proteinuria > 1g/day (~25-30%).

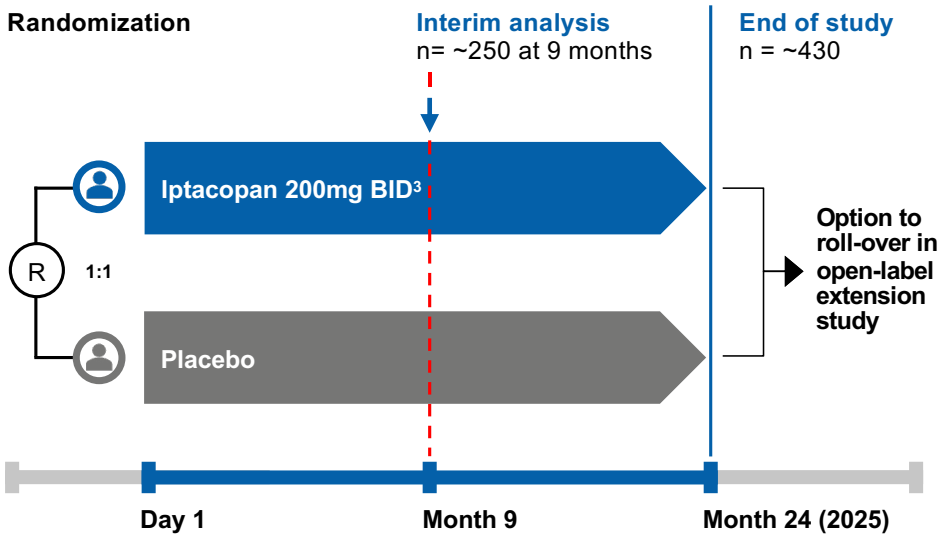
NOVARTIS | Reimagining Medicine

INNOVATION

Iptacopan demonstrated clinically meaningful and highly statistically significant proteinuria reduction in Ph3 APPLAUSE-IgAN

Ph3 APPLAUSE-IgAN

Biopsy-confirmed patients with IgA nephropathy at risk of progression with elevated proteinuria (UPCR[1] ≥1g/g) despite stable background therapy[2]



Positive top-line results at pre-specified interim analysis

- ☑ **Superiority vs placebo** in proteinuria reduction on top of optimized supportive care
- ☑ **Clinically meaningful** and highly statistically significant proteinuria reduction
- ☑ **Safety profile consistent** with previously reported data
- ☑ **Oral**

Next steps

In discussions with FDA to submit for **accelerated approval**

Study continues to assess superiority in slowing disease progression (eGFR slope) for full approval

IgAN – IgA nephropathy. eGFR - estimated glomerular filtration. 1. UPCR (urine protein-to-creatinine ratio) from 24-h urine collection. 2. Including at least maximally tolerated dose of ACEi/ARB for at least 90 days. 3. BID – twice daily.

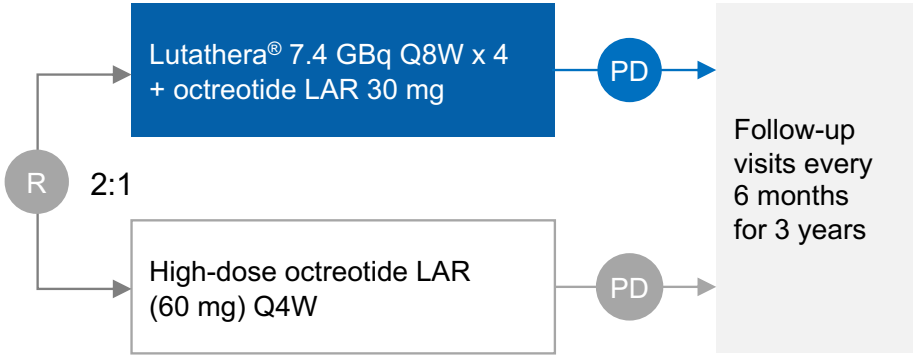
NOVARTIS | Reimagining Medicine

INNOVATION

Lutathera® Ph3 NETTER-2 results highlight the potential for radioligand therapy (RLT) in earlier disease settings

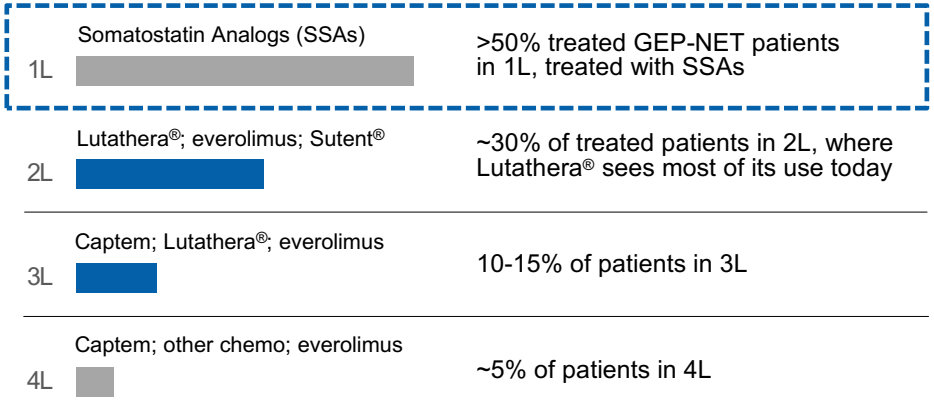
Demonstrated clinically meaningful and statistically significant benefit in first line setting

- Met primary endpoint of improvement in PFS and key secondary endpoint of ORR
- Safety consistent with well-established profile of Lutathera®



NETTER-2 supports potential acceleration of treatment with RLT to 1L

~170k NET patients in US; GEP-NET represent 55-70%



Next steps

Full data to be presented at upcoming medical meeting and provided to guideline committees

GEP-NET – gastroenteropancreatic neuroendocrine tumors.

Harry Kirsch

Chief Financial Officer

Financial review and 2023 guidance

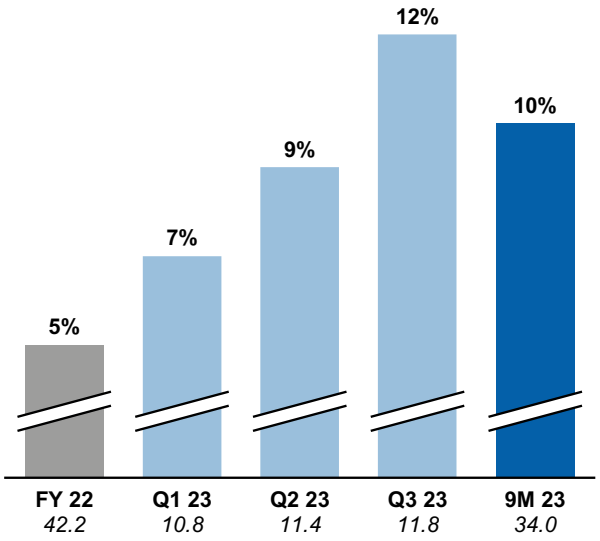
FINANCIAL PROFILE

2023 performance continues our track record of consistent top-line growth and core margin expansion

Continuing operations[1] performance, numbers restated post-Sandoz spin-off

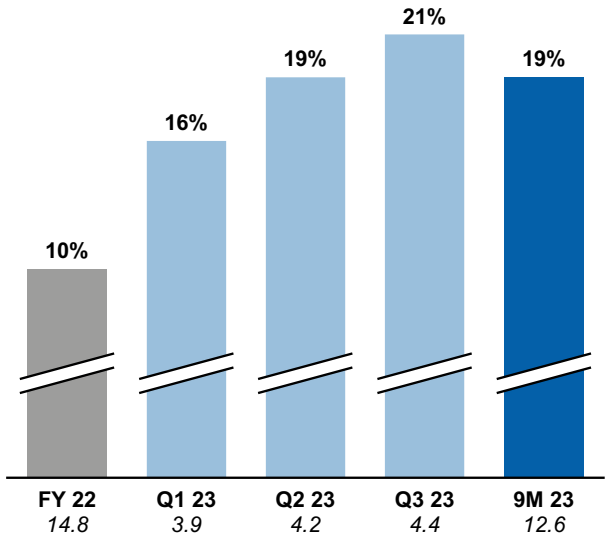
Net sales % growth

% cc, USD bn



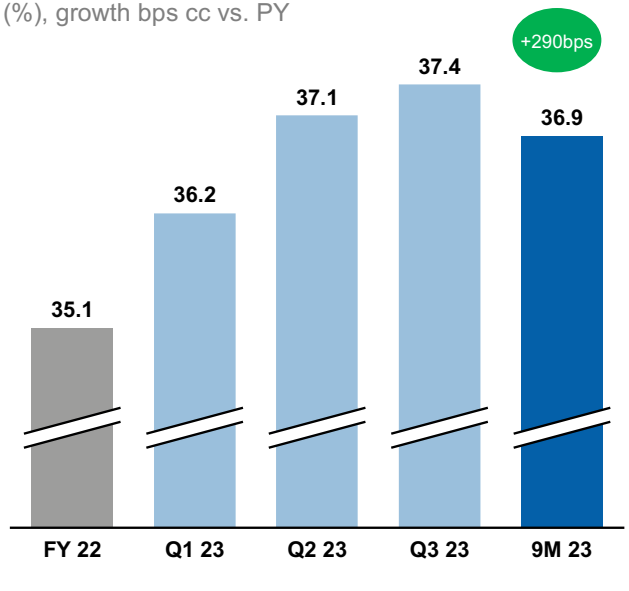
Core OpInc[2] % growth

% cc, USD bn



Core margin[2]

(%), growth bps cc vs. PY



In USD bn

1. As defined on page 37 of the Condensed Interim 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 48 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

FINANCIAL PROFILE

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

Continuing operations[1] USD million	Q3 2023	Change vs. PY % USD	Change vs. PY % cc[2]	9M 2023	Change vs. PY % USD	Change vs. PY % cc[2]
Net sales	11,782	12	12	34,017	8	10
Core operating income[2]	4,405	17	21	12,551	13	19
Operating income	1,762	-4	13	7,187	16	31
Net income	1,513	14	37	5,934	25	41
Core EPS (USD)[2]	1.74	24	29	4.95	21	28
EPS (USD)	0.73	20	45	2.84	31	49
Free cash flow[2]	5,043	24		11,019	27	

1. As defined on page 37 of the Condensed Interim 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 48 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

FINANCIAL PROFILE

Significant improvement in core margin for continuing operations

	Q3 2023				9M 2023			
	Net sales change vs. PY[1] (in % cc)	**Core operating income** change vs. PY[1] (in % cc)	**Core margin[1]** (%)	**Core margin** change vs. PY[1] (%pts cc)	**Net sales** change vs. PY[1] (in % cc)	**Core operating income** change vs. PY[1] (in % cc)	**Core margin[1]** (%)	**Core margin** change vs. PY[1] (%pts cc)
Continuing operations[2]	12	21	37.4	2.7	10	19	36.9	2.9
Discontinued operations[2]	6	-38	10.1	-9.3	8	-11	16.0	-3.7
Group	9	14	33.8	1.3	9	15	34.1	2.0

1. Constant currencies (cc), core results are non-IFRS measures. Explanation of non-IFRS measures can be found on page 48 of the Condensed Interim Financial Report 2. As defined on page 37 of the Condensed Interim Financial Report, Continuing operations include the retained business activities of Novartis, comprising the Innovative Medicines Division and the continuing Corporate activities and Discontinued operations include operational results from Sandoz business.

FINANCIAL PROFILE

Raising FY guidance for core operating income

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

Novartis (Continuing operations[1])

Net sales expected to grow high single digit

Unchanged from previous guidance

Core operating income expected to grow mid to high teens

Raised from low double digit to mid-teens

Key assumptions

- No US Entresto® Gx at risk launch in 2023
- No Sandostatin® LAR generics enter in the US in 2023

1. As defined on page 37 of the Condensed Interim 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 48 of the Condensed Interim Financial Report.

STRATEGY

Novartis maintains strong commitment to shareholder value creation

Investing in the business

Investments in organic business
R&D >USD 45bn, CAPEX >USD 5bn 2018-YTD 2023[1]

Value-creating bolt-ons
>USD 33bn 2018-YTD 2023

Substantial cash generation

Returning capital to shareholders

Consistently growing annual dividend[2]
>USD 42bn of dividends 2018-YTD 2023
No rebasing post Alcon and Sandoz spin-off

Share buybacks
>USD 30bn 2018-YTD 2023
New USD 15bn SBB commenced in Jul 2023

Whilst also creating shareholder value via numerous strategic actions

Jun 2018	Apr 2019	Nov 2021	Oct 2023
Divested consumer health JV	**Spun Alcon**	**Exited Roche stake**	**Spun Sandoz**

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

Vas Narasimhan, M.D.

Chief Executive Officer

Delivered a very strong quarter, upgraded FY 2023 guidance. Maintaining our commitment to shareholder value creation

Very strong Q3: sales +12%, core operating income +21% (cc, continuing operations)

Growth drivers continue to perform well in the market: incl. Kesimpta®, Entresto®, Kisqali® and Pluvicto®

Robust pipeline: innovation milestones for Cosentyx®, Pluvicto®, iptacopan, remibrutinib, Lutathera®

Successfully completed the Sandoz spin-off: focusing on our core business of innovative medicines

Raising 2023 FY guidance

Novartis Capital Markets Day, focus R&D

November 28, 2023
London

Key R&D assets will include:
Kisqali®, Pluvicto®, Scemblix®, iptacopan, remibrutinib

Additionally, a short update on strategy

Appendix

NOVARTIS | Reimagining Medicine

INNOVATION

2023 expected key events

		H1 2023	H2 2023	Status update – as of end Q3
Regulatory decisions	**Cosentyx® HS**	EU	US	EU approval (Q2)
	Cosentyx® 2ml AI	US		US approval (Q2)
	Cosentyx® IV		US	US approval (Q3)
	Leqvio® Hypercholesterolemia		JP, China	Japan and China approval in Q3
Submissions	**Iptacopan PNH (US/EU/JP)**	US/EU	JP	Filed in US, EU (Q2), JP (Q3)
	Kisqali® HR+/HER2- BC (adj)		US	Filed in EU in Q3, US submission planned in Q4
	Pluvicto® mCRPC, pre-taxane (US)		US	US submission expected in 2024
Readouts	**Kisqali® HR+/HER2- BC (adj)**		NATALEE Ph3 FIR	Primary endpoint met at interim analysis; 500 iDFS event milestone reached; data consistent with interim analysis (March 2023[1])
	Iptacopan IgAN		APPLAUSE-IgAN Ph3	Met pre-specified interim analysis primary endpoint in Q3
	Iptacopan C3G		APPEAR-C3G Ph3	
	Lutathera® GEP-NETs		NETTER-2	Met primary endpoint in Q3
Ph3 starts	**Iptacopan in IC-MPGN**		Ph3	APPARENT trial (Q2)
	Leqvio® CVRR primary prevention	Ph3		VICTORION-1P (Q1)
	Ianalumab in immune thrombocytopenia	Ph3		1L (VAYHIT1) and 2L (VAYHIT2) FPFV (H1)
	Ianalumab in systemic lupus erythematosus	Ph3		SIRIUS-SLE 1 and 2 (Q1)

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. Interim analysis in March 2023, data presented at ASCO 2023.

NOVARTIS | Reimagining Medicine

INNOVATION

Our pipeline projects at a glance

	Phase 1/2	Phase 3	Registration	Total
Oncology	28	11	2	41
Solid tumors	16	4	1	21
Hematology	12	7	1	20
Immunology	19	11	2	32
Neuroscience	5	5	0	10
Cardiovascular	5	10	0	15
Others (thereof IB&GH)	13 (9)	2 (1)	0	15
	70	39	4	113

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

NOVARTIS | Reimagining Medicine

INNOVATION

Novartis pipeline in Phase 1

16 lead indications

Lead indication

Oncology

Code	Name	Mechanism	Indication(s)
Solid tumors			
AAA603	^{177}Lu-NeoB	Radioligand therapy target GRPR	Multiple solid tumors
			Breast cancer
AAA614	AAA614	Radioligand therapy target FAP	Solid tumors
AAA817	^{225}Ac-PSMA-617	Radioligand therapy target PSMA	Metastatic castration-resistant prostate cancer
DFF332	DFF332	HIF2A inhibitor	Renal cell carcinoma
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			
DFV890	DFV890	NLRP3 inhibitor	Low risk myelodysplastic syndrome
MBG453	sabatolimab	TIM3 antagonist	Low risk myelodysplastic syndrome
PIT565	PIT565	-	B-cell malignancies
YTB323	rapcabtagene autoleucel	CD19 CAR-T	Adult ALL

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

Cardiovascular

Code	Name	Mechanism	Indication(s)
XXB750	XXB750	NPR1 agonist	Heart failure

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 | Reimagining Medicine

INNOVATION

Novartis pipeline in Phase 2

21 lead indications

Lead indication

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
INC424	Jakavi®	JAK1/2 inhibitor	Acute GVHD, pediatrics
			Chronic GVHD, pediatrics
MBG453	sabatolimab	TIM3 antagonist	Unfit acute myeloid leukemia
			Acute myeloid leukemia, maintenance
PHE885	durcabtagene autoleucel	BCMA cell therapy	4L multiple myeloma
PKC412	Rydapt®	Multi-targeted kinase inhibitor	Acute myeloid leukemia, pediatrics
YTB323	rapcabtagene autoleucel	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

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

Immunology

Code	Name	Mechanism	Indication(s)
CFZ533	iscalimab	CD40 inhibitor	Sjögren's
			Hidradenitis suppurativa
DFV890	DFV890	NLRP3 inhibitor	Knee osteoarthritis
			Familial cold auto-inflammatory syndrome
LNA043	LNA043	ANGPTL3 agonist	Knee osteoarthritis
			Osteoarthritis (combos)
LOU064	remibrutinib	BTK inhibitor	Food allergy
			Hidradenitis suppurativa
			Sjögren's
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	Autoimmune hepatitis
YTB323	rapcabtagene autoleucel	CD19 CAR-T	srSLE/LN

Others

Code	Name	Mechanism	Indication(s)
IB&GH			
KAE609	cipargamin	PfATP4 inhibitor	Malaria, severe
			Malaria, uncomplicated
KLU156	Ganaplacide + lumefantrine	Non-artemisinin plasmodium falciparum inhibitor	Malaria, uncomplicated
LXE408	LXE408	Proteasome inhibitor	Visceral leishmaniasis
QMF149	Atectura®	LABA + ICS	Asthma, pediatrics
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 | Reimagining Medicine

INNOVATION

Novartis pipeline in Phase 3

8 lead indications

Lead indication

Oncology

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)
AAA601[1]	Lutathera®	Radioligand therapy target SSTR	Gastroenteropancreatic neuroendocrine tumors, 1st line in G2/3 tumors (GEP-NET 1L G3)
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
MBG453	sabatolimab	TIM3 antagonist	Myelodysplastic syndrome
VAY736	ianalumab	BAFF-R inhibitor	1L Immune Thrombocytopenia
			2L Immune Thrombocytopenia
			warm Autoimmune Hemolytic Anemia

Neuroscience

Code	Name	Mechanism	Indication(s)
AMG334	Aimovig®	CGRPR antagonist	Migraine, pediatrics
BAF312	Mayzent®	S1P1,5 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

Cardiovascular

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))

Immunology

Code	Name	Mechanism	Indication(s)
AIN457	Cosentyx®	IL17A inhibitor	Giant cell arteritis
			Polymyalgia rheumatica
			Rotator cuff tendinopathy
IGE025	Xolair®	IgE inhibitor	Food allergy
LOU064	remibrutinib	BTK inhibitor	Chronic spontaneous urticaria
			Chronic spontaneous urticaria, pediatrics
			CINDU
QGE031	ligelizumab	IgE inhibitor	Food allergy
VAY736	ianalumab	BAFF-R inhibitor	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)
Others			
RTH258	Beovu®	VEGF Inhibitor	Diabetic retinopathy

1. ^{177}Lu-dotatate in US.

NOVARTIS | Reimagining Medicine

INNOVATION

Novartis pipeline in registration

Oncology

Code	Name	Mechanism	Indication(s)
Solid tumors			
LEE011	Kisqali®	CDK4/6 Inhibitor	HR+/HER2- BC (adj)
Hematology			
LNP023	iptacopan	CFB inhibitor	Paroxysmal nocturnal hemoglobinuria

Immunology

Code	Name	Mechanism	Indication(s)
AIN457	Cosentyx®	IL17A inhibitor	Hidradenitis suppurativa[1]
IGE025	Xolair®	IgE inhibitor	Auto-injector

1 lead indications

Lead indication

1. Approved in EU.

NOVARTIS | Reimagining Medicine

INNOVATION

Novartis submission schedule

New Molecular Entities: Lead and supplementary indications

Cardiovascular | Immunology | Neuroscience | Oncology | Non-core TA project

	2023	2024	2025	≥2026
Lead	**iptacopan** LNP023 PNH	**atrasentan** EXV811 IgAN	**pelacarsen** TQJ230 CVRR-Lp(a)	**^{177}Lu-NeoB** AAA603 Multiple Solid Tumors
		opnurasib JDQ443 2/3L NSCLC (mono)		**ianalumab** VAY736 2L Immune Thrombocytopenia
		remibrutinib LOU064 CSU		**iscalimab** CFZ533 Sjögren's syndrome
		sabatolimab MBG453 HR-MDS		**ligelizumab** QGE031 Food allergy
				LNA043 Knee osteoarthritis
				rapcabtagene autoleucel YTB323 High-risk large B-cell lymphoma
				TNO155 Solid tumors
				XXB750 Hypertension
				zigakibart FUB523 IgAN
				~~**cipargamin**~~ ~~KAE609~~ ~~Malaria severe~~
				~~**ganaplacide/lumefantrine**~~ ~~KLU156~~ ~~Malaria uncomplicated~~
				~~**LXE408**~~ ~~Visceral leishmaniasis~~
Supplementary		**iptacopan** LNP023 C3G		**ianalumab** VAY736 1L Immune Thrombocytopenia
		iptacopan LNP023 IgAN		**ianalumab** VAY736 wAIHA
		Pluvicto® AAA617 mCRPC, Pre-taxane		**ianalumab** VAY736 AIH
		Pluvicto® AAA617 mHSPC		**ianalumab** VAY736 Sjögren's syndrome
				~~**cipargamin**~~ ~~KAE609~~ ~~Malaria uncomplicated~~
				ianalumab VAY736 Lupus Nephritis
				ianalumab VAY736 SLE
				iptacopan LNP023 aHUS
				iptacopan LNP023 IC-MPGN
				opnurasib JDQ443 NSCLC (combo)
				rapcabtagene autoleucel YTB323 Lupus Nephritis
				remibrutinib LOU064 Multiple sclerosis
				remibrutinib LOU064 Sjögren's syndrome
				remibrutinib LOU064 CINDU
				sabatolimab MBG453 Unfit AML

NOVARTIS | Reimagining Medicine

INNOVATION

Novartis submission schedule

Supplementary indications for existing brands

Cardiovascular | Immunology | Neuroscience | Oncology | Non-core TA project

Existing brands

2023	2024	2025	≥2026			
Kisqali® ribociclib, LEE011 HR+/HER2- BC (adj)	**Jakavi®** ruxolitinib, INC424 Pediatrics Acute GVHD	**Cosentyx®** secukinumab, AIN457 GCA	**Aimovig®** erenumab, AMG334 Pediatric Migraine	**Kesimpta® 2** ofatumumab Multiple sclerosis, pediatrics	**Leqvio®** KJX839 Primary prevention	**Rydapt®** midostaurin, PKC412 Acute myeloid leukemia, pediatrics
Xolair® omalizumab, IGE025 Food allergy	**Jakavi®** ruxolitinib, INC424 Pediatrics Chronic GVHD	**Leqvio®** KJX839 Ped Hyperlipidemia	**Cosentyx®** secukinumab, AIN457 Tendinopathy	**Leqvio®** KJX839 CVRR-LDLC	**Mayzent® 2** siponimod, BAF312 Multiple sclerosis, pediatrics	**Scemblix®** ABL001 CML, 2L, pediatrics
	Lutathera® ^{177}Lu-oxodotreotide[1] GEP-NET 1L G3	**Zolgensma®** AVXS-101 OAV101 SMA IT	**Cosentyx®** secukinumab, AIN457 Polymyalgia rheumatica			
	Scemblix® ABL001 CML 1L					
	Adakveo SEG101 Sickle cell disease, pediatrics	**Beovu®** brolucizumab, RTH258 Diabetic retinopathy	**Atectura®** indacaterol + mometasone, QMF149 Asthma, pediatrics			
	Coartem® artemether + lumefantrine, COA566 Malaria uncompl., formula for <5kg	**Promacta®** eltrombopag, ETB115 Radiation sickness syndrome				

1. ^{177}Lu-dotatate in US. 2. Kesimpta and Mayzent: Pediatric trial in multiple sclerosis run in conjunction (NEOS).

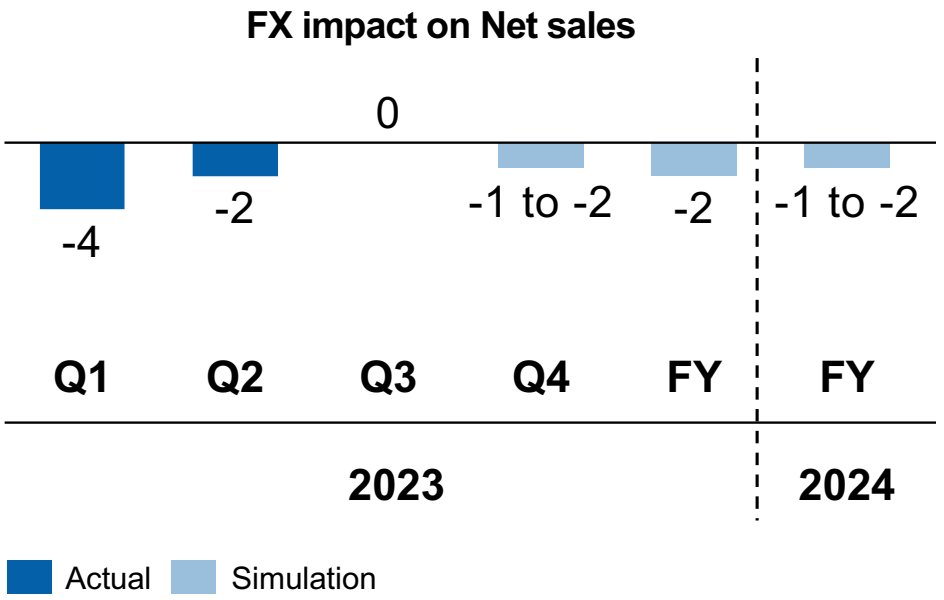
NOVARTIS | Reimagining Medicine

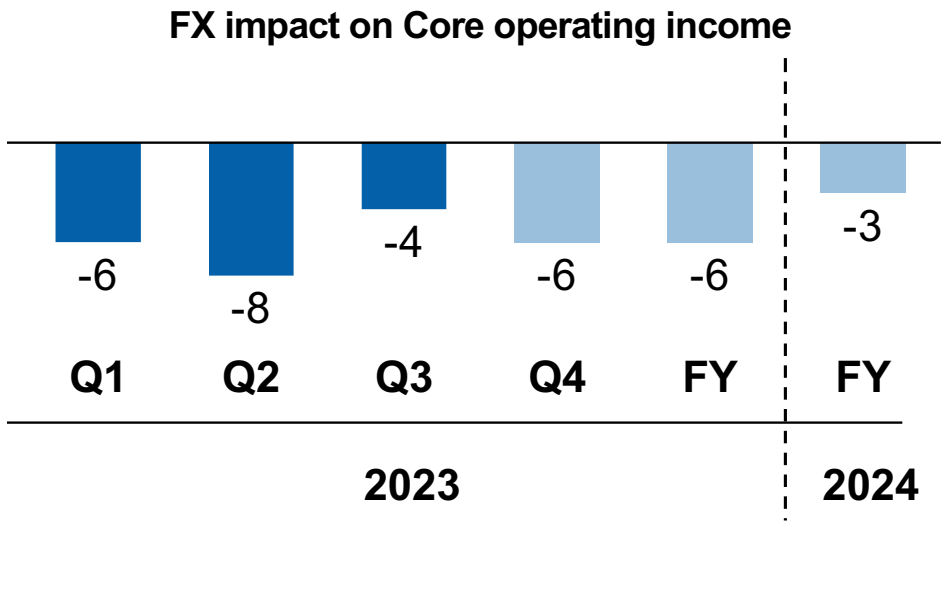
FINANCIAL PROFILE

Expected currency impact for full year 2023 and 2024

Currency impact vs. PY

%pts, assuming late-October exchange rates prevail in 2023 and 2024





NOVARTIS | Reimagining Medicine

FINANCIAL PROFILE

FY 2023 guidance on other financial KPIs

Barring unforeseen events; (in cc)

Continuing operations | Full year guidance

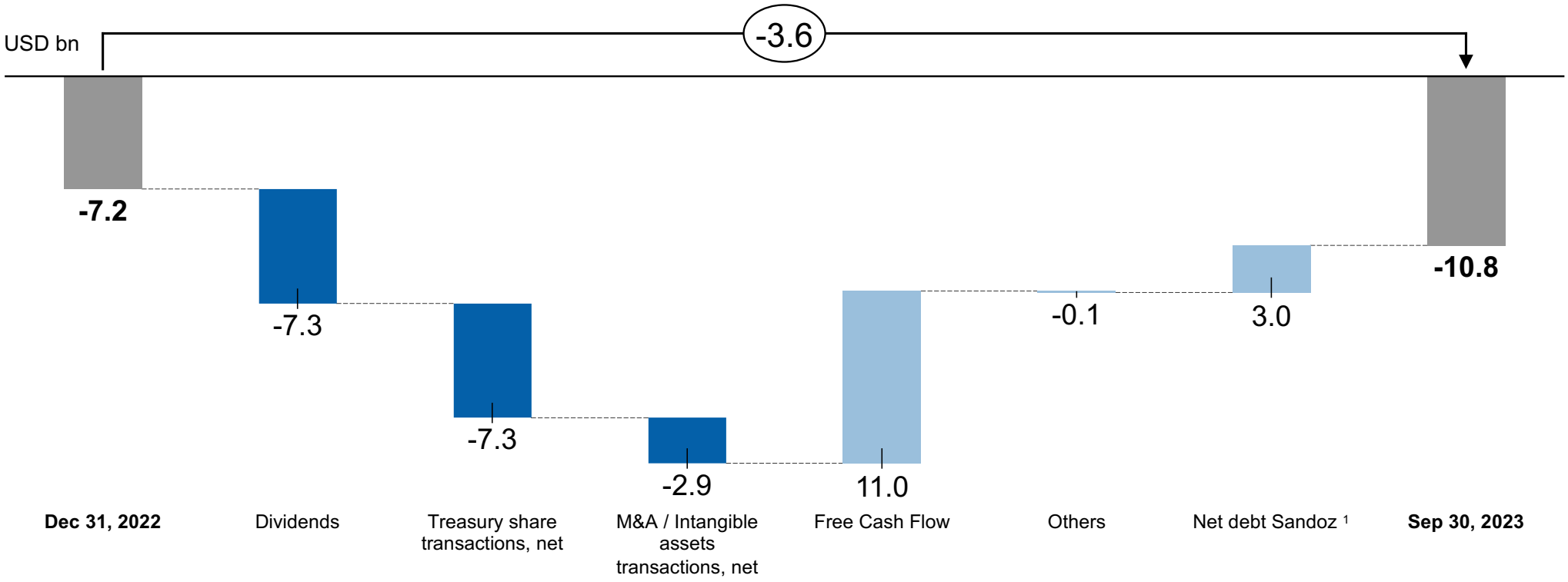
Core Net Financial Result	Expenses expected to be around 0.5bn
Core Tax Rate	Expected to be in the 15-16% range ▪ Structurally lower tax rate vs. Novartis incl. Sandoz due to different geographic mix

Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report.

NOVARTIS | Reimagining Medicine

FINANCIAL PROFILE

Net debt increased by USD 3.6bn mainly due to dividends and share buybacks, partially offset by FCF



1. Reflects USD 0.6bn cash and USD 3.7bn of financial debts of Sandoz as of Sep 30, 2023. In addition, on Oct 2, 2023, through a series of intercompany transactions in connection with the distribution (spin-off) of the Sandoz business to Novartis AG shareholders, USD 38m was paid in cash from a Novartis affiliate to the Sandoz business. Including this transaction, Sandoz cash on Oct 2, 2023, amounted to USD 0.7bn.

NOVARTIS | Reimagining Medicine

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

Cardiovascular

NOVARTIS | Reimagining Medicine

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)] *To demonstrate the superiority of iptacopan compared to placebo in reducing proteinuria at 6 months.* Log-transformed ratio to baseline in UPCR at the 12-month visit (both study treatment arms) [Time Frame: 12 months] *To evaluate the effect of iptacopan on proteinuria at 12 months.* Log-transformed ratio to 6-month visit in UPCR at the 12-month visit in the placebo arm. [Time Frame: 12 months] *To evaluate the effect of iptacopan on proteinuria at 12 months.*
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	TBD

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

Leqvio® - siRNA (regulation of LDL-C)

NCT03705234 ORION-4 (CKJX839B12301)

Indication	Hypercholesterolemia inc. Heterozygous Familial Hypercholesterolaemia (HeFH)
Phase	Phase 3
Patients	15000
Primary Outcome Measures	A composite of major adverse cardiovascular events, defined as: Coronary heart disease (CHD) death; Myocardial infarction; Fatal or non-fatal ischaemic stroke; or Urgent coronary revascularization procedure
Arms Intervention	Arm 1: every 6 months treatment Inclisiran sodium 300mg (given by subcutaneous injection on the day of randomization, at 3 months and then every 6-months) for a planned median duration of about 5 years Arm 2: matching placebo (given bysubcutaneous injection on the day of randomization, at 3 months and then every 6 months) for a planned median duration of about 5 years.
Target Patients	Patient population with mean baseline LDL-C ≥ 100mg/dL
Readout Milestone(s)	2026
Publication	TBD

Leqvio® - siRNA (regulation of LDL-C)

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

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	16500
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

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

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

NCT04023552 Lp(a)HORIZON (CTQJ230A12301)

Indication	Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein(a)
Phase	Phase 3
Patients	8323
Primary Outcome Measures	Time to the first occurrence of MACE (cardiovascular death, non-fatal MI, non-fatal stroke and urgent coronary re-vascularization)
Arms Intervention	TQJ230 80 mg injected monthly subcutaneously or matched placebo
Target Patients	Patients with a history of Myocardial infarction or Ischemic Stroke, or a clinically significant symptomatic Peripheral Artery Disease, and Lp(a) ≥ 70 mg/dL
Readout Milestone(s)	2025
Publication	TBD

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

Immunology

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

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

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: Experiemental - ianalumab s.c. q12w in addition to SoC Arm 3: Placebo comparator - Placebo s.c. q4w in addition to SoC
Target Patients	Patients with active Lupus Nephritis
Readout Milestone(s)	Primary 2027
Publication	TBD

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

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

ligelizumab - IgE Inhibitor

NCT04984876 (CQGE031G12301)

Indication	Food allergy
Phase	Phase 3
Patients	211
Primary Outcome Measures	1. Proportion of participants who can tolerate a single dose of ≥ 600 mg (1044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12
Arms Intervention	Arm 1: ligelizumab 240 mg subcutaneous injection for 52 weeks Arm 2: ligelizumab 120 mg subcutaneous injection for 52 weeks Arm 3: Placebo subcutaneous injection for first 8 weeks and ligelizumab 120 mg subcutaneous injection for 44 weeks Arm 4: Placebo 16 weeks and ligelizumab 120 mg/240 mg subcutaneous injection for 36 weeks Arm 5: Placebo subcutaneous injection for first 8 weeks and ligelizumab 240 mg subcutaneous injection for 44 weeks
Target Patients	Participants with a medically confirmed diagnosis of IgE-mediated peanut allergy
Readout Milestone(s)	2023
Publication	TBD

NOVARTIS | Reimagining Medicine

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
Publication	TBD

NOVARTIS | Reimagining Medicine

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

remibrutinib - BTK inhibitor

NCT05030311 REMIX-1 (CLOU064A2301)

Indication	Chronic inducible urticaria
Phase	Phase 3
Patients	348
Primary Outcome Measures	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	All arms oral, twice daily: Arm 1 Experimental Remibrutinib, symptomatic dermographism group Arm 2 Placebo symptomatic dermographism group Arm 3 Experimental Remibrutinib, cold urticaria group Arm 4 Placebo cold urticaria group Arm 5 Experimental Remibrutinib, cholinergic urticaria group Arm 6 Placebo cholinergic urticaria group
Target Patients	Adults suffering from CINDU inadequately controlled by H1-antihistamines
Readout Milestone(s)	2026
Publication	TBD

NOVARTIS | Reimagining Medicine

Neuroscience

NOVARTIS | Reimagining Medicine

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

NOVARTIS | Reimagining Medicine

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

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 (HFMSE) total score at the end of follow-up period 1 in treated patients compared to sham controls in the ≥ 2 to < 18 years age group
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

Oncology

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
Publication	TBD

ianalumab - 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 Ianalumab low dose (intravenously) Arm 2: experimental Ianalumab high dose (intravenously) Arm 3: placebo Comparatorn (intravenously)
Target Patients	Previously treated patients with warm Autoimmune Hemolytic Anemia
Readout Milestone(s)	2026
Publication	TBD

NOVARTIS | Reimagining Medicine

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)
Readout Milestone(s)	2025
Publication	TBD

Jakavi® - JAK1/2 inhibitor

NCT03491215 REACH4 (CINC424F12201)

Indication	Acute graft versus host disease
Phase	Phase 2
Patients	45
Primary Outcome Measures	Measurement of PK parameters Overall Response Rate (ORR)
Arms Intervention	Ruxolitinib
Target Patients	Pediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation
Readout Milestone(s)	2023
Publication	TBD

Jakavi® - JAK1/2 inhibitor

NCT03774082 REACH5 (CINC424G12201)

Indication	Chronic graft versus host disease
Phase	Phase 2
Patients	45
Primary Outcome Measures	Overall Response Rate (ORR)
Arms Intervention	Ruxolitinib 5mg tablets / pediatric formulation
Target Patients	Pediatric subjects with moderate and severe chronic Graft vs. Host disease after allogeneic stem cell transplantation
Readout Milestone(s)	2023
Publication	TBD

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)	2024
Publication	NA

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: 2024
Publication	TBD

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

sabatolimab - TIM3 antagonist

NCT04150029 STIMULUS-AML1 (CMBG453C12201)

Indication	Unfit acute myeloid leukaemia
Phase	Phase 2
Patients	86
Primary Outcome Measures	Incidence of dose limiting toxicities (Safety run-in patients only) Percentage of subjects achieving complete remission (CR)
Arms Intervention	Single arm safety and efficacy study of sabatolimab in combination with azacitidine and venetoclax
Target Patients	Newly diagnosed adult AML patients who are not suitable for treatment with intensive chemotherapy
Readout Milestone(s)	2023
Publication	TBD

sabatolimab - TIM3 antagonist

NCT04266301 STIMULUS-MDS2 (CMBG453B12301)

Indication	Myelodysplastic syndrome
Phase	Phase 3
Patients	500
Primary Outcome Measures	Overall survival
Arms Intervention	Sabatolimab 800 mg + azacitidine 75 mg/m2 Sabatolimab 800 mg + azacitidine 75 mg/m2 + placebo
Target Patients	Patients with intermediate, high or very high risk Myelodysplastic Syndrome (MDS) as Per IPSS-R, or Chronic Myelomonocytic Leukemia-2 (CMML-2)
Readout Milestone(s)	2024
Publication	TBD

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
Publication	TBD

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)	2024
Publication	TBD

Other

NOVARTIS | Reimagining Medicine

Ophthalmology

NOVARTIS | Reimagining Medicine

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

NOVARTIS | Reimagining Medicine

Global Health

NOVARTIS | Reimagining Medicine

Adakveo® - P-selectin inhibitor

NCT03474965 SOLACE-Kids (CSEG101B2201)

Indication	Sickle cell disease, pediatrics
Phase	Phase 2
Patients	100
Primary Outcome Measures	PK/PD and safety of SEG101 at 5 mg/kg
Arms Intervention	SEG101 (crizanlizumab) at a dose of 5 mg/kg by IV infusion ± Hydroxyurea/Hydroxycarbamide
Target Patients	Pediatric SCD patients with VOC
Readout Milestone(s)	H2-2021 (pediatric patients ≥12 year old) 2024 (pediatric patients <12 year old)
Publication	1. Matthew M. Heeney, David C. Rees, Mariane de Montalembert, Isaac Odame, R. Clark Brown, Yasser Wali, Thu Thuy Nguyen, Du Lam, Raquel Merino Herranz, Julie Kanter; Study Design and Initial Baseline Characteristics in Solace-Kids: Crizanlizumab in Pediatric Patients with Sickle Cell Disease. Blood 2020; 136 (Supplement 1): 22–24. doi: https://doi.org/10.1182/blood-2020-137081 2. Matthew M. Heeney, David C. Rees, Mariane De Montalembert, Isaac Odame, R. Clark Clark Brown, Yasser Wali, Thu Thuy Nguyen, Du Lam, Nadege Pfender, Julie Kanter; Initial Safety and Efficacy Results from the Phase II, Multicenter, Open-Label Solace-Kids Trial of Crizanlizumab in Adolescents with Sickle Cell Disease (SCD). Blood 2021; 138 (Supplement 1): 12. doi: https://doi.org/10.1182/blood-2021-144730

NOVARTIS | Reimagining Medicine

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

NOVARTIS | Reimagining Medicine

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)	2024
Publication	TBD

ganaplacide - Non-artemisinin plasmodium falciparum inhibitor

NCT04546633 KALUMI (CKAF156A2203)

Indication	Malaria, uncomplicated
Phase	Phase 2
Patients	292
Primary Outcome Measures	PCR-corrected and uncorrected Adequate Clinical and Parasitological Response (ACPR)
Arms Intervention	KAF156 and LUM-SDF QD (once daily) for 2 days in fasted condition KAF156 and LUM-SDF QD (once daily) for 2 days in fed condition
Target Patients	Malaria patients 6 months to < 18 years old
Readout Milestone(s)	2024
Publication	TBD

Abbreviations

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

NOVARTIS | Reimagining Medicine

References

Entresto®

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.
5 For forecasting purposes, we assume no generic entry before 2025.

Kesimpta®

1 Sept. 2023 numbers are estimated using weekly data through September 22, 2023, IQVIA NPA (Kesimpta®) and IQVIA NPA adjusted by NSP (all others). B-cell therapies as portion of MS market in NBRx.
2 Data on file.
3 The initial dosing period consists of 20 mg subcutaneous doses at Weeks 0, 1 and 2, thereafter once a month. Patient must take pen out of the refrigerator 15-30 minutes before self-administering.
4 Efficacy outcomes as measured by disability progression and brain volume change.
5 Cohen et al, Poster presented at American Academy of Neurology, Boston, 22-27 April 23.
6 Cohen et al, oral presentation at American Academy of Neurology, Boston, 22-27 April 23.