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Q1 2024 Results

Investor presentation
April 23, 2024

NOVARTIS | Reimagining Medicine

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Company overview

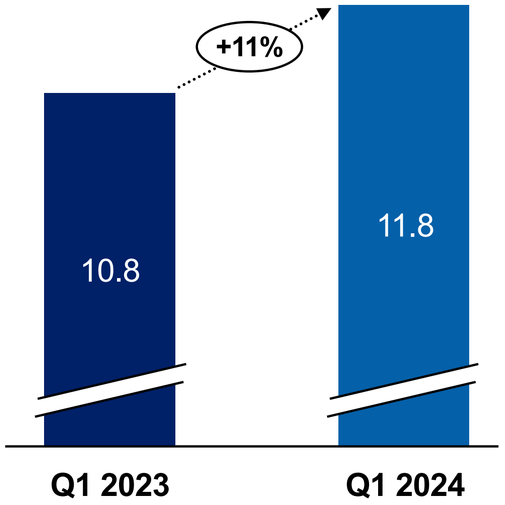
Vas Narasimhan, M.D.
Chief Executive Officer

NOVARTIS | Reimagining Medicine

Novartis delivered robust double-digit sales growth and core margin expansion in Q1, supporting a guidance upgrade for FY

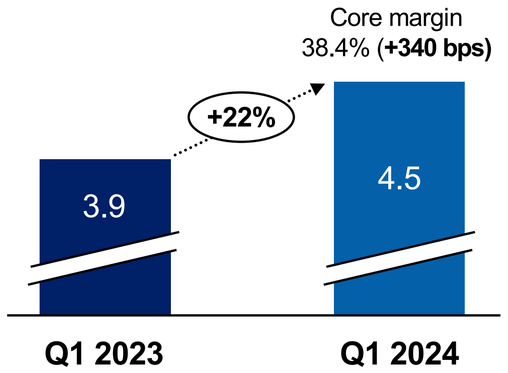
Sales

USD bn, % cc[1]



Core[1] operating income

USD bn, % cc[1]



Innovation milestones

Fabhalta® positive CHMP opinion for PNH

Iptacopan FDA submission for IgAN

Scemblix® 1L CML Ph3 readout

Pluvicto® Ph3 PSMAfore updated OS results

Remibrutinib Ph3 52-week data in CSU

1. Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Q1 growth was broad-based, with strong contributions from Entresto®, Kesimpta®, Cosentyx® and Kisqali®

Q1 sales

	Sales USD million	Growth vs. PY USD million	Growth vs. PY cc
Entresto® sacubitril/valsartan	1,879	480	36%
Kesimpta® (ofatumumab)	637	253	66%
Cosentyx® (secukinumab)	1,326	250	25%
KISQALI® ribociclib	627	212	54%
PLUVICTO®	310	99	47%
LEQVIO®	151	87	139%
SCEMBLIX® (asciminib)	136	60	83%
JAKAVI® ruxolitinib	478	64	18%
Xolair® Omalizumab	399	45	15%
ILARIS® (canakinumab)	356	28	14%
LUTATHERA®	169	20	14%

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

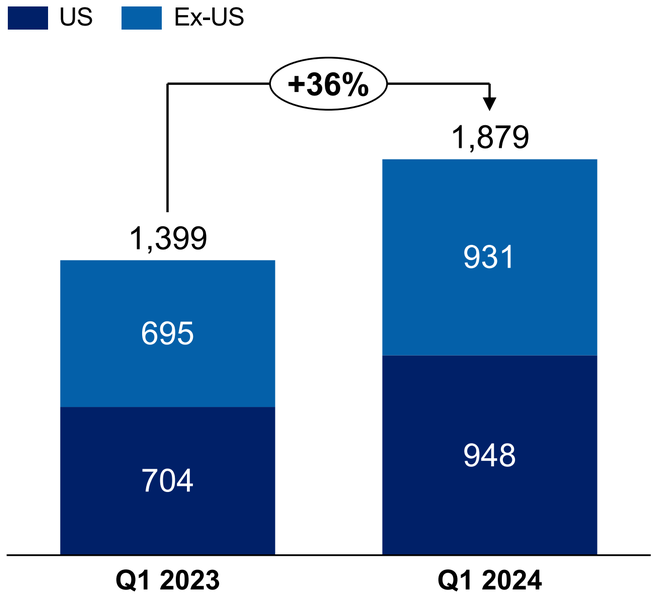
Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Entresto® continued strong double-digit growth, +36% in Q1

Entresto®

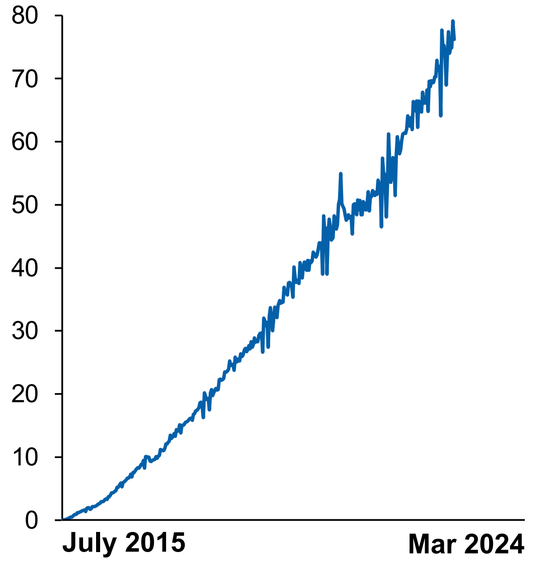
Sales evolution

USD m, % cc



US weekly TRx[1]

Total prescriptions (000)



Maintains strong momentum

- US: +35% cc
- Ex-US: +38% cc

Confidence in future growth

- Strong guideline position[2] (US/EU); 2024 ACC ECDP update strengthens ARNI position as 1L RASi for HFrEF
- Further penetration in HF globally and HTN in China/Japan[3]
- US: For forecasting purposes, we assume Entresto® LoE in mid-2025
- EU: RDP to Nov 2026[4]

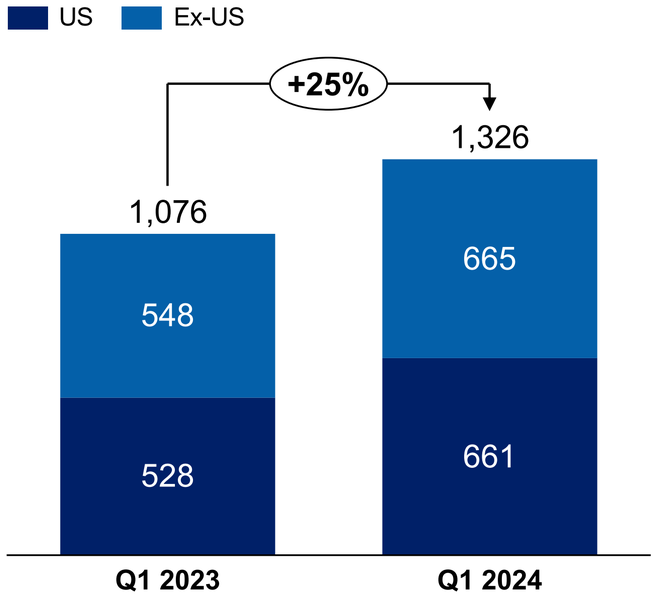
See last page for references (footnotes 1-4). ACC ECDP – American College of Cardiology Expert Consensus Decision Pathway. ARNI – angiotensin receptor neprilysin inhibitor. HFrEF – heart failure ejection fraction. TRx – total prescriptions. HTN – hypertension. LoE – loss of exclusivity. RDP – Regulatory data protection. Constant currencies (cc) is a non-IFRS measure. Explanation of non-IFRS measures can be found on page 34 of Interim Financial Report.

Cosentyx® grew +25% in Q1, fueled by demand in core indications and strong launches

Cosentyx®

Sales evolution

USD m, % cc



Strong growth across geographies

- US: +25% cc
- Ex-US: +24% cc

Highly competitive in core indications (PsO, PsA, AS, nr-axSpa)

- No.1 IL-17 in US dynamic market
- Leading originator biologic in EU and China

New launches accelerating growth

- HS: Dynamic market leadership (>50% NBRx) in US and Germany
- IV: Solid adoption in US ahead of permanent J-code (confirmed for July)

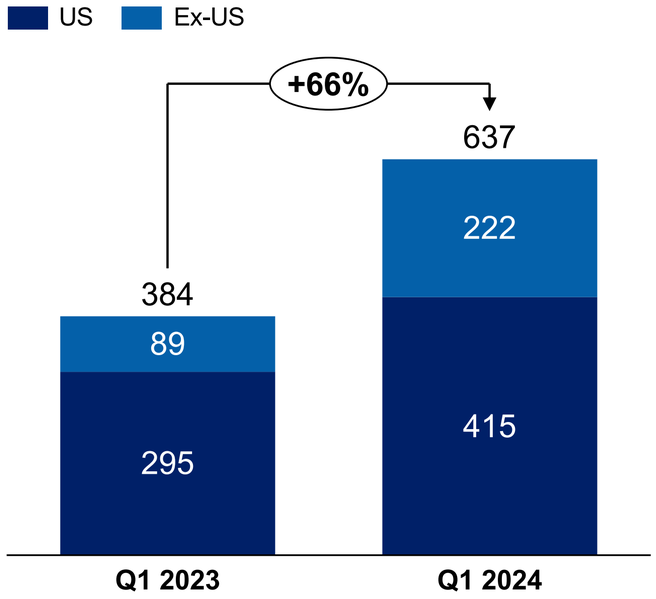
PsO – psoriasis. PsA – psoriatic arthritis. AS – ankylosing spondylitis. HS – Hidradenitis suppurativa. IL – interleukin. IV – intravenous. NBRx – New to brand prescriptions. nr-axSpA– non-radiographic axial spondyloarthritis. IV formulation indication: PsA, AS, nr-axSpA. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

Kesimpta® delivered +66% growth, with continued strong momentum in US and increasing penetration ex-US

Kesimpta

Sales evolution

USD m, % cc



Strong growth trajectory across all regions

- >100k patients treated worldwide, majority naïve or first switch[1]
- US (+41% cc): Demand-driven growth, NBRx volume +26% vs. PQ[2]
- Ex-US (+152% cc): NBRx leadership in 7/10 major markets[1]

Compelling product profile

- ALITHIOS 6-year OLE data demonstrates sustained efficacy and consistent safety profile[3,4]
  - 9 of 10 Kesimpta® patients free of disease activity (NEDA-3) at year 6 in both continuous and switch groups[3]
  - Treatment-naïve patients derive substantial benefits across multiple markers of disease activity[4]
- 1 minute a month self-administered dosing at home/anywhere[5]

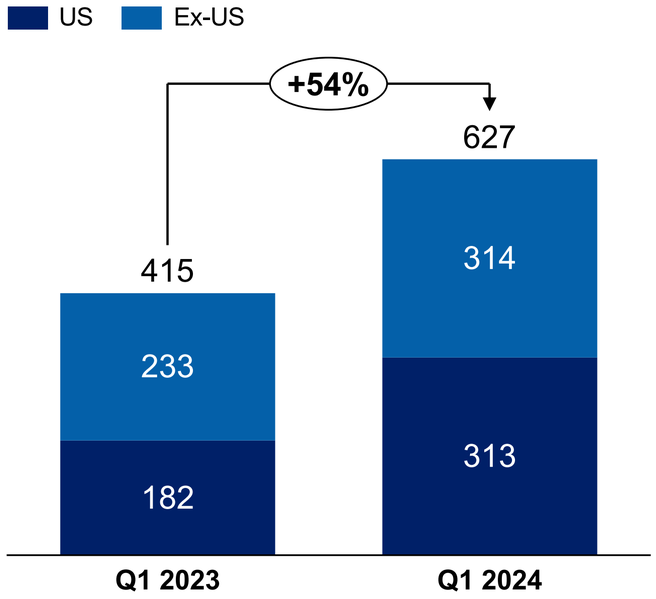
See last page for references (footnotes 1-5). NBRx – new to brand prescription. NEDA – no evidence of disease activity. OLE – open-label extension. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

Kisqali® grew +54% in mBC, with leading share of new patient starts

KISQALI®

Sales evolution

USD m, % cc



US: +72% growth, with increasing recognition of unique profile[1,2,3]

- Leading share in mBC NBRx at 45%[4]
- Steady growth in writers, with increasing depth

Ex-US: +39% growth, with NBRx leadership in mBC

- Fastest-growing CDK4/6 in Europe, and market leader in 1L pre-menopausal
- Successfully entered NRDL in China effective Q1 2024

Regulatory review for eBC ongoing

- Filed in US, EU in H2 2023; currently expect regulatory review to proceed as planned
- Manufacturing adjustments on track to ensure alignment with latest regulatory standards in eBC by end of Q2

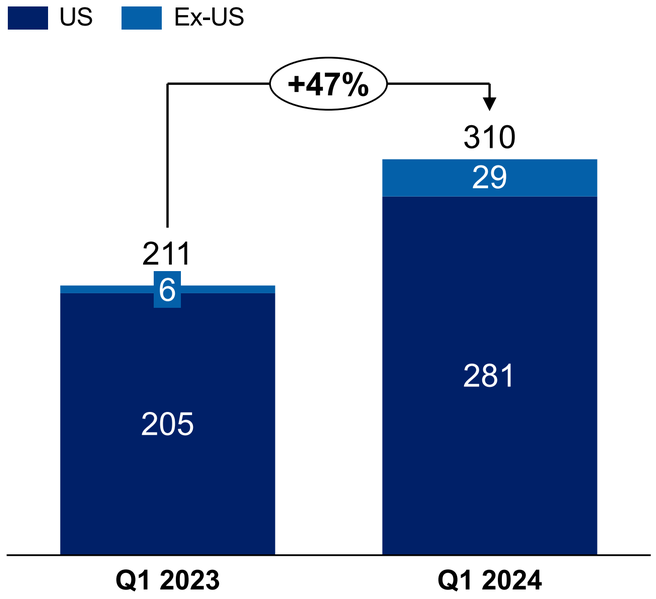
See last page for references (footnotes 1-4). eBC – early breast cancer. mBC – metastatic breast cancer. NBRx – new to brand prescription. NCCN – national comprehensive cancer network. AI – aromatase inhibitor. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

Pluvicto® demonstrated strong growth of +47% in Q1, driven by new patient starts in the US

PLUVICTO®

Sales evolution

USD m, % cc



Q1 performance

- Q1 sales grew +47% cc vs. PY, driven by demand
- 400+ treatment sites in the US
- Robust supply with >99.5% of injections administered on planned day[1]

Building momentum through 2024

- Continued focus on share expansion within established sites and expanding referral network
- Increasing contribution from ex-US

Additional indications

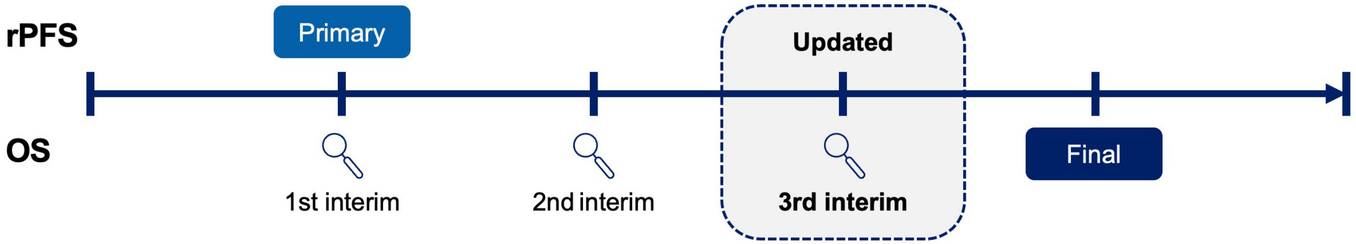
- PSMAfore (pre-taxane) submission-enabling OS readout achieved
- PSMAddition in mHSPC ongoing and PSMA-DC in localized oligometastatic disease started in Q1

mHSPC – metastatic hormone-sensitive prostate cancer. OS – overall survival. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of Interim Financial Report. 1. Apr 2024 YTD.

Pluvicto® PSMAfore submission-enabling OS readout achieved in Q1; on track to file for pre-taxane indication in H2

PLUVICTO®

PSMAfore analysis plan



Primary endpoint: **rPFS**

Key secondary endpoint: **OS**

Other secondary and exploratory endpoints

- rPFS2
- PFS and PFS2
- PSA50
- Time to SSE
- Time to soft tissue progression
- Time to chemotherapy
- HRQoL
- Safety and tolerability
- ORR, DCR, DOR
- Time to PSA progression
- Time to pain progression
- Biomarker associations

Updated OS analysis supports filing in H2

- OS HR < 1.0 in ITT population
- rPFS and other secondary efficacy endpoints consistent with previous results presented in 2023
- With additional 8 months of follow-up, Pluvicto® safety profile remains consistent with previous analyses
- Full results will be presented at an upcoming medical congress

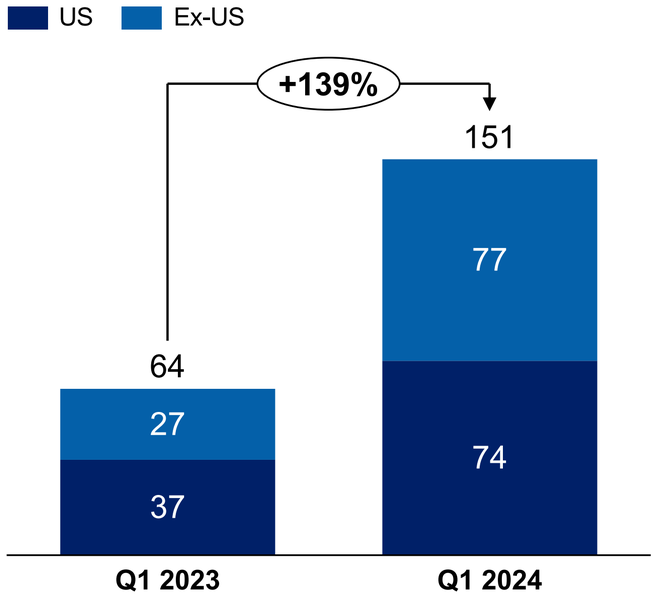
DCR – disease control rate. DOR – duration of response. HR – hazard ratio. HRQoL – heath-related quality-of-life. ITT – Intent to treat. PSA – prostate specific antigen. rPFS – radiographic progression free survival. SSE – symptomatic skeletal event. ORR – objective response rate. OS – overall survival.

Leqvio® adoption continued to expand steadily across the globe

LEQVIO® (inclisiran)

Sales evolution

USD m, % cc



US: Continued growth outpacing advanced lipid-lowering market[1]

- 3,850 facilities have ordered Leqvio® (+11% vs. PQ; +73% vs. PY)
- Increasing breadth and depth in high-potential HCPs and accounts
- ~55% of business from in-office buy and bill, the fastest-growing acquisition channel

Ex-US: Rollout continues

- 29 countries with public reimbursement, 39 with private (commercial) coverage
- Europe (top 3: DE, IT, UK) contributing 50% of International sales
- Strong early uptake in China self-pay market with >200 new patients per day

New data at ACC and simultaneous JACC publication support early initiation with Leqvio®

- V-INITIATE demonstrates more patients on Leqvio® achieved LDL-C goal vs. those on usual care[2]

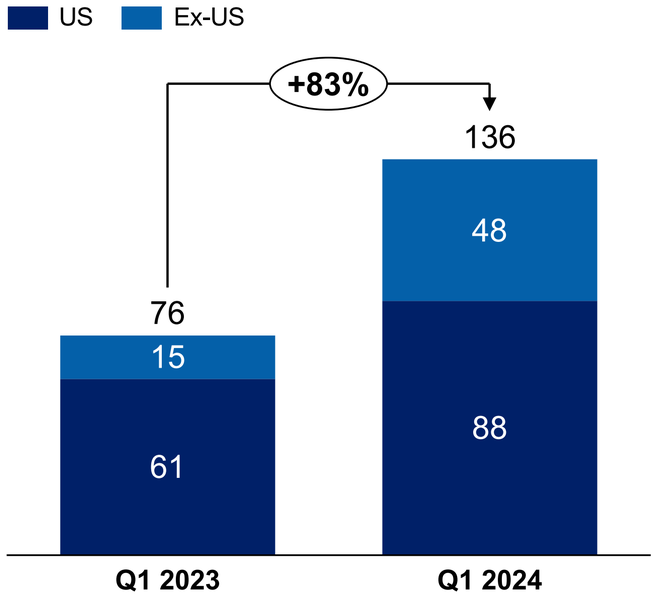
See last page for references (footnotes 1-2). ACC – American College of Cardiology. HCP – healthcare professional. JACC – Journal of the American College of Cardiology. LDL-C – low-density lipoprotein cholesterol. Constant currencies (cc) is a non-IFRS measure - explanation can be found on p34 of Interim Financial Report. Novartis obtained global rights to develop, commercialize Leqvio under license/collaboration agreement with Alnylam Pharmaceuticals.

Scemblix® grew +83% in Q1, driven by continued demand in 3L+ CML; 1L submission on track for H1

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Sales evolution

USD m, % cc



Continued momentum in core indication of 3L+ CML

- US: ~40%[1] NBRx share, with continued expansion of prescriber base
- Ex-US: 32%[2] total market share, driven by Japan, France and Germany
- Continued focus on driving breadth and appropriate switching post 2 TKIs

Positive Ph3 ASC4FIRST study enabling 1L submission in H1

- Both primary endpoints met showing superior MMR rates vs. all SoC TKIs in newly diagnosed Ph+ CML-CP patients
- Favorable safety and tolerability profile with fewer AEs and treatment discontinuations vs. SoC
- Full data to be presented at ASCO 2024

Ph+ CML-CP – Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase. SoC – Standard of care. 1. US: January rolling 3-months US IQVIA CML market sizing report (April 2024). 2 Ex-US: IPSOS & IQVIA Oncology Dynamics, EU5 and JP, MAT December 2023). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

Fabhalta®[1] US PNH launch showing positive early indicators; continue to expect modest ramp

FABHALTA (iptacopan) 200 mg capsules

Positive early launch indicators

- Rapid REMS certification of HCPs
- New writers and patient starts exceeding expectations
- Uptake across naïve and switch patients (from both C5i and C3i)
- HCPs and patients successfully navigating PA and medical exception process

Compelling product profile resonating with US customers

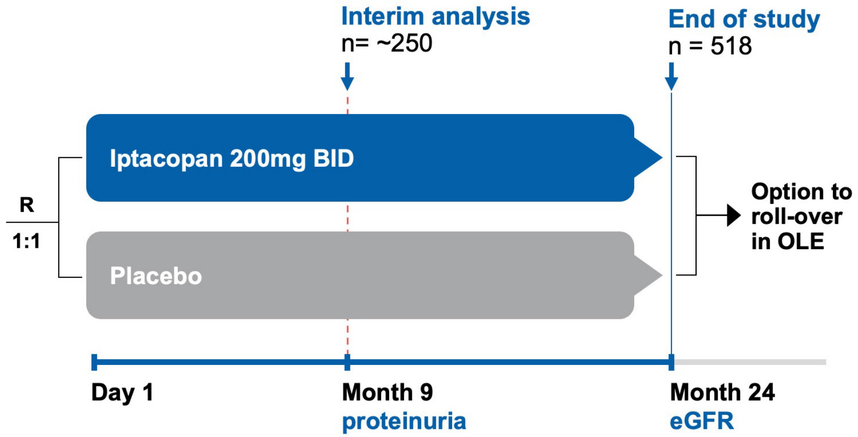
- ✓ Hb improvement vs. C5i for patients with residual anemia
- ✓ Comprehensive hemolysis control (IVH and EVH)
- ✓ Transfusion avoidance data
- ✓ Demonstrated safety profile
- ✓ Only oral monotherapy approved by FDA

Positive CHMP opinion for PNH received

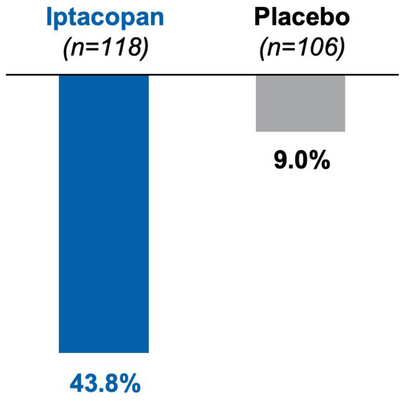
1. Iptacopan is the generic name for unapproved indications. HCP – healthcare professional. IVH – intravascular hemolysis. EVH – extravascular hemolysis. PA – prior authorization. PNH – paroxysmal nocturnal hemoglobinuria. REMS – risk evaluation and mitigation strategies. Hb – Hemoglobin.

Iptacopan Ph3 APPLAUSE-IgAN study demonstrated 38%[1] proteinuria reduction relative to placebo

Study design



Proteinuria reduction in IgAN patients[1]



- Clinically meaningful and statistically significant proteinuria reduction vs. placebo
- Complement activation is a key driver of glomerular inflammation in IgAN
- Favorable safety profile consistent with previously reported data
- ~30% of high-risk patients[2] progress to kidney failure in ~10 years

Next steps Submitted to FDA and received priority review in Q1; study continues to confirmatory endpoint (eGFR) in 2025

BID – twice daily. eGFR – estimated glomerular filtration rate. IgAN – IgA nephropathy. OLE – open label extension. 1. Adjusted relative % reduction at Month 9 (95% CI): 38.3% (26.0, 48.6); *P<0.0001*. Perkovic V, et al. Efficacy & Safety of Iptacopan in IgAN: Interim Results, Ph3 APPLAUSE-IgAN. WCN Apr 15, 2024. 2. IgAN patients with persistent proteinuria levels of ≥1 g/day are at higher risk of disease progression. Reich HN, et al. Remission of Proteinuria Improves Prognosis in IgAN. J Am Soc Nephrol. 2007.

Remibrutinib REMIX studies demonstrated robust efficacy and safety up to 52 weeks in CSU

High unmet need

400,000

CSU patients[1] in US not controlled on or refractory to AHs[2,5]

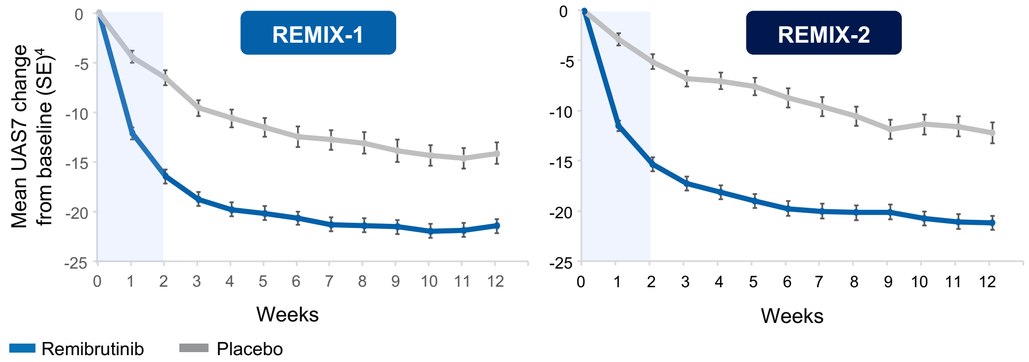
<20%

of patients still symptomatic with AHs advance to biologics[1]

Strong efficacy[3,4] with oral convenience

Significant improvement[6] in symptom control across all measures[7], as early as week 2

Primary endpoint (week 12)



Favorable long-term safety[3,4]

Consistent and favorable safety profile across REMIX studies confirmed at 52 weeks

- Overall rate of AEs comparable to placebo[3]
- Balanced liver function tests across both studies[3]

Next steps 52-week data will be presented at an upcoming medical congress in H1; global submissions in H2 2024

See last page for references (footnotes 1-7). AE – adverse event. AHs – antihistamines. CSU – chronic spontaneous urticaria. UAS – Urticaria Activity Score. HSS – Hives Severity Score. ISS – Itch Severity Score.

Expect to continue our innovation momentum in 2024...

2024 selected key events (expected)

		H1 2024	H2 2024	Q1 status update
Regulatory decisions	**Fabhalta® PNH**		EU, JP	CHMP positive opinion in Q1
	Kisqali® HR+/HER2- adj.BC		US, EU	
Submissions	**Atrasentan IgAN**	US		
	Fabhalta® (iptacopan) C3G		US, EU	US submission shifted to H2
	Fabhalta® (iptacopan) IgAN	US		US submission in Q1, received priority review
	Pluvicto® mCRPC, pre-taxane		US	Submission-enabling OS readout in April
	Remibrutinib CSU		US, EU, JP	Ph3 REMIX-1 and -2 52-week readout in Q1
	Scemblix® CML 1L	US	JP	
	Lutathera® GEP-NET 1L G2/G3	EU		
Readouts	**Scemblix® CML 1L**	Ph3 (ASC4FIRST)		Ph3 ASC4FIRST readout in Q1
	Zolgensma® SMA IT		Ph3 (STEER)	
	XXB750 Hypertension		Ph2	
Ph3 starts	**Pluvicto® oligometastatic PC**	Ph3		Ph3 PSMA-DC started in Q1
	Opnurasib 1L NSCLC (combo)[1]	Ph2/3		

Adj.BC – Adjuvant breast cancer. C3G – complement 3 glomerulopathy. CML – chronic myeloid leukemia. CSU – chronic spontaneous urticaria. GEP-NET – gastroenteropancreatic neuroendocrine tumors. IgAN – immunoglobulin A nephropathy. mCRPC – metastatic castration-resistant prostate cancer. NSCLC – non-small cell lung cancer. PNH – paroxysmal nocturnal hemoglobinuria. SMA – spinal muscular atrophy. 1. This is a seamless Ph2/3 trial.

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

Select key assets submission schedule

Core therapeutic areas

- CRM
- Immunology
- Neuroscience
- Oncology

2024	2025	2026-2028		
atrasentan IgAN[1]	**pelacarsen**[2] CVRR-Lp(a)	**Cosentyx®** Tendinopathy	**ianalumab** Sjögren's syndrome	**Pluvicto®** Oligometastatic PC
iptacopan IgAN[1]	**Pluvicto®** mHSPC	**Cosentyx®** Polymyalgia rheumatica	**ianalumab** Lupus Nephritis	**remibrutinib** CINDU
iptacopan C3G	**Zolgensma®** SMA IT	**ianalumab** 2L ITP	**ianalumab** SLE	**remibrutinib** Multiple sclerosis
remibrutinib CSU	**Cosentyx®** GCA	**ianalumab** 1L ITP	**iptacopan** IC-MPGN	**zigakibart** igAN
Pluvicto® mCRPC, pre-taxane	**Leqvio®** Hyperlipidemia ped	**ianalumab** wAIHA	**Leqvio®** CVRR-LDLC	
Scemblix® CML 1L				

1. US submission for accelerated approval. 2. Novartis obtained global rights to develop, manufacture and commercialize pelacarsen under a license and collaboration agreement with Ionis Pharmaceuticals.

Financial review and 2024 guidance

Harry Kirsch
Chief Financial Officer

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Q1 net sales grew +11% cc with core operating income up +22% cc[1]

Continuing operations[1] USD million	**Q1 2024**	Q1 2023	**Change vs. PY** % USD	% cc
Net sales	11,829	10,798	10	11
Core operating income	4,537	3,906	16	22
as % of net sales	*38.4%*	*36.2%*	*+2.2%pts*	*+3.4%pts*
Operating income	3,373	2,618	29	39
Net income	2,688	2,150	25	37
Core EPS	1.80	1.54	17	23
EPS	1.31	1.02	28	41
Free cash flow	2,038	2,684	-24	

1. As defined on page 26 of the Interim Financial Report, Continuing operations include the retained business activities of Novartis, comprising the innovative medicines business and the continuing Corporate activities and Discontinued operations include operational results from the Sandoz business. Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

Raising 2024 sales and core operating income guidance[1]

Expected, barring unforeseen events; growth vs. PY in cc[1]

Net sales

expected to grow

high-single to low double-digit

(from mid-single-digit)

Core operating income

expected to grow

low double-digit to mid-teens

(from high single-digit)

Key assumptions

- No US Entresto® Gx launch in 2024
- No US Promacta® Gx launch in 2024

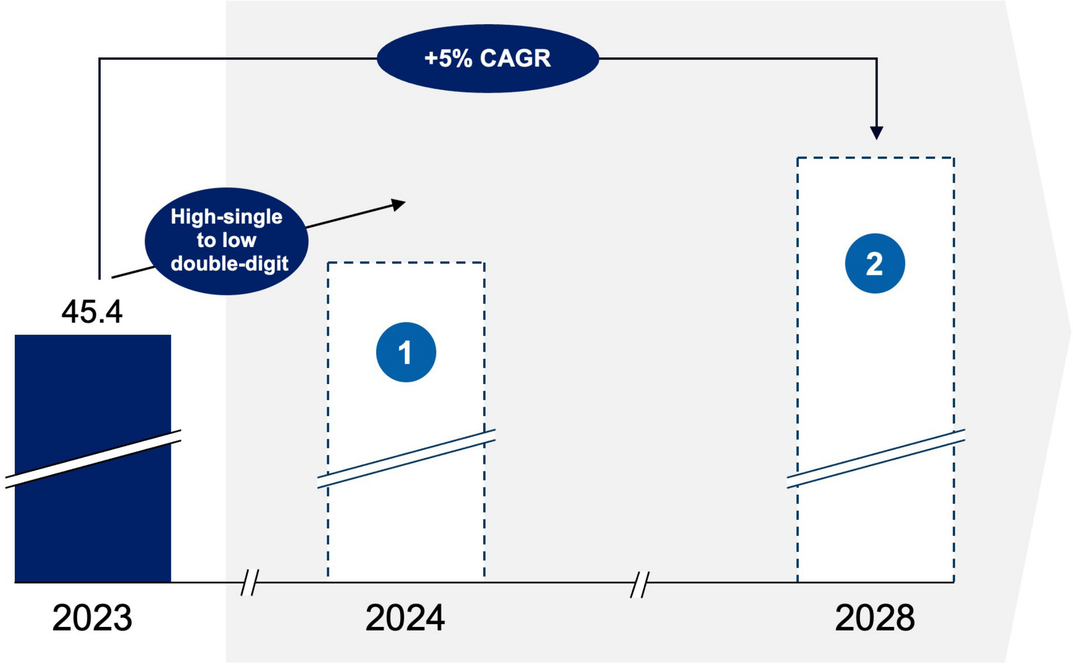
FY guidance on other financial KPIs

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

1. Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

Momentum in our key growth drivers strongly supports our mid-term outlook of +5% sales CAGR 2023-2028

Net sales
Illustrative, USD billion, % CAGR cc



1 2024
High-single to low double-digit

2 2023-2028
+5% CAGR

In-market growth brands grew 41% in Q1

KISQALI®
Kesimpta®
Cosentyx®
SCEMBLIX®
PLUVICTO™
LEQVIO®
Entresto®
zolgensma®

Pipeline assets

FABHALTA® (iptacopan)
remibrutinib
atrasentan
pelacarsen
ianalumab

Continuing our shareholder-friendly capital allocation strategy

Investing in the business

Investments in organic business
Ongoing investment in R&D and CapEx

Value-creating bolt-ons
Proposed acquisition of Morphosys and Arvinas licensing deal in Q1[1]

Substantial cash generation

Returning capital to shareholders

Consistently growing annual dividend[2]
USD 7.6bn dividend paid in March/April 2024[3] not rebased post Sandoz

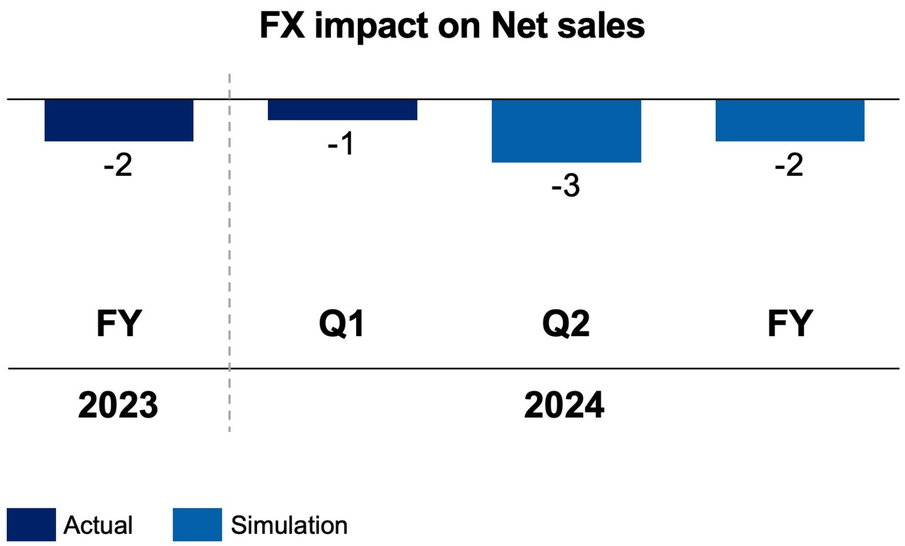
Share buybacks
Up to USD 15bn share buyback continuing, with up to USD 11.7bn still to be executed

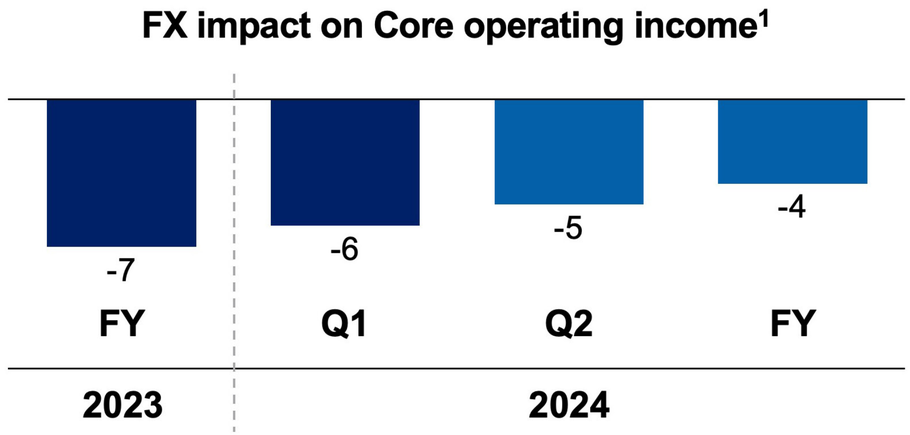
1. Subject to customary closing conditions. 2. In CHF. 3. USD 5.2bn annual net dividend payment in March, which is the gross dividend of USD 7.6bn reduced by the USD 2.4bn Swiss withholding tax that was paid in April 2024, according to its due date.

Expected currency impact for full year 2024

Currency impact vs. PY

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





1. Constant currencies (cc), core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 34 of the Interim Financial Report.

Conclusions

Vas Narasimhan, M.D.
Chief Executive Officer

NOVARTIS | Reimagining Medicine

Strong start to the year with double-digit sales growth and core margin expansion, allowing us to raise guidance for FY 2024

Strong momentum across all key growth brands and geographies

Our pipeline continued to advance, with multiple submissions and submission-enabling readouts

Continued confidence in our mid-term guidance of 5% cc sales CAGR 2023-2028, and 40%+ core operating income margin by 2027

2024 Novartis investor events

ASCO

June 2, 2024
Chicago, US

Focus:

Scemblix ASC4FIRST data and CML 1L opportunity

Renal Pipeline

H2 2024
Virtual

Focus:

Renal portfolio including iptacopan, atrasentan and zigakibart

Meet Novartis Management

November 20-21, 2024
London, UK

Focus:

Dialogue with management

Appendix

NOVARTIS | Reimagining Medicine

Our pipeline projects at a glance

	Phase 1/2	Phase 3	Registration	Total
Oncology	24	12	3	39
Solid tumors	17	6	3	26
Hematology	7	6	0	13
Immunology	15	10	0	25
Neuroscience	4	4	0	8
Cardiovascular, Renal and Metabolic	5	9	1	15
Others (thereof IB&GH)	11 (7)	4 (3)	1	16
	59	39	5	103

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

Novartis pipeline in Phase 1

14 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
			Glioblastoma multiforme
AAA604	AAA604	Radioligand therapy target integrin alpha-v, beta-3/beta-5	Solid tumors
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
QEQ278	QEQ278	NKG2D/-L pathway modulator	Solid tumors
Hematology			
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

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
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)
DLX313[1]	minzasolmin	Alpha-synuclein misfolding inhibitor	Parkinson's disease

Cardiovascular, Renal and Metabolic

Code	Name	Mechanism	Indication(s)
LNP023	Fabhalta®	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
LNA043	LNA043	ANGPTL3 agonist	Osteoarthritis
LOU064	remibrutinib	BTK inhibitor	Food allergy
			Hidradenitis suppurativa
LRX712	LRX712	-	Osteoarthritis
MAS825	MAS825	IL1B, IL18 Inhibitor	NLRC4-GOF indications
MHV370	MHV370	TLR7, TLR8 Antagonist	Sjögren's
NGI226	NGI226	-	Tendinopathy
QUC398	QUC398	ADAMTS5 inhibitor	Osteoarthritis
RHH646	RHH646	-	Osteoarthritis
VAY736	ianalumab	BAFF-R inhibitor, ADCC-mediated B-cell depletor	Autoimmune hepatitis
			Hidradenitis suppurativa
YTB323	rapcabtagene autoleucel	CD19 CAR-T	srSLE/LN

Others

Code	Name	Mechanism	Indication(s)
IB&GH			
EYU688	EYU688	NS4B inhibitor	Dengue
INE963	INE963	Plasmodium falciparum inhibitor)	Malaria, uncomplicated
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	Fabhalta®	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

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)
			Oligometastatic prostate cancer
AAA601[1]	Lutathera®	Radioligand therapy target SSTR	Gastroenteropancreatic neuroendocrine tumors (GEP-NET), 1st line in G2/3 tumors
BYL719	Vijoice®	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	Fabhalta®	CFB inhibitor	Atypical hemolytic uraemic syndrome
VAY736	ianalumab	BAFF-R inhibitor, ADCC-mediated B-cell depletor	1L Immune Thrombocytopenia
			2L Immune Thrombocytopenia
			warm Autoimmune Hemolytic Anemia

Cardiovascular, Renal and Metabolic

Code	Name	Mechanism	Indication(s)
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	Fabhalta®	CFB inhibitor	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. ^{177}Lu-dotatate in US.

Neuroscience

Code	Name	Mechanism	Indication(s)
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

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			
AMG334	Aimovig®	CGRPR antagonist	Migraine, pediatrics
KLU156	Ganaplacide + lumefantrine	Non-artemisinin plasmodium falciparum inhibitor	Malaria, uncomplicated
QMF149	Atectura®	LABA + ICS	Asthma, pediatrics
Others			
RTH258	Beovu®	VEGF Inhibitor	Diabetic retinopathy

Novartis pipeline in registration

Oncology

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

Cardiovascular, Renal and Metabolic

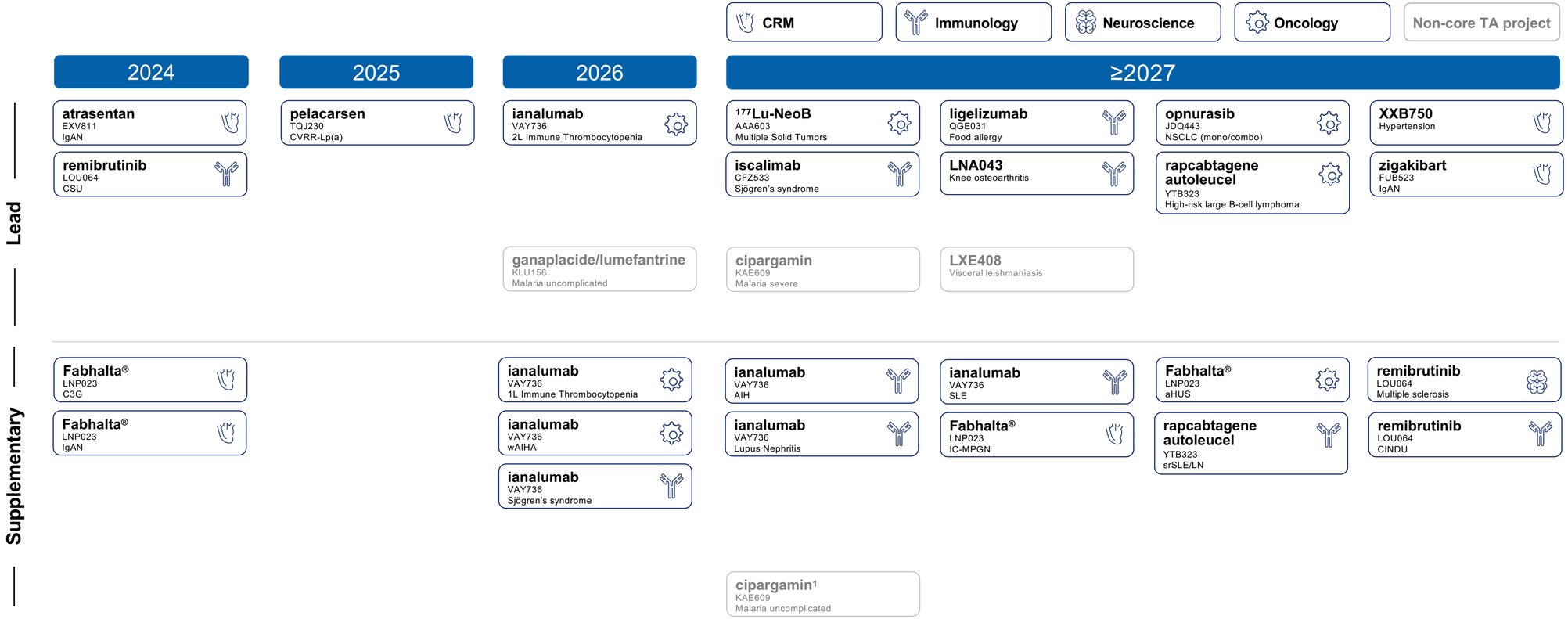
Code	Name	Mechanism	Indication(s)
LNP023	Fabhalta®	CFB inhibitor	IgA nephropathy

Others

Code	Name	Mechanism	Indication(s)
IB&GH			
COA566	Coartem®	Artemisinin combination therapy	Malaria, uncomplicated (<5kg patients)

Novartis submission schedule

New Molecular Entities: Lead and supplementary indications



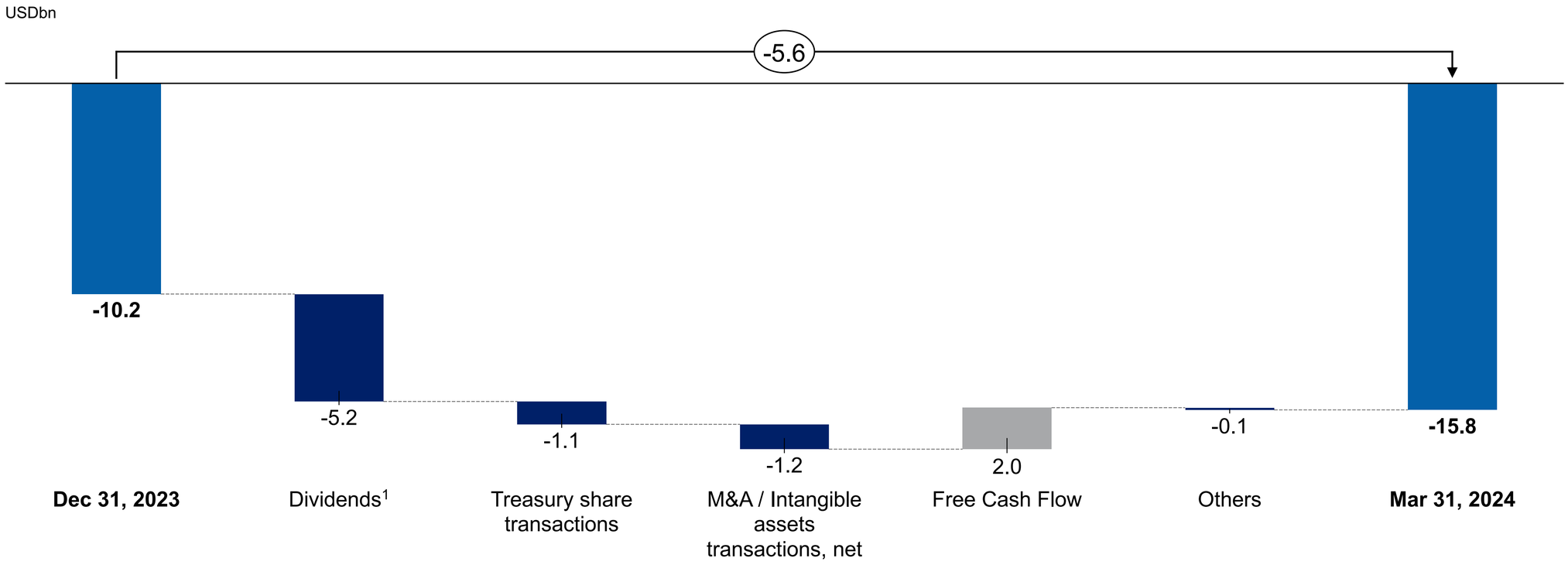
1. Part of triple combination therapy.

Novartis submission schedule

Supplementary indications for existing brands

1. ^{177}Lu-dotatate in US. 2. Event-driven trial endpoint. 3. Kesimpta and Mayzent: Pediatric trial in multiple sclerosis run in conjunction (NEOS).

Net debt increased by USD 5.6bn mainly due to the annual dividend payment



1. Annual net dividend payment in March (which is the gross dividend of USD 7.6 billion reduced by the USD 2.4 billion Swiss withholding tax that was paid in April 2024, according to its due date).

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, Renal and Metabolic

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

Fabhalta® - CFB inhibitor

NCT04578834 APPLAUSE-IgAN (CLNP023A2301)

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

Fabhalta® - CFB inhibitor

NCT05755386 APPARENT (CLNP023B12302)

Indication	Immune complex-mediated membranoproliferative glomerulonephritis
Phase	Phase 3
Patients	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	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

Fabhalta® - 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

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

Leqvio® - siRNA (regulation of LDL-C)

NCT05030428 VICTORION-2P (CKJX839B12302)

Indication	Secondary prevention of cardiovascular events in patients with elevated levels of LDL-C
Phase	Phase 3
Patients	16970
Primary Outcome Measures	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)

NCT04652726 ORION-16 (CKJX839C12301)

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

Leqvio® - siRNA (regulation of LDL-C)

NCT04659863 ORION-13 (CKJX839C12302)

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

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	350
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

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

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

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
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	349
Primary Outcome Measures	Number of participants with sustained remission
Arms Intervention	Experimental: Secukinumab 150 and 300 mg Placebo Comparator: Placebo
Target Patients	Patients with Giant Cell Arteritis (GCA)
Readout Milestone(s)	Primary 2025
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

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

remibrutinib - BTK inhibitor

NCT05030311 REMIX-1 (CLOU064A2301)

Indication	Chronic spontaneous urticaria
Phase	Phase 3
Patients	470
Primary Outcome Measures	Two independent endpoint scenarios: 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) LOU064 (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) 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) 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 (52-week actual)
Publication	24 weeks data at ACAAI Nov 2023. 52 weeks data in H1 2024

remibrutinib - BTK inhibitor

NCT05032157 REMIX-2 (CLOU064A2302)

Indication	Chronic spontaneous urticaria
Phase	Phase 3
Patients	455
Primary Outcome Measures	Two independent endpoint scenarios: 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 (52-week actual)
Publication	24 weeks data at ACAAI Nov 2023. 52 weeks data in H1 2024

remibrutinib - BTK inhibitor

NCT05976243 (CLOU064M12301)

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

Neuroscience

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

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 Comparator (intravenously)
Target Patients	Previously treated patients with warm Autoimmune Hemolytic Anemia
Readout Milestone(s)	2026
Publication	TBD

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)	2026
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)	2025
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: 2025
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

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

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

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	Arm 1: Experimental. Adult participants, alpelisib dose 1 (Stage 1) Arm 2: Experimental. Adult participants, alpelisib dose 2 (Stage 1) Arm 3: Experimental. Pediatric participants (6-17 years of age), alpelisib dose 2 (Stage 1) Arm 4: Experimental. Pediatric participants (6-17 years of age), alpelisib dose 3 (Stage 1) Arm 5: Experimental. Adult participants, alpelisib (Stage 2) Arm 6: Placebo comparator. Adult participants, placebo (Stage 2) Arm 7: Experimental. Pediatric participants (6-17 years of age), alpelisib (Stage 2) Arm 8: Placebo Comparator. Pediatric participants (6-17 years of age), placebo (Stage 2) Arm 9: Experimental. Pediatric participants (2-5 years of age), alpelisib (Stage 2)
Target Patients	Pediatric and adult patients with lymphatic malformations associated with a PIK3CA mutation
Readout Milestone(s)	2030
Publication	TBD

In-market Brands & Global Health

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

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

Coartem® - 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

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 ≥ 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 ≥ 5 kg Body Weight with uncomplicated P. Falciparum Malaria
Readout Milestone(s)	2025
Publication	TBD

References

Entresto® (slide 6 references)	
1	IQVIA National Prescription Audit.
2	AHA/ACC/HFSA/ESC.
3	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.
4	Extension of regulatory data protection to November 2026 in EU based on approval of pediatric indication.

Kesimpta® (slide 8 references)	
1	Data on file. January 2024.
2	Data on file and IQVIA. March 2024.
3	Wiendl H, Hauser S, Nicholas J, et al. Longer-term Safety and Efficacy of Ofatumumab in People With Relapsing Multiple Sclerosis for Up to 6 Years. Poster presentation at the American Academy of Neurology (AAN) 2024 Annual Meeting; April 13 – 18, 2024; Denver, CO.
4	Pardo G, Hauser S, Bar-Or A, et al. Longer-term (up to 6 Years) Efficacy of Ofatumumab in People with Recently Diagnosed and Treatment-Naïve Relapsing Multiple Sclerosis. Oral presentation at the American Academy of Neurology (AAN) 2024 Annual Meeting; April 13 – 18, 2024; Denver, CO.
5	As per stability technical specification data, when the patient is ready to inject, it typically takes less than 1 minute a month to administer. Once-monthly dosing begins after the initial dosing period, which consists of 20 mg subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA.

Kisqali® (slide 9 references)	
1	Only CDK4/6 with statistically significant OS benefit proven across all three Ph3 pivotal trials. Source: AHA/ACC/HFSA/ESC.
2	Consistent benefit regardless of combination partner, line of therapy, menopausal status, or site and number of metastases. Source: AHA/ACC/HFSA/ESC.
3	Only CDK4/6 with Category 1 NCCN3 recommendation in combination with AI. 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.
4	IQVIA National Prescription Audit.

Leqvio® (slide 12 references)	
1	Includes PCSK9 mAbs and bempedoic acid.
2	Michael J. Koren, et al. An Inclisiran First Strategy vs Usual Care in Patients with Atherosclerosis, Journal of the American College of Cardiology, 2024, ISSN 0735-1097.

Remibrutinib (slide 16 references)	
1	US only Novartis internal analysis.
2	H1-antihistamines at approved and increased doses. incl. drowsiness with increased dose.
3	Originally presented at ACAAI annual meeting 2023.
4	Full analysis set; observed data.
5	J. Bernstein et al., Annals of Allergy, Asthma & Immunology; Volume 131, Issue 5, Supplement 1, 2023.
6	Compared to placebo.
7	UAS7, ISS7, HSS7.