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Q2 2024 Results

Investor presentation
July 18, 2024

NOVARTIS | Reimagining Medicine

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

This communication is neither an offer to purchase nor a solicitation of an offer to sell shares of MorphoSys. The final terms and further provisions regarding the delisting purchase offer are available in the offer document published by Novartis BidCo AG (formerly known as Novartis data42 AG) (the “Bidder”). The offer document has been approved by the BaFin and has been filed with the U.S. Securities and Exchange Commission (the “SEC”). The solicitation and offer to buy shares of MorphoSys is only being made pursuant the offer document. In connection with the Offer, the Bidder and Novartis AG have filed Tender Offer Statement on Schedule TO with the SEC (together with the offer document, an Offer to Purchase including the means to tender and other related documents, the “Offer Documents”), the management board and supervisory board of MorphoSys have issued a joint reasoned statement in accordance with sec. 27 of the German Securities Acquisition and Takeover Act and MorphoSys has filed a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC (together with the joint reasoned statement, the “Recommendation Statements”). THE MORPHOSYS SHAREHOLDERS AND OTHER INVESTORS ARE URGED TO READ THE OFFER DOCUMENTS AND THE RECOMMENDATION STATEMENTS BECAUSE THEY CONTAIN IMPORTANT INFORMATION WHICH SHOULD BE READ CAREFULLY BEFORE ANY DECISION IS MADE WITH RESPECT TO THE OFFER. The Offer Documents and the Recommendation Statements have been distributed to all stockholders of MorphoSys in accordance with German and U.S. securities laws. The Tender Offer Statement on Schedule TO and the Solicitation/Recommendation Statement on Schedule 14D-9 are available for free at the SEC’s website at www.sec.gov. Additional copies may be obtained for free by contacting the Bidder or MorphoSys. Free copies of these materials and certain other offering documents are available on the Bidder’s website at www.novartis.com/investors/morphosys-acquisition or by contacting the Bidder’s investor relations department at +41 61 324 7944.

Company overview

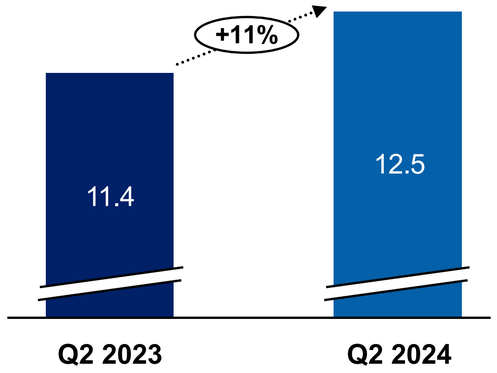
Vas Narasimhan, M.D.
Chief Executive Officer

NOVARTIS | Reimagining Medicine

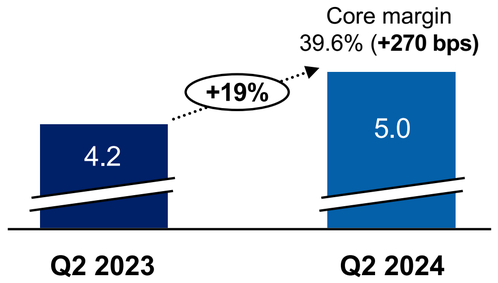
Novartis delivered a strong Q2 with double-digit sales growth and core margin expansion

Strong momentum in the business...

Sales
USD bn, % cc[1]



Core[1] operating income
USD bn, % cc[1]



... and in the pipeline

Innovation highlights

Fabhalta® PNH EU, Japan and China approval

Lutathera® pediatric GEP-NET US approval

Scemblix® 1L CML FDA submission, BTD

Kisqali® NATALEE updated data in eBC

Atrasentan IgAN FDA submission

Renal portfolio data presentations at ERA (Fabhalta®, atrasentan, zigakibart)

Support upgrade to FY 2024 core operating income guidance and continued confidence in mid-term growth prospects

1. Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Q2 growth was broad-based, with strong contributions from established growth drivers as well as newer launches

Q2 sales

	Sales USD million	Growth vs PY USD million	Growth vs PY cc
Entresto® sacubitril/valsartan	1,898	382	28%
Kesimpta® (ofatumumab)	799	310	65%
Cosentyx® (secukinumab)	1,526	254	22%
KISQALI® ribociclib	717	224	50%
PLUVICTO®	345	105	44%
LEQVIO®	182	104	134%
SCEMBLIX® (asciminib)	164	58	56%
Xolair® Omalizumab	427	65	22%
ILARIS® (canakinumab)	368	52	20%
zolgensma®	349	38	14%
JAKAVI® ruxolitinib	471	36	13%

Strong growth (+37% cc); expected to continue

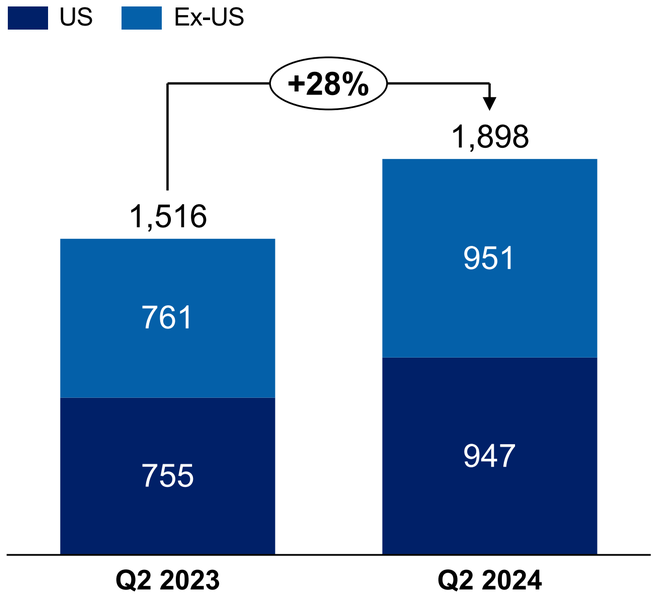
Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Entresto® delivered +28% growth in Q2, continuing its strong trajectory

Entresto®

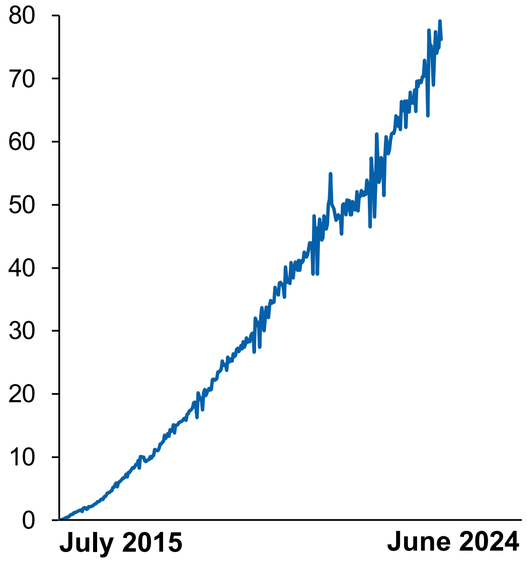
Sales evolution

USD m, % cc



US weekly TRx[1]

Total prescriptions (000)



Continued strong momentum in Q2

- US: +25%, fueled by consistent demand
- Ex-US: +30% cc, with strong contribution from China and Japan

Confidence in sustained performance

- Strong guideline position[2] (US/EU)
- Continued expansion of HCP prescriber base and increasing depth in cardiology
- US: For forecasting purposes, we assume Entresto® LoE in mid-2025
- EU: RDP to Nov 2026[3]

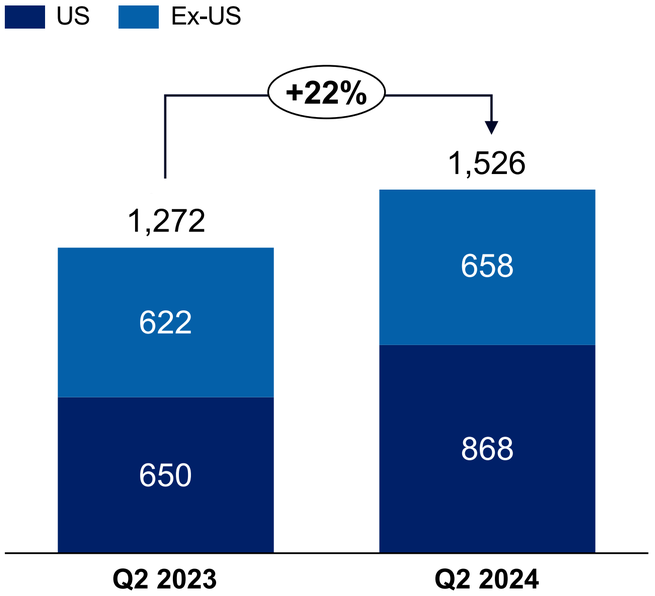
See last page for references (footnotes 1-3). LoE – loss of exclusivity. RDP – Regulatory data protection. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Cosentyx® grew +22% fueled by new launches as well as expansion in core indications

Cosentyx®

Sales evolution

USD m, % cc



Demand-driven growth across geographies

- US: +34%, driven by volume
- Ex-US: +10% cc, with volume partly offset by one-time pricing effects

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

- No.1 IL-17 in US dynamic market[1]
- Leading originator biologic in EU[2] and China[3]

New launches continue to accelerate growth

- HS: Dynamic market leadership in US (>60%) and DE (>50%) NBRx; reimbursed in key markets[4]
- IV[5]: Solid adoption in US (>700 accounts); further demand increase expected in H2 with permanent J-code (effective July 1)

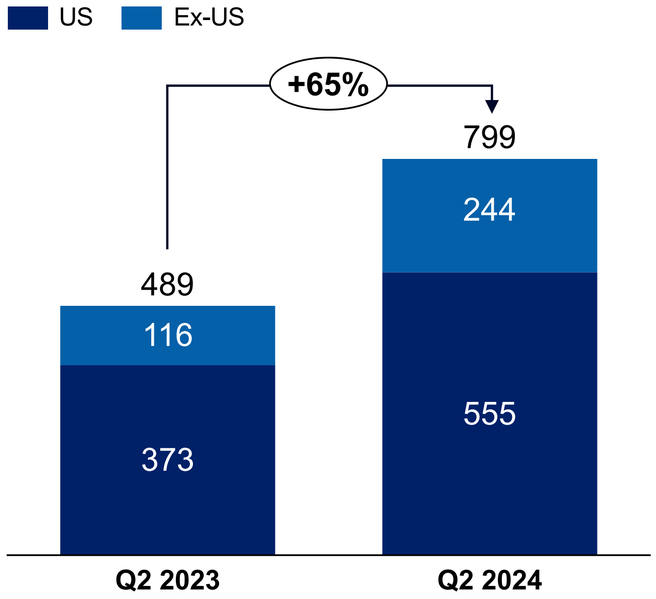
See last page for references (footnotes 1-5). PsO – psoriasis. PsA – psoriatic arthritis. AS – ankylosing spondylitis. nr-axSpA– non-radiographic axial spondyloarthritis. HS – Hidradenitis suppurativa. IL – interleukin. IV – intravenous. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Kesimpta® delivered +65% growth, with strong momentum globally

Kesimpta

Sales evolution

USD m, % cc



Strong growth trajectory with increasing contribution ex-US

- >100k patients treated worldwide, majority naïve or first switch[1]
- US (+49%): Demand-led growth with TRx volume +43% vs PY, gaining 4%pts share
- Ex-US (+118% cc): NBRx leadership in 7/10 major markets[2]

Continued confidence in compelling product profile

- Only self-administered B-cell treatment option – 1 minute a month dosing[3], no steroid pre-treatment required[4]
- Persistence and adherence in US real-world setting comparable to infused B-cell therapy at 18 and 24 months[5]
- Early and continued ARR reduction in recently diagnosed treatment-naïve patients (post-hoc analysis)[6]

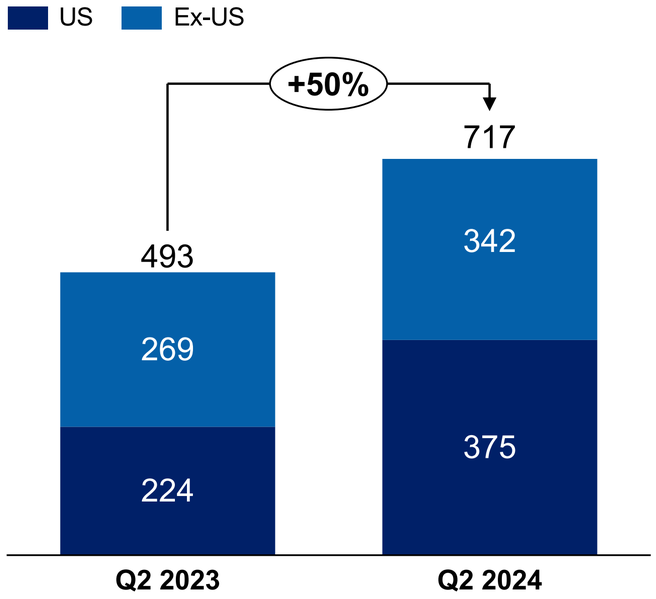
See last page for references (footnotes 1-6). NBRx – new to brand prescription. ARR – annualized relapse rate. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Kisqali® grew +50% in mBC with leading NBRx share in US and ex-US

KISQALI®

Sales evolution

USD m, % cc



US: +67% growth, gaining widespread adoption

- Leading share in mBC NBRx at 47%[1]
- 7k HCPs now prescribing and increasing depth, reflecting strong guideline position

Ex-US: +35% growth, as the preferred CDK4/6i[2]

- Leading share in mBC NBRx at 38%[2]
- Fastest-growing CDK4/6i in Europe, recognized with highest ESMO-MCBS score

eBC: On track for launch in H2

- Completed manufacturing adjustments; anticipating US approval by end of Q3
- Confident in broad label based on consistency of results across NATALEE population
- NATALEE update (median follow-up ~4 years): Continued clinically meaningful benefit with consistent safety profile; results to be presented at upcoming medical meeting

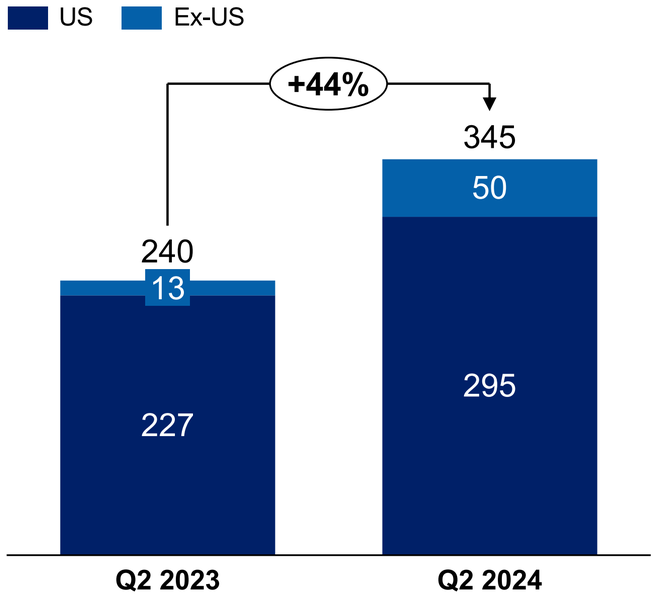
See last page for references (footnotes 1-2). eBC – early breast cancer. mBC – metastatic breast cancer. NBRx – new to brand prescription. AI – aromatase inhibitor.
Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Pluvicto® demonstrated continued steady growth of +44% vs PY

PLUVICTO®

Sales evolution

USD m, % cc



Q2 performance driven by new patient starts

- NBRx share in VISION population ~1/3; >50% in established RLT treatment sites
- 475+ treatment sites in the US (~25% growth vs PQ)

Expect continued steady growth in 2024

- Increasing US promotional efforts, including FF expansion in Q2 and DTC in Q3
- Phased launch of patient-ready dose to improve throughput at sites
- Germany pricing approved in Q2

New indications and geographies expected to accelerate growth

- FDA submission for PSMAfore on track for H2 2024
- China submission for VISION indication planned in H2 2024
- PSMAddition in mHSPC and PSMA-DC in oligometastatic disease progressing

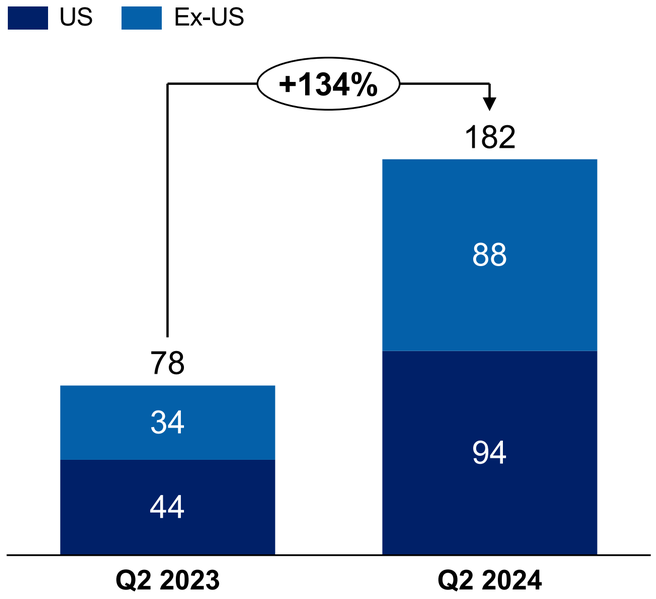
mHSPC – metastatic hormone-sensitive prostate cancer. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Strong Leqvio® growth with increasing global adoption

LEQVIO® (inclisiran)

Sales evolution

USD m, % cc



US: Growth outpacing advanced lipid-lowering market[1]

- 4,235 facilities have ordered Leqvio® (+8% vs PQ; +48% vs PY)
- Expanding breadth and depth in high-potential HCPs and accounts
- Continuing robust data generation, including Q2 RWE release showing 80% 12-month persistence rate, above comparators[2]

Ex-US: Rollout continues with >35 countries with reimbursement

- Strong market growth with injectable lipid lowering agents +24% vs PY[3]
- Leqvio share of business grew +6% vs competition
- Strong adoption in China (OOP) and Japan (reimbursed, >40% market share)

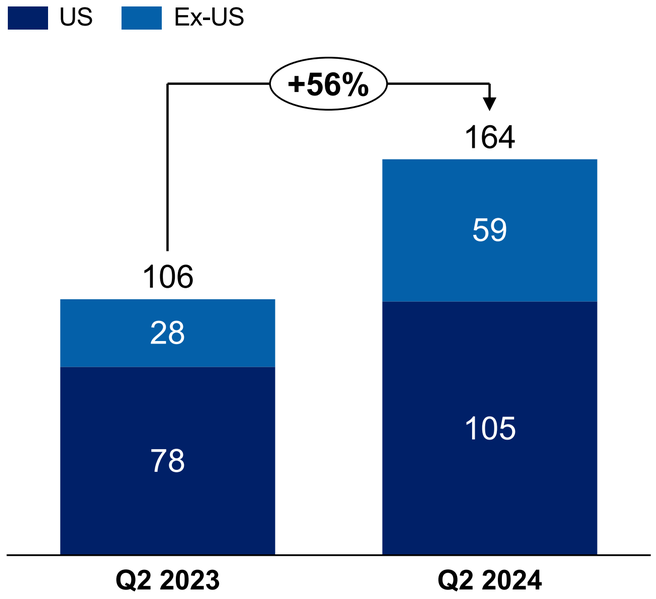
See last page for references (footnotes 1-3). HCP – healthcare professional. RWE – real world evidence Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. Novartis obtained global rights to develop, commercialize Leqvio under license/collaboration agreement with Alnylam Pharmaceuticals.

Scemblix® momentum continued in Q2, with US market leadership in 3L+; 1L CML submission under FDA Real-Time Oncology Review (RTOR)

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Sales evolution

USD m, % cc



Strong demand in core indication of 3L+ CML

- US: Market leader in both NBRx (44% share) and TRx (26% share)[1]
- Ex-US: Performance driven by Japan, Germany and Italy
- TRx and monthly prescribers continue to grow across all geographies
- Launch of 100mg SKU for T315I patients expected to moderate QoQ growth in H2

Confident in 1L opportunity, with FDA submission under RTOR

- Breakthrough Therapy designation received
- Positive feedback from ASCO and EHA; results published in NEJM
- Ex-US submissions starting in 2024 – 2025

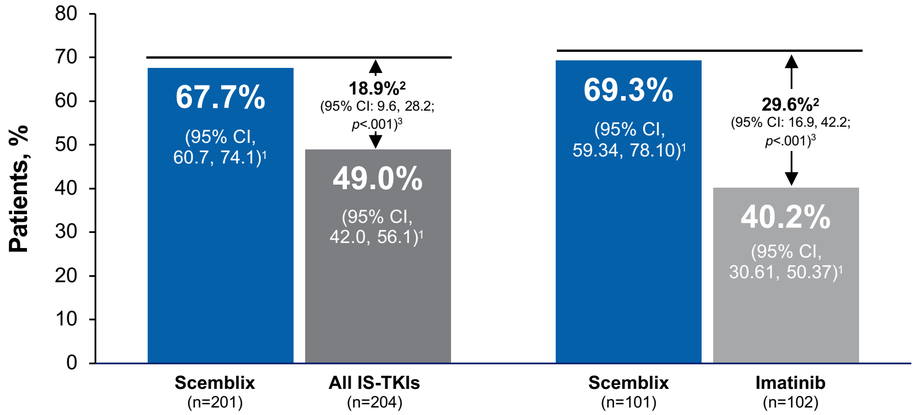
Source: 1. US: January rolling 3-months US IQVIA CML market sizing report (April 2024) - Ex-USA IQVIA Oncology Dynamics, EU5 and JP, MAT December 2023). Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Scemblix®: Ph3 ASC4FIRST study demonstrated superior efficacy with a favorable safety and tolerability profile vs SoC TKIs in 1L CML

2024 ASCO ANNUAL MEETING

Efficacy

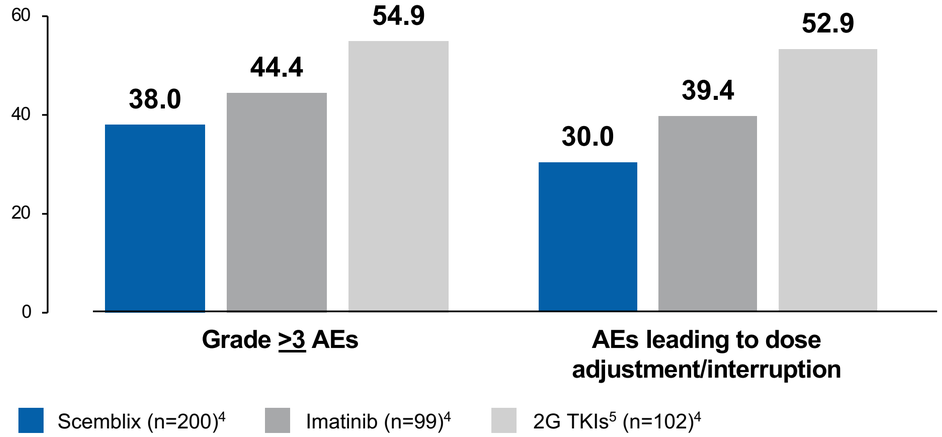
- **Superior MMR rates** vs IS-TKIs and vs imatinib alone



- **Earlier achievement of MMR and greater depth of responses**
- **Improvement vs 2G TKI** in MMR rate, speed and depth of responses

Safety and tolerability

- **Fewer grade ≥3 AEs**
- **Fewer dose adjustments/interruptions** needed to manage AEs



- **Half the rate of all-grade AEs** leading to discontinuation

See last page for references (footnotes 1-5). CI, confidence interval; CMH, Cochran-Mantel-Haenszel. NA, not applicable.

Fabhalta®[1] US PNH launch off to an encouraging start; ex-US approvals received in EU, China and Japan

Increasing intent to prescribe, reflecting compelling product profile

US launch update

Only oral monotherapy approved by FDA providing comprehensive hemolysis control (IVH and EVH)

- REMS certified HCPs ahead of competitive benchmarks
- Continued uptake across naive and switch patients (from both C5i and C3i)
- Patients treated across all hemoglobin levels, including Hb 10-12 g/dL
- Increasing commercial coverage and conversion of patients from bridge program to paid

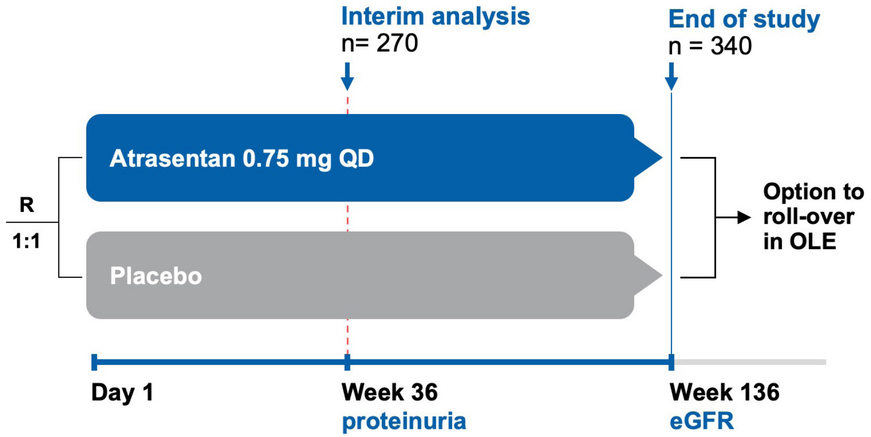
Ex-US update: Q2 approvals received in **Europe, China and Japan**

1. Iptacopan is the generic name (international non-proprietary name) of Fabhalta® for unapproved indications. HCP – healthcare professional. IVH – intravascular hemolysis. EVH – extravascular hemolysis. PNH – paroxysmal nocturnal hemoglobinuria. REMS – risk evaluation and mitigation strategies. Hb – Hemoglobin. US FDA approval received 12/05/2023. C5i – eculizumab and ravulizumab.

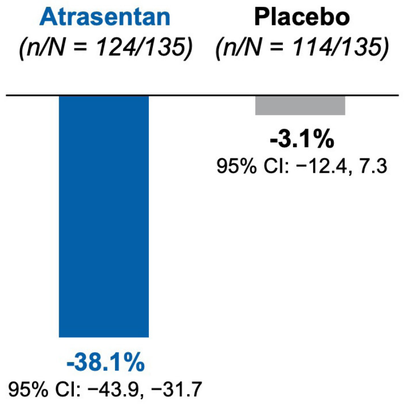
Atrasentan: Ph3 ALIGN-IgAN study demonstrated 36%[1] proteinuria reduction relative to placebo

61st ERA CONGRESS STOCKHOLM & VIRTUAL

Study design



Proteinuria reduction in IgAN patients at week 36



- Clinically meaningful and statistically significant proteinuria reduction
- Favorable safety profile consistent with previously reported data
- Potential foundational therapy, seamlessly added to supportive care
- Up to 50% of patients with persistent proteinuria progress to kidney failure within 10-20 years of diagnosis[2-7]

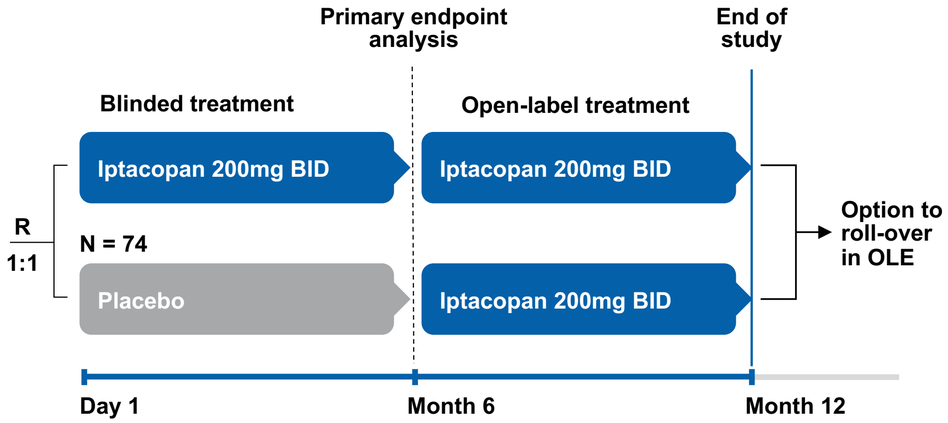
Next steps Submitted to FDA, study continues in blinded fashion to final analysis in 2026

See last page for references (footnotes 1-7). QD – once daily. eGFR – estimated glomerular filtration rate. IgAN – IgA nephropathy. OLE – open label extension.

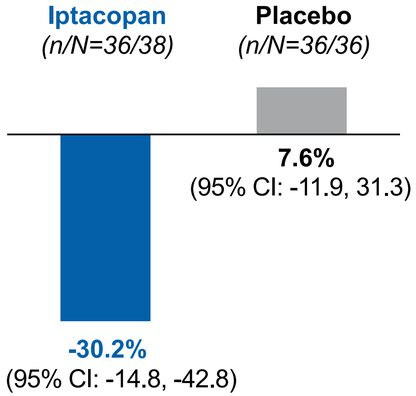
Iptacopan: Ph3 APPEAR-C3G study demonstrated 35%[1] proteinuria reduction relative to placebo

61st ERA CONGRESS STOCKHOLM & VIRTUAL

Study design



Proteinuria reduction in C3G patients at month 6



- Clinically meaningful and statistically significant proteinuria reduction
- Numerical improvement in eGFR
- Favorable safety profile consistent with previously reported data
- First potential treatment targeting the alternative complement pathway in C3G
- ~50% of patients develop kidney failure requiring dialysis or transplant within 10 years of diagnosis[2,3]

Next steps End-of-study results consistent with 6-month data; results to be presented at upcoming medical meeting
HA submissions planned for H2 2024

BID – twice daily. C3G – Complement 3 glomerulopathy. OLE – open label extension. HA – health authorities. 1. Kavanagh D, et al. Efficacy & Safety of iptacopan in patients with C3G: results from the Phase 3 APPEAR-C3G trial. ERA May 25, 2024. 2. Smith RJH, et al. Nat Rev Nephrol 2019;15:129-143. 3. Martin B, Smith RJH. In: Adam MP, Ardinger HH, Pagon RA, et al. GeneReviews® [Internet]. Updated 2018. University of Washington, Seattle; 1993-2022.

Expect to continue our innovation momentum in H2

2024 selected key events (expected)

		H1 2024	H2 2024	Q2 status update
Regulatory decisions	**Fabhalta® PNH**		EU, JP	EU, JP and China approval in Q2
	Kisqali® HR+/HER2- adj. BC		US, EU	
Submissions	**Atrasentan IgAN**	US		US submission in Q2
	Fabhalta® (iptacopan) C3G		US, EU	
	Fabhalta® (iptacopan) IgAN	US		US submission in Q1, received priority review
	Pluvicto® mCRPC, pre-taxane		US	Submission-enabling OS readout in April
	Remibrutinib CSU			Submissions shifting to 2025
	Scemblix® CML 1L	US	JP	US submission in Q2, granted Breakthrough Therapy Designation
	Lutathera® GEP-NET 1L G2/G3	EU		EU submission in Q2
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		Program discontinued to prioritize other key programs in portfolio

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.

Financial review and 2024 guidance

Harry Kirsch
Chief Financial Officer

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Q2 net sales grew +11% cc with core operating income up +19% cc[1]

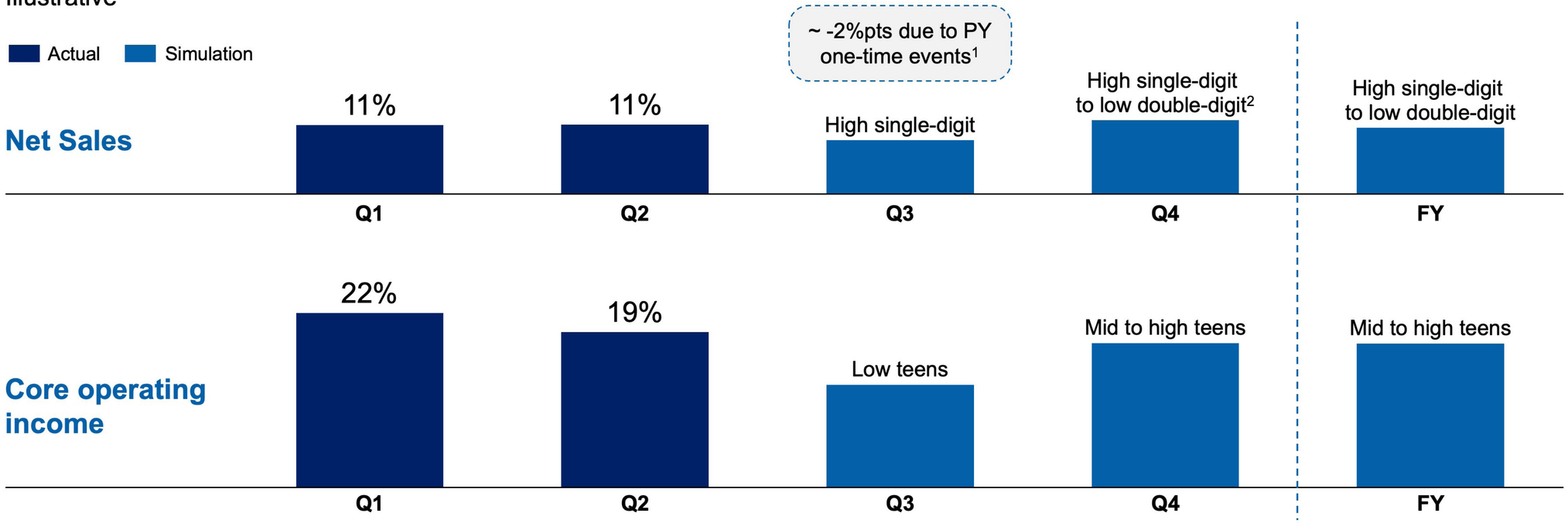
Continuing Operations[1,2] USD million	Q2 2023	**Q2 2024**	**Change vs PY** % USD	**Change vs PY** % cc	H1 2023	**H1 2024**	**Change vs PY** % USD	**Change vs PY** % cc
Total Net Sales	11,437	12,512	9	11	22,235	24,341	9	11
Core Operating income	4,240	4,953	17	19	8,146	9,490	16	21
as % of Net sales	*37.1%*	*39.6%*	*+2.5%pts*	*+2.7%pts*	*36.6%*	*39.0%*	*+2.4%pts*	*+3.1%pts*
Operating income	2,807	4,014	43	47	5,425	7,387	36	43
Net Income	2,271	3,246	43	49	4,421	5,934	34	43
Core EPS	1.69	1.97	17	21	3.23	3.77	17	22
EPS	1.09	1.60	47	52	2.12	2.91	37	47
Free cash flow	3,292	4,615	40		5,976	6,653	11	

1. Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. 2. As defined on page 33 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.

2024 with strong underlying growth dynamics in all quarters; Q3 growth lower due to PY one-timers

2024 growth vs. PY (cc)

Illustrative



1. PY Kesimpta revenue deduction adjustment in Europe and Sandoz inventory buildup sales. 2. Subject to US Gx. entry assumptions.

Raising 2024 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

Core operating income

expected to grow

mid to high teens

(from low double-digit to mid-teens)

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 0.7bn
- Core tax rate: Expected to be around 16.2%

1. Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

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
MorphoSys acquisition; multiple early-stage deals to strengthen RLT platform in H1

Substantial cash generation

Returning capital to shareholders

Consistently growing annual dividend[1]
USD 7.6bn dividend paid in H1 2024
not rebased post Sandoz

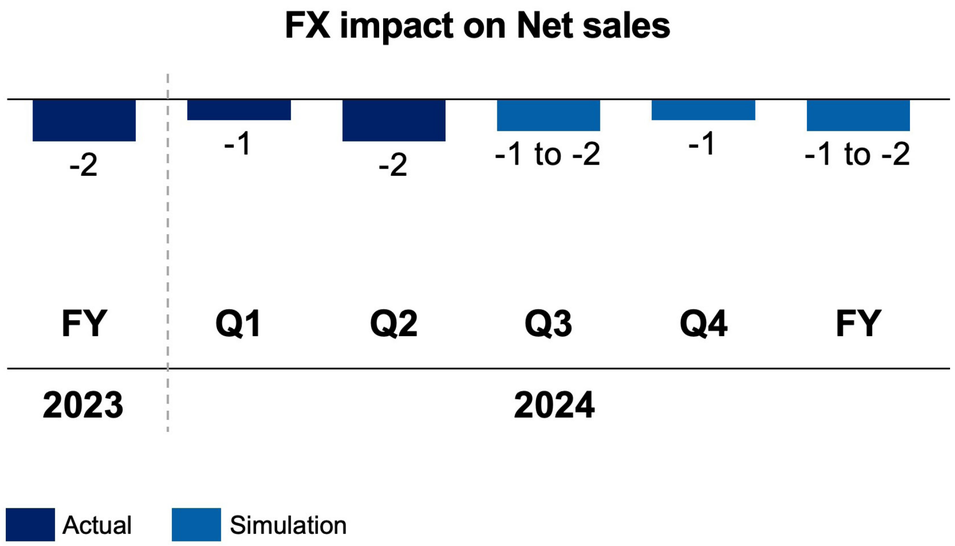
Share buybacks
Up to USD 15bn share buyback continuing, with up to USD 10.1bn still to be executed

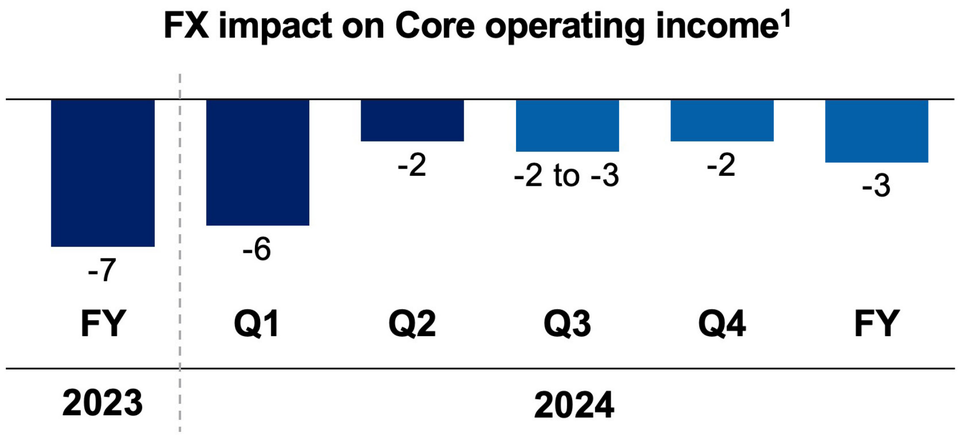
1. In CHF.

Expected currency impact for full year 2024

Currency impact vs PY

%pts, assuming mid-July exchange rates prevail in 2024





1. Core operating income is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Conclusions

Vas Narasimhan, M.D.
Chief Executive Officer

NOVARTIS | Reimagining Medicine

Continued momentum in Q2, with net sales up +11% and core operating income margin approaching 40%

Strong commercial execution across geographies and growth brands, supporting bottom-line guidance raise for FY2024

Pipeline continues to advance, with FDA submissions for Scemblix 1L and atrasentan IgAN, and updated data for Kisqali in eBC

On track to achieve our mid-term guidance of +5% cc sales CAGR 2023-2028 CAGR and 40%+ core operating income margin by 2027

Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Appendix

NOVARTIS | Reimagining Medicine

Our pipeline projects at a glance

	Phase 1/2	Phase 3	Registration	Total
Oncology	25	9	5	39
Solid tumors	18	4	4	26
Hematology	7	5	1	13
Immunology	17	9	0	26
Neuroscience	4	5	0	9
Cardiovascular, Renal and Metabolic	5	8	2	15
Others (thereof IB&GH)	11 (7)	4 (3)	1	16
	62	35	8	105

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

Novartis pipeline in Phase 1

17 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
AAA617	Pluvicto®	Radioligand therapy target PSMA	Metastatic neuroendocrine prostate cancer
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
JSB462	JSB462	Androgen receptor protein degrader	Prostate cancer
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)
IPX643	IPX643	-	Inflammation-driven diseases
MHV370	MHV370	TLR7, TLR8 Antagonist	Systemic lupus erythematosus
YMI024	YMI024	-	Inflammation-driven diseases

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
DZR123	tulmimetostat	EZH1, EZH2 inhibitor	Solid tumors & lymphomas
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. Novartis is developing minzasolmin jointly in collaboration with UCB; DLX313 is the Novartis compound code for UCB0599.

Novartis pipeline in Phase 3

7 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
BYL719	Vijoice®	PI3K-alpha inhibitor	Lymphatic malformations
Hematology			
DAK539	pelabresib	BET inhibitor	Myelofibrosis
LNP023	Fabhalta®	CFB inhibitor	Atypical hemolytic uraemic syndrome
VAY736	ianalumab	BAFF-R inhibitor, ADCC-mediated B-cell depletor	1L Immune Thrombocytopenia
			2L Immune Thrombocytopenia
			warm Autoimmune Hemolytic Anemia

Cardiovascular, Renal and Metabolic

Code	Name	Mechanism	Indication(s)
FUB523	zigakibart	Anti-APRIL	IgA nephropathy
KJX839	Leqvio®	siRNA (regulation of LDL-C)	CVRR-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))

Neuroscience

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

Immunology

Code	Name	Mechanism	Indication(s)
AIN457	Cosentyx®	IL17A inhibitor	Giant cell arteritis
			Polymyalgia rheumatica
LOU064	remibrutinib	BTK inhibitor	Chronic spontaneous urticaria
			Chronic spontaneous urticaria, pediatrics
			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

1 lead indication

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
AAA601[1]	Lutathera®	Radioligand therapy target SSTR	Gastroenteropancreatic neuroendocrine tumors (GEP-NET), 1st line in G2/3 tumors
Hematology			
ABL001	Scemblix®	BCR-ABL inhibitor	Chronic myeloid leukemia, 1st line

Cardiovascular, Renal and Metabolic

Code	Name	Mechanism	Indication(s)
EXV811	atrasentan	ET_A receptor antagonist	IgA nephropathy
LNP023	Fabhalta®	CFB inhibitor	IgA nephropathy

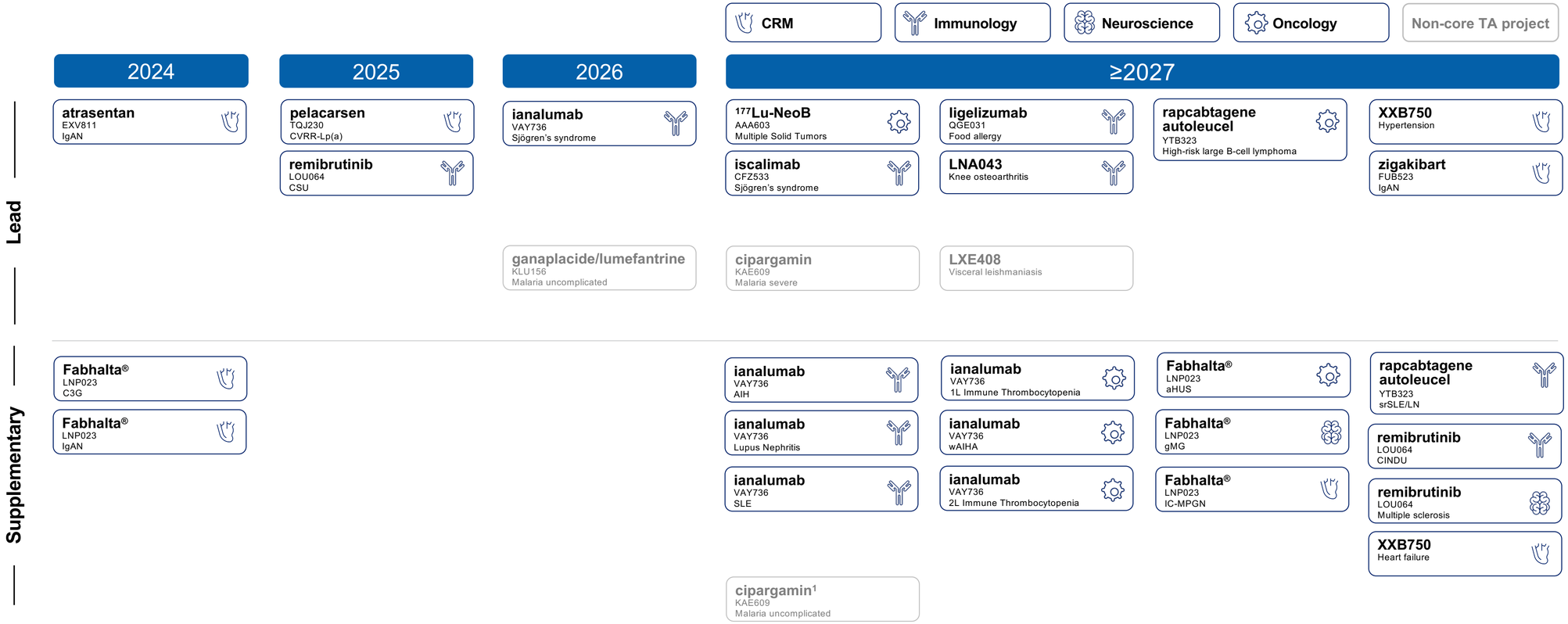
Others

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

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

Novartis submission schedule

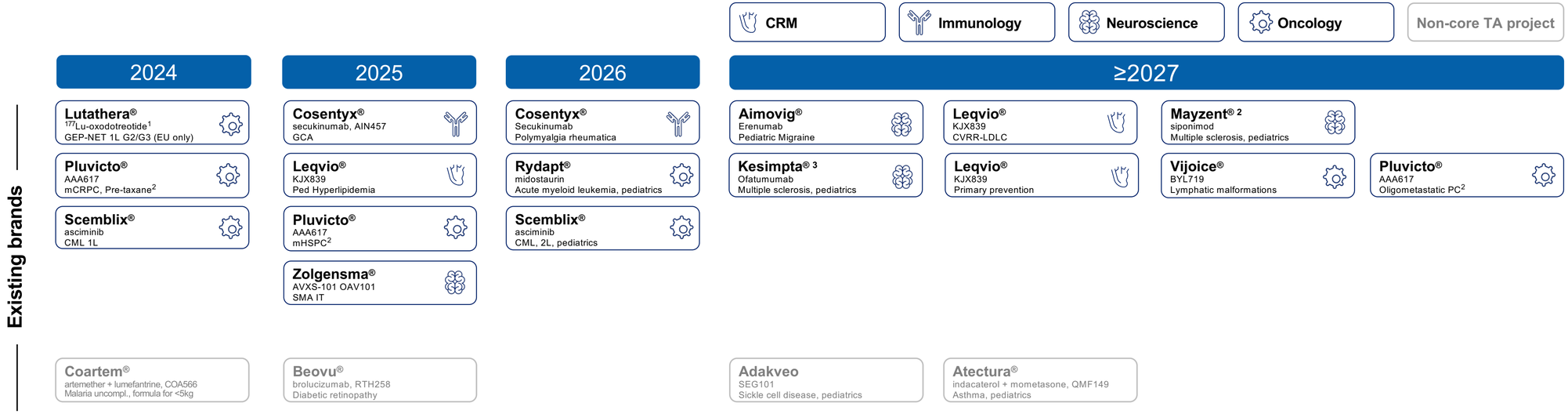
New Molecular Entities: Lead and supplementary indications



1. Part of triple combination therapy.

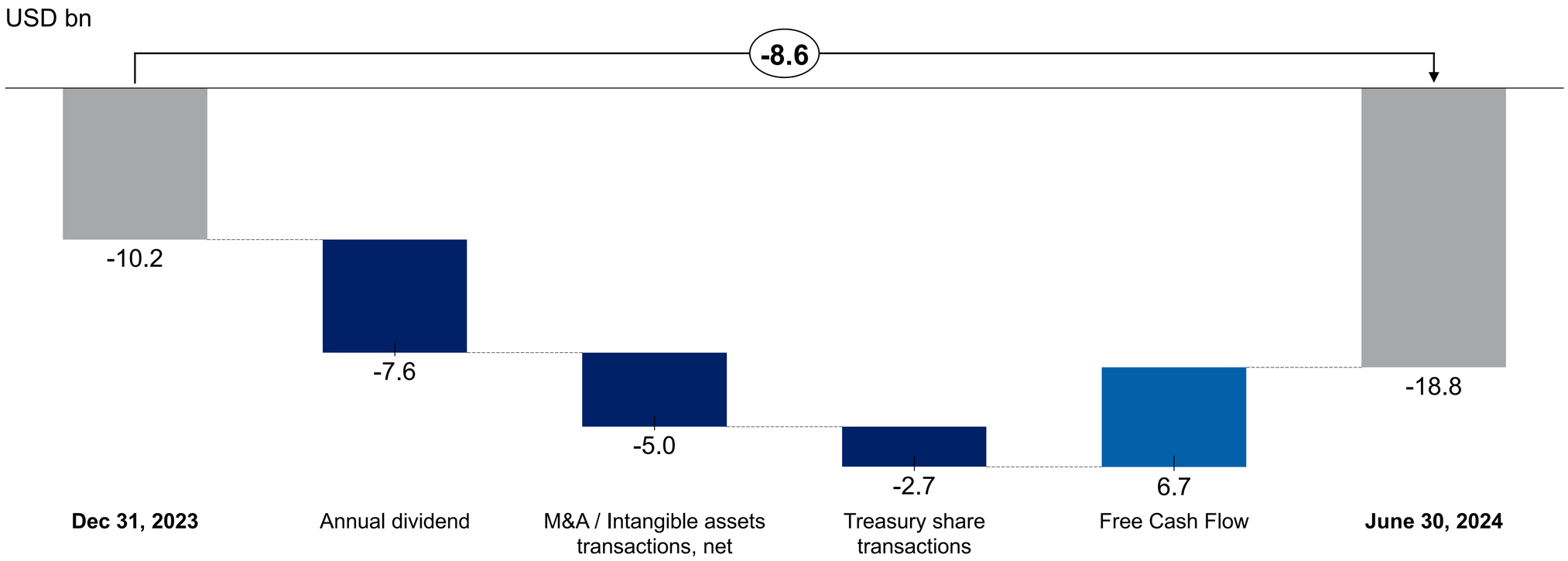
Novartis submission schedule

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 8.6bn mainly due to the annual dividend and M&A, partially offset by FCF



Free cash flow is a non-IFRS measures. An explanation of non-IFRS measures can be found on page 43 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

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 (Event driven)
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	WCN Poster April 2024: BEYOND: A Phase 3, Randomized, Double-Blind, Placebo-controlled Trial of Zigakibart in Adults with IgA Nephropathy. Trimarchi H., et. al.

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

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

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 (actual)
Publication	TBD

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

NCT05126277 SIRIUS-LN (CVAY736K12301)

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

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

NCT05349214 NEPTUNUS-2 (CVAY736A2302)

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

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

NCT05350072 NEPTUNUS-1 (CVAY736A2301)

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

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

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, ADCC-mediated B-cell depletor

NCT05624749 SIRIUS-SLE 2 (CVAY736F12302)

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

LNA043 - ANGPTL3 agonist

NCT04864392 ONWARDS (CLNA043A12202)

Indication	Knee osteoarthritis
Phase	Phase 2
Patients	576
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)	Actual (2024)
Publication	24-wk data at ACAAI Nov 2023 52-wk data at EAACI May 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)	Actual (2024)
Publication	24-wk data at ACAAI Nov 2023 52-wk data at EAACI May 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	120
Primary Outcome Measures	Annualized relapse rate (ARR) in target pediatric participants
Arms Intervention	Arm 1: Experimental ofatumumab - 20 mg injection/ placebo Arm 2: Experimental siponimod - 0.5 mg, 1 mg or 2 mg/ placebo Arm 3: Active Comparator fingolimod - 0.5 mg or 0.25 mg/ placebo
Target Patients	Children/adolescent patients aged 10-17 years old with Multiple Sclerosis (MS). The targeted enrollment is 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)	2027
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

Iptacopan - CFB inhibitor

CLNP023Q12301

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

Oncology

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

NCT05653349 VAYHIT1 (CVAY736I12301)

Indication	1L Immune Thrombocytopenia
Phase	Phase 3
Patients	225
Primary Outcome Measures	Time from randomization to treatment failure (TTF)
Arms Intervention	Arm 1: Experimental: 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)	2026
Publication	TBD

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

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, ADCC-mediated B-cell depletor

NCT05648968 VAYHIA (CVAY736O12301)

Indication	Warm autoimmune hemolytic anemia
Phase	Phase 3
Patients	90
Primary Outcome Measures	Binary variable indicating whether a patient achieves a durable response Durable response: hemoglobin level ≥10 g/dL and ≥2 g/dL increase from baseline, for a period of at least eight consecutive weeks between W9 and W25, in the absence of rescue medication or prohibited treatment
Arms Intervention	Arm 1: experimental 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

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	6 June 2024: SNMMI Abstract of the Year: [177Lu]Lu-PSMA-617 Extends Progression-Free Survival with Manageable Safety Profile in Taxane-Naïve Advanced Prostate Cancer Patients

Pluvicto® - Radioligand therapy target PSMA

NCT04720157 PSMAddition (CAAA617C12301)

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	Asciminib in Newly Diagnosed Chronic Myeloid Leukemia," published in the New England Journal of Medicine on 31-May-2024. Data presented at ASCO 2024 congress

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	54 Week FIR for CONDOR presented at ARVO 08-09May 2024. Encore presentation for CONDOR planned for EU Retina for 19-22 Sep 2024

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 1/2

Entresto® (slide 6 references)

1 IQVIA National Prescription Audit.
2 AHA/ACC/HFSA/ESC.
3 Extension of regulatory data protection to November 2026 in EU based on approval of pediatric indication.

Cosentyx® (slide 7 references)

1 Refers to NBRx. Indications: PsO, HS, SpA. Source: IQVIA National Source of Business (NSOB) 21 June 2024.
2 Refers to EU5. Indications: Pso, PsA, axSpA. Source: IQVIA LRx, FR: IQVIA Ltd, UK: IQVIA Analzyer, IT: Stethos, ES: Amber Market Research (April 2024).
3 Refers to hospital market value share. All indications of key immunology brands including those not relevant to Cosentyx. Source: IQVIA China Immunology Market Value Share (April 2024).
4 US, DE, UK, FR, ES, AU.
5 IV formulation indication: PsA, AS, nr-axSpA.

Kesimpta® (slide 8 references)

1 Data on file. January 2024
2 Data on file and IQVIA. March 2024. Markets are as follows: Germany, Japan, China, Australia, Canada, France, UK.
3 As per stability technical specification data, when the patient is ready to inject, it typically takes less than 1 minute a month to administer. Once-monthly dosing begins after the initial dosing period, which consists of 20 mg subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA. Patient must take pen out of the refrigerator 15-30 minutes before self-administering.
4 Kramer J, Linker R, Paling D, Czaplinski A, Hoffmann O, Yong VW, Barker N, Ross AP, Lucassen E, Gufran M, Hu X, Zielman R, Seifer G, Vermersch P. Tolerability of subcutaneous ofatumumab with long-term exposure in relapsing multiple sclerosis. Mult Scler J Exp Transl Clin. 2023 Oct 10;9(4):20552173231203816. doi: 10.1177/20552173231203816. PMID: 37829441; PMCID: PMC10566276.
5 Tai et al, Real World Persistence and Adherence to Ofatumumab vs Ocrelizumab in Patients with Multiple Sclerosis. Poster presented at CMSC 38th Annual Meeting May 29 - June 1, 2024:Nashville TN.
6 Gartner J, Hauser SL, Bar-Or A, et al. Efficacy and safety of ofatumumab in recently diagnosed, treatment-naïve patients with multiple sclerosis: results from ASCLEPIOS I and II. Mult Scler.2022;28(10):1562-1575.

Kisqali® (slide 9 references)

1 Of CDK4/6 mBC market, US rolling 3 months ending May 2024, IQVIA Breast Cancer Market Sizing report.
2 Of CDK4/6 mBC market, ex-US 3 months ending March 2024, IQVIA Breast Cancer Market Sizing report.

References 2/2

Leqvio® (slide 11 references)	
1	Includes PCSK9 mAbs and bempedoic acid.
2	Niu X et al. Poster presented at: National Lipid Association Scientific Sessions 2024; May 30-June 2, 2024. Las Vegas, NV. PO#158.
3	Data based on four markets (Japan, Germany, Spain, Italy). YoY vs. Q1 2023.

Scemblix® (slide 13 references)	
1	Clopper-Pearson 95% CI.
2	The common risk difference and its 95% CI estimated using the Mantel-Haenszel method after stratifying for (a) pre-randomization selected TKI, and (b) baseline ELTS risk groups (both IRT data).
3	Adjusted 1-sided p-value calculated based on the graphical gatekeeping procedure. The null hypothesis is rejected if the adjusted p-value is less than or equal to 0.025.
4	Safety analyses consisted of patients who received ≥1 dose of study drug. Patients were analyzed according to the study treatment received. The most common AEs leading to treatment discontinuation were lipase increases with Scemblix (1.5%), diarrhea and lymphopenia with imatinib (2.0% each), and pleural effusion with 2G TKIs (2.0%).
5	Investigator selected 2G TKIs – nilotinib, dasatanib, bosutinib.

Atrasentan (slide 15 references)	
1	Relative reduction in mean percentage change in UPCR from baseline (95% CI) for atrasentan compared with placebo: −36.1% (−44.6, −26.4), p<0.0001. Heerspink HJL, et al. Efficacy and safety of atrasentan in IgA nephropathy: A pre-specified interim analysis of a Phase 3 randomized controlled clinical trial. ERA. May 25, 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
3	Rodrigues J, et al. Clin J Am Soc Nephrol. 2017;12(4):677-686
4	Pitcher D et al. Clin J Am Soc Nephrol. 2023;18(6):727-738
5	Hastings MC et al. Kidney Int Rep. 2018;3(1):99-104
6	Sim JJ et al. Poster TH-PO615 presented at: ASN Kidney Week 2023; November 2-5, 2023; Philadelphia, PA.
7	Bobart SA et al. Nephrol Dial Transplant. 2021;36(5):840-847.