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Q3 2024 Results

Investor presentation
October 29, 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 46 of the Interim Financial Report.

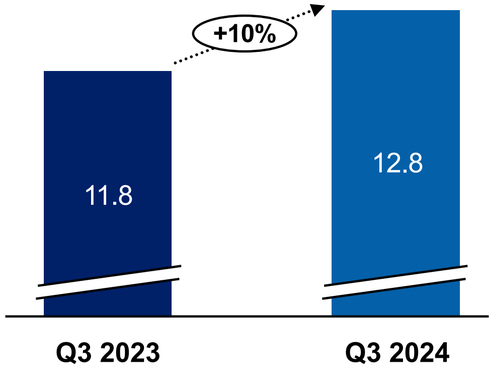
Company overview

Vas Narasimhan, M.D.
Chief Executive Officer

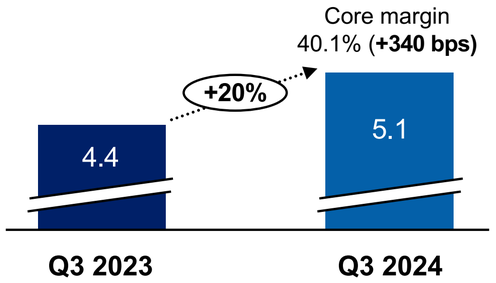
NOVARTIS | Reimagining Medicine

Novartis delivered strong operational performance and key pipeline milestones in Q3, supporting a further upgrade to FY 2024 guidance

Sales
USD bn, % cc[1]



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



Innovation highlights

Kisqali® FDA approval and CHMP positive opinion for HR+/HER2- stage II and III eBC

Fabhalta® FDA accelerated approval for IgA nephropathy

Pluvicto® FDA filing accepted for pre-taxane mCRPC

Scemblix® FDA Priority Review for 1L CML

Third raise to FY 2024 guidance[2]: Sales now expected to grow low double-digit, and core operating income to grow high teens

1. Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. 2. Please see detailed guidance assumptions on slide 20.

Q3 growth reflects strong performance from key growth drivers as well as newer launches

Q3 sales

	Sales USD million	Growth vs PY USD million	Growth vs PY cc
Entresto® sacubitril/valsartan	1,865	380	26%
Cosentyx® (secukinumab)	1,693	364	28%
KISQALI® ribociclib	787	225	43%
Kesimpta® (ofatumumab)	838	181	28%
PLUVICTO®	386	130	50%
LEQVIO®	198	108	119%
SCEMBLIX® (asciminib)	182	76	72%
FABHALTA® (iptacopan)	44	44	nm
JAKAVI® ruxolitinib	500	73	18%
Tafinlar® (dabrafenib) + Mekinist® (trametinib)	534	52	12%
Xolair® Omalizumab	418	49	15%

Strong growth (+34% cc); expected to continue

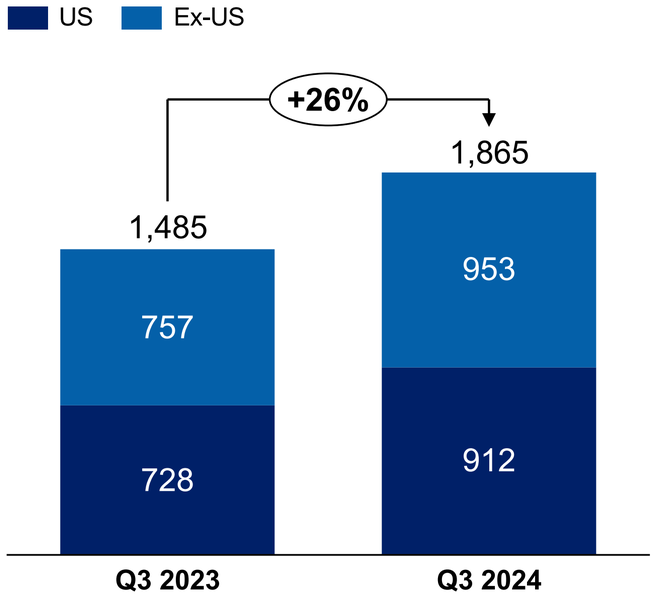
Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Entresto® sales continued to climb, increasing +26% in Q3

Entresto®

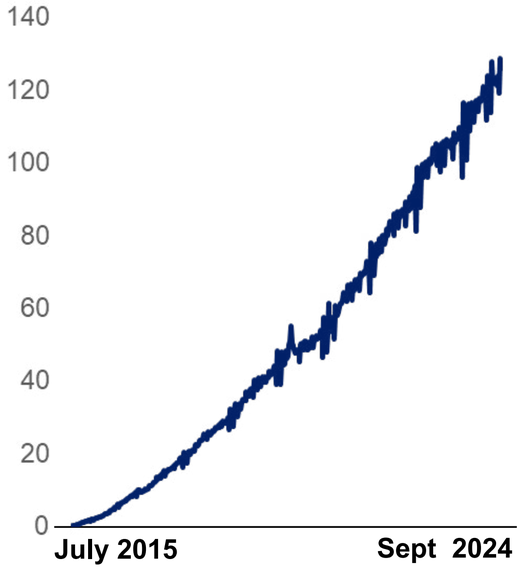
Sales evolution

USD m, % cc



US weekly TRx[1]

Total prescriptions (000)



Continued momentum in 10th year

- US: +25% with TRx growth +20%; ~45k NBRx and ~500k TRx per month
- Ex-US: +26% cc

Confidence in growth up to LoE

- Strong guideline position[2] (US/EU)
- Continued penetration in HF globally and HTN in China/Japan[3]
- US: For forecasting purposes, we assume Entresto® LoE in mid-2025[4]
- EU: RDP to Nov 2026[5]

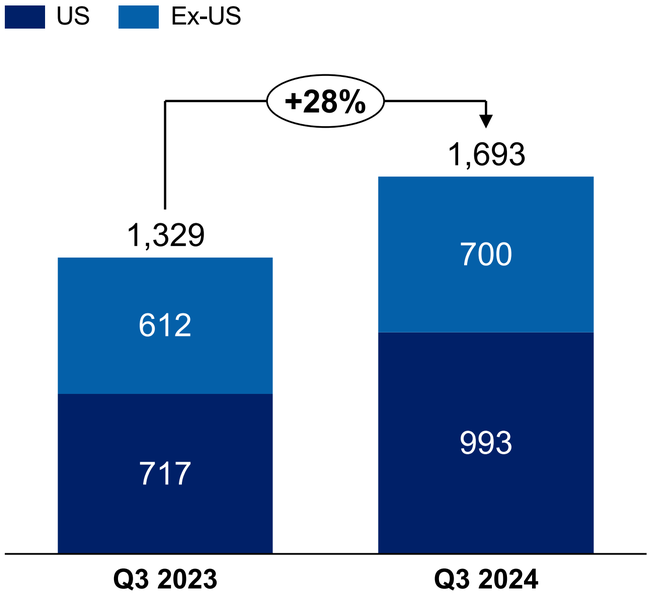
See page 70 for references (footnotes 1-5). TRx – total prescriptions. NBRx – new to brand prescription. HF – heart failure. HTN – hypertension. LoE – loss of exclusivity. RDP – Regulatory data protection. Constant currencies (cc) is a non-IFRS measure. Explanation of non-IFRS measures can be found on page 46 of Interim Financial Report.

Cosentyx® grew +28%, fueled by new launches as well as expansion in core indications

Cosentyx®

Sales evolution

USD m, % cc



Demand-driven growth across geographies

- US: +38%
- Ex-US: +16% cc

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: Accelerated adoption in US (>1,250 accounts, +52% QoQ) post permanent J-code (effective July 1)[5]

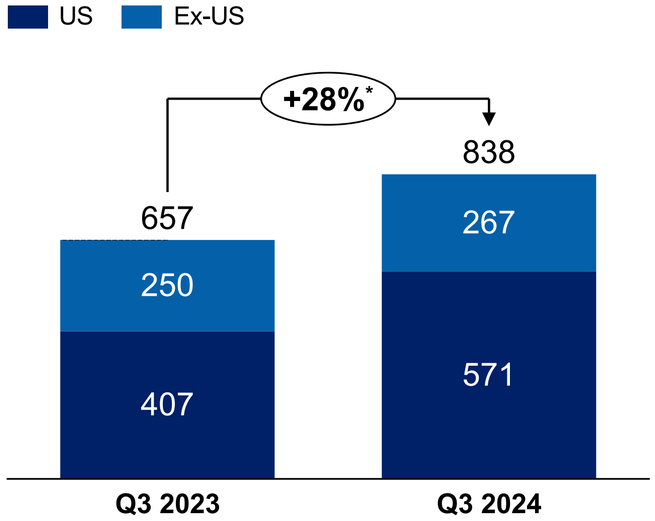
See page 70 for references (footnotes 1-5). PsO – psoriasis. PsA – psoriatic arthritis. AS – ankylosing spondylitis. nr-axSpA– non-radiographic axial spondyloarthritis. HS – Hidradenitis suppurativa. IL – interleukin. IV – intravenous. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Kesimpta® continued to see strong demand globally

Kesimpta

Sales evolution

USD m, % cc



*Without the PY one-time RD adjustment (USD 118m), sales growth **+56% cc**

Continued market share gains in key geographies

- >100k patients treated worldwide, majority naïve or first switch[1]
- US: Demand-led growth with TRx volume +38% vs PY, gaining +3.7pts share
- Ex-US: Strong underlying growth excluding one-time RD adjustment in PY[2]

New data at ECTRIMS reinforce benefits for 1L and switch patients

- ALITHIOS: Nearly 90% of 1L Kesimpta® patients had no disability progression independent of relapse activity for up to 6 years[3]
- OLIKOS: No new active lesions (Gd+ T1) 12 months after switching from anti-CD20 IV[4]

Confident in continued momentum based on compelling positioning

- First and only self-administered subcutaneous B-cell treatment option that can be dosed in 1 minute a month[5]
- To our knowledge, there are no Kesimpta® biosimilars currently in clinical development

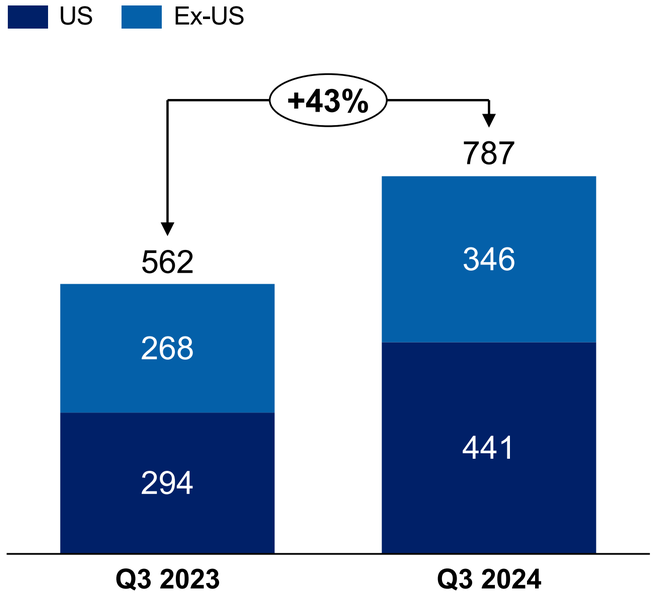
See page 70 for references (footnotes 1-4). 3. Open-label extension study. 4. US single-arm, open-label, Phase IIIb study. 5. As per stability technical specification data, when the patient is ready to inject, it typically takes less than 1 minute a month to administer. Once-monthly dosing begins after the initial dosing period, which consists of 20 mg subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA. Patient must take pen out of the refrigerator 15-30 minutes before self-administering. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Kisqali® continued to cement leadership in mBC, and launched in eBC with FDA approval and Category 1 NCCN guideline recommendation

KISQALI®

Sales evolution

USD m, % cc



US: +50% growth, gaining widespread adoption

- Leading share in mBC NBRx at 48%; now second in TRx share with 31%[1]
- 7.5k HCPs now prescribing and increasing depth, reflecting strong guideline position

Ex-US: +36% cc growth, as the preferred CDK4/6i[2]

- Leading share in mBC new starts at 43%[2]
- Fastest-growing CDK4/6i in Europe, recognized with highest ESMO-MCBS score

eBC: FDA approved with broad label; CHMP issued positive opinion

- US label includes patients with stage II and III eBC at high risk of recurrence, more than doubling the population eligible for CDK4/6i adjuvant therapy
- Category 1 preferred NCCN guidelines recommendation for full studied population

See page 70 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 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Kisqali® shows deepening benefit in eBC, reducing the risk of recurrence by 28.5% in a broad population of patients[1]

KISQALI®

NATALEE 4-year data

IDFS benefit cross pre-specified subgroups[1]

Subgroup	4-year IDFS rate, %	4-year IDFS absolute benefit, %
Intention-To-Treat Population	Kisqali® + ET: 88.5 ET alone: 83.6 (HR=0.715; 95% CI 0.609-0.840)	4.9
AJCC Tumor Stage II	Kisqali® + ET: 93.9 ET alone: 89.6 (HR=0.644; 95% CI 0.468-0.887)	4.3
AJCC Tumor Stage III	Kisqali® + ET: 84.3 ET alone: 78.4 (HR=0.737; 95% CI 0.611-0.888)	5.9
Node-negative disease	Kisqali® + ET: 92.1 ET alone: 87.0 (HR=0.666; 95% CI 0.397-1.118)	5.1

BARCELONA 2024 ESMO congress

- iDFS benefit continued to increase after completion of Kisqali treatment
- Benefit consistent across subgroups, including N0
- Consistent results across secondary endpoints, with a trend for improved OS
- No new safety signals identified

Data reinforce Kisqali's potential to address high unmet need across a broad population of eBC patients, who face significant risk of recurrence despite being treated with SoC adjuvant ET[2,3]

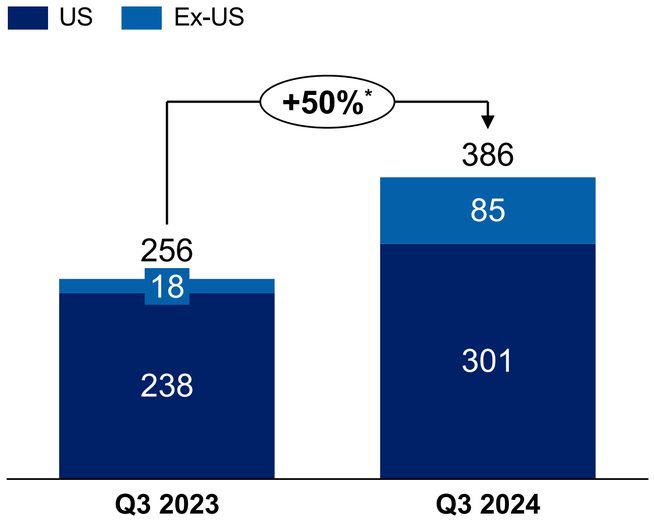
See page 71 for references (footnotes 1-3).

Pluvicto® continued steady performance in the post-taxane setting, laying the foundation for anticipated PSMAfore launch in 2025

PLUVICTO®

Sales evolution

USD m, % cc



*Without the one-time RD adjustment in Europe (USD 36m), sales growth **+36% cc**

Steady performance in Q3; Q4 expected to be broadly in line with Q3 excluding RD adjustment

- Increased US field force and launched DTC to drive HCP and patient awareness
- Continued site growth with ~530 treatment sites in the US (+6% vs PQ, +55% vs PY), expanding into community setting
- Ex-US launch progressing with pricing and reimbursement discussions; Q3 sales include one-time RD adjustment in Europe

New indications and geographies expected to accelerate growth

- PSMAfore filing accepted by FDA; preparing for launch in 2025
- China post-taxane and Japan pre/post-taxane submissions expected by YE
- PSMAddition in mHSPC and PSMA-DC in oligometastatic disease progressing
- Began construction on two new US RLT facilities to support expanding RLT portfolio

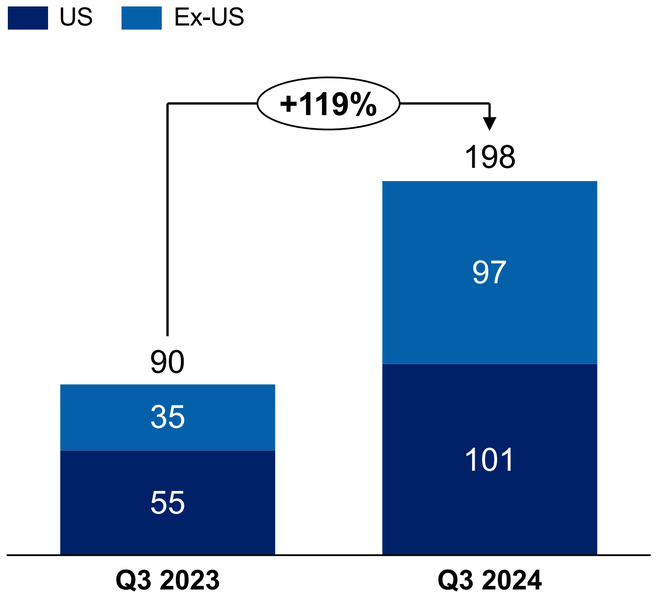
mHSPC – metastatic hormone-sensitive prostate cancer. Constant currencies (cc) is a non-IFRS measure. An explanation of non-IFRS measures can be found on page 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Leqvio® growth trend continued, with accelerating adoption ex-US

LEQVIO® (inclisiran)

Sales evolution

USD m, % cc



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

- 4,600 facilities, accounting for 30% of aLL market volume[2], have ordered Leqvio® (+7% vs PQ; +50% vs PY)
- Demand increasing across all channels (TRx +10% vs PQ; +94% vs PY)
- Targeted strategy resulting in market share gains among post-event CAD patients

Ex-US: Growth in all markets

- Now reimbursed in 39 countries, and commercially available in 73

Adding to Leqvio® body of evidence across ASCVD continuum

- Phase III V-MONO trial met primary endpoints, demonstrating superiority of Leqvio monotherapy vs both placebo and ezetimibe in LDL-C reduction[3]
- Data will be shared with HAs and presented at upcoming medical meeting

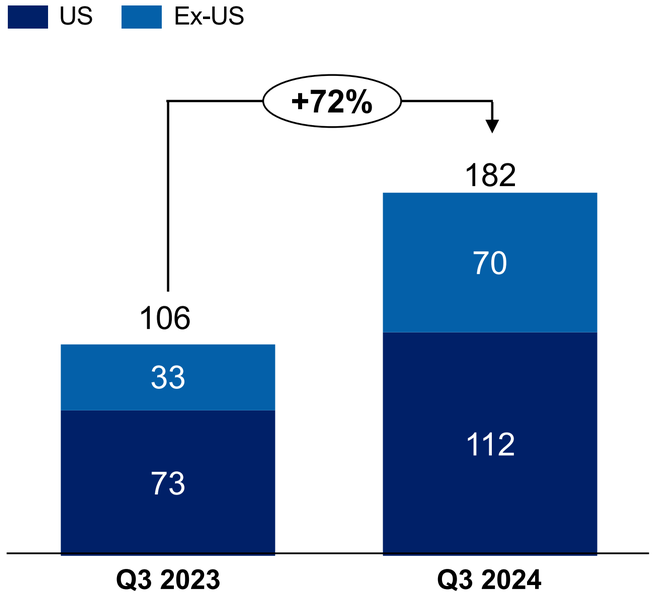
See page 71 for references (footnotes 1-3). aLL – advanced lipid lowering. CAD – Coronary Artery Disease. Constant currencies (cc) is a non-IFRS measure. An explanation can be found on page 46 of Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. Novartis obtained global rights to develop, manufacture, and commercialize Leqvio under license / collaboration agreement with Alnylam Pharmaceuticals.

Scemblix® grew +72% in Q3 as the preferred option for 3L+ CML

SCEMBLIX® (asciminib) 20 mg, 40 mg tablets

Sales evolution

USD m, % cc



Market leader in 3L+ NBRx and TRx across geographies

- US: Leader in TRx (26%) and NBRx share, driven by QoQ demand growth of 18%[1]; 9% growth in prescriber base QoQ[2]
- Ex-US: Sales continue strong trajectory (+115% cc) driven by NBRx, total market share[3] and prescriber base growth
- Continued success in 3L+ serves as strong foundation for 1L launch

Confident in 1L CML opportunity globally

- FDA granted priority review; preparing for launch in Q4
- Ex-US: China and Japan submissions completed

See page 71 for references (footnotes 1-3). CML – Chronic Myeloid Leukemia. Constant currencies (cc) is a non-IFRS measure. An explanation can be found on page 46 of Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Fabhalta® continued to see broad uptake in PNH, as the only oral monotherapy providing comprehensive hemolysis control

FABHALTA (iptacopan) 200 mg capsules

PNH: Only oral monotherapy for adults with PNH providing comprehensive control of IVH and EVH

US: Continued strong launch performance with majority of uptake from switch patients

- High compliance and continuation rate[1]
- Strong access with 70%+ coverage to label[2]
- Leading in NBRx share with >30%[3]

International: Strong initial uptake driven by DE and CN and broad prescribing HCP base

- Solid early patient activation (>175 patients) and >1k HCPs reached in first 3 months in top 3 markets[4]
- Utilization across naive and switch patients (from both C5i and C3i)[5]
- Recent launches in Japan, UK and granted early access program in France

See page 71 for references (footnotes 1-5). IVH – intravascular hemolysis. EVH – extravascular hemolysis. PNH – paroxysmal nocturnal hemoglobinuria. C5i – eculizumab and ravulizumab.

Fabhalta® received accelerated approval in the US as first and only complement inhibitor for IgAN

FABHALTA (iptacopan) 200 mg capsules

Received accelerated approval from FDA

Granted based on positive interim analysis data from APPLAUSE Ph3

Study continues to confirmatory endpoint (eGFR) at 24 months

Study completion data in 2025

Increasing HCP preference

Positive HCP feedback on efficacy and safety profile

Growing belief in the role of alternative pathway

Favorable perceptions of onboarding process

Positive early launch momentum

Rapid REMS certification of HCPs (>1k since launch)[1]

New writers and patient starts exceeding expectations

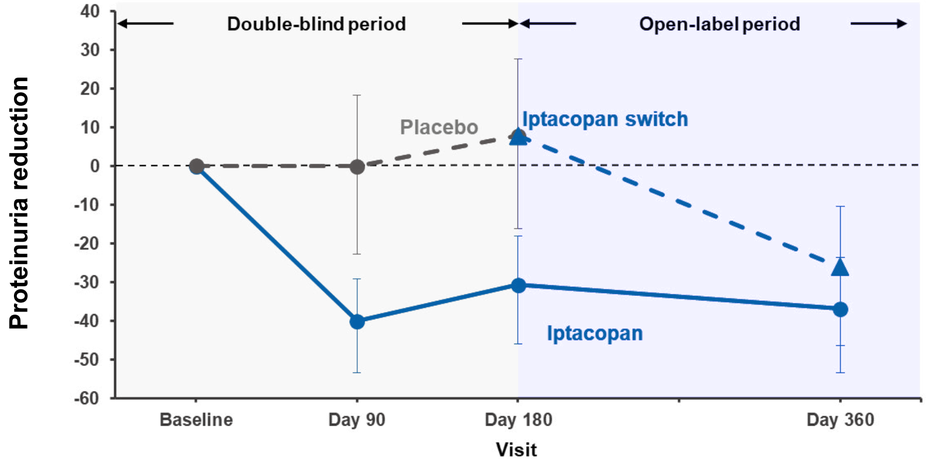
Leveraging portfolio synergies for broad/quick access

Positioning for patients with persistent proteinuria and glomerular inflammation; pricing consistent with PNH indication

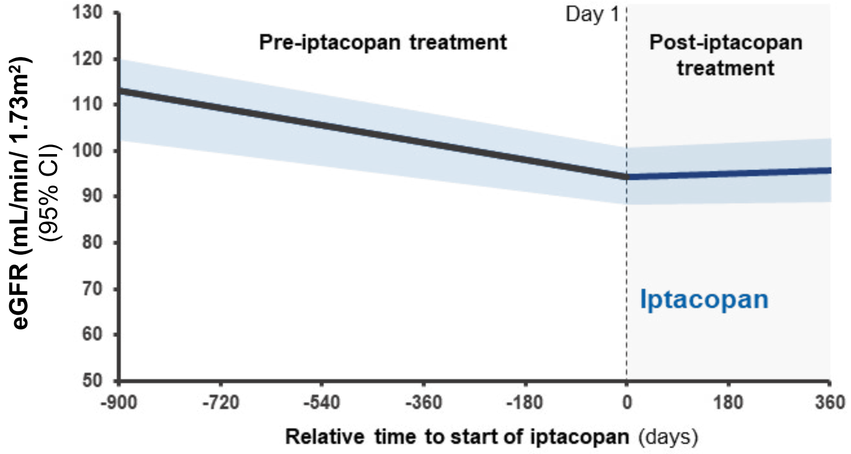
See page 72 for reference (footnote 1).

Iptacopan: 12-month APPEAR-C3G data presented at ASN[1] support global regulatory filings by year-end 2024

Change in UPCR[2] - reduction sustained over 12 months and replicated in placebo arm after switch to iptacopan



Stabilization of eGFR[3,4] - change in eGFR slope vs historic slope decline maintained over 12 months



Next steps 〉 Ongoing health authority reviews in EU and other countries. Submission expected in US by year-end.

See page 72 for references (footnotes 1-4). Iptacopan is the INN (international non-proprietary name) of Fabhalta® for unapproved indications.

Continued progress on innovation milestones in Q3

2024 selected key events (expected)

		H1 2024	H2 2024	Q3 status update
Regulatory decisions	**Fabhalta® PNH**		EU, JP	EU, JP and China approval in Q2
	Kisqali® HR+/HER2- adj.BC		US, EU	US approval in Q3; CHMP positive opinion in Q4
Submissions	**Atrasentan IgAN**	US		US submission in Q2
	Fabhalta® (iptacopan) C3G		US, EU	EU, JP and China submissions in Q3
	Fabhalta® (iptacopan) IgAN	US		US accelerated approval and China submission in Q3
	Pluvicto® mCRPC, pre-taxane		US	US submission in Q3
	Remibrutinib CSU			Ph3 REMIX-1 and -2 52-week readout in Q1; submissions expected 2025
	Scemblix® CML 1L	US	JP	FDA granted priority review; China and Japan submissions in Q3
	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)	On track
	XXB750 Hypertension		Ph2	NVS will not advance further development following current scientific assessment and review of available data
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

NOVARTIS | Reimagining Medicine

Q3 net sales grew +10% cc with core operating income up +20% cc[1]

Continuing Operations[1,2] USD million	Q3 2023	**Q3 2024**	**Change vs PY** % USD	% cc	9M 2023	**9M 2024**	**Change vs PY** % USD	% cc
Total Net Sales	11,782	12,823	9	10	34,017	37,164	9	11
Core operating income	4,405	5,145	17	20	12,551	14,635	17	20
Core margin	*37.4%*	*40.1%*	*+2.7%pts*	*+3.4%pts*	*36.9%*	*39.4%*	*+2.5%pts*	*+3.2%pts*
Operating income	1,762	3,627	106	123	7,187	11,014	53	61
Net Income	1,513	3,185	111	121	5,934	9,119	54	62
Core EPS	1.74	2.06	18	20	4.95	5.83	18	21
EPS	0.73	1.58	116	127	2.84	4.50	58	67
Free cash flow	5,043	5,965	18		11,019	12,618	15	

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 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. 2. As defined on page 35 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.

Raising 2024 sales and core operating income guidance[1]

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

Net sales

expected to grow

low double-digit

(from high single to low double-digit)

Core operating income

expected to grow

high teens

(from mid- to high teens)

Key assumptions

- We assume Tasigna®, Promacta® and Entresto® US generic entry mid-2025 for forecasting purposes[2]

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%

See page 72 for references (footnotes 1-2). Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 46 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
Multiple early-stage deals to strengthen our RLT platform, renal pipeline and AI capabilities in 9M

Substantial cash generation

Returning capital to shareholders

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

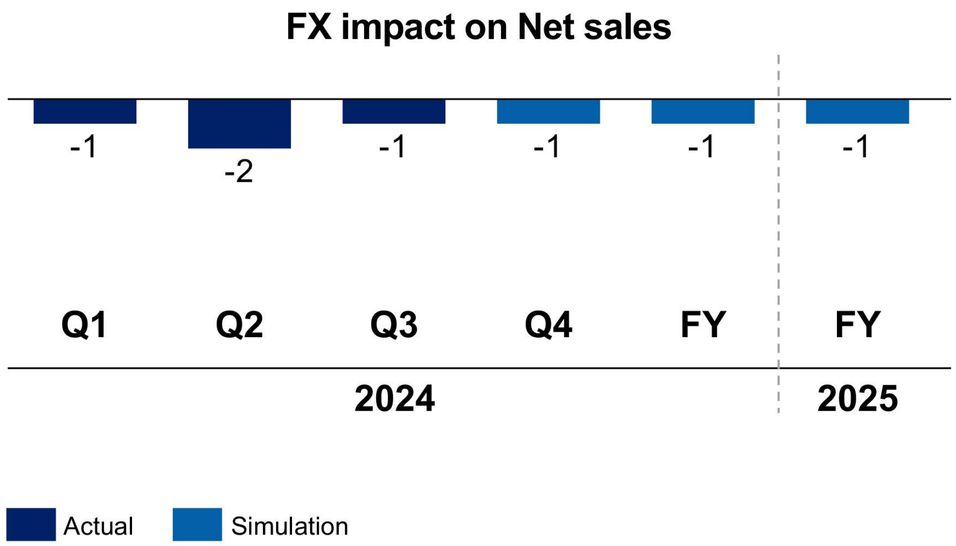
Share buybacks
Up-to USD 15bn share buyback continuing, with up to USD 7.9bn still to be executed

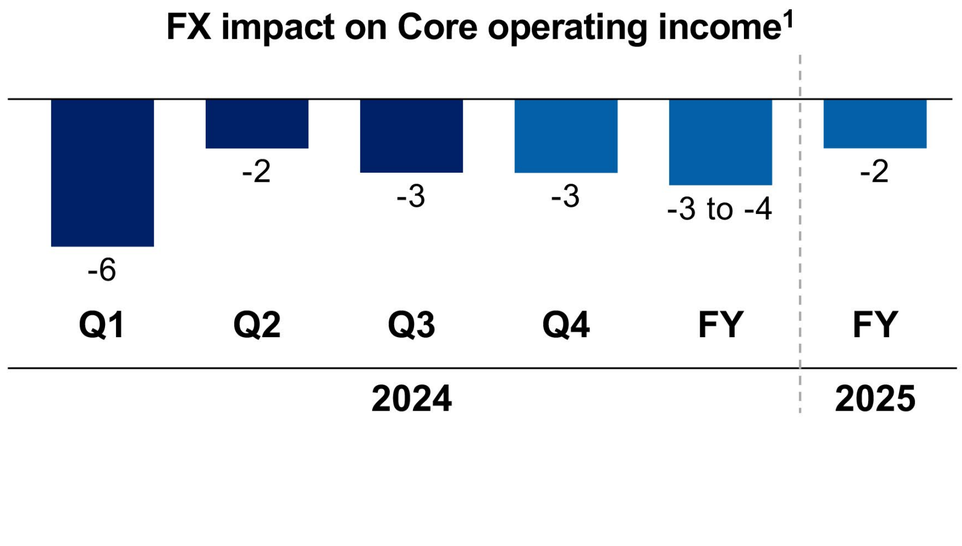
1. In CHF.

Expected currency impact for full year 2024 and 2025

Currency impact vs PY

%pts, assuming late-October exchange rates prevail in 2024 and 2025





Actual Simulation

1. Constant currencies (cc), core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 46 of the Interim Financial Report.

Conclusions

Vas Narasimhan, M.D.
Chief Executive Officer

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Continued strong business momentum in Q3, with +10% net sales growth and +20% core operating income growth

Raised FY 2024 guidance for a third time

Achieved important indication expansions for Kisqali and Fabhalta, and completed FDA submission for Pluvicto PSMAfore

On track to achieve our mid-term guidance of +5% cc sales CAGR 2023-2028, with 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 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

Join us in London for

Meet Novartis Management

November 20-21, 2024

NOVARTIS | Reimagining Medicine

Appendix

NOVARTIS | Reimagining Medicine

Our pipeline projects at a glance

	Phase 1/2	Phase 3	Registration	Total
Oncology	27	8	5	40
Solid tumors	21	3	4	28
Hematology	6	5	1	12
Immunology	18	8	0	26
Neuroscience	6	5	0	11
Cardiovascular, Renal and Metabolic	4	7	2	13
Others (thereof IB&GH)	10 (7)	4 (3)	(1)	15
	65	32	9	105

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

Novartis pipeline in Phase 1

19 lead indications

Lead indication

Oncology

Code	Name	Mechanism	Indication(s)
Solid tumors			
AAA603	^{177}Lu-NeoB	Radioligand therapy target GRPR	Breast cancer
			Glioblastoma multiforme
AAA604	AAA604	Radioligand therapy target integrin alpha-v, beta-3/beta-5	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
FXX489	^{177}Lu-NNS309	Radioligand therapy	Solid tumors
GIZ943	GIZ943	-	Solid tumors
HRO761	HRO761	Werner inhibitor	Solid tumors
IAG933	IAG933	-	Mesothelioma
ITU512	ITU512	HbF inducing agent (WIZ degrader)	Sickle cell disease
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
YTB323	rapcabtagene autoleucel	CD19 CAR-T	Multiple sclerosis

Immunology

Code	Name	Mechanism	Indication(s)
IPX643	IPX643	-	Inflammation-driven diseases
MHV370	MHV370	TLR7, TLR8 Antagonist	Systemic lupus erythematosus
PIT565	PIT565	-	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

20 lead indications

Lead indication

Oncology

Code	Name	Mechanism	Indication(s)
Solid tumors			
AAA601	Lutathera®	Radioligand therapy target SSTR	GEPNET, pediatrics
			1L ES-SCLC
			Glioblastoma
AAA603	^{177}Lu-NeoB	Radioligand therapy target GRPR	Multiple solid tumors
AAA614	AAA614	Radioligand therapy target FAP	Solid tumors
DZR123	tulmimetostat	EZH1, EZH2 inhibitor	Solid tumors & lymphomas
Hematology			
ABL001	Scemblix®	BCR-ABL inhibitor	Chronic myeloid leukemia, 2L, pediatrics
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
VHB937	VHB937	TREM2 stabilizer and activator	Amyotrophic lateral sclerosis

Cardiovascular, Renal and Metabolic

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

Immunology

Code	Name	Mechanism	Indication(s)
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	Hidradenitis suppurativa
			Systemic scleroderma
YTB323	rapcabtagene autoleucel	CD19 CAR-T	srSLE/LN

Others

Code	Name	Mechanism	Indication(s)
IB&GH			
EYU688	EYU688	NS4B inhibitor	Dengue fever
INE963	INE963	Plasmodium falciparum inhibitor)	Malaria, uncomplicated
KAE609	cipargamin	PfATP4 inhibitor	Malaria, severe
			Malaria, uncomplicated
LXE408	LXE408	Proteasome inhibitor	Visceral leishmaniasis
SEG101	Adakveo®	P-selectin inhibitor	Sickle cell disease, pediatrics
Others			
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

6 lead indications

Lead indication

Oncology

Code	Name	Mechanism	Indication(s)
Solid tumors			
AAA617	Pluvicto®	Radioligand therapy target PSMA	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, 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
			Chronic inducible urticaria
VAY736	ianalumab	BAFF-R inhibitor, ADCC-mediated B-cell depletor	Sjögren's
			Lupus Nephritis
			Systemic lupus erythematosus

Others

Code	Name	Mechanism	Indication(s)
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			
AAA601[1]	Lutathera®	Radioligand therapy target SSTR	Gastroenteropancreatic neuroendocrine tumors (GEP-NET), 1st line in G2/3 tumors
AAA617	Pluvicto®	Radioligand therapy target PSMA	Metastatic castration-resistant prostate cancer (mCRPC), pre-taxane
INC424	Jakavi®	JAK1/2 inhibitor	Acute GVHD, pediatrics
			Chronic GVHD, pediatrics
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	C3 glomerulopathy

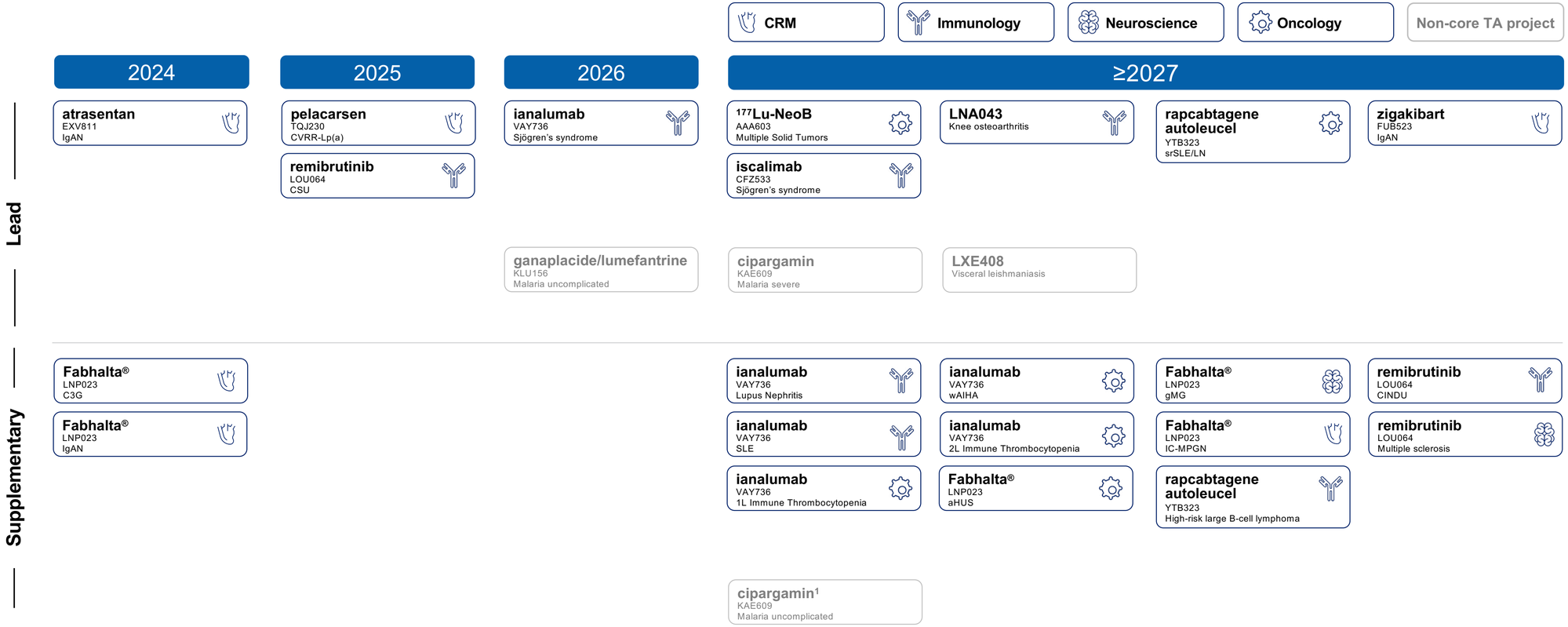
Others

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



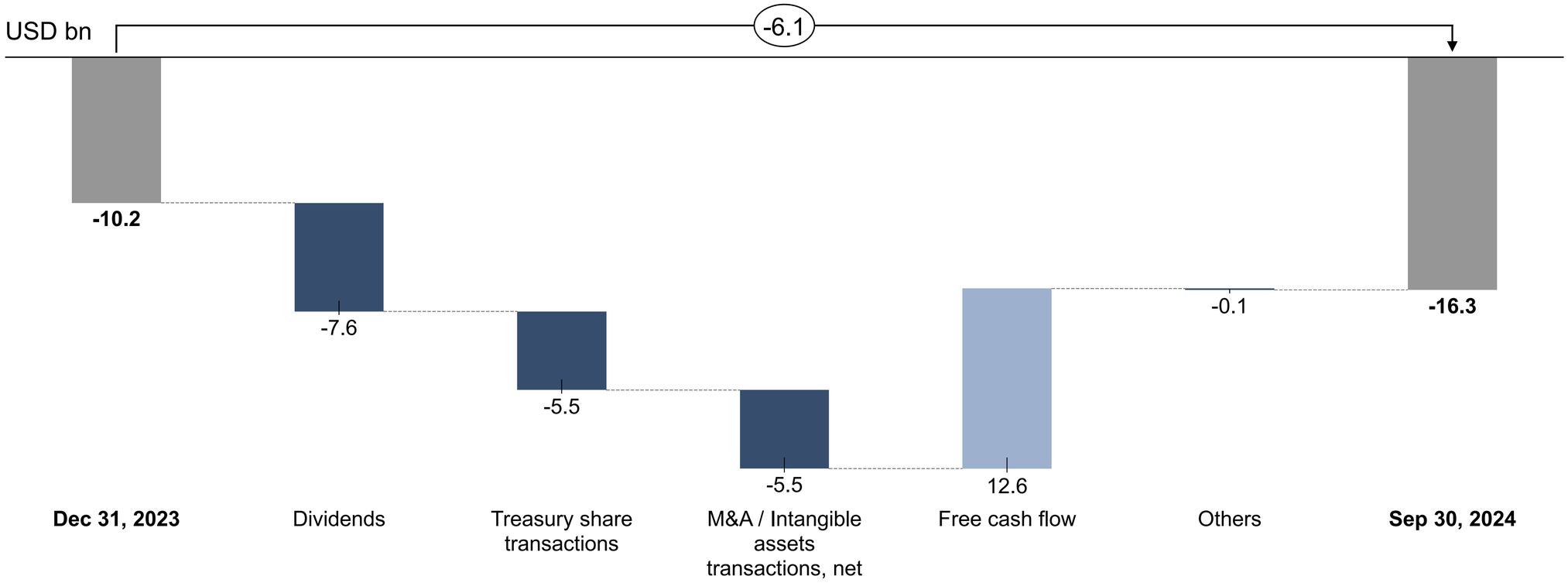
1. Part of triple combination therapy.

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 6.1bn due to the annual dividend, share buybacks 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 46 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

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

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

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 weeks data at ACAAI Nov 2023 52 weeks 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 weeks data at ACAAI Nov 2023 52 weeks 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 120 participants with multiple sclerosis which will include at least 5 participants with body weight (BW) ≤40 kg and at least 5 participants with age 10 to 12 years in each of the ofatumumab and siponimod arms. There is a minimum 6 month follow up period for all participants (core and extension). Total duration of the study could be up to 7 years.
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	Age descending treatment evaluating IV KAE609 doses versus active comparator, IV Artesunate. Follow on therapy for all arms: 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, 2 dispersible 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 (ganaplacide/ lumefantrine) is the fixed dose combination 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 1/3

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	Timing of Entresto US generic entry is subject to ongoing patent and regulatory litigation.
5	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 and SpA combined. Source: IQVIA National Source of Business (NSOB) YTD September 6, 2024.
2	Refers to EU5. Indications: Pso, PsA, axSpA. Source: DE: IQVIA LRx; FR: IQVIA Ltd; UK: IQVIA Analyzer, Stethos; IT: Stethos, Elma (June 2024); ES: IQVIA, Amber Market Research (April 2024 data extrapolated to June).
3	Hospital value share. Market definition includes all approved immunology brands with at least one indication overlapping with Cosentyx" Source: IQVIA China Immunology Market Value Share (August 2024).
4	US, DE, UK, FR, ES, AU. Source: IQVIA.
5	IV formulation indication: PsA, AS, nr-axSpA. Source: IQVIA mastered 867 data.

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	Bar-Or et al. Early Initiation of Ofatumumab Delays Disability Progression in People With Relapsing Multiple Sclerosis: 6-Year Results From ALITHIOS Open-Label Extension Study. Poster P058 presented at the 40th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, Copenhagen, Denmark; 18–20 September 2024.
4	Hua et al. Efficacy and Safety in Patients with Relapsing Multiple Sclerosis Who Switched to Subcutaneous Ofatumumab From Intravenous Anti-CD20 Therapies: Results From the US single-arm, open-label, Phase IIIb OLIKOS Study. Poster P405 presented at the 40th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, Copenhagen, Denmark; 18–20 September 2024.

Kisqali® (slide 9 references)

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

References 2/3

Kisqali® (slide 10 references)

1	Fasching PA. Adjuvant Ribociclib (RIB) Plus Nonsteroidal Aromatase Inhibitor (NSAI) in Patients (Pts) With HR+/HER2− Early Breast Cancer (EBC): 4-Year Outcomes From the NATALEE Trial. LBA13. Proffered Paper presented at the European Society for Medical Oncology Congress, September 16, 2024. Barcelona, Spain.
2	Pan H, Gray R, Braybrooke J, et al. 20-Year Risks of Breast-Cancer Recurrence after Stopping Endocrine Therapy at 5 Years. N Engl J Med. 2017;377(19):1836-1846.
3	Yardley D et al. Baseline (BL) characteristics and efficacy endpoints for patients (pts) with node-negative (N0) HR+/HER2− early breast cancer (EBC) in NATALEE. Presented at the American Society of Clinical Oncology Annual Meeting, May 31, 2024. Chicago, USA..

Leqvio® (slide 12 references)

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

Scemblix® (slide 13 references)

1	US: June rolling 3-months US IQVIA CML market sizing report (September 2024).
2	July-August data; QoQ comparison vs April-May.
3	Ex-US (EU4 :IQVIA Oncology Dynamics + JP:MDV + DE: LRx).

Fabhalta® (slide 14 references)

1	Commercial Specialty Pharmacy Data, September 2024.
2	Novartis internal data.
3	VEEVA claims data, January 2023 - May 2024.
4	DE, CN, JP.
5	Fabhalta HCP ATUs, September 2024.

References 3/3

Fabhalta® (slide 15 references)

1 United BioSource LLC. Generally, a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

Iptacopan (slide 16 references)

1 ASN 2024 presentation Smith R., et al.

2 Primary endpoint. Model estimated geometric mean of ratio to baseline in % change (95% CI) in proteinuria measured via 24-hour UPCR.

3 Exploratory endpoint.

4. eGFR slopes per year analyzed using a linear mixed effects model including time (analysis day before or after change point (day 1 of iptacopan treatment) as a continuous covariate, participant-level intercept and slope (time) as random effects. Intercurrent events handled with a treatment policy strategy.

Guidance (slide 20 references)

1 Constant currencies (cc) and core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 46 of the Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY.

2 Timing of Entresto US generic entry is subject to ongoing patent and regulatory litigation.