# Novartis Strategy & Growth Update

Vas Narasimhan, CEO J.P. Morgan Healthcare Conference January 8, 2024



Reimagining Medicine



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## Novartis differentiated profile offers an attractive shareholder value creation opportunity

#### **Focused strategy**

Pure-play innovative medicines with 4 core therapeutic areas and 2+3 technology platforms

Substantial cash generation; focusing on **bolt-on M&A/BD&L**, **strong and growing dividend**, **and SBB** 

#### **Attractive growth prospects**

Strong 2023, raising full year guidance 3 times

Upgraded mid-term sales guidance to **+5% CAGR** (2022-2027); **mid-single-digit** beyond

Increasing core margin to ~40%+ by 2027

#### Robust pipeline

10 positive Ph3 readouts/presentations in past year Focused pipeline on 83 projects<sup>1</sup> in areas of high unmet need

>15 key submissions planned 2024-27

#### **ESG** leader

**Focus on material factors** to create value: innovation, access to medicines and human capital

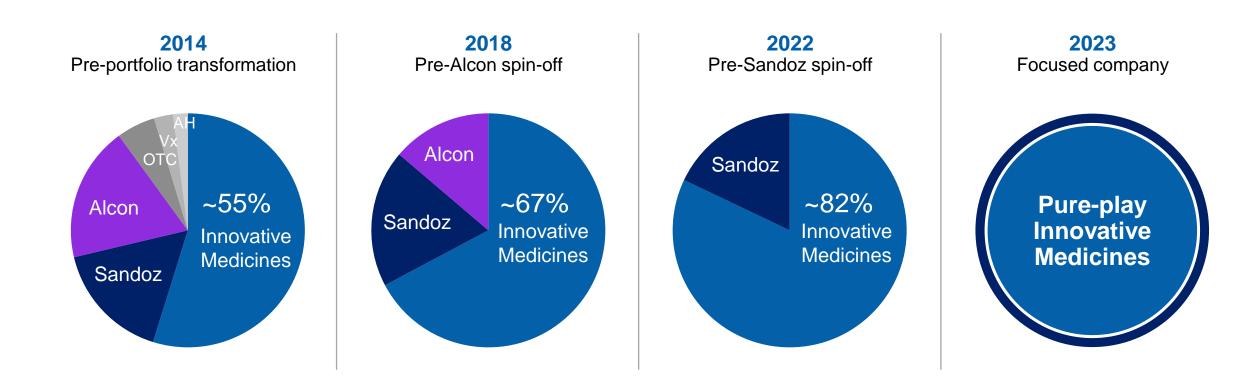
#1 in Sustainalytics<sup>2</sup>; leaders in ATMI (reaching >250m patients); AA in CDP climate and water

1. Confirmatory development projects. 2. Pharmaceuticals subindustry group. ATMI – Access to Medicines Index.

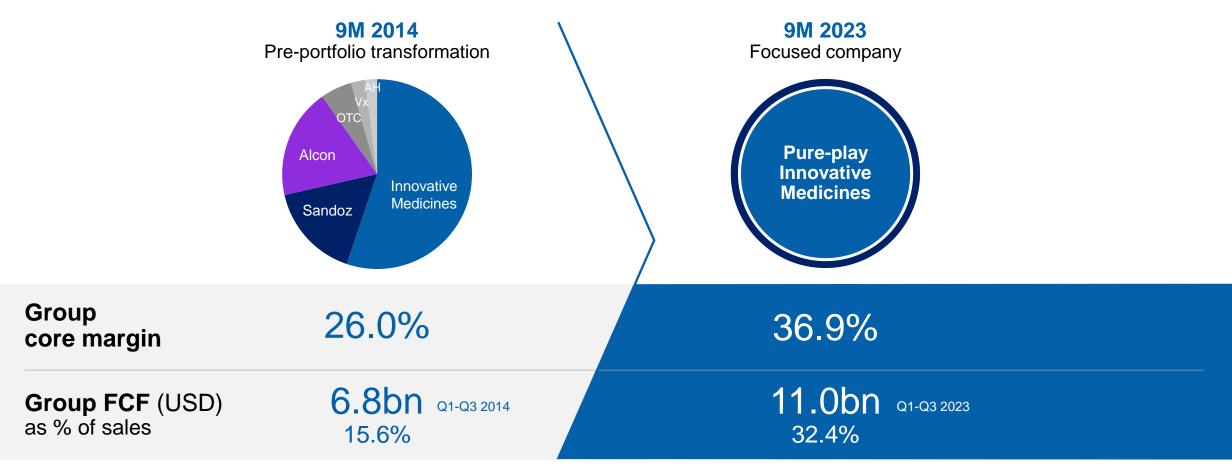
SBB – Share Buyback.



### Novartis transformation into a pure-play innovative medicines company...



### ... has delivered substantial increases in core margin and FCF...

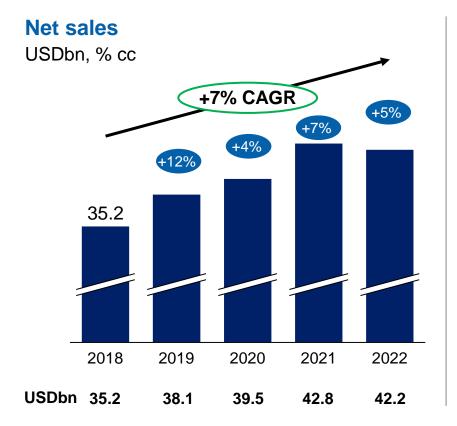


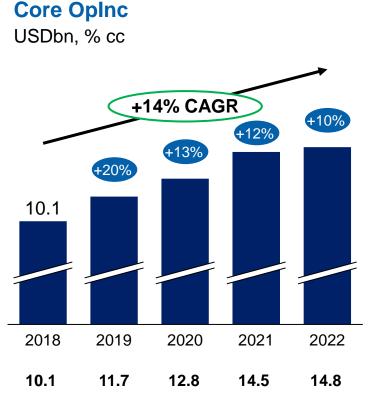
9M 2014 figures reflecting revised free cash flow definition, 2023 figures reflect Continuing Operations.

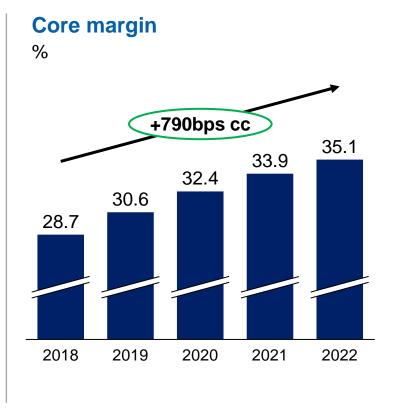


## ... while continuing to deliver strong operational performance within the single Innovative Medicines division (continuing operations)

Continuing operations performance, numbers restated post-Sandoz spin-off







### We remain committed to executing our focused strategy...

Deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in R&D and novel access approaches

#### **Focus**

#### 4 core Therapeutic areas

Cardiovascular-Renal-Metabolic, Immunology, Neuroscience, Oncology

#### 2 + 3 technology platforms

Chemistry, Biotherapeutics xRNA, Radioligand, Gene & Cell Therapy

#### 4 priority geographies

US, China, Germany, Japan

#### **Priorities**

### Accelerate growth and deliver returns



Deliver **high-value medicines** (including launch excellence)

## Strengthen foundations



Unleash the power of our people

Scale data science and technology

Build trust with society

#### **Execution**

## Delivering through operational excellence



Driving efficiencies and agile resource allocation

Improving R&D productivity

### ... and continuing to create significant shareholder value

#### **Investing in the business**

#### Returning capital to shareholders

#### Investments in organic business

R&D >USD 45bn, CAPEX >USD 5bn 2018-Sep 20231

Value-creating bolt-ons

>USD 33bn 2018-2023

Substantial cash generation

#### Consistently growing annual dividend<sup>2</sup>

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

#### Share buybacks

>USD 32bn 2018-2023

New up-to USD 15bn SBB ongoing since Jul 2023 with just under USD 13bn to be executed

#### Whilst also creating shareholder value via numerous strategic actions

Jun 2018

Divested consumer
health JV

Apr 2019
Spun Alcon

Nov 2021 **Exited Roche stake** 

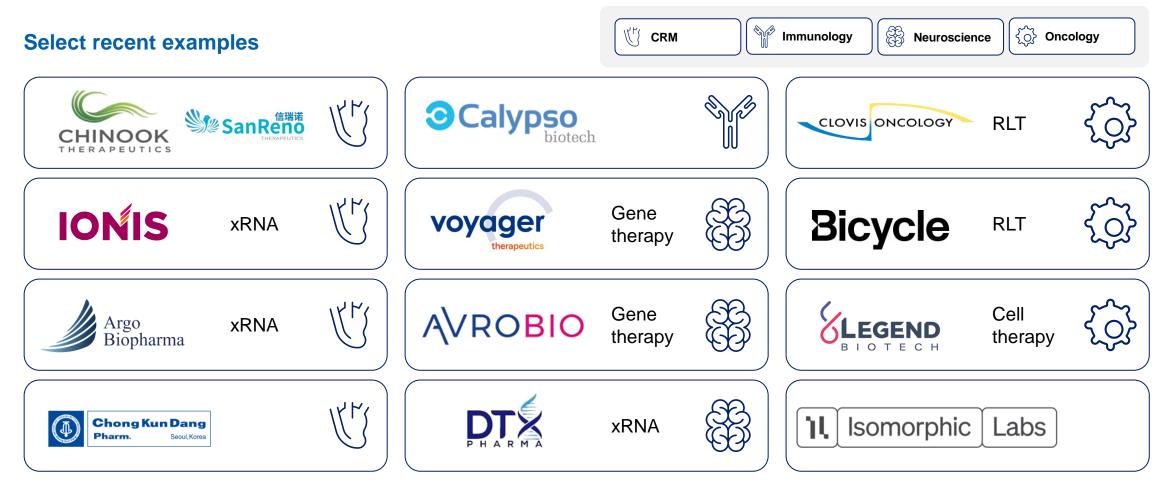
Oct 2023

Spun Sandoz

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



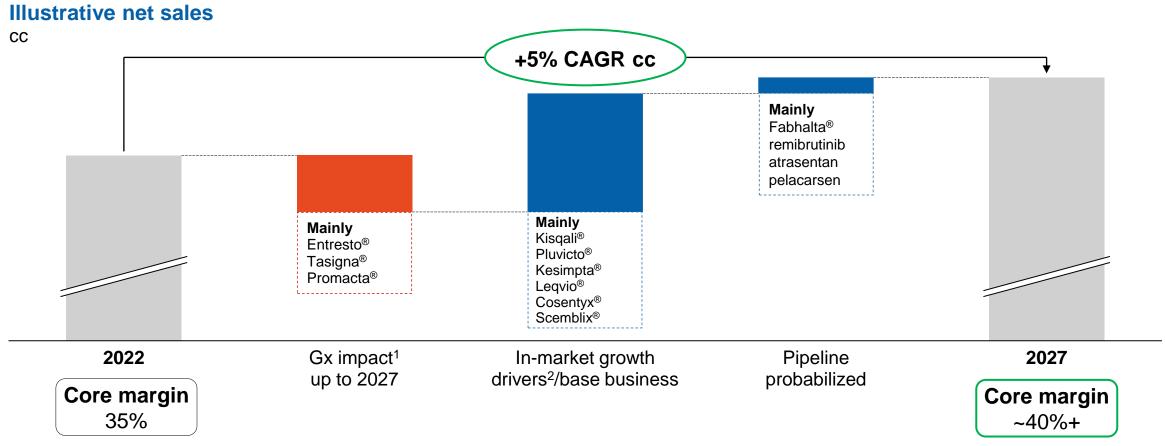
## We have signed >15 strategic deals during the last year, totaling >6bn USD, to enhance our pipeline across core therapeutic areas and technology platforms



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



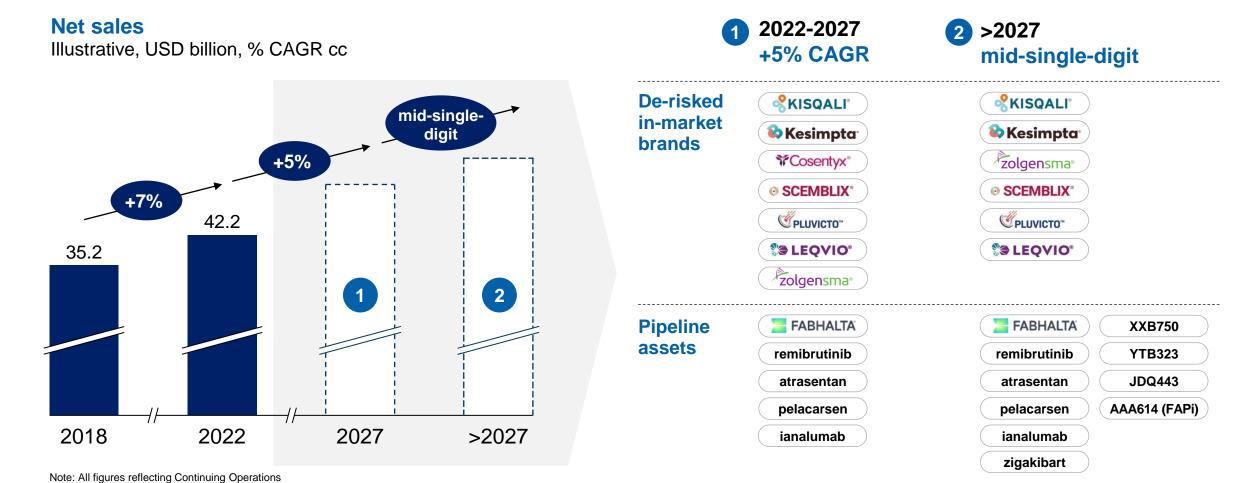
## Expect to deliver mid-term sales CAGR of +5% and core margin of ~40%+, mainly driven by de-risked in-market brands...



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



### ... which will also be the foundation for mid-single-digit growth beyond 2027





### 6+ currently marketed brands with multi-billion USD potential...

#### Q3 2023 sales annualized (selected brands)

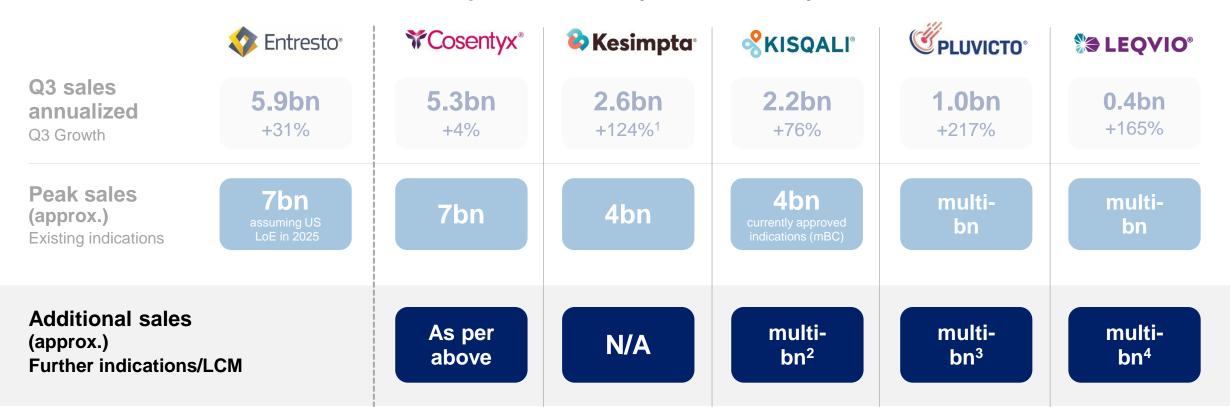
USDbn, Q3 growth in cc	Entresto®	<b>∜</b> Cosentyx®	<b>№</b> Kesimpta <sup>®</sup>	<b>≪</b> KISQALI°	<b>PLUVICTO</b> °	<b>\$</b> LEQVIO®
Q3 sales annualized Q3 Growth	<b>5.9bn</b> +31%	<b>5.3bn</b> +4%	<b>2.6bn</b> +124% <sup>1</sup>	<b>2.2bn</b> +76%	<b>1.0bn</b> +217%	<b>0.4bn</b> +165%
Peak sales (approx.) Existing indications	<b>7bn</b> assuming US LoE in 2025	7bn	4bn	4bn currently approved indications (mBC)	multi- bn	multi- bn

<sup>1.</sup> Without a one-time revenue deduction adjustment recorded in Q3, sales growth +86% cc.



### ... with additional upside from indication expansion

#### With expected exclusivity to 2030 and beyond



<sup>1.</sup> Without a one-time revenue deduction adjustment recorded in Q3, sales growth +86% cc. 2. Adjuvant, early HR+/HER2- breast cancer. 3. Pre-taxane metastatic castration-resistant prostate cancer, metastatic hormone-sensitive prostate cancer, Oligometastatic prostate cancer. 4. CVRR-LDLC, secondary & primary prevention.



## We have a strong presence and expertise in the therapeutic and disease areas we focus on...

Select examples	Cardiovascular, Renal and Metabolic	Immunology	Neuroscience	Oncology
Disease areas (selected)	<ul><li> Heart failure &amp; hypertension</li><li> Atherosclerosis</li><li> Rare renal, acute kidney injury</li></ul>	<ul> <li>Psoriasis, Psoriatic arthritis</li> <li>Spondylitis/Spondylarthritis</li> <li>HS, CSU, CINDU</li> <li>Sjögren's, SLE, LN</li> <li>Food Allergy</li> </ul>	<ul> <li>Multiple sclerosis</li> <li>Neurodegeneration (Alzheimer's, Parkinson's)</li> <li>Neuromuscular (building on Spinal Muscular Atrophy, including ALS)</li> </ul>	<ul> <li>Breast cancer</li> <li>Prostate cancer</li> <li>Lung cancer</li> <li>CML, NHL, MM, AML, MDS</li> <li>PNH, ITP, wAIHA</li> </ul>

### ... supported by anchor brands within each therapeutic area...

Select examples	Cardiovascular, Renal and Metabolic	Immunology	Neuroscience	Oncology
Disease areas (selected)	<ul> <li>Heart failure &amp; hypertension</li> <li>Atherosclerosis</li> <li>Rare renal, acute kidney injury</li> </ul>	<ul> <li>Psoriasis, Psoriatic arthritis</li> <li>Spondylitis/Spondylarthritis</li> <li>HS, CSU, CINDU</li> <li>Sjögren's, SLE, LN</li> <li>Food Allergy</li> </ul>	<ul> <li>Multiple sclerosis</li> <li>Neurodegeneration (Alzheimer's, Parkinson's)</li> <li>Neuromuscular (building on Spinal Muscular Atrophy, including ALS)</li> </ul>	<ul> <li>Breast cancer</li> <li>Prostate cancer</li> <li>Lung cancer</li> <li>CML, NHL, MM, AML, MDS</li> <li>PNH, ITP, wAIHA</li> </ul>
Anchor brands	Entresto®	**Cosentyx*	Kesimpta <sup>®</sup> Zolgensma <sup>®</sup>	SKISQALI° LUTATHERA°  ©PLUVICTO™ © SCEMBLIX°

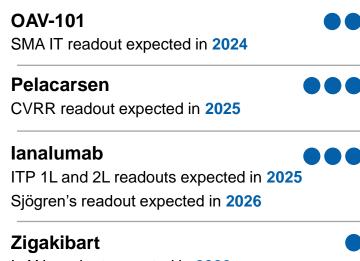
### ... and a robust pipeline with submissions by 2027

Select examples	Cardiovascular, Renal and Metabolic	Immunology	Neuroscience	Oncology
Disease areas (selected)	<ul><li>Heart failure &amp; hypertension</li><li>Atherosclerosis</li><li>Rare renal, acute kidney injury</li></ul>	<ul> <li>Psoriasis, Psoriatic arthritis</li> <li>Spondylitis/Spondylarthritis</li> <li>HS, CSU, CINDU</li> <li>Sjögren's, SLE, LN</li> <li>Food Allergy</li> </ul>	<ul> <li>Multiple sclerosis</li> <li>Neurodegeneration (Alzheimer's, Parkinson's)</li> <li>Neuromuscular (building on Spinal Muscular Atrophy, including ALS)</li> </ul>	<ul> <li>Breast cancer</li> <li>Prostate cancer</li> <li>Lung cancer</li> <li>CML, NHL, MM, AML, MDS</li> <li>PNH, ITP, wAIHA</li> </ul>
Anchor brands	Entresto®	**Cosentyx®	Kesimpta <sup>®</sup> Zolgensma <sup>®</sup>	RISQALI° LUTATHERA°  © PLUVICTO™ © SCEMBLIX°
Assets with planned	iptacopan, atrasentan, zigakibart	Cosentyx® Multiple indications	<b>Zolgensma</b> ® SMA IT	Kisqali® HR+/HER2-BC (adjuvant)
submission by 2027	iptacopan c3G	remibrutinib CSU, CINDU	remibrutinib Multiple sclerosis	Pluvicto® mCRPC pre-taxane, mHSPC
(selected)	pelacarsen CVRR-Lp(a)	ianalumab Sjögren's		Scemblix® CML 1L
	<b>Leqvio</b> ® Ped Hyperlipidemia, CVRR-LDLC			Fabhalta <sup>®</sup> (iptacopan)

### Over the past year, we delivered 10 positive Ph3 readouts/presentations<sup>1</sup> on assets with significant sales potential

#### **Select examples**





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

Event-driven trial endpointUS submission for accelerated approval.



<sup>1.</sup> Kisqali NATALEE, Pluvicto PSMAfore, Fabhalta APPOINT-PNH, iptacopan APPLAUSE-IgAN, iptacopan APPEAR-C3G, atrasentan ALIGN, remibrutinib CSU REMIX-1 and REMIX-2, Lutathera NETTER-2, Scemblix ASC4FIRST.

### Kisqali<sup>®</sup>: Ph3 NATALEE study shows robust benefit across broad population of eBC patients, regardless of disease stage, menopausal or nodal status

Robust efficacy	HR	95% CI
√ iDFS – total population	0.75	(0.63, 0.89)
√ iDFS – stage II	0.70	(0.50, 0.99)
√ iDFS – stage III	0.76	(0.62, 0.93)
√ iDFS – node negative	0.72	(0.41, 1.27)
√ iDFS – node positive	0.76	(0.63, 0.91)
✓ DDFS	0.75	(0.62, 0.90)
OS	0.89	(0.66, 1.20)

#### **Favorable safety**

- ✓ No new safety signals
- √ 3-year regimen of ribociclib 400mg well tolerated in eBC
- Incidence of most frequently observed AEs was stable with additional follow-up,
- ✓ No AESIs or clinically relevant AEs increased >1%
- ✓ Only 0.8% increase in discontinuations in updated analysis

Filed with EMA in Q3 2023, and submitted to FDA in Q4 2023

Unprobabilized estimated peak sales of all asset indications in late-stage development:



Data presented at San Antonio Breast Cancer Symposium, December 2023.



### Pluvicto<sup>®</sup>: Ph3 PSMAfore study shows robust efficacy with favorable safety and quality of life compared to daily oral ARPI in pre-taxane mCRPC

#### Robust efficacy

#### Pluvicto® vs. ARPI arm

Robust Cilibaby	Tidvioto VS. Aiti Tallii
√ rPFS¹	HR <b>0.41</b> (0.29, 0.56)
✓ Median rPFS²	<b>12.0</b> vs. 5.6 months
✓ PSA50 response	<b>57.6%</b> vs. 20.4%
√ Time to SSE	HR <b>0.35</b> (0.22, 0.57)
✓ ORR³	<b>50.7%</b> vs. 14.9%
√ Time to worsening (FACT-P <sup>4</sup> )	HR <b>0.59</b> (0.47, 0.72)
√ Time to worsening (BPI-SF <sup>5</sup> )	HR <b>0.69</b> (0.56, 0.85)
Crossover-adjusted OS	HR <b>0.80</b> (0.48, 1.33)
Unadjusted OS (84% crossover)	HR 1.16 (0.83, 1.64)

#### Favorable safety profile

- √ Vast majority of AEs low-grade
- Grade 3-4 AEs: 33.9% Pluvicto® vs. 43.1% ARPI
- SAEs: 20.3% Pluvicto® vs. 28.0% ARPI
- ✓ AEs leading to discontinuation<sup>6</sup>: 5.7% vs. 5.2%
- ✓ AEs leading to dose adjustment<sup>6</sup>: 3.5% vs. 15.1%
- ✓ Renal toxicity SAEs<sup>6</sup>: acute kidney injury 0.9% vs. 1.3%; hematuria 0% vs. 1.3%

Overall exposure to Pluvicto® ~2.000 patient-vears

(including VISION, PSMAfore and post-marketing experience)

#### FDA submission expected in 2024, with ~75% information fraction on OS

Unprobabilized estimated peak sales of all asset indications in late-stage development:



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



## Fabhalta® (iptacopan): Ph3 APPLY and APPOINT studies raise the bar for efficacy and safety in PNH

		APPOINT Adult PNH patients naive to complement inhibitor therapy		APPLY Adult PNH patients with residual anemia (Hb<10g/dL) despite treatment with anti-C5s		
	Improved hemoglobin levels	92.2% Hb ≥2g/dl increase from baseline	<b>62.8%</b> Hb level ≥12g/dl	82.3% Hb ≥2g/dl increase from baseline vs. 2% with C5i	68.8% Hb level ≥12g/dl vs. 1.8% with C5i	
	Lower need for transfusions	97.6% RBC transfusion avoidance		94.8% RBC transfusion avoidance vs.	. 25.9% with C5i	
0	Improved QoL and safety	Reduced patient-reported	d fatigue   Demonstrated sa	afety with no serious breakth	rough hemolysis <sup>1</sup>	

> Fabhalta approved for PNH in US, filed with EMA in Q2 2023

Unprobabilized estimated peak sales of all asset indications in late-stage development:



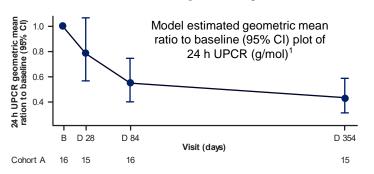
1. During the 24-week core treatment period.



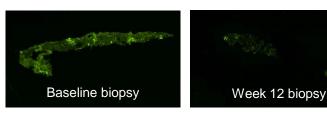
## Iptacopan: Ph3 APPEAR study demonstrates clinically meaningful and statistically significant proteinuria reduction in patients with C3G

#### Ph2 showed sustained benefits up to 1 year

Primary endpoint native kidney

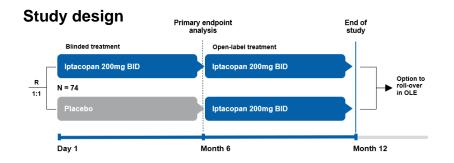


Primary endpoint transplanted kidney<sup>2</sup>



#### Ph3 met primary endpoint<sup>3</sup>

- Clinically meaningful and statistically significant proteinuria reduction at six-month analysis
- Safety profile consistent with previously reported data
- Data will be discussed with global HAs and presented at an upcoming medical meeting



C3G submissions expected in 2024

RoE – Roll-over extension. UPCR – urine protein creatinine ratio. CI – confidence interval. 1. ASN 2022 poster. 2. Kidney biopsy baseline → Week 12 C3 Deposit Score. Wong EK, et al. ePoster ASN 2021. 3. December 202:



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

Assets	2021	2022	2023	2024	2025	2026+	Comments
Iptacopan	Ph3 - A	APPLAUS	SE	*			Positive clinically meaningful IA <sup>1</sup> (primary endpoint)
Atrasentan	Ph3 - A	ALIGN		*			Positive clinically meaningful IA <sup>1</sup> (primary endpoint)
Zigakibart			F	Ph3 – BE\	OND <sup>2</sup>		UPCR submission-enabling readout expected 2026

US submission for accelerated approval

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

Unprobabilized estimated peak sales of all asset indications in late-stage development: Iptacopan 🔵 🔵 > USD 3bn Atrasentan 🔵 > USD 1bn Zigakibart 🔵 > USD 1bn

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



## Remibrutinib: Ph3 REMIX-1 and REMIX-2 studies show robust efficacy and significant symptom improvement as early as week 2 in CSU

Robust efficacy		remibrutinib vs. placebo REMIX-1/REMIX-2		
	mprovements in urticaria activity statistically significant	UAS7¹ (urticaria)	-6.32/-7.86	
	mprovements in itch statistically significant	ISS7¹ (itch)	-2.68/-3.32	
~	mprovements in hives statistically significant	HSS7 <sup>1</sup> (hives)	-3.65/-4.55	
		p<.0	01	

Symptom improvement as early as week 2		% of remibrutinib patients REMIX-1/REMIX-2		
<b>✓</b>	Significant symptom improvement as early as week 2 and sustained up to week 12	UAS7≤6²	33.3/30.0	
✓	~1/2 of patients had well-controlled disease at week 12	UAS7≤6³	50.2/47.5	
<b>✓</b>	~1/3 of patients were free of itch and hives at week 12	UAS7=0 <sup>3</sup>	31.1/27.9	
		p<	.001	

#### > CSU submissions expected in 2024

Unprobabilized estimated peak sales of all asset indications in late-stage development:



> USD 3bn

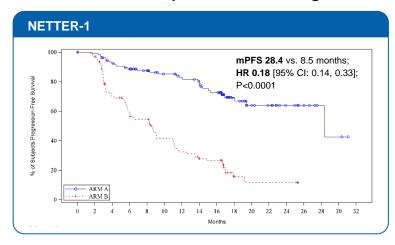
Originally presented at ACAAI annual meeting 2023. Full analysis set imputed data. 1. Change from baseline at week 12, treatment difference in least squares mean remibrutinib vs. placebo. 2. Week 2, using a logistic regression model.



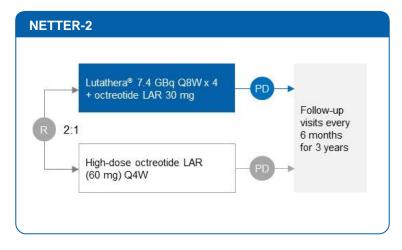
## Lutathera®: Ph3 NETTER-2 results highlight the potential for radioligand therapy (RLT) in early GEP NET tumors

#### **Maximize NET**

NETTER-1: FDA awarded broad label allowing use in GEP NET independent of line or grade



NETTER-2: New Ph3 study met primary endpoint in 1L G2/G3 GEP NET



#### **Go Beyond NET**

Potential to improve SoC in high unmet need diseases



#### SCLC

Neuroendocrine origin, like NET Highly sensitive to radiation



#### **GBM**

In clinic for ndGBM and rGBM Potential to establish new SoC in combo with EBRT+TMZ (induction) followed by combo with TMZ (maintenance)

#### GEP-NET 1L G3 EU submission expected in 2024

GBM – glioblastoma. SCLC – small cell lung cancer.

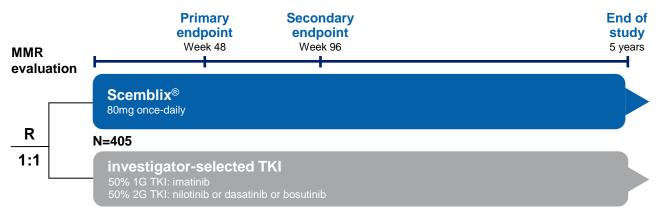


### Scemblix®: ASC4FIRST pivotal head-to-head trial in 1L CML-CP demonstrated clinically meaningful benefits vs SoC TKIs

#### Both primary endpoints<sup>1</sup> met

- Scemblix showed clinically meaningful and statically significant improvements in MMR rate vs. SoC TKIs
- Favorable safety and tolerability profile with fewer AFs and treatment discontinuations vs. SoC TKIs and no new safety signals observed
- Data will be presented at an upcoming medical congress

#### **Study design**



Achievement of MMR (BCR-ABL1 ≤ 0.1%) is associated with higher rates of EFS, PFS and OS<sup>2</sup>

**Population:** Newly diagnosed adult patients with CML-CP with no prior TKI

CML-CP 1L submission expected in 2024

Unprobabilized estimated peak sales of all asset indications in late-stage development:

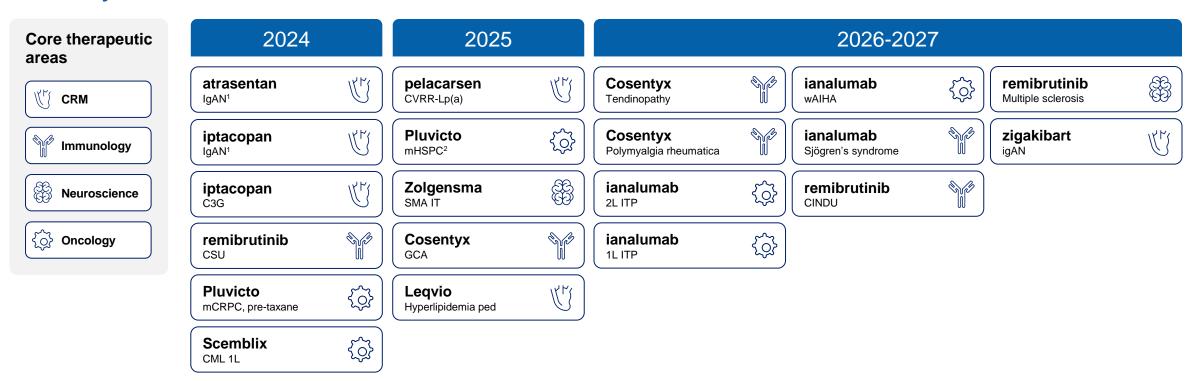


CML-CP – chronic myeloid leukemia in chronic phase. MMR – major molecular response (BCR-ABL 1IS ≤0.1%). SoC – Standard of care. TKI – tyrosine kinase inhibitor. 1. Primary endpoints: (1) Superiority of Scemblix vs. investigator choice TKI and/or (2) superiority of Scemblix vs. imatinib subgroup alone, both endpoints as assessed by MMR at 48 weeks 2. Saussele S et al. Leukemia; 32(5):1222-8; 2018; Hochhaus et al., Leukemia; 34:966-84, 2020.



### Expect to deliver >15 key submissions in core therapeutic areas by 2027

#### **Select key assets submission schedule**

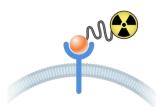


<sup>1.</sup> US submission for accelerated approval. 2. Event-driven trial endpoint



## Advancing three breakthrough technology opportunities that could potentially unlock substantial mid-to-long-term growth for Novartis

## Radioligand therapies in solid tumors

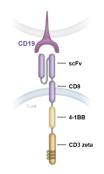


RLT therapies achieving **better efficacy** with **lower side effects** e.g. prostate, neuroendocrine

Promising platform due to more effective patient selection (imaging) and precision targeting tumor cells

Significant market opportunity with **potential in other solid tumors**: e.g. lung, breast, GI

## CAR-T in immunology



Promising early data for CD19 CAR-T in SLE<sup>1</sup>

Potential cures in a range of refractory

B-cell driven autoimmune diseases

Potential in SLE, Sjögren's, severe rheumatoid arthritis, and other neurological diseases

## siRNA in neuroscience and cardiovascular



Improving adherence whilst maintaining efficacy in cardiovascular

Technologies delivering **nucleic assets to the brain** have shown promising early data

Major market **opportunities** in **neurodegenerative**, **neuromuscular** and **cardiovascular** diseases

1. Hernandez, JC, Barba, P, Alberich, ML, et al. (2023) An Open-Label, Multicenter, Ph1/2 Study to Assess Safety, Efficacy and Cellular Kinetics of YTB323 (rapcabtagene autoleucel), a Rapidly Manufactured CAR-T Therapy Targeting CD19 on B Cells, for Severe Refractory Systemic Lupus Erythematosus: Preliminary Results; [abstract]. Arthritis Rheumatol. 75 (suppl 9).

## Continuing to build trust with society, focusing on material environmental, social and governance factors that drive value whilst mitigating risks

#### Value creation

## Innovation and access to medicines

Future-proof pipeline addressing unmet medical and societal needs

Broad access to our medicines, including underserved populations

**Dedicated Global Health unit** 

## Human Capital

Diversity, Equity & Inclusion

Culture

Talent



#### **Risk mitigation**

## **Environmental Sustainability**

Climate

Water

Waste



## **Ethical Standards**

**Ethics** 

Compliance

Human rights



#### **Enablers**

Governance, transparency, Non-financial reporting

Management systems & tools



#### Right thing to do

Reaching more patients with innovative medicines

Creating sustainable social and economic impact

Building trust with society



## Novartis differentiated profile offers an attractive shareholder value creation opportunity

#### **Focused strategy**

Pure-play innovative medicines with 4 core therapeutic areas and 2+3 technology platforms

Substantial cash generation; focusing on **bolt-on M&A/BD&L**, **strong and growing dividend**, **and SBB** 

#### **Attractive growth prospects**

Strong 2023, raising full year guidance 3 times

Upgraded mid-term sales guidance to **+5% CAGR** (2022-2027); **mid-single-digit** beyond

Increasing core margin to ~40%+ by 2027

#### Robust pipeline

10 positive Ph3 readouts/presentations in past year Focused pipeline on 83 projects<sup>1</sup> in areas of high unmet need

>15 key submissions planned 2024-27

#### **ESG** leader

**Focus on material factors** to create value: innovation, access to medicines and human capital

#1 in Sustainalytics<sup>2</sup>; leaders in ATMI (reaching >250m patients); AA in CDP climate and water

1. Confirmatory development projects. 2. Pharmaceuticals subindustry group. ATMI – Access to Medicines Index.

SBB – Share Buyback.

