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- 2 legislative and regulatory developments and economic conditions;
- 3 delay or inability in obtaining regulatory approvals or bringing products to market;
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## Roche

2023 results

Basel, 1 February 2024





## Group

Thomas Schinecker Chief Executive Officer

## Roche

## **Performance**

Outlook



## 2023 guidance exceeded

	Guidance	Results		
Group sales growth <sup>1</sup>	Low single digit decline	+1%		
Core EPS growth <sup>1</sup>	Broadly in line with sales decline	+6% (+1% excl. resolution of  tax disputes in 2023)		
Dividend outlook	Further increase dividend in Swiss francs <sup>2</sup>	CHF 9.60 ✓		

<sup>&</sup>lt;sup>1</sup>At Constant Exchange Rates (CER); <sup>2</sup> 2023 dividend as proposed by the Board of Directors



### 2023: Strong base business growth across both divisions

#### Group sales +1% at CER driven by strong base business of +8%

- Strong Pharma (+9% at CER) and Diagnostics (+7% at CER) base business growth
- COVID-19 sales decreased by CHF -4.3bn and AHR by CHF -1.1bn, in line with guidance
- Core OP margin stable, Core EPS growth +6%, Operating Free Cash Flow of +4% at CHF 18.2bn (all at CER)

#### Key milestones achieved in Q4

- Pharma regulatory: Approval for Vabysmo in RVO (US) and Tecentriq SC (EU), and US priority review granted for Xolair in food allergy
- Pharma readouts: Positive Ph III (INAVO120) inavolisib in 1L PIK3CA-mut HR+ BC, Ph III (EMBARK) results for Elevidys in DMD and positive Ph III
  (OUtMATCH) Xolair in food allergy
- Diagnostics launches: LightCycler Pro, Anti-HEV IgG/IgM and HBeAg Quant
- Deals: Telavant (anti-TL1A), Carmot (Dual GLP-1/GIP RA) and LumiraDx (PoC technology platform)<sup>1</sup>

#### Significant newsflow in 2024

- Pivotal readouts: Ph III (SKYSCRAPER-01) tiragolumab in 1L NSCLC, Ph IIIs (STARGLO & SUNMO) Columvi / Lunsumio in 2L+ DLBCL, Ph III (VERONA) Venclexta in 1L MDS, Ph III (REGENCY) Gazyva in LN and Ph III (LUMINESCE) Enspryng in gMG
- Ph III enabling readouts: Ph I/II (Brainshuttle AD) trontinemab in AD, Ph IIb (PADOVA) prasinezumab in PD, Ph II (MANATEE) Evrysdi + GYM329 in SMA, Ph II (GOLDEN STUDY) ASO factor B in GA, Ph II (BARDENAS/ALLUVIUM) vamikibart in DME and Ph II (KARDIA-2) zilebesiran in hypertension
- Diagnostics launches: i601 mass spectrometry, Accu-Chek SmartGuide (CGM), cobas c703 and ISE neo, cobas 6800 / 8800 v2.0, cobas pro serology solution, cobas Liat Respiratory Panel and cobas Respiratory flex

¹Contingent on deal closing; Growth numbers and rates at CER (Constant Exchange Rates); AHR=Avastin,Herceptin,Rituxan/MabThera; RV0=retinal vein occlusion; HER2+=human epidermal growth factor receptor positive; HR+=hormone receptor positive; PIK3CA-mut=phosphoinositide 3-kinase mutant; BC=breast cancer; anti-HEV IgG/IgM=anti-hepatitis E virus immunoglobulin G/immunoglobulin M; HBeAg=hepatitis B e-antigen; TL1A=TNF-like ligand 1A; GLP-1=glucagon-like peptide 1; GIP RA=glucose-dependent insulinotropic polypeptide receptor agonist; PoC=point of care; NSCLC=non-small cell lung cancer; DLBCL=diffuse large B-cell lymphoma; SC=subcutaneous; MDS=myelodysplastic syndromes; LN=lupus nephritis; gMG=generalized myasthenia gravis; PD=Parkinson's disease; AD=Alzheimer's disease; SMA=spinal muscular atrophy; ASO=antisense oligonucleotide; GA=geographic atrophy; DME=diabetic macular edema; CGM=continuous glucose monitoring; ISE=ion selective electrode; DMD=Duchenne muscular dystrophy



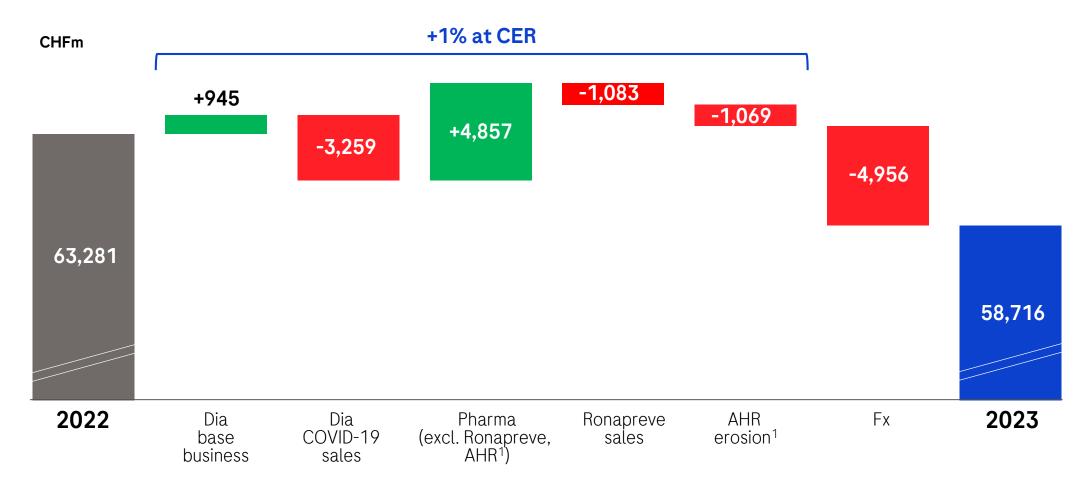
# **2023: Strong base business growth** Guidance exceeded with Group sales up by +1% at CER

	2023	2022	Change in %		Excl.	
	CHFbn	CHFbn	CHF	CER	C19 <sup>1</sup>	
Pharmaceuticals Division	44.6	45.6	-2	6	9	
Diagnostics Division	14.1	17.7	-20	-13	7	
Roche Group	58.7	63.3	-7	1	8	



## 2023: Base business more than compensates for COVID-19 impact

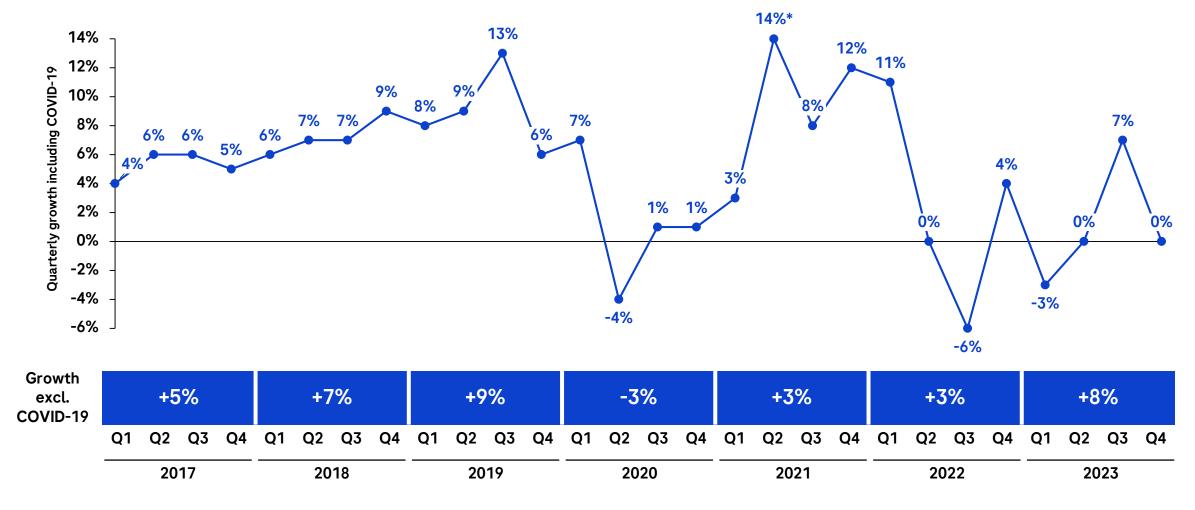
COVID-19 and AHR<sup>1</sup> impact as expected; currency headwinds intensified throughout 2023





### Acceleration of our growth momentum in 2023

Q4 2023 growth impacted by base effect from Ronapreve sales in Japan in 2022



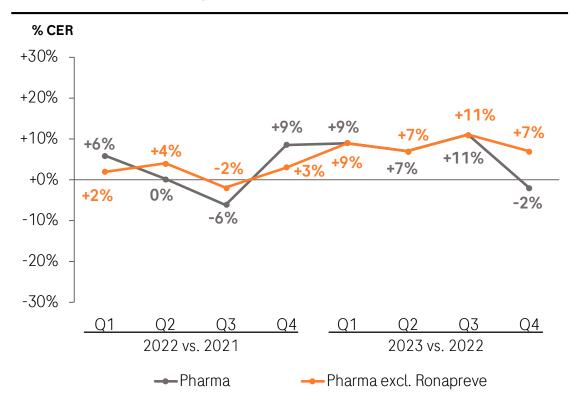
<sup>\*</sup>Q2 2020 sales severely impacted by COVID-19 pandemic onset; Growth rates at CER (Constant Exchange Rates) of the respective year



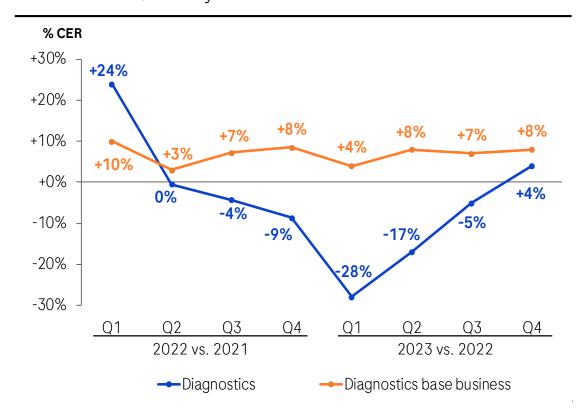
## 2023: Base businesses in both divisions growing high single digit

More than offsetting COVID-19 sales (CHF 4.3bn) erosion

**Pharma**Quarterly sales evolution 2022-2023



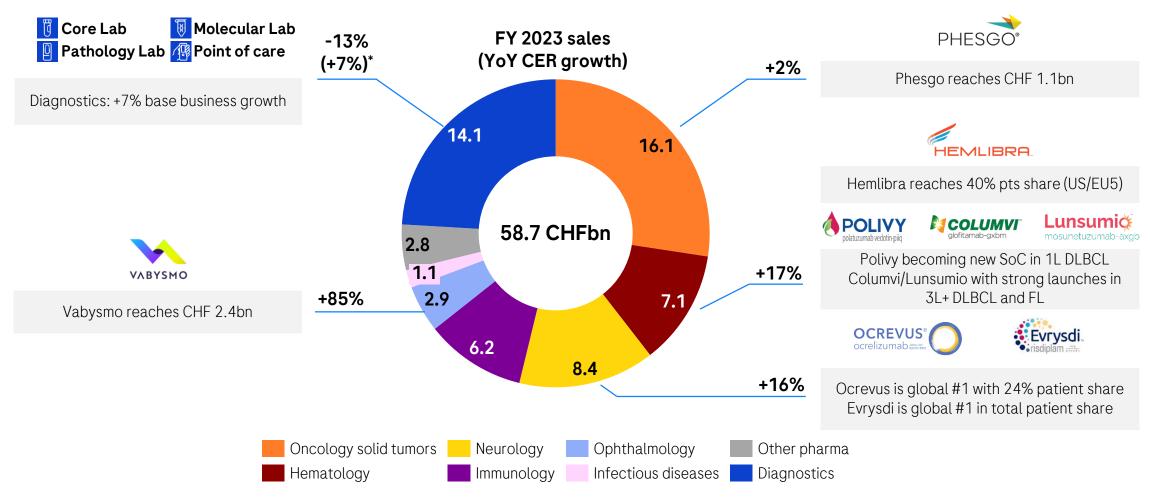
**Diagnostics**Quarterly sales evolution 2022-2023





## Key growth drivers of the Roche portfolio in 2023

Establishing new leadership positions while further diversifying our portfolio



Definition of Pharmaceuticals TA split used in the FY 2023 Financial Report vs. IR Presentation explained on slide 172; \*Diagnostics base business growth at +7%



### Strategy and organizational development 2023

Important progress made to set up the organization for continued success



#### **Digital Health strategy**

- Portfolio focus defined
- One technology platform
- One Center of Excellence for digital product development

#### Disease area strategies

 Cardiovascular & metabolic and Neurology strategies defined

#### **Group strategy**

 To be presented at Pharma Day 2024

#### Pharma strategy

 To be presented at Pharma Day 2024



#### **R&D Excellence**

- Productivity analysis
- Six levers defined to accelerate delivery; implementation ongoing
- End-to-end portfolio committee
- Investment in latest technologies to expedite R&D (e.g., AI/ML/LLM, «lab in a loop», IHB)<sup>1</sup>
- Acceleration of promising projects

#### **External opportunities**

- Increased focus on de-risked, clinical stage deals (e.g., anti-TL1A)
- Expansion into new therapeutic areas with high disease burden



#### Organization

#### **Corporate Executive Committee**

 All Pharma R&D functions represented from early to late stage and partnering

#### **Operating Model**

 Simplify, clarify and align structure, processes & technology

#### <u>Diagnostics / Diabetes Care</u> integration

 Integration to increase portfolio synergies and operational efficiencies; completed in 2024

#### Foundation Medicine (FMI)

Shift to Diagnostics to leverage portfolio synergies



#### People & Culture

#### **Corporate Executive Committee**

- New: Divisional CEOs, Head of Corporate Strategy & Sustainability, Head Global Product Development
- Gender parity achieved

#### New key executive positions

- Chief Diversity Officer
- Chief Sustainability Officer

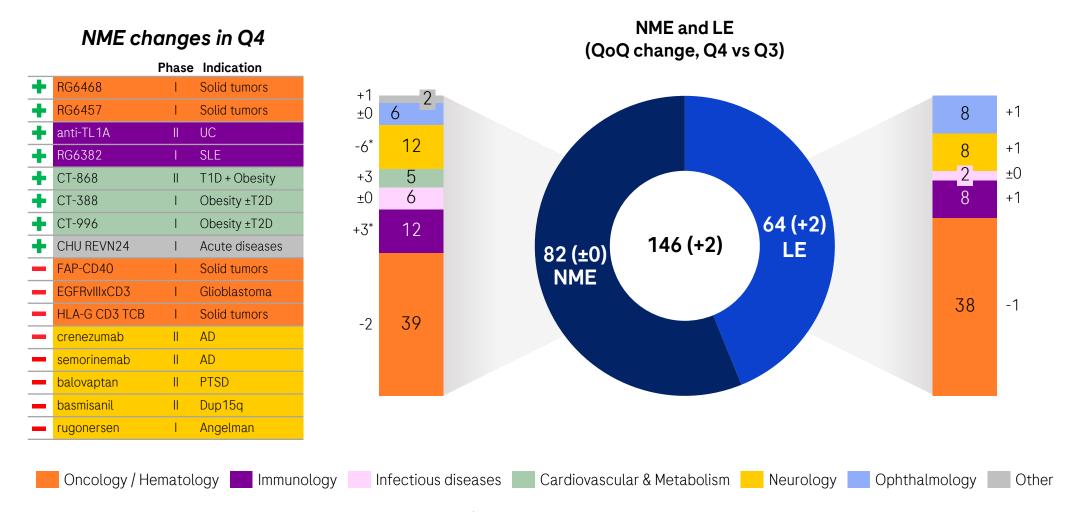
#### Culture

- High employee engagement and company culture scores
- Debate leading to better, faster decisions by empowered people
- Excellence in delivery of ambitious goals



### Pipeline update: Strengthening Pharma pipeline

Trade-offs made in Q4 to increase the overall portfolio value and speed up development

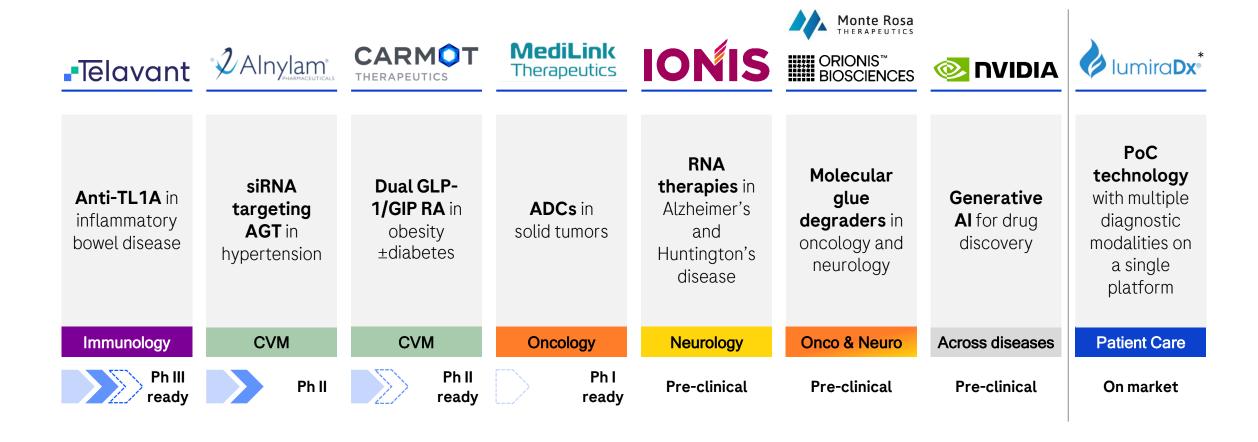


<sup>\*</sup>Selnoflast lead indication was changed from Neurology to Immunology, no selnoflast projects were added/terminated; NME=new molecular entity; LE=line extension; UC=ulcerative colitis; SLE=systemic lupus erythematosus; AD=Alzheimer's disease; PTSD=post-traumatic stress disorder; Dup15q=Chromosome 15q11.2-13.1 duplication; CD=Crohn's disease; T1D/T2D=type-1/2 diabetes; Includes all assets from Ph I to Registration



## Pipeline acceleration through partnering and acquisitions

Recent deals increasingly focused on de-risked assets with significant potential



<sup>\*</sup>Contingent on deal closing; CVM=cardiovascular & metabolism; siRNA=small interfering RNA; AGT=angiotensinogen; TL1A=Tumor necrosis factor-like cytokine 1A; GLP-1=glucagon-like peptide-1; GIP=glucose-dependent insulinotropic polypeptide; RA=receptor agonist; Al=artificial intelligence; ADC=antibody-drug conjugate; PoC=point of care



#### ESG achievements 2023

Sustainability is part of everything we do

**Top 3 position in DJSI** 

Reducing Scope 1 & 2 GHG emissions

WHO prequalification for HPV molecular test

Novel antibiotic class with potential anti-CRAB activity<sup>2,3</sup>

S&P Global ESG Score

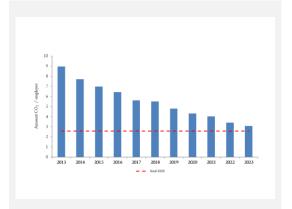


Data Availability:

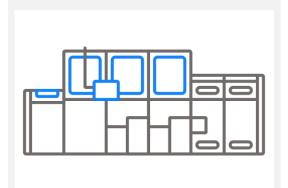
Very High

Methodology Year: 2023

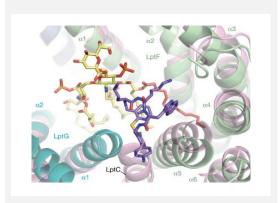
Roche and Chugai ranked as 3rd and 2nd in the DJSI 2023



79% reduction in Scope 1 & 2 GHG emissions since 2004



Will help prevent 74m new cases of cervical cancer in 78 LMICs, supporting WHO goals<sup>1</sup>



pRED & Harvard scientists discovered a potential new antibiotic class for the first time in over 50 yrs



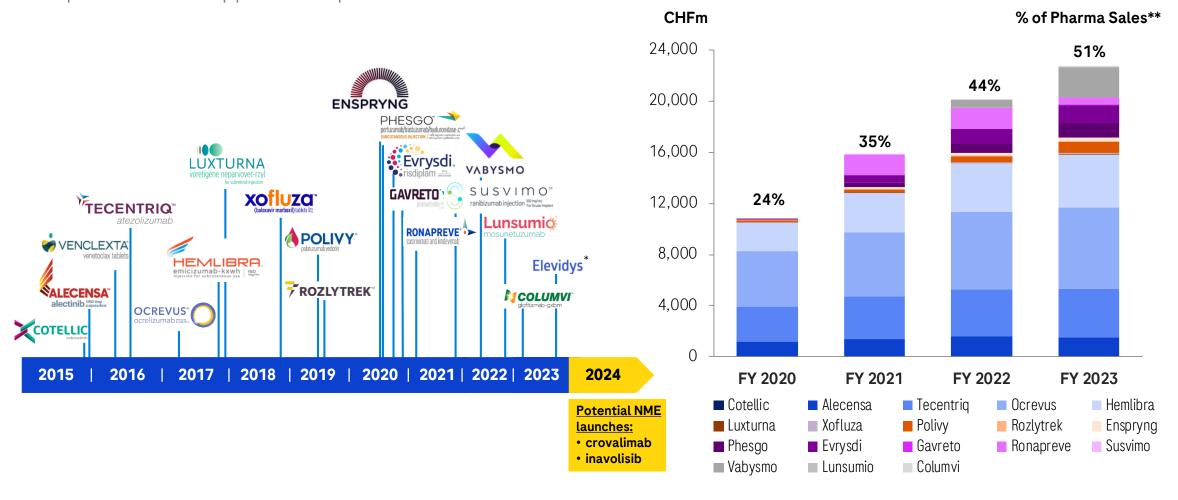
## **Performance**

**Outlook** 



### Young portfolio to drive growth in the near- to mid-term

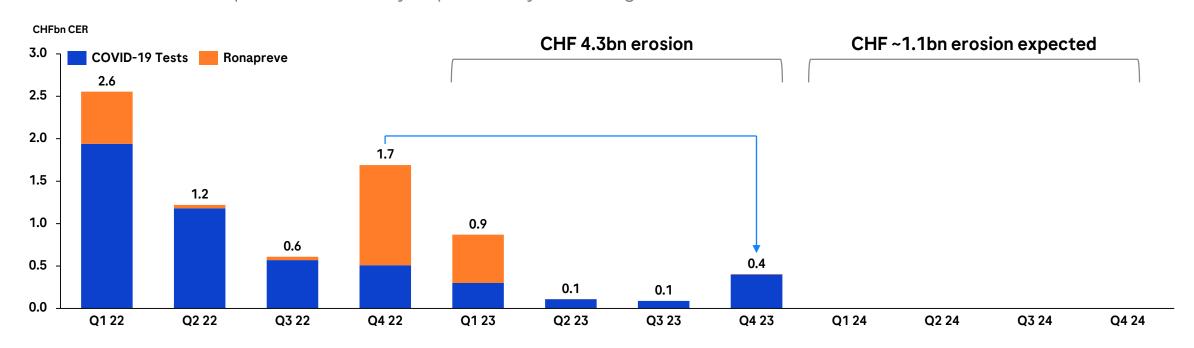
Two potential NME approvals expected for 2024: crovalimab in PNH and inavolisib in HR+ breast cancer





### Declining COVID-19 related headwinds in 2024

Q1 2024 is the final quarter materially impacted by declining COVID-19 sales



#### Roche had a significant contribution to ending the COVID-19 pandemic

16 COVID-19 products

~ 3 million patients treated with Ronapreve & Actemra

~ 2 billion COVID-19 tests

~ CHF 19bn in sales\*

<sup>\*</sup>COVID-19 sales referring to COVID-19 diagnostic tests, Ronapreve and Actemra sales; all values at CER (Constant Exchange Rate) of the respective year



**Key growth drivers beyond 2025**Many opportunities with significant market potential in both divisions

Pharmaceuticals Pharmaceutical					Diagnostics			
	NME	Indication	Newsflow	Timing		Product	Description	Launch
63	tiragolumab	NSCLC	Final Ph III data	H2 2024		i601 mass spec	Total solution for clinical mass	2024
<b>₽</b>	inavolisib	ВС	US/EU filing	2024			spectrometry and first reagent ipack	
Oncology / Hematology	divarasib	NSCLC	Ph I/II readout	2024/25		Ф	cobas pro serology solution	Roche blood safety solution for the US donor screening market
	giredestrant	ВС	Ph III readout	2025		cobas c703 & ISE	High-throughput clinical chemistry	2024
	Elevidys	DMD	Ph III readout	2024/25	Core Lab	neo	and ISE testing on cobas pro	2024
Sta .	prasinezumab	PD	Ph IIb readout	2024		Elecsys Amyloid Plasma Panel	Rule-out blood-based test for amyloid pathology detection in AD	2025
Neurology	Evrysdi + GYM329	SMA	Ph II readout	2024		cobas 6800/8800	3 1 03	
Neurology	trontinemab	AD	Ph I/II readout	2024	<del></del>	v2.0	flexibility, throughput and automation	2024
	fenebrutinib	MS	Ph III readout	2025	₹	cobas	Novel TAGS® multiplex technology for	2024
0.5	Gazyva	LN	Ph III readout	2024	Molecular Lab	Respiratory flex	respiratory testing on cobas x800	2024
<u>ම</u> ප්ර	anti-TL1A	IBD	Ph III initiation	2024		Next generation sequencing	Nanopore sequencer with unique sequencing by expansion technology	2025+
Immunology	astegolimab	COPD	Ph III readout	2025		sequencing	sequencing by expansion technology	
	vamikibart (anti-IL6)	DME/UME	Ph II/III readout	2024/25		Accu-Chek	Roche's first generation continuous	2024
Ophthalmology	ASO factor B	GA	Ph II readout	2024	Diabetes Care	SmartGuide	glucose monitoring solution	
<b>E</b> 3	zilebesiran	HT	Ph II readout	2024		cobas Liat Resp.	Detection & differentiation of four	0004
Cardiovascular & Metabolism	CT-388/868/996 (GLP-1/GIP)	Obesity	Ph I/II readout	2024	Point of Care	panel	most prevalent respiratory targets	2024



#### Positive 2024 outlook

#### Sales drivers<sup>1</sup>



Continued strong base business growth in both divisions



COVID-19 sales expected to decline by roughly CHF 1.1bn

LOE<sup>2</sup> impact of roughly CHF 1.6bn expected

Group sales growth<sup>1</sup>

Mid single digit sales growth



### 2024 guidance

Group sales growth<sup>1</sup>

Mid single digit sales growth

Core EPS growth<sup>1</sup>

Broadly in line with sales growth excl. impact from resolution of tax disputes in 2023

**Dividend outlook** 

Further increase dividend in Swiss francs

<sup>&</sup>lt;sup>1</sup>At Constant Exchange Rates (CER)





## **Finance**

Alan Hippe Chief Financial Officer



### IR events currently planned for 2024

Additional events driven by readouts



#### Neurology Update Mar 11

15:00 - 16:30 CET Virtual event

- Neurology franchise update
- Elevidys Ph III (EMBARK) in Duchenne muscular dystrophy
- trontinemab Ph I/II
   (Brainshuttle<sup>™</sup> AD) in
   Alzheimer's disease (cohort 4 dose escalation)
- prasinezumab Ph II (PASADENA) in Parkinson's disease (4 year OLE data)



#### Diagnostics Day May 22

13:00 - 15:30 BST London & virtual

- Deep-dive into the current product portfolio
- Updates on key development projects and upcoming launches, including mass spectrometry, continuous glucose monitoring (CGM), next generation sequencing and other products in development



#### Pharma Day Sep 30

tba London & virtual

- Update on Group & Pharma strategy
- Deep-dive into the current product portfolio
- Building blocks for future growth: Late stage portfolio update
- Update on R&D excellence



### **Results**

Cash & balance sheet

Reporting changes

Currency guidance & outlook



# **2023: Group performance**Sales increase of +1% and Core EPS increase of +6%

	2023	2022	Change in %	
	CHFm	CHFm	CHF	CER
Sales	58,716	63,281	-7	1
Core operating profit as % of sales	<b>19,240</b> 32.8	<b>22,173</b> <i>35.0</i>	-13	-1
Core net income as % of sales	<b>15,804</b> 26.9	<b>17,530</b> 27.7	-10	3
Core EPS (CHF)	18.57	20.30	-9	6
IFRS net income	12,358	13,531	-9	7
as % of sales	21.0	21.4		
Operating free cash flow as % of sales	<b>15,768</b> 26.9	<b>17,673</b> 27.9	-11	4
Free cash flow as % of sales	<b>11,288</b> 19.2	<b>13,041</b> 20.6	-13	4



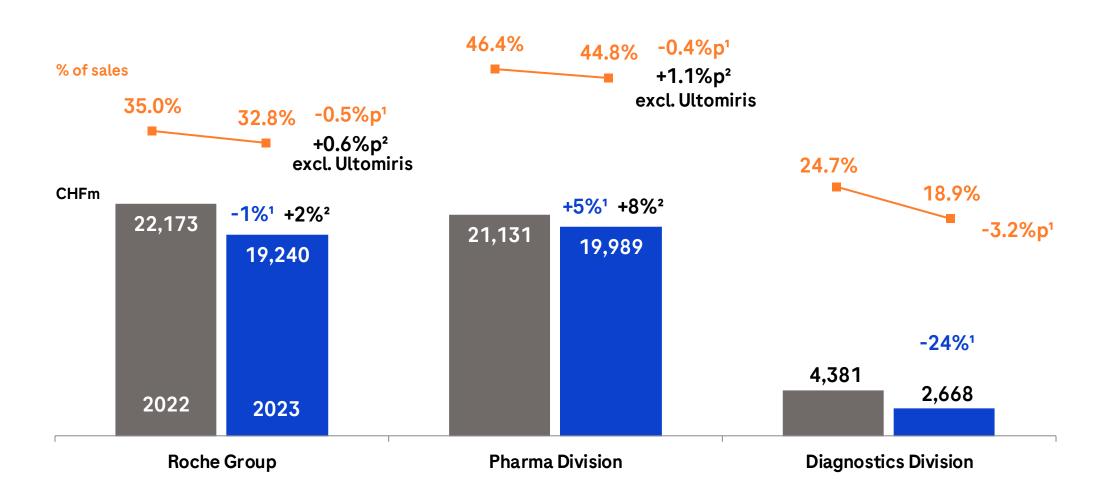
### 2023: Group operating performance

Core OP lower by -1% due to higher operating expenses and lower other revenue (Ultomiris base effect 2022)

	20	23	2023 vs. 2022		
	CHFm	abs. CER	<b>CER</b> growth		
Sales	58,716	+391	1%		
Other revenue	1,725	-664	-27% //		
Cost of sales	-15,251	+1,350	-8%		
R&D	-13,237	-709	5%		
SG&A	-13,518	-590	4%		
OOI&E	805	+44	6%		
Core operating profit	19,240	-178	-1%		
Core OP in % of sales	32.8%		-13% in CHF		
At CER	34.4%				
	(2022: 34.9%)				



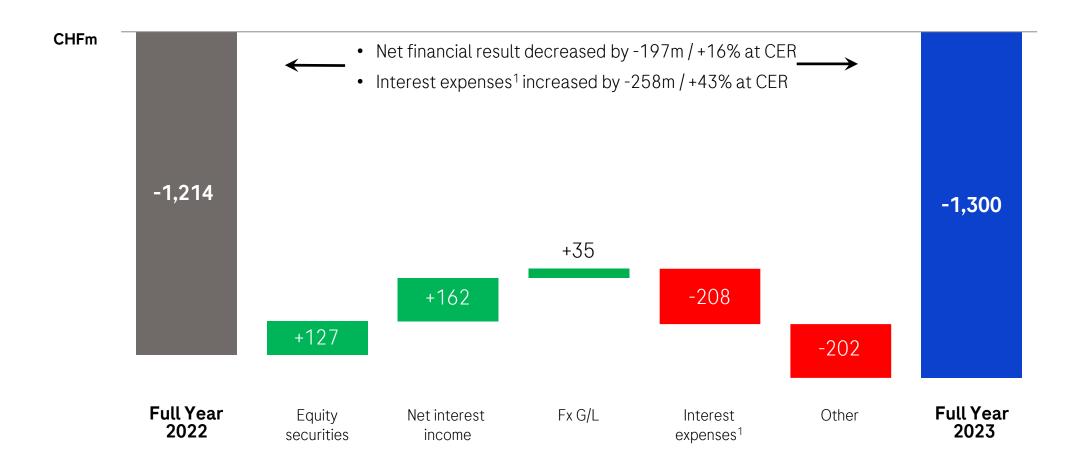
## 2023: Core operating profit and margin





#### 2023: Core net financial result

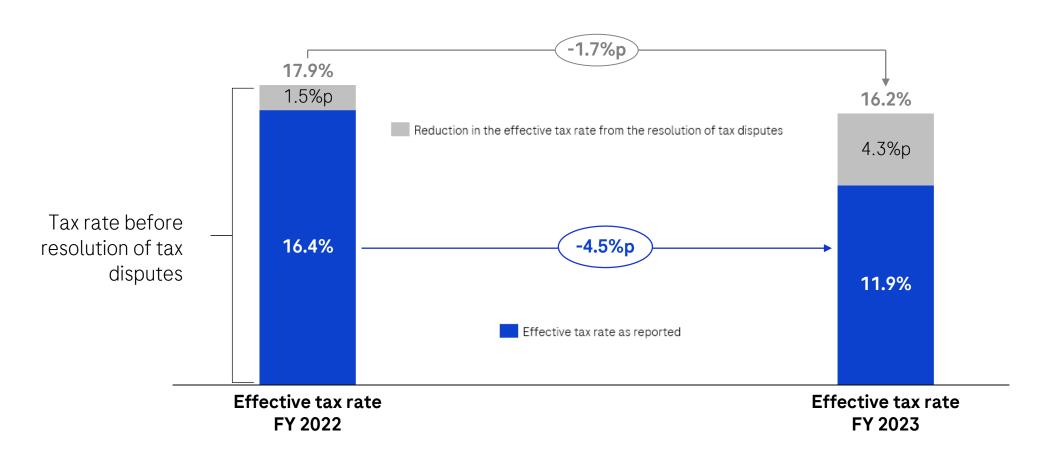
Decrease due to increased interest expenses, partially offset by interest income





### 2023: Group Core tax rate

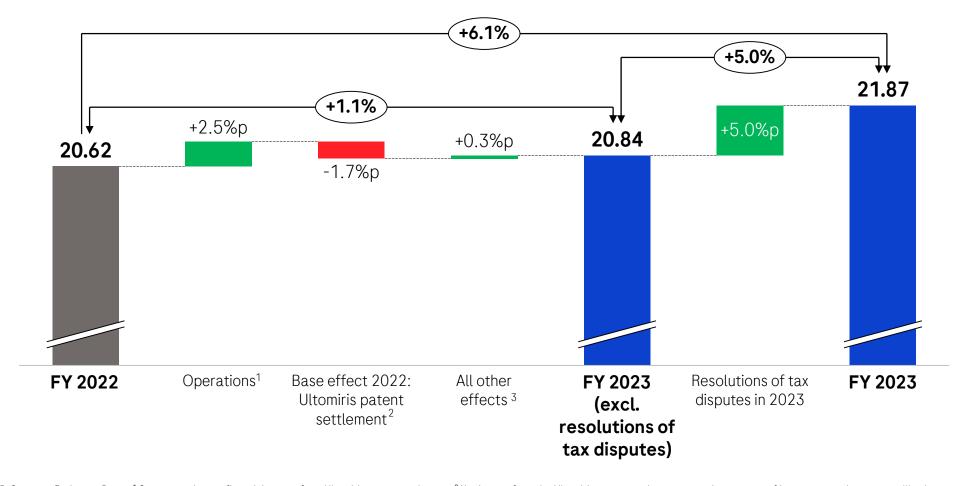
Decrease in core tax rate mainly due to higher impact from the resolution of tax disputes in 2023 compared to 2022 and lower profits from high tax jurisdictions





### 2023: Core EPS development

Effects of resolutions of tax disputes in 2023 and increase in operations partially offset by Ultomiris base effect



All values at CER=Constant Exchange Rates; <sup>1</sup> Core operating profit excl. impacts from Ultomiris patent settlement; <sup>2</sup> Net impact from the Ultomiris patent settlement: gross income, net of income tax and non-controlling interests; <sup>3</sup> Effects from changes in Non-operating expenses excl. effects from changes in the income tax charges excl. the effect of resolution of tax disputes in 2023 and the effect of the Ultomiris patent settlement on the 2022 tax expense, effects from changes in Noncontrolling interest amounts excluding effects of the Ultomiris patent settlement in 2022, effects of changes in number of shares



#### 2023: Non-core and IFRS income

Non-core operating exp. lower vs. PY due to lower impairments of IA partly offset by higher spend in GRP

	2022	2023	Var.	Change in %	
	CHFm	CHFm	at CER	CHF	CER
Core operating profit	22,173	19,240	-178	-13	-1
Global restructuring plans	-969	-2,038	-1,153		
Amortisation of intangible assets	-933	-711	+189		
Impairment of intangible assets <sup>1</sup>	-2,837	-1,199	+1,566		
M&A and alliance transactions	20	-19	-39		
Legal & Environmental <sup>2</sup>	22	122	+107		
Total non-core operating items	-4,697	-3,845	+670		
IFRS Operating profit	17,476	15,395	+492	-12	+3
Total financial result & taxes	-3,945	-3,037	+482		
IFRS net income	13,531	12,358	+973	-9	+7



### **Results**

Cash & balance sheet

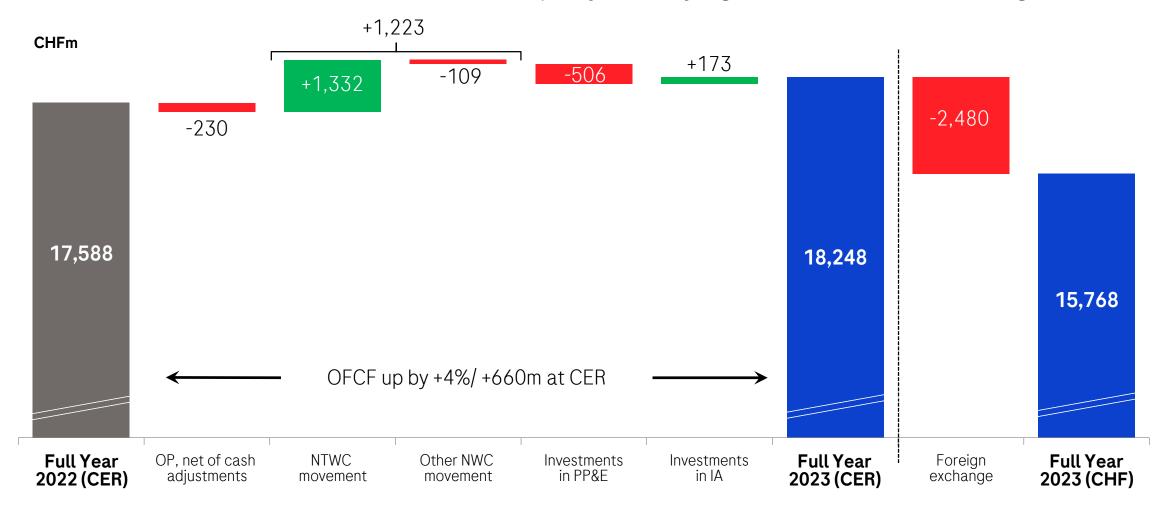
Reporting changes

Currency guidance & outlook



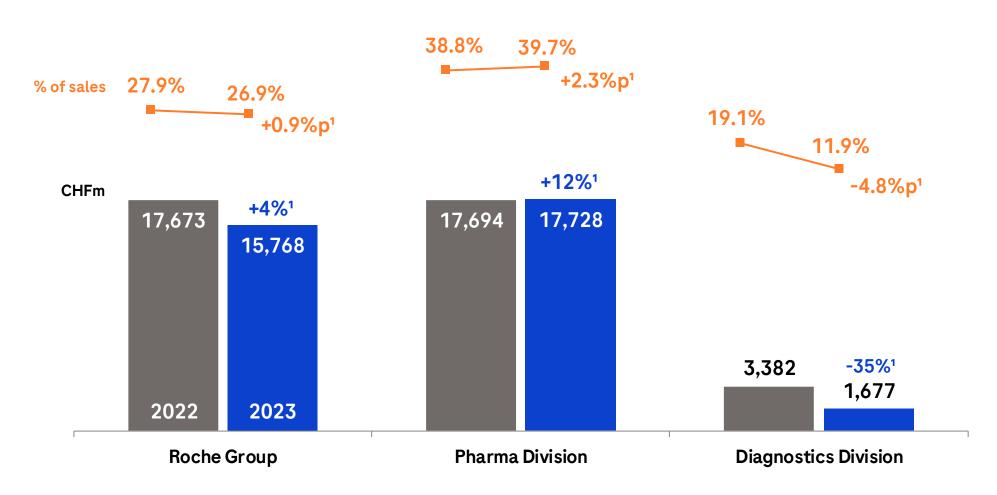
### 2023: Group Operating Free Cash Flow

OFCF +4%; NWC movement and lower IA investments partly offset by higher inv. in PP&E and declining cash OP





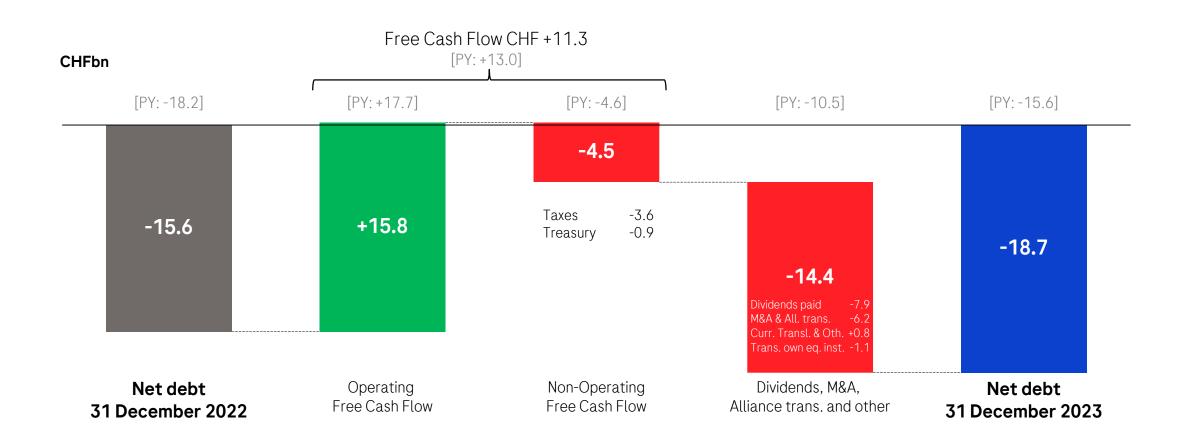
### 2023: Operating free cash flow and margin





### 2023: Group net debt development

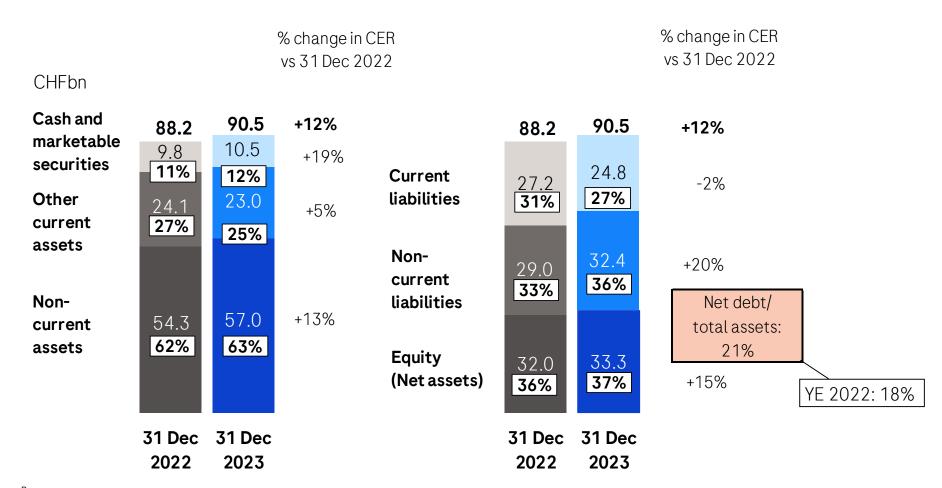
Net debt higher by CHF 3.1bn vs. YE 2022





### Balance sheet 31 December 2023

Equity ratio at 37% (31 Dec 2022: 36%) and net debt to assets at 21% (31 Dec 2022: 18%)



CER=Constant Exchange Rates



**Results** 

Cash & balance sheet

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Currency guidance & outlook



## Restatements to be applied in 2024

Foundation Medicine shifted to the Diagnostics Division effective Jan 1, 2024

#### **Income statement (Core)**

# Pharmaceuticals Division - CHFm Sales Other revenue Cost of sales Research and development Selling, general and administration Other operating income (expense) Core operating profit Core operating profit margin

Diagnostics Division - CHFm
Sales
Other revenue
Cost of sales
Research and development
Selling, general and administration
Other operating income (expense)
Core operating profit
Core operating profit margin

#### Half Year 2023

Published	Delta	Restated
22,681	-170	22,511
806	-8	798
-4,107	71	-4,036
-5,617	110	-5,507
-3,444	136	-3,308
699	0	699
11,018	139	11,157
48.6%	1.0%p	49.6%

Published	Delta	Restated
7,098	170	7,268
31	8	39
-3,349	-71	-3,420
-832	-110	-942
-1,342	-136	-1,478
13	0	13
1,619	-139	1,480
22.8%	-2.4%p	20.4%

#### Full Year 2023

Published	Delta	Restated
44,612	-347	44,265
1,667	-19	1,648
-8,343	149	-8,194
-11,490	204	-11,286
-7,215	263	-6,952
758	1	759
19,989	251	20,240
44.8%	0.9%p	45.7%

Published	Delta	Restated
14,104	347	14,451
58	19	77
-6,908	-149	-7,057
-1,747	-204	-1,951
-2,899	-263	-3,162
60	-1	59
2,668	-251	2,417
18.9%	-2.2%p	16.7%



**Results** 

Cash & balance sheet

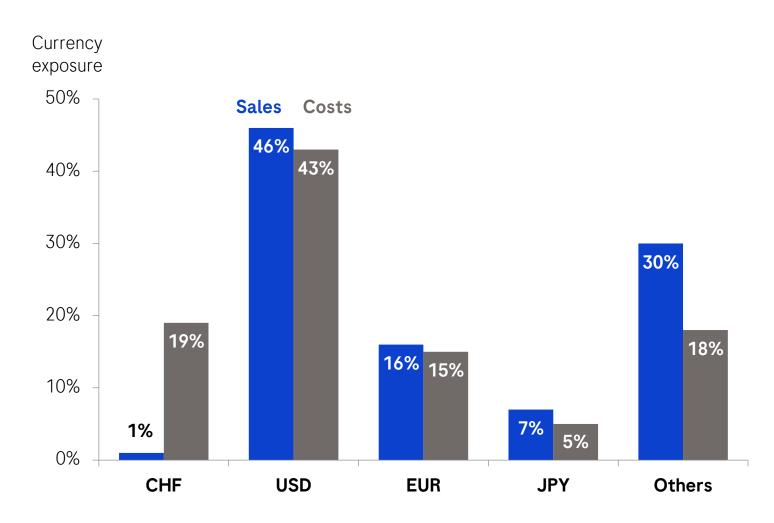
Reporting changes

**Currency guidance & outlook** 



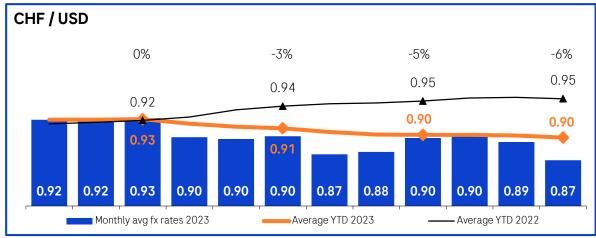
## 2023: Group currency exposure

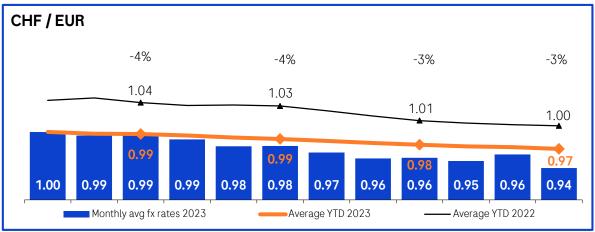
Overall solid natural hedge





## 2023: Currency impact and outlook





In 2023 impact <sup>1</sup> is (%p):				
	Q1	НҮ	Sep YTD	FY
Sales	-4	-6	-7	-8
Core operating profit		-8		-12
Core EPS		-9		-15
2024 currency	impact exp	ected1 (hase)	d on 20 Dec 21	023 EX ratos)

**2024 currency impact expected**<sup>1</sup> (based on 29 Dec 2023 FX rates):

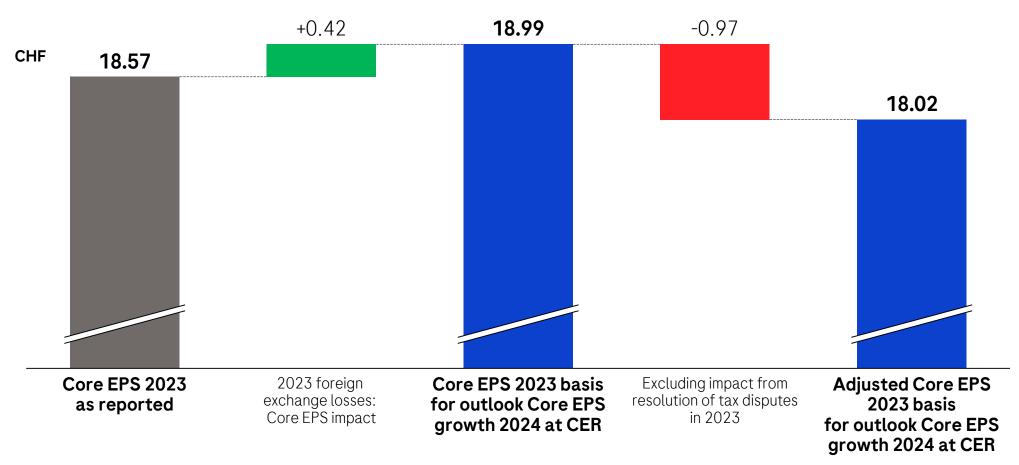
Around -6%p on Sales, -8%p on Core OP and -9%p on Core EPS

<sup>&</sup>lt;sup>1</sup>On group growth rates



## **2023: Core EPS**

2023 Core EPS adjusted to CHF 18.02 is basis for Core EPS outlook 2024 at CER





## 2024 guidance

Group sales growth<sup>1</sup>

Mid single digit sales growth

Core EPS growth<sup>1</sup>

Broadly in line with sales growth excl. impact from resolution of tax disputes in 2023

**Dividend outlook** 

Further increase dividend in Swiss francs

<sup>&</sup>lt;sup>1</sup>At Constant Exchange Rates (CER)





## **Pharmaceuticals Division**

Teresa Graham CEO Roche Pharmaceuticals



## 2023: Pharmaceuticals sales

All regions ex-Japan delivering strong growth, intensifying currency headwinds throughout 2023

	2023 2022 Change in %		ge in %	CER w/o	
	CHFm	CHFm	CHF	CER	Ronapreve
Pharmaceuticals Division	44,612	45,551	-2	6	9
United States	23,606	23,322	1	8	8
Europe	8,306	8,143	2	6	7
Japan	3,745	4,949	-24	-14	6
International	8,955	9,137	-2	13	14



## 2023: Pharmaceuticals core operating profit

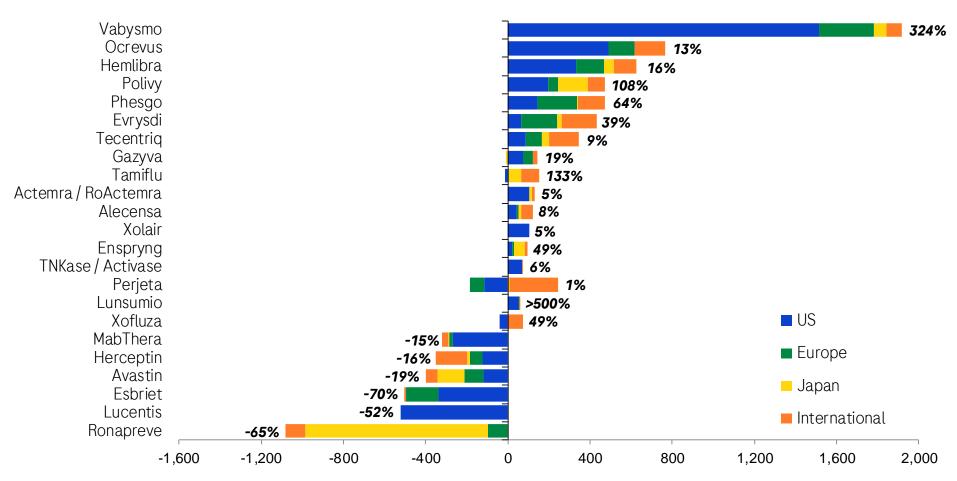
Core operating profit broadly in line with sales growth

	202	2023 vs. 2022	
	CHFm abs. CER		<b>CER</b> growth
Sales	44,612	+2,705	6%
Other revenue	1,667	-656	-27%
Cost of sales	-8,343	+114	-1%
R&D	-11,490	-725	6%
SG&A	-7,215	-409	6%
OOI&E	758	+25	3%
Core operating profit	19,989	+1,054	5%
Core OP in % of sales At CER	44.8% 45.8% (2022: 46.2%)		-5% in CHF



## 2023: Young portfolio delivering strong growth

Vabysmo sales exceed CHF 2bn and Phesgo achieves blockbuster status

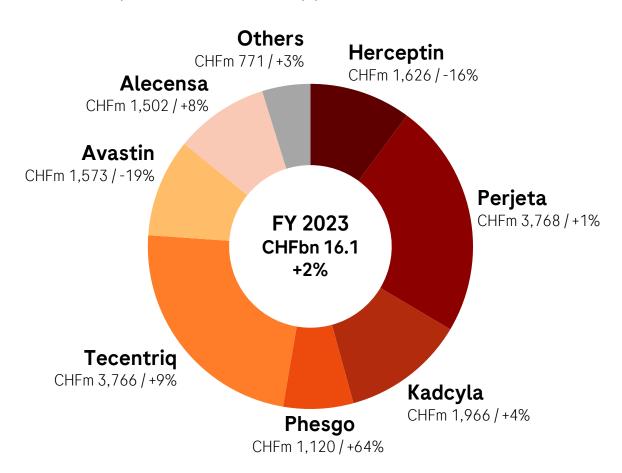






## Strong Phesgo launch continues, now at 39% conversion rate\*

Tecentriq SC achieves EU approval



#### CHFm / YoY CER growth

#### Q4 update

- Perjeta: growth driven by International; Q4 sales impacted by an adjustment in the reserves related to US government programs
- Tecentriq: growth driven by adjuvant NSCLC and 1L HCC
- Kadcyla: growth in International compensating for US/EU
  - 7-years KATHERINE data reinforces OS and IDFS benefit in adj. HER2+ BC
- Alecensa: global market leader in 1L ALK+ mNSCLC
- Positive Ph III (INAVO120) for inavolisib + palbociclib + fulvestrant in 1L PIK3CA-mut HR+ BC

#### Outlook 2024

- Tecentrig SC for various indications: US approval
- Alecensa in adj. ALK+ NSCLC: US/EU approval
- Inavolisib in 1L PIK3CA-mut HR+ BC: US/EU filing
- Ph III (SKYSCRAPER-01) tiragolumab + Tecentriq in 1L PD-L1+ NSCLC final OS results expected in H2 2024



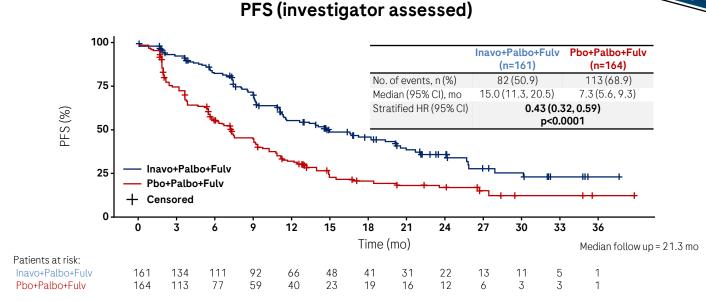


Inavolisib more than doubles PFS in 1L PIK3CA-mut HR+ breast cancer

Additional Ph III trials ongoing, including head-to-head vs. alpelisib and in combination with Phesgo

#### Ph III development program Inavolisib 1L PIKC3A-mut HR+ HER2- mBC (INAVO120) Inavolisib Post CDK4/6i PIK3CAmut/HR+/HER2-BC (INAVO121) Inavolisib 75 -1L PIK3CA-mut/HER2+BC (INAVO122) PFS (%) 50 **Giredestrant** 1L ER+/HER2- mBC (perservERA) endocrine sensitive Inavo+Palbo+Fulv **Giredestrant** 1L ER+/HER2- mBC Pbo+Palbo+Fulv (pionERA) endocrine resistant Censored **Giredestrant** Adjuvant ER+/HER2-BC (lidERA) **Giredestrant** Patients at risk: 1L maint ER+/HER2+ BC (heredERA) Inavo+Palbo+Fulv Pbo+Palbo+Fulv 113 ✓ Positive data

#### Ph III (INAVO120) inavolisib in 1L PIK3CA-mut HR+ mBC1



- Inavolisib combination reduced the risk of disease progression by 57% (HR=0.43); OS was immature, but with clear positive trend (HR=0.64)
- Data to be submitted to health authorities, with the view of bringing a potential new SoC to HR+ breast cancer patients with PIK3CA mutations
- Two additional Ph III in *PIK3CA*-mut breast cancer ongoing: inavolisib + fulvestrant vs. alpesilib + fulvestrant (INAVO121) in post-CDKi 1/2/3L HR+ HER2- breast cancer and inavolisib + Phesgo (INAVO122) in 1L HER2+ breast cancer

<sup>1</sup>Jhaveri KL et al., SABCS 2023; PFS=progression-free survival; PIK3CA-mut=phosphatidylinositol 3-kinase, catalytic, alpha polypeptide mutated; HR+=hormone-receptor positive; ER+=estrogen receptor positive; HER2=human epidermal growth factor receptor 2; (m)BC=(metastatic) breast cancer; CDK=cyclin-dependent kinase; inavo=inavolisib; Palbo=palbociclib; fulv=fulvestrant; Pbo=placebo; mo=months; HR=hazard ratio; Cl=confidence interval; OS=overall survival



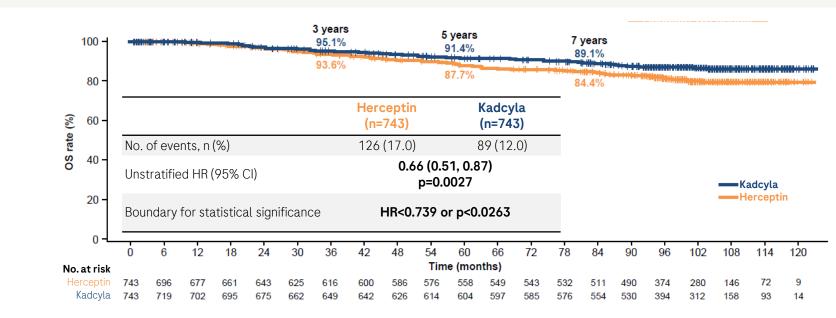


## Kadcyla as SoC in early HER2+ BC with residual invasive disease

First targeted therapy to show significant OS benefit in this patient population







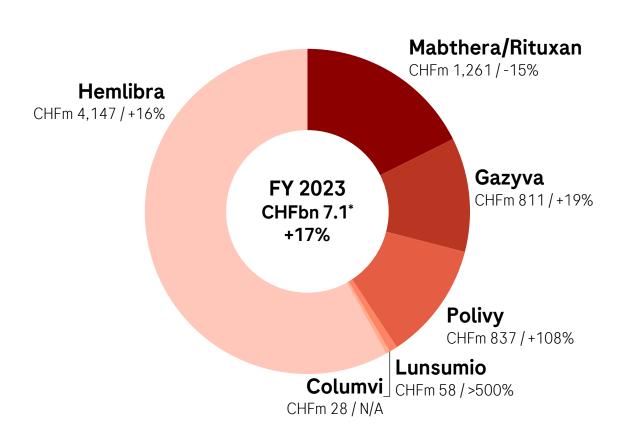
- Kadcyla achieved an OS improvement (HR=0.66) with an absolute OS benefit of 4.7% at 7 years vs. Herceptin in early-stage breast cancer, further substantiating it's SoC status in this setting with >80k patients treated globally
- Long-term data showed continued IDFS benefit (HR=0.54) with an absolute IDFS benefit of 13.7% at 7 years vs. Herceptin
- Kadcyla's safety profile was consistent with previous findings and no new safety signals were identified





## Hemlibra reaches 40% patient share in US/EU5

Polivy US patient share in 1L DLBCL (IPI 0-5) climbing to 21%



#### CHFm / YoY CER growth

#### Q4 update

- Hemlibra: continued penetration across all approved pts segments with ~24,000 patients treated globally
  - Positive Ph III (HAVEN 7) results in infants with Hemophilia A presented at ASH 2023
- Polivy: strong 1L DLBCL uptake in all major markets
  - US: NCCN guidelines updated to category 1 recommendation for Polivy in all stages of 1L DLBCL\*\*
- Gazyva: growth driven by combinations in 1L CLL
- Lunsumio: driven by strong 3L+ FL launch
- Columvi: driven by strong 3L+ DLBCL launch

#### Outlook 2024

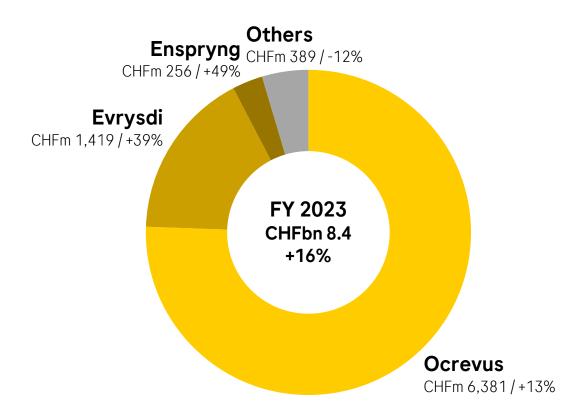
- Crovalimab in PNH: US/EU approval
- Ph III (STARGLO) Columvi + GemOx in 2L+ DLBCL readout
- Ph III (SUNMO) Lunsumio + Polivy in 2L+ DLBCL readout
- Ph III (VERONA) Venclexta + azacitidine in 1L MDS readout





## Ocrevus market leader in US/EU5 with 24% global patient share

Elevidys Ph III (EMBARK) results to be shared with health authorities



#### Q4 update

- Ocrevus: >300k patients treated globally; higher retention rate than other MS medicines
- Evrysdi: global market leader in pts share (>45% in US, Japan and EU5); >11,000 patients treated globally
- Ph III (EMBARK) of Elevidys in DMD did not reach primary endpoint, but showed positive efficacy outcomes on all timed functional key endpoints

#### Outlook 2024

- Ocrevus 6m SC: US/EU approval
- Ph III (EMBARK) Elevidys data to be presented at MDA, and to be shared with EMA
- Ph III (LUMINESCE) Enspryng in gMG readout
- Ph II (MANATEE) Evrysdi + GYM329 in SMA interim readout
- Ph IIb (PADOVA) prasinezumab in PD readout
- Ph lb/lla (Brainshuttle<sup>™</sup> AD) trontinemab in AD updated data

CHFm / YoY CER growth



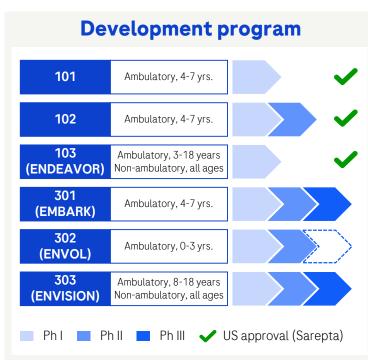


## Elevidys

IR Neurology

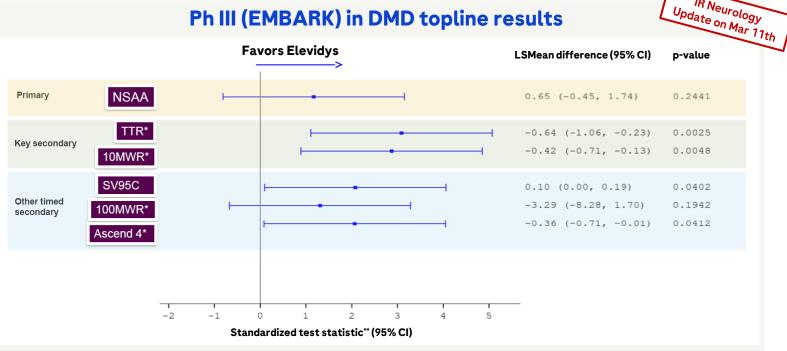
## Elevidys providing clinically meaningful benefits in DMD

Ph III (EMBARK) results favoring Elevidys treatment on all key secondary endpoints



- Ph III (ENVISION) in older ambulatory and all ages non-ambulatory patients is ongoing
- Ph II (ENVOL) in 0-3 year old ambulatory patients initiated in Q4





- NSAA increased compared to placebo at 52 weeks but the primary endpoint was not met
- For all key pre-specified secondary functional endpoints, TTR and 10MWR, clinically meaningful and statistically significant treatment benefits were observed across age groups
- No new safety signals observed, reinforcing the favorable and manageable safety profile
- EMA and other global regulators to be engaged

<sup>\*</sup>Timed function tests sign reversed to align favorable directions among effect endpoints; \*\*Blue lines plot standardized t test statistic (+/- 1.96) after dividing LSMean (95% CI) by standard error; DMD=Duchenne muscular dystrophy; NSAA=North Star Ambulatory Assessment; TTR=time to rise; 10MWR/100MWR=10/100-m walk/run velocity; SV95C=stride velocity; 95th centile; Ascend 4=time to ascend 4 steps; LSM=least-squares mean; CI=confidence interval; Elevidys in collaboration with Sarepta



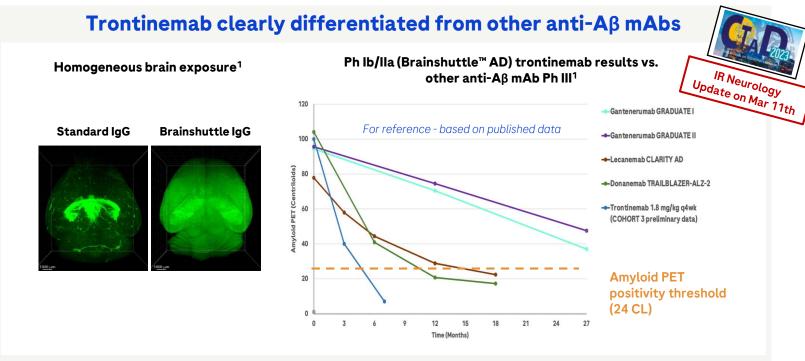


## Trontinemab in AD clears $A\beta$ more rapidly than conventional mAbs

First Aβ-targeting antibody Brainshuttle™ with Ph Ib/IIa in Alzheimer's disease currently ongoing

## **Trontinemab** (Brainshuttle™ anti-Aβ mAb) **Brain tissue** Blood **Transferrin** receptor 1 Aß binder Active TfR1 transport at the capillary level

- Trontinemab uses Roche's proprietary Brainshuttle<sup>™</sup> technology, combining an Aβ binding mAb with a transferrin receptor (TfR1) shuttle module
- Designed for efficient transport across the BBB to target aggregated forms of A $\beta$  and remove amyloid plagues in the brain



- Trontinemab demonstrated rapid and robust amyloid plaque reduction at relatively low doses (1.8 mg/kg Q4W), compared with standard anti-Aβ mAb
- Interim PD and safety data (including a low ARIA incidence) support further investigation in the ongoing Ph Ib/IIa (Brainshuttle™ AD) study
- Updated Ph lb/lla data to be presented at upcoming conference (AD/PD)

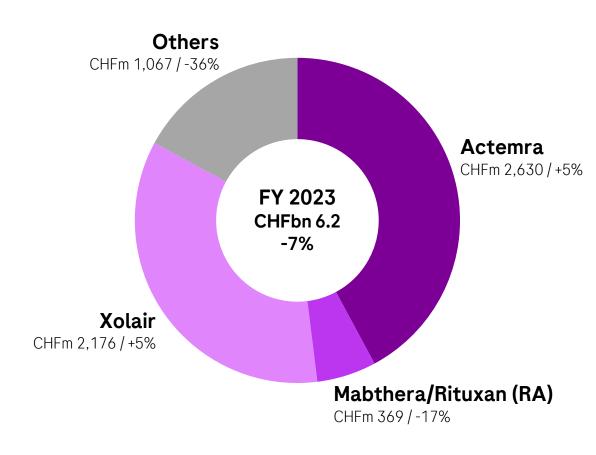
1Kulic L et al., CTAD 2023; Gantenerumab GRADUATE I /II: presentation at CTAD 2022, publication in preparation; Lecanemab CLARITY AD: N Engl J Med 2023; 388:9-21; Donanemab TRAILBLAZER-ALZ-2: JAMA. 2023; 330(6):512-527; AD=Alzheimer's disease; CL=centiloid unit; PET=positron emission tomography; mAb=monoclonal antibody; Aβ=amyloid β; q4w=every 4 weeks; PD=pharmacodynamics; NME=new molecular entity; ARIA=amyloid-related imaging abnormalities; BBB=blood-brain barrier





## Xolair in food allergy filed in the US, approval expected in Q1 2024

Gazyva Ph III (REGENCY) in lupus nephritis to readout in 2024



#### Q4 update

- Xolair: growth driven by strong CSU performance; market shares in Asthma declining
- Actemra: strong US performance in RA
- Updated positive Ph II data for ASO Factor B in IgA nephropathy presented at ASN Kidney Week 2023

#### Outlook 2024

- Xolair: US approval in food allergy expected in Q1
- Actemra biosimilars expected in the US
- Ph III (REGENCY) Gazyva in lupus nephritis readout
- Ph III trials of anti-TL1A in IBD to be initiated

#### CHFm / YoY CER growth

CER=Constant Exchange Rates; IgA=immunoglobulin A; RA=rheumatoid arthritis; IBD=inflammatory bowel disease; TL1A=Tumor necrosis factor-like cytokine 1A; CSU=chronic spontaneous urticarial; ASO=antisense oligonucleotide; ASO factor B in collaboration with Ionis

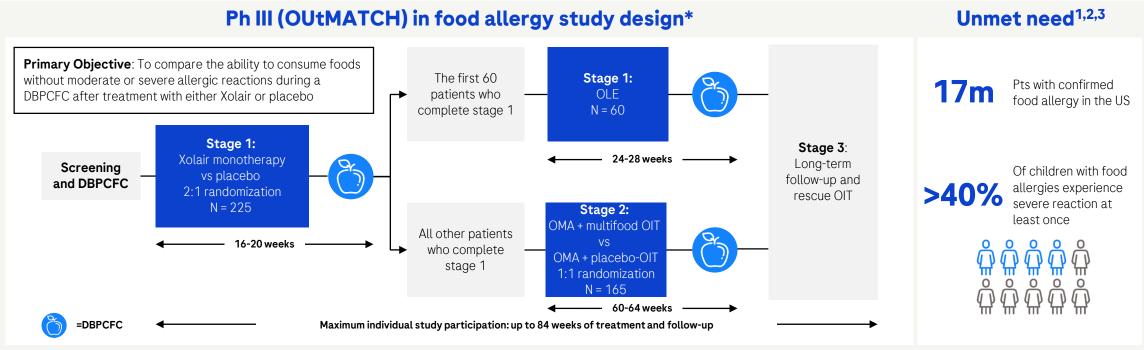




## Xolair: first medicine to reduce allergic reactions to multiple foods

Xolair. Omalizumab

FDA priority review ongoing and decision expected for Q1 2024



- Interim analysis from first-of-its-kind Ph III (OUtMATCH) showed Xolair significantly increased the amount of peanut, milk, egg and cashew needed to cause an allergic reaction
- 17m people in the US have confirmed food allergies; more than 40% of children and more than half of adults with food allergies have experienced a severe reaction at least once
- If approved, Xolair would be the first medicine to reduce allergic reactions to multiple foods following an accidental exposure

<sup>\*</sup>The phase III OUtMATCH study is being sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, and conducted by the NIAID-funded Consortium of Food Allergy Research (CoFAR) across 10 clinical sites throughout the U.S. The study is also supported by Genentech, a member of the Roche Group, and Novartis Pharmaceuticals Corporation. Detailed results from the OUtMATCH study have been submitted by NIAID and CoFAR to a peer-reviewed journal; Gupta RS et al. JAMA Netw Open. 2019; Warren CM et al. Curr Allergy Asthma Rep. 2020; Gupta RS et al. Pediatrics. 2018; DBPCFC=double-blind, placebo-controlled food challenge; OIT=oral immunotherapy; OLE=open label extension; OMA=omalizumab.

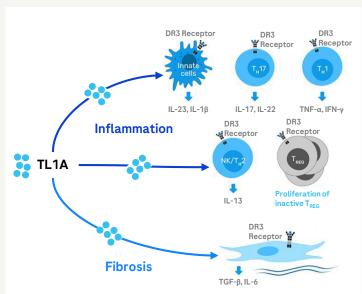




## Anti-TL1A with first-in-class and best-in-disease potential in IBD

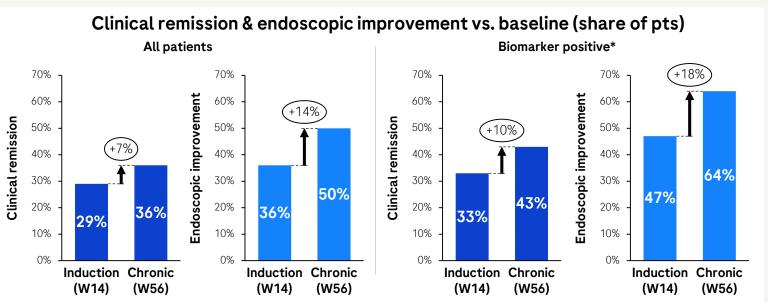
Initiation of Ph III studies in IBD ongoing; additional potential in several other auto-immune diseases

## anti-TL1A (RVT-3101)



- TL1A binds to DR3 receptor, stimulating downstream inflammation and fibrosis processes
- Dysregulated TL1A with clinical links to multiple immune-mediated diseases

#### Ph IIb (TUSCANY-2) anti-TL1A in ulcerative colitis



- Strong Ph IIb ulcerative colitis data for all-comers and biomarker positive pts; sustained clinical remission (75%) and endoscopic improvement (80%) from induction to chronic phase
- Favorable safety and tolerability profile
- Ph III trials in IBD to be initiated in 2024
- Anti-TL1A has potential for improved clinical outcomes in multiple auto-immune diseases

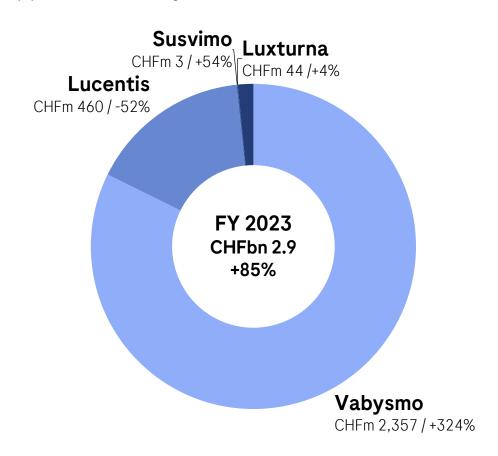
<sup>\*</sup>biomarker not yet disclosed; TL1A=Tumor necrosis factor-like cytokine 1A; DR3 receptor=dopamine 3 receptor; IBD=inflammatory bowel disease; RA=rheumatoid arthritis; SoC=standard of care





## Vabysmo reaching US market share of 22% in nAMD and 15% in DME\*

US approval for Vabysmo's third indication RVO achieved



#### Q4 update

- Vabysmo: 42% of US new patient starts are naive
- US approval for Vabysmo in RVO achieved, 2 months ahead of PDUFA date
- Vabysmo reimbursement achieved in all EU5
- New long-term data for Vabysmo in RVO shows sustained retinal drying, driving extended durability and sustained vision improvements
- Ph III (SatraGO1/2) of Enspryng in TED initiated

#### Outlook 2024

- Vabysmo in RVO: EU approval
- Susvimo in nAMD: US commercial relaunch
- Susvimo in DME/DR: US filing
- Ph II (BARDENAS/ALLUVIUM) vamikibart (anti-IL6) in DME readout
- Ph II (GOLDEN STUDY) ASO factor B in GA readout

#### CHFm / YoY CER growth

\*based on November 2023 Verana patient claims data; CER=Constant Exchange Rates; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; RVO=retinal vein occlusion; TED=thyroid eye disease; GA=geographic atrophy; ASO=antisense oligonucleotide; ASO factor B in collaboration with Ionis

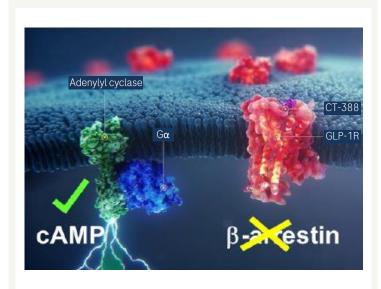




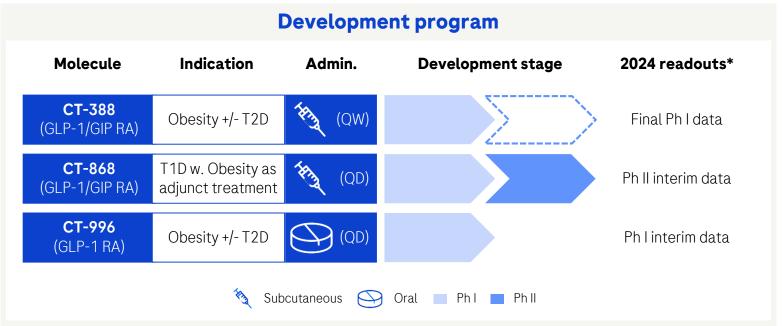
## Dual GLP-1/GIP agonist (CT-388) with best-in-class potential in obesity

Early stage readouts for all incretins expected in 2024; new trials to be initiated

#### **GLP-1/GIP RA (CT-388)**



- Elimination of β-arrestin coupling minimizes/avoids receptor degradation
- cAMP biased molecules show synergy between GLP-1 and GIP, leading to reduced blood glucose, food intake and body weight



- Broad development program in obesity with promising initial results; potential to combine with different Roche molecules
- CT-388's differentiated molecular pharmacology may enable more patients to achieve >15-20% weight loss with good tolerability via optimized dosing and titration scheme
  - Early Ph I results of up to -8% weight reduction at 4 weeks; Final readout end of 2024
  - Ph II in obesity +/- T2D to be initiated in 2024

<sup>\*</sup>Outcome studies are event-driven: timelines may change; GLP-1=glucagon-like peptide-1; GIP=glucose-dependent insulinotropic polypeptide; RA=receptor agonist; T2D=type-2 diabetes; QW=once weekly; QD=once daily



## 2023: Key newsflow\*

	Compound	Indication	Milestone	
	Hemlibra	Moderate hemophilia A	EU approval	<u> </u>
人	Polivy + R-CHP	1L DLBCL	US approval	<b>✓</b>
00000	Vabysmo	RVO	US approval/EU filing	<b>✓</b>
	Tecentriq	Subcutaneous administration	US approval/EU filing	US 2024 / <b>✓ EU filing</b>
Regulatory	Columvi (glofitamab)	3L+DLBCL	US/EU approval	<b>✓</b>
	Xofluza	Influenza (paediatric 1+ yrs.)	EU approval	<b>✓</b>
	Tecentriq + Avastin	Adjuvant HCC	Ph III IMbrave050	<b>✓</b>
	Tecentriq + chemo	Neoadjuvant / adjuvant TNBC	Ph III GeparDouze/NSABP B-59	2024
	Tecentriq	Adjuvant SCCHN	Ph III IMvoke010	×
	Tecentriq + chemo	Adjuvant TNBC	Ph III IMpassion030	X
	Tiragolumab + Tecentriq	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	H2 2024
	Tiragolumab + Tecentriq + chemo	1L esophageal cancer	Ph III SKYSCRAPER-08 (China only)	<b>✓</b>
	Venclexta + dexamethasone	t(11;14) R/R MM	Ph III CANOVA	X
<u>—</u>	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA	2024
	Alecensa	Adjuvant ALK+ NSCLC	Ph III ALINA	<b>✓</b>
lacksquare	Phesgo OBI (on body injector)	HER2+ BC	Ph I (pivotal)	✓
Clinical results	Crovalimab	PNH	Ph III COMMODORE 1/2	<b>✓</b>
our results	Columvi + GemOx	2L+ DLBCL	Ph III STARGLO	2024
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO	2024
	Elevidys (Delandistrogene moxeparvovec)	DMD	Ph III EMBARK	Full data to be shared
	Ocrevus 6m SC	RMS / PPMS	Ph III OCARINA II	✓
	TNKase	Stroke patients 4.5-24h	Ph III TIMELESS	X
	Susvimo	DME	Ph III PAGODA	<b>✓</b>
	Susvimo	DR	Ph III PAVILION	<b>✓</b>
	Xolair	Food allergy	Ph III OUtMATCH	<b>✓</b>

#### Additional 2023 newsflow:

- Fenebrutinib Positive Ph II (FENopta) results in RMS
- Elevidys US approval in DMD for 4 and 5 years old (Sarepta)
- **Zilebesiran** Ph II (KARDIA-1) positive topline results
- Tiragolumab + Tecentriq + Avastin: Positive Ph I/II (MORPHEUS) results in 1L HCC
- Inavolisib + palbociclib + fulvestrant Positive Ph III (INAVO120) results in 1L HR+ PIK3CA-mut BC

Milestone



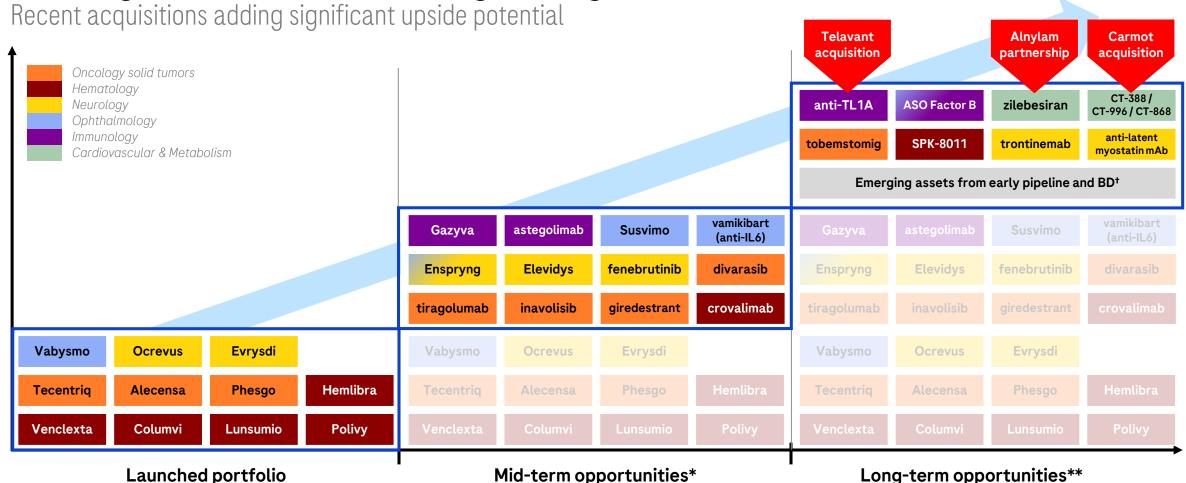
# 2024: Key newsflow\*

•	Compound	Indication	Milestone	
	Alecensa	Adjuvant ALK+ NSCLC	US/EU approval	
	inavolisib + palbociclib + fulvestrant	1L PIK3CA-mut HR+ BC	US/EU filing	
£	Tecentriq	Subcutaneous administration	US/EU approval	<b>✓</b> EU
$\triangle$	crovalimab	PNH	US/EU approval	
0000	Elevidys	DMD	EMA interaction ongoing	
Regulatory	Ocrevus 6m SC	RMS/PPMS	US/EU approval	
negatatory	Susvimo	DME/DR	US filing	
	Vabysmo	RVO	EU approval	
	Xolair	Food allergy	US approval	
	tiragolumab + Tecentriq	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	
	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA	
	Columvi + GemOx	2L+ DLBCL	Ph III STARGLO	
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO	
	Gazyva	Lupus nephritis	Ph III REGENCY	
	Enspryng	generalized Myasthenia gravis	Ph III LUMINESCE	
	Evrysdi + GYM329	SMA	Ph II MANATEE	
	prasinezumab	Parkinson's disease	Ph IIb PADOVA	
Clinical results	trontinemab	Alzheimer's disease	Ph Ib/IIa Brainshuttle™ AD	
	vamikibart (anti-IL6)	DME	Ph II BARDENAS/ALLUVIUM	
	ASO factor B	Geographic atrophy	Ph II GOLDEN STUDY	
	zilebesiran	Hypertension	Ph II KARDIA-2	
	СТ-388	Obesity w/wo T2D (QW SC)	Ph I	
	CT-868	T1D w. Obesity (QD SC)	Ph II	
	СТ-996	Obesity w/wo T2D (QW oral)	Ph I	

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## Building blocks for mid- to long-term growth



<sup>\*</sup>mid-term defined as filing 2024-2026, \*\*long-term defined as filing after 2026, BD=business development; fincluding GSM=Gamma-secretase modulator (GSM)





# **Diagnostics Division**

Matt Sause CEO Roche Diagnostics



## 2023: Diagnostics sales

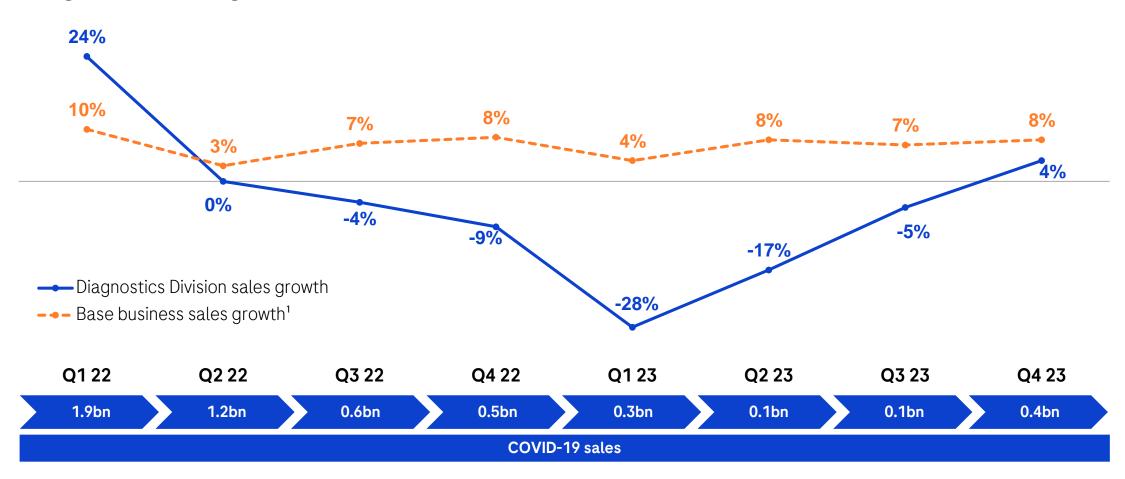
Strong base business growth, partially offsetting COVID-19 sales decrease

	2023 2022		Change in %		Excl.
	CHFm	CHFm	CHF	CER	C19 <sup>1</sup>
Diagnostics Division	14,104	17,730	-20	-13	7
Core Lab	7,750	7,775	0	9	
Molecular Lab	2,220	3,450	-36	-30	
Pathology Lab	1,388	1,318	5	14	
Point of Care	1,379	3,589	-62	-58	
Diabetes Care	1,367	1,598	-14	-4	



## Diagnostics sales growth by quarter

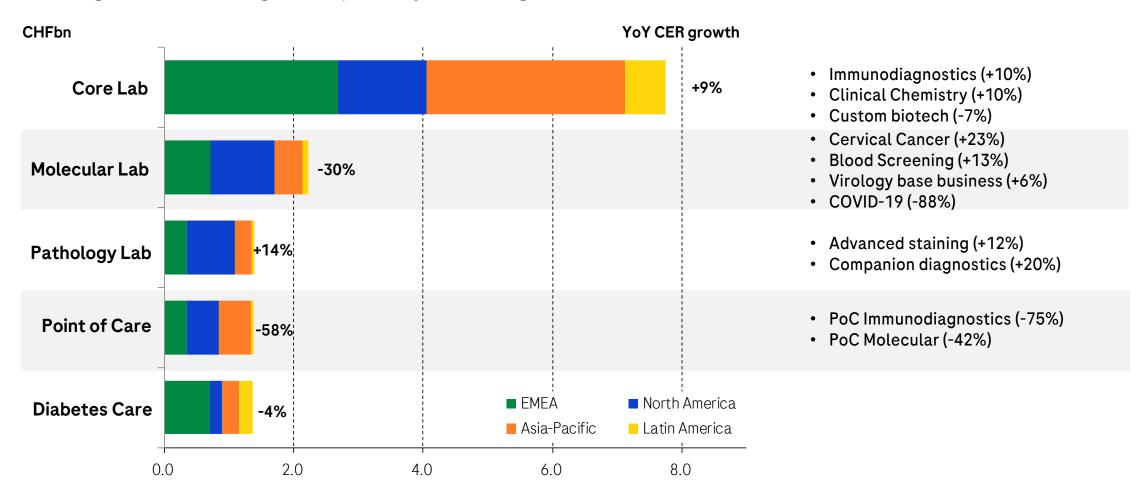
Strong base business growth in Q4 2023





## 2023: Diagnostics highlights

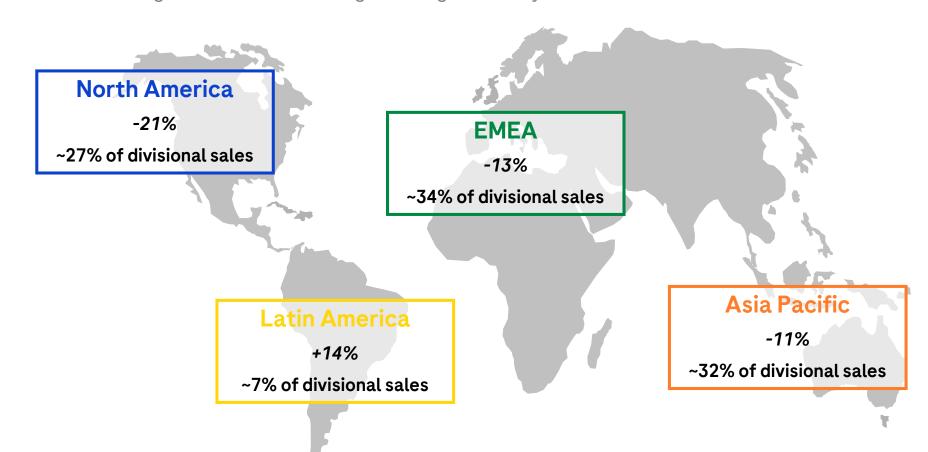
Strong base business growth, partially offsetting COVID-19 sales decrease





## 2023: Diagnostics regional sales

Strong base business growth across all regions; significantly lower COVID-19 sales





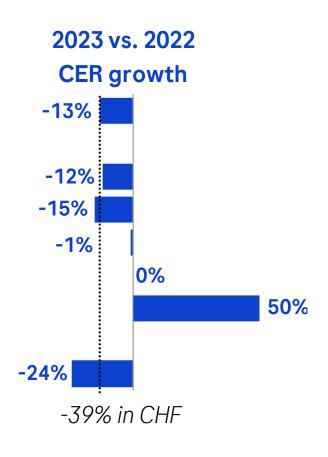
## 2023: Diagnostics core operating profit

Decline due to drop in COVID-19 sales

<b>~</b>	П	9	7
	u		J

	СПРМ	abs. CER
Sales	14,104	-2,314
Other revenue	58	-8
Cost of sales	-6,908	+1,236
R&D	-1,747	+16
SG&A	-2,899	-12
OOI&E	60	+22
Core operating profit	2,668	-1,061

Core OP in % of sales 18.9%
At CER 21.5%
(2022: 24.7%)

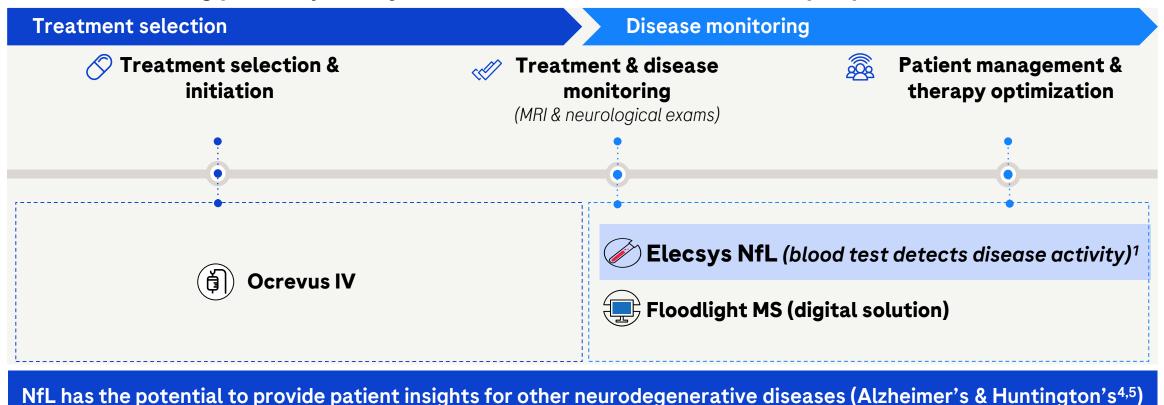




## FDA Breakthrough Device Designation status for Elecsys NfL

Aids in detection of disease activity and progression of Multiple Sclerosis

#### Role of NfL along patient journey for MS (disease burden $\sim$ 3 million people<sup>2,3</sup>)



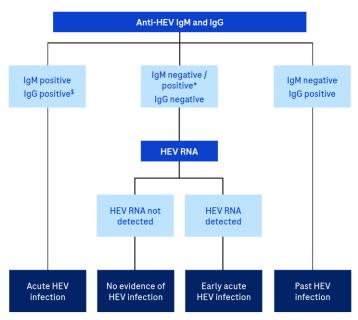
NfL=neuro filament light chain; MRI=magnetic resonance imaging; <sup>1</sup>Research Use Only (RUO) not linked to any specific indication; <sup>2</sup>Walton C, King R, Rechtman L, et al. Insights from the Atlas of MS, third edition; <sup>3</sup>MS Society UK (2024) mssociety.org.uk/about-ms/types-of-ms/relapsing-remitting-ms; <sup>4</sup>Mayo Clinic Laboratories NFLC (2024) mayocliniclabs.com/api/sitecore/TestCatalog/DownloadTestCatalog?testId=616854; <sup>5</sup>post critical-care applications are under exploration



## Elecsys®Anti-HEV IgM & Anti-HEV IgG

Combination test will enable diagnosis of acute and chronic infections for better patient management

#### Interpretation of testing for HEV<sup>1</sup>



\* Detection of anti-HEV IgM alone does not diagnose HEV infection; \$ rising anti-HEV IgG titer HEV, hepatitis E virus; IgG, immunoglobulin G; IgM, immunoglobulin M; RNA: ribonucleic acid.

#### **Unmet medical need**

- 20 million new annual infections, resulting in more than 70,000 deaths 1,2
- ⅓ of global population at risk of HEV infection<sup>1</sup>
- Anti-HEV IgM for the detection of acute HEV added to the WHO Essential Diagnostics List in Q4 2023<sup>3</sup>

#### **Medical Value**

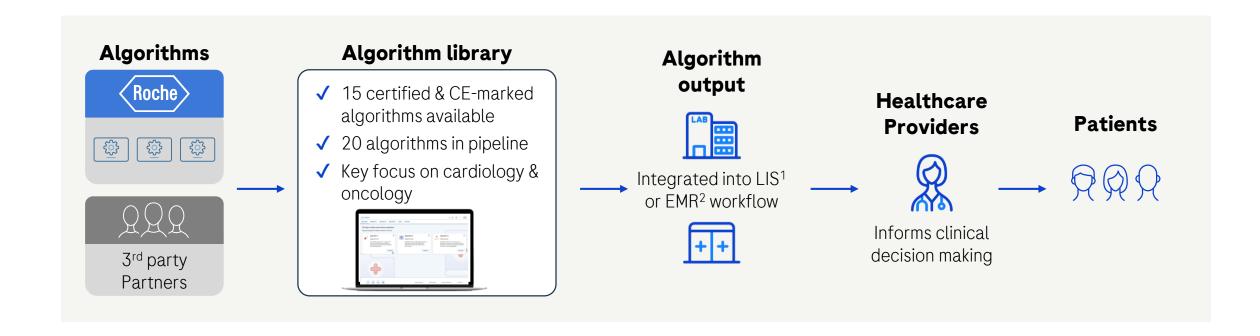
- Early identification in vulnerable groups (pregnant women, patients with chronic liver disease)
- Differential diagnosis in people with symptoms of acute hepatitis
- Confirming possible cause of other disorders accompanying hepatitis

The tests complete Roche's panel for differential diagnosis of acute viral hepatitis (HAV, HBV, HCV, HEV)



## navify Algorithm Suite

Providing trusted decision support for clinicians

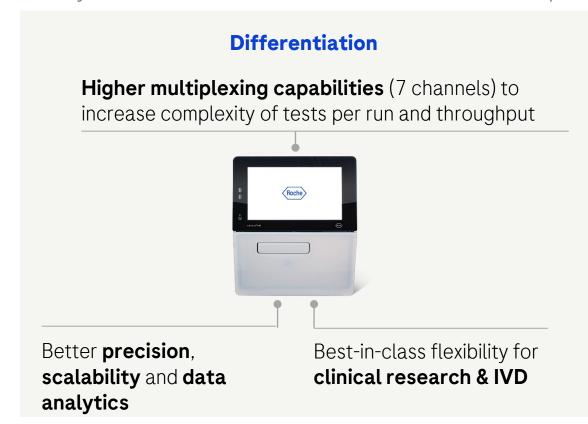


Digital platform offering lab customers & clinicians a broad menu of medical algorithms used to inform clinical decisions



## **LightCycler PRO®**

First system labeled for research and IVD with broad portfolio of molecular diagnostics tests



#### **Key applications**

- Rapid response to outbreaks and new pathogens
- Immuno-oncology routine testing
- Applied research and biomarker discovery
- Human genetics and population genomics

#### **Market opportunity**

- Launched in Q4 2023 for IVD use in CE mark countries and the US
- Supports 200+ assays from TiB Molbiol<sup>1</sup>
- Addressable lab developed test market CHF 500 million, instrument market CHF 200 million

LightCycler PRO + TiB Molbiol is a groundbreaking & cost effective offering for the innovators' PCR segment



## Diagnostics key launches 2023

Area	Product	Description	Markets	Status
Core Lab	CCM Vertical	Modular transportation system, integrated into the existing cobas connection modules, allowing for overhead sample transportation over different work areas or different floors enabling effective use of lab space	Global	<b>~</b>
	cobas pro integrated solutions	Scalable and modular serum work area analyzer for mid to high volume clinical chemistry and immunochemistry testing	China	<b>~</b>
	cobas pure integrated solutions	Serum work area analyzer for low to mid volume clinical chemistry and immunochemistry testing on a footprint of two square meters	China	<b>~</b>
Molecular Lab	LightCycler Pro	Flexible real-time PCR instrument with dual IVD and research mode as well as enhanced system features	US & CE	<b>~</b>
Point of Care	cobas pulse	Handheld device combining professional glucose meter and a digital platform to host digital clinical decision support applications (from Roche and third parties)	US	2024
Pathology Lab	IDH1 R132H (IDH Glioma)	Neuropathology Immunohistochemistry (IHC) solution supporting the detection of tumor cells with the IDH1 R132H mutation aiding pathologists to render a diagnosis of gliomas	US	<b>~</b>
Core Lab	Anti-HEV IgG and Anti-HEV IgM	Anti-HEV IgM: Immunoassay aiding in the diagnosis of acute HEV infection in clinical settings; Anti-HEV IgG: Immunoassay aiding in the detection of a recent or past HEV infection and enabling accurate seroprevalence determinations. The two assays expand the hepatitis panel (HAV, HBV, HCV, HEV) on the same analytical platform	CE	<b>~</b>
	HBeAg Quant	Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B viral infection	CE	<b>~</b>
	IL-6 Neonatal sepsis (claim extension)	Only immunoassay available on the market with dedicated claim and supporting evidence aiding in diagnosis of sepsis in neonates, with potential to reduce newborn mortality	CE	<b>~</b>
	RUO Amyloid Plasma Assays (pTau181 & ApoE4)	Two qualitative immunoassays measuring the phosphorylated Tau 181 protein and apolipoprotein E4 in human plasma for research use only	US	<b>~</b>
Pathology Lab	RUO Digital Pathology Algorithm: PD-L1 SP142	Digital pathology algorithm aiding pathologists in scoring PD-L1 (SP142) breast samples, ensuring a standardized approach and an adjunctive tool to augment diagnostic confidence for research use only	Global	<b>~</b>
	navify Algorithm Suite	Digital solution providing access to an open library of certified IVD-based clinical algorithms	Selected markets <sup>1</sup>	
Lab Insights	Menu for navify Algorithm Suite	Certified clinical algorithms for oncology applications such as colon and liver cancers	Selected markets <sup>1</sup>	<b>~</b>
	cobas infinity lab 3.05	Next-generation lab middleware enabling ecosystem of cloud-based solutions for quality control and instrument maintenance	Global	<b>~</b>
	navify Marketplace	Digital marketplace offering lab customers full range of innovative applications (from Roche and third parties)	Selected markets <sup>1</sup>	
	navify Sample Tracking	Open digital solution offering sample tracking beyond the lab setting (from IVD-sample creation to lab reception) to improve testing traceability and quality	Selected markets <sup>1</sup>	~
	Core Lab  Molecular Lab Point of Care Pathology Lab  Core Lab  Pathology Lab	Core Lab  Cobas pro integrated solutions cobas pure integrated solutions LightCycler Pro  Point of Care  Pathology Lab  IDH1 R132H (IDH Glioma)  Anti-HEV IgG and Anti-HEV IgM  Core Lab  HBeAg Quant  IL-6 Neonatal sepsis (claim extension) RUO Amyloid Plasma Assays (pTau181 & ApoE4) RUO Digital Pathology Algorithm: PD-L1 SP142 navify Algorithm Suite Menu for navify Algorithm Suite Cobas infinity lab 3.05 navify Marketplace	CCM Vertical Modular transportation system, integrated into the existing cobas connection modules, allowing for overhead sample transportation over different work areas or different floors enabling effective use of lab space cobas pro integrated solutions cobas pro integrated solutions and object of the property of t	CCM Vertical Modular transportation system, integrated into the existing cobas connection modules, allowing for overhead sample transportation over different work areas or different floors enabling effective use of lab space  Cobas pro integrated solutions Cobas pour eintegrated solutions cobas pure integrated solutions and part of the solutions of the solution of the solutions of the solutions of the solutions of the solution of the solutio

Description

1Selected markets: 14 countries with first releases; CE=European conformity; RUO=research use only; PCR=polymerase chain reaction; IVD=in vitro diagnostic; IDH=isocitrate dehydrogenase; HEV=Hepatitis E virus; HAV=Hepatitis A virus; HBV=Hepatitis B virus; HCV=Hepatitis C virus



## Diagnostics key launches 2024

	Area	Product	Description	Markets	Status
Instruments Automation	Core Lab	i601 mass spectrometry system	Launch of an unique total solution for clinical mass spectrometry testing: fully automated, integrated and IVD-compliant	CE	
		cobas c703	Introducing high-throughput clinical chemistry testing to cobas pro integrated solutions	CE	
		cobas ISE neo	Introducing high-throughput ISE testing to cobas pro integrated solutions	CE	
	Diabetes Care	Accu-Chek SmartGuide (Continuous Glucose Monitoring)	Launch of Roche's first generation Continuous Glucose Monitoring (CGM) solution	CE	
	Molecular Lab	cobas 6800/8800 v2.0	Upgraded system with increased flexibility, higher throughput and greater automation to enable broader test menu. Retrofittable with existing cobas 6800/8800 installed base	CE	
	Pathology Lab	Primary Diagnosis Claim on DP600 US	FDA 510k Primary Diagnosis clearance on DP600 scanner as a critical step to advance Digital Pathology	US	
Tests	Core Lab	cobas pro serology solution (blood screening)	FDA approval of our serology Roche Blood Safety Solution (RBSS) for the US donor screening market (largest donor screening market globally)	US	
	Point of Care	cobas Liat Respiratory Panel (SARS-CoV-2, Flu A/B & RSV)	Detection and differentiation of four respiratory targets: SARS-CoV-2, Influenza A, Influenza B & respiratory syncytial virus (RSV)	US EUA	
	Molecular Lab	cobas Respiratory flex	Using novel Temperature Assisted Generation of Signal (TAGS®) Multiplex technology & digital reflex approach, enables strategic efficiency with flexible testing for cobas x800 Systems	CE US	
		cobas Malaria (blood screening)	RT qualitative PCR test on the cobas® x800 systems detecting all five plasmodium species that occur in humans. Utilized for malaria screening of blood donors, blood products, organs, and tissues	CE US	
	Pathology Lab	VENTANA Kappa Lambda Dual ISH mRNA Probe Cocktail	Aid in diagnosis of B-cell lymphomas and plasma cell neoplasms	CE US	
Digital solutions	Diagnostics Insights	navify Analytics family	Supports lab directors/managers to track, review, identify trends/challenges and optimize operations. Has four apps tailored to Core, Pathology, Molecular Labs and Point of Care	Global	



## **Invitation to Roche Diagnostics Investor Day 2024**

Innovating Diagnostics, shaping healthcare, changing lives

#### cobas i601 mass spectrometry system



#### **Highlights:**

- Mass spectrometry
- Continuous glucose monitoring
- Next generation sequencing
- Point of care
- Upcoming molecular diagnostics launches
- Neurology biomarkers in development

#### Roche Diagnostics Day on May 22

London / hybrid event

14:00 - 16:30 CEST / 13:00 - 15:30 BST 08:00 - 10:30 am EDT / 05:00 - 07:30 am PDT Doing now what patients need next