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- 1 pricing and product initiatives of competitors;
- 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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- 6 increased government pricing pressures;
- 7 interruptions in production;
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- 9 litigation;
- 10 loss of key executives or other employees; and
- 11 adverse publicity and news coverage.

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## **Growing through Innovation**

***Severin Schwab*** | CEO Roche

*Octavian Conference, 12 January 2023*

**Pharma rejuvenation & positioning**

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**Diagnostics upcoming opportunities**

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**Outlook**

# Broadest set of technology platforms available

Roche being a pioneer in antibodies, ADCs and bi-specifics

Small molecules	mAb	Bi-specifics	Fusion protein	Antibody drug conjugate	Cyclic peptides	Neoantigen vaccines	Personalized T cells	Allogeneic CAR-T cells
		 2:1 format 1:1 format						
<ul style="list-style-type: none"> <li>• ipatasertib</li> <li>• inavolisib</li> <li>• giredestrant</li> <li>• KRAS G12C<sup>i</sup></li> <li>• belvarafenib</li> <li>• SHP2<sup>i</sup></li> <li>• BRAF1 (3)</li> <li>• ARPi</li> <li>• camonsertib<sup>1</sup></li> </ul> <p>Target oncogenes, induce apoptosis, suppress tumor growth</p>	<ul style="list-style-type: none"> <li>• tiragolumab</li> <li>• CD25 mAb</li> <li>• codrituzumab</li> <li>• CD137</li> <li>• TGFβ (SOF10)</li> </ul> <p>Amplify immune response</p>	<ul style="list-style-type: none"> <li>• glofitamab</li> <li>• cibusatamab</li> <li>• HER2 x CD3</li> <li>• glypican-3 x CD3</li> <li>• cevostamab</li> <li>• PD1 x LAG3</li> <li>• HLA-A2-WT1 x CD3</li> <li>• HLA-A2-MAGE-A4 x CD3</li> <li>• MAGE-A4ImmTAC</li> <li>• EGFRvIII x CD3</li> <li>• GPRC5D x CD3</li> <li>• CD19 x CD28</li> </ul> <p>Engage and activate T cells to kill tumour cells</p>	<ul style="list-style-type: none"> <li>• PD1-IL2v</li> <li>• CD19-4-1BBL</li> <li>• FAP-4-1BBL</li> <li>• IL15/IL15Ra-Fc</li> <li>• FAP-CD40</li> </ul> <p>Amplify immune response</p>	<ul style="list-style-type: none"> <li>• preclinc</li> </ul> <p>Targeted toxic payload</p>	<ul style="list-style-type: none"> <li>• KRASI (LUNA18)</li> </ul> <p>Potential new drug class in size between small molecules and proteins</p>	<ul style="list-style-type: none"> <li>• autogene cevumeran</li> <li>• VB10.NEO</li> <li>• PBMC HPV vaccine</li> </ul> <p>Patient's neo-antigens for anti-tumour immune response</p>	<ul style="list-style-type: none"> <li>• Programmed T cells</li> </ul> <p>Patient's neo-antigens for anti-tumour immune response</p>	<ul style="list-style-type: none"> <li>• P-BCMA-ALLO1<sup>2</sup></li> <li>• P-CD19CD20-ALLO1<sup>2</sup></li> </ul> <p>Chimeric T cell receptors targeted to receptors expressed on tumor cells</p>
<ul style="list-style-type: none"> <li>• fenebrutinib</li> <li>• ralmitaront</li> <li>• alogabat</li> <li>• selnoflast</li> <li>• Abx MCP</li> <li>• LepB inhibitor</li> <li>• balovaptan</li> </ul>	<ul style="list-style-type: none"> <li>• crovalimab</li> <li>• prasinezumab</li> <li>• semorinemab</li> <li>• bepranemab</li> <li>• TLR7 mAb</li> <li>• astegolimab</li> <li>• latent myostatin</li> <li>• anti-IL-6</li> <li>• vixarelimab<sup>3</sup></li> </ul>	<ul style="list-style-type: none"> <li>• FIXa x FX</li> <li>• VEGF x Ang2 DutaFab</li> </ul>	<ul style="list-style-type: none"> <li>• brain shuttle gantenerumab</li> <li>• brain shuttle CD20</li> <li>• efmardocokin alfa</li> </ul>	<p><b>Recombinant proteins</b></p> <ul style="list-style-type: none"> <li>• TNKase</li> <li>• zinpentraxin alfa</li> </ul>	<p><b>Antisense RNA</b></p> <ul style="list-style-type: none"> <li>• ASO factor B<sup>5</sup></li> <li>• HBV siRNA</li> <li>• PDL1 LNA</li> <li>• rugonersen</li> <li>• tominersen</li> </ul>	<p><b>Gene therapy</b></p> <ul style="list-style-type: none"> <li>• OpRegen<sup>4</sup></li> </ul>	<p><b>Stem cell therapy</b></p> <ul style="list-style-type: none"> <li>• OpRegen<sup>4</sup></li> </ul>	<p><b>Oncolytic adenovirus</b></p>

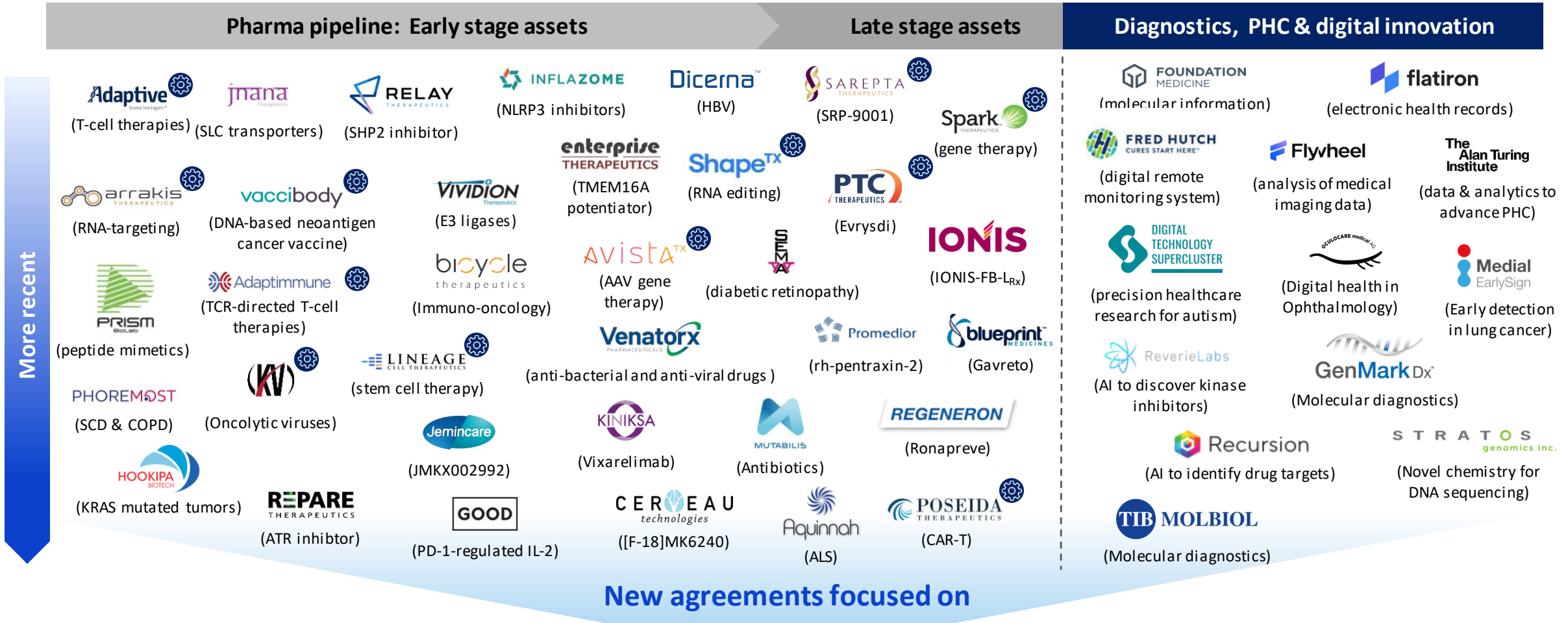
List of pipeline molecules shown below is not complete; <sup>1</sup> Repare Therapeutics managed, <sup>2</sup> Poseida Therapeutics managed, <sup>3</sup> Kiniksa Pharmaceuticals managed, <sup>4</sup> Lineage Cell Therapeutics managed, <sup>5</sup>IONIS managed

= Oncology pipeline

= Neuroscience and I2O pipeline

# BD focus on pipeline acceleration, Diagnostics and digital innovation

Development stage at time of deal/partnership start

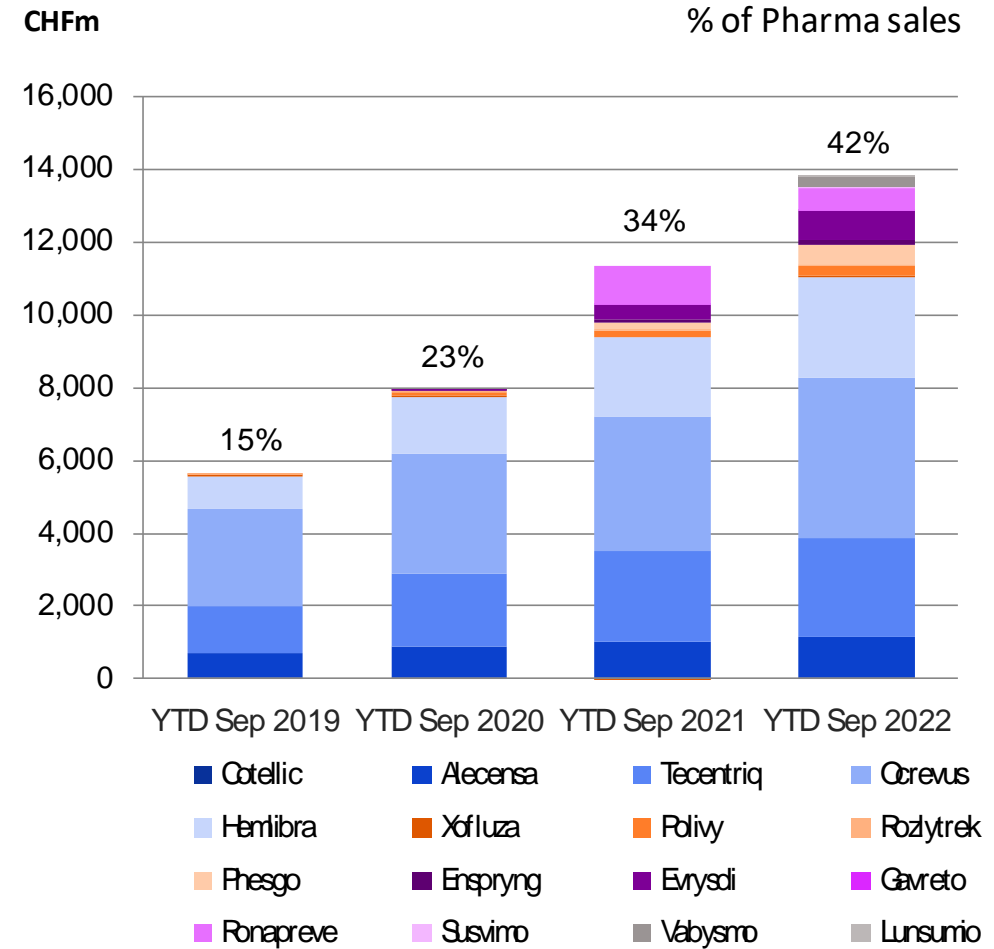
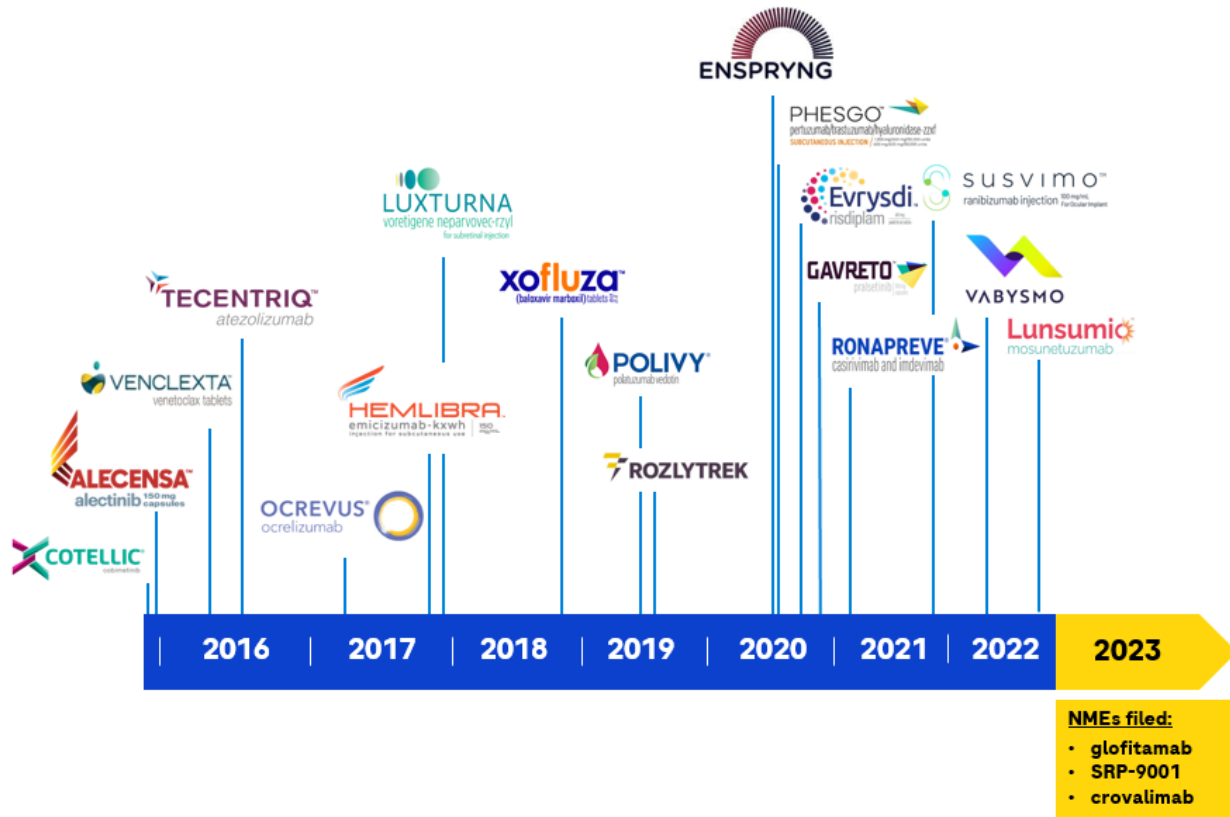


Non-exhaustive and illustrative overview of deals and partnerships signed over recent years; PHC=personalized healthcare; (drug modalities)

= Deal/partnership includes novel platform technologies

# Pharma portfolio rejuvenation on-going

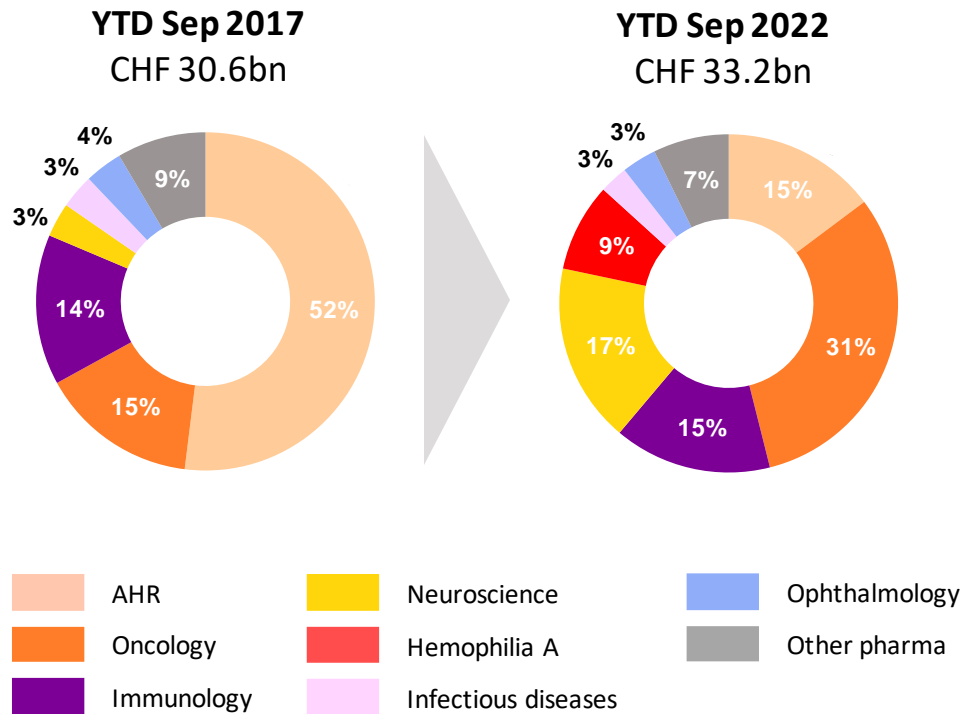
Medicines launched since the end of 2015 account for 42% of sales \*



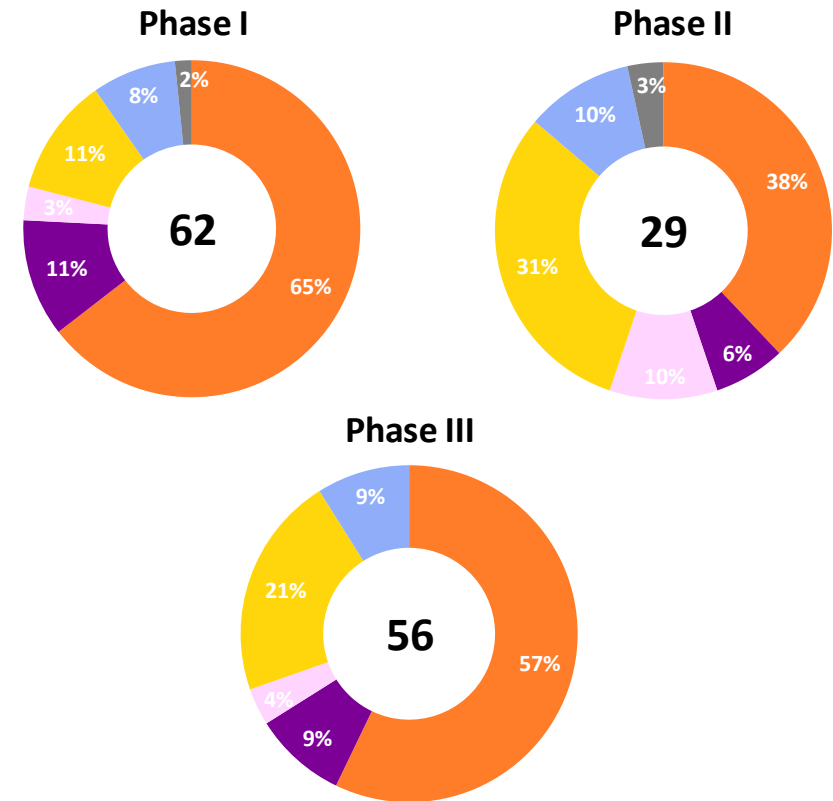
\* Venclerxa sales booked by AbbVie and therefore not included

# Evolving as leader in Ophthalmology, Neuroscience, Hematology

## YTD Sep 2022 Pharma sales



## Record number of NMEs and AIs (YTD Sep 2022)



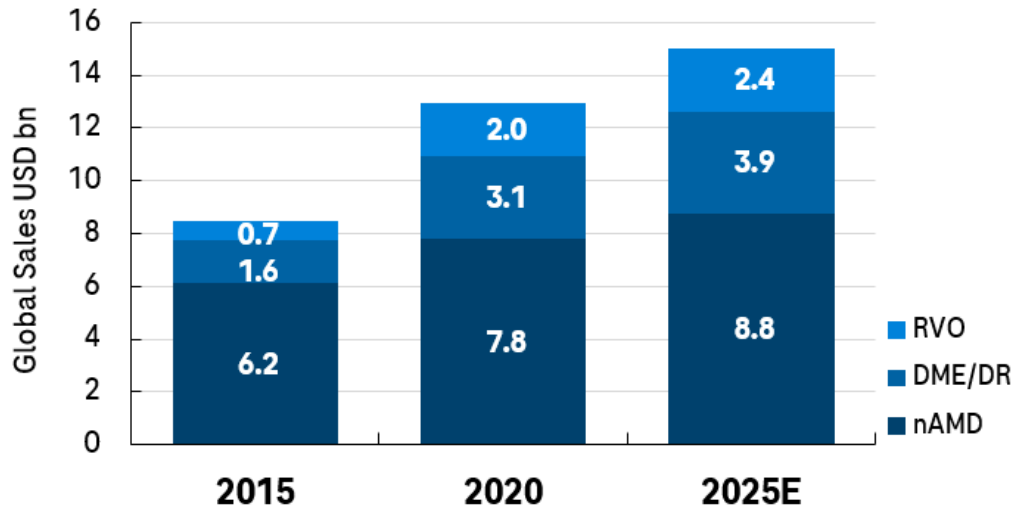


# Ophthalmology: Set to become a market leader

HC systems recognize importance of durability to overall outcomes and costs



Global retina market growing to USD 15 bn<sup>1</sup>



*Longer dosing intervals to improve compliance and treatment outcomes, as well as leading to cost savings*

## Initial uptake in high unmet need patients

- Strong customer uptake with switching coming primarily from aflibercept
- Uptake across both nAMD and DME patients with more nAMD patients, as expected by epidemiology

## Expect expanded use with reimbursement security

- US: broad coverage for ~90% of lives including policies at most national accounts. Establishment of permanent J-code on Oct 1 drives acceleration in uptake in both “switch” and treatment naive patients
- Japan: strong uptake in the second largest retina market
- UK: NICE reimbursed Vabysmo just one week after the MHRA’s approval
- EU: Approved in September

## Broaden to additional indications, formulations

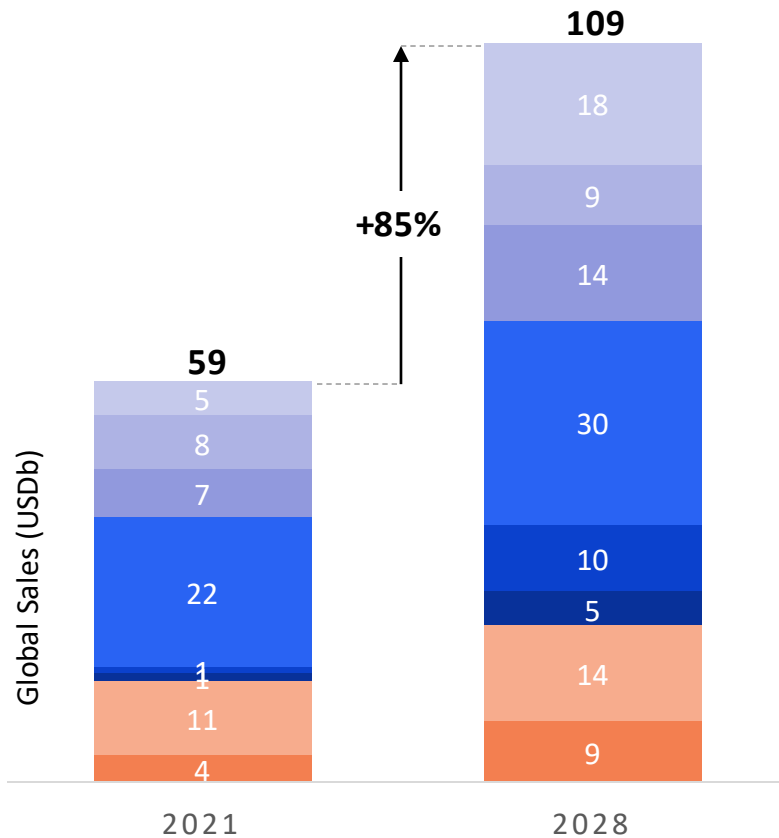
- Positive Ph III (COMINO / BALATON) results in RVO to be presented
- Prefilled syringe under development

1. Source: EvaluatePharma Jan 2021; CHMP=Committee for Human Medicinal Products; NICE=National Institute for Health and Care Excellence; MHRA=Medicines & Healthcare Products Regulatory Agency; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; RVO=retinal vein occlusion

# Hematology market expected to grow substantially

Roche has one of the broadest hematology portfolios with ~20 agents in 10+ diseases

Global hematology market growing to USD 109bn<sup>1</sup>



Roche's hematology portfolio is well positioned in a growing market

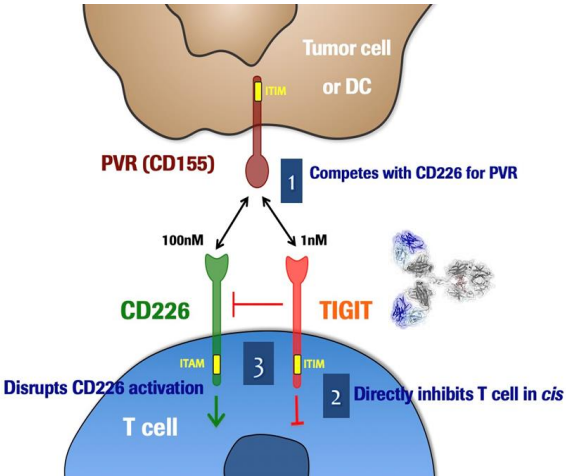
<b>DLBCL</b>	POLIVY <sup>+</sup> polatuzumab vedotin oint	Lunsumio	glofitamab (CD20 x CD3), CD19 x 4-1BBL, CD19 x CD28
<b>FL</b>	GAZYVA <sup>+</sup> obinutuzumab	Lunsumio	
<b>CLL</b>	GAZYVA <sup>+</sup> obinutuzumab	VENCLEXTA* venetoclax tablets	Lunsumio
<b>Multiple Myeloma</b>	VENCLEXTA* venetoclax tablets	cevastamab (FcRH5 x CD3), GPRC5D x CD3, P-BCMA-ALLO1, IL15	
<b>AML</b>	VENCLEXTA* venetoclax tablets	HLA-A2-WT1 x CD3	
<b>MDS</b>			
<b>Hemophilia A</b>	HEMLIBRA	SPK-8011 (AAV-based gene tx), NXT007 (FIX x FX)	
<b>Other non- malignant</b>	crovalimab (C5i) in PNH, aHUS, SCD		

<sup>1</sup> Source of market data: EvaluatePharma Nov 2022, Cowen Therapeutic area report 2022, Other malignant heme includes ALL, HL, CML, Waldenström's and other smaller indications. Other non-malignant heme includes PNH, aHUS & SCD. \*Developed in collaboration with AbbVie; +In collaboration with Seagen Inc; aHUS=atypical hemolytic uremic syndrome; AML=acute myeloid leukemia; DLBCL=diffuse large B cell lymphoma; FL=follicular lymphoma; CLL=chronic lymphocytic leukemia; MDS=myelodysplastic syndromes; PNH=paroxysmal nocturnal hemoglobinuria; SCD=sickle-cell disease; AAV=adeno-associated virus; Tx=treatment/therapy

# Tiragolumab development program with read-outs in 2023

Early data (SKYSCRAPER-01) show encouraging efficiency in 1L PDL1+ NSCLC

## Anti-TIGIT mAb



- Fully human IgG1/kappa Ab with intact Fc region that blocks the binding of TIGIT to its receptor PVR
- Could restore anti-tumor responses and thereby complement the activity of anti-PD-L1/PD-1 antibodies

## Tiragolumab development program

	Indication	Ph 1	Ph 2	Ph 3	
Lung cancer	1L NSCLC: PD-L1 high	SKYSCRAPER-01			Results 2023
	1L ES-SCLC	SKYSCRAPER-02			✗
	Stage III unres. NSCLC	SKYSCRAPER-03			
	Neoadj / Adj NSCLC	SKYSCRAPER-05			
	1L NSq NSCLC	SKYSCRAPER-06			
Additional solid tumors	Locally advanced ESCC	SKYSCRAPER-07			
	1L ESCC (China)	SKYSCRAPER-08			Results 2023
	2L+ PD-L1+ CC	SKYSCRAPER-04			Presentation planned H1 2023
Novel combinations	Melanoma (+PD1-LAG3)	SKYSCRAPER-09			

- SKYSCRAPER-01 did not meet its co-primary PFS endpoint. The co-primary OS endpoint was immature at the first IA. A numeric improvement was observed in both PFS and OS at the first analysis.
- The study will continue to the next OS interim analysis, projected in 1Q 2023
- Tiragolumab + Tecentriq was well-tolerated and no new safety signals were identified
- SKYSCRAPER-04 will be presented in 1H 2023

Ab=Antibody; SCLC=Small Cell Lung Cancer; NSCLC=Non-Small Cell Lung Cancer; ESCC=esophageal squamous cell carcinoma; NSq=non-squamous; IA=Interim analysis; PFS=Progression-free survival; OS=Overall survival; FA=final analysis

# Key late-stage pipeline readouts 2023

\*



	Compound	Indication	Data readout	
2023	Tecentriq + chemo	Neoadjuvant / adjuvant NSCLC	Ph III IMpower030	Oncology
	Tecentriq + Avastin	Adjuvant HCC	Ph III IMbrave050	Oncology
	Tecentriq + chemo	Neoadjuvant / adjuvant TNBC	Ph III GeparDouze/NSABP B-59	Oncology
	Tecentriq	Adjuvant SCCHN	Ph III IMvoke010	Oncology
	Tecentriq + chemo	Adjuvant TNBC	Ph III IMpassion030	Oncology
	Tiragolumab + Tecentriq	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	Oncology
	Tiragolumab + Tecentriq + chemo	1L esophageal cancer	Ph III SKYSCRAPER-08 (China only)	Oncology
	Venclexta + dexamethasone	t(11;14) R/R MM	Ph III CANOVA	Hematology
	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA	Hematology
	Alecensa	Adjuvant ALK+ NSCLC	Ph III ALINA	Oncology
	Phesgo OBI	HER2+ BC	Ph I (pivotal)	Oncology
	Crovalimab	PNH	Ph III COMMODORE 1/2	Hematology
	Glofitamab + GemOx	2L+ DLBCL	Ph III STARGLO**	Hematology
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO**	Hematology
	Delandistrogene moxeparvovec	DMD	Ph III EMBARK	Neuroscience
	Ocrevus 6m SC home administration	RMS / PPMS	Ph III OCARINA II	Neuroscience
	TNKase	Stroke patients 4.5-24h	Ph III TIMELESS	Neuroscience
	Susvimo	DME	Ph III PAGODA	Ophthalmology
	Susvimo	DR	Ph III PAVILION	Ophthalmology
	Xolair	Food allergy	Ph III OUTMATCH	Immunology

\* Outcome studies are event-driven: timelines may change; \*\* Results are event-driven; read-outs expected in 2023/24

**Pharma rejuvenation & positioning**

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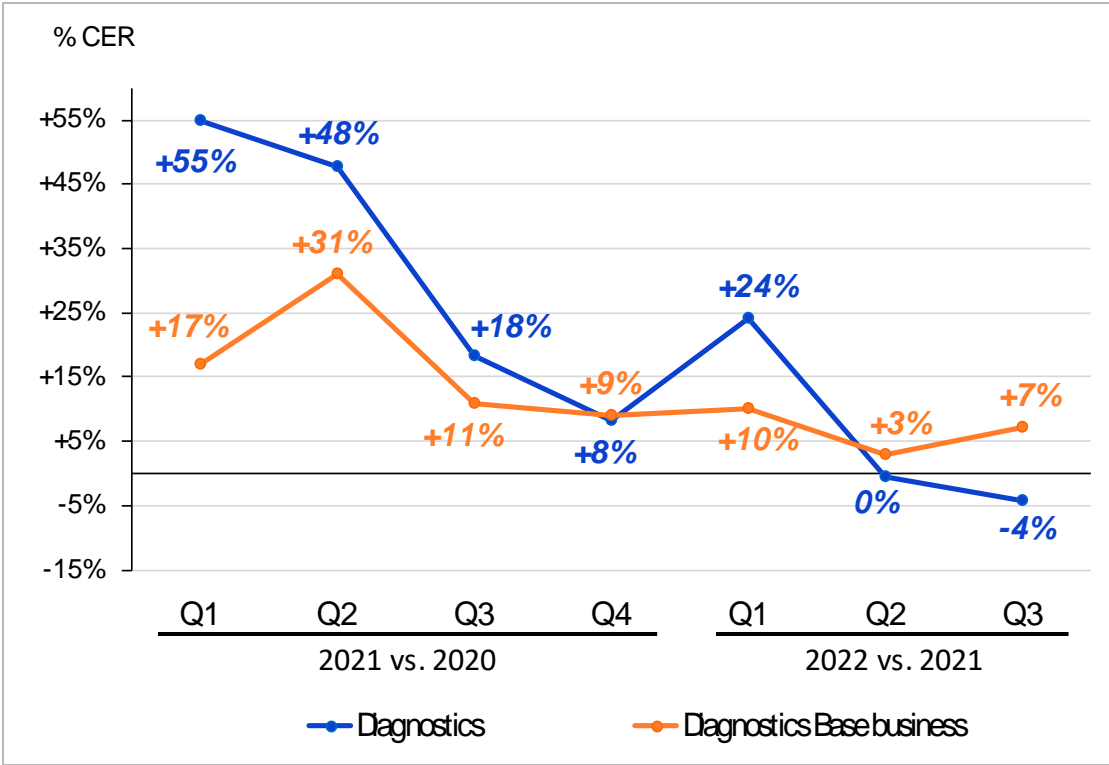
**Diagnostics upcoming opportunities**

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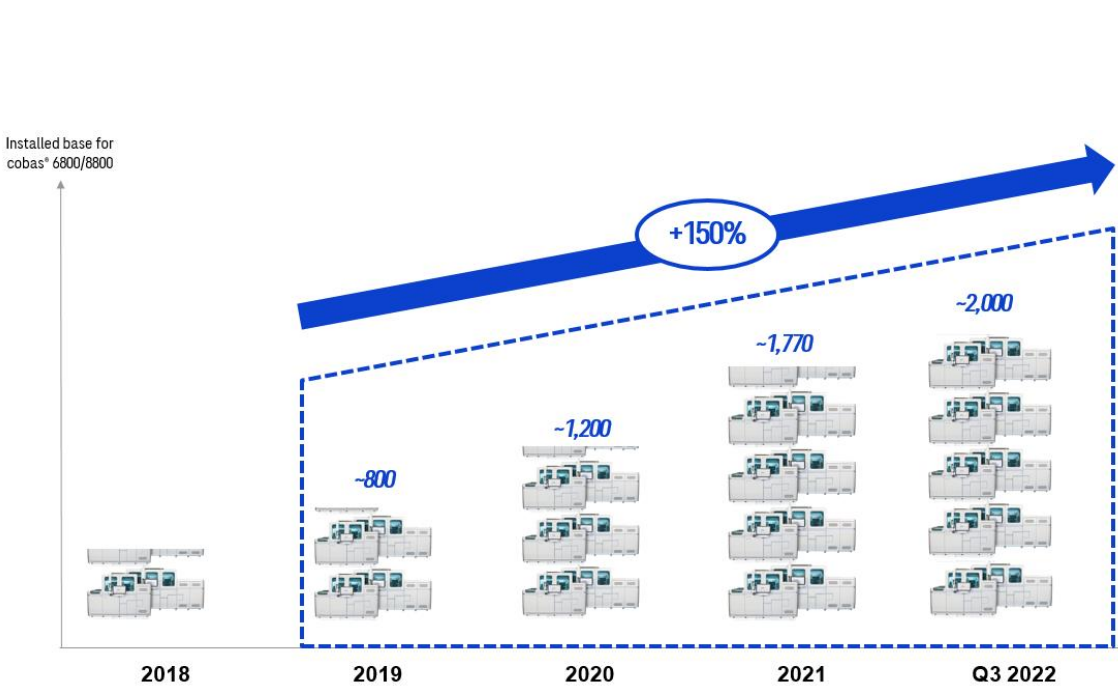
**Outlook**

# High throughput testing solution driving Diagnostics base business

**Diagnostics**  
Quarterly sales evolution 2021-2022



**Installed base for cobas 6800/8800**  
Sales evolution 2018- Q3 2022

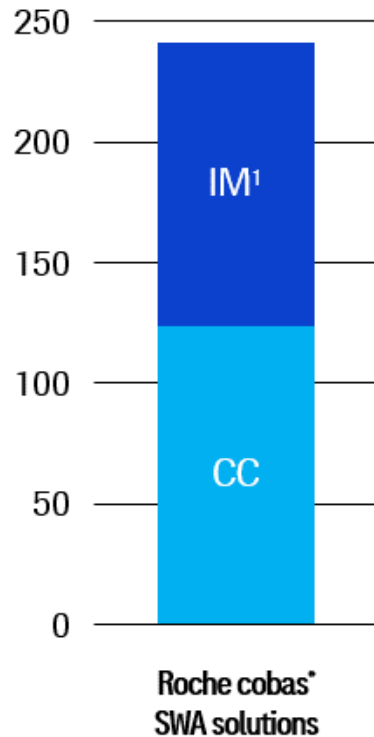


Growth rates at CER (Constant Exchange Rates)

# Serum Work Area (SWA) menu expansion driving future growth

>240 assays running on >100k installed cobas® SWA instruments

## Broad IM + CC assay menu



## Launched in 2021 & 2022

Immuno chemistry assays	
EBV EBNA IgG (CE)	IGRA SARS-CoV-2 (CE)
EBV VCA IgG (CE)	HCV Duo (CE)
EBV IgM (CE)	Anti-HAV II <sup>2</sup> (CN)
Anti-p53 (CE)	HBsAg Confirmatory <sup>2</sup> (US)
GAAD (CE)	AFP-L3 (CE)
NT-proBNP claim extension <sup>1</sup> (CE)	FT4 IV <sup>2</sup> (CE)
TnT-hs claim extension <sup>1</sup> (CE)	Alzh CSF biomarker (US)
PCT CE claim extension <sup>1</sup> (CE)	
Vit D total III <sup>2</sup> (CE)	
Anti-HBe (US)	
Sirolimus (CN)	
HBsAg Confirmatory <sup>2</sup> (CE)	
Alzh CSF biomarkers (CE)	

Clinical chemistry assays	
Fentanyl <sup>3</sup> (CE, US)	Benz 2 <sup>2</sup> (US)
sTfR Gen 2 <sup>2</sup> (CE)	NH3L2 (CN)
CRP4 (CN)	

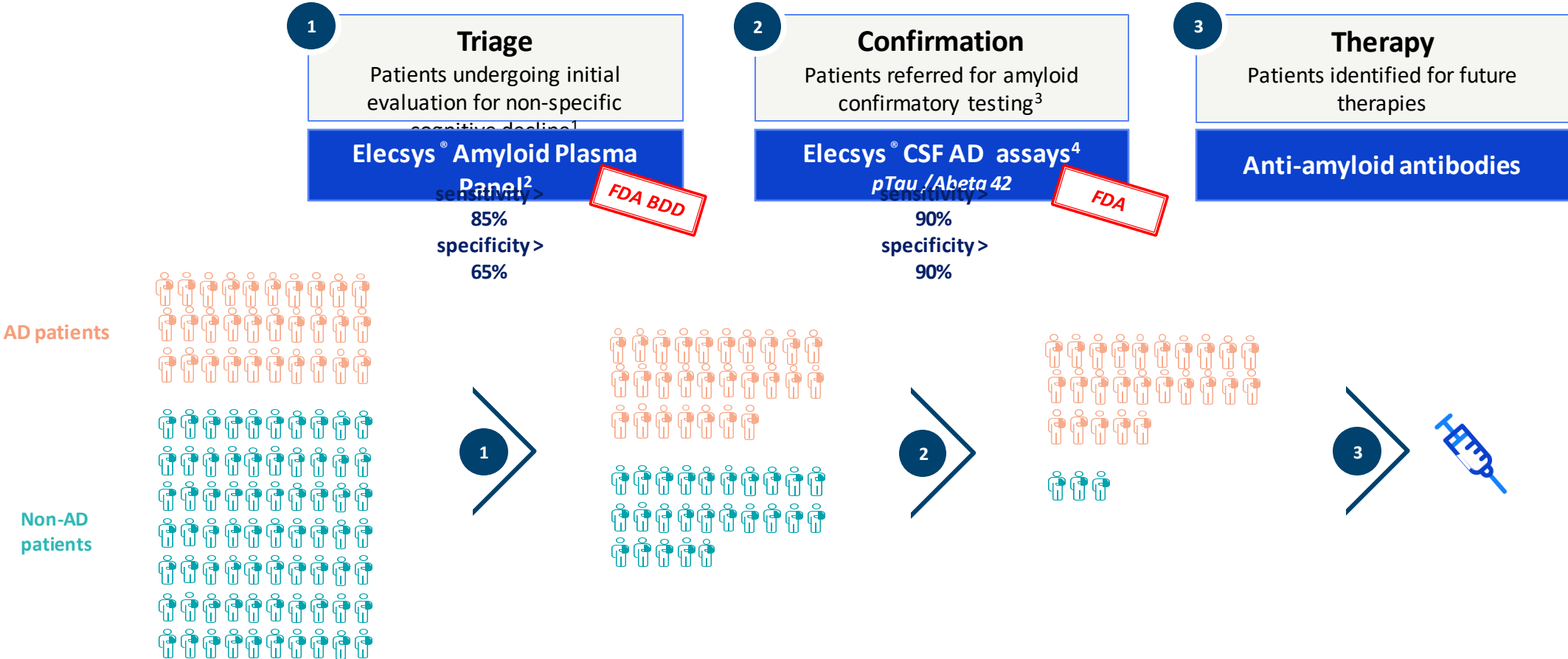
  

Launched in 2021	Launched in 2022
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IM: Immunochemistry; CC: Clinical chemistry; <sup>1</sup> Claim extension, <sup>2</sup> Product update; <sup>3</sup> Partner Channel

# Elecsys<sup>®</sup> Amyloid Plasma Panel clinical results

Addressing the unmet need of early detection of Alzheimer's disease pathology



<sup>1</sup> Assumed prevalence of AD 30% in symptomatic patients; <sup>2</sup> Mean of clinical performance data from retrospective cohorts measured with Elecsys Amyloid Plasma Panel; <sup>3</sup> Alternative to PET scan; <sup>4</sup> FDA approval

= 10 patients



**Pharma rejuvenation & positioning**

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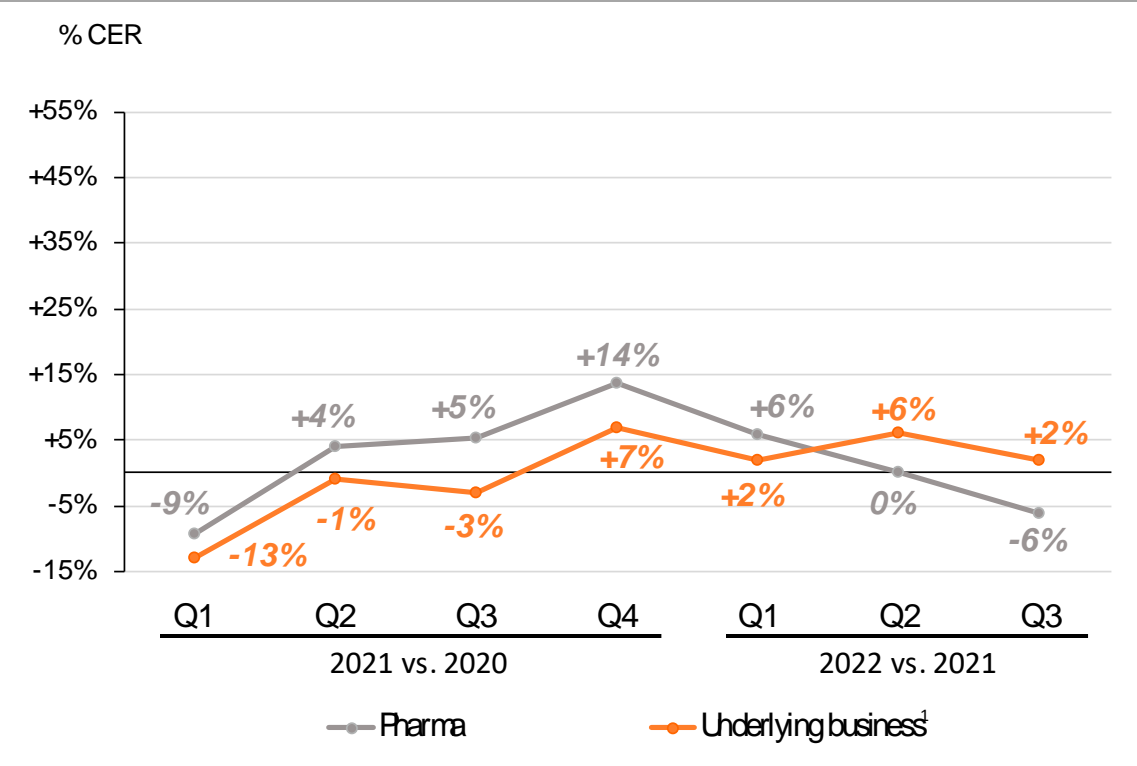
**Diagnostics upcoming opportunities**

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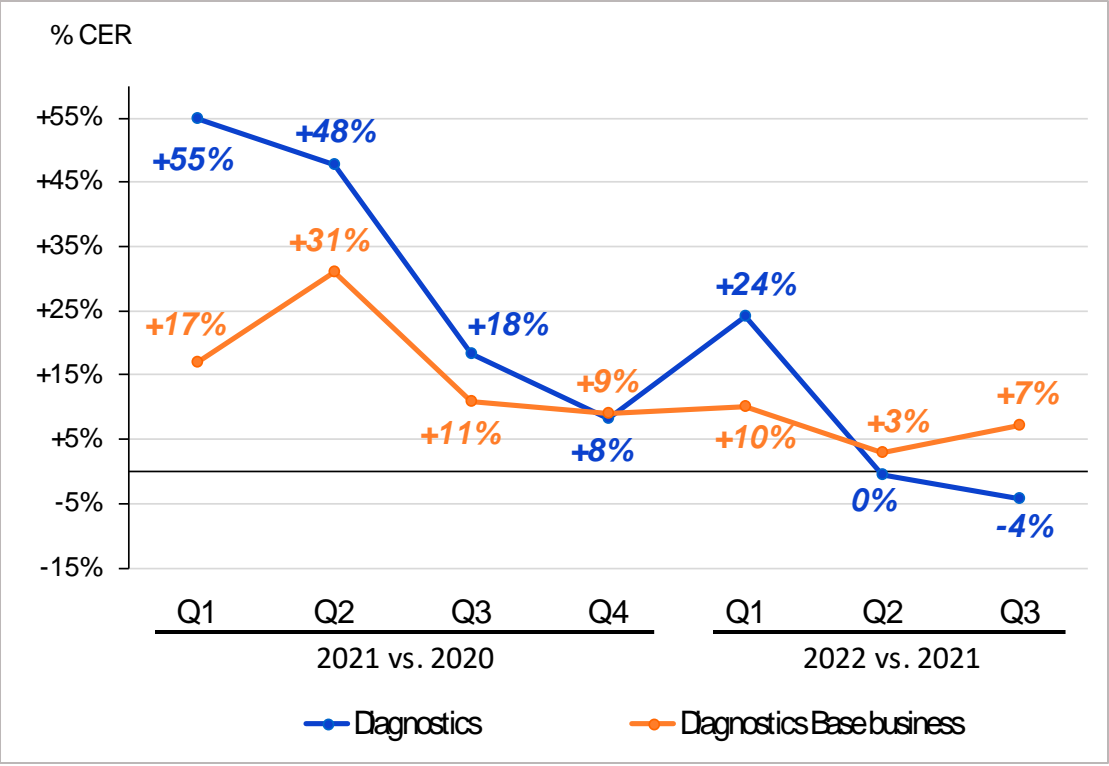
**Outlook**

# YTD Sep 2022: Solid underlying sales growth in both divisions

**Pharma**  
Quarterly sales evolution 2021-2022



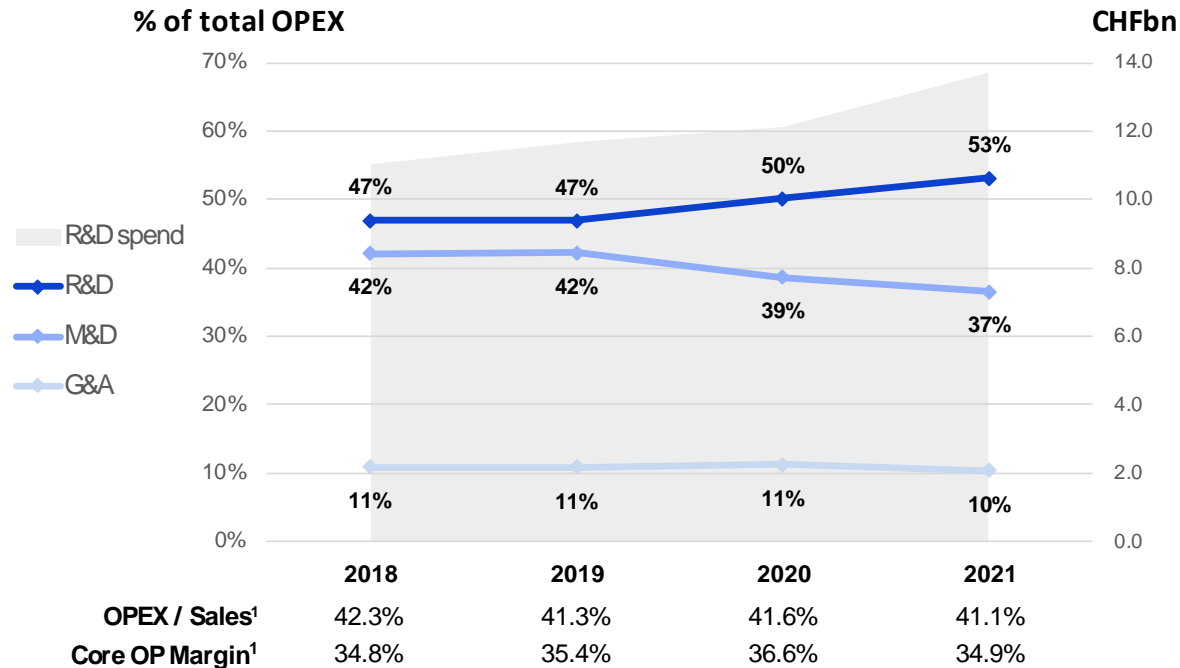
**Diagnostics**  
Quarterly sales evolution 2021-2022



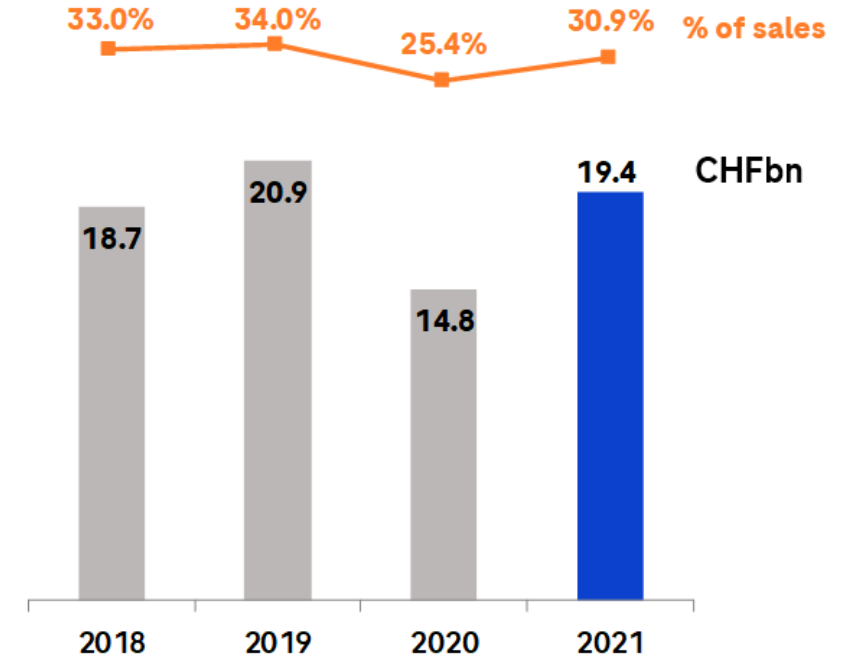
Growth rates at CER (Constant Exchange Rates); <sup>1</sup> Excl. Ronapreve and Actemra

# Reallocating resources while securing margins and cash flow

## Operating expenses (OPEX) and Core OP 2018 - 2021



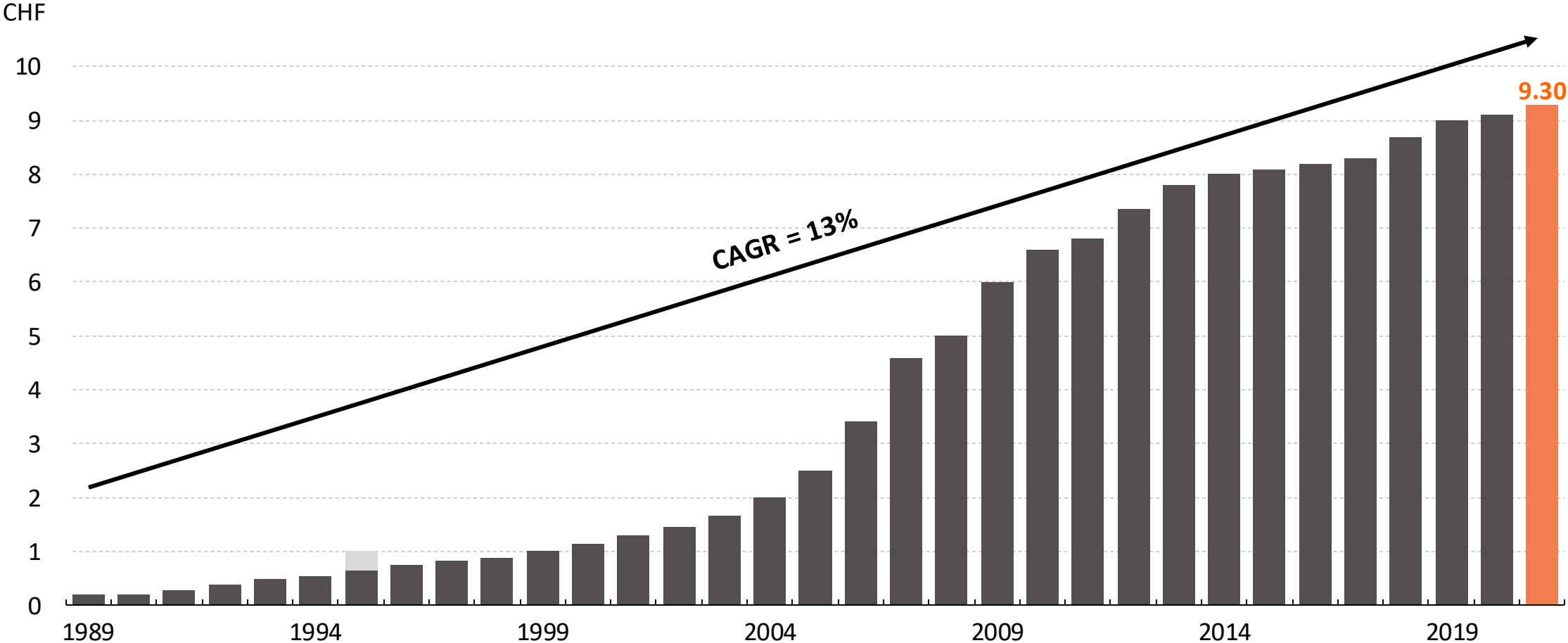
## Operating free cash flow



- Cross-company alignment to support innovation: Transformation ongoing in G&A, M&D, Finance and R&D
- Pharma: Exploring new platform technologies and developing industry-leading pipeline
- Diagnostics: Developing new solutions for mass spectroscopy and DNA sequencing and continuously broadening the portfolio
- Driving digitalisation throughout the entire Pharma/Diagnostics value chains

<sup>1</sup> Calculated using figures at CER (Constant Exchange Rates); OPEX = G&A + M&D + R&D

# 2021: 35<sup>th</sup> consecutive annual dividend increase



2021 dividend as proposed by the Board of Directors; Note: For 1995, a special dividend was paid out to mark F. Hoffmann-La Roche's 100th anniversary in 1996

# 2022 outlook confirmed

**Group sales growth<sup>1</sup>**

- Stable to low-single digit

**Core EPS growth<sup>1</sup>**

- Low- to mid-single digit

**Dividend outlook**

- Further increase dividend in Swiss francs

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

**Doing now what patients need next**