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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;
- 4 fluctuations in currency exchange rates and general financial market conditions;
- 5 uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
- 6 increased government pricing pressures;
- 7 interruptions in production;
- 8 loss of or inability to obtain adequate protection for intellectual property rights;
- 9 litigation;
- 10 loss of key executives or other employees; and
- 11 adverse publicity and news coverage.

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ZKB Swiss equity conference Zürich 2023

Roche business update

Alan Hippe |

Chief Financial & Information Officer Roche Group

Performance Update

Strategy and Outlook

Latest pipeline Update

Our achievements

Roche is continuously shifting the standard of care

A legacy of patient and business impact...

16

Blockbuster drugs in 2022, up from 7 in 2012

#1

in neurology and hemophilia A¹

#3

in oncology¹

#1

in *in vitro* diagnostics¹

#1

top pharma as ranked by rare disease patient groups²

#1

Pharma in AI readiness³

...with a track record of establishing standard of care across new therapeutic areas



First and only therapy approved for RMS/PPMS



First bispecific antibody in AMD and DME



First and only prophylactic treatment for hemophilia A with/without inhibitors



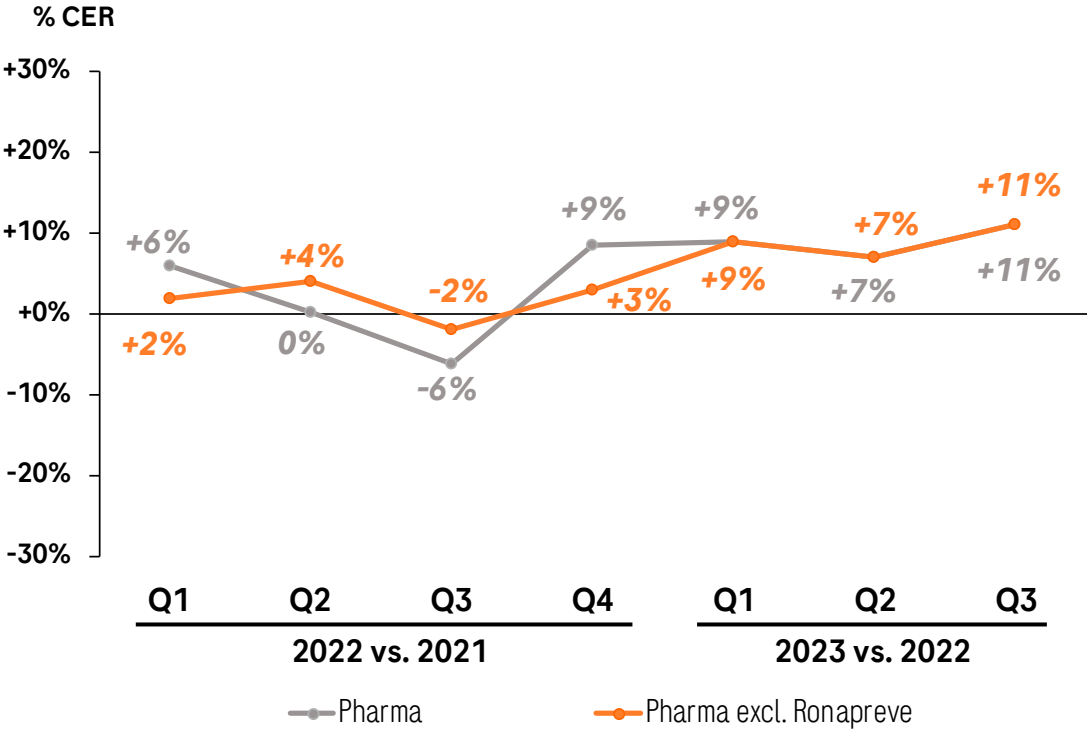
First-in-class splicing modifier for the treatment of SMA

¹based on FY 2022 sales (Evaluate/Bloomberg); ²Patient View, 2023; ³CBInsight, 2023; AI=artificial intelligence; RMS=relapsing; PPMS=primary progressive multiple sclerosis; AMD=age-related macular degeneration; DME=diabetic macular edema; SMA=spinal muscular atrophy

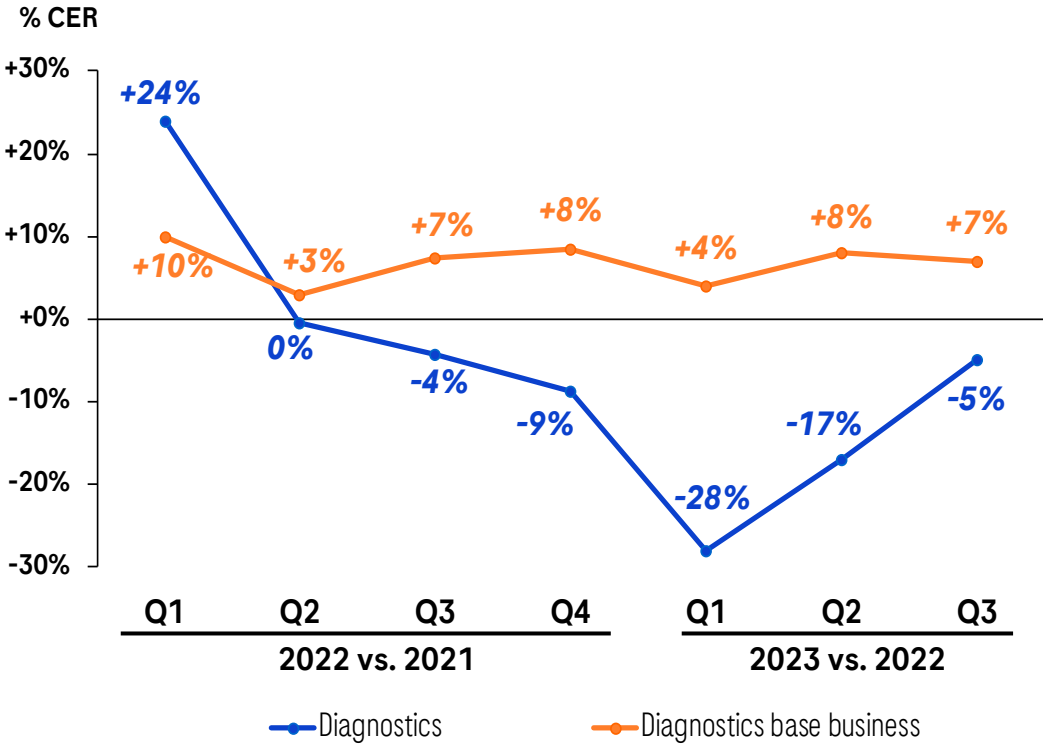
YTD Sep 2023: Strong base business growth in both divisions

COVID-19 impact to reduce significantly by end of Q1 2024

Pharma
Quarterly sales evolution 2022-2023



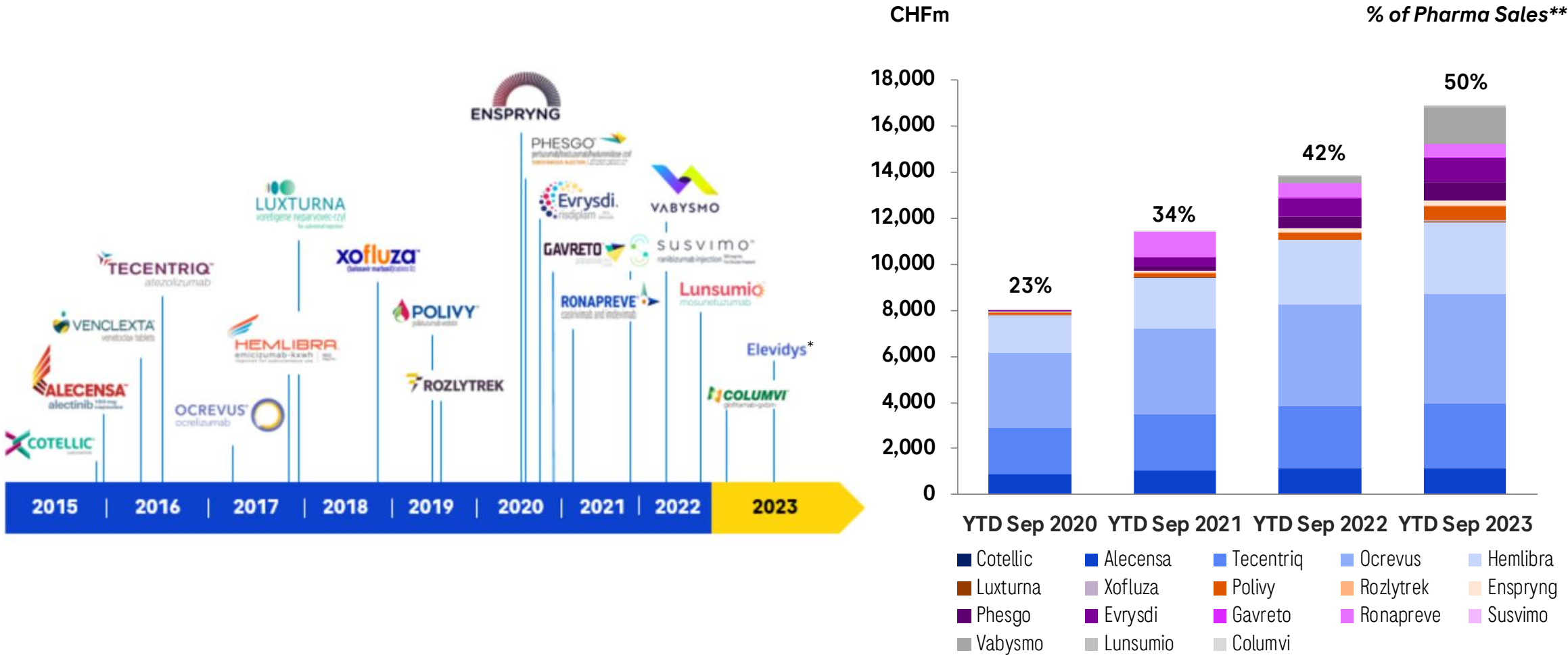
Diagnostics
Quarterly sales evolution 2022-2023



Growth rates at CER (Constant Exchange Rates) of the respective year

Young portfolio driving Pharma division growth momentum

Keeping historic launch momentum with two NMEs approved in 2023



Young portfolio defined as all launches since end of 2015; * Elevidys: Accelerated US approval by partner company Sarepta; ** Venclexta sales booked by AbbVie and therefore not included

FY guidance confirmed - strong half year performance

Base business with continued strong momentum; COVID sales washed-out by Q1 24

Guidance¹

HY Results



Pharma: Key products with strong growth and momentum from ongoing launches

Diagnostics: Base business with solid growth



COVID-19 sales for Diagnostics and Pharma expected to decline by roughly CHF 5bn

AHR² sales expected to erode by roughly CHF 1.6bn

Pharma: +8% in CER; +32% from products launched since 2015 ✓

Diagnostics: +6% in CER ✓

COVID-19 sales: CHF -2.7bn ✓

AHR² sales: CHF -0.6bn ✓

¹ At Constant Exchange Rates (CER); ² AHR: Avastin, Herceptin, Rituxan/MabThera

FY 2023 guidance confirmed



Group sales growth¹

Low single digit decline

Core EPS growth¹

Broadly in line with sales decline

Dividend outlook

Further increase dividend in Swiss francs

¹At Constant Exchange Rates (CER)

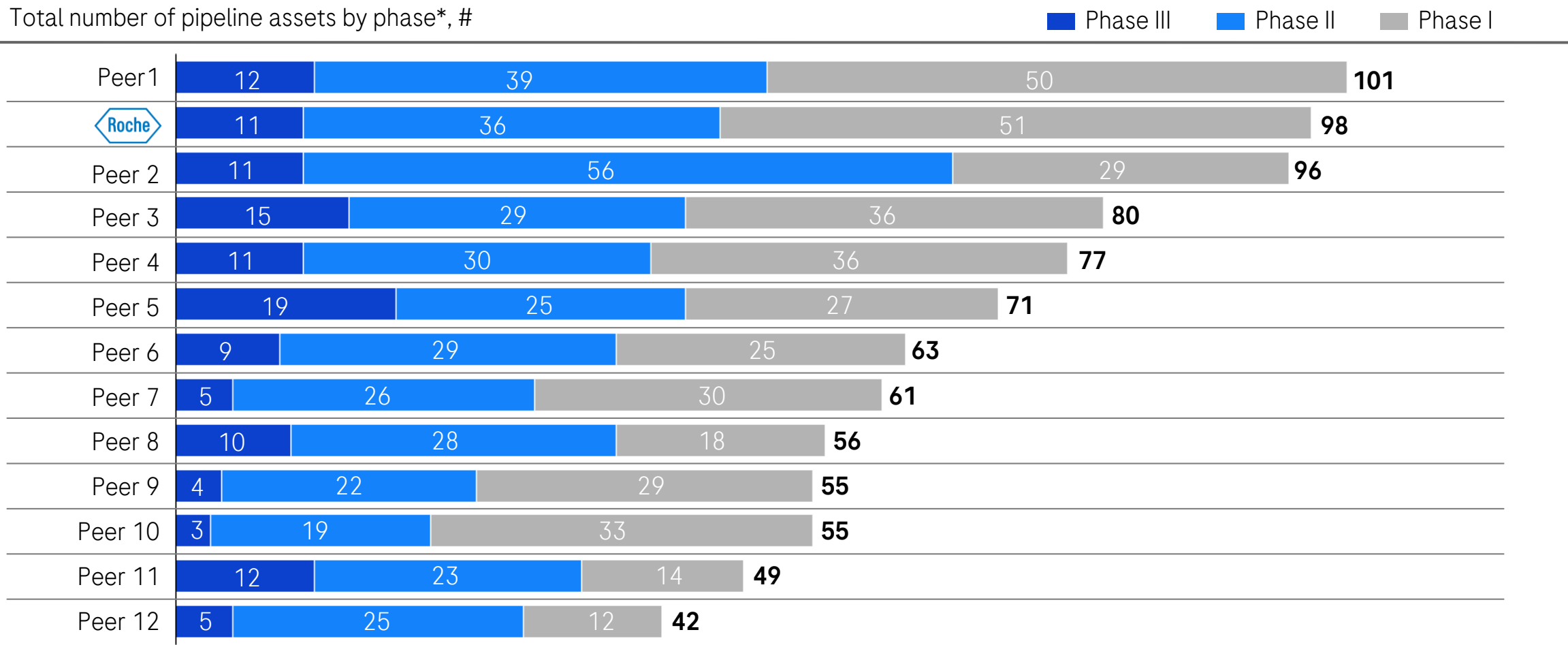
Performance Update

Strategy and Outlook

Latest pipeline Update

Number of pipeline assets in Phase I to III

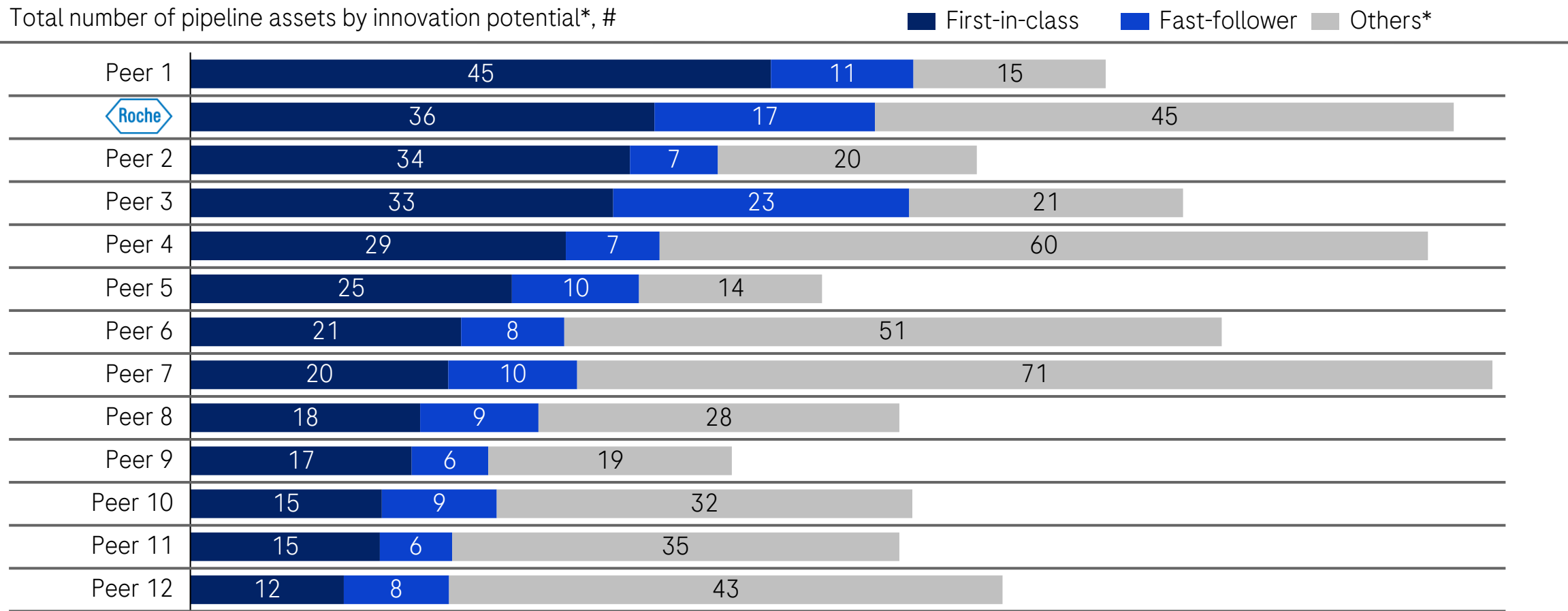
Roche ranks #2 in total pipeline volume



*Excludes pipeline products in pre-registration, registration and filed; Peer 1-12 are other large-cap Pharma
 Source: Pharmaprojects (February 2023), McKinsey attrition analytics

Pipeline assets segmented by innovation potential

Roche ranks #2 in number of NMEs with first-in-class potential



*NMEs that are neither first-in-class or best-in-disease, or without disclosed MoA, are grouped as 'Others'; Peer 1-12 are other large-cap Pharma
 Source: Pharmaprojects (March 2023)

Pipeline acceleration via partnering

Deals of the past two years increasingly focused on clinical stage NMEs*

TA	NME	Indication	Partner	Development stage
	P-CD19CD20-ALLO1	B-cell malignancies		Pre-clin. → Ph I
	P-BCMA-ALLO1	Multiple myeloma		Ph I
	AR degrader	mCRPC		Ph I
	camonsertib	Solid tumors		Ph I
	KSQ-4279	Solid tumors		Ph I
	OpRegen	Geographic atrophy		Ph II
	ASO factor B	IgAN		Ph II → Ph III ✓
	vixarelimab	IPF & SSC-ILD		Ph II
	zilebesiran	Hypertension		Ph II ✓
	Anti-TL1A mAb	UC, CD, autoimmune diseases		Ph II → Ph III ✓

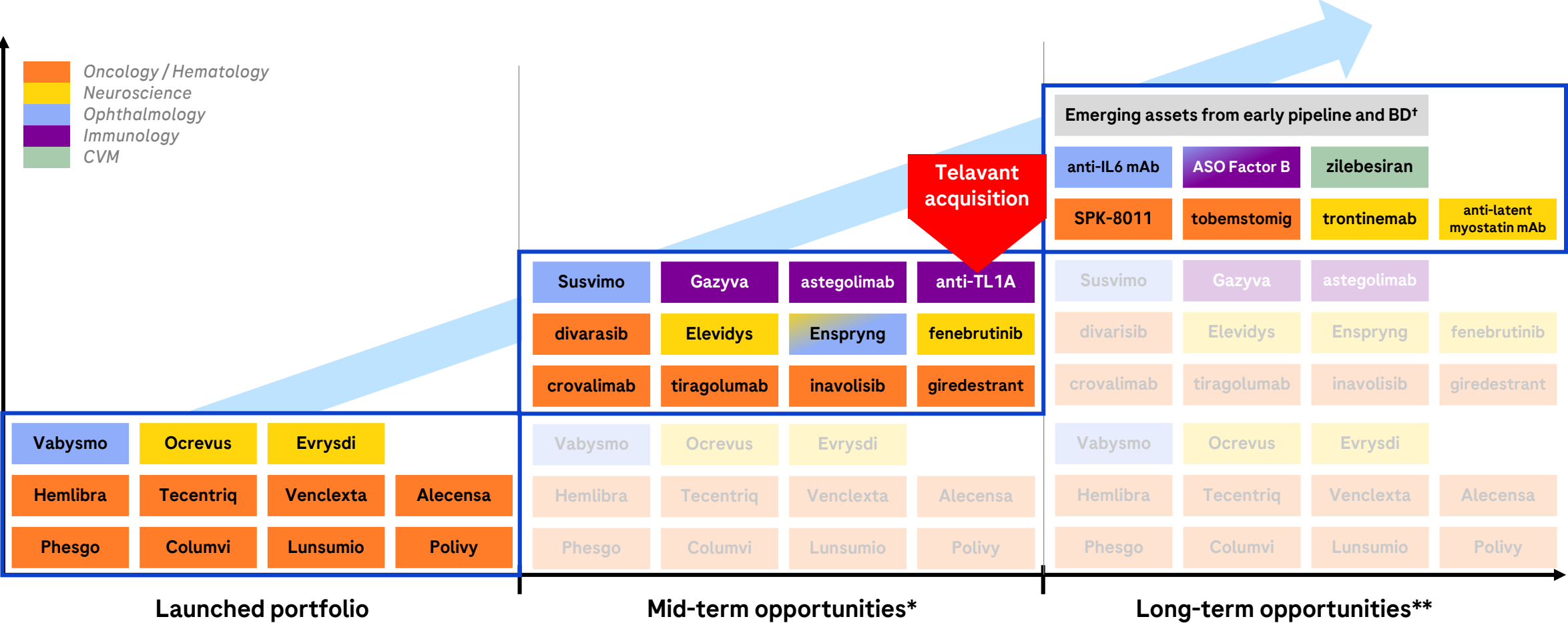
Telavant acquisition

Immunology
 Cardiovascular & Metabolism
 Oncology / Hematology
 Ophthalmology
 Development stage at time of deal
 Current development stage
 Positive proof of concept data

*Table shows clinical stage NME deals completed 2021-2023 YTD; TA=therapeutic area; mCRPC=metastatic castrations-resistant prostate cancer; AR=androgen receptor; IgAN=immunoglobulin A nephropathy; ASO=antisense oligonucleotide; IPF=idiopathic pulmonary fibrosis; SSC-ILD=systemic sclerosis-interstitial lung disease

Building blocks for future growth through 2030

Anti-TL1a mAb with significant upside added through Telavant acquisition

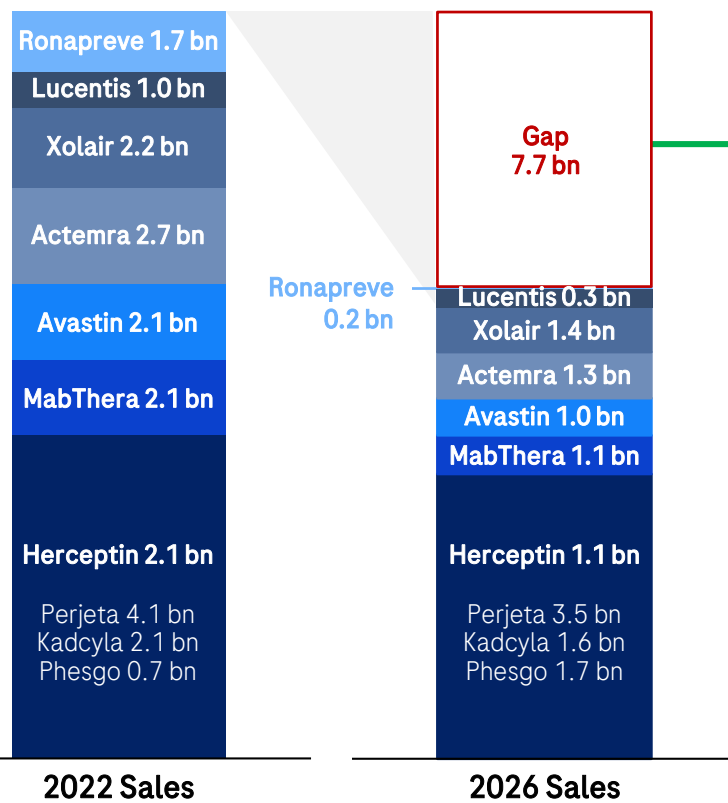


CVM = cardiovascular / metabolism; *mid-term defined as filing 2024-2026, **long-term defined as filing after 2026, BD=business development; †including GSM=Gamma-secretase modulator (GSM)

Consensus outlook 2022-26*

Growth driven by our young on-market portfolio; potential pipeline up-side

Biosimilar gap (22-26)



Consensus sales growth (22-26)

Post-HY 2023 consensus survey

Vabysmo	4.3 bn
Tecentriq	1.7 bn
Hemlibra	1.6 bn
Ocrevus	1.5 bn
Polivy	1.4 bn
Evrysdi	1.2 bn
Lunsumio	0.7 bn
Columvi	0.5 bn
Gazyva	0.4 bn
Alecensa	0.3 bn
Enspryng	0.3 bn
Susvimo	0.2 bn
Other in-market ¹	(0.5) bn
Pipeline Ph III²	2.4 bn
thereof Elevidys	0.8 bn
thereof tiragolumab	0.7 bn
thereof giredestrant	0.3 bn
thereof crovalimab	0.3 bn
thereof fenebrutinib	0.2 bn
Total	16.1 bn

Potential up-side³

Additional up-side by late-stage NMEs / LEs poorly or not yet covered:

Oncology (inavolisib, divarasib, tobemstomig, autogene cevumeran), **Hematology** (SPK-8011), **Ophthalmology** (ASO factor B in GA, anti-IL-6 mAb, Enspryng in TED), **Neuroscience** (Enspryng in gMG, anti-latent myostatin mAb, trontinemab, prasinezumab), **Immunology** (Gazyva in LN, astegolimab, ASO Factor B in IgAN, anti-TL 1A in IBD & other), **Cardiovascular & Metabolism** (zilebesiran)

*All estimates are based on Post HY 2023 consensus collected by FTI Consulting on behalf of Roche (n=18); ¹ Activase/TnKase, Esbriet, Pulmozyme, CellCept, Erivedge, Cotellic, Gavreto, Xofluza, Rozlytrek; Luxturna

² included in >50% of the sell-side models; ³Assets covered on average by only 17% of the sell side models; NME=new molecular entity; LE=line extensions

Performance Update

Strategy and Outlook

Latest pipeline Update

2023: Key late-stage newsflow*



	Compound	Indication	Milestone	
Regulatory	Hemlibra	Moderate hemophilia A	EU approval	✓
	Polivy + R-CHP	1L DLBCL	US approval	✓
	Vabysmo	RVO	US approval/EU filing	✓ EU filing
	Tecentriq	Subcutaneous administration	US approval/EU filing	US 2024 / ✓ EU filing
	Columvi (glofitamab)	3L+ DLBCL	US/EU approval	✓
Phase III / pivotal readouts	Xofluza	Influenza (paediatric 1+ yrs.)	EU approval	✓
	Tecentriq + Avastin	Adjuvant HCC	Ph III IMbrave050	✓
	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	✗
	Tiragolumab + Tecentriq	1L PDL 1+ NSCLC	Ph III SKYSCRAPER-01	Q1 2024
	Tiragolumab + Tecentriq + chemo	1L esophageal cancer	Ph III SKYSCRAPER-08 (China only)	2024
	Venclexta + dexamethasone	t(11;14) R/R MM	Ph III CANOVA	✗
	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA	
	Alecensa	Adjuvant ALK+ NSCLC	Ph III ALINA	✓
	Phesgo OBI (on body injector)	HER2+ BC	Ph I (pivotal)	✓
	Crovalimab	PNH	Ph III COMMODORE 1/2	✓
	Columvi + GemOx	2L+ DLBCL	Ph III STARGLO	2024
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO	2024
	Elevidys (Delandistrogene moxeparvovec)	DMD	Ph III EMBARK	
	Ocrevus 6m SC	RMS / PPMS	Ph III OCARINA II	✓
	TNKase	Stroke patients 4.5-24h	Ph III TIMELESS	✗
	Susvimo	DME	Ph III PAGODA	✓
	Susvimo	DR	Ph III PAVILION	✓
	Xolair	Food allergy	Ph III OUTMATCH	

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** Ph III (INAVO120) data expected Q4 2023

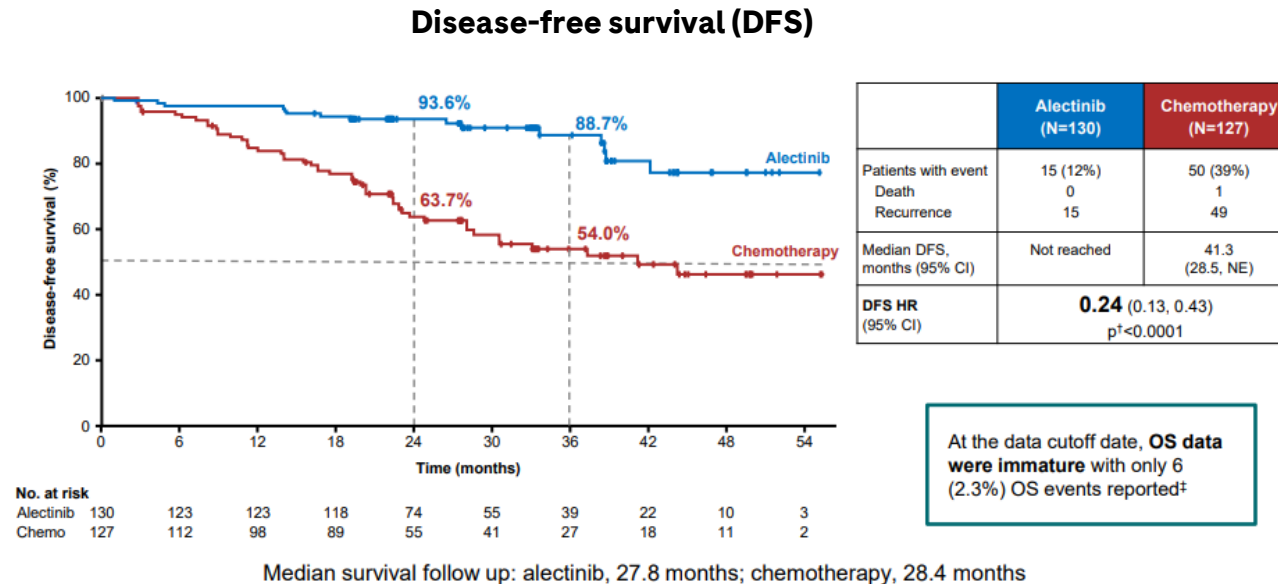
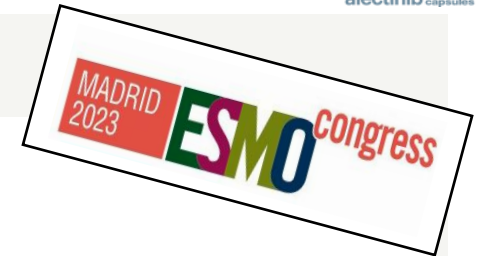
* Outcome studies are event-driven: timelines may change

Alecensa: Unprecedented Ph III results in adjuvant ALK+ NSCLC

Ph III (HORIZON-01) in unresectable NSCLC ongoing



Ph III (ALINA) Alecensa results in adjuvant ALK+ NSCLC



- Ph III (ALINA) met primary endpoint of DFS with a HR of 0.24
- First-in-class global filing ongoing; US/EU launches expected in 2024
- Ph III (HORIZON-01) in unresectable NSCLC and Ph III (TAPISTRY) multi-cohort tumor-agnostic studies ongoing

Fenebrutinib in RMS and PPMS

Brain-penetrant, non-covalent BTKi with potential for best-in-class efficacy and safety



BTKi competitive landscape¹

Fenebrutinib	Tolebrutinib	Evobrutinib	Remibrutinib
Non-covalent Reversible	Covalent Irreversible	Covalent Irreversible	Covalent Irreversible
WB B cell IC₅₀: 8 nM	10 nM	84 nM	18 nM
WB Myeloid cell IC₅₀: 31 nM	166 nM	1660 nM	67 nM
Ph III - ongoing	Ph III - FDA partial clinical hold	Ph III - FDA partial clinical hold	Ph III - ongoing
RMS, PPMS (vs Ocrevus)	RMS, SPMS, PPMS (vs placebo)	RMS	RMS

Ph III program overview

Indication	Trial design	Ph I	Ph II	Ph III
RMS	<i>vs placebo</i>	FENopta		✓
RMS	<i>vs teriflunomide</i>	FENhance 1/2		
PPMS	<i>vs Ocrevus</i>	FENTrepid		

✓ Positive data readout, primary and secondary endpoints achieved

- Potential to be best-in-class given high potency, high selectivity, reversibility, and only H2H study vs Ocrevus
- Large safety database of >2,500 pts who have been dosed with fenebrutinib*
- Selectivity and reversibility may limit off-target effects and potentially contribute to better long term safety

Fenebrutinib could disrupt the oral market segment, currently comprising >40% of the global MS market

1. Kramer, et al (2023) nature reviews neurology 289-304 ;Crawford, et al.(2018) J Med Chem 61, 2227-2245; Francesco, et al., ACTRIMS-ECTRIMS (2017) 200644. Haselmayer, et al. (2019) J Immunol 202, 2888-2906; Angst D, et al. (2020) J Med Chem 63, 5102-5118. H2H=head-to-head; MS=Multiple sclerosis; RMS=relapsing multiple sclerosis; PPMS=primary progressive multiple sclerosis; SPMS=Secondary progressive multiple sclerosis; BTK=Bruton’s tyrosine kinase; nM=nanomolar; WB=whole blood; *As of Sept 2023: including non-MS Ph I/II studies

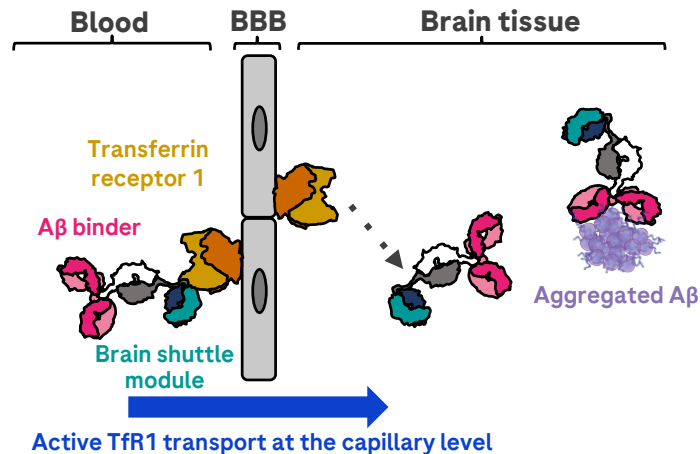
Trontinemab in Alzheimer's disease

First dose finding data for Brainshuttle™ anti-Aβ presented at CTAD

Roche

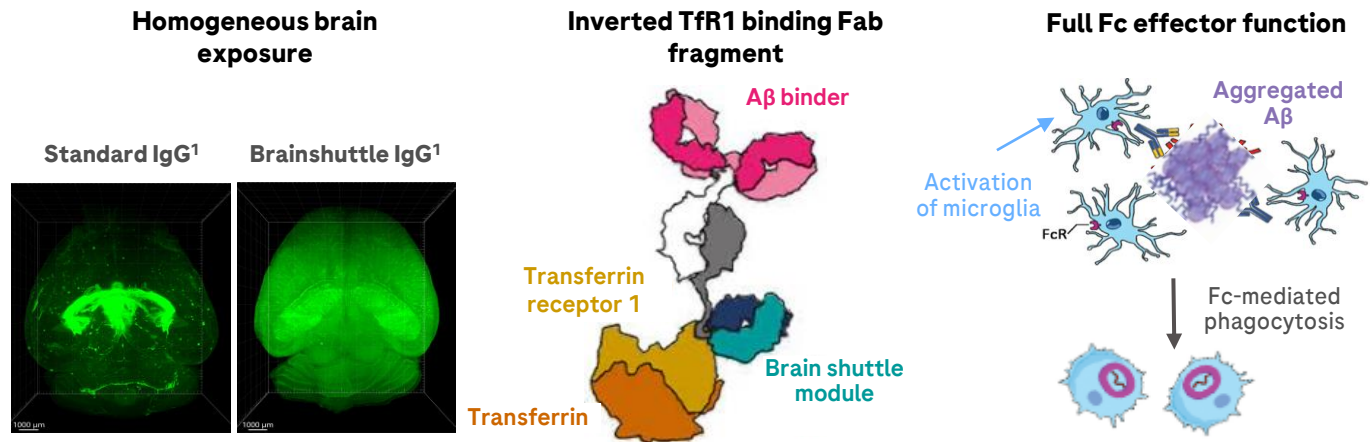


Trontinemab (Brainshuttle™ anti-Aβ Ab)



- Trontinemab is a novel molecular entity, based on Roche's proprietary Brainshuttle™ technology, combining an Aβ binding mAb with a transferrin receptor (TfR1) shuttle module
- Trontinemab is designed for efficient transport across the BBB to target aggregated forms of Aβ and remove amyloid plaques in the brain

Trontinemab is differentiated from conventional anti-Aβ mAbs and other brain delivery technologies



- Brainshuttle™ technology results in increased CNS exposure and broader, more homogeneous brain distribution¹ leading to deep and fast amyloid clearance
- The inverted TfR1 binding Fab fragment prevents undesired TfR1 targeted immune responses (ADCC) via “steric hindrance” leading to an improved safety profile
- Full Fc effector function is preserved to induce effective microglia activation and Fc mediated phagocytosis of Aβ plaques in the brain which is essential for efficacy

1. Whole-brain imaging highlights the distribution of classical IgG vs. Brainshuttle™ IgG targeting a neuronal target in mouse brains. Mouse brains were perfused and chemically fixed 5 days after a single IV dose of fluorescently-labelled Brainshuttle™-IgG (3 mg/kg) or two consecutive IV doses of IgG (2x 6 mg/kg). Images show a 3D volume rendering of the whole brain acquired with a light-sheet microscope; AD=Alzheimer's disease; TfR1=Transferrin receptor protein 1; IgG=Immuno-globulin G; BBB=blood brain barrier; mAb=monoclonal antibody; Aβ=Amyloid β; Ab=Antibody; Tf=Transferrin ; CNS=Central nervous system; ADCC=Antibody dependent cell mediated cytotoxicity

Important launches ahead in Diagnostics

Diagnostics to deliver mid to high single digit growth in coming years

Core & Molecular Lab



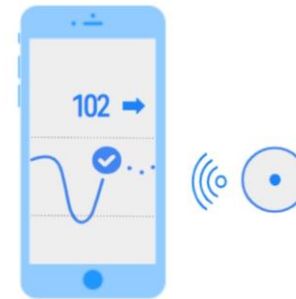
- Menu expansion driving growth, averaging >25 assay launches/approvals per year¹
- >240 assays running on >100k installed cobas® serum work area instruments
- >2.5k installed cobas® 6800/8800/5800 instruments

Mass spectrometry



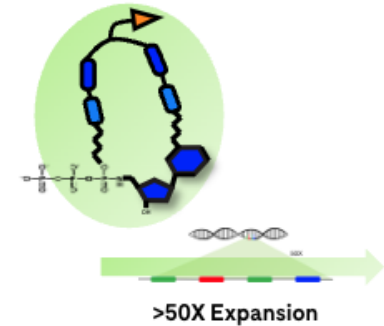
- First fully integrated and automated mass spectrometry
- Launch menu complimentary to immunoassay offering, including >40 key parameters at launch
- CE launch planned for end of 2024 (FDA approval expected in 2025)

Continuous glucose monitoring (CGM)



- Subcutaneously inserted sensor to measure glucose values in interstitial fluid
- Personalized management of diabetes
- Digital tools to support disease management for users and healthcare professionals

Next generation sequencing (NGS)



- Unique sequencing by expansion technology, significantly improving nanopore performance
- Nanopore system delivers flexible run size at competitive cost

1. average 2018 – 2022; excludes claim extensions for new instruments, excludes Biotin updated assays, COVID-19, Custom Biotech, TiB Molbiol & Genmark, RUOs, IVDR transitions; CGM=continuous glucose monitoring; NGS=next generation sequencing

Upcoming Roche IR events

Updates on Neuroscience, Digitalization, ASH presentations and Diagnostics

Neuroscience Update Oct 30

Virtual event

- Covering ECTRIMS & CTAD data:
- Ocrevus Ph III (OCARINA II) in MS
- fenebrutinib Ph II (FENopta) in MS
- trontinemab Ph I dose escalation in AD
- GSM (Gamma secretase modulator) Ph I in AD

Digitalization Day Nov 29

Virtual event

- Presenting Roche digital efforts in Pharma and Diagnostics, covering big data/RWD collections and data mining approaches using AI/ML
- Highlighting use cases across the value chain, including early R&D, clinical development, regulatory, manufacturing, supply chain and commercialization

ASH Update TBA

Virtual event

- Key data submitted:
- Ph Ib Lunsumio combo in DLBCL
- Ph Ib Columvi combo in 1L DLBCL
- Ph III (POLARIX) for Polivy in different genetic subtypes
- Ph III (COMMODORE 1 & 2) for crovalimab in PNH

Diagnostics Day May 22, 2024

London & virtual

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

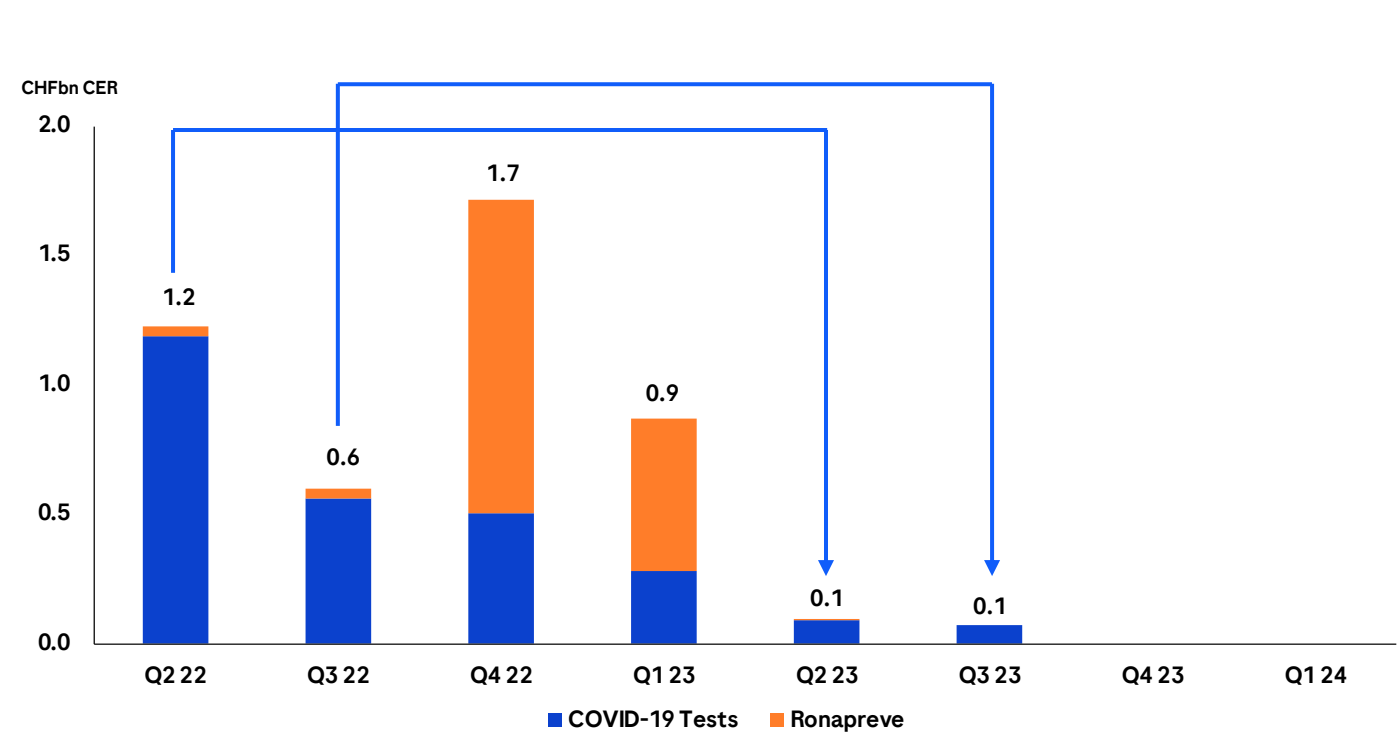
Angiogenesis 2023 ✓ Virtual Mon, 13 Feb 16:30-18:00 CET	Roche ESG Day ✓ Virtual Tue, 23 May 15:30-17:00 CEST	EHA 2023 ✓ Virtual Mon, 12 Jun 16:30-17:30 CEST	Roche Pharma Day ✓ London Mon, 11 Sep 10:30-14:30 BST	Neuroscience Update ✓ Virtual Mon, 30 Oct 17:00-18:15 CET	Digitalization Day Virtual Wed, 29 Nov 13:30-15:30 CET	ASH 2023 Virtual Dec TBA	Diagnostics Day Virtual / hybrid Wed, 22 May 2024 TBA
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MS=multiple sclerosis; AD=Alzheimer’s disease; RWD=real-world data; AI/ML=artificial intelligence and machine learning; DLBCL=diffuse large B-cell lymphoma; PNH=Paroxysmal nocturnal hemoglobinuria



Roche played a significant role in fighting the pandemic

Q4 2023 and Q1 2024 are the final quarters impacted by the decline in COVID-19 products



- TIB MOLBIOL LightMix® Modular SARS-CoV-2
- ePlex® Respiratory Pathogen Panel 2
- cobas® SARS-CoV-2 on the cobas® Liat®
- cobas® SARS-CoV-2 on the cobas® 6800/8800
- cobas® SARS-CoV-2 & Influenza A/B
- cobas® SARS-CoV-2 Variant set 1 (RUO)
- SARS-CoV-2 rapid antigen
- Elecsys® SARS-CoV-2 antigen
- SARS-CoV-2 rapid antigen nasal
- SARS-CoV-2 rapid antigen nasal self-testing
- Elecsys® Anti-SARS-CoV-2
- Elecsys® IL-6
- SARS-CoV-2 rapid antibody
- Elecsys® Anti-SARS-CoV-2 S

~ 3 million patients
treated with Ronapreve and Actemra since 2020

~ 2 billion COVID-19 tests
sold since 2020

~ CHF 18bn
total COVID-19 sales* since 2020

*COVID-19 sales referring to COVID-19 diagnostic tests, Ronapreve and Actemra sales; CER=Constant Exchange Rates of the respective year

Key late-stage pipeline assets with 1bn+ sales potential*

Oncology, Hematology

	tiragolumab NSCLC, HCC, ESCC, SCCHN	●●
	giredestrant HR+ BC	●●
	divarasib KRAS+ NSCLC, CRC	●
	inavolisib PI3Km BC	●
	crovalimab PNH, aHUS, SCD, LN	●

	Tecentriq Adj. SCCHN / HCC, tira combo	●●
	Columvi 2L DLBCL, 1L DLBCL	●
	Lunsumio 2L DLBCL, R/R FL, 1LFL	●

Neuroscience, Cardiometabolic

	Elevidys DMD	●●
	fenebrutinib RMS, PPMS	●●
	anti-latent myostatin mAb SMA, FSHD	●
	zilebesiran hypertension	●●

	Ocrevus SC, high dose	●●
	Enspryng gMG, MOGAD, AIE, TED	●

Immunology, Ophthalmology

	astegolimab COPD	●●
	ASO Factor B IgAN, GA	●●
	anti-IL-6 UME, DME	●●
	anti-TL1A UC, CD	●●

	Gazyva LN, SLE, MN	●
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	Oncology / Hematology
	Neuroscience
	Ophthalmology
	Immunology
	CVM

9 late-stage NMEs with CHF>2 bn each in peak sales potential

4 late-stage NMEs with CHF >1bn each in peak sales potential

2 marketed products with LEs that could add CHF>2 bn each in peak sales potential

4 marketed products with LEs that could add CHF>1 bn each in peak sales potential

● 1bn+ sales potential ●● 2bn+ sales potential

*8 with 2bn+ opportunities; LE=line extensions