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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;
- 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;
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- 9 litigation;
- 10 loss of key executives or other employees; and
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### Roche

HY 2022 results

Basel, 21 July 2022





Group

Severin Schwan
Chief Executive Officer

Roche

**HY 2022 performance** 

Outlook

### **HY 2022: Good Group performance**



### Group sales +5% driven by both divisions

- Pharma portfolio performing well (+3%) outgrowing biosimilar erosion
- Diagnostics with strong growth momentum (+11%) including good base business growth (+6%)

### Key products growing strongly; new launches with significant sales potential

- Pharma growth drivers Hemlibra, Ocrevus, Evrysdi, Phesgo and Tecentriq with strong momentum
- Promising new launches with Vabysmo in ophthalmology and Polivy & Lunsumio in hematology
- Diagnostics receives EUA for SARS-CoV-2 DUO test and BDD for Alzheimer's disease amyloid plasma panel tests\*; new launches of Elecsys® HCV DUO Immunoassay and Monkeypox assays; Benchmark Ultra PLUS and Digital Pathology slide scanner

#### **Upcoming late-stage newsflow in 2022**

- Pharma: Tecentriq in adjuvant HCC and neoadjuvant NSCLC; tiragolumab + Tecentriq in esophageal cancer; Venclexta in MM; Vabysmo in RVO; Susvimo in DME & DR and gantenerumab in Alzheimer's disease
- Diagnostics: Elecsys® IGRA SARS-CoV-2, Elecsys® pTau/AB42 ratio Gen2 CSF (FDA), Digital LightCycler, cobas® 5800 (FDA), cobas® pure (FDA), cobas® pulse (FDA)

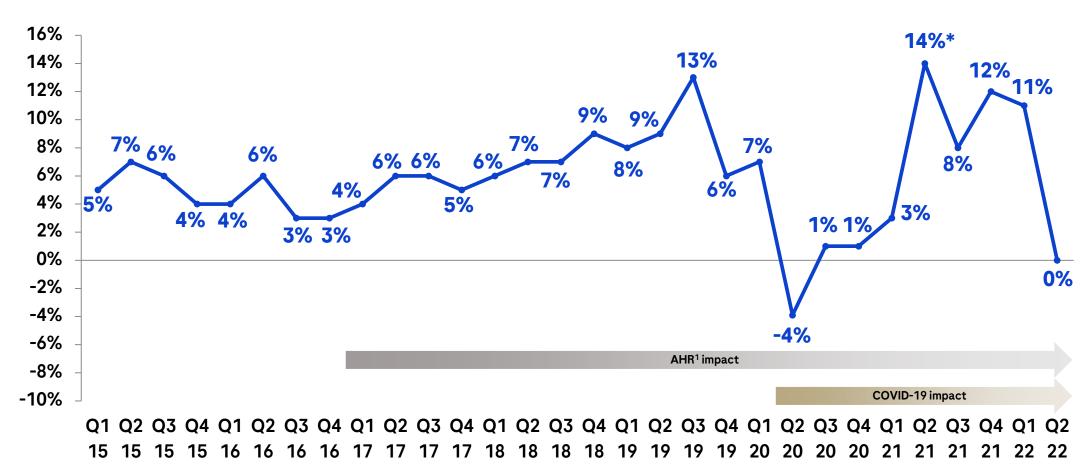




	2022	2021	Change in %	
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	22.3	21.7	3	3
Diagnostics Division	9.9	9.0	10	11
Roche Group	32.3	30.7	5	5

# Roche

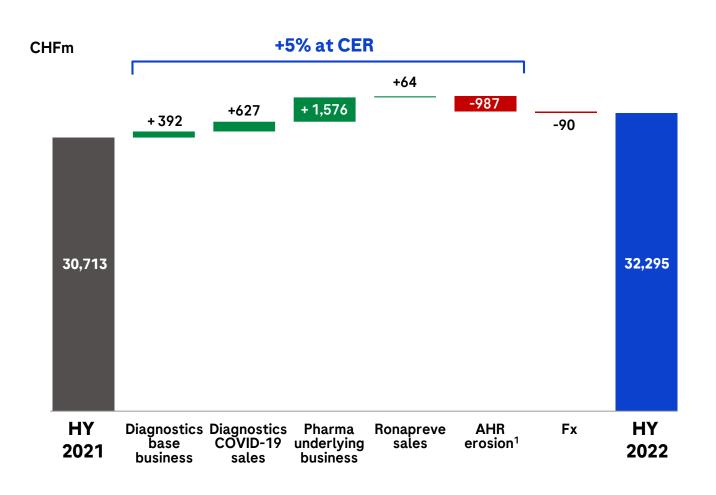
# Quarterly sales performance: As guided COVID-19 sales coming down in Q2



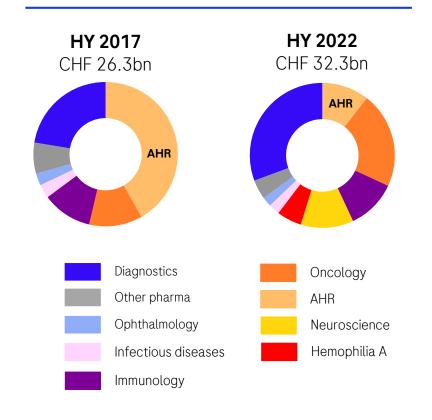
Growth rates at CER (Constant Exchange Rates); \* Q2 2020 sales severely impacted by COVID-19 pandemic onset; <sup>1</sup>AHR: Avastin, Herceptin, Rituxan/MabThera

### HY 2022: Portfolio diversification progressing





#### **Diversification of Roche business**

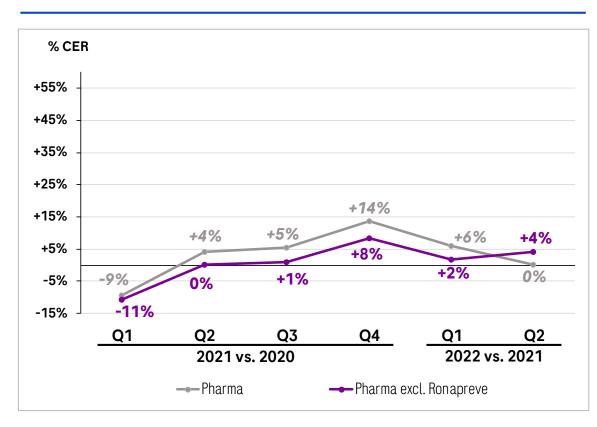


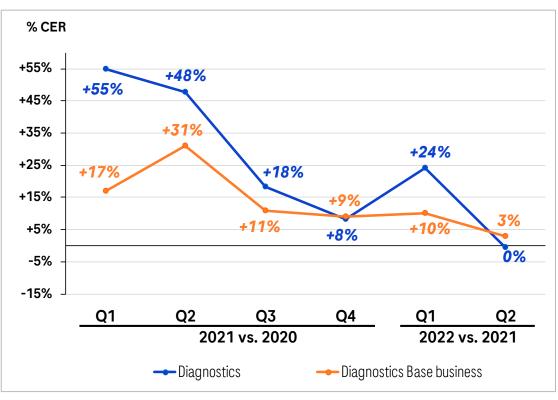




Pharma
Quarterly sales evolution 2021-2022

Diagnostics **Quarterly sales evolution 2021-2022** 



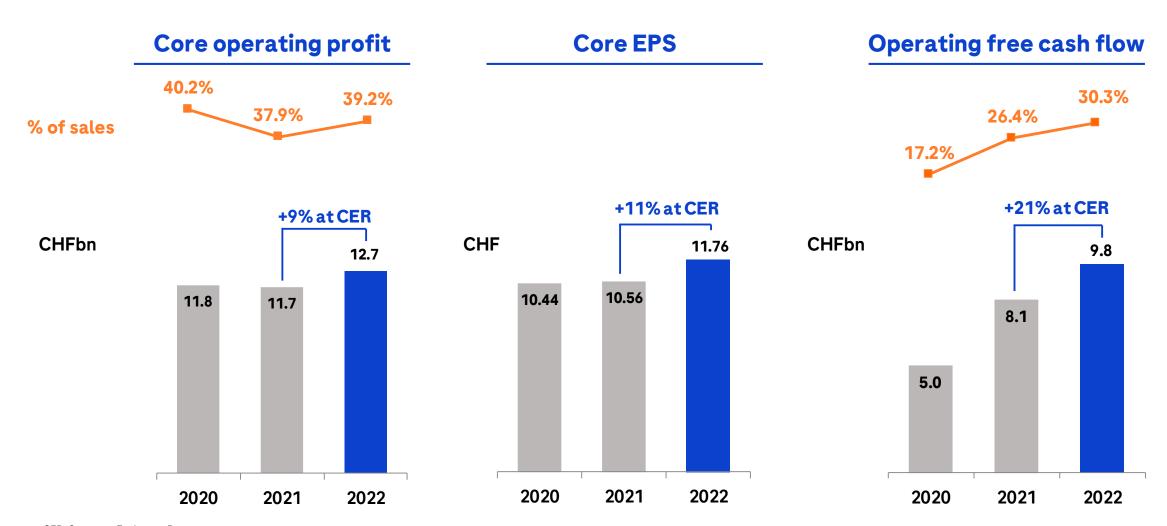


Growth rates at CER (Constant Exchange Rates)

### HY 2022: Growth of profitability and Core EPS



Benefit from Ultomiris patent settlement and share repurchase



CER=Constant Exchange Rates

### 2 NMEs launched in 2022: Vabysmo and Lunsumio



Roche: Leading in bispecific antibodies

First-in-class bispecifics launched in ophthalmology and malignant hematology

#### • First bispecific mAb that bridges activated factor IX (FIXa) and **ENSPRYNG** FX to restore function of missing FVIII PHESGO" 2017 Approved for severe, moderate and mild hemophilia A and for patients with inhibitors Evrysdi. HEMLIBRA **GAVRETO** xofluza • First bispecific mAb to simultaneously target VEGF-A and Ang2 RONAPREVE >> POLIVY to reduce neovascularization and inflammation to stabilise VENCLEXTA vessels Susvimo™ ROZLYTREK Approved by FDA in nAMD and DME; RVO trials ongoing **ALECENSA VABYSMO** OCREVUS" VABYSMO 2022 Lunsumic COTELLIC T cell engaging bispecific mAb that binds simultaneously to CD20 on the surface of malignant B cells and to CD3 on the 2019 2020 2021 2022 2015 2016 surface of T cells, thereby activating T cell induced cancer cell killing Lunsumid Approved by EMA in FL, DLBCL trials ongoing



## HY 2022 performance

**Outlook** 

### 2022: Upcoming newsflow



#### **Pharma**

Ongoing and upcoming launches

**Vabysmo** in DME/nAMD

**Susvimo** in nAMD

Polivy in 1L DLBCL

Lunsumio in 3L+FL

Late stage pipeline read outs

tiragolumab + Tecentriq studies
NSCLC, Cervical, Esophageal cancer

Tecentriq adjuvant studies

HCC, neoadjuvant NSCLC

Venclexta in MM (t11;14)

Vabysmo in RVO

Susvimo in DMR/DR

**gantenerumab** in Alzheimer's disease

### **Diagnostics**

Real-time PCR molecular testing for low
volume labs
Serum work area analyzer for low-to-medium sized labs
Device combining glucose meter and digital platform
Measure T-cell release of IFN-y following simulation by SARS-COV-2 specific antigens
Novel digital PCR platform
Detect amyloid disease & enable a broader availability of testing for Alzheimer's Disease

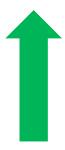
Neuroscience Oncology
Ophthalmology Diagnostics

**Upcoming** launches

### 2022 sales outlook confirmed

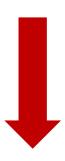


#### Sales drivers<sup>1</sup>



Pharma: New products with accelerating growth

Diagnostics: Base business with strong growth



AHR<sup>2</sup> biosimilars: Roughly CHF -2.5 bn sales erosion

COVID-19 sales for Diagnostics and Pharma around CHF 5 bn



- Guidance stable to low-single digit group sales growth
- Group sales to grow high-single digit if COVID-19 sales and AHR get excluded
- Guidance based on a scenario with significantly reduced COVID-19 impact in H2

<sup>1</sup>At Constant Exchange Rates (CER); <sup>2</sup> AHR=Avastin, Herceptin, Rituxan/MabThera

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### 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)

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### **Pharmaceuticals Division**

Bill Anderson CEO Roche Pharmaceuticals





New products compensate for biosimilar erosion

	2022	2021	Chang	∍ in %	
	CHFm	CHFm	CHF	CER	
Pharmaceuticals Division	22,347	21,671	3	3	
United States	11,363	10,802	5	1	
Europe	4,104	4,485	-8	-4	
Japan	2,202	1,808	22	34	
International	4,678	4,576	2	2	

CER=Constant Exchange Rates 18

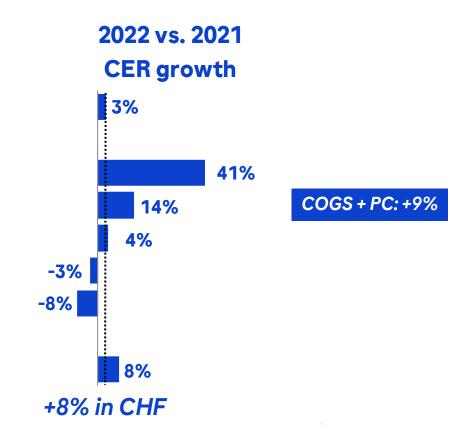




Core operating profit growth driven by patent settlement

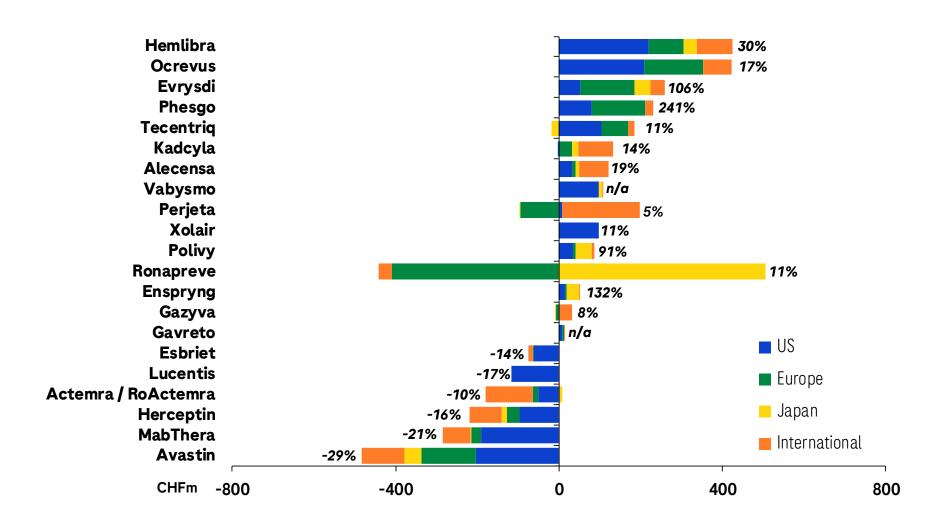
	2	2022		
	CHFn	n	% sales	
alaa	22.74	7	100	

Sales	22,347	100
Royalties & other op. inc.	1,918	8.6
Cost of sales	-4,430	-19.8
M & D	-3,096	-13.9
R & D	-5,729	-25.6
G & A	-692	-3.1
Core operating profit	10,318	46.2



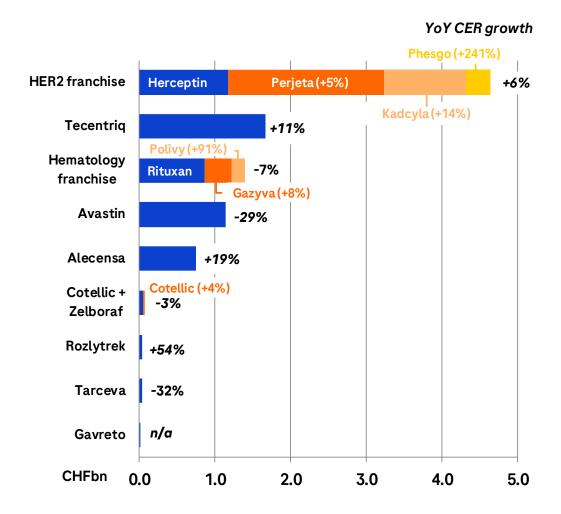






### HY 2022: Oncology portfolio rejuvenation on-going





#### **HER2 franchise**

- Kadcyla (+14%) with growth ex-US due to adjuvant BC
- Perjeta (+5%) driven by International
- Phesgo (CHF 325m): Conversion and geographic expansion ongoing

### **Tecentriq**

Growth (+11%) driven by adjuvant NSCLC, 1L HCC and 1L SCLC

### Hematology franchise

- Venclexta\*: Growth driven by 1L AML and 1L & R/R CLL
- Gazyva (+8%): Growth due to 1L FL and in 1L CLL
- Polivy (+91%): Growth acceleration in the US due to R/R DLBCL;
   EU approval in 1L DLBCL (POLARIX) achieved
- Lunsumio: EU approval in 3L+ FL achieved

#### **Alecensa**

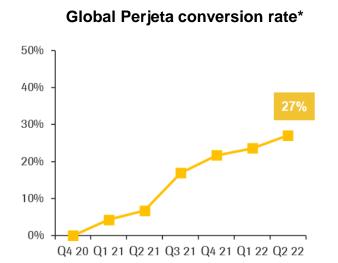
• Strong growth (+19%) driven by all regions

### HER2+ franchise: High efficacy and safety bar established in eBC



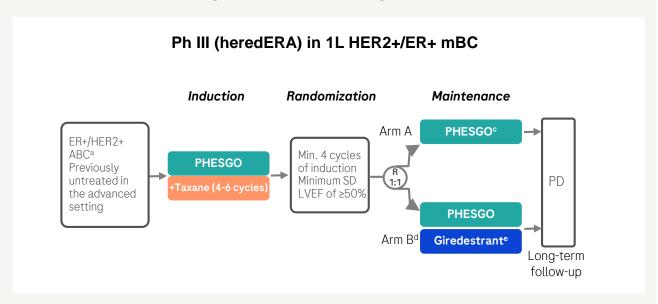
Perjeta conversion rate at 27% in early launch countries

# Phesgo with strong global launch



- Phesgo SC significantly cuts healthcare costs and resource use
- Perjeta conversion rate reaches 27% in early launch countries
- P+H in eBC (APHINITY): 8-year follow up data presented at ESMO Virtual Plenary showing a 28% reduction in the risk of recurrence or death for high risk, lymph-node positive patients

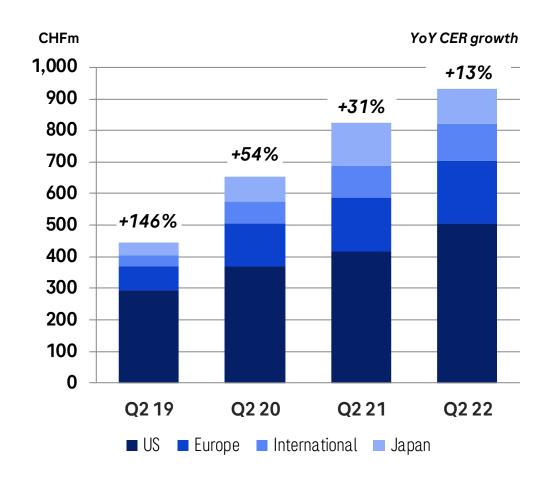
#### Continuing to build on existing standard of care



- HER2+/HR+ BC with distinctive disease biology
- Ph III (heredERA) of Phesgo + giredestrant in 1L HER2+/ER+ mBC started enrollment in Q2 2022, and aims to improve:
  - efficacy by comprehensive blockade of both HER2 and ER pathways
  - treatment related QOL, with a patient centric regimen

### Tecentriq overview: Adjuvant program to read out in 2022/23





### **Tecentriq Q2 update**

- Ph III (IMvoke010) in adjuvant SCCHN continues to final analysis
- Japan: Sales impacted by mandatory price cut

### **Lung franchise (NSCLC, SCLC)**

- EU: Approval in adjuvant PDL1+ NSCLC achieved;
   Growth driven by 1L SCLC
- US: Strong launch in adjuvant PDL1+ NSCLC

#### GI franchise (HCC)

US/EU/Japan: Growth driven by 1L HCC

#### Outlook 2022

- Further growth due to first-to-market indications
- Ph III Tecentriq adjuvant studies in HCC and neoadjuvant NSCLC reading out
- Ph III tiragolumab + Tecentriq in 1L EC reading out

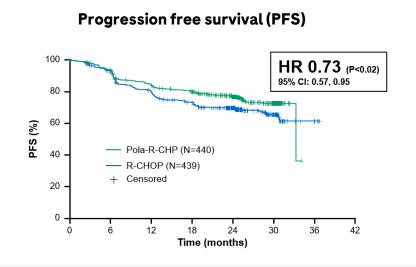
### Hematology franchise: Setting new standards of care





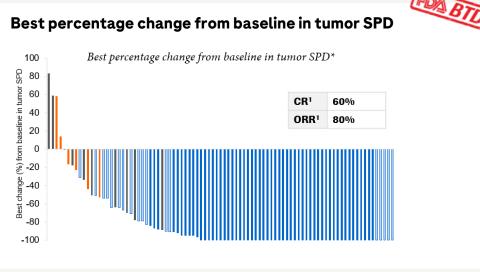
First-in-class EU approvals in 1L DLBCL and 3L+ FL

### Ph III (POLARIX) Polivy + R-CHP in 1L DLBCL



- Polivy + R-CHP significantly prolongs PFS with a HR of 0.73 in patients with intermediate and high risk 1L DLBCL
- Safety of Polivy + R-CHP and R-CHOP comparable
- EU approval in 1L DLBCL achieved; Filed in US, Japan and China
- Ph III (SUNMO) Polivy + Lunsumio in 2L+ SCT ineligible DLBCL FPI in Q2 2022





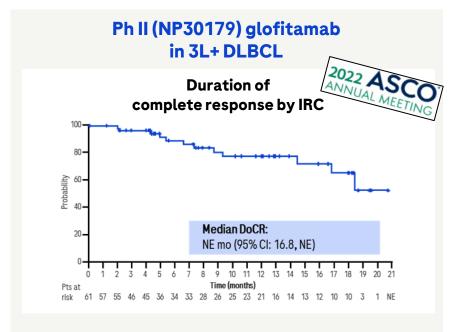
- 60% CR rate (greater than 14% historical control) with the majority of responses lasting for at least 18 months
- Fixed duration treatment; Favorable tolerability profile suitable for outpatient setting (CRS low grade and cycle 1)
- EU approval in 3L+ FL achieved; Filed in US with priority review granted
- Ph III (CELESTIMO) Lunsumio + lenalidomide in 2L+ FL started in Q4 2021

### Hematology franchise development program



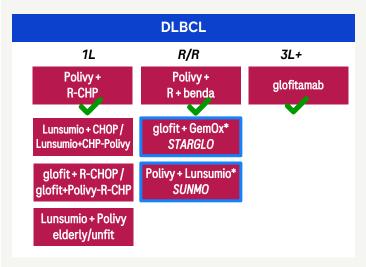


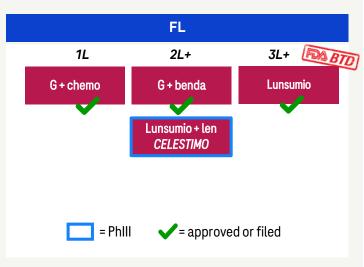
Potential first-in-class & best-in-class combinations



- Primary endpoint met; CR: 39.4% in heavily pre-treated, highly refractory patients
- CRs achieved were early and durable even after fixed-duration treatment (max. 12 cycles)
- Glofitamab was well tolerated with low rate of treatment discontinuations; CRS was mostly low grade
- EU: Filed in 3L+ DLBCL in Q2 2022

### Most advanced clinical development program





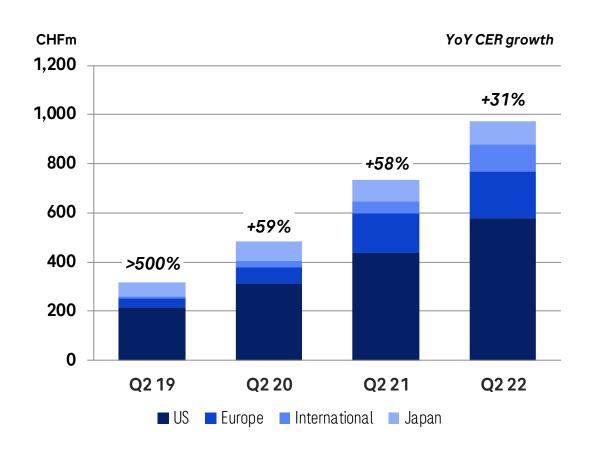
- Lunsumio: Attractive profile for the outpatient setting and across a broad range of indications and settings; no hospitalization required
- Glofitamab: Best-in-class efficacy potential with high CR rates, durable responses and manageable CRS with fixed treatment duration
- Ph III development program in NHL with pivotal read-outs starting in 2023/24: Glofit+ GemOx (STARGLO) in 2L+ DLBCL; Polivy + Lunsumio (SUNMO) in 2L+ DLBCL; Lunsumio + lenalidomide (CELESTIMO) in 2L+ FL
- Update on novel combinations in 1L DLBCL to be presented at ASH 2022

### Hemophilia A franchise: Hemlibra new global standard of care



35% US/EU-5 patient share reached





### Hemophilia Q2 update

- Nearly 18,000 patients treated globally
- Hemlibra continues to penetrate across all approved patient segments
- Ph III (HAVEN 6) strong data in mild/moderate patients presented at ISTH 2022

#### Outlook 2022

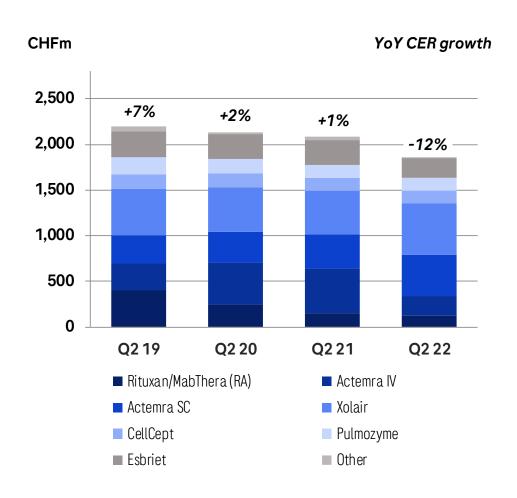
- US/EU: Further patient share gains in non-inhibitors
- EU: Label expansion to include mild/moderate patients (HAVEN 6) expected
- Ph III (HAVEN 7) in infants (0-1 year) interim results expected

CER=Constant Exchange Rates 26

### **Immunology franchise**



### Actemra COVID-19 sales declining and first Esbriet generic competition



### **Immunology Q2 update**

Gazyva: Ph III (INShore) in PNS initiated

#### **Actemra (-23%)**

- Strong decline of COVID-19 driven sales
- Remains leading RA monotherapy in EU-5
- Shift from IV to SC; SC sales accounting for >65%

### **Xolair (+13%)**

- Remains the leader in biologics asthma market
- Continued growth in CSU

#### **Esbriet (-21%)**

US: Generic competition

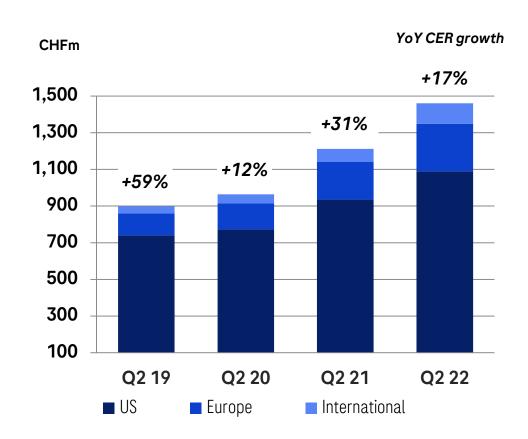
#### Outlook 2022

Actemra: Limited COVID-19 sales due to fewer hospitalizations





Fenebrutinib development programs in RMS and PPMS well on track



### Q2 update

- >250.000 patients treated globally
- No.1 treatment in US and EU-5
- Higher persistence compared with patients treated with other MS treatments
- Ph III (OCARINA II) for Ocrevus 6-month SC dosing started
- Ph III program (FENhance I/II, FENtrepid) for fenebrutinib in RMS and PPMS well on track

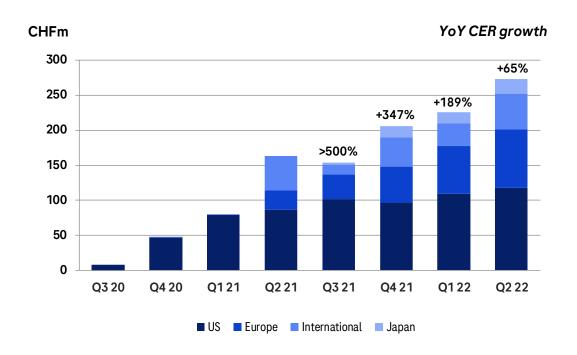
#### Outlook 2022

US/EU: Further market share gains expected

### SMA franchise: Evrysdi with strong global momentum



US with >20% and Germany with >30% share



### Q2 update

- >5,000 patients treated world wide (commercial, clinical trials, compassionate use)
- Retention rate of ~90% due to treatment satisfaction
- US: Growth driven by switch and naive patient starts; US approval for patients <2 months old achieved</li>
- EU: Strong launches in early launch countries
- Ph II/III (MANATEE) Evrysdi + anti-myostatin combination study started

#### Outlook 2022

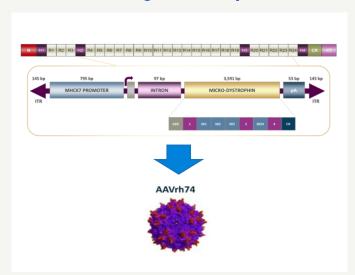
- Continued growth and market share gains over all market segments expected
- EU: Label extension (<2 months old) based on Ph II RAINBOWFISH expected

### Duchenne muscular dystrophy franchise update



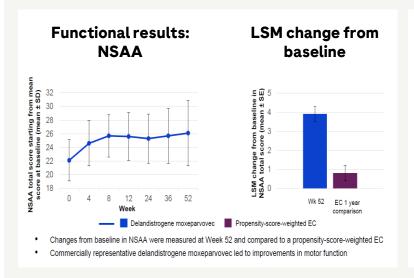


#### **Delandistrogene moxeparvovec**

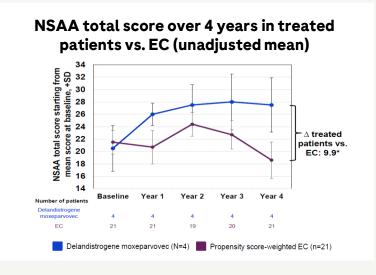


- Targeted delivery of micro-dystrophin transgene to key muscle tissue can enable meaningful and durable functional response
- AAVrh74 vector: low likelihood of pre-existing immunity and high tropism for skeletal & cardiac muscles
- Expression potentiated by the MHCK7 promoter in cardiac & skeletal muscles

#### Ph Ib ENDEAVOR (Study 103)



#### **Ph I (Study 101)**



- In ENDEAVOR participants gained a mean 4.0 points in NSAA over 1 year vs baseline. The treatment difference vs an external control was 3.2 points which is clinically meaningful and highly statistically significant (p < 0.0001)
- · Consistent transduction, expression and safety demonstrated
- 4-year follow up for Study 101 (n=4): Patients maintained NSAA gain over 4 years at an age at which a decline would be expected (8-10 yrs)
- Ph III (EMBARK) on track to be fully enrolled by H2 2022; Ph III (ENVOL; study 302) in 0-3 year olds and Ph III (ENVISION, study 303) in older ambulatory / non ambulatory patients to be initiated in H2 2022

### Ophthalmology franchise: Excellent Vabysmo launch

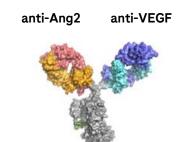




### Building a global ophthalmology franchise

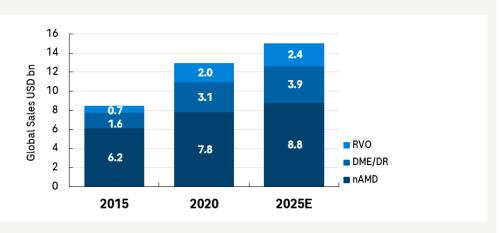
#### Vabysmo in nAMD and DME





- First IVT therapy inhibiting two distinct disease pathways by simultaneously binding to Ang-2 and VEGF-A
- Potentially improved vascular stability and reduced retinal inflammation
- Vision gains and anatomical improvements achieved with 80% of patients reaching Q3M dosing or longer and >60% Q4M dosing
- Over 70,000 vials distributed in first 5 months of US launch
- Strong customer uptake with switching coming primarily from aflibercept
- Broad coverage for ~80% of lives including policies at most national accounts
- Real world data (TRUCKEE study) presented at ASRS 2022; results consistent with efficacy and safety seen in development studies
- Ph III (COMINO / BALATON) in RVO reading out in H2 2022

### Global retina market growing to USD 15 bn



- Market growth driven by aging population and diabetic epidemic
- Rapid market transition to next generation products expected
- Innovative meachanism of actions to improve standard of care
- Longer dosing intervals to improve compliance and treatment outcomes, as well as leading to cost savings

### Ophthalmology franchise: Vabysmo in nAMD

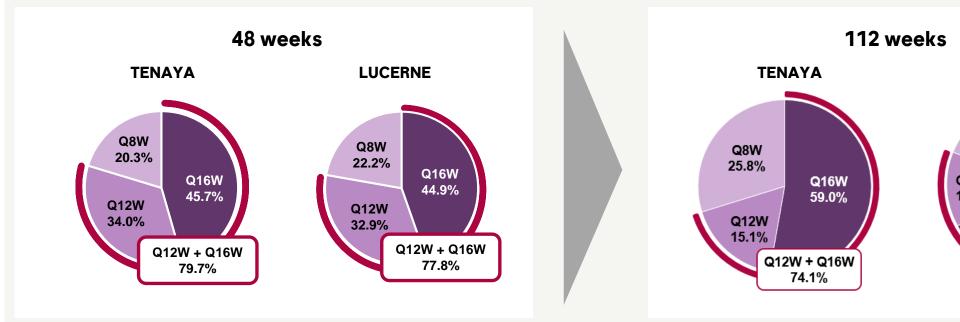


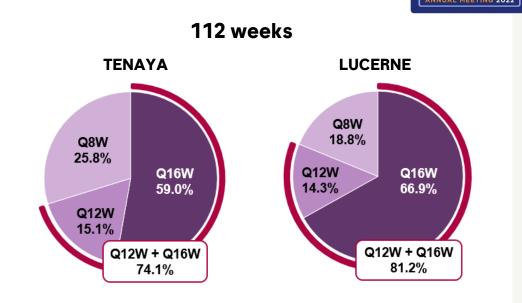


At 112 weeks Q16W dosing increases to ≥ 60%

### Ph III (LUCERNE, TENAYA) in nAMD: Dosing intervals of patients at year 1 and 2







- New dual MoA to promote vascular stability, potentially leading to a more durable therapy with maintanance of long-term vision gains
- Proportion of patients achieving Q16W dosing increased from >45% at week 52 to ≥ 60% at week 112; Vabysmo given at interval of up to every 4 months achieved comparable vision gains and reductions in central subfield thickness (CST) versus aflibercept given every two months
- At two years of treatment Vabysmo was well tolerated. No cases of retinal vasculitis or occlusive retinal vasculitis were reported in the Ph III studies
- Ph III extension studies (AVONELLE-X in nAMD & Rhone-X in DME) for Vabysmo to generate long-term (up to 4 years) safety and tolerability data ongoing

### 2022: Key late-stage news flow\* and upcoming IR events



	Compound	Indication	Milestone	
Regulatory	Vabysmo	nAMD/DME	US/EU approval	<b>✓</b> US
	Susvimo	nAMD	EU approval	2023
	Lunsumio (mosunetuzumab)	3L+ FL	US/EU approval	<b>✓</b> EU
	Tecentriq	Adjuvant NSCLC	EU approval	<b>✓</b>
	Hemlibra	Mild to moderate hemophilia A	EU approval	
	Polivy + R-CHP	1L DLBCL	EU/US approval	<b>✓</b> EU
	glofitamab	3L+ DLBCL	Ph lb NP30179	<b>✓</b>
	Tecentriq + tiragolumab + chemo	1L ES-SCLC	Ph III SKYSCRAPER-02	X
	Tecentriq + chemo	Adjuvant SCCHN	Ph III IMvoke010	2023
	Tecentriq + tiragolumab	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	Continues to OS IA
	Tecentriq	Adjuvant RCC	Ph III IMmotion010	X
Phase III / pivotal readouts	giredestrant	2/3L HR+ mBC	Ph II acelERA	X
	Tecentriq + Avastin	Adjuvant HCC	Ph III IMbrave050	
	Venclexta + dexamethasone	t(11;14) R/R MM	Ph III CANOVA	
	Tecentriq + chemo	Neoadjuvant NSCLC	Ph III IMpower030	
	Tecentriq + tiragolumab + chemo	1L esophageal cancer	Ph III SKYSCRAPER-08	
	Alecensa	Adjuvant ALK+ NSCLC	Ph III ALINA	2023
	gantenerumab	Alzheimer's disease	Ph III GRADUATE 1/2	
	Susvimo	DME	Ph III PAGODA	
	Susvimo	DR	Ph III PAVILION	

Virtual event
Angiogenesis
Monday, 14 February

16:30 to 17:45 CEST

Virtual event MDA Roche ESG Day Access to Healthcare

15:00 to 16:30 CEST

Monday, 16 May

Virtual event 

ASCO

Monday, 6 June

16:00 to 17:30 CEST

Roche Pharma Day London

10:00 to 15:00 BST

Monday, 12 September

Virtual event ASH TBA

Wednesday, 16 March

16:30 to 17:30 CEST

<sup>\*</sup> Outcome studies are event-driven: timelines may change; OS=overall survival; IA=interim analysis





**Diagnostics Division** 

Thomas Schinecker CEO Roche Diagnostics





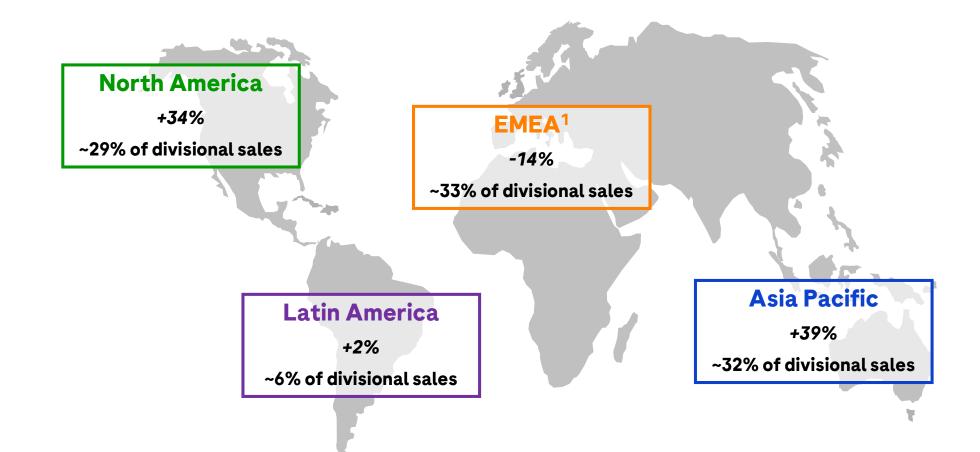
Sales increase of +11% driven by COVID-19 testing and base business

	2022	2021	Change in %	
	CHFm	CHFm	CHF	CER
Diagnostics Division	9,948	9,042	10	11
Core Lab <sup>1</sup>	3,875	3,770	3	4
Point of Care <sup>1</sup>	2,609	1,798	45	46
Molecular Lab <sup>1</sup>	1,980	1,990	-1	1
Diabetes Care	832	894	-7	-5
Pathology Lab	652	590	11	10

### HY 2022: Diagnostics Division regional sales



Very strong growth in Asia Pacific and North America

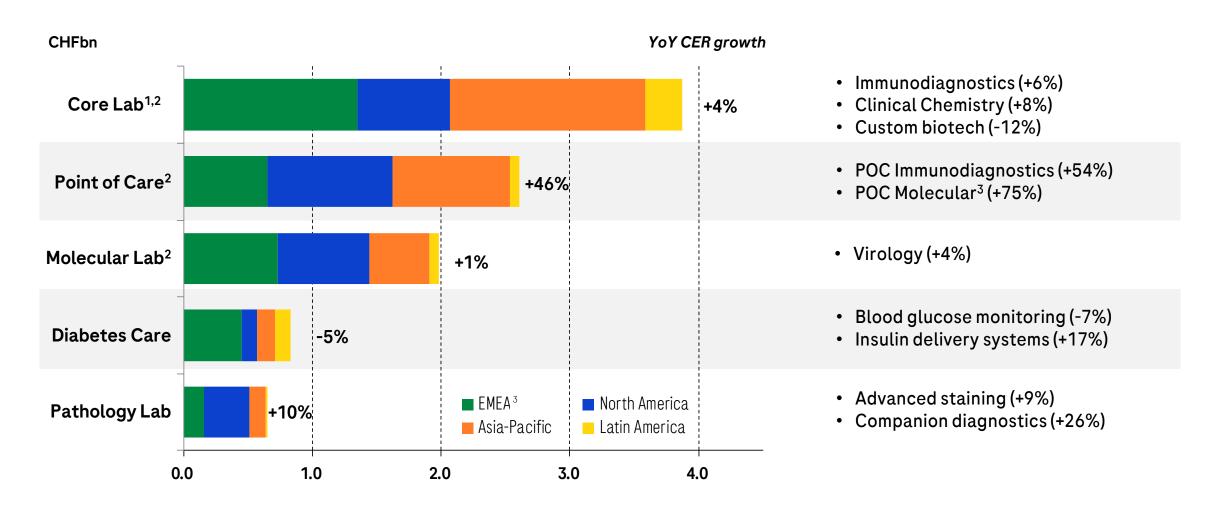


Growth rates at CER (Constant exchange Rates); <sup>1</sup> Europe, Middle East and Africa

# **HY 2022: Diagnostics Division highlights**



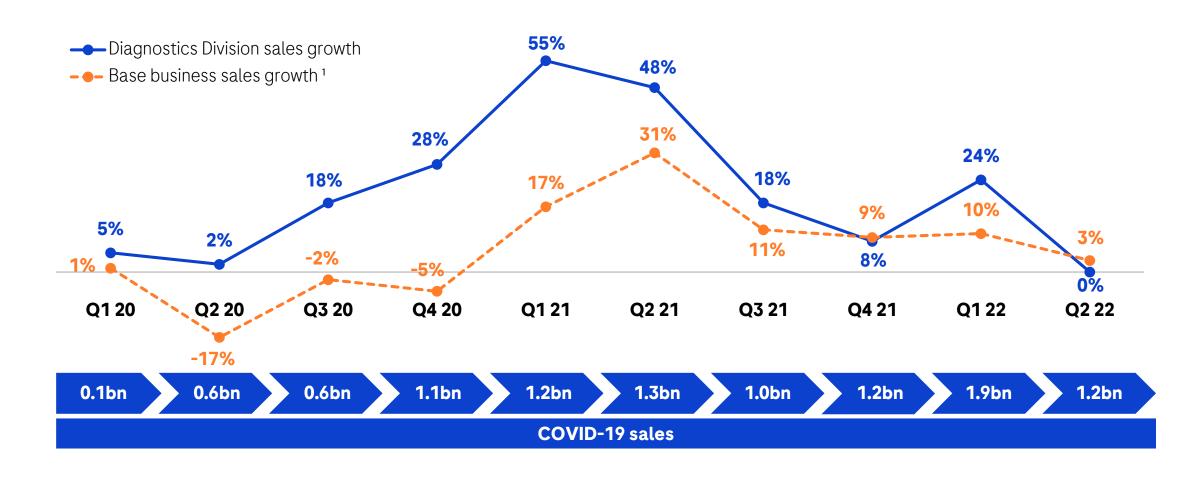
Strong growth despite a high base in HY 2021



# Diagnostics Division sales growth by quarter



Strong COVID-19 sales and base business growth



# **HY 2022: Diagnostics Division**



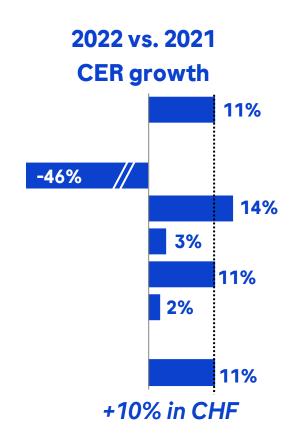
39

Strong core operating profit growth of +11%

20	22		
CHFm	%	sa	les

2022

Sales	9,948	100
Royalties & other op. inc.	25	0.3
Cost of sales	-4,875	-49.1
M & D	-1,363	-13.7
R & D	-899	-9.0
G & A	-276	-2.8
Core operating profit	2,560	25.7



CER=Constant Exchange Rates

# Upcoming launch of Elecsys® IGRA SARS-CoV-2



Improving the understanding of immunity against SARS-CoV-2

# Testing workflow Step 1 T-Cell Stimulation Quantification of IFN-y (on Roche IA instrument) Positive Negative SARS-CoV-2 specific tube

**Positive control:** Mitogen stimulus, controls for sample quality and T-cell fitness

Negative control: no stimulus, controls for baseline IFN- $\gamma$  level

**SARS-CoV-2 specific tube**: contains SARS-CoV-2 specific antigens in coating, stimulates Anti-SARS-CoV-2 T-Cell response

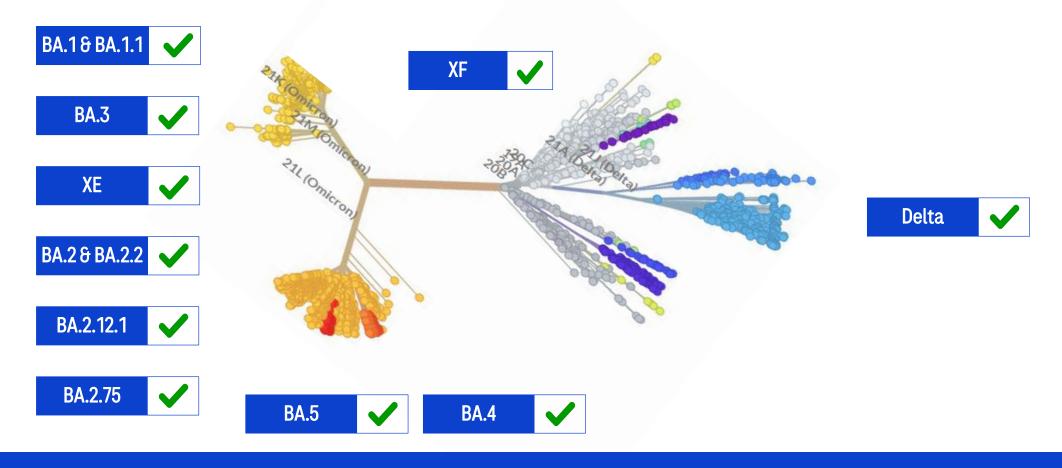
Quality control passed ? SARS-CoV-2 specific IFN-γ response, determines reactivity

- Detects T-cell mediated immune response by measuring IFN-γ release upon stimulation with 189 SARS-CoV-2 specific antigens, indicative of past exposure or vaccination
- Complements SARS-CoV-2 antibody tests to better understand host response and protective immunity
- May support risk stratification for progression to severe disease and/or protection

# TIB-Molbiol SARS-CoV-2 menu for monitoring new variants



Detecting major variants in hours vs a week for sequencing



BA.5 is becoming the dominant SARS-CoV-2 variant

# Monkeypox assays supplied to WHO



Three assays developed in record time to monitor epidemiologic spread of the virus



#### LightMix® Modular Orthopox Viruses

New

Detects all orthopox viruses (e.g. monkeypox, cowpox, camelpox)

#### LightMix® Modular Monkeypox Viruses

New

Detects all variants of monkeypox viruses only

#### LightMix® Modular Orthopox Subtyping

New

Detects all orthopox viruses. If positive, simultaneously indicate if monkeypox and differentiate West African from Central African monkeypox type

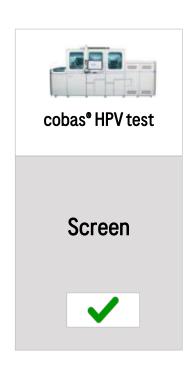
# cobas® HPV self-sampling solution

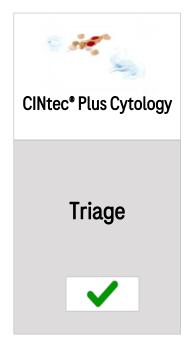


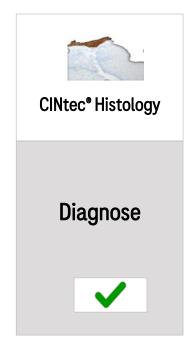
Increasing screening adherence to potentially reach 1.7bn women globally

**342,000 women** die per year of cervical cancer, ~90% in LMIC with majority unscreened <sup>2</sup>









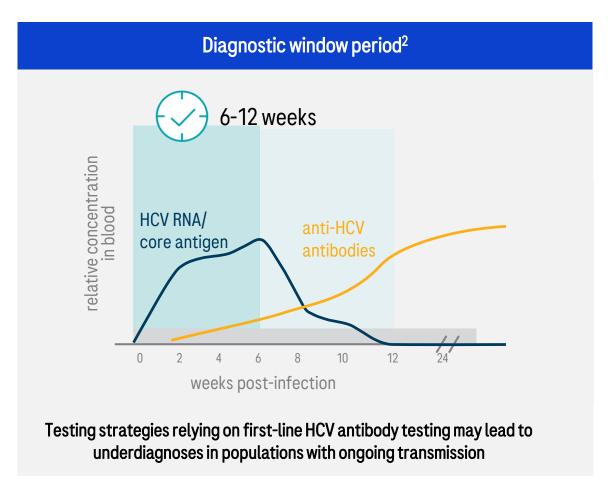


90% correlation between clinician collected endocervical and self-collected vaginal specimens<sup>1</sup>

# Elecsys® HCV DUO Immunoassay<sup>1</sup>



# Early diagnosis of hepatitis C virus (HCV) enables optimal treatment



- 58m people being chronically infected globally (80% unaware<sup>3</sup>) and about 1.5m new infections per year
- Hepatitis C leading cause for liver cancer and curative treatments are available<sup>4</sup>
- Shortening diagnostics window by up to 3 weeks compared to HCV antibody test
- Dual detection of antigen and antibody simplifies the HCV testing/screening algorithm while complementing RNA testing
- WHO elimination strategy aims to significantly reduce new infections and deaths by 2030

# BenchMark ULTRA PLUS system<sup>1</sup>



# Next instrument generation for tissue advanced staining

#### **Optimized workflow**

- Shortened reagent validation
- Reduced turnaround time
- Fewer manual interventions

#### Quality

- Proven, industry leading stain quality
- Robust detection kits



#### Flexible solutions

- View, manage, complete and print system data remotely
- Optimized protocols and slide staining based on individual staining drawers

#### Broadest menu<sup>2</sup>

- 200 + ready to use or pre-dilute assays
- Most complete companion diagnostics assay menu

#### CHF 2.3bn accessible market<sup>3</sup>

#### **VENTANA DP 600 slide scanner**



# Enhancing digital pathology with high volume slide scanner

#### High volume scanning

240 slide capacity (40x more than DP200)

# CENTAMA CONT.

#### Leverages optical system of DP 200

consistent image quality

#### Flexible workflows

improve efficiency

Continuous loading

walk-away automation



<sup>1</sup>Available in CE market; <sup>2</sup> Internal and third parties

# Roche analyst virtual event on diagnostics division



AACC 2022 in Chicago



July 26, 6-7:15pm CDT



#### Speakers:

- Thomas Schinecker, CEO Roche Diagnostics
- **Ann Costello,** Global Head Roche Diagnostics Solutions
- **Cindy Perettie,** Head of Roche Molecular Labs
- Palani Kumaresan, Head of Research & Development Roche Diagnostics
- Matt Sause, President & CEO Roche Diagnostics North America

# **Key launches 2022**



	Area	Product	Description	Market	Status
Pathology Lab  Core Lab		BenchMark ULTRA PLUS	Automated immunohistochemistry/in situ hybridization (ISH) advanced staining platform with enhanced software capabilities, workflow and testing efficiency	US & CE	<b>V</b>
		DP600	High capacity pathology slide scanner for high volume digitization applications	WW	
		cobas® pure integrated solutions	Serum work area analyzer for low-to-medium sized labs	US	
ilisti ullielits	Molecular Lab	cobas® 5800	Real-time PCR molecular testing for low volume labs	US	
	Moloodidi Lab	Digital LightCycler	Novel digital PCR platform for lab developed tests (LDTs) and in-vitro diagnostics labs	WW	
	POC	cobas® pulse	Handheld device combining professional Glucose Meter and a digital platform to host Roche owned and 3rd party digital clinical decision support applications	US	
		HER2 Low Breast	Assay for diagnosis of HER2 low expression breast cancer	US	
	Pathology Lab	PRAME	First immunohistochemistry assay for differential diagnosis of benign from malignant melanocytic lesions in skin cancer	US & CE	
		HPV Self Sampling	Self sample collection device for patients at home to collect sample for cervical cancer testing	CE	
Tests	Core Lab	cobas® HCV Duo	Antigen/antibody combined assay for faster diagnosis of hepatitis C	CE	
16313		Elecsys pTau/AB42 ratio Gen2 (CSF)	Detect amyloid disease and enable a broader availability of testing for patients suspected of Alzheimer's Disease	US	
		cobas® SARS-CoV-2 DUO	Automated RT-PCR assay for use on the cobas® 6800/8800 systems	US <sup>2</sup> & OUS <sup>1</sup>	
	Molecular Lab	cobas® 5800 Menu Expansion	Assays to test for SARS-CoV-2, chlamydia trachomatis (CT)/neisseria gonorrhoeae (NG) and cytomegalovirus (CMV)	US & CE	
Lab Insights Digital Solutions		Chronic Kidney Disease InSight	Digital solution (mobile app and dashboard) providing insights for chronic kidney disease patient management	CE	
	Lab Insights	Cervical Cancer Screening	Digital solution (mobile app and workflow) improving the management of screening programs for cervical cancer	CE	
		cobas® infinity edge suite	Portfolio of digital products to support decentralization of testing and data, to launch commercially with an open ecosystem	CE	
		Lab Insights Platform	Data integration platform for laboratory customers across disciplines	CE	
		Payer Dashboard	Population-level insights via dashboard for HCPs, Admins and Payers	OUS <sup>3</sup>	<b>~</b>
	Diabetes Care	mySugar Pump V2.0	Extended functionalities (e.g. temporary basal rate import from a connected insulin pump), expanded smartphone compatibility	OUS <sup>3</sup>	





**Finance** 

Alan Hippe Chief Financial Officer

# HY 2022 results

Focus on cash and balance sheet

**Outlook** 



# HY 2022: Highlights



#### **Business**

- Group sales growth of +5% driven by good performance of Pharmaceuticals and Diagnostics division
- Pharma established products and new launches performing well; Diagnostics continuing with strong double-digit sales
- Core operating profit up +9% and Core EPS growth +11% (including +6.1%p net accretion Novartis share repurchase and 3.5%p from Ultomiris patent settlement)

#### **Cash flow**

- Operating Free Cash Flow of CHF 9.8bn, +21% growth driven by strong operating results and movements in net working capital
- Net debt higher by CHF 2.7bn vs. Dec 31st 2021

#### **Net financial result**

• Core net financial expense increased by CHF -370m driven by loss on equity securities

#### **IFRS**

• Net income +12% driven by the operating results and lower intangible assets amortization



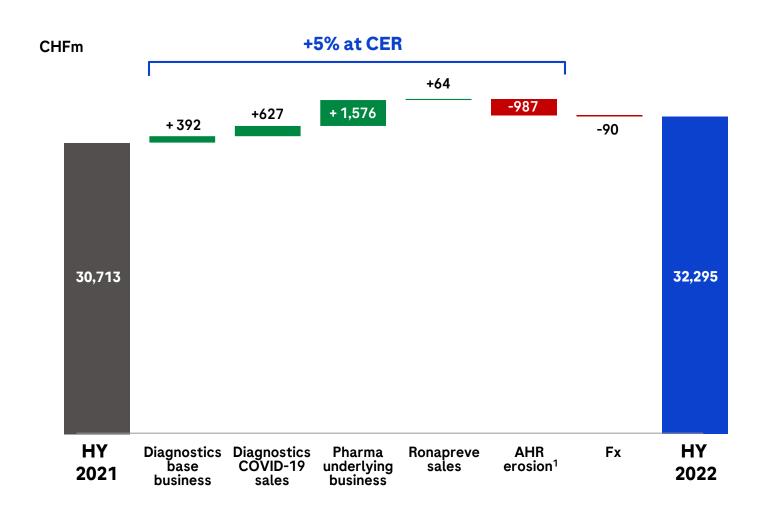


	2022	2021	Change in %	
	CHFm	CHFm	CHF	CER
Sales	32,295	30,713	5	5
Core operating profit	12,668	11,652	9	9
as % of sales	39.2	37.9		
Core net income	10,160	9,527	7	7
as % of sales	31.5	31.0		
Core EPS (CHF)	11.76	10.56	11	11
IFRS net income	9,161	8,216	12	12
as % of sales	28.4	26.8		
Operating free cash flow	9,782	8,117	21	21
as % of sales	30.3	26.4		
Free cash flow	7,097	6,038	18	18
as % of sales	22.0	19.7		

CER=Constant Exchange Rates 52

# HY 2022: Growing topline compensating biosimilar erosion

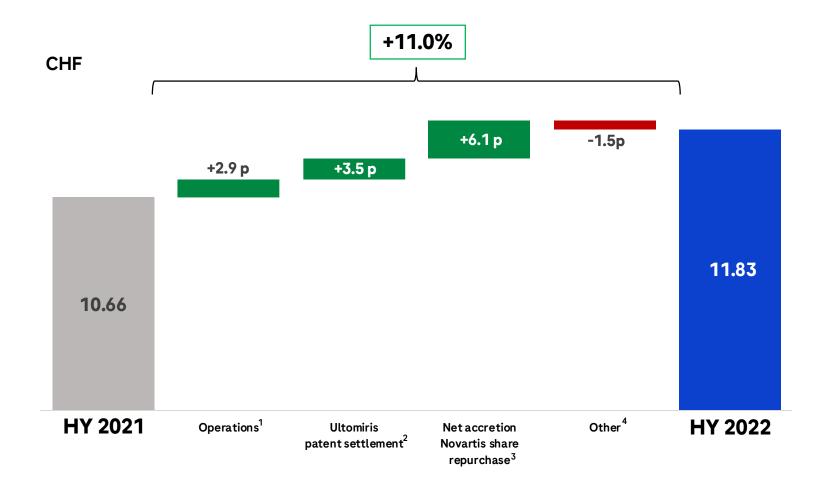








Strong EPS development driven by growth in operations and accretion effect

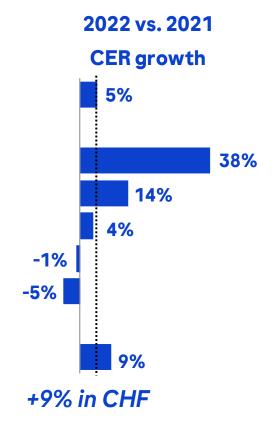






Core OP up +9% driven by higher gross profit and ROOI, OPEX stable

	2022		
	CHFm	abs. CER	
Sales	32,295	+1,672	
Royalties & other op. inc.	1,943	+536	
Cost of sales	-9,305	-1,119	
M & D	-4,459	-159	
R & D	-6,628	+85	
G & A	-1,178	+63	
Core operating profit	12,668	+1,078	

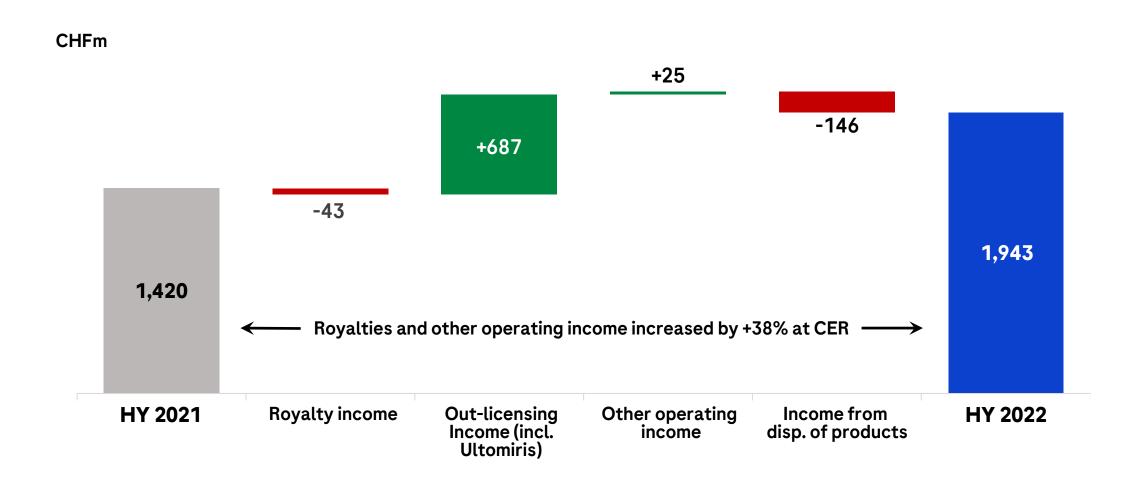


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# HY 2022: Royalties and other operating income



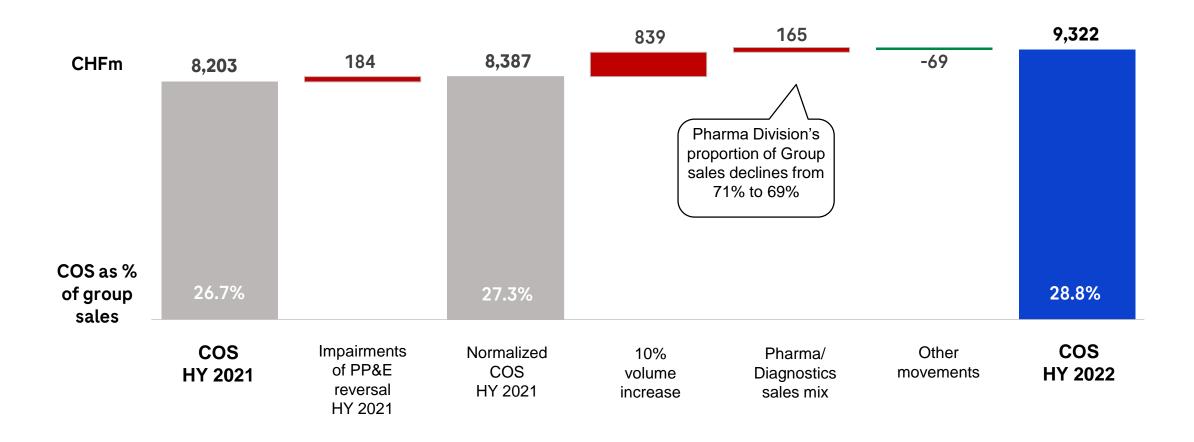
Higher income mainly driven by Ultomiris patent settlement



# HY 2022: Group Core cost of sales (COS)

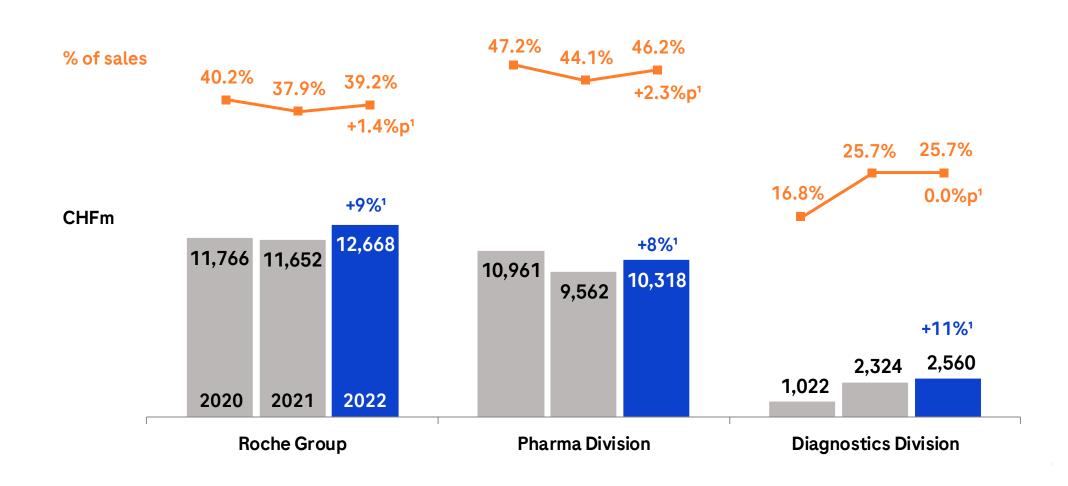


Increase due to PP&E reversal in 2021, volume growth and change in the Pharma/Diagnostics sales mix



# HY 2022: Core operating profit and margin



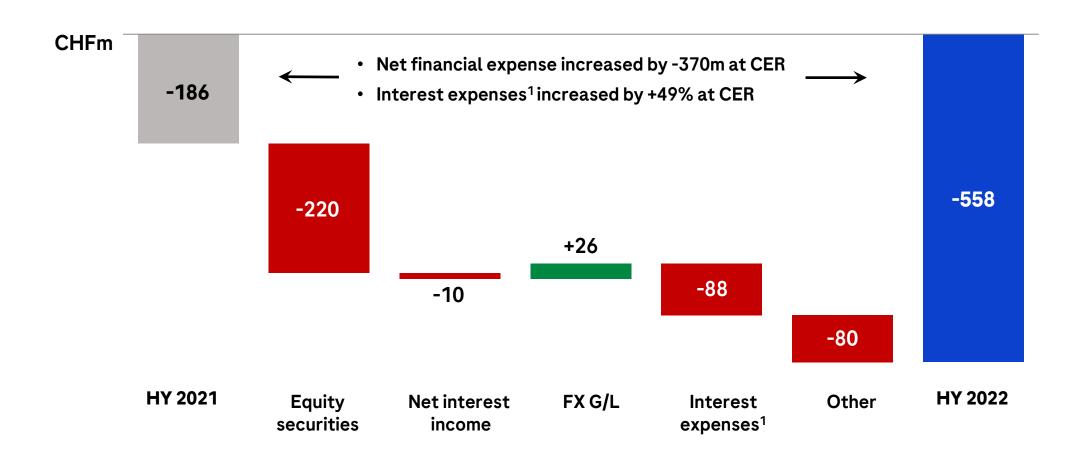


58

# HY 2022: Core net financial result



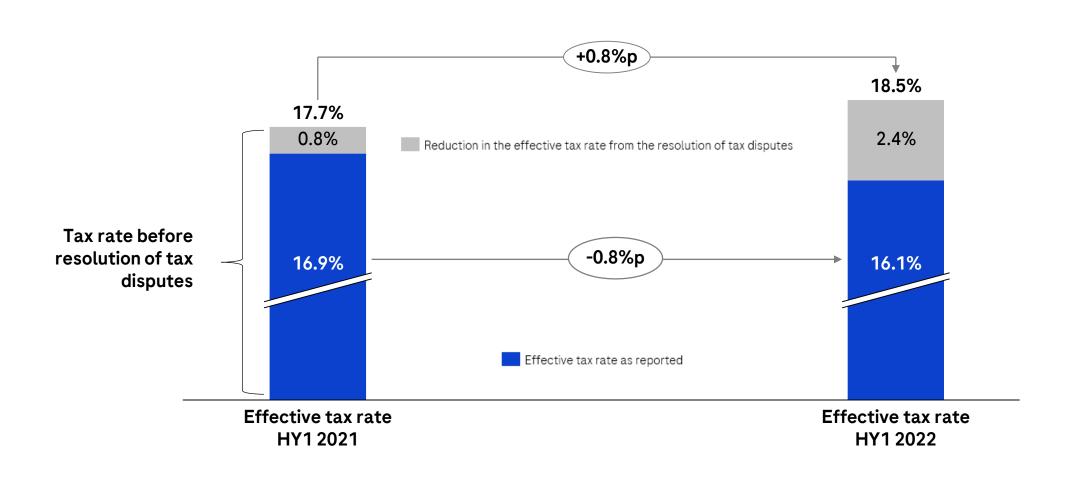
Higher net financial expenses driven by loss on Equity securities and higher interest expenses







Tax rate before resolution of tax disputes increased due to higher profits in higher tax jurisdictions





#### HY 2022: Non-core and IFRS income

Decrease in non-core operating expenses driven by lower amortisation of intangible assets due to Esbriet and lower costs for global restructuring plans

	2021	2022	2022		Change in %	
	CHFm	CHFm	CHFm	CHF	CER	
Core operating profit	11,652	12,668	1,017	+9	+9	
Global restructuring plans	-511	-265	246			
Amortisation of intangible assets	-830	-468	362			
Impairment of intangible assets <sup>1</sup>	-165	-423	-258			
M&A and alliance transactions	-37	17	54			
Legal & Environmental <sup>2</sup>	-32	19	51			
Total non-core operating items	-1,575	-1,120	455			
IFRS Operating profit	10,077	11,547	1,469	+15	+15	
Total financial result & taxes	-1,861	-2,386	-525			
IFRS net income	8,216	9,161	944	+12	+12	

# HY 2022 results

Focus on cash and balance sheet

**Outlook** 

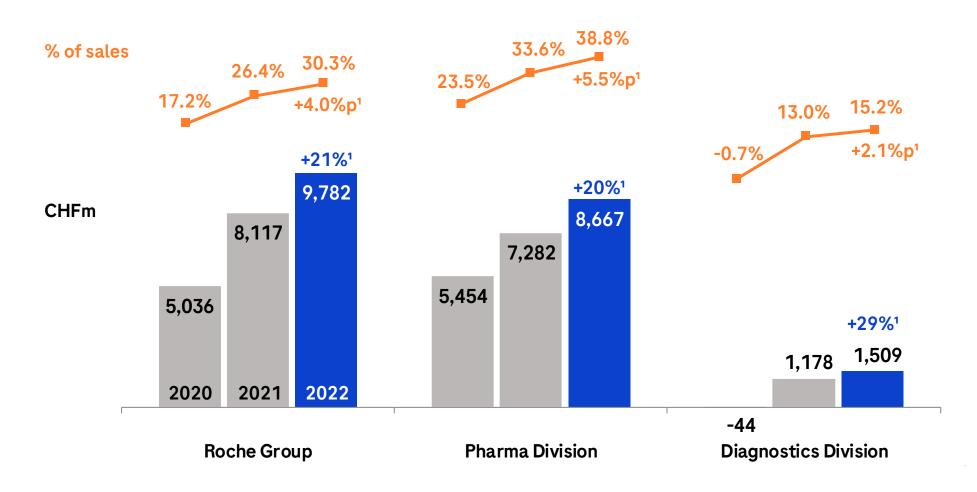


# HY 2022: Operating free cash flow and margin



63

OFCF of +21% driven by higher OP, net of cash adjustments and NWC movements

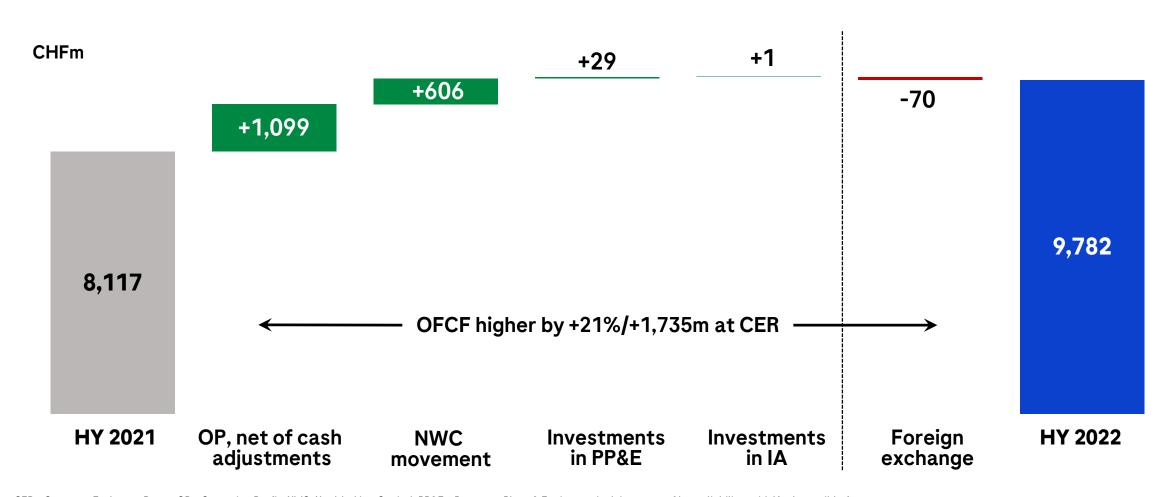


<sup>1</sup> At CER=Constant Exchange Rates

# HY 2022: Group operating free cash flow



OFCF up by +21% driven by higher Operating Profit, net of cash adjustments

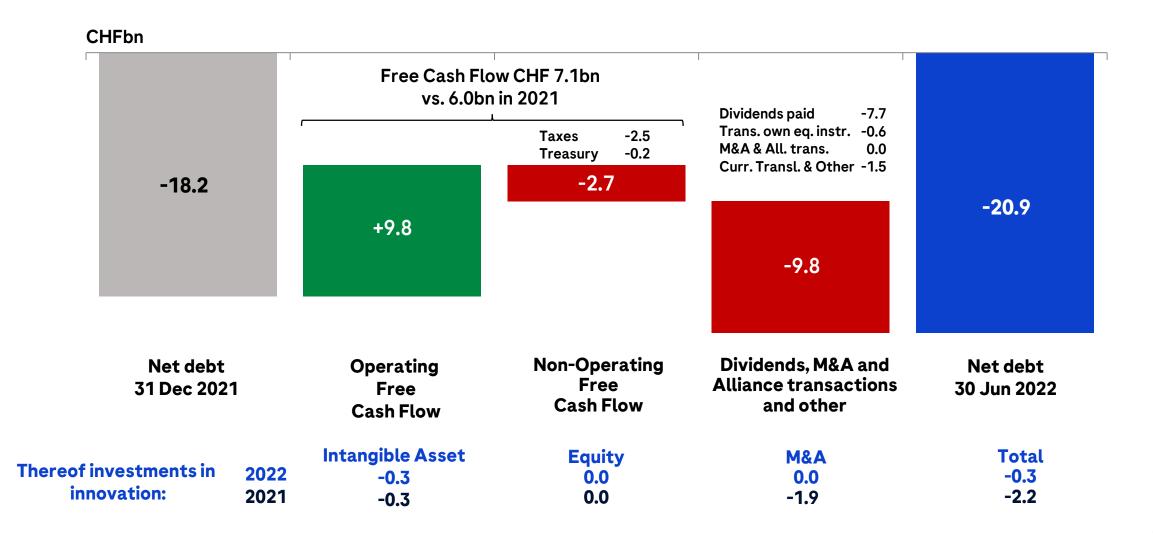








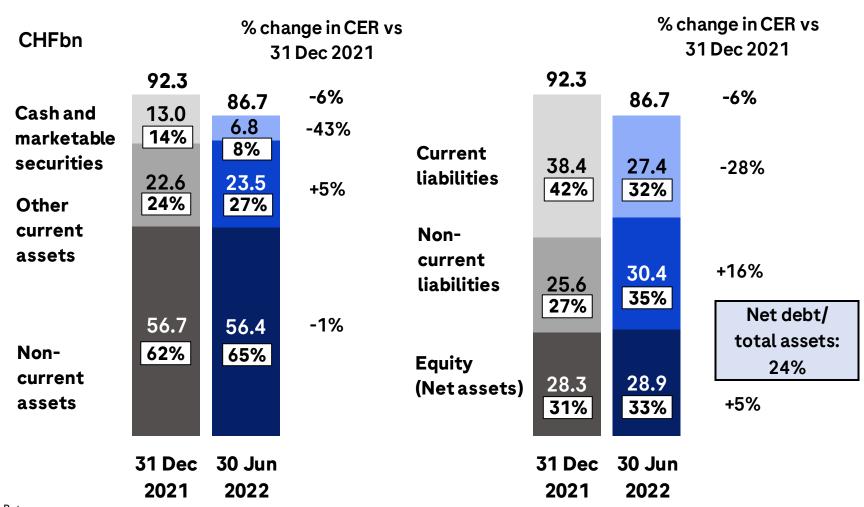
Net debt higher by CHF -2.7bn compared to previous YE 2021



#### Balance sheet 30 June 2022



Equity ratio at 33% (YE 2021: 31%) and net debt to assets at 24% (YE 2021: 20%)



CER = Constant Exchange Rates 66

# HY 2022 results

Focus on cash and balance sheet

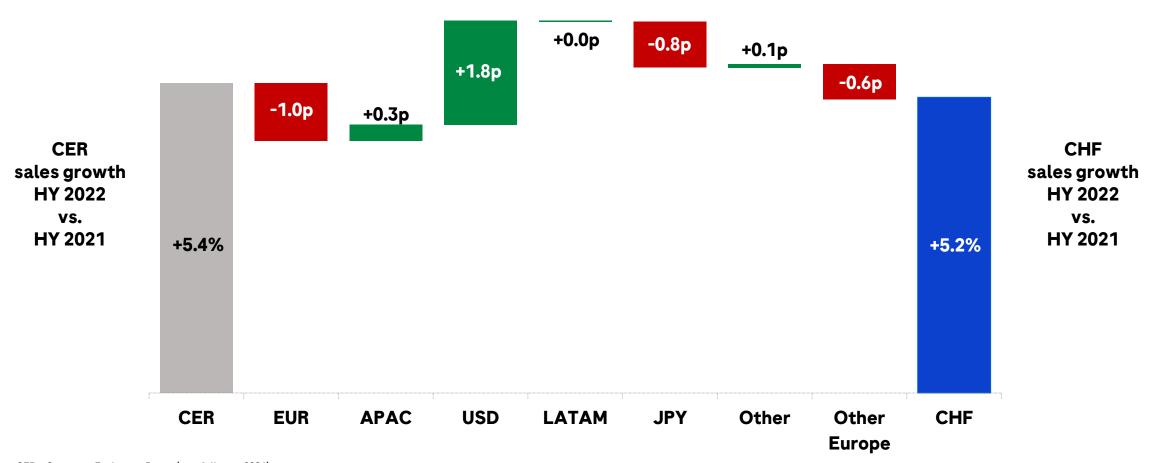
**Outlook** 



# Exchange rate impact on sales growth



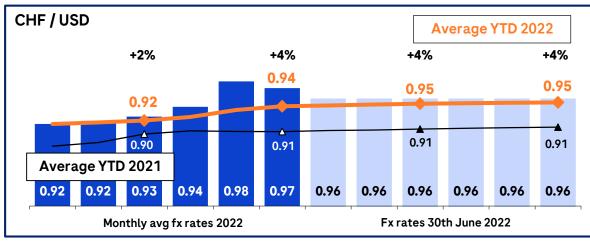
Negative impact driven by the EUR, JPY and "other Europe", partially offset by USD

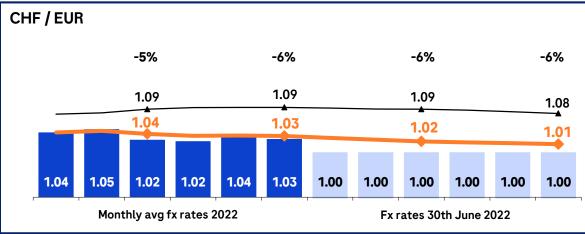


CER = Constant Exchange Rates (avg full year 2021)

# Low currency impact expected in 2022







# Assuming the 30 June 2022 exchange rates remain stable until end of 2022, 2022 impact<sup>1</sup> is expected to be (%p):

	Q1	НҮ	Sep YTD	FY
Sales	-1	0	-1	-1
Core operating profit		0		-1
Core EPS		0		-1

<sup>1</sup>On group growth rates

# 2022 outlook



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)

70

Doing now what patients need next



# **Roche Group development pipeline**

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

**Spark** 

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

### Changes to the development pipeline



#### HY 2022 update

New to phase I
----------------

#### 2 NMEs:

RG6351 NME – retinal disease RG6526 camonsertib – solid tumors

#### 1 AI:

RG6264 Phesgo OBI - HER2+ BC

#### New to phase II

#### 1 NME:

RG6237 latent myostatin + Evrysdi - SMA

#### New to phase III

#### 4 Als:

RG1594 Ocrevus SC - PPMS & RMS RG6171 giredestrant + Phesgo - 1L ER+/HER2+

RG1450 gantenerumab – early Alzheimer's RG7828 Lunsumio (mosunetuzumab) + Polivy -2L+ SCT ineligible DLBCL

#### New to registration

#### Removed from phase I

#### 1 NME:

RG6338 NME - metabolic diseases

#### 2 Als:

**RG7440** ipatasertib + rucaparib - mCRPC, solid tumors

**RG7440** ipatasertib - prostate cancer, pretreated

#### Removed from phase II

#### 1 NME:

RG6173 anti-tryptase - asthma

#### 1 AI:

RG6171 giredestrant - 2/3L ER+/HER2- mBC

#### Removed from phase III

#### **Approvals**

#### 1 NME (EU):

RG7828 Lunsumio (mosunetuzumab) - 3L FL

#### 1 AI (US):

**RG7916** Evrysdi SMA presymptomatic pediatric <2mo

#### 2 Als (EU):

RG7596 Polivy – 1L DLBCL RG7446 Tecentriq - NSCLC adj

## Roche Group development pipeline



Phase I	(49 NMEs + 11 Als)
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		•
RG6007	HLA-A2-WT1 x CD3	AML
RG6026	glofitamab monotherapy + combos	heme tumors
RG6058	tiragolumab combos	heme & solid tumors
RG6076	CD19-4-1BBL combos	heme tumors
RG6129	HLA-A2-MAGE-A4 x CD3	solid tumors
RG6160	cevostamab (FcRH5 x CD3)	r/r multiple myeloma
RG6171	giredestrant (SERD)	solid tumors
RG6114	inavolisib (mPI3K alpha inh)	solid tumors
RG6156	EGFRvIII x CD3	glioblastoma
RG6180	autogene cevumeran ± T	solid tumors
RG6185	belvarafenib (pan-RAF inh) + Cotellic	±T solid tumors
RG6189	FAP-CD40 ± T	solid tumors
RG6194	runimotamab (HER2 x CD3)	ВС
RG6234	GPRC5D x CD3	multiple myeloma
RG6264	Phesgo OBI	HER2+ BC
RG6279	PD1-IL2v±T	solid tumors
RG6286	-	colorectal cancer
RG6290	MAGE-A4 ImmTAC ± T	solid tumors
RG6292	CD25 MAb ± T	solid tumors
RG6323	IL15/IL15Ra-Fc ± T	solid tumors
RG6330	KRAS G12C	solid tumors
RG6333	CD19 x CD28 + glofitamab	r/r NHL
RG6344	BRAF inhibitor (3)	solid tumors
RG6392	-	oncology
RG6433	SHP2i	solid tumors
RG6440	TGFβ (SOF10)	solid tumors
RG6526**	camonsertib	solid tumors
RG7446	Morpheus platform	solid tumors
RG7601	Venclexta ± azacitidine	r/r MDS
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL monotherapy + combos	solid tumors

	RG7828	Lunsumio (mosunetuzum monotheraphy + combos	heme filmors
	CHU	FIXa x FX	hemophilia
ı	CHU	glypican-3 x CD3	solid tumors
	CHU	codrituzumab	НСС
	CHU	CD137 switch antibody	solid tumors
	CHU	LUNA18	solid tumors
	CHU	SPYK04	solid tumors
	SQZ	PBMC vaccine	solid tumors
	RG6287	-	IBD
	RG6341	-	asthma
	RG6418	selnoflast (NLRP3 inh)	inflammation
	RG6315	-	immunologic disorders
	RG7828	Lunsumio (mosunetuzum	ab) SLE
	RG7880	efmarodocokin alfa	aGVHD
	RG6006	Abx MCP	bacterial infections
	RG6319	•	plicated urinary tract infection
	RG6035	BS-CD20 MAb	multiple sclerosis
	RG6091	rugonersen (UBE3A LNA	) Angelman syndrome
١	RG6163	-	psychiatric disorders
	RG6182	-	neurodegenerative diseases
	RG6237	latent myostatin	neuromuscular disorders
	RG6289	-	Alzheimer´s
	RG7637	-	neurodevelopmental disorders
	RG6120	VEGF-Ang2 DutaFab	nAMD
	RG6312	-	geographic atrophy
	RG6351	NME	retinal disease
	RG6501*	OpRegen	geographic atrophy
	RG7921	-	nAMD
	CHU	AMY109	endometriosis

#### Phase II (22 NMEs + 11 Als)

RG6026	glofitamab+chemo	1L ctDNA high risk DLBCL
	tiragolumab+T	NSCLC
	tiragolumab+T+chemo	1L non-squamous NSCLC
RG6058	tiragolumab+T+chemo	NSCLC neoadj-adj
	tiragolumab+T	cervical cancer
	tiragolumab+T	1L PD-L1+ mSCCHN
RG6107	crovalimab	sickle cell disease
RG6139	PD1 x LAG3	solid tumors
RG6180	autogene cevumeran + pembroliz	umab 1L melanoma
RG6354	zinpentraxin alfa (PRM-151)	myelofibrosis
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016 hemophilia A w	vith inhibitors to factor VIII
RG7601	Venclexta + carfilzomib	r/r MM t(11;14)
CHU	Oncolytic Type 5 adenovirus	esophageal cancer
RG6149	astegolimab (Anti-ST2)	COPD
RG6299 <sup>†</sup>	ASO factor B	IgA nephropathy
RG7854/RG79 07/RG6346/ RG60841	TLR7 ago(3)/CpAM(2)/ siRNA/PDL1 LNA	HBV
RG6359	SPK-3006	Pompe disease
RG6100	semorinemab	Alzheimer's
RG6102	BS-gantenerumab	Alzheimer's
RG6237	latent myostatin + Evrysdi	SMA
RG6416	bepranemab	Alzheimer's
RG7412	crenezumab famili	ial Alzheimer's healthy pts
RG7816	alogabat (GABA Aa5 PAM)	ASD
RG7906	ralmitaront	schizophrenia
RG7935	prasinezumab	Parkinson's
RG6147	galegenimab (HtrA1)	geographic atrophy
RG6179	-	DME
RG7774	-	retinal disease
RG6299 <sup>†</sup>	ASO factor B	geographic atrophy

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases



CHU - Chugai managed
†IONIS managed
SQZ - SQZ Biotechnology managed
\*Lineage Cell Therapeutics managed
\*\*Repare Therapeutics managed

<sup>1</sup>combination platform RG-No - Roche/Genentech T=Tecentriq BS=Brain Shuttle OBI=On-Body Delivery System

## Roche Group development pipeline



#### Phase III (10 NMEs + 43 Als)

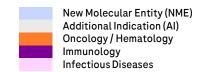
RG3502	Kadcyla + T	2L+ HER-2+ PD-L1+ mBC	RG7601	Venclexta	r/r MM t(11:14)
1103302	Kadcyla + T	HER-2+ eBC high-risk	1107001	Venclexta + azacitidin	e 1L MDS
RG6026	glofitamab + chemo	2L+ DLBCL		Lunsumio (mosunetuz	umab)+ 2L+FL
	tiragolumab+T	1L esophageal cancer	RG7828	lenalidomide	
RG6058	tiragolumab + T	1L PD-L1+ NSCLC		Lunsumio (mosunetuz Polivy	umab) + 2L+ DLBCL
	•	nced esophageal cancer	RG7853	Alecensa	ALK+ NSCLC adj
	•	unresectable 1L NSCLC	RG3648	Xolair	food allergy
RG6107	crovalimab	PNH	RG6354	zinpentraxin alfa (PRM	C,
	crovalimab	aHUS		Gazyva	lupus nephritis
RG6114	inavolisib (mPI3K alpha inh)	1L HR+ mBC	RG7159	Gazyva	membranous nephropathy
	giredestrant (SERD)	1L ER+/HER2- mBC		·	ystemic lupus erythematosus
RG6171	giredestrant (SERD)	ER+ BC adj		·	influenza, pediatric (0-1 year)
	giredestrant (SERD) + Phesgo	1L ER+/HER2+ BC	RG6152	Xofluza	influenza direct transmission
RG7440	ipatasertib + abiraterone	1L CRPC			orodromal to mild Alzheimer's
	Tecentriq + platinum chemo	NSCLC neoadj	RG1450	gantenerumab	early Alzheimer's
	Tecentriq	NMIBC, high risk		Ocrevus higher dose	RMS & PPMS
	Tecentriq	RCC adj	RG1594	Ocrevus SC	RMS & PPMS
	Tecentriq + cabozantinib	RCC adv	RG6042	tominersen	Huntington's
	Tecentriq + cabozantinib	2L NSCLC	RG6168	Enspryng	myasthenia gravis
	T ± chemo	SCCHN adj	RG6356	. , ,	eparvovec (SRP-9001) DMD
RG7446	T + capecitabine or carbo/gem	1L TNBC	RG7845	fenebrutinib	RMS
	T + paclitaxel	TNBC adj	RG7845	fenebrutinib	PPMS
	T + Avastin	HCC adj		Susvimo (PDS)	DME
	T ± chemo	± chemo 1L mUC	RG6321	Susvimo (PDS)	DR
	Tecentriq SC	2L NSCLC		Susvimo (PDS)	wAMD, 36-week
	Tecentriq	ctDNA+ high-risk MIBC	20224	Vabysmo (faricimab)	BRVO
	T+ lurbinectedin	1L maintenance SCLC	RG7716	Vabysmo (faricimab)	CRVO
				, , , , , , , , , , , , , , , , , , , ,	

#### Registration US & EU (4 NMEs + 8 Als)

	1	
RG6013	Hemlibra <sup>1</sup>	mild to moderate hemophilia A
RG6026	glofitamab²	3L+ DLBCL
RG6396	Gavreto <sup>1</sup>	RET+ MTC, TC
RG7596	Polivy <sup>3</sup>	1L DLBCL
RG7828	Lunsumio (mosunetuzuma	b) <sup>4</sup> 3 L+ FL
RG6321	Susvimo (PDS) 1	wAMD
RG7716	Vabysmo (faricimab) 1	DME
NG//10	Vabysmo (faricimab) 1	wAMD
RG6152	Xofluza	influenza, pediatric
RG56413+	Pananraya?	CARS CoV 2 hoopitalised
RG6412	Ronapreve <sup>2</sup>	SARS-CoV-2 hospitalised
RG1569	Actemra <sup>4</sup>	COVID-19 pneumonia
RG7916	Evrysdi <sup>1</sup>	SMA pediatric <2months

<sup>&</sup>lt;sup>1</sup> Approved in US, filed in EU

T=Tecentriq
PDS=Port Delivery System with ranibizumab





<sup>&</sup>lt;sup>2</sup> Filed in the EU

<sup>&</sup>lt;sup>3</sup> Approved in EU

 $<sup>^{\</sup>rm 4}$  Approved in EU, filed in US

#### NME submissions and their additional indications



bepranemab

Alzheimer's

alogabat

(GABA Aa5 PAM)

ASD

fenebrutinib

RMS

fenebrutinib

PPMS

ralmitaront

schizophrenia

prasinezumab

Parkinson's

RG6416

**RG7816** 

**RG7845** 

**RG7845** 

**RG7906** 

**RG7935** 

#### Projects in phase II and III

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

Metabolism Neuroscience Ophthalmology Other

√ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
PDS=Port Delivery System with ranibizumab
Mosun=mosunetuzumab
†IONIS managed

				RG6058	tiragolumab + T Stage III unresectable 1L NSCLC	RG6107	<b>crovalimab</b> sickle cell disease	RG7907/ RG7854/ RG6346/ RG6084	TLR7 ago (3)/CpAM (2) /siRNA/ PDL1 LNA HBV	RG6321	Susvimo (PDS) wAMD, 36-week refill
RG6026	<b>glofitamab</b> 3L+DLBCL √	RG6058	tiragolumab + T 1L PD-L1+ NSCLC	RG6107	<b>crovalimab</b> aHUS	RG6139	PD1xLAG3 solid tumors	RG1450	<b>gantenerumab</b> early Alzheimer's	RG6147	galegenimab (HtrA1) geographic atrophy
RG6058	<b>tiragolumab + T</b> 1L esophageal cancer (CN)	RG6321	Susvimo (PDS) DME	RG6114	inavolisib (mPI3K alpha inh) 1L HR+ BC	RG6171	giredestrant (SERD) 1L ER+/HER2- mBC	RG6100	<b>semorinemab</b> Alzheimer's	RG6179	<b>NME</b> DME
RG6107	crovalimab PNH(CN)	RG6321	Susvimo (PDS) DR (US)	RG6354	zinpentraxin alfa ( <b>PRM-151)</b> IPF	RG6171	<b>giredestrant</b> <b>(SERD)</b> ER+ BC adj	RG6102	brain shuttle gantenerumab Alzheimer's	RG6299†	ASO factor B geographic atrophy
RG1450	<b>gantenerumab</b> prodromal to mild Alzheimer's	RG7716	<b>Vabysmo</b> (faricimab) BRVO/CRVO	RG6356	delandistrogene moxeparvovec (SRP-9001) DMD	RG6171	giredestrant (SERD) + Phesgo 1L ER+/HER2+ BC	RG6237	latent myostatin + Evrysdi SMA	RG7774	<b>NME</b> retinal disease

glofitamab + chemo

2L DLBCL glofitamab + chemo

1L ctDNA+ high risk

DLBCL

tiragolumab + T

1L PD-L1+ cervical

cancer

tiragolumab + T

locally adv esophageal

cancer

tiragolumab + T

1L non-sq NSCLC

tiragolumab + T

1L PD-L1+ mSCCHN

tiragolumab+T+/-

chemo

NSCLC neoadj/adj

**RG6026** 

**RG6026** 

**RG6058** 

**RG6058** 

**RG6058** 

**RG6058** 

**RG6058** 

2022

2023

2024

2025 and beyond

autogene cevumeran

1L melanoma

zinpentraxin alfa

(PRM-151)

myelofibrosis

Lunsumio (mosun) +

lenalidomide

2L FL Lunsumio (mosun) +

**Polivy** 

2L+DLBCL (US)

astegolimab

(anti-ST2)

COPD

**ASO factor B** 

IgA nephropathy

**RG6180** 

RG6354

**RG7828** 

**RG7828** 

**RG6149** 

RG6299<sup>†</sup>

## Al submissions for existing products



Projects in phase II and III

2022		20	23			2024	202	5 and beyond
<b>Polivy</b> 1L DLBCL (US)	RG7853	<b>Alecensa</b> ALK+ NSCLC adj	RG6152	<b>Xofluza</b> influenza, pediatric (0-1 year)	RG6168	<b>Enspryng</b> myasthenia gravis	RG1594	Ocrevus higher dose RMS & PPMS
<b>Tecentriq ± chemo</b> 1L mUC	RG7446	Tecentriq + capecitabine or carbo/gem TNBC	RG6152	<b>Xofluza</b> direct transmission	RG7159	<b>Gazyva</b> lupus nephritis	RG7159	<b>Gazyva</b> systemic lupus erythematosus
<b>Actemra</b> COVID-19 pneumonia <sup>1</sup> √	RG7601	<b>Venclexta</b> r/r MM t(11:14)	RG3648	<b>Xolair</b> food allergy	RG7601	<b>Venclexta + azacitidine</b> 1L MDS	RG7159	<b>Gazyva</b> membranous nephropathy
Ronapreve** ARS-CoV-2 hospitalized (EU) √	RG7446	<b>Tecentriq</b> SCCHN adj	RG1594	Ocrevus SC RMS & PPMS	RG7446	<b>Tecentriq</b> ctDNA+ high-risk MIBC	RG7446	<b>Tecentriq+ lurbinectedin</b> 1l maintenance SCLC
	RG7446	<b>Tecentriq</b> <sup>2</sup> NSCLC neoadj					RG7446	<b>Tecentriq</b> High risk NMIBC
	RG7446	<b>Tecentriq + Avastin</b> HCC adj					RG7446	<b>Tecentriq + paclitaxel</b> TNBC adj
	RG7446	<b>Tecentriq + cabozantinib</b> RCC adv					RG3502	<b>Kadcyla + Tecentriq</b> HER-2+ eBC high-risk
	RG7446	<b>Tecentriq + cabozantinib</b> 2L NSCLC					RG3502	<b>Kadcyla + Tecentriq</b> 2L+ HER-2+ PD-L1+ mBC
	RG7446	<b>Tecentriq SC</b> 2L NSCLC						
	RG6396	<b>Gavreto</b> Tumor agnostic				Oncology / Hemato Immunology Infectious Diseases		Ophthalmology Other
	RG6264	Phesgo OBI HER2+ BC				New Molecular Ent Additional Indication	on (AI)	Metabolism Neuroscience

RG6413+ RG6412

**RG1569** 

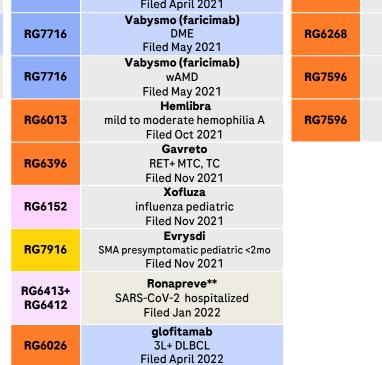
**RG7446** 

**RG7596** 

## Major pending approvals 2022



US		US EU			
RG6152	<b>Xofluza</b> influenza pediatric Filed March 2020	RG6321	Susvimo (PDS) wAMD Filed April 2021	RG6268	<b>Rozlytrek</b> ROS1+ NSCLC Filed Oct 2021
RG7828	<b>Lunsumio (mosunetuzumab)</b> 3L+ FL Filed Dec 2021	RG7716	<b>Vabysmo (faricimab)</b> DME Filed May 2021	RG6268	<b>Rozlytrek</b> NTRK+ solid tumors Filed Nov 2021
RG1569	Actemra COVID-19 pneumonia Filed Jan 2022	RG7716	<b>Vabysmo (faricimab)</b> wAMD Filed May 2021	RG7596	<b>Polivy</b> 1L DLBCL Filed Nov 2021
		RG6013	<b>Hemlibra</b> mild to moderate hemophilia A Filed Oct 2021	RG7596	<b>Polivy</b> r/r DLBCL Filed Dec 2021
		RG6396	<b>Gavreto</b> RET+ MTC, TC Filed Nov 2021		
		RG6152	<b>Xofluza</b> influenza pediatric Filed Nov 2021		
		RG7916	<b>Evrysdi</b> SMA presymptomatic pediatric <2mo Filed Nov 2021		



Metabolism

Other

Neuroscience

Ophthalmology

PDS=Port Delivery System with ranibizumab \*\*Ronapreve (casirivimab+imdevimab also known as REGEN-COV in the US) developed in collaboration with Regeneron Pharmaceuticals

Japan-Chugai

**RG7596** 

**RG7159** 

Polivy

1L DLBCL Filed Dec 2021 Gazyva 1L ČLL

Filed March 2022

# Major granted approvals 2022

Infectious Diseases



	US EU		EU	China		Ja	apan-Chugai
RG7716	<b>Vabysmo (faricimab)</b> DME Jan 2022	RG7596	<b>Polivy</b> 1L DLBCL May 2022	RG7446	<b>Tecentriq</b> NSCLC adj March 2022	RG1569	<b>Actemra</b> COVID-19 pneumonia Jan 2022
RG7716	<b>Vabysmo (faricimab)</b> wAMD Jan 2022	RG7446	<b>Tecentriq</b> NSCLC adj June 2022	RG1569	<b>Actemra</b> RA SC April 2022	RG7716	<b>Vabysmo (faricimab)</b> DME March 2022
RG1569	<b>Actemra</b> GCA IV Feb 2022	RG7828	<b>Lunsumio (mosunetuzumab)</b> 3L+ FL June 2022			RG7716	<b>Vabysmo (faricimab)</b> wAMD March 2022
RG7916	Evrysdi SMA presymptomatic pediatric <2mo May 2022					RG1273	<b>Perjeta + Herceptin</b> HER-2+ CRC March 2022
						RG7446	<b>Tecentriq</b> NSCLC adj May 2022
						RG6013	<b>Hemlibra</b> acquired Hemophilia A June 2022
						RG105	<b>Rituxan</b> NMOSD June 2022
	New Molecular Entity (NME)		Metabolism				
	Additional Indication (AI)		Neuroscience				
	Oncology / Hematology		Ophthalmology				

**Status as of July 21, 2022 79** 



#### Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

**Spark** 

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

### Hemlibra



### Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients without inhibitors to factor VIII	Hemophilia A patients with and without inhibitors to Factor VIII, dos every 4 weeks				
Phase/study	Phase III HAVEN 3	Phase III HAVEN 4				
# of patients	N=135	N=46				
Design	Patients on FVIII episodic treatment prior to study entry:  • ARM A: Hemlibra prophylaxis qw  • ARM B: Hemlibra prophylaxis q2w  • ARM C: Episodic FVIII treatment; switch to Hemlibra prophylaxis possible after 24 weeks  Patients on FVIII prophylaxis prior to study entry:  • ARM D: Hemlibra prophylaxis qw	Multicenter, open-label, non-randomized study to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of Hemlibra administered every 4 weeks.  • Part 1: Pharmacokinetic run-in part (N=6)  • Part 2: Expansion part (N=40)				
Primary endpoint	<ul> <li>Number of bleeds over 24 weeks</li> </ul>	<ul> <li>Number of bleeds over 24 weeks</li> </ul>				
Status	<ul> <li>FPI Q3 2016, recruitment completed Q2 2017</li> <li>Study met primary and key secondary endpoints Q4 2017</li> <li>FDA granted Breakthrough Therapy Designation April 2018</li> <li>Data presented at WFH 2018</li> <li>Filed in US (priority review) and EU in Q2 2018</li> <li>Data published in NEJM 2018; 379: 811-822</li> </ul>	<ul> <li>FPI Q1 2017, recruitment completed Q2 2017</li> <li>Pharmacokinetic run-in data at ASH 2017</li> <li>Positive interim analysis outcome reported Q4 2017</li> <li>Data presented at WFH 2018</li> <li>Interim data filed in US and EU in Q2 2018</li> <li>Data published in Lancet Haematology 2019 Jun;6(6):e295-e305</li> </ul>				
	•Approved in US Q4	2018 and EU Q1 2019				
CT Identifier	NCT02847637	NCT03020160				

### Hemlibra



### Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients with and without inhibitors to Factor VIII	Hemophilia A mild to moderate patients without inhibitors to Factor VIII
Phase/study	Phase III HAVEN 5	Phase III HAVEN 6
# of patients	N=85	N=70
Design	Patients with Hemophilia regardless of FVIII inhibitor status on prophylactic or episodic treatment prior to study entry: • Arm A: Hemlibra prophylaxis qw • Arm B: Hemlibra prophylaxis q4w • Arm C: No prophylaxis (control arm)	Multicenter, open-label study to evaluate the safety, efficacy, pharmacokinetics, and pharmacodynamics of Hemlibra in patients with mild or moderate Hemophilia A without FVIII inhibitors  - Hemlibra qw (1.5mg/kg), q2w (3.0mg/kg) or q4w (6.0mg/kg) (patients preference)
Primary endpoint	<ul> <li>Number of bleeds over 24 weeks</li> </ul>	Safety and efficacy
Status	<ul> <li>FPI Q2 2018</li> <li>Recruitment completed Q1 2019</li> <li>Filed in China Q2 2020</li> <li>Approved in China Q2 2021</li> </ul>	<ul> <li>FPI Q1 2020</li> <li>Recruitment completed Q1 2021</li> <li>Interim data presented at ASH 2021 and primary data presented at ISTH 2022</li> <li>Filed in EU Q4 2021</li> </ul>
CT Identifier	NCT03315455	NCT04158648

#### **Alecensa**



### New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK+ advanced NSCLC	Adjuvant ALK+ NSCLC
Phase/study	Phase III ALEX	Phase III ALINA
# of patients	N=286	N=255
Design	<ul> <li>ARM A: Alecensa 600mg BID</li> <li>ARM B: Crizotinib 250mg BID</li> </ul>	<ul> <li>ARM A: Alecensa 600mg BID</li> <li>ARM B: Platinum-based chemotherapy</li> </ul>
Primary endpoint	Progression-free survival	Disease-free survival
Status	<ul> <li>Recruitment completed Q3 2015</li> <li>Primary endpoint met Q1 2017</li> <li>Data presented at ASCO 2017, 2018, ESMO 2017, 2018</li> <li>Data published in NEJM 2017; 377:829-838</li> <li>CNS data presented at ESMO 2017</li> <li>Final PFS and updated OS presented at ESMO 2019</li> <li>Approved in US Q4 2017 (priority review) and in EU Q4 2017</li> </ul>	<ul> <li>FPI Q3 2018</li> <li>Recruitment completed Q4 2021</li> </ul>
CT Identifier	NCT02075840	NCT03456076

## Kadcyla

# Roche

## First ADC for HER2-positive breast cancer

Indication	HER2-positive early breast cancer (BC) high-risk patients	2L+ HER-2 positive PD-L1 positive metastatic breast cancer (mBC)	HER2-positive early breast cancer (BC) high-risk patients
Phase/study	Phase III KATHERINE	Phase III KATE 3	Phase III ASTEFANIA
# of patients	N=1,484	N=320	N=1700
Design	<ul><li>ARM A: Kadcyla 3.6mg/kg q3w</li><li>ARM B: Herceptin</li></ul>	<ul> <li>ARM A: Kadcyla plus Tecentriq</li> <li>ARM B: Herceptin plus placebo</li> </ul>	<ul> <li>ARM A: Kadcyla plus Tecentriq</li> <li>ARM B: Kadcyla plus placebo</li> </ul>
Primary endpoint	<ul> <li>Invasive disease-free survival</li> </ul>	■ Progression-free survival and overall survival	<ul> <li>Invasive disease-free survival</li> </ul>
Status	<ul> <li>Recruitment completed Q4 2015</li> <li>Stopped at pre-planned interim data analysis for efficacy Q4 2018</li> <li>Data presented at SABCS 2018</li> <li>BTD granted by FDA in Q1 2019</li> <li>US filling completed under RTOR Q1 2019 and filed in EU Q1 2019</li> <li>Approved in US Q2 2019 and in EU Q4 2019</li> <li>Data published in NEJM 2019; 380:617-628</li> </ul>	• FPI Q1 2021	• FPI Q2 2021
CT Identifier	NCT01772472	NCT04740918	NCT04873362

In collaboration with ImmunoGen, Inc.

## Perjeta



#### First-in-class HER2 dimerization inhibitor

Indication	Adjuvant HER2-positive breast cancer (BC)
Phase/study	Phase III APHINITY
# of patients	N=4,803
Design	<ul> <li>ARM A: Perjeta (840mg loading dose, 420mg q3w) plus Herceptin for 52 weeks plus chemotherapy (6-8 cycles)</li> <li>ARM B: Placebo plus Herceptin (52 weeks) plus chemotherapy (6-8 cycles)</li> </ul>
Primary endpoint	■ Invasive disease-free survival (iDFS)
Status	<ul> <li>Primary endpoint met Q1 2017</li> <li>Data presented at ASCO 2017 and published in NEJM 2017; 377:122-131</li> <li>Filed in US and EU Q3 2017</li> <li>Approved in US Q4 2017 (priority review) and EU Q2 2018</li> <li>6-year iDFS data presented at SABCS 2019</li> <li>8-year iDFS data presented at ESMO virtual 2022</li> </ul>
CT Identifier	NCT01358877

## Phesgo

# Roche

#### FDC of Perjeta and Herceptin for subcutaneous administration

Indication	HER2-positive early breast cancer (BC)		HER2-positive breast cancer (BC)
Phase/study	Phase III FeDeriCa	Phase II PHranceSCa	Phase I <sup>1</sup>
# of patients	N=500	N=160	N=144
Design	FDC of Perjeta and Herceptin for SC administration (Phesgo) in combination with chemotherapy in neoadjuvant/adjuvant setting  • ARM A: Perjeta IV plus Herceptin IV plus chemotherapy  • ARM B: Phesgo plus chemotherapy	<ul> <li>ARM A: Perjeta and Herceptin IV followed by Phesgo</li> <li>ARM B: Phesgo followed by IV</li> </ul>	<ul> <li>Arm A: Phesgo administered using a handheld syringe with hypodermic needle (SC)</li> <li>ARM B: Phesgo administered using the onbody delivery system (OBI)</li> </ul>
Primary endpoint	<ul> <li>Trough Serum Concentration (Ctrough) of Perjeta during cycle 7</li> </ul>	<ul> <li>Percentage of patients who preferred Perjeta and Herceptin FDC SC</li> </ul>	<ul><li>AUC0-62*, Cmax**</li></ul>
Status	<ul> <li>Primary endpoint met Q3 2019</li> <li>Data presented at SABCS 2019</li> <li>Data published in Lancet Oncology 2021 Jan;22(1):85-97</li> </ul>	<ul> <li>FPI Q4 2018</li> <li>Final analysis completed, 85% patients preferred FDC SC</li> <li>Data presented at ESMO 2020</li> <li>Data published in <i>Eur J Cancer</i> 2021 Jul;152:223-232</li> </ul>	• FPI Q2 2022
	<ul> <li>Filed in US Dec 2019 &amp; in EU Jan 2020; Approved in US Q2 2020 and EU Q4 2020</li> </ul>		
CT Identifier	NCT03493854	NCT03674112	NCT05275010

<sup>&</sup>lt;sup>1</sup>In collaboration with West Pharmaceuticals

<sup>\*</sup>AUCO-62=comparability of area under the time-concentration curve from the start of dosing to 63 days; \*\*Cmax=maximum serum concentration for pertuzumab and trastuzumab within Phesgo; FDC=Fixed-dose combination;

Phesgo=FDC of Perjeta and Herceptin for SC administration; HER2=Human Epidermal growth factor Receptor 2, IV=intravenous; SC=Subcutaneous; ASCO=American Society of Clinical Onclogy; NEJM=New England Journal of Medcine; SABCS=San Antonio Breast Cancer Symposium; Eur J Cancer=European Journal of Cancer; ESMO=European Society for Medical Oncology



### Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	Adjuvant NSCLC	Neoadjuvant NSCLC
Phase/study	Phase III IMpower010	Phase III IMpower030
# of patients	N=1,280	N=450
Design	Following adjuvant cisplatin-based chemotherapy  • ARM A: Tecentriq  • ARM B: Best supportive care	<ul> <li>ARM A: Tecentriq plus platinum-based chemotherapy</li> <li>ARM B: Platinum-based chemotherapy</li> </ul>
Primary endpoint	Disease-free survival	Event-free survival
Status	<ul> <li>Trial amended from PD-L1+ selected patients to all-comers</li> <li>FPI for all-comer population Q4 2016</li> <li>Recruitment completed Q3 2018</li> <li>Study met primary endpoint Q1 2021</li> <li>Data presented at ASCO, WCLC and ESMO 2021</li> <li>Filed in US (priority review) and EU Q2 2021</li> <li>Approved in US Q4 2021 and EU Q2 2022</li> </ul>	<ul> <li>FPI Q2 2018</li> <li>Recruitment completed Q3 2021</li> </ul>
CT Identifier	NCT02486718	NCT03456063



### Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L maintenance extensive-stage SCLC	2L NSCLC previously treated with an immune checkpoint inhibitor
Phase/study	Phase III IMforte <sup>1</sup>	Phase III CONTACT-01
# of patients	N=450	N=366
Design	<ul> <li>ARM A: Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin</li> <li>ARM B: Platinum-etoposide + Tecentriq followed by maintenance Tecentriq</li> </ul>	<ul> <li>ARM A: Tecentriq plus cabozantinib</li> <li>ARM B: Docetaxel</li> </ul>
Primary endpoint	Progression-free survival and overall survival	Overall survival
Status	• FPI Q4 2021	<ul> <li>FPI Q3 2020</li> <li>Recruitment completed Q4 2021</li> </ul>
CT Identifier	NCT05091567	NCT04471428



### Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L NSCLC	Stage IV NSCLC
Phase/study	Phase II/III B-FAST	Phase lb/III IMscin001 <sup>1</sup>
# of patients	Modular design	N=371
Design	<ul> <li>Cohort A: ALK+ (Alecensa)</li> <li>Cohort B: RET+ (Alecensa)</li> <li>Cohort C: bTMB-high (Tecentriq)</li> <li>Cohort D: ROS1+ (Rozlytrek)</li> <li>Cohort E: BRAF+ (Zelboraf plus Cotellic plus Tecentriq)</li> <li>Cohort F: EGFR Exon 20+ (Tecentriq, Avastin, carboplatin, pemetrexed)</li> <li>Cohort G: GDC-6036 or Docetaxel</li> </ul>	<ul> <li>Phase Ib</li> <li>Dose finding, Tecentriq SC followed by Tecentriq IV</li> <li>Phase III</li> <li>2L NSCLC non inferiority of Tecentriq SC vs Tecentriq IV</li> </ul>
Primary endpoint	<ul> <li>Cohort A/B/D: Objective response rate</li> <li>Cohort C/D: Progression-free survival</li> <li>Cohort E: Time in response</li> <li>Cohort F: Investigator-assessed objective response rate</li> </ul>	Observed concentration of Tecentriq in serum at cycle 1
Status	<ul> <li>FPI Q3 2017</li> <li>Recruitment completed for cohort A Q3 2018 and cohort C Q3 2019</li> <li>Cohort A: primary endpoint met Q3 2019; approved in US Q1 2021</li> <li>Cohort C: did not show statistical significance for primary endpoint, data presented at ESMO 2021</li> <li>Cohort F: FPI Q2 2021</li> </ul>	<ul> <li>FPI Q4 2018</li> <li>FPI in phase III part Q4 2020</li> <li>Recruitment completed Q1 2022</li> </ul>
CT Identifier	NCT03178552	NCT03735121

<sup>&</sup>lt;sup>1</sup>SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase



### Anti-PD-L1 cancer immunotherapy – SCCHN and melanoma

Indication	Adjuvant squamous cell carcinoma of the head and neck (SCCHN)
Phase/study	Phase III IMvoke010
# of patients	N=406
Design	- ARM A: Tecentriq 1200mg q3w - ARM B: Placebo
Primary endpoint	Event-free survival and overall survival
Status	<ul> <li>FPI Q1 2018</li> <li>Recruitment completed Q1 2020</li> </ul>
CT Identifier	NCT03452137



### Anti-PD-L1 cancer immunotherapy – urothelial carcinoma

Indication	1L metastatic urothelial carcinoma (UC)	High-risk non-muscle-invasive bladder cancer (MIBC)	ctDNA+, high-risk muscle-invasive bladder cancer (MIBC)
Phase/study	Phase III IMvigor130	Phase III ALBAN	Phase III IMvigor011
# of patients	N=1,200	N=516	N=495
Design	<ul> <li>ARM A: Tecentriq plus gemcitabine and carboplatin or cisplatin</li> <li>ARM B: Tecentriq monotherapy</li> <li>ARM C: Placebo plus gemcitabine and carboplatin or cisplatin</li> </ul>	<ul> <li>ARM A: BCG induction and maintenance</li> <li>ARM B: Tecentriq plus BCG induction and maintenance</li> </ul>	<ul> <li>ARM A: Tecentriq monotherapy</li> <li>ARM B: Placebo</li> </ul>
Primary endpoint	<ul> <li>Progression-free survival, overall survival and safety</li> </ul>	Recurrence-free survival	<ul> <li>Recurrence-free survival</li> </ul>
Status	<ul> <li>FPI Q3 2016</li> <li>FPI for arm B (amended study) Q1 2017</li> <li>Recruitment completed Q3 2018</li> <li>Study met co-primary endpoint of PFS Q3 2019</li> <li>Data presented at ESMO 2019 and AACR 2021</li> <li>Data published in Lancet 2020 May 16;395(10236):1547-1557</li> </ul>	• FPI Q4 2018	■ FPI Q2 2021
CT Identifier	NCT02807636	NCT03799835	NCT04660344



## Anti-PD-L1 cancer immunotherapy – renal cell cancer

Indication	Adjuvant renal cell carcinoma (RCC)	Advanced renal cell carcinoma (RCC) after immune checkpoint inhibitor treatment
Phase/study	Phase III IMmotion010	Phase III Contact-03 <sup>1</sup>
# of patients	N=778	N=500
Design	<ul> <li>ARM A: Tecentriq monotherapy</li> <li>ARM B: Placebo</li> </ul>	<ul> <li>ARM A: Tecentriq plus cabozantinib</li> <li>ARM B: Cabozantinib</li> </ul>
Primary endpoint	<ul> <li>Investigator-assessed disease-free survival</li> </ul>	Progression-free survival and overall survival
Status	<ul> <li>FPI Q1 2017</li> <li>Recruitment completed Q1 2019</li> <li>Study did not meet its primary endpoint of DFS Q2 2022</li> </ul>	<ul> <li>FPI Q3 2020</li> <li>Recruitment completed Q4 2021</li> </ul>
CT Identifier	NCT03024996	NCT04338269



### Anti-PD-L1 cancer immunotherapy – hepatocellular carcinoma

Indication	1L hepatocellular carcinoma (HCC)	Adjuvant hepatocellular carcinoma (HCC)
Phase/study	Phase III IMbrave150	Phase III IMbrave050
# of patients	N=501	N=668
Design	ARM A: Tecentriq plus Avastin     ARM B: Sorafenib	ARM A: Tecentriq plus Avastin     ARM B: Active surveillance
Primary endpoint	Overall survival and progression free survival	Recurrence-free survival
Status	<ul> <li>FPI Q1 2018</li> <li>Recruitment completed Q1 2019</li> <li>Data presented at ESMO Asia 2019</li> <li>US filing completed under RTOR Q1 2020; filed in EU Q1 2020</li> <li>Data published in NEJM 2020;382:1894-1905</li> <li>Approved in US Q2 2020 and EU Q4 2020</li> </ul>	<ul> <li>FPI Q4 2019</li> <li>Recruitment completed Q4 2021</li> </ul>
CT Identifier	NCT03434379	NCT04102098



### Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Previously untreated metastatic triple negative breast cancer (TNBC)	
Phase/study	Phase III IMpassion130	Phase III IMpassion132
# of patients	N=902	N=572
Design	<ul> <li>ARM A: Tecentriq plus nab-paclitaxel</li> <li>ARM B: Placebo plus nab-paclitaxel</li> </ul>	<ul> <li>ARM A: Tecentriq plus capecitabine or carbo/gem</li> <li>ARM B: Placebo plus capecitabine or carbo/gem</li> </ul>
Primary endpoint	<ul> <li>Progression-free survival and overall survival (co-primary endpoint)</li> </ul>	Overall survival
Status	<ul> <li>Study met co-primary endpoint of PFS in both PD-L1+ and ITT populations Q3 2018</li> <li>Primary PFS and interim OS data presented at ESMO 2018 and ASCO 2019</li> <li>Data published in NEJM 2018; 379:2108-2121</li> <li>US accelerated approval Q1 2019 – US indication voluntarily withdrawn Q3 2021</li> <li>Approved in EU Q3 2019</li> <li>Final OS presented at ESMO Asia 2020</li> </ul>	• FPI Q1 2018
CT Identifier	NCT02425891	NCT03371017

# Roche

### Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Neoadjuvant triple negative breast cancer (TNBC)	Adjuvant triple negative breast cancer (TNBC)
Phase/study	Phase III IMpassion031	Phase III IMpassion030
# of patients	N=333	N=2,300
Design	<ul> <li>ARM A: Tecentriq plus nab-paclitaxel</li> <li>ARM B: Placebo plus nab-paclitaxel</li> </ul>	<ul> <li>ARM A: Tecentriq plus paclitaxel followed by AC followed by Tecentriq plus AC, followed by Tecentriq maintenance</li> <li>ARM B: Placebo plus paclitaxel followed by AC followed by placebo</li> </ul>
Primary endpoint	<ul> <li>Percentage of participants with pathologic complete response</li> </ul>	<ul> <li>Invasive disease-free survival</li> </ul>
Status	<ul> <li>FPI Q3 2017</li> <li>Recruitment completed Q2 2018</li> <li>Study met primary endpoint Q2 2020</li> <li>Data presented at ESMO 2020</li> <li>Data published in Lancet 2020;396 (10257):1090-1100</li> <li>Filed in EU Q4 2020 - application withdrawn Q3 2021</li> </ul>	• FPI Q3 2018
CT Identifier	NCT03197935	NCT03498716

#### **Venclexta**



### Novel small molecule Bcl-2 selective inhibitor – chronic lymphocytic leukemia

Indication	Untreated chronic lymphocytic leukemia (CLL) patients with coexisting medical conditions	Relapsed or refractory chronic lymphocytic leukemia (CLL)	Untreated fit chronic lymphocytic leukemia (CLL) patients
Phase/study	Phase III CLL14	Phase III MURANO	Phase III CristaLLo
# of patients	N=445	N=389	N=165
Design	<ul> <li>ARM A: Venclexta plus Gazyva</li> <li>ARM B: Chlorambucil plus Gazyva</li> </ul>	<ul> <li>ARM A: Venclexta plus Rituxan</li> <li>ARM B: Rituxan plus bendamustine</li> </ul>	<ul> <li>ARM A: Venclexta plus Gazyva</li> <li>ARM B: Fludarabine plus cyclophosphamide plus Rituxan or bendamustine plus Rituxan</li> </ul>
Primary endpoint	<ul> <li>Progression-free survival</li> </ul>	Progression-free survival	<ul> <li>MRD negativity rate in peripheral blood at 15 months</li> </ul>
Status	<ul> <li>Study met primary endpoint at pre-specified interim analysis Q4 2018</li> <li>BTD granted by FDA Q1 2019</li> <li>US filing completed under RTOR Q1 2019</li> <li>Filed in EU Q2 2019</li> <li>Data presented at ASCO 2019, ASH 2019, ASH 2020 and EHA 2021 and EHA 2022</li> <li>Data published in NEJM 2019; 380:2225-2236</li> <li>Approved US Q2 2019 and EU Q1 2020</li> </ul>	<ul> <li>Study met primary endpoint at interim analysis</li> <li>Data presented at ASH 2017</li> <li>Filed in US Q4 2017 and EU Q1 2018</li> <li>Data published in NEJM 2018; 378:1107-20</li> <li>Updated data presented at ASCO 2018, ASH 2019 and ASH 2020</li> <li>Approved in US Q2 2018 (priority review)</li> <li>EU approval Q4 2018</li> </ul>	• FPI Q2 2020
CT Identifier	NCT02242942	NCT02005471	NCT04285567

#### **Venclexta**



#### Novel small molecule Bcl-2 selective inhibitor – multiple myeloma

Indication	Relapsed or refractory multiple myeloma (MM)		
Phase/study	Phase I	Phase lb/II	Phase III CANOVA
# of patients	N=117	N=120	N=244
Design	<ul> <li>Dose escalation cohort:</li> <li>Venclexta dose escalation</li> <li>Safety expansion cohort (t11;14):</li> <li>Venclexta expansion</li> <li>Combination:</li> <li>Venclexta plus dexamethasone</li> </ul>	<ul> <li>Venclexta plus carfilzomib plus dexamethasone in t(11;14) positive r/r MM</li> </ul>	<ul> <li>Venclexta plus dexamethazone vs pomalidomide plus dexamethasone in t(11;14) positive r/r MM</li> </ul>
Primary endpoint	<ul> <li>Safety and maximum tolerated dose</li> </ul>	<ul> <li>Safety, objective response rate,</li> <li>Pharmacokinetics, Pharmacodynamics</li> </ul>	Progression-free survival
Status	<ul> <li>FPI Q4 2012</li> <li>Data presented at ASCO 2015</li> <li>Updated data presented at ASCO 2016 and ASH 2016</li> <li>Data published in Blood 2017; 130(22):2401-2409 and Am J Hematol 2021 Apr 1;96(4):418-427</li> </ul>	<ul> <li>FPI Q1 2017</li> <li>Data published Blood Adv 2021 Oct 12;5(19):3748-3759</li> </ul>	• FPI Q4 2018
CT Identifier	NCT01794520	NCT02899052	NCT03539744

#### **Venclexta**



#### Novel small molecule Bcl-2 selective inhibitor – myelodysplastic syndromes

Indication	Relapsed or refractory myelodysplastic syndromes (MDS)	Treatment-naive myelodysplastic syndromes (MDS)	Newly diagnosed higher-risk myelodysplatic syndrome (MDS)
Phase/study	Phase Ib	Phase Ib	Phase III VERONA
# of patients	N=70	N=129	N=500
Design	Cohort 1:  • ARM A: Venclexta 400 mg  • ARM B: Venclexta 800 mg  Cohort 2:  • ARM A: Venclexta plus azacitidine  Study expansion:  • Venclexta or Venclexta plus azacitidine	<ul> <li>Dose escalation cohort:</li> <li>Venclexta plus azacitidine dose escalation</li> <li>Safety expansion cohort</li> </ul>	<ul> <li>ARM A: Venclexta plus azacitidine</li> <li>ARM B: Placebo plus azacitidine</li> </ul>
Primary endpoint	<ul> <li>Safety, efficacy, Pharmacokinetics and Pharmacodynamics</li> </ul>	<ul> <li>Safety, Pharmacokinetics, RPTD</li> </ul>	Complete remission rate and overall survival
Status	<ul> <li>FPI Q1 2017</li> <li>Recruitment completed Q1 2022</li> </ul>	<ul> <li>FPI Q1 2017</li> <li>Data presented at ASH 2019, ASH 2020 and ASCO 201</li> <li>BTD granted by FDA July 2021</li> <li>Recruitment completed Q1 2022</li> </ul>	■ FPI Q4 2020
CT Identifier	NCT02966782	NCT02942290	NCT04401748

## Polivy (polatuzumab vedotin)



### ADC targeting CD79b to treat B cell malignancies

Indication	1L DLBCL
Phase/study	Phase III POLARIX
# of patients	N=879
Design	- ARM A: Polivy plus R-CHP - ARM B: R-CHOP
Primary endpoint	Progression-free survival
Status	<ul> <li>FPI Q4 2017</li> <li>Recruitment completed Q2 2019</li> <li>Study met primary endpoint Q3 2021</li> <li>Data presented at ASH 2021</li> <li>Filed in EU, Japan and China Q4 2021</li> <li>Published in NEJM 2022 Jan 27;386(4):351-363</li> <li>Approved in EU Q2 2022</li> </ul>
CT Identifier	NCT03274492

## Rozlytrek (entrectinib)



#### CNS-active and selective inhibitor of NTRK/ROS1

Indication	Locally advanced or metastatic tumors with ROS1 gene rearrangement	Locally advanced or metastatic tumors with NTRK1/2/3 gene rearrangement	Pediatric tumors with NTRK 1/2/3, ROS-1 or ALK rearrangement
Phase/study	Phase II STARTRK2	Phase II STARTRK2	Phase I/Ib STARTRK - NG
# of patients	N~300 total	N~300 total	N~80
Design	Single arm with Baskets based on tumor type and genomic alteration status	Single arm with Baskets based on tumor type and genomic alteration status	Single arm with Baskets based on tumor type and genomic alteration status
Primary endpoint	Objective response rate	Objective response rate	<ul> <li>Maximum tolerated dose and RPTD</li> </ul>
	<ul><li>FPI Q1 2016</li><li>Data presented at WCLC 2018</li></ul>	<ul><li>FPI Q1 2016</li><li>Data presented at ESMO 2018</li></ul>	<ul> <li>FPI Q2 2016</li> <li>Initial data presented at ASCO 2019</li> </ul>
Status	<ul> <li>Breakthrough Therapy Designation granted by FDA (Q2 2017), PRIME designation granted by EMA (Q1 2018) and Sakigake Designation granted by MHL (Q4 2017) for NTRK fusion-positive, locally advanced or metastatic solid tumors</li> <li>Filed in US Q4 2018 and EU Q1 2019</li> <li>Approved in US Q3 2019 and EU Q3 2020</li> <li>Published in Lancet Oncol. 2020 Feb;21(2):261-271 and 271-282</li> </ul>		
CT Identifier	NCT02568267	NCT02568267	NCT02650401

## Gavreto (pralsetinib, RG6396)

# Roche

### Highly selective RET inhibitor

Indication	RET+ NSCLC, thyroid cancer and other advanced solid tumors	1L RET fusion-positive, metastatic NSCLC
Phase/study	Phase I/II ARROW	Phase III AcceleRET Lung
# of patients	N=647	N=250
Design	<ul> <li>Part 1: Gavreto 30-600mg dose escalation</li> <li>Part 2: Gavreto 400mg dose expansion</li> </ul>	<ul> <li>Arm A: Gavreto 400mg</li> <li>Arm B: Platinum-based chemotherapy +/- pembrolizumab</li> </ul>
Primary endpoint	Safety and efficacy	Progression-free survival
Status	<ul> <li>Data presented at ASCO (NSCLC) and ESMO (MTC) 2020</li> <li>Filed in US and EU for RET fusion-positive NSCLC and US for RET-mutant MTC and RET fusion-positive thyroid cancer</li> <li>Approved in US Q3 2020 in RET fusion-positive NSCLC, in Q4 2020 in RET-mutant MTC and RET fusion-positive thyroid cancer</li> <li>Updated data presented at ASCO 2021 and 2022</li> <li>Data published in Lancet Oncol 2021 Jul;22(7):959-969 and Lancet Diabetes &amp; Endocrinology Aug 2021;9(8):491-501</li> <li>Approved in EU for RET fusion-positive NSCLC Q4 2021</li> </ul>	Study initiated in Q1 2020
CT Identifier	NCT03037385	NCT04222972



Indication	3L+ FL, 3L+ DLBCL & other relapsed or refractory NHL	1L DLBCL	Relapsed or refractory DLBCL
Phase/study	Phase I/II	Phase lb/II	Phase Ib
# of patients	N=746	N=160	N=262
Design	<ul> <li>Dose escalation study of Lunsumio as single agent and in combination with Tecentriq</li> <li>Expansion cohorts for r/r FL, r/r DLBCL and SC in r/r NHL</li> </ul>	<ul> <li>Lunsumio plus CHOP</li> <li>Lunsumio plus CHP plus Polivy</li> <li>Lunsumio plus CHP-Polivy vs Rituximab plus CHP-Polivy</li> </ul>	<ul> <li>Lunsumio plus Polivy, randomised cohorts</li> <li>ARM A: Lunsumio SC plus Polivy</li> <li>ARM B: Rituximab plus Polivy</li> </ul>
Primary endpoint	<ul> <li>Safety, tolerability, dose/schedule, PK and response rates</li> </ul>	<ul><li>Safety/tolerability and response</li></ul>	<ul> <li>Safety/tolerability and response</li> </ul>
Status	<ul> <li>Data in r/r NHL presented at ASH 2018 and 2019, and in r/r FL at ASH 2020 and ASH 2021</li> <li>BTD granted by FDA Q2 2020</li> <li>SC cohort FPI Q2 2021</li> <li>Filed in EU and rolling submission submitted in US Q4 2021</li> <li>Approved in EU Q2 2022</li> <li>Filed in US (priority review) Q2 2022</li> </ul>	<ul> <li>FPI Q1 2019</li> <li>Data for Lunsumio plus CHOP presented at ASH 2020</li> </ul>	<ul> <li>FPI Q3 2018</li> <li>Initial data presented at ASCO and ASH 2021</li> </ul>
CT Identifier	NCT02500407	NCT03677141	NCT03671018



Indication	1L DLBCL & 2L DLBCL following 1L induction	Relapsed or refractory 2L+ FL
Phase/study	Phase I	Phase Ib
# of patients	N=92 + 80 (cohort C)	N=27
Design	<ul> <li>Cohort A: Lunsumio monotherapy (after a response to prior systemic chemotherapy)</li> <li>Cohort B: Lunsumio monotherapy (1L treatment in elderly/frail)</li> <li>Cohort C: Lunsumio SC plus Polivy in 1L elderly/unfit</li> </ul>	<ul> <li>Lunsumio plus lenalidomide safety run-in for phase III</li> <li>Lunsumio SC plus lenalidomide</li> </ul>
Primary endpoint	Safety/tolerability and response	Safety/tolerability and response
Status	<ul> <li>FPI Q2 2019 – Cohort B</li> <li>FPI Q3 2019 – Cohort A</li> <li>Initial data presented at ASH 2020 (cohort B)</li> <li>Cohort C: FPI Q1 2021</li> </ul>	<ul> <li>FPI Q3 2020</li> <li>Initial data presented at ASH 2021</li> </ul>
CT Identifier	NCT03677154	NCT04246086



Indication	2L+FL	Relapsed or refractory FL	Relapsed or refractory CLL
Phase/study	Phase III CELESTIMO	Phase lb/II	Phase lb/II
# of patients	N=400	N=118	N=56
Design	ARM A: Lunsumio plus lenalidomide     ARM B: Rituxan plus lenalidomide	<ul> <li>ARM A: Lunsumio plus tiragolumab</li> <li>ARM B: Lunsumio plus tiragolumab plus Tecentriq</li> <li>Dose escalation phase</li> <li>Dose expansion phase</li> </ul>	• Lunsumio monotherapy (3L+ CLL)
Primary endpoint	<ul> <li>Progression-free survival</li> </ul>	<ul> <li>Phase Ib: Dose-limiting toxicity</li> <li>Phase II: Best complete response</li> </ul>	<ul> <li>Safety, dose-limiting toxicity and RPTD</li> </ul>
Status	• FPI Q4 2021	• FPI Phase Ib Q2 2022	• FPI Q1 2022
CT Identifier	NCT04712097	NCT05315713	



Indication	2L+ SCT ineligible DLBCL
Phase/study	Phase III SUNMO
# of patients	N=222
Design	- ARM A: Lunsumio plus Polivy - ARM B: R + GemOx
Primary endpoint	Progression-free survival
Status	• FPI Q2 2022
CT Identifier	NCT05171647

## Ocrevus (ocrelizumab, RG1594)



### Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Relapsing multiple sclerosis (RMS)		Primary progressive multiple sclerosis (PPMS)		
Phase/study	Phase III OPERA I	Phase III OPERA II	Phase III ORATORIO		
# of patients	N=821	N=835	N=732		
Design	<ul> <li>96-week treatment period:</li> <li>ARM A: Ocrevus 2x300mg IV followed by 600mg IV every 24 weeks</li> <li>ARM B: Interferon β-1a (Rebif)</li> </ul>	<ul> <li>96-week treatment period:</li> <li>ARM A: Ocrevus 2x300mg IV followed by 600mg IV every 24 weeks</li> <li>ARM B: Interferon β-1a (Rebif)</li> </ul>	120-week treatment period:  • ARM A: Ocrevus 2x300mg IV every 24 weeks  • ARM B: Placebo		
Primary endpoint	<ul> <li>Annualized relapse rate at 96 weeks versus Rebif</li> </ul>	<ul> <li>Annualized relapse rate at 96 weeks versus Rebif</li> </ul>	<ul> <li>Sustained disability progression versus placebo by EDSS</li> </ul>		
Status	<ul> <li>Primary endpoint met Q2 2015, OLE ongoing</li> <li>Primary data presented at ECTRIMS 2015</li> <li>Updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018</li> <li>Data published in NEJM 2017; 376:221-234</li> <li>Data published on COVID-19 in Mult Scler Relat Disord on Ocrevus treated people with MS, doi.org/10.1016/j.msard.2020.102725</li> </ul>		<ul> <li>Primary endpoint met Q3 2015</li> <li>Primary data presented at ECTRIMS 2015, updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018</li> <li>Data published in NEJM 2017; 376:209-220</li> </ul>		
	<ul> <li>Approved in US Q1 2017 and EU Q1 2018</li> </ul>				
CT Identifier	NCT01247324	NCT01412333	NCT01194570		

## Ocrevus (ocrelizumab, RG1594)



### Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Relapsing and primary progressive multiple sclerosis (RMS & PPMS)	Primary progressive multiple sclerosis (PPMS)
Phase/study	Phase IIIb ENSEMBLE PLUS	Phase IIIb ORATORIO-HAND
# of patients	N=1,225	N ~ 1000
Design	<ul> <li>Substudy of ongoing phase IIIb, open-label, single-arm ENSEMBLE study</li> <li>Shorter two-hour infusion time</li> </ul>	120-week treatment period:  - ARM A: Ocrevus 600mg IV q24w  - ARM B: Placebo
Primary endpoint	<ul> <li>Safety, measured by the proportion of patients with IRRs following the first randomised 600 mg infusion (frequency/severity assessed during and 24- hours post infusion)</li> </ul>	Time to upper limb disability progression confirmed for at least 12 weeks
Status	<ul> <li>Filed in US and EU Q1 2020</li> <li>Approved in EU Q2 2020 and US Q4 2020</li> <li>Data published Neurol, Neuroimmunol and Neuroinflamm Sept 2020; 7(5), e807</li> </ul>	• FPI Q3 2019
CT Identifier	NCT03085810	NCT04035005

IV=intravenous; IRR=Infusion Related Reaction

## Ocrevus (ocrelizumab, RG1594)



### Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple sclerosis (RMS)	PPMS & RMS
Phase/study	Phase IIIb GAVOTTE	Phase IIIb MUSETTE	Phase III Ocarina II <sup>1</sup>
# of patients	N ~ 699	N ~ 786	N ~ 232
Design	<ul> <li>120-week treatment period:</li> <li>ARM A: Ocrevus 600mg IV every 24 weeks</li> <li>ARM B: Ocrevus 1200mg if body weight</li> <li>75kg or 1800mg if body weight &gt; or equal to</li> <li>75kg every 24 weeks</li> </ul>	<ul> <li>120-week treatment period:</li> <li>ARM A: Ocrevus 600mg IV every 24 weeks</li> <li>ARM B: Ocrevus 1200mg if body weight &lt;75kg or 1800mg if body weight &gt; or equal to 75kg every 24 weeks</li> </ul>	- ARM A: Ocrevus IV - ARM B: Ocrevus SC
Primary endpoint	<ul> <li>Superiority of Ocrevus higher dose versus approved dose on cCDP</li> </ul>	<ul> <li>Superiority of Ocrevus higher dose versus approved dose on cCDP</li> </ul>	<ul> <li>Serum Ocrevus area under the concentration-time curve (AUCW1-12) at week 12</li> </ul>
Status	• FPI Q4 2020	<ul> <li>FPI Q4 2020</li> <li>Recruitment completed Q4 2021</li> </ul>	• FPI Q2 2022
CT Identifier	NCT04548999	NCT04544436	NCT05232825

# Evrysdi (risdiplam, RG7916)

# Roche

#### Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)		
Phase/study	Phase II/III FIREFISH	Phase II/III SUNFISH	Phase II JEWELFISH
# of patients	N=21 (Part 1), 41 (Part 2)	N=51 (Part 1), 180 (Part 2)	N=174
Design	Open-label study in infants with type 1 SMA  • Part 1 (dose-finding): At least 4 weeks  • Part 2 (confirmatory): 24 months	Randomized, double-blind, placebo-controlled study in adult and pediatric patients with type 2 or type 3 SMA:  Part 1 (dose-finding): At least 12 weeks  Part 2 (confirmatory): 24 months	<ul> <li>Open-label single arm study in adult and pediatric patients with previously treated SMA type 1, 2 and 3</li> </ul>
Primary endpoint	<ul><li>Safety, tolerability, PK/PD and efficacy</li></ul>	<ul><li>Safety, tolerability, PK/PD and efficacy</li></ul>	Safety, tolerability, PK/PD
Status	<ul> <li>12-month data from Part 1 presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019</li> <li>Study met primary endpoint in part 2 Q1 2020</li> <li>Part 2 1-year data presented at AAN 2020, part 1 2-year data at WMS 2020</li> <li>Part 1 data published in NEJM 2021;384:915-923</li> <li>Part 2 2-year data presented at AAN 2021</li> <li>Part 2 1-year data published in NEJM 2021;385:427-435</li> <li>3-year data presented at EPNS 2022</li> </ul>	<ul> <li>Recruitment completed for part 2 Q3 2018</li> <li>12-month data from Part 1 presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019</li> <li>Study met primary endpoint in part 2 Q4 2019</li> <li>Part 2 1-year data presented at SMA Europe 2020, 2-year data at MDA 2021 and 3-year data at MDA 2022</li> <li>Part 2 data 1-year published in Lancet Neurology, Dec 2021</li> </ul>	<ul> <li>FPI Q1 2017</li> <li>Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, WMS 2019, CureSMA 2020 and 2021</li> <li>Recruitment completed Q1 2020</li> </ul>
	<ul> <li>Orphan drug designation granted by FDA Q1 2017 and EU Q1 2019, PRIME designation in Q4 2018</li> <li>Approved in US Q3 2020 and EU Q1 2021</li> </ul>		
CT Identifier	NCT02913482	NCT02908685	NCT03032172

# Evrysdi (risdiplam, RG7916)



#### Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)	
Phase/study	Phase II RAINBOWFISH	Phase II/III MANATEE
# of patients	N=25	N=180
Design	Open-label, single-arm, multicenter study in infants aged from birth to 6 weeks who have been genetically diagnosed with Spinal muscular atrophy but are not yet presenting with symptoms	ARM A:  Part 1: GYM329 plus Evrysdi for 24 weeks, followed by GYM329 plus Evrysdi for 72 weeks  Part 2: GYM329 plus Evrysdi for 72 weeks  ARM B:  Placebo plus Evrysdi comparator
Primary endpoint	<ul> <li>Proportion of participants with two copies of the SMN2 gene (excluding the known SMN2 gene modifier mutation c.859G&gt;C) and baseline CMAP&gt;=1.5 millivolt who are sitting without support</li> </ul>	<ul> <li>Change from baseline in revised hammersmith scale (RHS) score after week 72 of treatment</li> <li>Safety, PK/PD and muscle biomarkers</li> </ul>
Status	<ul> <li>FPI Q3 2019</li> <li>Recruitment completed Q1 2022</li> <li>Initial data presented at CureSMA, WMS 2021 and MDA 2022</li> <li>Filed in US and EU Q4 2021</li> <li>Approved in US Q2 2022</li> </ul>	<ul> <li>FPI Part 1 Q2 2022</li> <li>Orphan Drug Designation granted by FDA in Q4 2021 for GYM329</li> </ul>
CT Identifier	NCT03779334	NCT05115110

## Enspryng (satralizumab, RG6168, SA237)



#### Anti-IL-6 receptor humanized monoclonal antibody

Indication	Neuromyelitis optica spectrum disorder (NMOSD)	
Phase/study	Phase III SAkuraStar	Phase III SAkuraSky
# of patients	N=95	N=83
Design	Enspryng monotherapy: • ARM A: Enspryng 120mg SC monthly • ARM B: Placebo SC monthly	<ul> <li>Add-on therapy of Enspryng:</li> <li>ARM A: Enspryng 120mg SC monthly</li> <li>ARM B: Placebo SC monthly</li> <li>Both arms on top of baseline therapies: azathioprine, mycophenolate mofetil or oral corticosteroids</li> </ul>
Primary endpoint	•Efficacy (time to first relapse), safety and PK/PD	<ul> <li>Efficacy (time to first relapse), safety and PK/PD</li> </ul>
Status	<ul> <li>Primary endpoint met Q4 2018</li> <li>Data presented at ECTRIMS 2019</li> <li>Published in Lancet Neurology 2020; 19(5): 402-412</li> <li>BTD granted</li> </ul>	<ul> <li>FPI Q3 2017</li> <li>Primary endpoint met Q3 2018</li> <li>Data presented at ECTRIMS 2018 and AAN 2019</li> <li>Published in NEJM 2019; 381:2114-2124</li> <li>by FDA Q4 2018</li> </ul>
	Filed in EU Q3 2019; US acceptance of filing Q4 2019 Approved in US Q3 2020 and EU Q2 2021	
CT Identifier	NCT02073279	NCT02028884

<sup>\*</sup>Trials managed by Chugai (Roche opted-in)

# Enspryng (satralizumab, RG6168, SA237)



#### Anti-IL-6 receptor humanized monoclonal antibody

Indication	Generalised myasthenia gravis (MG)	Myelin oligodendrocyte glycoprotein antibody disease (MOGAD)
Phase/study	Phase III Luminesce	Phase III METEOROID
# of patients	N=240	N=152
Design	ARM A: Enspryng plus standard of care     ARM B: Placebo plus standard of care	•ARM A: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses q4w •ARM B: Placebo
Primary endpoint	<ul> <li>Mean change from baseline in total MG-ADL score at week 24 in AChR+ population</li> </ul>	Time from randomization to the first occurrence of a MOGAD relapse
Status	<ul> <li>Orphan Drug Designation granted in US Q1 2021</li> <li>FPI Q4 2021</li> </ul>	<ul> <li>FPI expected Q3 2022</li> <li>Orphan Drug Designation granted by FDA in Q4 2021</li> </ul>
CT Identifier	NCT04963270	NCT05271409

# Gazyva (obinutuzumab)

# Roche

#### Immunology development program

Indication	Lupus nephritis		Membranous nephropathy
Phase/study	Phase II NOBILITY	Phase III REGENCY	Phase III MAJESTY
# of patients	N=126	N=252	N=140
Design	<ul> <li>ARM A: Gazyva 1000mg IV plus mycophenolate mofetil / mycophenolic acid</li> <li>ARM B: Placebo IV plus mycophenolate mofetil / mycophenolic acid</li> </ul>	<ul> <li>ARM A: Gazyva 1000mg IV (6 doses through Week 52) plus mycophenolate mofetil</li> <li>ARM B: Gazyva 1000 mg IV (5 doses through Week 52) plus mycophenolate mofetil</li> <li>ARM C: Placebo IV plus mycophenolate mofetil</li> </ul>	<ul> <li>ARM A: Gazyva 1000mg IV dosed at baseline and weeks 0, 2, 24, and 26 on top of reninangiotensin inhibitors</li> <li>ARM B: Tacrolimus treatment for 12 months</li> </ul>
Primary endpoint	<ul> <li>Percentage of participants who achieve complete renal response (CRR)</li> </ul>	<ul> <li>Percentage of participants who achieve complete renal response (CRR)</li> </ul>	<ul> <li>Percentage of patients who achieve complete remission at week 104</li> </ul>
Status	<ul> <li>Recruitment completed Q4 2017</li> <li>Primary endpoint met Q2 2019</li> <li>BTD granted by the FDA Q3 2019</li> <li>Data presented at ASN and ACR 2019</li> <li>Published in <i>Ann Rheum Dis</i> 2022 Jan;81(1):100-107</li> </ul>	• FPI Q3 2020	• FPI Q2 2021
CT Identifier	NCT02550652	NCT04221477	NCT04629248

# Gazyva (obinutuzumab)



### Immunology development program

Indication	Systemic lupus erythematosus (SLE)
Phase/study	Phase III ALLEGORY
# of patients	N=200
Design	<ul> <li>ARM A: Gazyva 1000mg IV on Day 1 and Weeks 2, 24 and 26.</li> <li>ARM B: Placebo IV</li> </ul>
Primary endpoint	• Percentage of participants who achieve Systemic Lupus Erythematosus Responder Index (SRI) at week 52
Status	• FPI Q4 2021
CT Identifier	NCT04963296

## Actemra/RoActemra (tocilizumab, RG-1569)



#### Interleukin 6 receptor inhibitor

Indication	Adult hospitalised with severe COVID-19 pneumonia	
Phase/study	Phase III COVACTA <sup>1</sup>	Phase III REMDACTA <sup>2</sup>
# of patients	N=450	N=650
Design	ARM A: Actemra plus standard of care     ARM B: Placebo plus standard of care	<ul> <li>ARM A: Remdesivir plus Actemra</li> <li>ARM B: Remdesivir plus placebo</li> </ul>
Primary endpoint	<ul> <li>Clinical status assessed using 7-Category Ordinal Scale (Day 28)</li> </ul>	<ul> <li>Time to hospital discharge or ready for discharge</li> </ul>
Status		<ul> <li>FPI Q2 2020</li> <li>Recruitment completed Q1 2021</li> <li>Primary endpoint not met Q1 2021</li> <li>Published in <i>Intensive Care Med</i> 2021 doi: 10.1007/s00134-021-06507-x</li> <li>EU Q3 2021</li> <li>In EU Q4 2021</li> </ul>
CT Identifier	NCT04320615	NCT04409262

# Actemra/RoActemra (tocilizumab, RG-1569)



#### Interleukin 6 receptor inhibitor

Indication	Adult hospitalised with severe COVID-19 pneumonia	
Phase/study	Phase II MARIPOSA	Phase III EMPACTA
# of patients	N=100	N=379
Design	<ul> <li>ARM A: 8 mg/kg Actemra plus standard of care</li> <li>ARM B: 4mg/kg Actemra plus standard of care</li> </ul>	Conducted in sites known to provide critical care to underserved and minority populations that often do not have access to clinical trials  • ARM A: Actemra plus standard of care  • ARM B: Placebo plus standard of care
Primary endpoint	Pharmacodynamics and pharmacokinetics	<ul> <li>Cumulative proportion of participants requiring mechanical ventilation by day 28</li> </ul>
Status		<ul> <li>FPI Q2 2020</li> <li>Primary endpoint met Q3 2020</li> <li>Published in NEJM 2021 Jan 7;384(1):20-30</li> <li>EU Q3 2021</li> <li>in EU Q4 2021</li> </ul>
CT Identifier	NCT04363736	NCT04372186

NEJM=New England Journal of Medicine

#### Xolair



#### Humanized monoclonal antibody that selectively binds to IgE

Indication	Food allergy	
Phase/study	Phase III OUtMATCH <sup>1</sup>	
# of patients	N=225	
Design	• Xolair by SC injection either q2w or q4w for 16 to 20 weeks	
Primary endpoint	• Number of participants who successfully consume ≥600mg of peanut protein without dose-limiting symptoms	
Status	• FPI Q3 2019	
CT Identifier	NCT03881696	

## Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)



#### Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Systemic lupus erythematosus (SLE)
Phase/study	Phase I
# of patients	N=50
Design	<ul> <li>ARM A: Lunsumio SC on either Day 1 or on Days 1 and 8</li> <li>ARM B: Fractionated (divided) dose of Lunsumio SC on Days 1 and 8</li> </ul>
Primary endpoint	- Safety
Status	• FPI January 2022
CT Identifier	NCT05155345

SC=subcutaneous

## Susvimo (PDS)



#### First eye implant to achieve sustained delivery of a biologic medicine

Indication	Wet age-related macular degeneration (wAMD)		
Phase/study	Phase III Archway	Phase II+III extension Portal	Phase IIIb Velodrome
# of patients	N=418	N=1,000	N=442
Design	<ul> <li>ARM A: Port delivery system with ranibizumab q24w</li> <li>ARM B: Intravitreal ranibizumab q4w</li> </ul>	<ul> <li>Patients from LADDER or Archway will receive refills of 100mg/mL ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)</li> </ul>	<ul> <li>ARM A: Port delivery system with ranibizumab q36w</li> <li>ARM B: Port delivery system with ranibizumab q24w</li> </ul>
Primary endpoint	<ul> <li>Change in BCVA from baseline at the average of week 36 and week 40</li> </ul>	<ul> <li>Safety and long term efficacy</li> </ul>	<ul> <li>Change in BCVA from baseline averaged over weeks 68 and 72</li> </ul>
Status	<ul> <li>FPI Q3 2018</li> <li>Recruitment completed Q2 2019</li> <li>Study met primary endpoint Q2 2020</li> <li>Primary endpoint data presented at ASRS 2020, 44/48 week data at Angiogenesis 2021 and 2-year data at Angiogenesis 2022</li> <li>Filed in US (PRIME) and EU Q2 2021</li> <li>Approved in US Q4 2021</li> </ul>	• FPI Q3 2018	• FPI Q3 2021
CT Identifier	NCT03677934	NCT03683251	NCT04657289

## Susvimo (PDS)



#### First eye implant to achieve sustained delivery of a biologic medicine

Indication	Diabetic macular edema (DME)	Diabetic retinopathy (DR) without center-involved diabetic macular edema (DME)
Phase/study	Phase III Pagoda	Phase III Pavilion
# of patients	N=545	N=160
Design	ARM A: Port delivery system with ranibizumab q24w     ARM B: Intravitreal ranibizumab q4w	<ul> <li>Arm A: Intravitreal ranibizumab (X2) followed by PDS implant (refill q36w)</li> <li>Arm B: Q4w comprehensive clinical monitoring until participants receive PDS (refill q36w)</li> </ul>
Primary endpoint	<ul> <li>Change in BCVA from baseline at the average of week 48 and week 52</li> </ul>	<ul> <li>Percentage of participants with a ≥2-step improvement from baseline on the ETDRS-DRSS at Week 52</li> </ul>
Status	<ul> <li>FPI Q3 2019</li> <li>Recruitment completed Q2 2021</li> </ul>	<ul> <li>FPI Q3 2020</li> <li>Recruitment completed Q3 2021</li> </ul>
CT Identifier	NCT04108156	NCT04503551

# Vabysmo (faricimab)

# Roche

#### Bispecific antibody to simultaneously bind Ang-2 and VEGF-A

Indication	Center-involving diabetic macular edema (CI-DME)		
Phase/study	Phase III YOSEMITE		Phase III RHINE
# of patients	N=940		N=951
Design	<ul> <li>ARM A: Faricimab q8w</li> <li>ARM B: Faricimab PTI up to q16w</li> <li>ARM C: Aflibercept, q8w</li> </ul>		<ul> <li>ARM A: Faricimab q8w</li> <li>ARM B: Faricimab PTI up to q16w</li> <li>ARM C: Aflibercept, q8w</li> </ul>
Primary endpoint	<ul> <li>Change from baseline in BCVA at 1 year</li> </ul>		<ul> <li>Change from baseline in BCVA at 1 year</li> </ul>
Status	<ul> <li>FPI Q3 2018</li> <li>Recruitment completed Q3 2019</li> <li>Study met primary endpoint Q4 2020</li> <li>Data presented at Angiogenesis 2021</li> </ul>		<ul> <li>FPI Q4 2018</li> <li>Recruitment completed Q3 2019</li> <li>Study met primary endpoint Q4 2020</li> <li>Data presented at Angiogenesis 2021</li> </ul>
Status		<ul> <li>Filed in US and EU Q2 2021</li> <li>Published in the Lancet 2022 Feb 19;399(10326):741-755.</li> <li>2-year data presented at Angiogenesis 2022</li> <li>Approved in US Q1 2022</li> </ul>	
CT Identifier	NCT03622580		NCT03622593

# Vabysmo (faricimab)

# Roche

#### Bispecific antibody to simultaneously bind Ang-2 and VEGF-A

Indication	Wet age related macular degeneration (wAMD)	
Phase/study	Phase III TENAYA Phase III LUCERNE	
# of patients	N=671	N=658
Design	<ul> <li>ARM A: Faricimab 6.0mg q16w flexible after 4 IDs</li> <li>ARM B: Aflibercept 2.0mg q8w after 3 IDs</li> </ul>	<ul> <li>ARM A: Faricimab 6.0mg q16w flexible after 4 IDs</li> <li>ARM B: Aflibercept 2.0mg q8w after 3 IDs</li> </ul>
Primary endpoint	- Change from baseline in BCVA week 40, 44 & 48	<ul> <li>Change from baseline in BCVA week 40, 44 &amp; 48</li> </ul>
Status	<ul> <li>FPI Q1 2019</li> <li>Recruitment completed Q4 2019</li> <li>Study met primary endpoint Q1 2021</li> <li>Data presented at Angiogenesis 2021</li> </ul>	<ul> <li>FPI Q1 2019</li> <li>Recruitment completed Q4 2019</li> <li>Study met primary endpoint Q1 2021</li> <li>Data presented at Angiogenesis 2021</li> </ul>
Otatus	<ul> <li>Filed in US and EU Q2 2021</li> <li>Published in Lancet 2022 Feb 19;399(10326):729-740</li> <li>Approved in US Q1 2022</li> <li>2-year data presented at ASRS 2022</li> </ul>	
CT Identifier	NCT03823287	NCT03823300

# Vabysmo (faricimab)



#### Bispecific antibody to simultaneously bind Ang-2 and VEGF-A

Indication	Macular edema (ME) secondary to branch retinal vein occlusion (RVO)	Macular edema (ME) secondary to central retinal vein occlusion (RVO)
Phase/study	Phase III BALATON	Phase III COMINO
# of patients	N=570	N=750
Design	<ul> <li>ARM A: Faricimab, q4w/PTI</li> <li>ARM B: Aflibercept, q4w</li> </ul>	<ul> <li>ARM A: Faricimab, q4w/PTI</li> <li>ARM B: Aflibercept, q4w</li> </ul>
Primary endpoint	<ul> <li>Change from baseline in BCVA at week 24</li> </ul>	<ul> <li>Change from baseline in BCVA at week 24</li> </ul>
Status	<ul><li>FPI Q1 2021</li><li>Recruitment completed Q1 2022</li></ul>	<ul> <li>FPI Q1 2021</li> <li>Recruitment completed Q1 2022</li> </ul>
CT Identifier	NCT04740905	NCT04740931

# Xofluza (baloxavir marboxil, RG6152, S-033188)



Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza		
Phase/study	Phase III miniSTONE 1 (0-1 year old)	Phase III miniSTONE 2 (1- <12 years old )	Phase IIIb CENTERSTONE
# of patients	N=30	N=176	N=3,160
Design	Xofluza on Day 1 (based on body weight and age) in healthy pediatric patients from birth to <1 year with influenza-like symptoms	Healthy pediatric patients 1 to <12 years of age with influenza-like symptoms  • ARM A: Xofluza  • ARM B: Tamiflu	Reduction of direct transmission of influenza from otherwise healthy patients to household contacts  • ARM A: Xofluza  • ARM B: Placebo
Primary endpoint	- Safety	<ul> <li>Safety</li> </ul>	<ul> <li>Percentage of household contacts who are PCR- positive for influenza by day 5 post randomization of index patients</li> </ul>
Status	• FPI Q1 2019	<ul> <li>Primary endpoint met Q2 2019</li> <li>Data presented at OPTIONS X 2019</li> <li>Filed in US Q1 2020</li> <li>Data published in <i>Pediatric Infectious Disease</i> 2020 Aug;39(8):700-705</li> <li>Not approved in the US, determining path forward with the FDA</li> <li>Filed in EU Q4 2021</li> </ul>	■ FPI Q4 2019
CT Identifier	NCT03653364	NCT03629184	NCT03969212



Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

**Spark** 

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

# Ipatasertib (RG7440, GDC-0068)



#### Highly selective small molecule inhibitor of Akt

Indication	1L castration-resistant prostate cancer (CRPC)
Phase/study	Phase III IPATential 150
# of patients	N=1,100
Design	<ul> <li>ARM A: Ipatasertib plus abiraterone</li> <li>ARM B: Placebo plus abiraterone</li> </ul>
Primary endpoint	• rPFS in patients with PTEN loss tumors and overall population
Status	<ul> <li>FPI Q2 2017</li> <li>Recruitment completed Q1 2019</li> <li>Study met co-primary endpoint in rPFS in patients with PTEN loss tumors Q2 2020</li> <li>Data presented at ESMO 2020 and interim OS at ASCO 2022</li> <li>Published in Lancet 2021; 398:131-142</li> </ul>
CT Identifier	NCT03072238



Indication	1L NSCLC PD-L1 TPS>50%	Stage III unresectable 1L NSCLC
Phase/study	Phase III SKYSCRAPER-01	Phase III SKYSCRAPER-03
# of patients	N=500-560	N=800
Design	ARM A: Tiragolumab plus Tecentriq     ARM B: Placebo plus Tecentriq	<ul> <li>ARM A: Tiragolumab plus Tecentriq for up to 12 months</li> <li>ARM B: Durvalumab for up to 12 months</li> </ul>
Primary endpoint	Overall survival and progression-free survival	Progression-free survival
Status	<ul> <li>FPI Q1 2020</li> <li>Recruitment completed Q3 2021</li> <li>Study did not meet its co-primary endpoint of PFS Q2 2022</li> </ul>	• FPI Q3 2020
CT Identifier	NCT04294810	NCT04513925



Indication	Metastatic and/or recurrent PD-L1+ cervical cancer (CC)	Neoadjuvant and adjuvant NSCLC	1L non-squamous NSCLC
Phase/study	Phase II SKYSCRAPER-04	Phase II SKYSCRAPER-05	Phase II/III SKYSCRAPER-06
# of patients	N=172	N=82	N=500
Design	ARM A: Tiragolumab plus Tecentriq     ARM B: Tecentriq	<ul> <li>ARM A: (PD-L1 high) neoadjuvant tiragolumab plus Tecentriq followed by adjuvant tiragolumab plus Tecentriq or adjuvant chemotherapy</li> <li>ARM B: (PD-L1 all-comers) neoadjuvant tiragolumab plus Tecentriq plus chemo followed by adjuvant tiragolumab plus Tecentriq</li> </ul>	<ul> <li>ARM A: Tiragolumab plus Tecentriq plus pemetrexed plus chemo followed by maintenance tiragolumab plus Tecentriq plus pemetrexed</li> <li>ARM B: Placebo plus pembrolizumab plus pemetrexed plus chemo followed by maintenance placebo plus pembrolizumab plus pemetrexed</li> </ul>
Primary endpoint	Objective response rate	<ul> <li>Pathologic complete response, major pathological response and safety</li> </ul>	<ul> <li>Objective response rate, progression-free survival and overall survival</li> </ul>
Status	• FPI Q2 2020	■ FPI Q2 2021	• FPI Q4 2020
CT Identifier	NCT04300647	NCT04832854	NCT04619797



Indication	Locally advanced esophageal cancer (EC)	1L esophageal cancer (EC)	1L recurrent/metastatic PD-L1 positive squamous cell head and neck carcinoma (SCCHN)
Phase/study	Phase III SKYSCRAPER-07	Phase III SKYSCRAPER-08	Phase II SKYSCRAPER-09
# of patients	N=750	N=500	N=120
Design	<ul> <li>ARM A: Tiragolumab plus Tecentriq</li> <li>ARM B: Tecentriq plus placebo</li> <li>ARM C: Placebo plus placebo</li> </ul>	<ul> <li>ARM A: Tiragolumab plus Tecentriq plus cisplatin and paclitaxel</li> <li>ARM B: Placebo plus placebo plus cisplatin and paclitaxel</li> </ul>	ARM A: Tiragolumab plus Tecentriq     ARM B: Tecentriq plus placebo
Primary endpoint	<ul> <li>Progression-free survival (A vs C)</li> <li>Overall survival (A vs C, hierarchical, B vs C hierarchical)</li> </ul>	<ul> <li>Overall survival and progression-free survival</li> </ul>	Objective response rate
Status	• FPI Q3 2020	<ul> <li>FPI Q4 2020</li> <li>Recruitment completed Q4 2021</li> </ul>	<ul><li>FPI Q1 2021</li><li>Recruitment completed Q2 2022</li></ul>
CT Identifier	NCT04543617	NCT04540211	NCT04665843



Indication	Solid tumors	NSCLC	Relapsed or refractory multiple myeloma (MM) or r/r B-cell NHL
Phase/study	Phase I	Phase II CITYSCAPE	Phase I
# of patients	N=540	N=135	N=52
Design	<ul> <li>Phase Ia: Dose escalation and expansion of tiragolumab</li> <li>Phase Ib: Dose escalation and expansion of tiragolumab in combination with Tecentriq and/or other anti-cancer therapies</li> </ul>	<ul> <li>ARM A: Tecentriq plus tiragolumab</li> <li>ARM B: Tecentriq monotherapy</li> </ul>	<ul> <li>Phase Ia: Tiragolumab monotherapy</li> <li>Phase Ib: Tiragolumab plus daratumumab (r/r MM) or rituximab (r/r NHL)</li> </ul>
Primary endpoint	<ul> <li>Safety, tolerability, PK variability and preliminary efficacy</li> </ul>	<ul> <li>Overall response rate and progression-free survival</li> </ul>	<ul> <li>Safety, tolerability, PK/PD and preliminary efficacy</li> </ul>
Status	<ul> <li>FPI Q2 2016</li> <li>Data presented at AACR 2020</li> </ul>	<ul> <li>FPI Q3 2018</li> <li>Recruitment completed Q2 2019</li> <li>Data presented at ASCO 2020 and WCLC and ESMO IO 2021</li> <li>BTD granted by FDA Q4 2020</li> </ul>	■ FPI Q2 2019
CT Identifier	NCT02794571	NCT03563716	NCT04045028

## Glofitamab (CD20-TCB, RG6026)



## Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Relapsed or refractory Non-Hodgkin's lymphoma (NHL)		
Phase/study	Phase I	Phase lb	Phase I
# of patients	N=700	N=140	N=18-36
Design	Cohort 1: Single-agent dose escalation study Initial dose escalation Expansion cohort in r/r DLBCL Expansion cohort in r/r FL All patients will receive pretreatment with a single dose of Gazyva (1000mg) Cohort 2: Glofitamab plus Gazyva (i.e. continuous treatment with Gazyva)	Dose escalation and expansion  • ARM A: Glofitamab plus Tecentriq  • ARM B: Glofitamab plus Polivy	Glofitamab SC - Part 1 dose escalation
Primary endpoint	• Efficacy, safety, tolerability and pharmacokinetics	■ Safety	- Safety
Status	<ul> <li>FPI Q1 2017</li> <li>Data presented at ASH 2018, ICML and ASH 2019; EHA and ASH 2020; ASCO, EHA, ICML and ASH 2021; ASCO and EHA 2022</li> <li>Data published online March 2021 J Clin Oncology 39:18:1959-1970</li> <li>Filed in EU April 2022</li> </ul>	<ul> <li>Arm A: FPI Q2 2018</li> <li>Data presented at ASH 2019 and ASH 2021</li> <li>Arm B: FPI Q4 2020</li> </ul>	• FPI Q3 2021
CT Identifier	NCT03075696	NCT03533283	ISRCTN17975931

## Glofitamab (CD20-TCB, RG6026)



## Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Non-Hodgkin's lymphoma (NHL)	2L+ SCT-ineligible DLBCL
Phase/study	Phase Ib	Phase III STARGLO
# of patients	Part I: 15-60 Part II: ~66-104	N=270
Design	<ul> <li>Part I: Dose-finding for the combination of glofitamab plus G/R-CHOP in r/r indolent NHL</li> <li>Part II: Dose expansion glofitamab plus G/R-CHOP or R-CHOP in 1L DLBCL</li> <li>Part III: Glofitamab plus R-CHP plus Polivy</li> </ul>	<ul> <li>ARM A: Glofitamab plus gemcitabine and oxaliplatin, followed by up to 4 cycles of glofitamab monotherapy</li> <li>ARM B: Rituxan in combination with gemcitabine and oxaliplatin</li> <li>A single dose of Gazyva will be administered 7 days prior to the first dose of glofitamab</li> </ul>
Primary endpoint	- Safety	Overall survival
Status	<ul> <li>Part I: FPI Q1 2018</li> <li>Part II: FPI Q1 2021</li> <li>Data presented at ASH 2021</li> </ul>	• FPI Q1 2021
CT Identifier	NCT03467373	NCT04408638

## Glofitamab (CD20-TCB, RG6026)



## Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	1L ctDNA high risk DLBCL
Phase/study	Phase II
# of patients	N=40
Design	• Glofitamab plus R-CHOP (glofitamab is introduced as a consolidation to R-CHOP at cycle 3-8 in patients ctDNA+ at cycle 2)
Primary endpoint	• EOT PET-CR
Status	• FPI Q1 2022
CT Identifier	NCT04980222

## Inavolisib (RG6114, GDC-0077)



#### A potent, orally available, and selective PI3Kα inhibitor

Indication	PIK3CA-mutant HR+ metastatic breast cancer (mBC)	PIK3CA mutant solid tumors and metastatic ER+ HER2-neg breast cancer
Phase/study	Phase III INAVO120	Phase I
# of patients	N=400	N=256
Design	<ul> <li>ARM A: Inavolisib plus palbociclib plus fulvestrant</li> <li>ARM B: Placebo plus palbociclib plus fulvestrant</li> </ul>	Monotherapy and in combination with standard of care (letrozole; letrozole plus palbociclib; fulvestrant)  • Stage 1: Dose escalation  • Stage 2: Dose expansion
Primary endpoint	Progression-free survival	Safety, tolerability and pharmacokinetics
Status	• FPI Q1 2020	<ul> <li>FPI Q4 2016</li> <li>Preclinical/molecule discovery data presented at AACR 2017</li> <li>Data presented at SABCS 2019, 2020 and 2021</li> </ul>
CT Identifier	NCT04191499	NCT03006172

## Giredestrant (SERD (3), RG6171, GDC-9545)



#### A selective estrogen receptor degrader or downregulator

Indication	ER+ HER2-neg metastatic breast cancer (mBC)	ER+ HER2-neg Stage I-III operable breast cancer (BC)	Neoadjuvant ER+ breast cancer (BC)
Phase/study	Phase I	Phase I	Phase II coopERA Breast Cancer
# of patients	N=181	N=75	N=221
Design	<ul> <li>Dose escalation and expansion at RPTD</li> <li>Giredestrant monotherapy and in combination with palbociclib and/or LHRH agonist</li> </ul>	<ul> <li>Open-label, pre-operative administration</li> <li>Dose escalation</li> </ul>	<ul> <li>ARM A: Giredestrant followed by giredestrant plus palbociclib</li> <li>ARM B: Anastrazole followed by anastrazole plus palbociclib</li> </ul>
Primary endpoint	<ul> <li>Safety</li> </ul>	<ul><li>Safety, tolerability and PK/PD</li></ul>	<ul> <li>Safety, tolerability and PK/PD</li> </ul>
Status	<ul> <li>FPI Q4 2017</li> <li>Data presented at SABCS 2019, ASCO 2020, ASCO 2021 and SABCS 2021</li> </ul>	<ul><li>FPI Q3 2019</li><li>Data presented at ASCO 2021</li></ul>	<ul> <li>FPI Q3 2020</li> <li>Data presented at ESMO and SABCS 2021; ASCO 2022</li> </ul>
CT Identifier	NCT03332797	NCT03916744	NCT04436744

# **Giredestrant (SERD (3), RG6171, GDC-9545)**



#### A selective estrogen receptor degrader or downregulator

Indication	2L/3L ER+/HER2-negative metastatic breast cancer (mBC)	1L ER+ metastatic breast cancer (mBC)	Adjuvant ER+ breast cancer (BC)
Phase/study	Phase II acelERA Breast Cancer	Phase III persevERA Breast Cancer	Phase III lidERA Breast Cancer
# of patients	N=303	N=978	N=4,100
Design	<ul> <li>ARM A: Giredestrant monotherapy</li> <li>ARM B: Endocrine monotherapy (fulvestrant or aromatase inhibitor)</li> </ul>	<ul> <li>ARM A: Giredestrant plus palbociclib</li> <li>ARM B: Letrozole plus palbociclib</li> </ul>	<ul> <li>ARM A: Giredestrant monotherapy</li> <li>ARM B: Tamoxifen or aromatase inhibitor</li> </ul>
Primary endpoint	<ul> <li>Progression-free survival</li> </ul>	<ul> <li>Progression-free survival</li> </ul>	<ul> <li>Invasive disease-free survival</li> </ul>
Status	<ul> <li>FPI Q4 2020</li> <li>Recruitment completed Q4 2021</li> <li>Study did not meet its primary endpoint Q2 2022</li> </ul>	• FPI Q4 2020	■ FPI Q3 2021
CT Identifier	NCT04576455	NCT04546009	NCT04961996

## **Giredestrant (SERD (3), RG6171, GDC-9545)**



#### A selective estrogen receptor degrader or downregulator

Indication	1L ER+/HER2-positive breast cancer (BC)	
Phase/study	Phase III heredERA	
# of patients	N=812	
Design	Induction Phesgo plus taxane followed by maintenance with either:  - ARM A: Giredestrant plus Phesgo  - ARM B: Phesgo	
Primary endpoint	<ul> <li>Progression-free survival</li> </ul>	
Status	• FPI Q2 2022	
CT Identifier	NCT05296798	

# zinpentraxin alfa (PRM-151, RG6354)



### Recombinant human innate immunity protein pentraxin-2

Indication	Idiopathic pulmonary fibrosis (IPF)		Myelofibrosis
Phase/study	Phase II	Phase III STARSCAPE	Phase II
# of patients	N=117	N=658	N=125
Design	<ul> <li>Randomized, double-blind, placebo-controlled trial: 4-week screening period, 24-week randomized treatment period, 4-week follow-up visit (week 28)</li> <li>Zinpentraxin alfa at days 1, 3 and 5, then every 4 weeks vs placebo</li> </ul>	<ul> <li>Randomized, double-blind, placebo-controlled trial: 4-week screening period, 52-week randomized treatment period</li> <li>Zinpentraxin alfa at days 1, 3 and 5, then every 4 weeks vs placebo</li> </ul>	Multiple dose study of zinpentraxin alfa
Primary endpoint	<ul> <li>Least-squares mean change in FVC percentage of predicted value from baseline to week 28</li> </ul>	•Absolute change from baseline to week 52 in FVC	Bone marrow response rate
Status	<ul> <li>Study met primary endpoint</li> <li>Data published in JAMA 2018;319(22):2299- 2307 and Lancet Respir Med 2019 Aug;7(8):657- 664</li> </ul>	• FPI Q1 2021	- Study completed Q1 2021
CT Identifier	NCT02550873	NCT04552899	NCT01981850



#### A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH)	Paroxysmal nocturnal hemoglobinuria (PNH) patients switching from a C5 inhibitor
Phase/study	Phase I/II COMPOSER	Phase III COMMODORE 1
# of patients	N=59	N=250
Design	Healthy volunteers and treatment naïve and pretreated patients with PNH:  • Part 1: Single ascending dose study in healthy subjects  • Part 2: Intra-patient single ascending dose study in PNH patients  • Part 3: Multiple-dose study in PNH patients  • Part 4: Dose confirmation in PNH patients	<ul> <li>ARM A: Crovalimab</li> <li>ARM B: Eculizumab</li> <li>ARM C: Patients switching to crovalimab from ravulizumab, higher than labeled doses of eculizumab &amp; C5 SNP patients (descriptive-arm)</li> </ul>
Primary endpoint	■ Safety, PK, PD	<ul> <li>Non-inferiority of crovalimab compared to eculizumab - mean % change in LDH level (measure of haemolysis) from baseline to week 25</li> </ul>
Status	<ul> <li>Part 1: FPI Q4 2016</li> <li>Part 2/3: FPI Q2 2017</li> <li>Part 4: FPI Q2 2019</li> <li>Nonclinical data published in Scientific Reports 2017 Apr; 7(1):1080</li> <li>Data presented for Part 2 and 3 at ASH 2018 and 2019</li> </ul>	■ FPI Q3 2020
CT Identifier	NCT03157635	NCT04432584



### A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naive patients	Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naive patients (China only)	
Phase/study	Phase III COMMODORE 2	Phase III COMMODORE 3	
# of patients	N=200	N=51	
Design	- ARM A: Crovalimab - ARM B: Eculizumab	<ul> <li>Crovalimab loading dose IV on Day 1, followed by weekly crovalimab SC doses for 4 weeks</li> </ul>	
Primary endpoint	<ul> <li>Non-inferiority of crovalimab compared to eculizumab:</li> <li>% patients with transfusion avoidance from baseline through week 25</li> <li>% patients with haemolysis control, as measured by LDH &lt;= 1.5ULN from week 5-25</li> </ul>	<ul> <li>Percentage of patients with transfusion avoidance from baseline through week 25</li> <li>Mean percentage of participants with hemolysis control (week 5 through week 25)</li> </ul>	
Status	• FPI Q4 2020	<ul> <li>FPI Q1 2021</li> <li>Recruitment completed Q3 2021</li> <li>Study met its co-primary endpoints Q1 2022</li> </ul>	
CT Identifier	NCT04434092	NCT04654468	



#### A humanized monoclonal antibody against complement C5

Indication	Atypical hemolytic uremic syndrome (aHUS) study 1 - adults	Atypical hemolytic uremic syndrome (aHUS) study 2 - paediatrics	
Phase/study	Phase III COMMUTE-a	Phase III COMMUTE-p	
# of patients	N=90	N=35	
Design	Single-arm study of aHUS patients  • Cohort 1: not previously treated with C5i  • Cohort 2: switching from C5i  • Cohort 3: known C5 polymorphism	Single-arm study of aHUS patients  • Cohort 1: not previously treated with C5i  • Cohort 2: switching from C5i ≤18y/o	
Primary endpoint	<ul> <li>Cohort 1+3: proportion of patients with complete TMA response anytime between baseline and week 25</li> <li>Cohort 2: proportion of patients with maintained TMA control from baseline through week 25</li> </ul>	<ul> <li>Cohort 1: proportion of patients with complete TMA response anytime between baseline and week 25</li> <li>Cohort 2: proportion of patients with maintained TMA control from baseline through week 25</li> </ul>	
Status	• FPI Q4 2021	■ FPI Q4 2021	
CT Identifier	NCT04861259	NCT04958265	

# Roche

### A humanized monoclonal antibody against complement C5

Indication	Sickle cell disease (SCD) acute treatment	Sickle cell disease (SCD) chronic VOC prevention	
Phase/study	Phase Ib CROSSWALK-a	Phase IIa CROSSWALK-c	
# of patients	N=30	N=90	
Design	ARM A: Crovalimab ARM B: Placebo	ARM A: Crovalimab ARM B: Placebo	
Primary endpoint	- Safety	<ul><li>VOC rate, up to 48 weeks</li></ul>	
Status	• FPI Q1 2022	• FPI Q1 2022	
CT Identifier	NCT04912869	NCT05075824	

SCD=Sickle Cell Disease; VOC=Vaso-occlusive crises

# Crenezumab (RG7412)



#### Humanized monoclonal antibody targeting all forms of Ab

Indication	Alzheimer's prevention initiative (API) Colombia	
Phase/study	Phase II Cognition study	
# of patients	N=252	
Design	<ul> <li>ARM A: PSEN1 E280A mutation carriers receive crenezumab SC or IV</li> <li>ARM B: PSEN1 E280A mutation carriers receive placebo</li> <li>ARM C: non-mutation carriers receive placebo</li> </ul>	
Primary endpoint	<ul> <li>Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score at 260 weeks treatment</li> <li>Annualized rate of change in an Episodic Memory Measure: Free and Cued Selective Reminding Task (FCSRT)</li> </ul>	
Status	<ul> <li>FPI Q4 2013</li> <li>Recruitment completed Q1 2017</li> <li>Study did not meet its co-primary endpoints Q2 2022</li> </ul>	
CT Identifier	NCT01998841	

## Gantenerumab (RG1450)



#### Fully human monoclonal antibody binding aggregated forms of AB

Indication	Prodromal to mild Alzheimer's disease		
Phase/study	Phase III GRADUATE 1	Phase III GRADUATE 2	Phase II GRADUATION
# of patients	N=1,016	N=1,016	N=192
Design	104-week SC treatment period: - ARM A: Gantenerumab - ARM B: Placebo	104-week SC treatment period:  • ARM A: Gantenerumab  • ARM B: Placebo	104-week SC treatment period: gantenerumab SC treatment q1w dosing regimen
Primary endpoint	<ul> <li>Change in CDR-SOB at 27 months</li> </ul>	<ul> <li>Change in CDR-SOB at 27 months</li> </ul>	<ul> <li>Change from baseline in deposited amyloid (PET centiloid levels)</li> </ul>
Status	<ul> <li>FPI Q2 2018</li> <li>Recruitment completed Q2 2020</li> <li>BTD grant</li> </ul>	<ul> <li>FPI Q3 2018</li> <li>Recruitment completed Q2 2020</li> <li>ed by FDA Sep 2021</li> </ul>	<ul> <li>FPI Q4 2020</li> <li>Recruitment completed Q3 2021</li> </ul>
CT Identifier	NCT03443973	NCT03444870	NCT04592341

# Gantenerumab (RG1450)



## Fully human monoclonal antibody binding aggregated forms of AB

Indication	Prodromal Alzheimer's disease	Mild Alzheimer's disease	Cognitively unimpaired participants at risk for or at the earliest stages of Alzheimer's disease
Phase/study	Phase II/III SCarlet RoAD <sup>1</sup>	Phase III Marguerite RoAD <sup>1</sup>	Phase III SKYLINE <sup>2</sup>
# of patients	N=799	N=389	N=1200
Design	<ul> <li>104-week SC treatment period:</li> <li>ARM A: Gantenerumab (225 mg)</li> <li>ARM B: Gantenerumab (105 mg)</li> <li>ARM C: Placebo</li> </ul>	104-week SC treatment period: - ARM A: Gantenerumab - ARM B: Placebo	<ul> <li>ARM A: Gantenerumab q1w or q2w (patient preference)</li> <li>ARM B: Placebo</li> </ul>
Primary endpoint	<ul> <li>Change in CDR-SOB at 2 years</li> <li>Sub-study: change in brain amyloid by PET at 2 years</li> </ul>	<ul> <li>Change in ADAS-Cog and CDR-SOB at 2 years (co- primary)</li> </ul>	<ul> <li>Cognitive composite (PACC5)</li> </ul>
Status	<ul> <li>Phase I PET data: Archives of Neurology, 2012 Feb;69(2):198-207</li> <li>Recruitment completed Q4 2013</li> <li>Dosing stopped due to futility Q4 2014</li> <li>FPI in open label extension study Q4 2015</li> <li>Published in Alzheimers Res Ther 2017 Dec 8;9(1):95</li> </ul>	<ul> <li>FPI Q1 2014</li> <li>Recruitment stopped Q4 2015</li> <li>FPI Q1 2016 for open label extension</li> </ul>	• FPI Q2 2022
	■ 36 OLE data published in .		
CT Identifier	NCT01224106	NCT02051608	NCT05256134

# Tominersen (RG6042, HTT ASO)



## Antisense oligonucleotide (ASO) targeting human HTT mRNA

Indication	Huntington's disease					
Phase/study	Phase I/IIa	Phase II OLE				
# of patients	N=46	N=46				
Design	Multiple ascending doses of tominersen administered intrathecally to adult patients with early manifest Huntington's Disease	Patients from phase I are enrolled into OLE				
Primary endpoint	Safety, tolerability and PK/PD	<ul> <li>Longer term safety, tolerability and PK/PD</li> </ul>				
Status	<ul> <li>FPI Q3 2015</li> <li>Data presented at CHDI 2018 and AAN 2018</li> <li>PRIME designation granted 2018</li> <li>Published in NEJM 2019; 380:2307-2316</li> </ul>	<ul> <li>FPI Q1 2018</li> <li>PK/PD data presented at AAN 2019</li> <li>Update presented at CHDI 2020</li> <li>Study completed, patients moved to GEN-EXTEND OLE</li> </ul>				
CT Identifier	NCT02519036	NCT03342053				

# Tominersen (RG6042, HTT ASO)



## Antisense oligonucleotide (ASO) targeting human HTT mRNA

Indication	Huntington's disease					
Phase/study	Phase III Generation HD1	Phase III GEN-EXTEND				
# of patients	N=791	N=1,050				
Design	<ul> <li>ARM A: Tominersen 120mg q2w</li> <li>ARM B: Tominersen 120mg q4m</li> <li>ARM C: Placebo q2w</li> </ul>	OLE study in patients participating in prior Roche and Genentech sponsored studies  • ARM A: Tominersen 120mg q2w  • ARM B: Tominersen 120mg q4m				
Primary endpoint	<ul><li>cUHDRS globally</li><li>TFC USA only</li></ul>	<ul> <li>Long term safety, tolerability</li> </ul>				
Status	<ul> <li>FPI Jan 2019</li> <li>Q1 2019 protocol modified to allow for bi-monthly vs four-monthly dosing, FPI for new protocol July 2019</li> <li>Recruitment completed Q2 2020</li> <li>Dosing stopped in Q1 2021 based on IDMC recommendation regarding the potential benefit/risk profile for study participants. No new safety signals identified.</li> <li>Data presented at EHDN and CHDI 2022</li> </ul>	• FPI Q2 2019 • Dosing stopped in Q1 2021				
CT Identifier	NCT03761849	NCT03842969				

## Fenebrutinib (RG7845, GCD-0853)



### Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multip	le sclerosis (RMS)
Phase/study	Phase III FENtrepid	Phase III FENhance 1	Phase III FENhance 2
# of patients	N=946	N=736	N=736
Design	<ul> <li>ARM A: Fenebrutinib twice daily oral</li> <li>ARM B: Ocrevus 2x300mg IV q24w</li> </ul>	<ul> <li>ARM A: Fenebrutinib twice daily oral</li> <li>ARM B: Teriflunomide once daily oral</li> </ul>	<ul> <li>ARM A: Fenebrutinib twice daily oral</li> <li>ARM B: Teriflunomide once daily oral</li> </ul>
Primary endpoint	<ul><li>Time to onset of cCDP12</li></ul>	<ul> <li>Time to onset of cCDP12 and annualized relapse rate</li> </ul>	<ul> <li>Time to onset of cCDP12 and annualized relapse rate</li> </ul>
Status	• FPI Q4 2020	• FPI Q1 2021	• FPI Q1 2021
CT Identifier	NCT04544449	NCT04586023	NCT04586010



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Molecule	Indication	Phase	# of patients	Status	CT Identifier		
	Oncology						
FAP-4-1BBL (RG7827)	Solid tumors	I	~150	FPI Q2 2018 Data presented at ESMO 2020 Recruitment completed Q2 2021			
	3L+ MSS mCRC	lb	80	FPI Q3 2021 Combination study with cibisatamab	NCT04826003		
CD19-4-1BBL (RG6076)	R/R B cell non-Hodgkin's lymphoma	I	362	Part I: FPI Q3 2019 Part II: FPI Q3 2020	NCT04077723		
PD1-IL2v (RG6279)	Solid tumors	I	348	Part I: FPI Q2 2020; recruitment completed Q4 2021 Part II: FPI Q1 2022	NCT04303858		
	CEA-positive solid tumors	la	149	FPI Q4 2014 Data presented at ASCO 2017	NCT02324257		
cibisatamab (CEA x CD3, RG7802)		lb	228	FPI Q1 2016 Data presented at ASCO 2017	NCT02650713		
	3L+ MSS mCRC	lb	46	FPI Q1 2019	NCT03866239		
	Solid tumors	I	320	FPI Q4 2019	NCT04140500		
PD1-LAG3 (RG6139)	Solid tumors	II	210	FPI Q2 2021 Randomized trial, compared with nivolumab	NCT04785820 TALIOS		





Molecule	Indication	Phase	# of patients	Status	CT Identifier		
Oncology							
	Solid tumors	ı	110	FPI Q4 2019	NCT04158583		
CD25 (RG6292)	Advanced and metastatic solid tumors	I	160	Part I: FPI Q1 2021 Part II: FPI Q4 2021	NCT04642365		
Anti-GPRC5D (RG6234)	Multiple myeloma	1	240	FPI Q4 2020	NCT04557150		
HLA-A2-WT1 x CD3 (RG6007)	AML	I	160	FPI Q4 2020	NCT04580121		
FAP-CD40 (RG6189)	Solid tumors	1	280	FPI Q2 2021	NCT04857138		
HLA-A2-MAGE-A4 x CD3 (RG6129)	Solid tumors	I	180	FPI Q1 2022	NCT05129280		
BRAFi (3) (RG6344)	Solid tumors	I	292	FPI Q1 2022	ISRCTN13713 551		
CD19xCD28 (RG6333)	R/R B cell non-Hodgkin's lymphoma	I	~200	FPI Q1 2022 Combination study with glofitamab	NCT05219513		
EGFRvIIIxCD3 (RG6156)	Glioblastoma	I	~200	FPI Q2 2022	NCT05187624		

# pRED neuroscience development programs -1



Molecule	Indication	Phase	# of patients	Status	CT Identifier		
Neuroscience Neuroscience							
Brain Shuttle-gantenerumab (BS-gantenerumab, RG6102)	Alzheimer's disease	lla	~120	FPI Q1 2021	NCT04639050		
Brain Shuttle-CD20 (BS-CD20, RG6035)	Multiple sclerosis	I	30	FPI Q3 2021	ISRCTN16295 177		
ralmitaront		II	36	FPI Q4 2018; Recruitment completed Q3 2019			
(partial TAAR1 agonist, RG7906)	Schizophrenia	II	247	FPI Q4 2019	NCT03669640 (TWAIN I)		
prasinezumab¹ (anti-αSynuclein, RG7935, PRX002)	Parkinson's disease	II	316	The study did not meet its primary endpoint, but showed a reduced clinical decline of core motor signs (MDS UPDRS partIII). Data presented at MDS & ADPD 2020-22. The Open Label Extension is ongoing.	NCT03100149 (PASADENA)		
		IIb	575	FPI Q2 2021	NCT04777331 (PADOVA)		
alogabat (GABA-Aa5 PAM, RG7816)	Autism spectrum disorder	II	105	FPI Q1 2021	NCT04299464 (Aurora)		
NME (RG7637)	Neurodevelopmental disorders	I	80	FPI Q3 2020	NCT04475848		
rugonersen (UBE3A LNA, RG6091)	Angelman syndrome	I	66	FPI Q3 2020	NCT04428281		
NME (RG6182)	Neurodegenerative disorder	I	30	FPI Q4 2020			

Partner: <sup>1</sup>Prothena BS=Brain Shuttle





Molecule	Indication	Phase	# of patients	Status	CT Identifier		
Neuroscience Neuroscience							
NME (RG6289)	Alzheimer's disease	I	138	FPI Q4 2021			
NME (RG6163)	Psychiatric disorders	I	84	FPI Q1 2022			

Partner: <sup>1</sup>Prothena; BS=Brain Shuttle





Molecule	Indication	Phase	# of patients	Status	CT Identifier	
Immunology						
selnoflast (NLRP3i, RG6418)	Ulcerative colitis	lb	18	FPI Q4 2021 Recruitment completed Q2 2022		
	Chronic obstructive pulmonary disease	lb	102	FPI Q2 2022		

Ophthalmology Control of the Control						
NME (RG6179) <sup>1</sup>	DME	I	90	FPI Q3 2019	DOVETAIL	
		II	160	FPI Q4 2021	NCT05151744 (BARDENAS)	
		II	320	FPI Q4 2021	NCT05151731 (ALLUVIUM)	
VEGF-Ang2 DutaFab (RG6120)	nAMD	I	~50	FPI Q4 2020	NCT04567303	
NME (RG7774)	Retinal disease	II	135	FPI Q2 2020	NCT04265261 (CANBERRA)	

Partner: <sup>1</sup>Sesen Bio

# pRED infectious diseases development programs



Molecule	Indication	Phase	# of patients	Status	CT Identifier			
	Infectious Diseases							
TLR7 agonist (3) (RG7854)	Chronic hepatitis B	I	150	FPI Q4 2016 Data presented at APASL 2019	NCT02956850			
CpAM (RG7907)	Chronic hepatitis B	1/11	192	FPI Q4 2016 Data presented at EASL 2018, 2019 & 2020	NCT02952924			
CPAM (NG/70/)		I	22	FPI Q1 2021 Recruitment completed Q2 2021	NCT04729309			
TLR7 agonist (3)/ CpAM/siRNA/ PDL1 LNA (RG7854/RG7907/RG6346/RG6084)	Chronic hepatitis B	II	275	FPI Q3 2020	NCT04225715 (PIRANGA)			
PDL1 LNA (RG6084)	Chronic hepatitis B	1	35	FPI Q1 2019 Part Ia: completed Part Ib: initiated				
Abx MCP (RG6006)	A. baumannii infections	I	204	FPI Q4 2020	NCT04605718			

Abx MCP=antibiotic macrocyclic peptide 155



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# gRED oncology development programs



Molecule	Indication	Phase	# of patients	Status	CT Identifier		
Oncology							
KRAS G12C (RG6330)	Metastatic solid tumors with KRAS G12C mutation	I	270	FPI Q3 2020	NCT04449874		
cevostamab (anti-FcRH5 x CD3; RG6160)	R/R multiple myeloma	I	300	FPI Q3 2017 Data presented at ASH 2020, ASH 2021	NCT03275103		
runimotamab (HER2 x CD3, RG6194)	Metastatic HER2-expressing cancers	I	440	FPI Q2 2018	NCT03448042		
NME (RG6286)	Locally advanced or metastatic colorectal cancer	I	67	FPI Q3 2020	NCT04468607		
IL15/IL15Ra-Fc (RG6323) <sup>1</sup>	Solid tumors	1/11	250	FPI Q1 2020	NCT04250155		
12 13/12 13na-FC (NG0323)	R/R multiple myeloma	I	60	FPI Q2 2022	NCT05243342		
autogene cevumeran (Individualized Neoantigen-Specific	Solid tumors	la/IIb	271	FPI Q4 2017 Data presented at AACR 2020 Recruitment completed Q1 2022	NCT03289962		
Therapy (iNeST); RG6180) <sup>2</sup>	1L advanced melanoma	II	132	FPI Q1 2019	NCT03815058 (IMcode001)		
SHP2i (RG6344)	Solid tumors	la	~50	FPI Q1 2020	NCT04252339		
belvarafenib (RG6185)³	nRASmt CPI-experienced melanoma	lb	83	FPI Q2 2021	NCT04835805		
NME (RG6392)	Oncology	I	60	FPI Q4 2021	ISRCTN92655 801		

Partner: <sup>1</sup>Xencor, <sup>2</sup>BioNTech, <sup>3</sup>Hanmi

# gRED immunology and ophthalmology development programs



Molecule	Indication	Phase	# of patients	Status	CT Identifier						
	Immunology										
efmarodocokin alfa (IL-22Fc, RG7880)	aGVHD	lb	18	FPI Q4 2020	NCT04539470						
NME (RG6287, GDC-8264)	Inflammatory bowel disease		68	FPI Q1 2020 Recruitment completed Q3 2021	EUDRACT201 9-002613-19						
	Inflammatory diseases	I	16	FPI Q4 2021							
NME (RG6315, MTBT1466A)	Immunologic disorders	ı	~24	FPI Q3 2020							
astegolimab (Anti-ST2, (RG6149, AMG 282, MSTT1041A) <sup>1</sup>	Chronic obstructive pulmonary disease	IIb	930	FPI Q4 2021	NCT05037929						
NME (RG6341, GDC-6599)	Asthma	la/lb	84	FPI Q4 2021							

Ophthalmology									
galegenimab (HtrA1, RG6147)	Geographic atrophy	II	360	FPI Q2 2019	NCT03972709 (GALLEGO)				
NME (RG6312)	Geographic atrophy	la	63	FPI Q4 2020	NCT04615325				
NME (RG6351)	Retinal disease	1	42-78	FPI Q2 2022					

Partner: <sup>1</sup>Amgen 158



# gRED neuroscience and infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier					
Neuroscience Neuroscience										
semorinemab (RG6100) <sup>1</sup>	Prodromal to mild Alzheimer's disease	11	457	FPI Q4 2017 Primary endpoint not met Q3 2020 Data presented at CTAD 2020	NCT03289143 (TAURIEL)					
	Mild-to-moderate Alzheimer's disease	П	272	FPI Q1 2019 One of two co-primary endpoints met Q3 2021 Data presented at CTAD 2021 The Open Label Extension is ongoing	NCT03828747 (LAURIET)					

Infectious Diseases									
LepB inhibitor (RG6319)	Complicated urinary tract infection	1	56	FPI Q1 2022					

Partner: <sup>1</sup>AC Immune



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# Hemophilia A

# Spark Roche Roche

# Unique gene therapy platform

Molecule		SPK-8011 (RG6357)						
Indication	Hem	ophilia A	Hemophilia A with inhibitors to Factor VIII					
Phase/study	Phase I	Phase I/II	Phase I/II					
# of patients	N=100	N=30	N=30					
Design	<ul> <li>Long term follow up study of patients who have received SPK-8011 in any prior Spark- sponsored SPK-8011 study</li> </ul>	<ul> <li>Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8011</li> </ul>	<ul> <li>Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8016 in individuals with FVIII inhibitors</li> </ul>					
Primary endpoint	<ul> <li>Safety</li> </ul>	<ul> <li>Safety and changes from baseline in FVIII activity levels at week 52</li> </ul>	<ul> <li>Safety; peak and steady state FVIII activity levels at week 52</li> </ul>					
Status	- Ongoing	<ul> <li>FPI Q1 2017</li> <li>Updated data presented at ISTH 2020 and 2021</li> <li>Recruitment completed Q1 2021</li> <li>Data published in NEJM 2021; 385:1961-1973</li> </ul>	• FPI Q1 2019					
CT Identifier	NCT03432520	NCT03003533	NCT03734588					

# Pompe disease

# Spark Roche Roche

# Unique gene therapy platform

Molecule	SPK-3006 (RG6359)										
Indication	Pompe disease										
Phase/study	Phase I/II RESOLUTE										
# of patients	N=20										
Design	• Gene transfer study for late-onset Pompe disease										
Primary endpoint	• Safety										
Status	• FPI Q4 2020										
CT Identifier	NCT04093349										



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CHFm	HY 2021	HY 2022	% change CER		
Pharmaceuticals Division	21,671	22,347	+3		
United States	10,802	11,363	+1		
Europe	4,485	4,104	-4		
Japan	1,808	2,202	+34		
International	4,576	4,678	+2		
Diagnostics Division	9,042	9,948	+11		
United States	1,849	2,511	+31		
Europe	3,574	2,799	-17		
Japan	324	380	+29		
International	3,295	4,258	+30		
Group	30,713	32,295	+5		
United States	12,651	13,874	+5		
Europe	8,059	6,903	-10		
Japan	2,132	2,582	+33		
International	7,871	8,936	+14		

## Pharma Division sales HY 2022



## **Top 20 products**

	Glob	al	US			ре	Jap	an	Internat	tional
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	2,910	17	2,140	11	539	34	-	-	231	43
Perjeta	2,061	5	740	1	457	-17	120	-1	744	34
Hemlibra	1,826	30	1,098	26	360	30	180	19	188	89
Tecentriq	1,758	11	951	13	383	19	218	-7	206	9
Actemra / RoActemra	1,455	-10	664	-7	420	-3	174	4	197	-37
Herceptin	1,179	-16	263	-27	233	-11	28	-28	655	-11
Avastin	1,142	-29	342	-38	116	-53	263	-13	421	-20
MabThera	1,117	-21	691	-22	105	-17	17	-8	304	-19
Kadcyla	1,074	14	415	-1	350	10	68	23	241	52
Xolair	1,025	11	1,025	11	-	-	-	-	-	-
Alecensa	745	19	207	19	149	7	114	6	275	37
Ronapreve	609	11	-	-	65	-86	467	-	77	-30
Lucentis	572	-17	572	-17	-	-	-	-	-	-
TNKase / Activase	559	-10	531	-10	-	-	-	-	28	1
Evrysdi	500	106	227	32	152	489	38	-	83	65
Esbriet	457	-14	313	-17	127	-2	-	-	17	-36
Gazyva	349	8	161	2	95	-6	28	-2	65	88
Phesgo	325	241	138	155	163	338	-	-	24	403
Pulmozyme	279	0	184	2	51	-11	-	-	44	4
CellCept	270	-8	20	-16	68	-7	29	-8	153	-6
Pharma Division	22,347	3	11,363	1	4,104	-4	2,202	34	4,678	2

CER = Constant Exchange Rates (avg. full year 2021)

### Pharma Division sales HY 2022

# Roche

#### **Product sales Pharmaceuticals Division**

	Globa	al	US		Euro	ре	Jap	an	Internat	ional
_	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	2,910	17	2,140	11	539	34	-	-	231	43
Perjeta	2,061	5	740	1	457	-17	120	-1	744	34
Hemlibra	1,826	30	1,098	26	360	30	180	19	188	89
Tecentriq	1,758	11	951	13	383	19	218	-7	206	9
Actemra / RoActemra	1,455	-10	664	-7	420	-3	174	4	197	-37
Herceptin	1,179	-16	263	-27	233	-11	28	-28	655	-11
Avastin	1,142	-29	342	-38	116	-53	263	-13	421	-20
MabThera	1,117	-21	691	-22	105	-17	17	-8	304	-19
Kadcyla	1,074	14	415	-1	350	10	68	23	241	52
Xolair	1,025	11	1,025	11	-	-	-	-	-	-
Alecensa	745	19	207	19	149	7	114	6	275	37
Ronapreve	609	11	-	-	65	-86	467	-	77	-30
Lucentis	572	-17	572	-17	-	-	-	-	-	-
TNKase / Activase	559	-10	531	-10	-	-	-	-	28	1
Evrysdi	500	106	227	32	152	489	38	-	83	65
Esbriet	457	-14	313	-17	127	-2	-	-	17	-36
Gazyva	349	8	161	2	95	-6	28	-2	65	88
Phesgo	325	241	138	155	163	338	-	-	24	403
Pulmozyme	279	0	184	2	51	-11	-	-	44	4
CellCept	270	-8	20	-16	68	-7	29	-8	153	-6
Polivy	177	91	77	86	46	16	43	*	11	97
Erivedge	131	2	82	-3	30	6	-	-	19	22
Vabysmo	109	-	101	-	-	-	7	-	1	-
Enspryng	84	132	24	192	4	*	55	102	1	201
Rozlytrek	34	54	22	44	5	79	3	18	4	262
Cotellic	24	4	7	8	8	-9	-	-	9	16
Gavreto	12	-	9	-	3	-	-	-	-	-
Xofluza	4	-145	1	-117	_	-	-	-	3	*
Susvimo	2	-	2	-	-	-	-	-	-	-
Other Products	1,558	-13	356	-19	175	-21	350	-2	677	-14
Pharma Division	22,347	3	11,363	1	4,104	-4	2,202	34	4,678	2

CER = Constant Exchange Rates (avg. full year 2021); \* over 500%

# Pharma Division CER sales growth<sup>1</sup> in %



## Global top 20 products

	Q1/21	Q2/21	Q3/21	Q4/21	Q1/22	Q2/22
Ocrevus	16	31	7	25	18	17
Perjeta	2	7	2	3	1	9
Hemlibra	33	58	37	38	30	31
Tecentriq	26	31	23	17	8	13
Actemra / RoActemra	22	12	57	21	3	-23
Herceptin	-35	-35	-26	-6	-19	-11
Avastin	-40	-40	-37	-30	-32	-27
MabThera	-46	-34	-42	-26	-21	-20
Kadcyla	17	21	11	16	9	18
Xolair	-6	3	8	14	9	13
Alecensa	14	25	18	15	23	16
Ronapreve	-	-	-	-	272	-91
Lucentis	-7	2	-10	2	-26	-9
TNKase / Activase	-17	3	3	22	-20	1
Evrysdi	-	-	*	347	189	65
Esbriet	-8	1	-5	-7	-6	-21
Gazyva	-2	18	10	10	7	9
Phesgo	-	-	*	*	410	168
Pulmozyme	-23	-13	-7	5	-3	2
CellCept	-5	-3	3	-2	-12	-3

CER = Constant Exchange Rates; \* over 500%; 1 Q1-Q4/21 vs Q1-Q4/20; Q1-Q2/22 vs Q1-Q2/21

# Pharma Division CER sales growth<sup>1</sup> in %



#### Top 20 products by region

	US					Euro	ре			Jap	an		International			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Ocrevus	0	23	12	10	36	26	34	34		-	-	-	35	51	29	62
Perjeta	2	-2	-1	4	-8	-8	-21	-12	(	-3	-1	-1	16	24	32	37
Hemlibra	36	33	28	24	26	53	31	29	2	30	15	24	138	55	63	115
Tecentriq	10	2	10	15	16	41	14	24	7:	34	-5	-9	62	24	0	17
Actemra / RoActemra	143	67	22	-31	10	18	-4	-2	2	5 5	12	-2	-14	-55	-30	-44
Herceptin	-52	-34	-26	-29	-20	-3	-13	-9	-3	-36	-30	-27	-7	17	-18	-3
Avastin	-50	-45	-39	-36	-69	-49	-56	-49	ļ	5 0	-12	-13	-11	-24	-23	-17
MabThera	-49	-32	-20	-24	-33	-13	-19	-16	-30	-17	-15	-2	-25	-15	-23	-13
Kadcyla	0	3	0	-1	16	16	8	12	5	42	28	20	16	38	26	81
Xolair	8	14	9	13	-	-	-	-		. <u>-</u>	-	-	-	-	-	-
Alecensa	9	18	25	14	7	9	5	8	1	5	7	5	40	25	45	29
Ronapreve	-	-	-	-	-	-	-61	-99		-	-	-	-	-	-	-68
Lucentis	-10	2	-26	-9	-	-	-	-		-	-	-	-	-	-	-
TNKase / Activase	2	22	-21	1	-	-	-	-		-	-	-	17	7	-3	4
Evrysdi	*	112	36	28	-	*	*	227		-	-	-	-	*	*	-5
Esbriet	-2	-7	-4	-28	0	0	-5	1			-	-	-73	-36	-36	-36
Gazyva	3	11	0	3	10	2	-5	-8	10	-7	8	-10	43	56	75	101
Phesgo	*	236	187	134	-	-	*	188		-	-	-	-	*	*	278
Pulmozyme	-10	6	0	5	-10	-15	-11	-12	-18	3 22	11	44	12	45	-4	14
CellCept	-18	-31	-15	-17	-2	3	-7	-7		' -9	-8	-9	13	3	-14	3

CER = Constant Exchange Rates; \* over 500%; 1Q3-Q4/21 vs Q3-Q4/20; Q1-Q2/22 vs Q1-Q2/21

# CER sales growth (%)

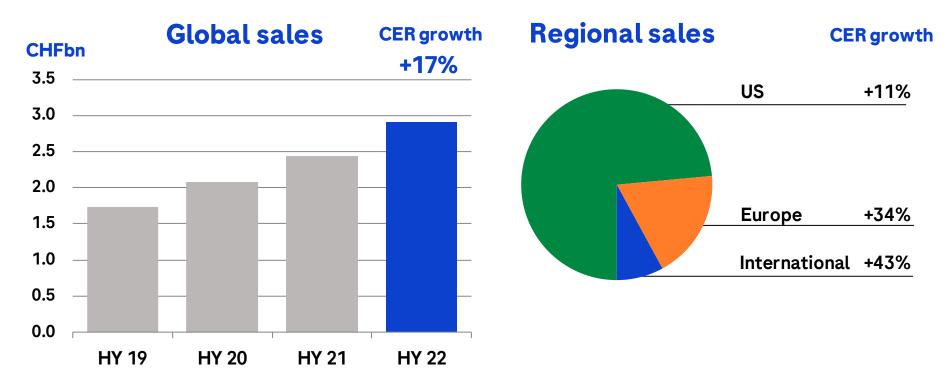


Quarterly development

		<b>2021</b> v	s. 2020		2022 vs. 2021			
	Q1	Q2	Q3	Q4	Q1	Q2		
Pharmaceuticals Division	-9	4	5	14	6	0		
United States	-14	0	0	8	2	1		
Europe	-6	15	1	19	-1	-6		
Japan	-7	7	60	46	69	3		
International	0	4	2	9	0	4		
<b>Diagnostics Division</b>	55	48	18	8	24	0		
Roche Group	3	14	8	12	11	0		

#### **Ocrevus**





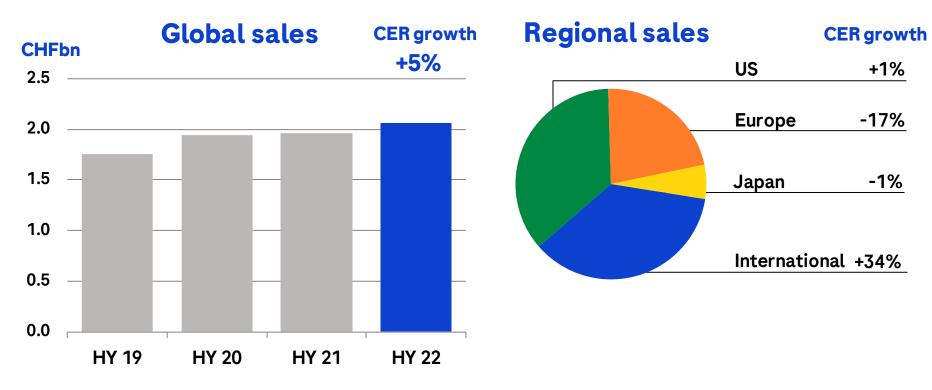
#### HY 2022 sales of CHF 2,910m

• US: Moving into earlier lines displacing orals; COVID-19 impact still felt

• EU: Moving into earlier lines displacing orals; COVID-19 impact still felt

# Perjeta





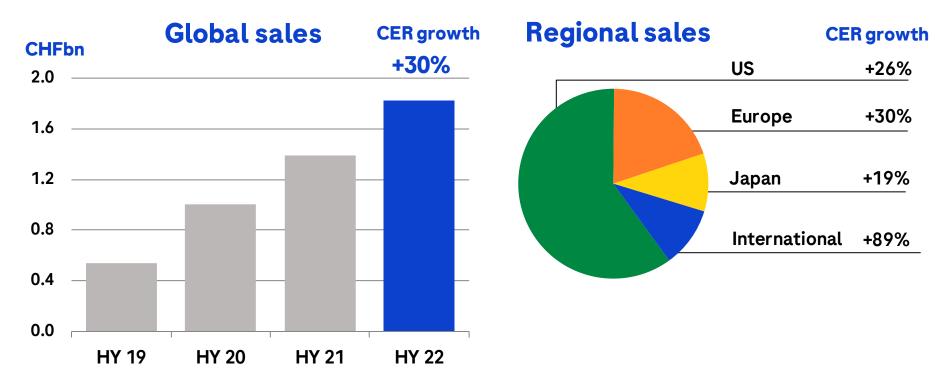
#### **HY 2022 sales of CHF 2,061m**

- US: Cannibalization from Phesgo
- EU: Cannibalization from Phesgo
- International: Accelerated growth in all regions

#### Hemlibra



172

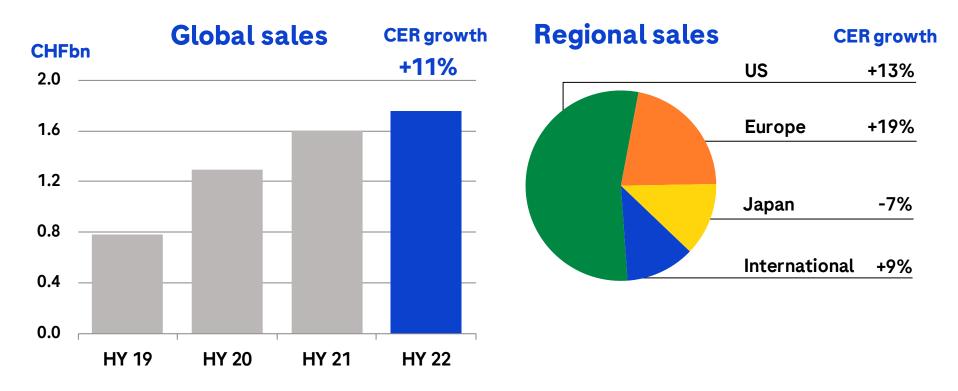


#### **HY 2022 sales of CHF 1,826m**

- US: Continued share gains in non-inhibitor patients
- EU: Continued share gains in non-inhibitor severe patients with market shares > 50% in France, UK and GER, Italy, Spain >20%
- Japan: Strong uptake in non-inhibitor patients
- International: Accelerating momentum driven by becoming new SoC in key markets

## **Tecentriq**



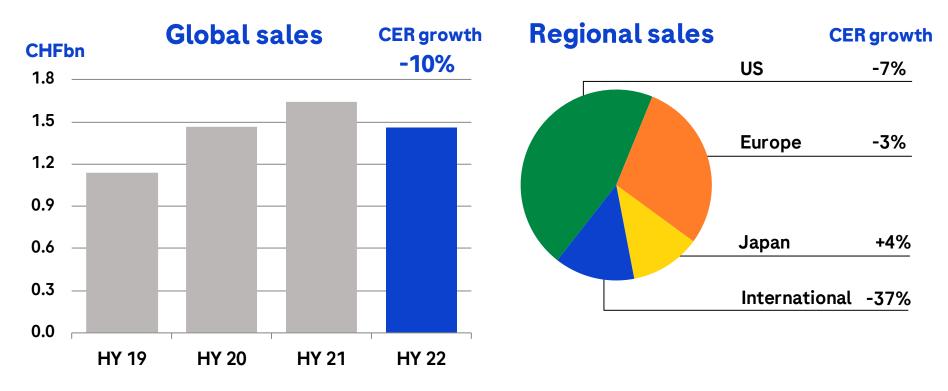


#### HY 2022 sales of CHF 1,758m

- US: Growth driven by first-in-class launches in adjuvant PDL1+ NSCLC, in 1L HCC and 1L SCLC
- EU: Growth driven by first-in-class launches in adjuvant PDL1+ NSCLC, in 1L HCC and 1L SCLC
- Japan: 11% price cut in Q3 2021

## Actemra / RoActemra





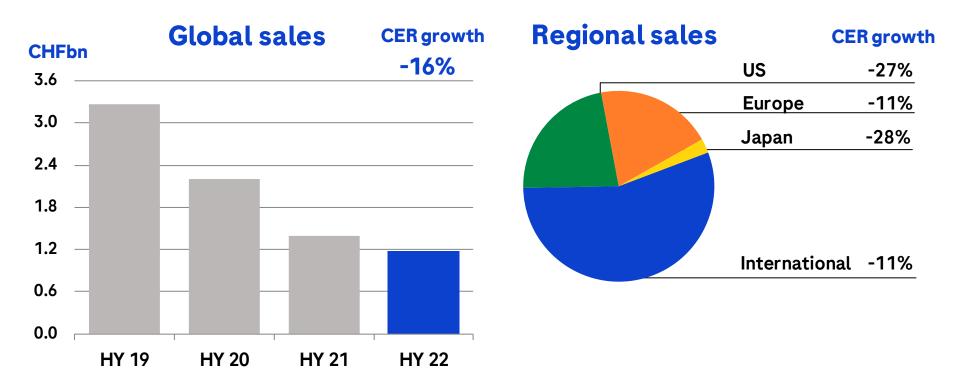
#### HY 2022 sales of CHF 1,455m

- US: Actemra SC share in RA keeps increasing; Limited COVID-19 sales in Q2 as hospitalizations have come down significantly
- EU: Market leadership in 1L RA monotherapy maintained; Limited COVID-19 sales in Q2 as hospitalizations have come down significantly

International: Limited COVID-19 sales in Q2 as hospitalizations have come down significantly

## Herceptin



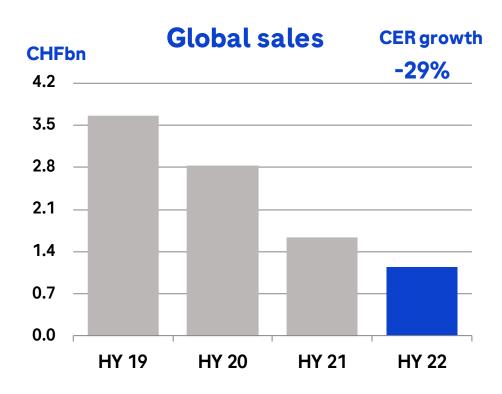


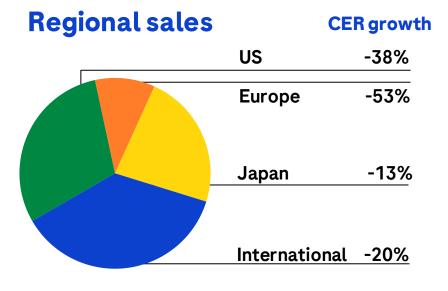
#### HY 2022 sales of CHF 1,179m

- US: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Cannibalization from Phesgo
- EU: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Cannibalization from Phesgo
- Japan: Decline due to biosimilars
- International: Decline due to biosimilars

#### **Avastin**





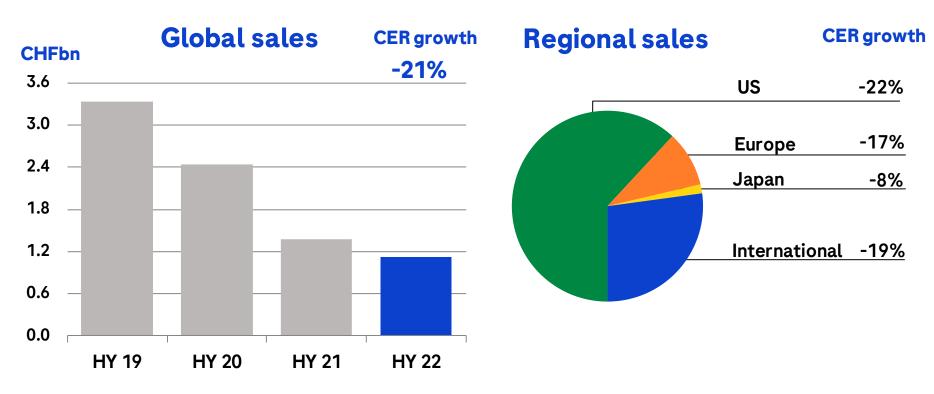


#### HY 2022 sales of CHF 1,142m

- US: Biosimilar erosion slowing
- EU: Biosimilar erosion slowing
- Japan: Limited decline due to biosimilars with narrow labels
- International: Biosimilar erosion slowing

## Rituxan / Mabthera



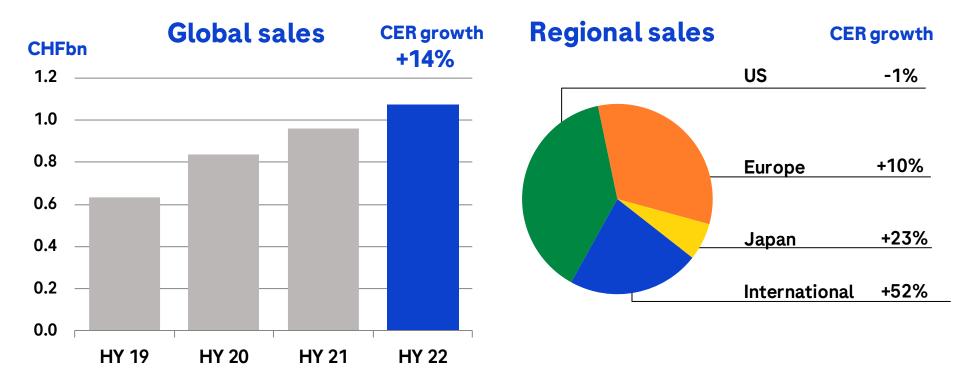


#### **HY 2022 sales of CHF 1,117m**

- US: Biosimilar erosion slowing
- EU: Biosimilar erosion slowing
- Japan: Biosimilar erosion slowing
- International: Biosimilar erosion slowing

# Kadcyla



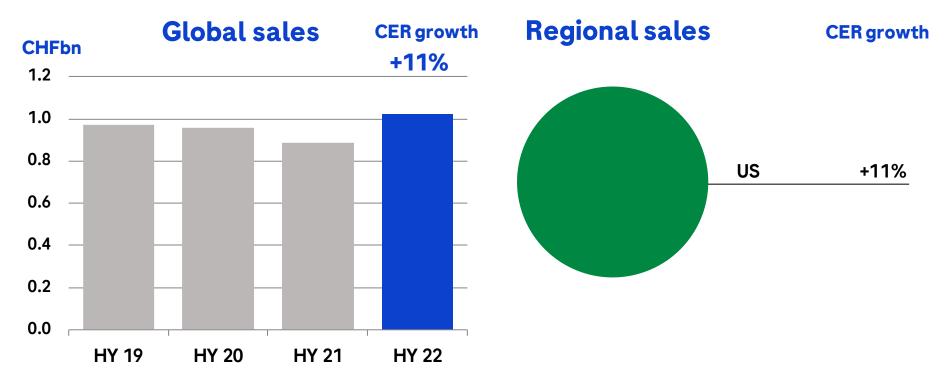


#### HY 2022 sales of CHF 1,074m

- US: Growth in adjuvant eBC; share decline in metastatic BC due to competition
- EU: Strong uptake in adjuvant eBC in patients with residual disease after neoadjuvant treatment
- International: Growth driven by all regions

## Xolair



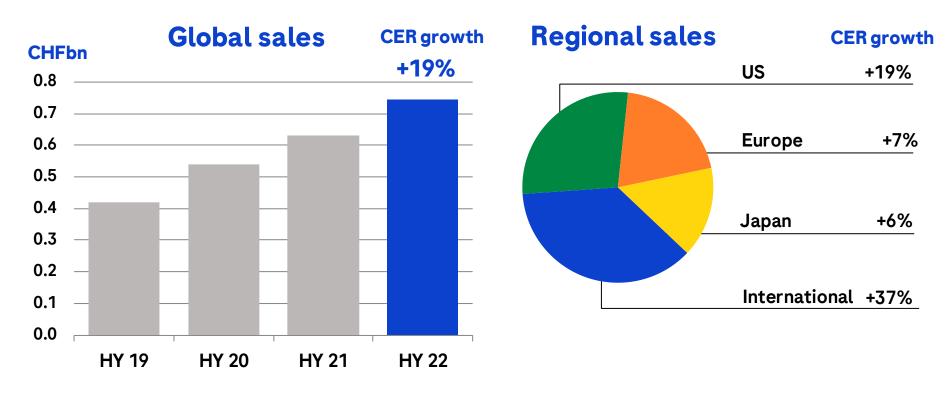


#### **HY 2022 sales of CHF 1,025m**

US: Xolair remains market leader in growing biologics asthma market; Growth driven by chronic idiopathic urticaria (CIU)

#### Alecensa



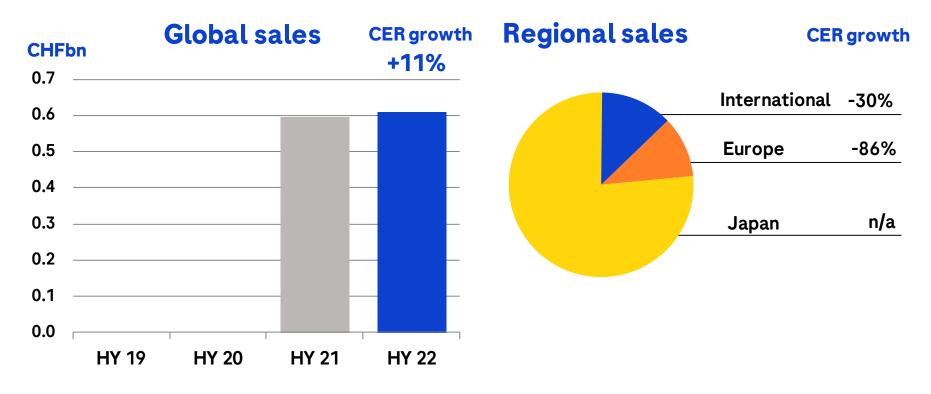


#### HY 2022 sales of CHF 745m

- US: New patient share in 1L at around 70%
- EU: EU-5 new patient share in 1L at around 70%
- Japan: New patient share in 1L reaching >70%
- International: Strong growth driven by China

## Ronapreve





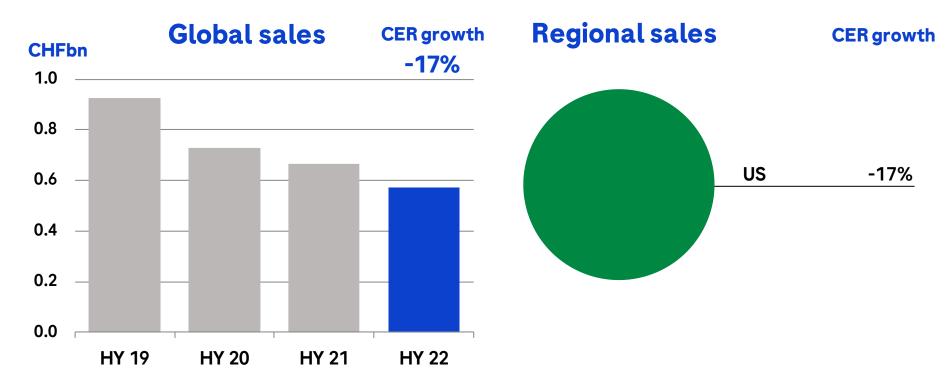
#### HY 2022 sales of CHF 609m

• EU: Limited sales potential left as Ronapreve has low activity against Omicron variants

Japan: Additional sales to the government (overall CHF 1.6bn for FY 2022)

## Lucentis



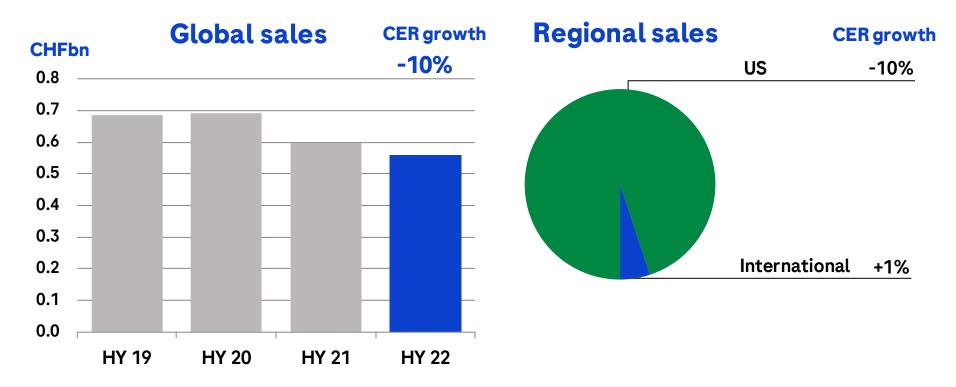


#### HY 2022 sales of CHF 572m

Impacted by switching to Vabysmo and upcoming biosimilar launches

# **TNKase / Activase**



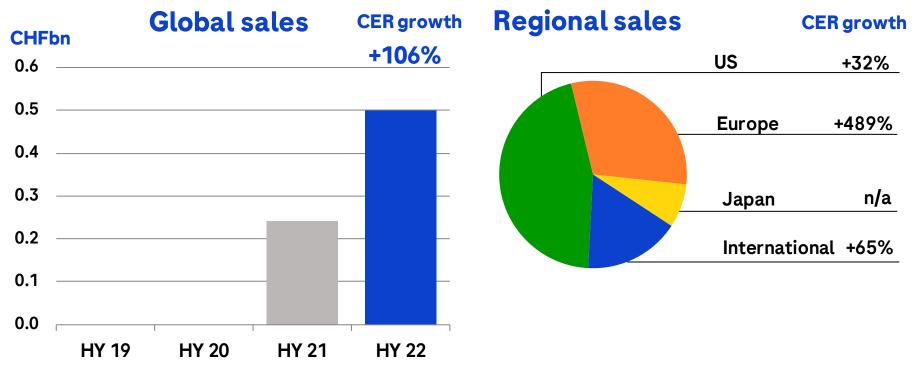


#### HY 2022 sales of CHF 559m

US: Sales impacted by COVID-19 and purchasing patterns

## **Evrysdi**



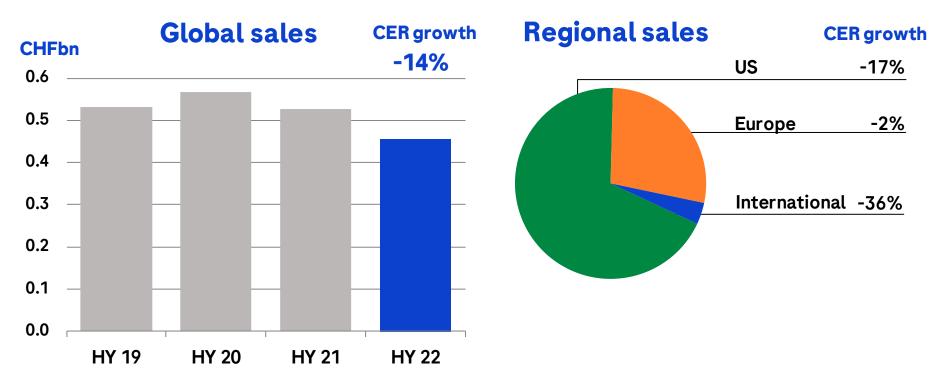


#### HY 2022 sales of CHF 500m

- US: Strong growth driven by switch and treatment-naïve patients; market share increasing >20%
- EU: Excellent growth driven by Germany and launches in key markets UK, Italy and France
- International: Strong growth in all regions

## **Esbriet**





#### HY 2022 sales of CHF 457m

US: Generics have entered the market in Q2

• EU: Generic entry expected soon



Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

**Spark** 

Pharma sales appendix

**Diagnostics sales appendix** 

Foreign exchange rates information





By Region and Customer Area (vs. 2021)

	Reported											Restatement <sup>3</sup>												
	Global CHFm %CER		EMEA¹ CHFm %CER		NOA CHFm %CER		APAC CHFm %CER		LATAM CHFm %CER			Global CHFm %CER		EMEA¹ CHFm %CER		NOA CHFm %CER		APAC CHFm %CER		LATAM CHFm %CER				
Core Lab <sup>2,3</sup>	3,834	4	1,313	6	714	2	1,521	3	286	12		3,875	4	1,352	5	716	1	1,521	3	286	12			
Point of Care <sup>3</sup>	2,289	43	585	-53	802	600	830	714	72	-30		2,609	46	652	-50	974	333	908	713	75	-28			
Molecular Lab³	2,341	7	838	2	888	7	544	20	71	-19		1,980	1	732	2	714	-1	466	6	68	-21			
Diabetes Care	832	-5	454	-3	116	-30	144	1	118	24		832	-5	454	-3	116	-30	144	1	118	24			
Pathology Lab	652	10	160	11	348	8	132	13	12	30		652	10	160	11	348	8	132	13	12	30			
Diagnostics Div.	9,948	11	3,350	-14	2,868	34	3,171	39	559	2		9,948	11	3,350	-14	2,868	34	3,171	39	559	2			





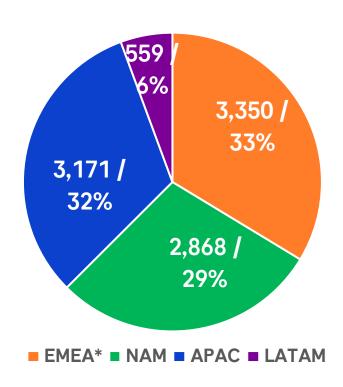
	Reported												Restatement <sup>3</sup>											
	Q1 21 CHFm %CER		<b>Q2 21</b> CHFm %CER		Q3 21 CHFm %CER		Q4 21 CHFm %CER		Q1 22 CHFm %CER		Q2 22 CHFm %CER		Q1 21 CHFm %CER		Q2 21 CHFm %CER		Q3 21 CHFm %CER		Q4 21 CHFm %CER		Q1 22 CHFm %CER		Q2 22 CHFm %CER	
Core Lab <sup>2,3</sup>	1,765	31	1,961	36	1,884	12	1,863	10	1,873	8	1,961	1	1,786	31	1,984	36	1,907	12	1,883	9	1,896	8	1,979	1
Point of Care <sup>3</sup>	716	281	900	424	442	143	525	-2	1,302	84	987	10	806	255	992	464	617	222	719	15	1,466	84	1,143	15
Molecular Lab <sup>3</sup>	1,107	86	1,109	19	1,238	21	1,358	15	1,376	26	965	-13	996	87	994	9	1,040	5	1,144	7	1,189	21	791	-20
Diabetes Care	460	13	434	7	400	-7	396	-2	417	-7	415	-3	460	13	434	7	400	-7	396	-2	417	-7	415	-3
Pathology Lab	282	9	308	32	299	4	313	7	318	14	334	7	282	9	308	32	299	4	313	7	318	14	334	7
Diagnostics Div.	4,330	55	4,712	48	4,263	18	4,455	8	5,286	24	4,662	0	4,330	55	4,712	48	4,263	18	4,455	8	5,286	24	4,662	0

# HY 2022: Diagnostics Division regional sales

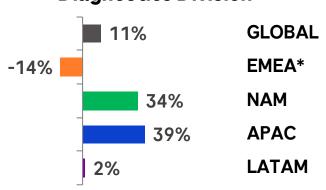


Growth driven by Asia Pacific and North America

Sales YTD CHFm & % of total sales
Total YTD Sales = 9,948

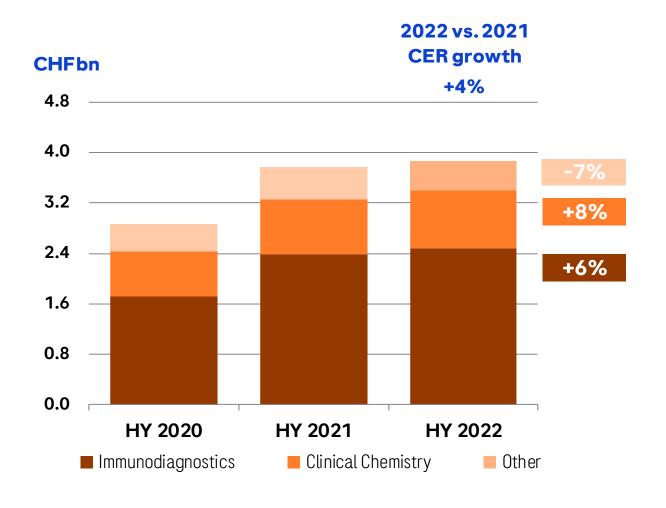


# Sales growth at CER Diagnostics Division



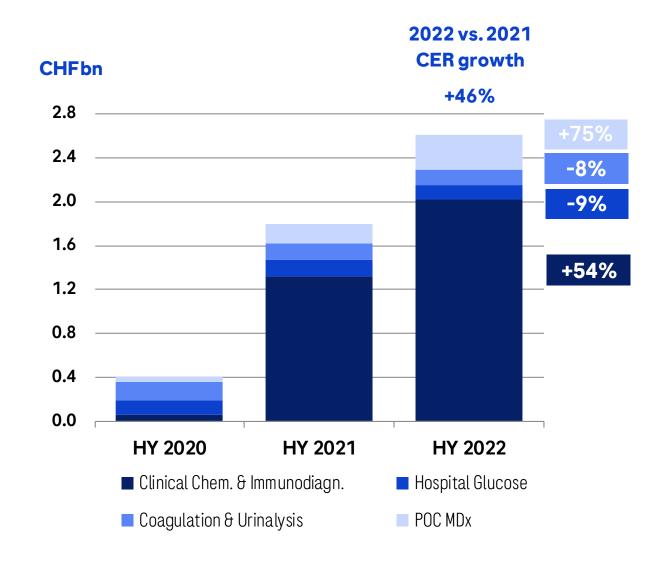
## **Core Lab**





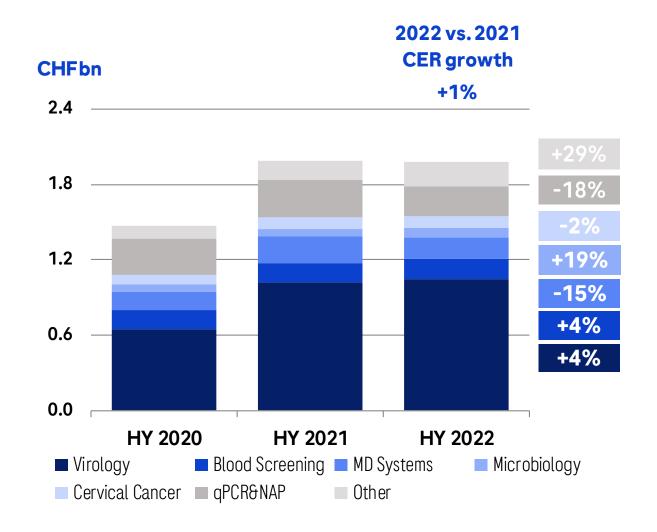
## **Point of Care**





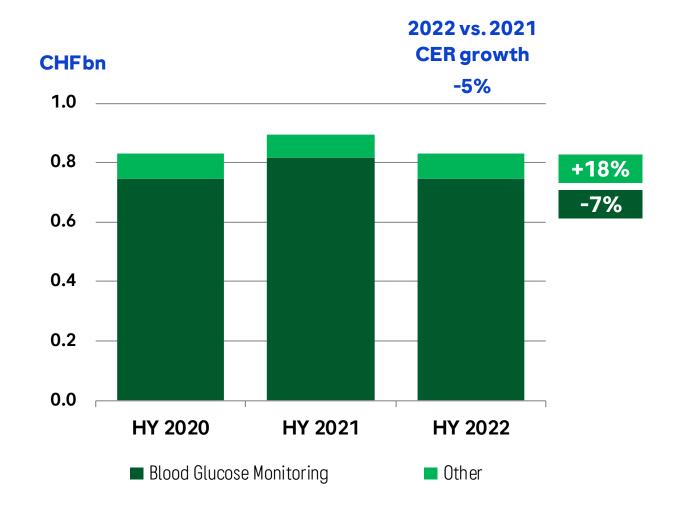
#### **Molecular Lab**





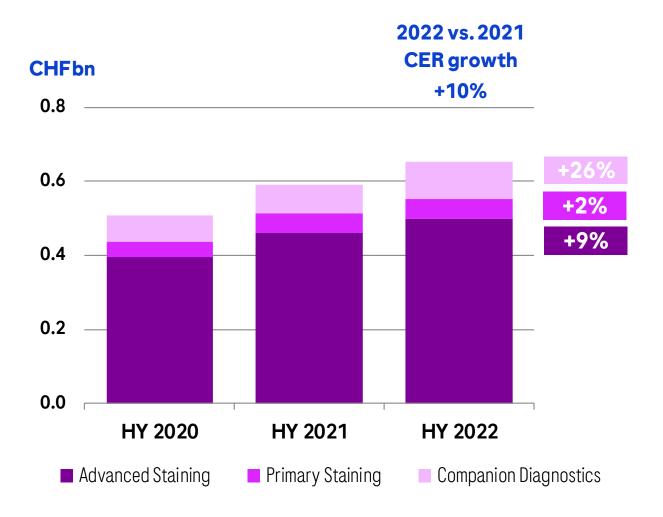
## **Diabetes Care**





# **Pathology Lab**







Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

**Spark** 

Pharma sales appendix

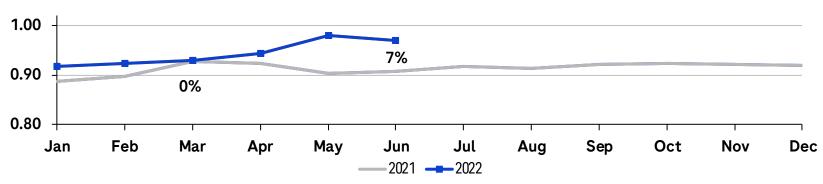
Diagnostics sales appendix

Foreign exchange rates information

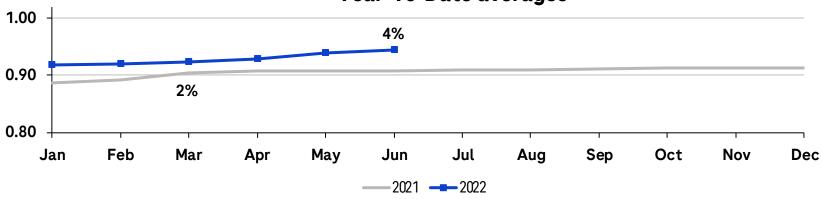
# CHF/USD





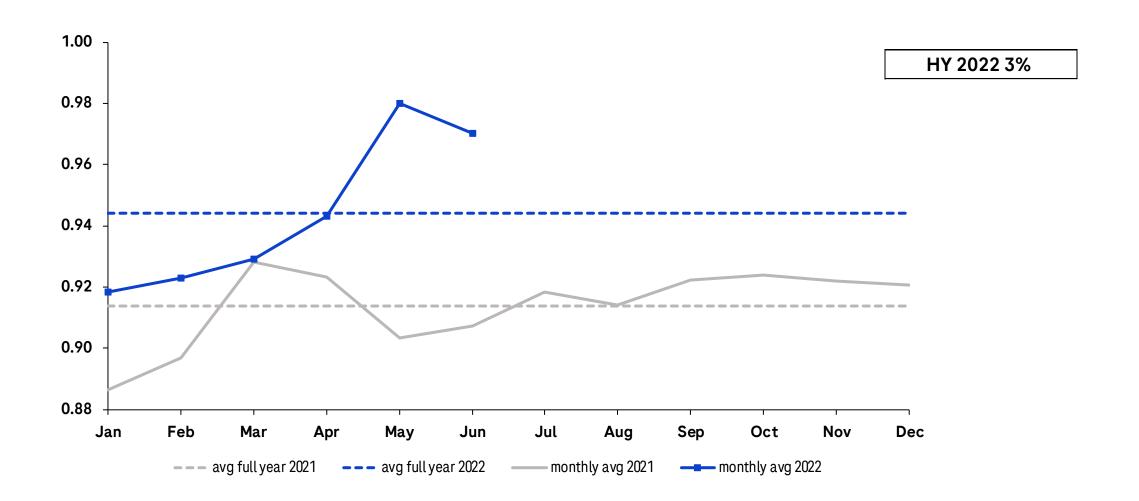


#### **Year-To-Date averages**



# CHF/USD

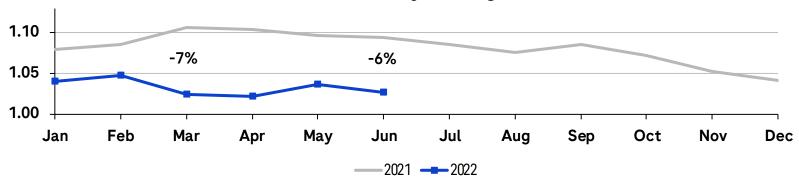


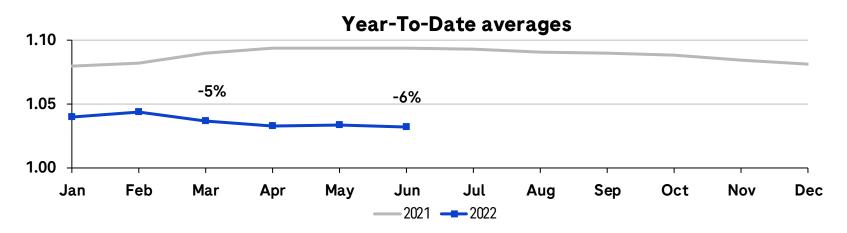


# **CHF/EUR**



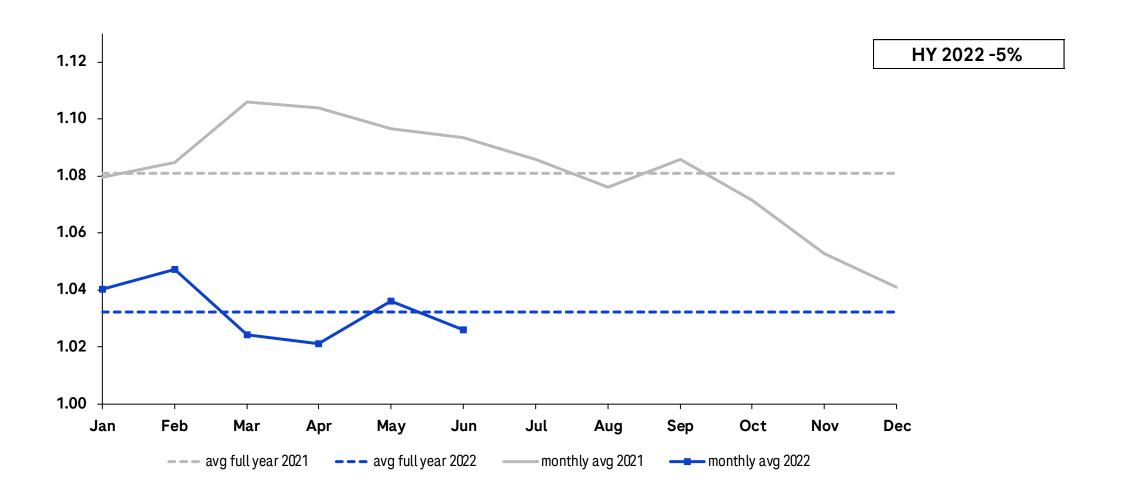






# **CHF/EUR**

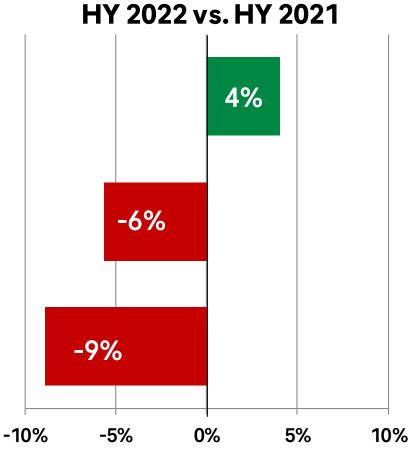




# **Average CHF Exchange Rates**





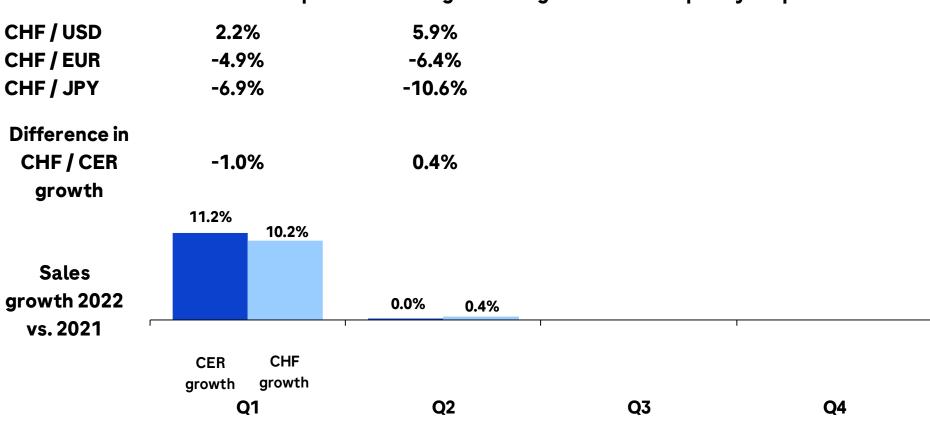






Q2 2022: negative impact of JPY and EUR, positive impact of USD

#### Development of average exchange rates versus prior year period

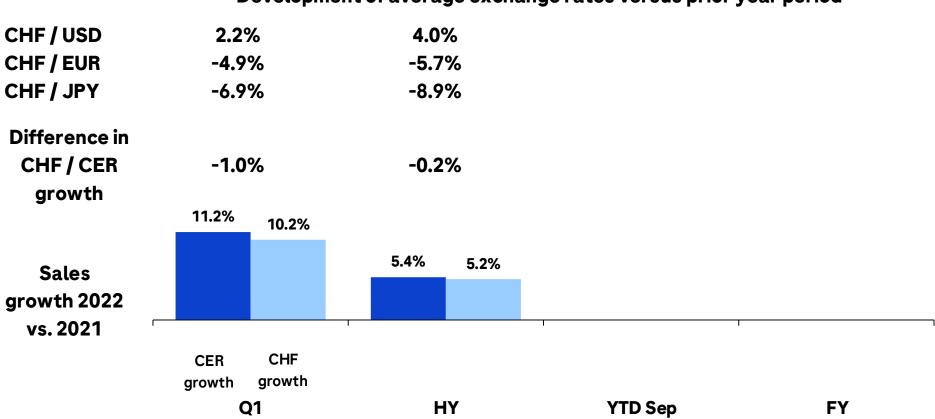






HY 2022: negative impact of JPY and EUR, positive impact of USD

#### Development of average exchange rates versus prior year period



Doing now what patients need next