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

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# 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)

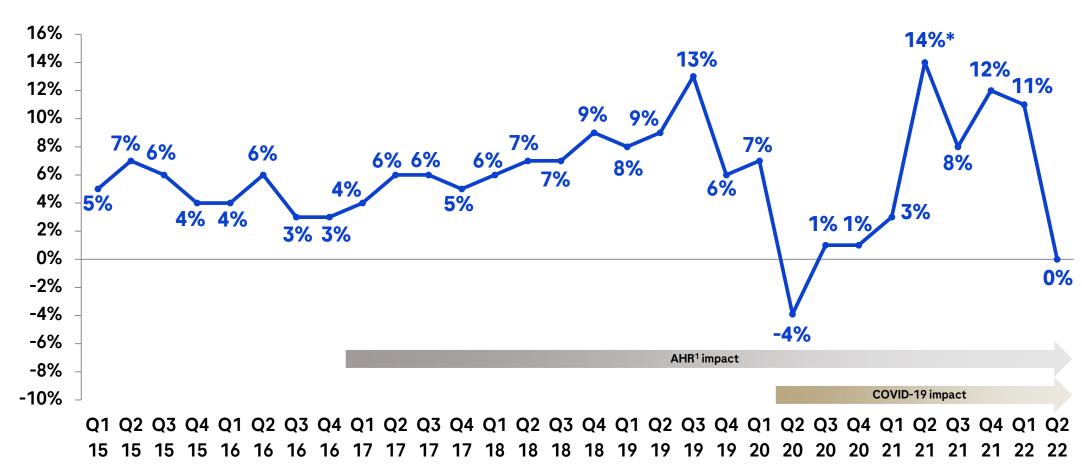




	2022	2021	Change in %	
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	22.3	21.7	3	3
Diagnostics Division	9.9	9.0	10	11
Roche Group	32.3	30.7	5	5

# Roche

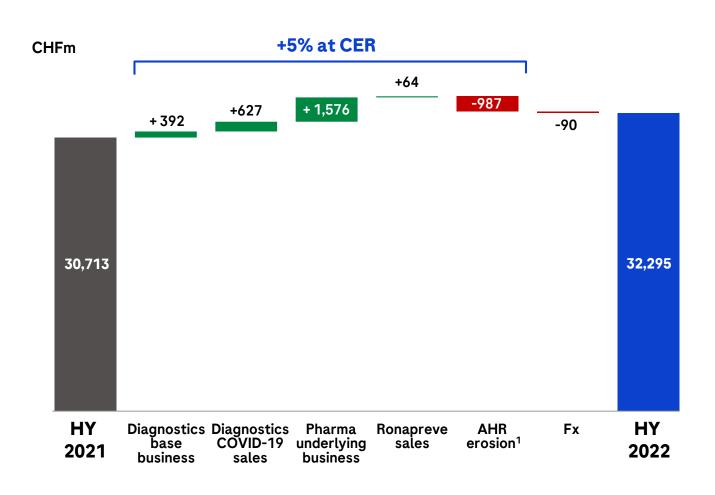
# Quarterly sales performance: As guided COVID-19 sales coming down in Q2



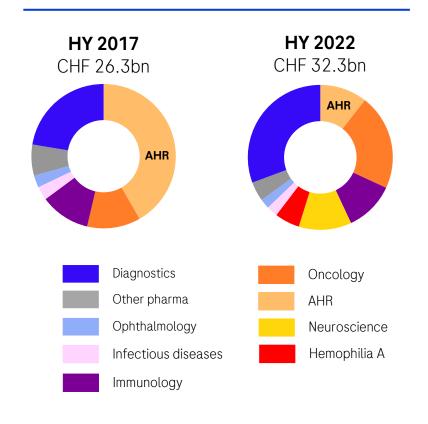
Growth rates at CER (Constant Exchange Rates); \* Q2 2020 sales severely impacted by COVID-19 pandemic onset; 1AHR: Avastin, Herceptin, Rituxan/MabThera

# HY 2022: Portfolio diversification progressing





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

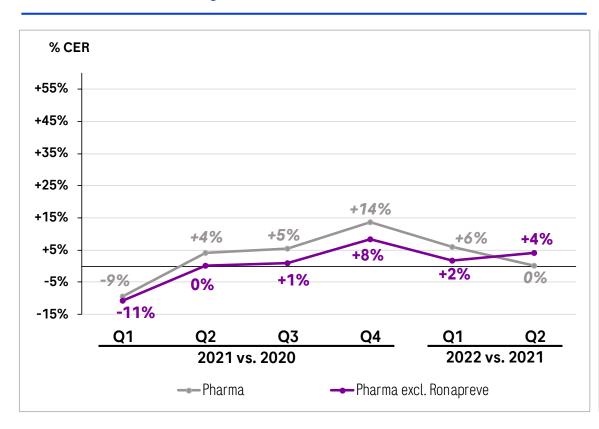


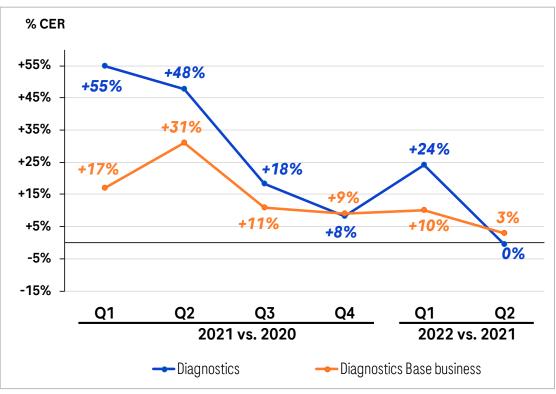




Pharma
Quarterly sales evolution 2021-2022

Diagnostics **Quarterly sales evolution 2021-2022** 

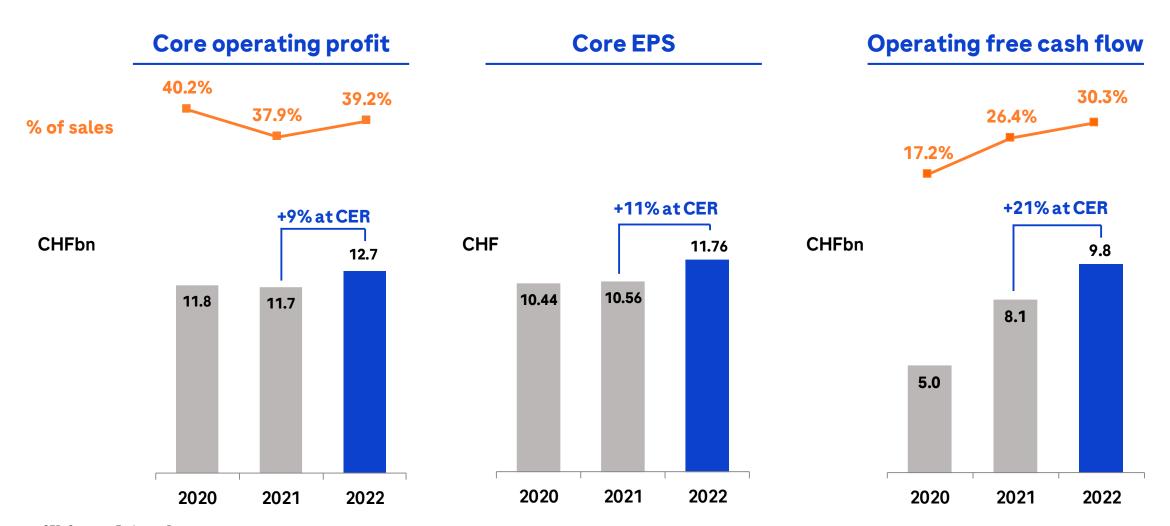




# HY 2022: Growth of profitability and Core EPS



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

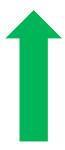


**Upcoming** launches

### 2022 sales outlook confirmed

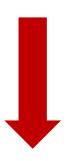


#### Sales drivers<sup>1</sup>



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

### 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	Change 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

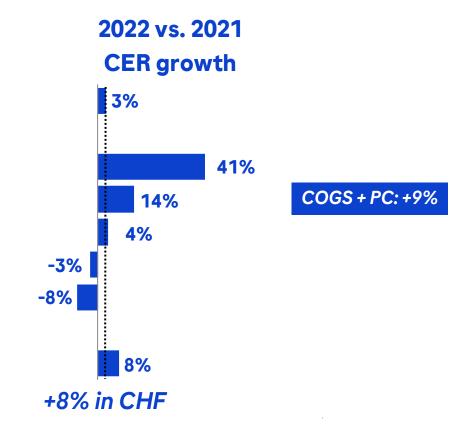




Core operating profit growth driven by patent settlement

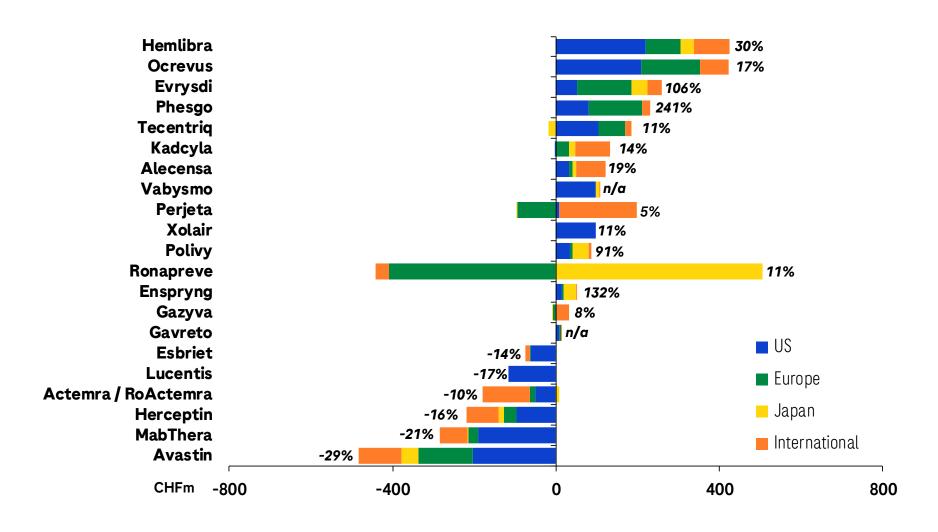
	20	2022		
	CHFm	% sales		
Sales	22,347	100		

Jaies	22,577	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
Core operating profit	10,318	46



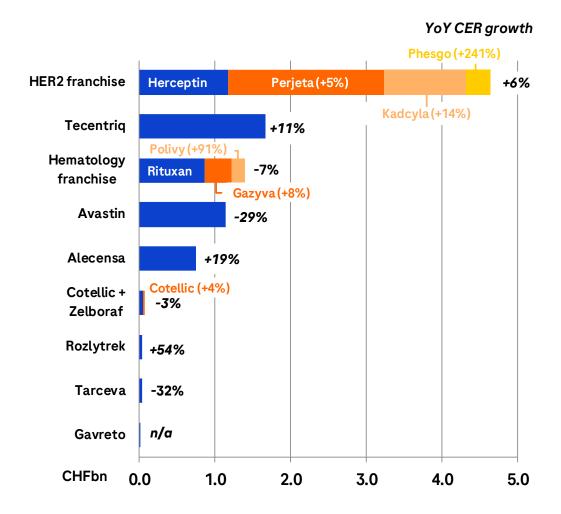






## HY 2022: Oncology portfolio rejuvenation on-going





#### **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**

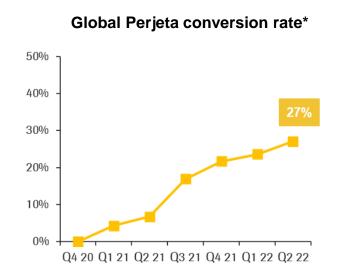
• Strong growth (+19%) driven by all regions

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



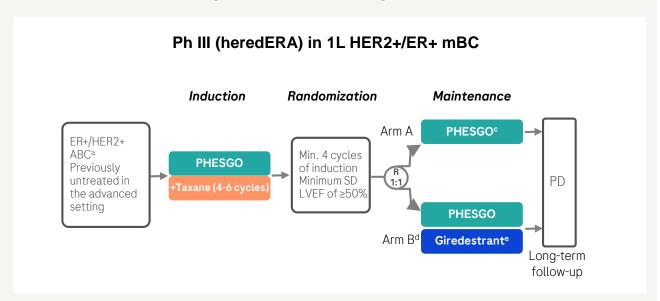
Perjeta conversion rate at 27% in early launch countries

# 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

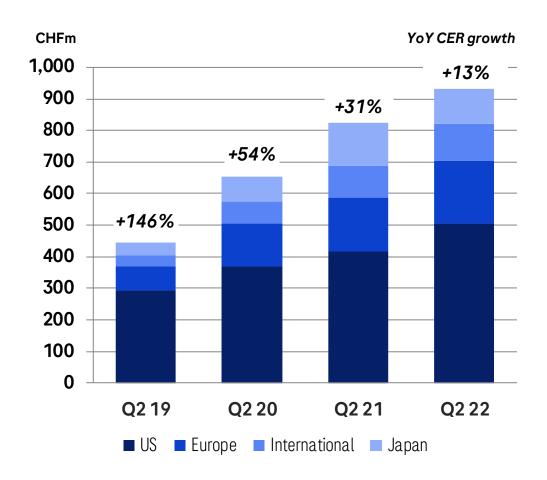
#### Continuing to build on existing standard of care



- 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

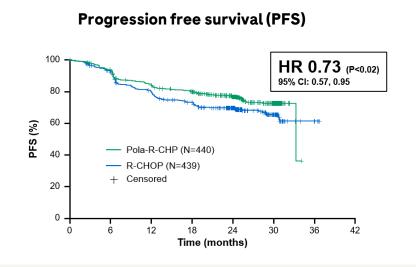
## Hematology franchise: Setting new standards of care





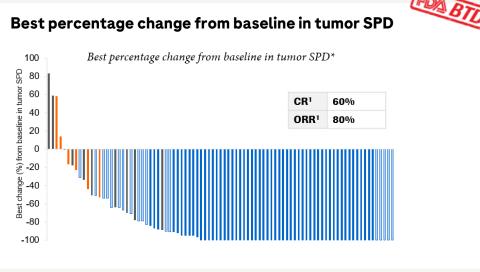
First-in-class EU approvals in 1L DLBCL and 3L+ FL

### 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





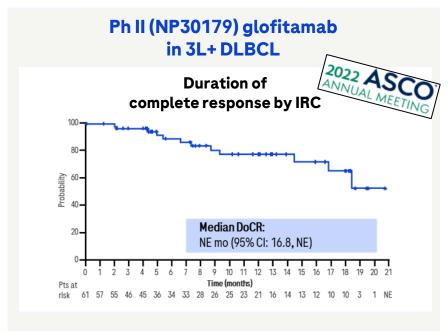
- 60% CR rate (greater than 14% historical control) with the majority of responses lasting for at least 18 months
- Fixed duration treatment; Favorable tolerability profile suitable for outpatient setting (CRS low grade and cycle 1)
- EU approval in 3L+ FL achieved; Filed in US with priority review granted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

### Hematology franchise development program



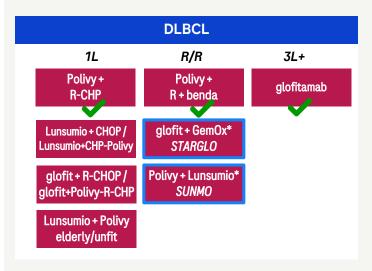


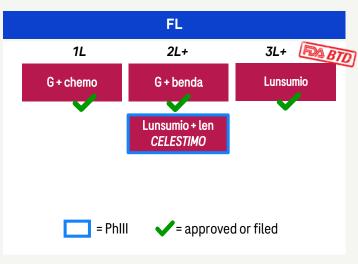
Potential first-in-class & best-in-class combinations



- 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





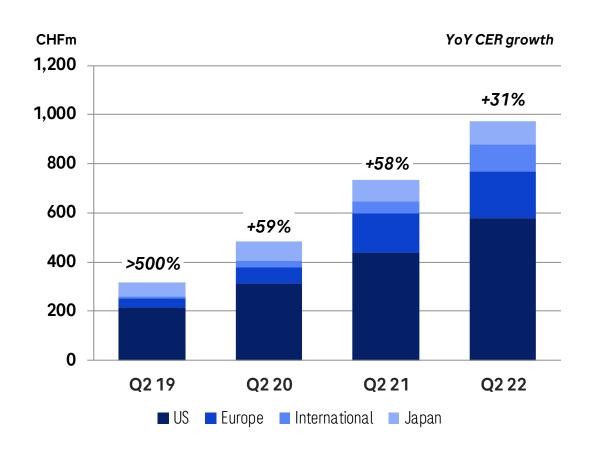
- Lunsumio: Attractive profile for the outpatient setting and across a broad range of indications and settings; no hospitalization required
- Glofitamab: Best-in-class efficacy potential with high CR rates, durable responses and manageable CRS with fixed treatment duration
- Ph III development program 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

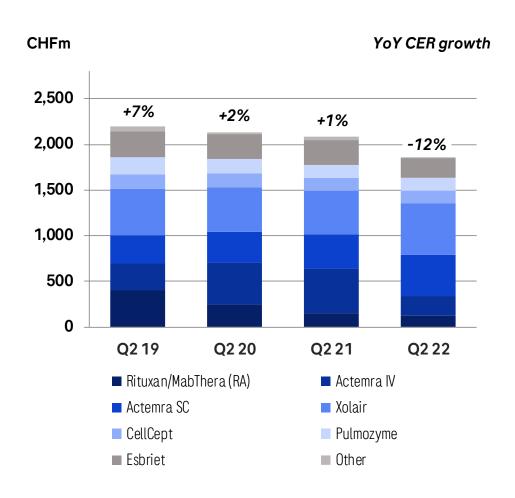
- US/EU: Further patient share gains in non-inhibitors
- EU: Label expansion to include mild/moderate patients (HAVEN 6) expected
- Ph III (HAVEN 7) in infants (0-1 year) interim results expected

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

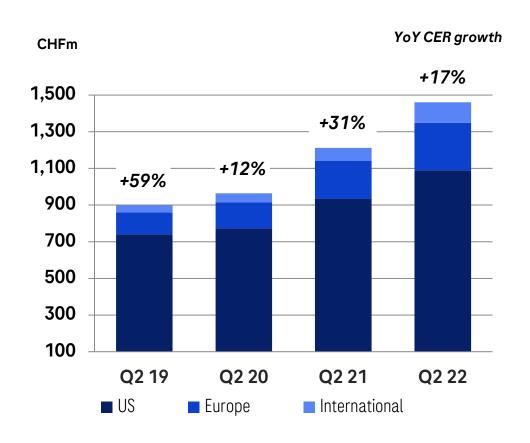
#### Outlook 2022

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
- Highest persistence amongst MS medicines
- 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

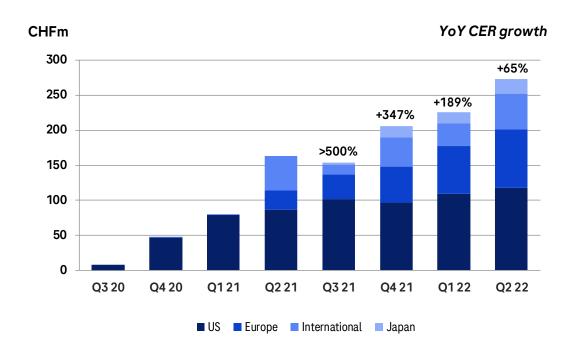
#### Outlook 2022

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

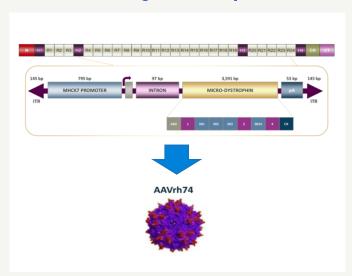
- Continued growth and market share gains over all market segments expected
- EU: Label extension (<2 months old) based on Ph II RAINBOWFISH expected

### Duchenne muscular dystrophy franchise update



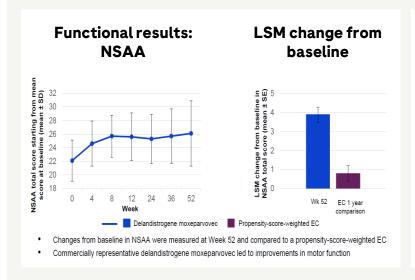


#### **Delandistrogene moxeparvovec**

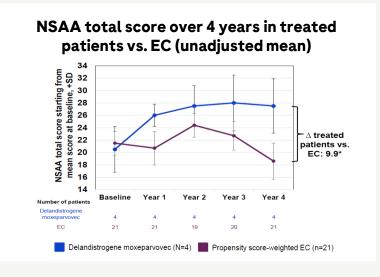


- Targeted delivery of micro-dystrophin transgene to key muscle tissue can enable meaningful and durable functional response
- AAVrh74 vector: low likelihood of pre-existing immunity and high tropism for skeletal & cardiac muscles
- Expression potentiated by the MHCK7 promoter in cardiac & skeletal muscles

#### 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

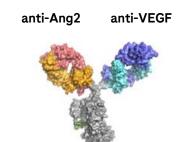




### Building a global ophthalmology franchise

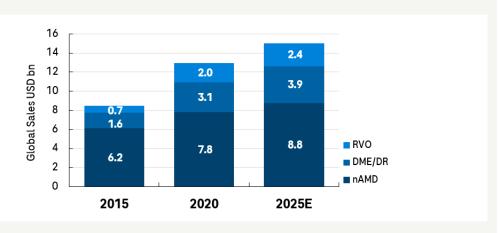
#### Vabysmo in nAMD and DME





- 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

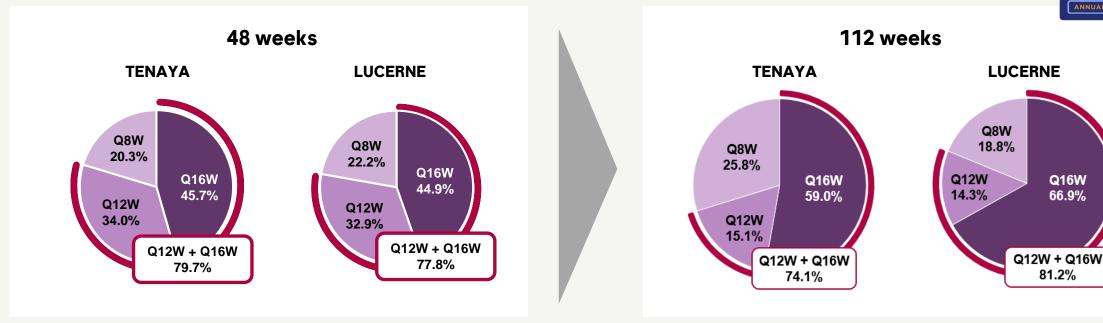




At 112 weeks Q16W dosing increases to ≥ 60%

### 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	×
	Tecentriq + chemo	Adjuvant SCCHN	Ph III IMvoke010	2023
	Tecentriq + tiragolumab	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	Continues to OS IA
Phase III / pivotal readouts	Tecentriq	Adjuvant RCC	Ph III IMmotion010	X
	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

/ Roch

Roche ESG Day
Access to Healthcare

Monday, 16 May

15:00 to 16:30 CEST

Virtual event 
ASCO

Monday, 6 June

16:00 to 17:30 CEST

Roche Pharma Day London Monday, 12 September

10:00 to 15:00 BST

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





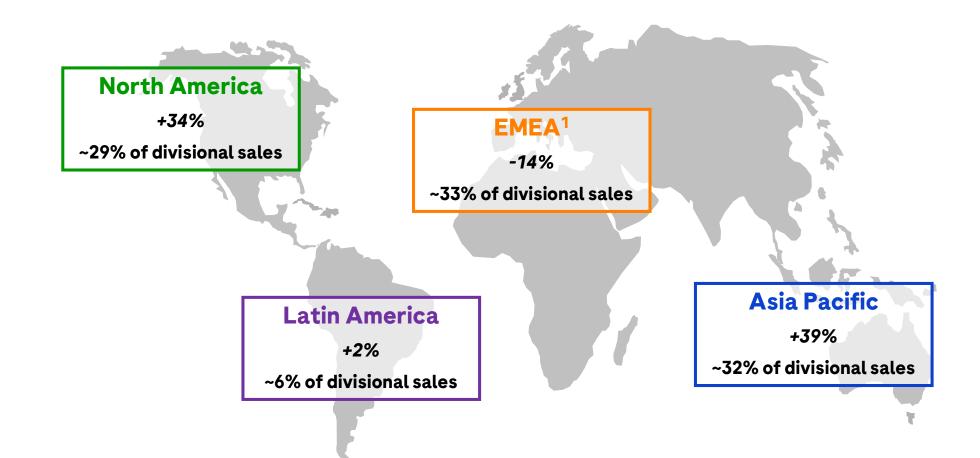
Sales increase of +11% driven by COVID-19 testing and base business

	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

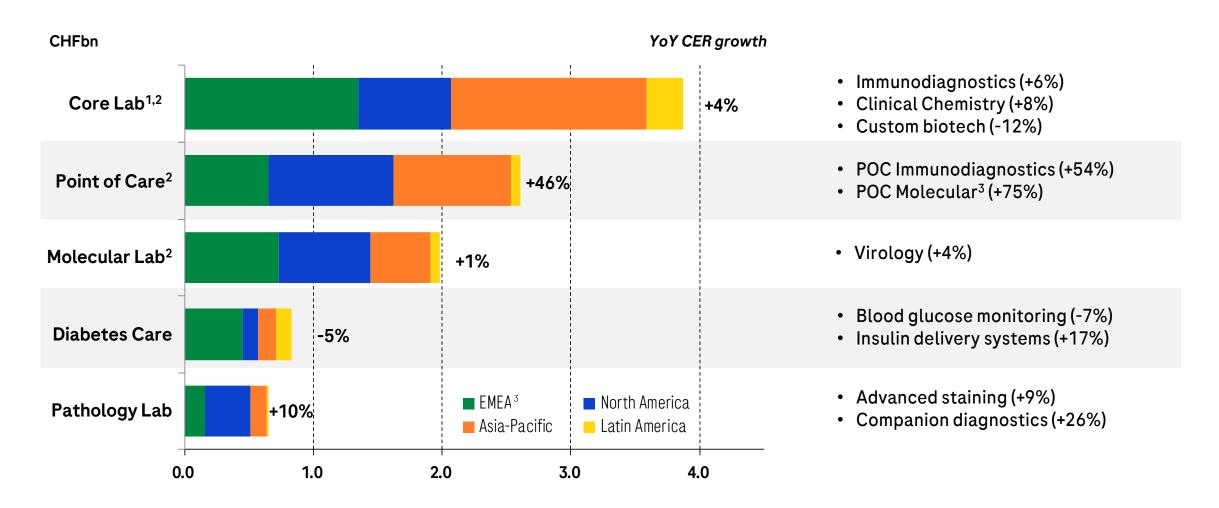


Growth rates at CER (Constant exchange Rates); <sup>1</sup> Europe, Middle East and Africa

# **HY 2022: Diagnostics Division highlights**



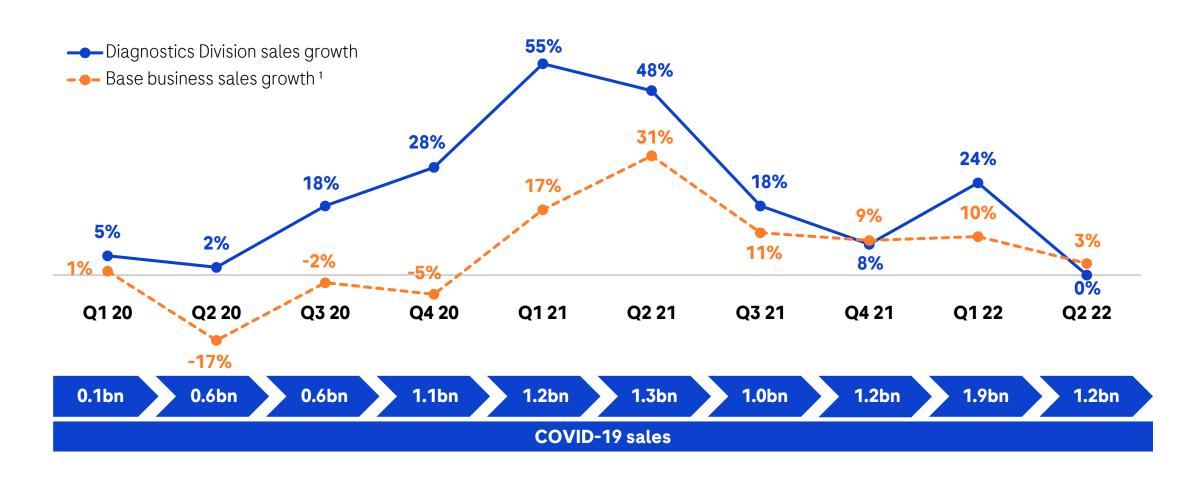
Strong growth despite a high base in HY 2021



# Diagnostics Division sales growth by quarter



Strong COVID-19 sales and base business growth



# **HY 2022: Diagnostics Division**



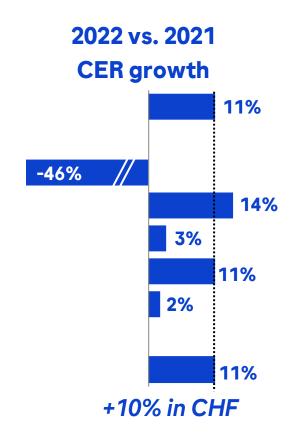
39

Strong core operating profit growth of +11%

20	22	
CHFm	%	sales

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** Step1 Step 2 **T-Cell Stimulation** Quantification of IFN-y (on Roche IA instrument) SARS-CoV-2 Positive Negative Control Control specific tube

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

**Negative control**: no stimulus, controls for baseline IFN-y level

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

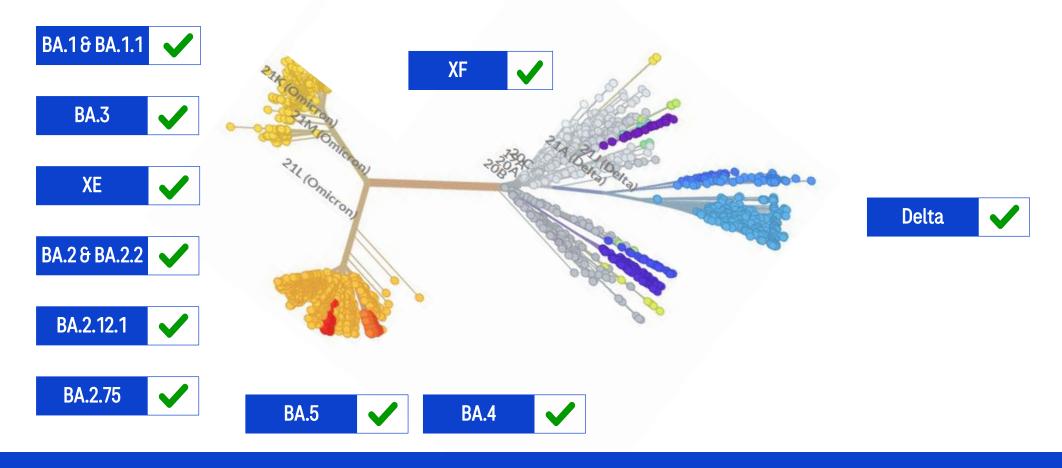
Quality control passed (?) SARS-CoV-2 specific IFN-y response, determines reactivity

- 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

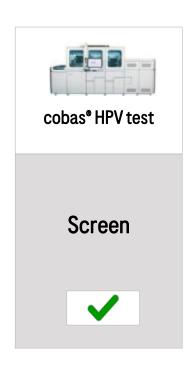
# cobas® HPV self-sampling solution

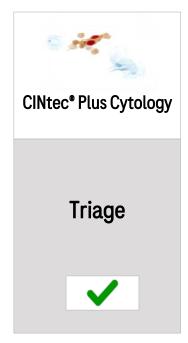


Increasing screening adherence to potentially reach 1.7bn women globally

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









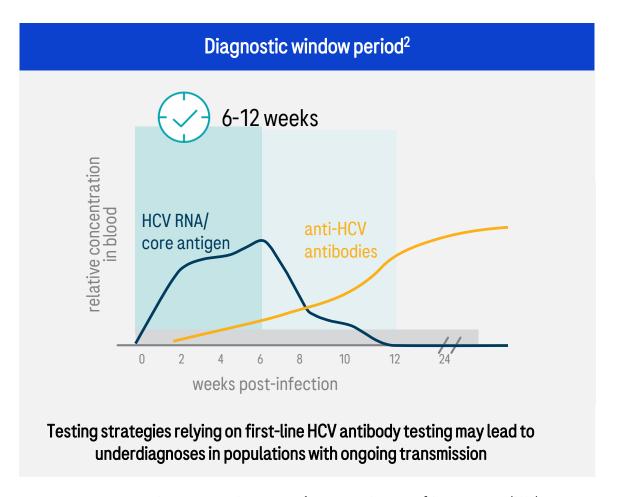


90% correlation between clinician collected endocervical and self-collected vaginal specimens<sup>1</sup>

# 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)



### 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	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	
Instruments	Core Lab	cobas® pure integrated solutions	Serum work area analyzer for low-to-medium sized labs	US	
ilisti dillelits	Molecular Lab	cobas® 5800	Real-time PCR molecular testing for low volume labs	US	
	Molecular 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		cobas® HCV Duo	Antigen/antibody combined assay for faster diagnosis of hepatitis C	CE	
16313	Core Lab	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	
		Chronic Kidney Disease InSight	Digital solution (mobile app and dashboard) providing insights for chronic kidney disease patient management	CE	
Digital Solutions	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	
octutions		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>	
	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



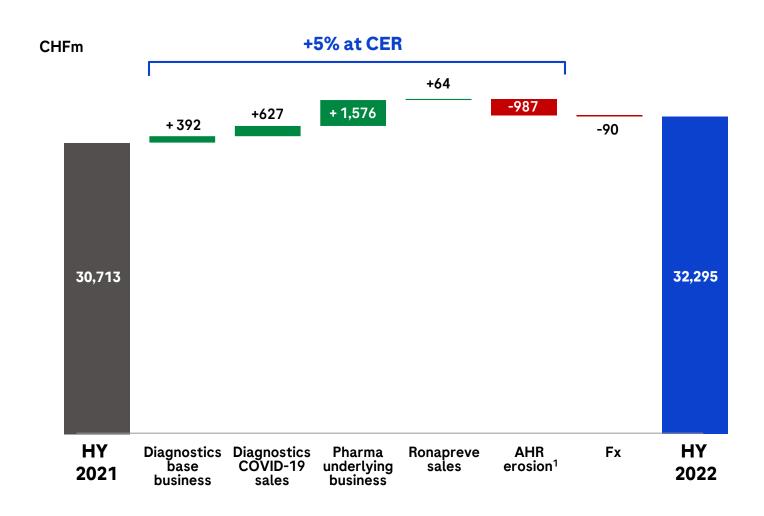


	2022	2021	Change	e in %
	CHFm	CHFm	CHF	CER
Sales	32,295	30,713	5	5
Core operating profit	12,668	11,652	9	9
as % of sales	39.2	37.9		
Core net income	10,160	9,527	7	7
as % of sales	31.5	31.0		
Core EPS (CHF)	11.76	10.56	11	11
IFRS net income	9,161	8,216	12	12
as % of sales	28.4	26.8		
Operating free cash 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

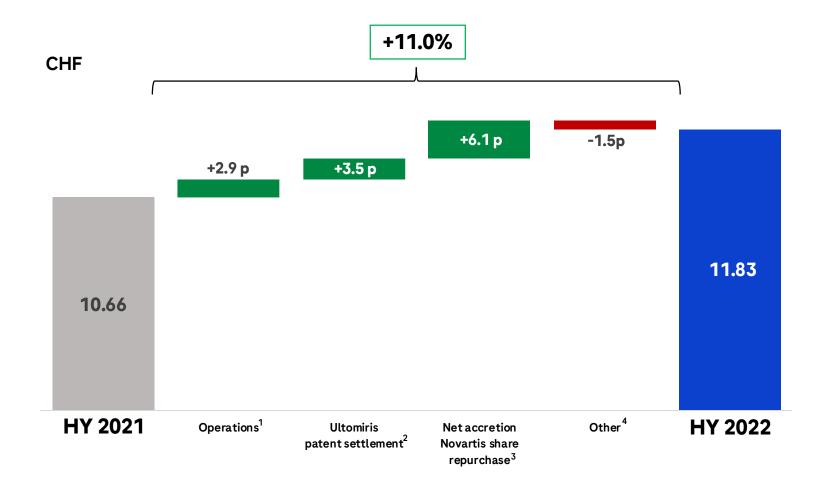








Strong EPS development driven by growth in operations and accretion effect



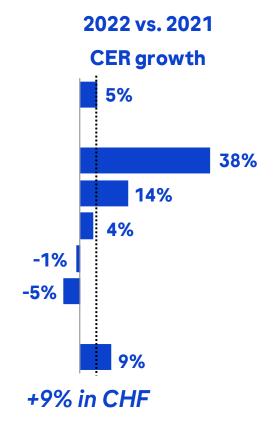




55

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

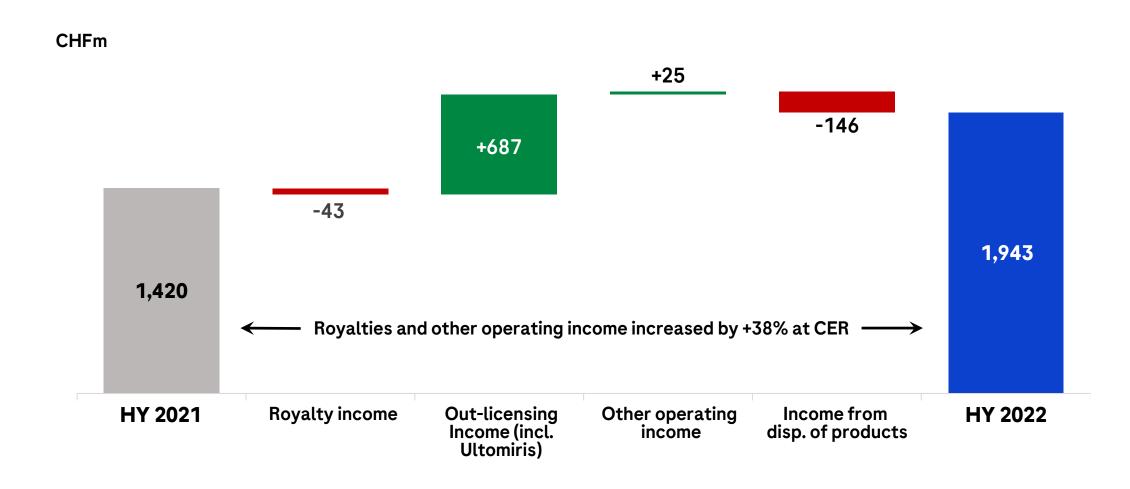
	20	22
	CHFm	abs. CER
Sales	32,295	+1,672
Royalties & other op. inc.	1,943	+536
Cost of sales	-9,305	-1,119
M & D	-4,459	-159
R & D	-6,628	+85
G & A	-1,178	+63
Core operating profit	12,668	+1,078



# HY 2022: Royalties and other operating income



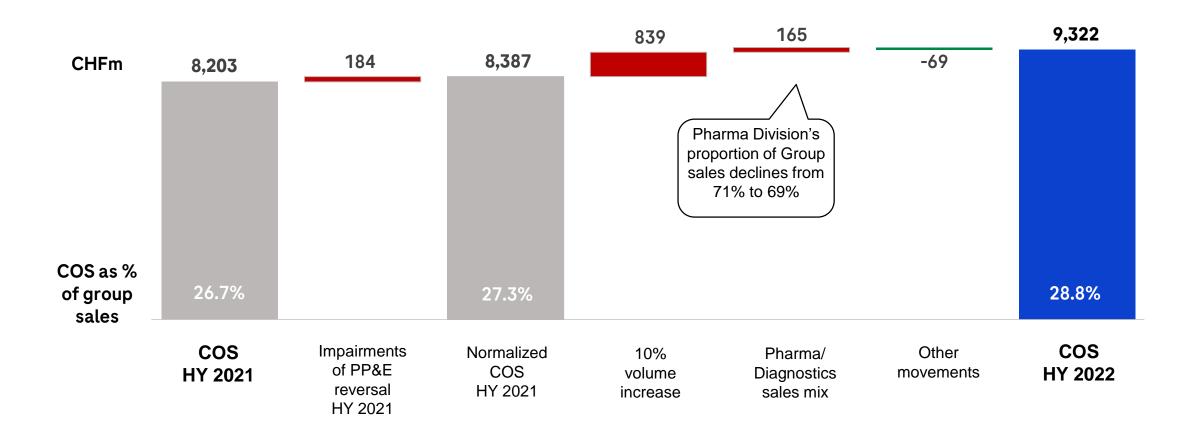
Higher income mainly driven by Ultomiris patent settlement



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

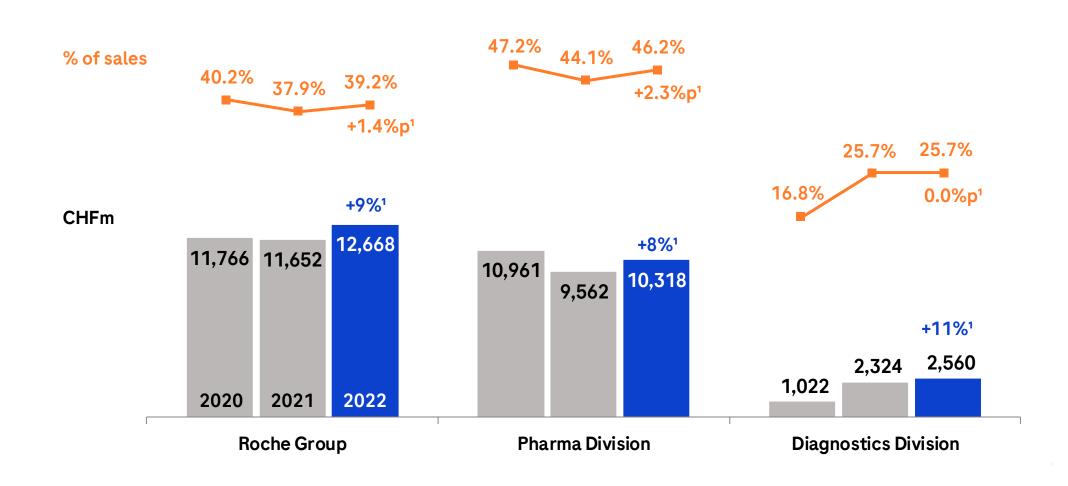


Increase due to PP&E reversal in 2021, volume growth and change in the Pharma/Diagnostics sales mix



# HY 2022: Core operating profit and margin



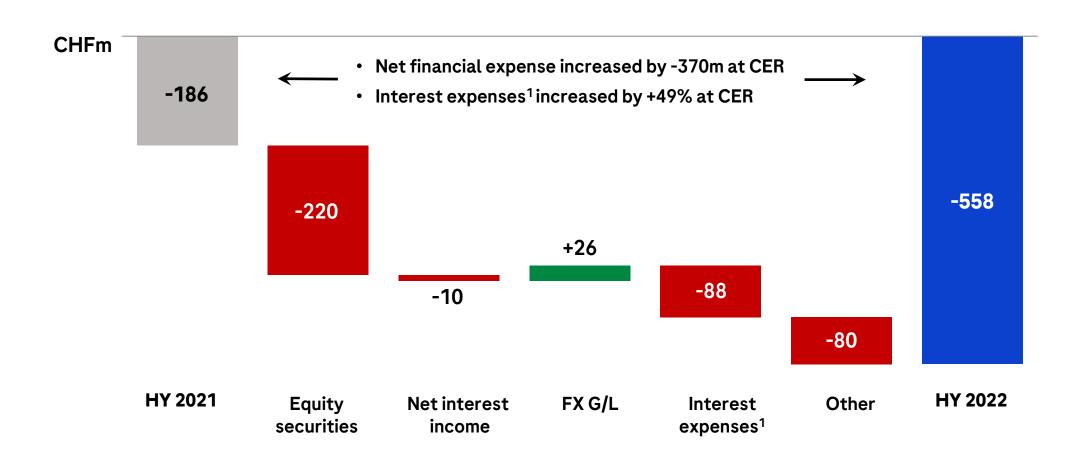


58

### HY 2022: Core net financial result



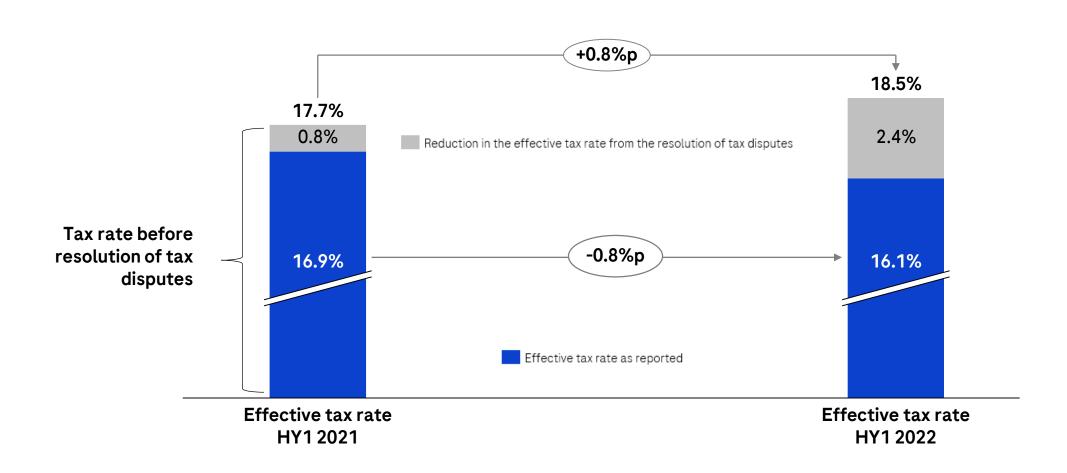
Higher net financial expenses driven by loss on Equity securities and higher interest expenses







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





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

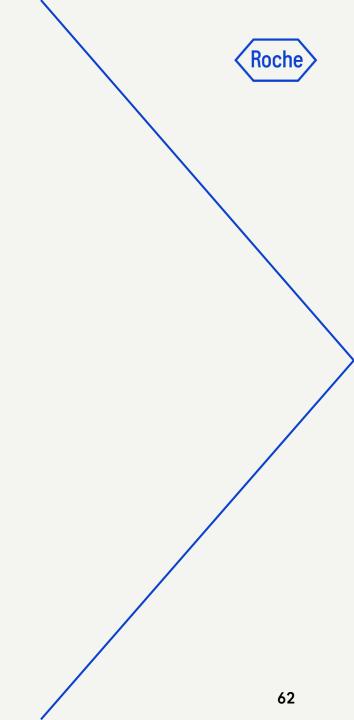
Decrease in non-core operating expenses driven by lower amortisation of intangible assets due to Esbriet and lower costs for global restructuring plans

	2021	2022		Chang	ge 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** 

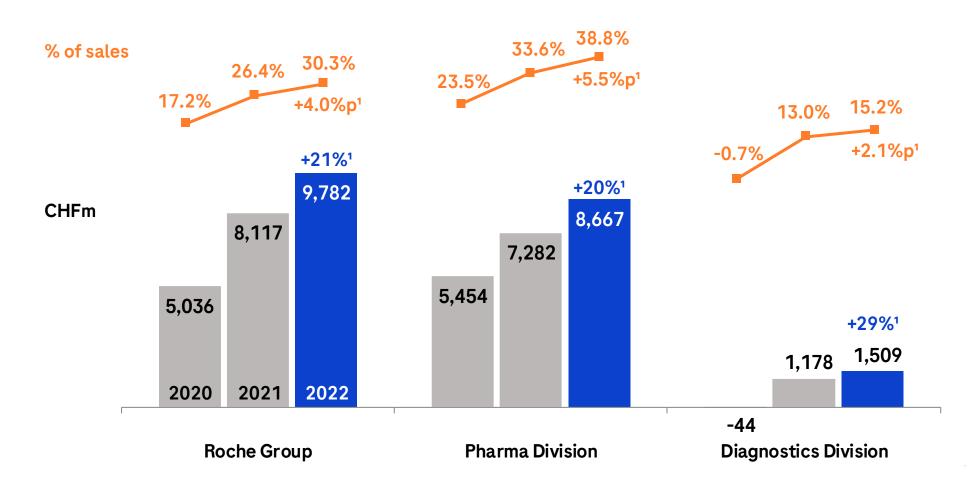


# HY 2022: Operating free cash flow and margin



63

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

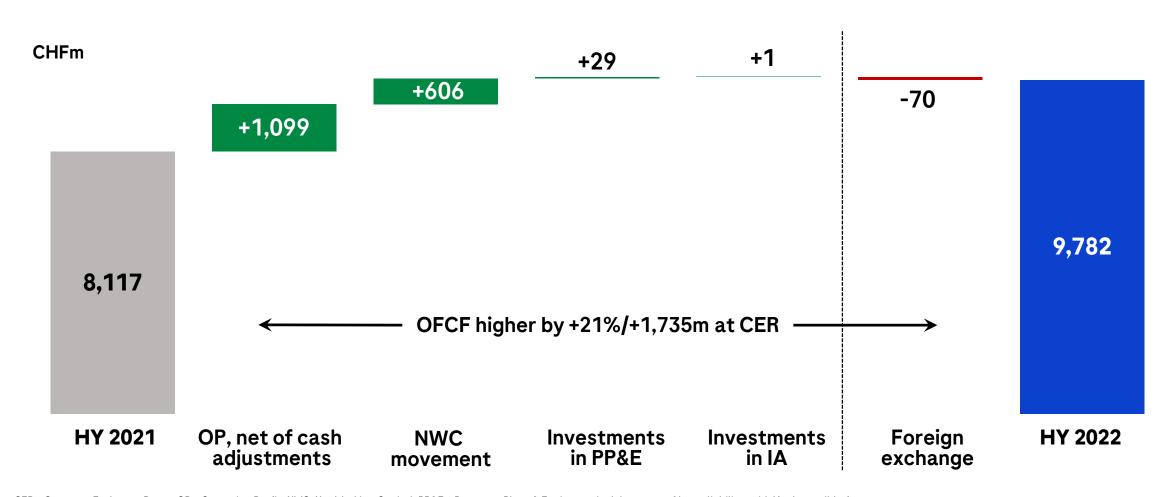


<sup>1</sup> At CER=Constant Exchange Rates

# HY 2022: Group operating free cash flow



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

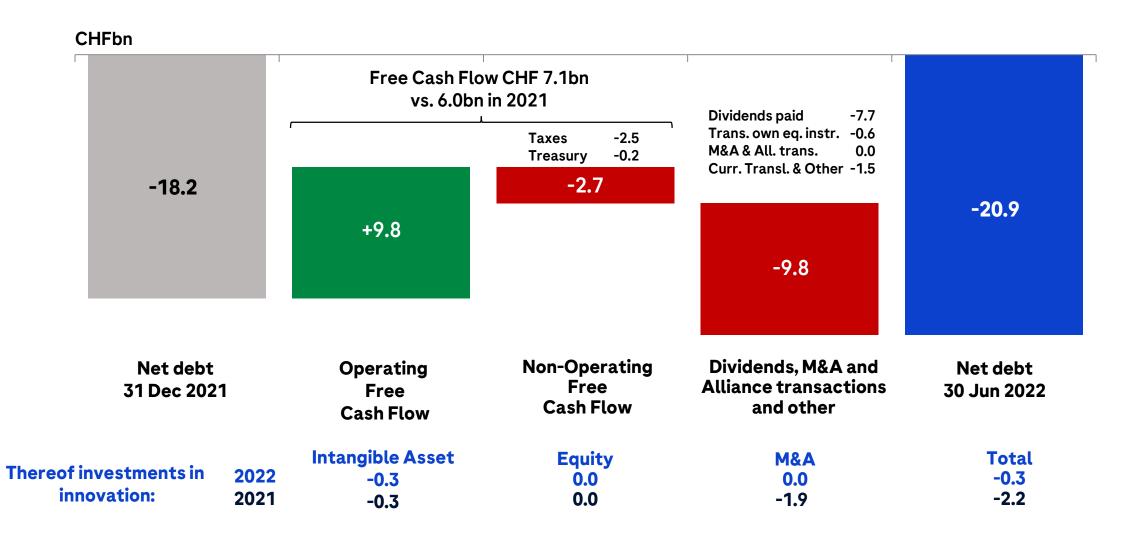








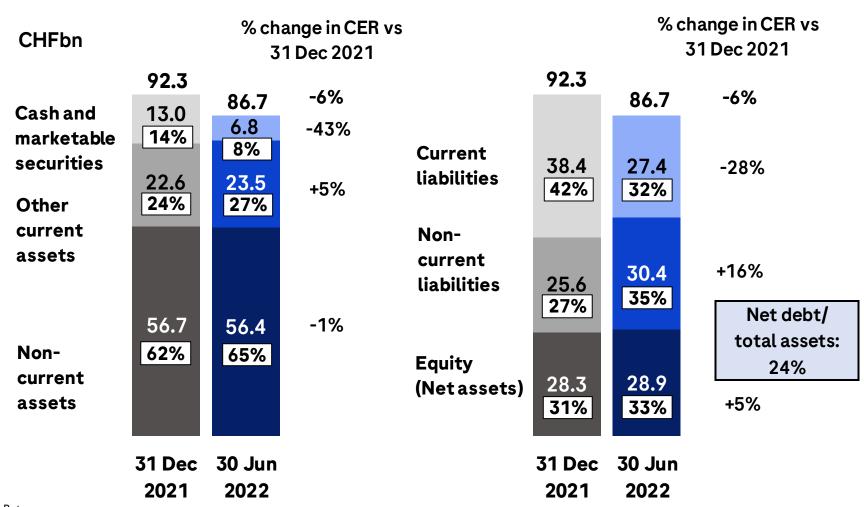
Net debt higher by CHF -2.7bn compared to previous YE 2021



### 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

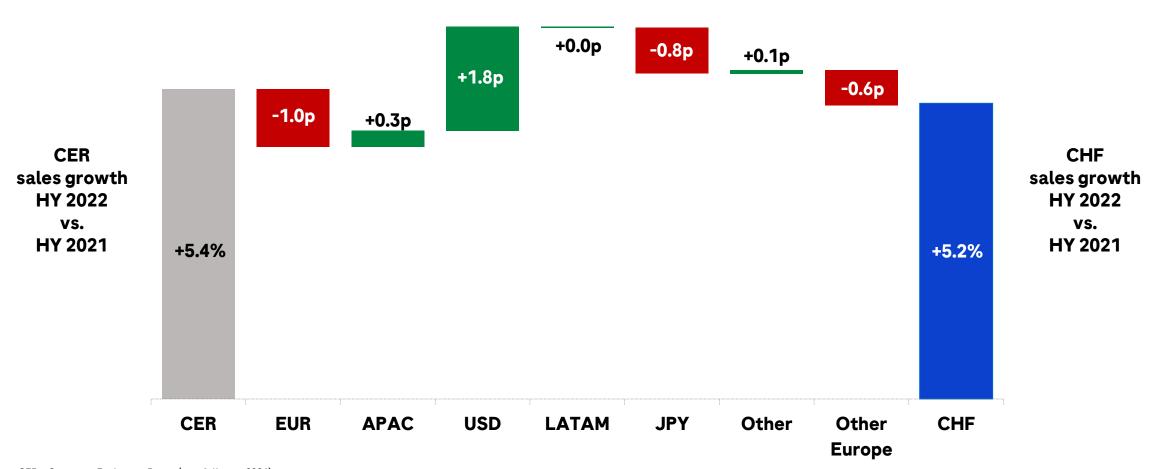
**Outlook** 



# Exchange rate impact on sales growth



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

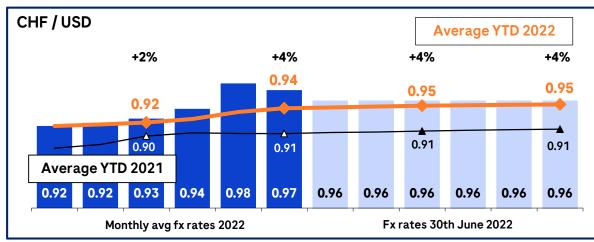


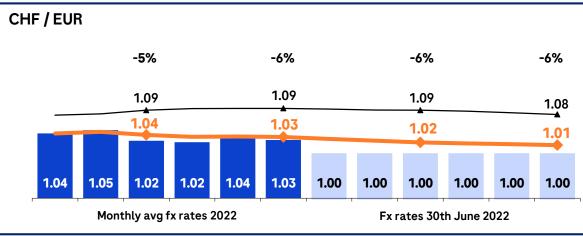
CER = Constant Exchange Rates (avg full year 2021)

68

# 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	HY	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

Status as of July 21, 2022

# Roche Group development pipeline



Phase I	(49 NMEs + 11 Als)	
---------	--------------------	--

		•
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	ab) heme tumors
CHU	FIXaxFX	hemophilia
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
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)	
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	<b>NMEs + 11</b>	ΔIs
i ilase ii l	42	I I : CJIPI	AI3

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 + pembrolizu	ımab 1L melanoma
RG6354	zinpentraxin alfa (PRM-151)	myelofibrosis
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016 hemophilia A w	ith 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	al 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)

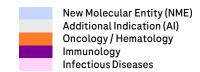
RG3502	Kadcyla + T	2L+ HER-2+ PD-L1+ mBC	RG7601	Venclexta	r/r MM t(11:14)
1103302	Kadcyla + T	HER-2+ eBC high-risk	1107001	Venclexta + azacitidi	ne 1L MDS
RG6026	glofitamab + chemo	2L+ DLBCL		Lunsumio (mosunetu	zumab) + 2L+ FL
	tiragolumab + T	1L esophageal cancer	RG7828	lenalidomide	
RG6058	tiragolumab + T	1L PD-L1+ NSCLC		Lunsumio (mosunetu	zumab) + 2L+ DLBCL
NG0036	tiragolumab + T locally advar	nced esophageal cancer	RG7853	Polivy Alecensa	ALK+ NSCLC adj
	tiragolumab + T stage III	unresectable 1L NSCLC	RG3648	Xolair	food allergy
RG6107	crovalimab	PNH	RG6354	zinpentraxin alfa (PR	3,
NG0 107	crovalimab	aHUS	1100334	Gazyva	lupus nephritis
RG6114	inavolisib (mPI3K alpha inh)	1L HR+ mBC	RG7159	Gazyva	membranous nephropathy
	giredestrant (SERD)	1L ER+/HER2- mBC	1107 137	,	systemic lupus erythematosus
RG6171	giredestrant (SERD)	ER+ BC adj		Xofluza	influenza, pediatric (0-1 year)
	giredestrant (SERD) + Phesgo	1L ER+/HER2+ BC	RG6152	Xofluza	influenza direct transmission
RG7440	ipatasertib + abiraterone	1L CRPC		gantenerumab	prodromal to mild Alzheimer's
	Tecentriq + platinum chemo	NSCLC neoadj	RG1450	gantenerumab	early Alzheimer's
	Tecentriq	NMIBC, high risk		Ocrevus higher dose	-
	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	1L mUC	RG6321	Susvimo (PDS)	DR
	Tecentriq SC	2L NSCLC		Susvimo (PDS)	wAMD, 36-week
	Tecentriq	ctDNA+ high-risk MIBC	D0774/	Vabysmo (faricimab)	BRVO
	T+ lurbinectedin	1L maintenance SCLC	RG7716	Vabysmo (faricimab)	CRVO
				-	

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

RG6013	Hemlibra <sup>1</sup>	mild to moderate hemophilia A
RG6026	glofitamab <sup>2</sup>	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+	Ronapreve <sup>2</sup>	SARS-CoV-2 hospitalised
RG6412	·	•
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





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<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>

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# Al submissions for existing products



Projects in phase II and III

		RG6264	<b>Phesgo OBI</b> HER2+ BC				New Molecular En	ion (AI)	Metabolism Neuroscience
		RG6396	<b>Gavreto</b> Tumor agnostic				Oncology / Hemati Immunology Infectious Disease		Ophthalmology Other
		RG7446	<b>Tecentriq SC</b> 2L NSCLC						
		RG7446	<b>Tecentriq + cabozantinib</b> 2L NSCLC					RG3502	<b>Kadcyla + Tecentriq</b> 2L+ HER-2+ PD-L1+ mBC
		RG7446	<b>Tecentriq + cabozantinib</b> RCC adv					RG3502	<b>Kadcyla + Tecentriq</b> HER-2+ eBC high-risk
		RG7446	<b>Tecentriq + Avastin</b> HCC adj					RG7446	<b>Tecentriq + paclitaxel</b> TNBC adj
		RG7446	<b>Tecentriq²</b> NSCLC neoadj					RG7446	<b>Tecentriq</b> High risk NMIBC
RG6413+ RG6412	Ronapreve** SARS-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
RG1569	<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
RG7446	<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
RG7596	<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
	2022		20	)23			2024	202	25 and beyond

√ Indicates submission to health authorities has occurred Unless stated otherwise submissions are planned to occur in US and EU <sup>1</sup>Approved in EU, filed in US

<sup>2</sup>filing timeline based on data from interim analysis

PDS=Port Delivery System with ranibizumab OBI=On-Body Delivery System

\*\*Ronapreve (casirivimab+imdevimab also known as REGEN-COV in the US) developed in collaboration with Regeneron Pharmaceuticals

# Major pending approvals 2022



	US		EU		China
RG6152	<b>Xofluza</b> influenza pediatric Filed March 2020	RG6321	Susvimo (PDS) wAMD Filed April 2021	RG6268	<b>Ro</b> : ROS <sup>^</sup> Filed
RG7828	<b>Lunsumio (mosunetuzumab)</b> 3L+FL Filed Dec 2021	RG7716	<b>Vabysmo (faricimab)</b> DME Filed May 2021	RG6268	Ro: NTRK+ s Filed
RG1569	Actemra COVID-19 pneumonia Filed Jan 2022	RG7716	<b>Vabysmo (faricimab)</b> wAMD Filed May 2021	RG7596	<b>P</b> 1L Filed
		RG6013	<b>Hemlibra</b> mild to moderate hemophilia A Filed Oct 2021	RG7596	<b>P</b> r/r Filed
		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		

		China
	RG6268	<b>Rozlytrek</b> ROS1+ NSCLC Filed Oct 2021
	RG6268	<b>Rozlytrek</b> NTRK+ solid tumors Filed Nov 2021
	RG7596	<b>Polivy</b> 1L DLBCL Filed Nov 2021
Α	RG7596	<b>Polivy</b> r/r DLBCL Filed Dec 2021
no		

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

RG6413+

RG6412

RG6026



Ronapreve\*\*

SARS-CoV-2 hospitalized

Filed Jan 2022 glofitamab

3L+ DLBCL Filed April 2022

> 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		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				

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Doing now what patients need next