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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

Q1 2022 Sales

Basel, 25 April 2022





Group

Severin Schwan
Chief Executive Officer

Roche

Q1 2022 performance

Outlook

Q1 2022: Strong performance for Pharma and Diagnostics



Strong Group sales +11% driven by both divisions

- Pharma performing well (+6%) and delivering on current products and new launches
- Diagnostics maintaining growth momentum (+24%) including strong base business growth (+10%)

Portfolio rejuvenation ongoing with successful launches and Diagnostics increasing installed base

- Pharma with successful launch of Vabysmo and Susvimo in ophthalmology; upcoming launches for Polivy in 1L DLBCL & CD20xCD3 bispecifics in hematology
- Diagnostics received EUA for the SARS-CoV-2 rapid antigen test; significant increase of installed base in molecular diagnostics contributing to strong base business growth; molecular testing solutions launched to track SARS-CoV-2 Omicron variants

Innovative late-stage pipeline with strong potential for future growth & significant news flow ahead

- Pharma: Read-outs in oncology for Tecentriq in four adjuvant indications, tiragolumab + Tecentriq combination in various indications and gantenerumab in Alzheimer's disease
- Diagnostics: BenchMark ULTRA PLUS, Digital Pathology Slide Scanner, Digital LightCycler, Elecsys pTau/AB42 ratio Gen2 CSF (FDA)

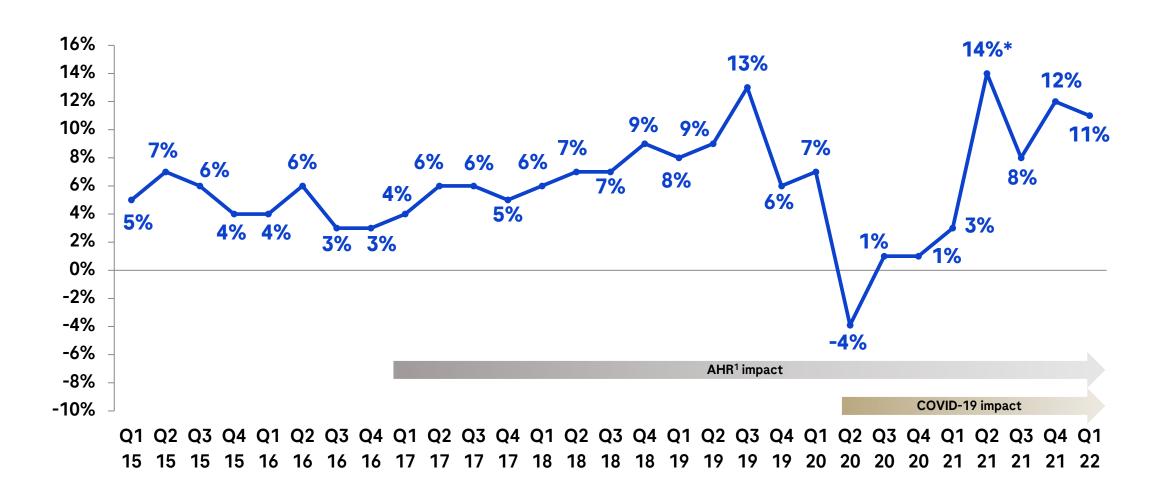


Q1 2022: Group sales growth driven by strong performance in both divisions

	2022	2021	Change in %	
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	11.2	10.6	5	6
Diagnostics Division	5.3	4.3	22	24
Roche Group	16.4	14.9	10	11

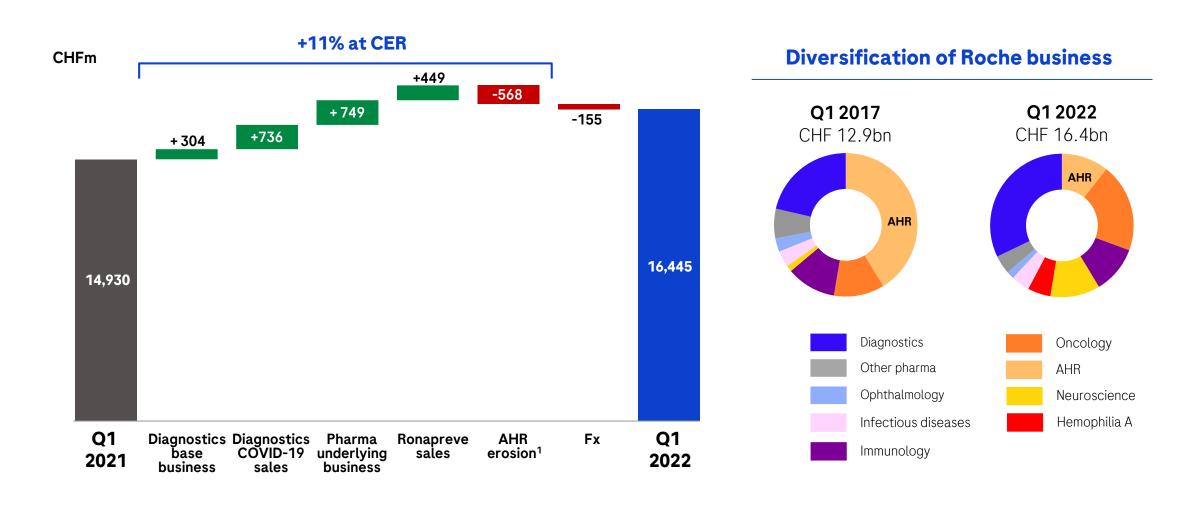
Q1 2022: Group sales +11% driven by both divisions





Q1 2022: Strong underlying business momentum







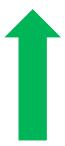
Q1 2022 performance

Outlook

2022 sales outlook confirmed

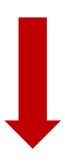


Sales drivers¹



Pharma: New products with accelerating growth

Diagnostics: Base business with strong growth



AHR² 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 where the Delta/Omicron variants represent the last major wave

2022: Upcoming newsflow



Pharma

Ongoing and upcoming launches

Vabysmo in DME/nAMD

Susvimo in nAMD

Polivy in 1L DLBCL

mosunetuzumab in FL

glofitamab in DLBCL

Late stage pipeline

3 tiragolumab + Tecentriq studies NSCLC, Cervical, Esophageal

4 Tecentriq adjuvant studies Head & Neck, Renal, HCC, neoadjuvant NSCLC

gantenerumab in Alzheimer's disease

Diagnostics

Automated **BenchMark** immunohistochemistry/in situ **ULTRA PLUS** hybridization advanced staining platform High capacity pathology slide **DP600** scanner for high volume digitization applications **Digital** Novel digital PCR platform LightCycler Detect amyloid disease & **Elecsys** pTau/AB42 ratio enable a broader availability of Gen2 CSF (FDA) testing for Alzheimer's Disease



Upcoming

launches

First Roche ESG event focusing on access to healthcare





Roche ESG Event on May 16 Access to Healthcare

15:00 - 16:30 CEST / 14:00 - 15:30 BST 09:00 - 10:30 am EDT / 6:00 - 7:30 am PDT

Our 10-year ambitions to be achieved by 2030



Pharmaceuticals: Double medical advances at less costs to society



Diagnostics: Double patient access to novel, high-medical-value diagnostics solutions

2022 outlook



Group sales growth¹

Stable to low-single digit

Core EPS growth¹

• Low- to mid-single digit (including accretion of 4.4%p from share repurchase)

Dividend outlook

Further increase dividend in Swiss francs

¹At Constant Exchange Rates (CER)





Pharmaceuticals Division

Bill Anderson CEO Roche Pharmaceuticals





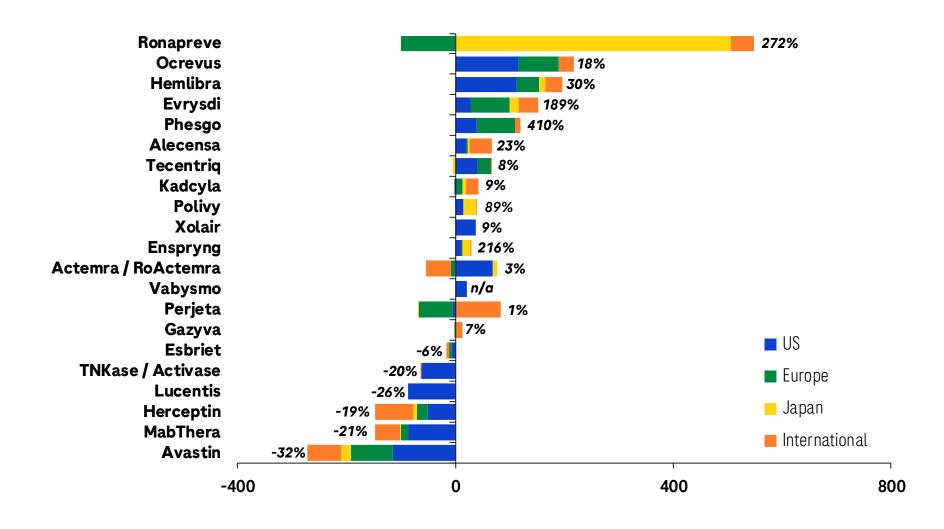
Good growth momentum

	2022	2021	Chang	e in %
	CHFm	CHFm	CHF	CER
Pharmaceuticals Division	11,159	10,600	5	6
United States	5,489	5,292	4	2
Europe	2,072	2,175	-5	-1
Japan	1,337	852	57	69
International	2,261	2,281	-1	0

CER=Constant Exchange Rates 16

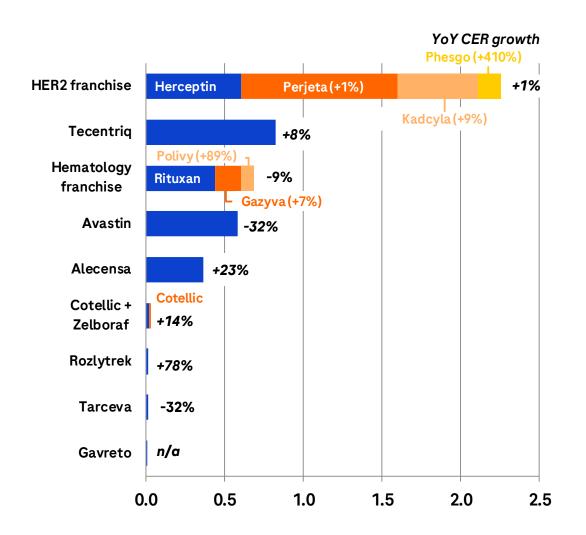






Q1 2022: Oncology portfolio rejuvenation progressing well





HER2 franchise

- Kadcyla (+9%) with growth ex-US due to adjuvant BC
- Perjeta (+1%) growth cannibalized by successful Phesgo launch
- Phesgo (CHF 146m): Conversion and geographic expansion ongoing

Tecentriq

Growth (+8%) driven by adjuvant NSCLC, 1L HCC and 1L SCLC

Avastin franchise

Biosimilar erosion in all regions

Hematology franchise

- Venclexta*: Growth driven by 1L AML and 1L and R/R CLL
- Gazyva (+7%): Growth due to 1L FL and in 1L CLL
- Polivy (+89%): Growth acceleration in Q1 partly due to R/R DLBCL; Positive CHMP opinion in 1L DLBCL (POLARIX)
- Mosunetuzumab: Positive CHMP opinion in 3L+ FL

Alecensa

• Growth (+23%) driven by all regions, especially International and US

HER2 franchise: Phesgo with strong global launch

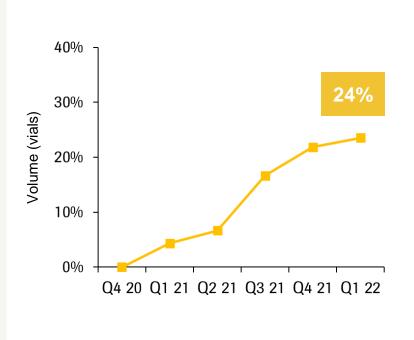




Perjeta conversion rate approaching 25% in early launch countries

Phesgo cutting administration time & costs Treatment option Administration and observation schedule* Total time 0.5 - 1.5 hours 2 - 6 h Ply 15 - 8 min 15 - 30 min Ranges driven by differences in loading and maintenance

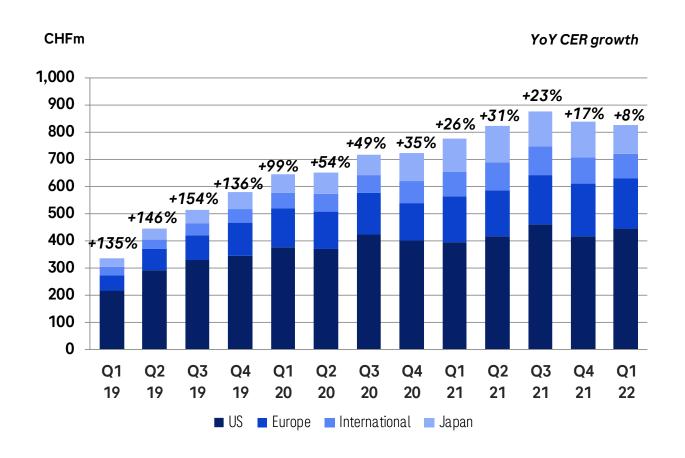
Global Perjeta conversion rate**



- Phesgo administration results in significantly reduced healthcare costs and resource use
- First approved by FDA and EMA in 2020

Tecentriq overview: Adjuvant program to read out in 2022





Tecentriq Q1 update

- US: Sales still impacted by label changes
- Japan: Sales impacted by mandatory price cut

Lung franchise (NSCLC, SCLC)

- EU: Growth driven by 1L SCLC; Positive CHMP opinion in adjuvant PDL1+ NSCLC
- US: Strong launch in adjuvant PDL1+ NSCLC

GI franchise (HCC)

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

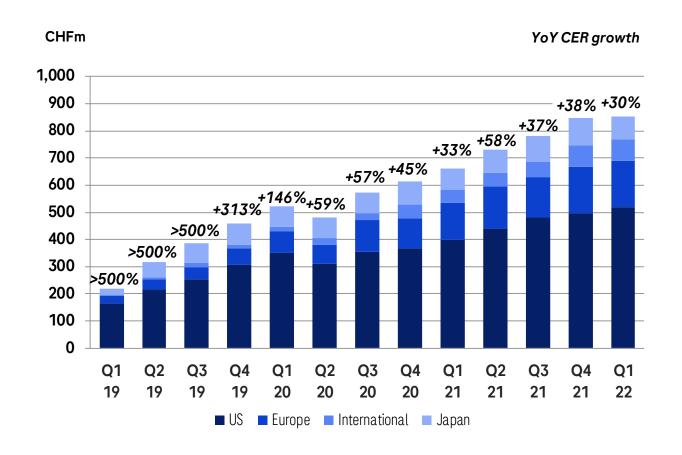
Outlook 2022

- Further growth due to first-to-market indications adjuvant PDL1+ NSCLC and 1L HCC
- 4 Ph III Tecentriq adjuvant studies and 3 Ph II/III tiragolumab
 + Tecentriq studies reading out

Hemophilia A franchise: Hemlibra accepted as new standard of care



34% US/EU-5 patient share reached



Hemophilia Q1 update

- Nearly 17,000 patients currently treated globally
- Hemlibra continues to penetrate across all approved patient types
- EU: Non-inhibitors market shares of >50% in the UK and >40% in France achieved

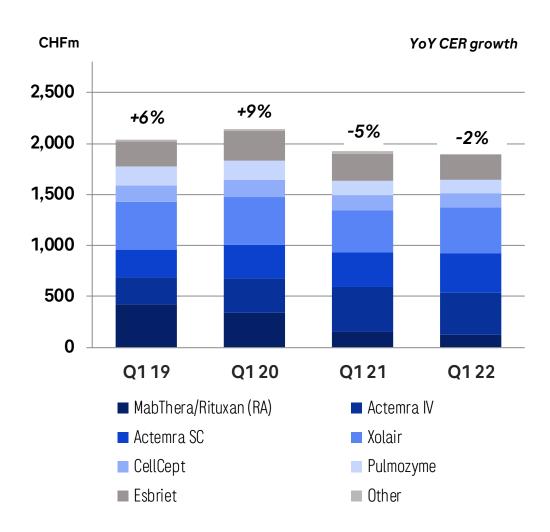
Outlook 2022

- US/EU: Further patient share gains in non-inhibitors
- EU: Label expansion to include mild/moderate patients (HAVEN 6) expected

CER=Constant Exchange Rates 21

Immunology franchise: Still moved by COVID-19





Immunology Q1 update

Actemra (+3%)

- Remains leading RA monotherapy in EU-5
- Shift from IV to SC continues with SC sales accounting for >50%
- Around 50% of IV sales expected to be due to COVID-19

Xolair (+9%)

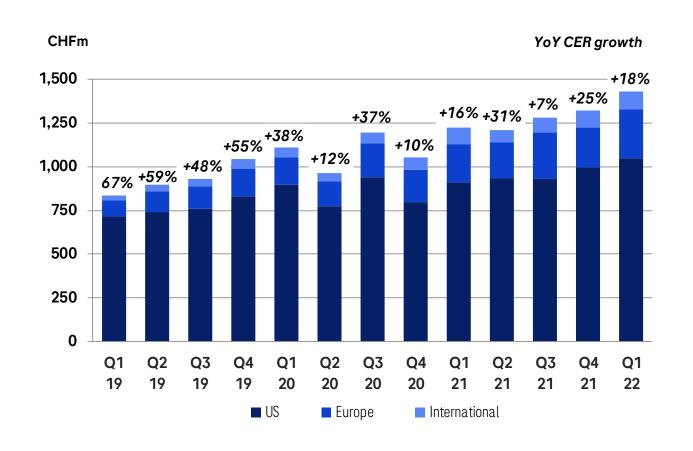
Remains the leader in biologics asthma market; Continued growth in CSU

Outlook 2022

 Actemra: COVID-19 sales expected to decline with lower hospitalization rates

MS franchise: Ocrevus global market share reaches 20%





Q1 update

- US/EU still impacted by COVID-19
- Mitigation plans for late stage MS development programs initiated due to situation in Ukraine/Russia
- Ph III (OCARINA II) for Ocrevus 6-month SC dosing initiated

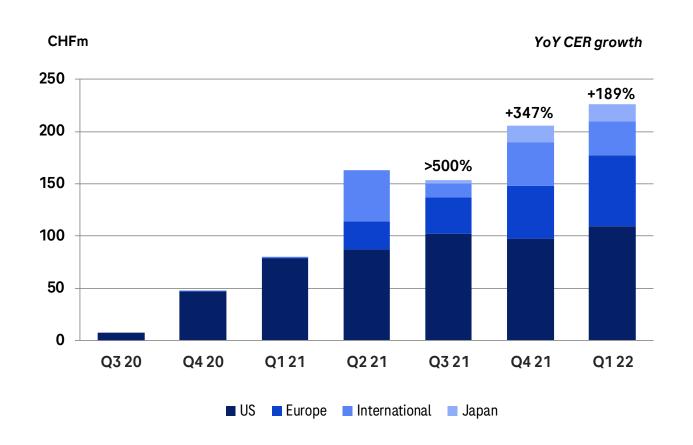
Outlook 2022

Further market share gains expected

SMA franchise: Evrysdi with strong US and EU launches



Most prescribed treatment in the US with >20% share; Germany with >30% share



Q1 update

- ~5,000 patients treated world wide (commercial, clinical trials, compassionate use)
- US: Growth driven by switch and naive patient starts
- EU: Strong launches in early launch countries
- Ph II/III (MANATEE) Evrysdi + anti-myostatin combination study initiated

Outlook 2022

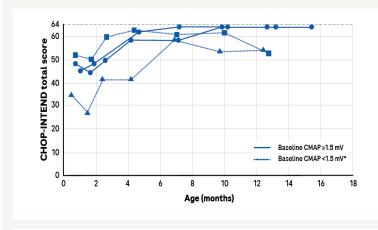
- Continued growth and market share gains expected
- US/EU: Label extension (<2 months old) based on Ph II RAINBOWFISH expected (priority review)

SMA franchise: New data in presymptomatic SMA

Indication extension for <2 months of age filed with FDA and EMA

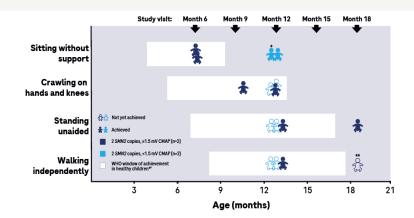


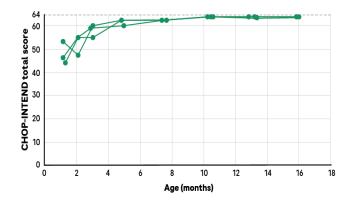
Ph II (RAINBOWFISH): 1 year interim results in infants (<2 months of age)



4 infants with 2 SMN2 copies:

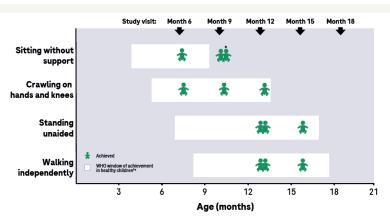
- Most infants treated for >12 months achieved near-maximum **CHOP-INTEND** scores
- Most infants achieved motor milestones within WHO windows for healthy children





3 infants with >2 SMN2 copies:

- All infants treated for >12 months achieved the maximum CHOP-INTEND score
- Most infants achieved motor milestones within WHO windows for healthy children



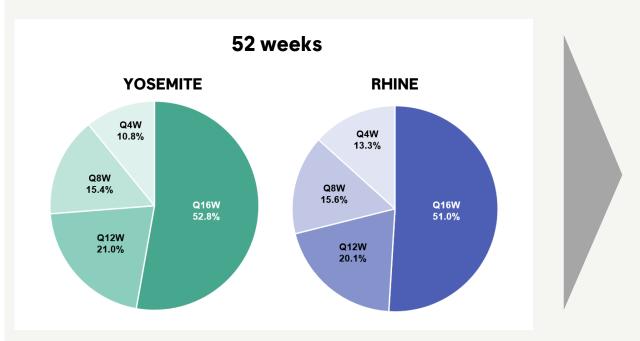


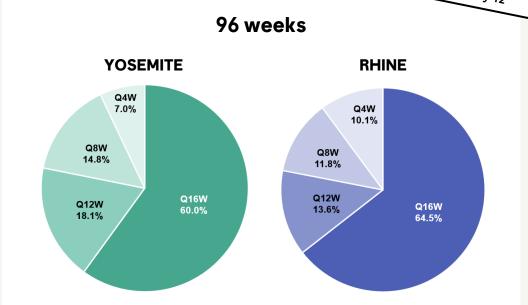
Ophthalmology franchise: Follow-up data for Vabysmo in DME

Proportion of patients achieving Q16W dosing increases to ≥ 60% at week 96

Ph III (YOSEMITE, RHINE) in DME: Dosing intervals of patients at year 1 and 2

Angiogenesis, Exudation, Degeneration 2022 February 12





- Anti-VEGF/Ang2 bispecific mAb with new dual mechanism of action to promote vascular stability
- Proportion of patients achieving Q16W dosing increased from >50% at week 52 to ≥ 60% at week 96; 1-year BCVA gains and improved anatomic outcomes (including CST) were maintained through year 2
- 2-year data in nAMD to be presented at upcoming conference

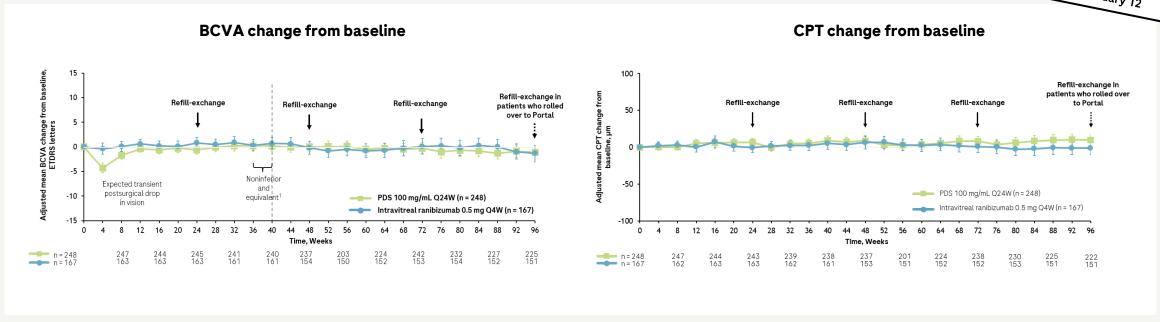
Ophthalmology franchise: Follow-up data for Susvimo in nAMD



Vision and anatomical outcomes maintained through year 2

Ph III (ARCHWAY) in nAMD: 2-year results for Susvimo Q24W dosing

Angiogenesis, Exudation, Degeneration 2022 February 12



- First eye implant with continuous drug delivery offering 6-month dosing alternative to frequent eye injections
- Long-term vision and anatomic results through year 2 were comparable with monthly ranibizumab injections; safety profile well characterized and manageable
- Ph III (PAGODA, PAVILION) results in DME/DR expected in late 2022, Ph III (VELODROME) testing Q9M dosing on-going

2022: Key late-stage newsflow* and upcoming IR events



	Compound	Indication	Milestone	
	Vabysmo	nAMD/DME	US/EU approval	US✔
	Susvimo	nAMD	EU approval	
Regulatory	mosunetuzumab	3L+FL	US/EU approval	
negulatory	Tecentriq	Adjuvant NSCLC	EU approval	
	Hemlibra	Mild to moderate hemophilia A	EU approval	
	Polivy + R-CHP	1L DLBCL	EU/US approval	
	glofitamab	3L+ DLBCL	Ph lb NP30179	✓
	Tecentriq + tiragolumab + chemo	1L ES-SCLC	Ph III SKYSCRAPER-02	X
	Tecentriq + chemo	Adjuvant SCCHN	Ph III IMvoke010	
	Tecentriq + tiragolumab	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	
	Tecentriq	Adjuvant RCC	Ph III IMmotion010	
	giredestrant	2/3L HR+ mBC	Ph II acelERA	X
Phase III / pivotal	Tecentriq + chemo	Adjuvant HCC	Ph III IMbrave050	
readouts	Venclexta + dexamethasone	t(11;14) 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 Virtual event MDA

Roche ESG Day Access to Healthcare Virtual event **ASCO**

Roche Pharma Day

Monday, 12 September

16:30 to 17:45 CEST

Wednesday, 16 March 16:30 to 17:30 CEST

Monday, 16 May 15:00 to 16:30 CEST

Monday, 6 June 16:00 to 17:30 CEST

TBC



^{*} Outcome studies are event-driven: timelines may change





Diagnostics Division

Thomas Schinecker CEO Roche Diagnostics





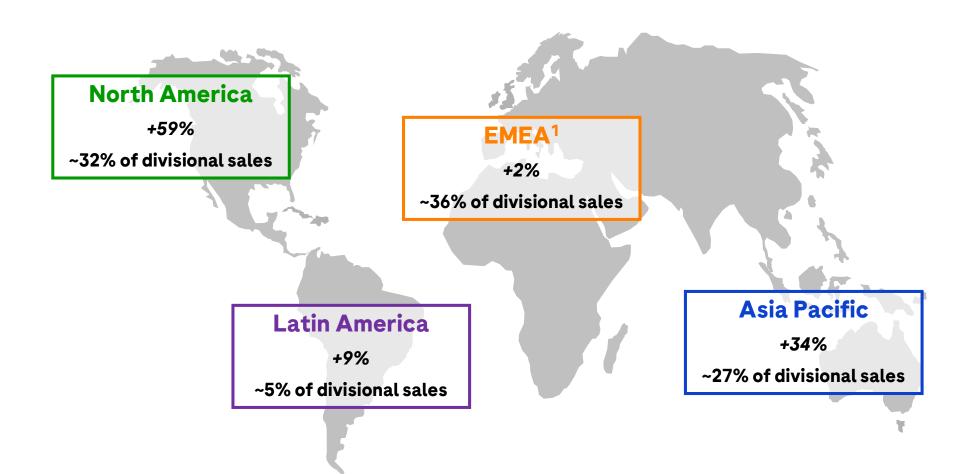
Sales increase of +24% driven by COVID-19 testing and base business

	2022	2021	Change	e in %
	CHFm	CHFm	CHF	CER
Diagnostics Division	5,286	4,330	22	24
Core Lab ¹	1,896	1,786	6	8
Point of Care ¹	1,466	806	82	84
Molecular Lab ¹	1,189	996	19	21
Diabetes Care	417	460	-9	-7
Pathology Lab	318	282	13	14

Q1 2022: Diagnostics Division regional sales



Very strong growth in all regions; rapid antigen test sales contributing to US growth

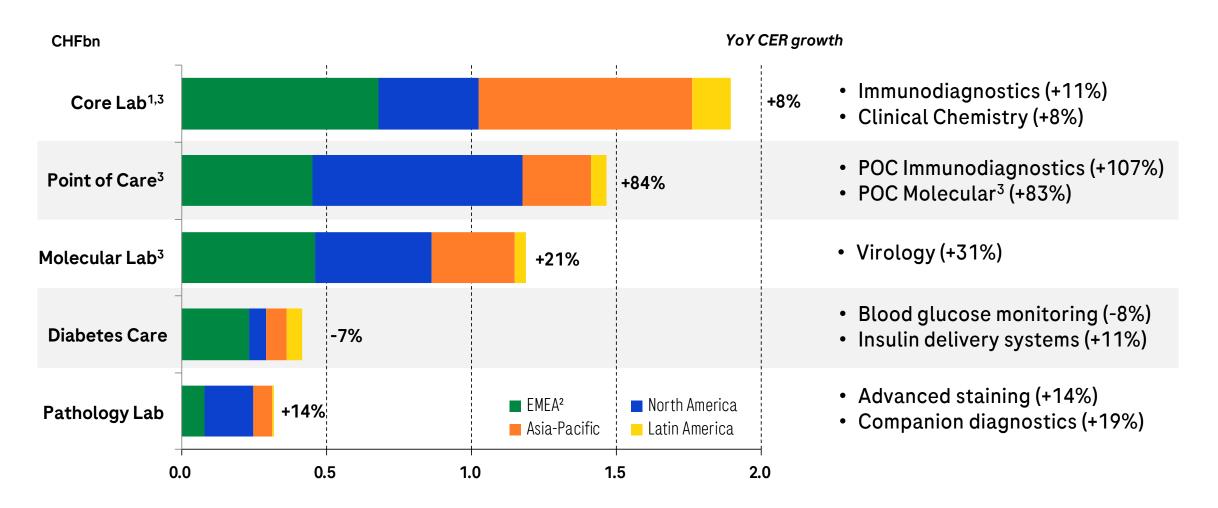


Growth rates at CER (Constant exchange Rates); ¹ Europe, Middle East and Africa

Q1 2022: Diagnostics Division highlights



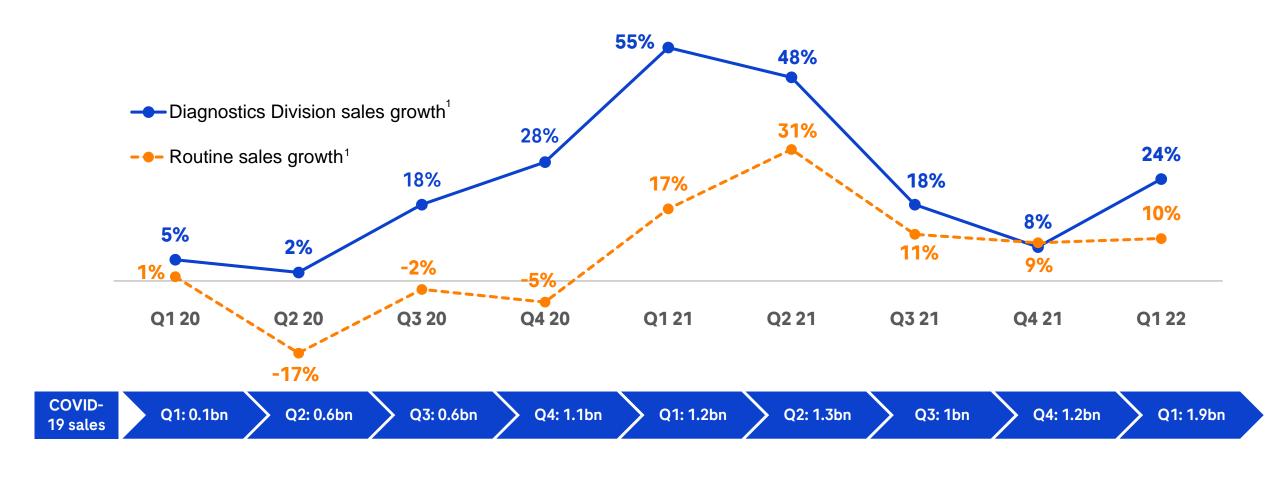
Strong growth despite a high base in Q1 2021



Diagnostics Division sales growth by quarter



Very strong COVID-19 and base business growth



cobas® 5800/6800/8800 molecular menu expansion driving growth



Further growing the installed base in 2022

Donor Screening]	Blood Borne Disease)	Sexual Health		Transplant		Respiratory		Antimicro	bial Stewardship
MPX	~	HIV-1	✓	HPV	✓	CMV	✓	Flu A/B & RSV (OMNI)	✓	MTB-RIF/INH	✓
WNV	/	HBV	✓	CT/NG	~	EBV	✓	МТВ	~	C.diff	~
DPX	✓	HCV	✓	TV/MG	✓	BKV	V	MAI	/		
HEV	~	HIV-1/2 Qual	~	PivNG	✓	ADV Quant		SARS-CoV-2	~		
CHIKV/DENV	✓	HSV-1/2/VZV (OMNI)	✓	HPV Self-sampling		HSV-1/2/VZV		SARS-CoV-2 & Flu A/B	✓		
Zika	✓	HBV RNA (IA)	✓	BV/CV				SARS-CoV-2 Variant	~		
Malaria		HBV RNA		MG Resistance				Influenza A/B & RSV	~		
				NG Resistance				AMER	~		
								Parainfluenza 1-4	~		
							SARS CoV-2 DUO			Launched in 2021 In development	
					1		MPLX Respiratory			in development	
	-										

>1,900 cobas® 6800/8800 installed base

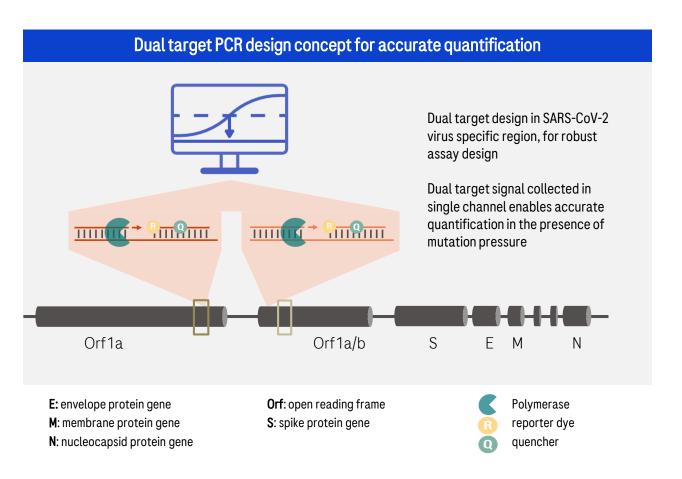
>500 cobas® 5800 placements expected in 2022

MPX=multiplex detection of HIV-1, HIV-2, HCV=Hepatitis C and HBV=Hepatitis B; WNV=West Nile virus; DPX=duplex detection of parvovirus B19 and HAV; HEV=Hepatitis E virus; CHIKV=chikungunya virus; DENV=Dengue virus; CMV=Cytomegalovirus; MTB=Mycobacterium tuberculosis; MAl=Mycobacterium avium-intracellulare infection; RIF=rifampicin; INH=isoniazid (detection of RIF/INH resistance in MTB positive samples); TV=trichomonas vaginalis; MG=mycoplasma genitalium; EBV=Epstein-Barr virus post-transplant monitoring; BKV=BK virus post-transplant monitoring; ADV=Adenovirus post-transplant monitoring; HSV-1/2/VZV=multiplex detection of Herpes simplex virus 1 and 2 and Varicella-zoster virus; MPLX=detect and discriminate multiple (up to 14) pathogens associated with a clinical syndrome, including SARS-CoV-2; Malaria=mosquito-borne infectious disease; SARS-CoV-2=2019 novel coronavirus; HSV=Herpes Simplex Virus; VZV=Varicella-zoster virus, the cause of chickenpox and herpes zoster (also called shingles); PivNG=Neisseria Gonorrhoeae Piv Gene Target; ADV=Adenovirus; AMER= Adenovirus, metapneumovirus, rhinovirus; HBV RNA (IA) = HBV RNA Investigational Assay; HPV=Human papillomavirus; CT/NG=Chlamydia Trachomatis and Neisseria Gonorrhoeae: C.diff=Clostridioides difficile: RSV=Respiratory syncytial: Flu A/B=Influenza B

Upcoming launch of cobas® SARS-CoV-2 DUO



Providing accurate diagnosis of SARS-CoV-2 infection for proper patient management

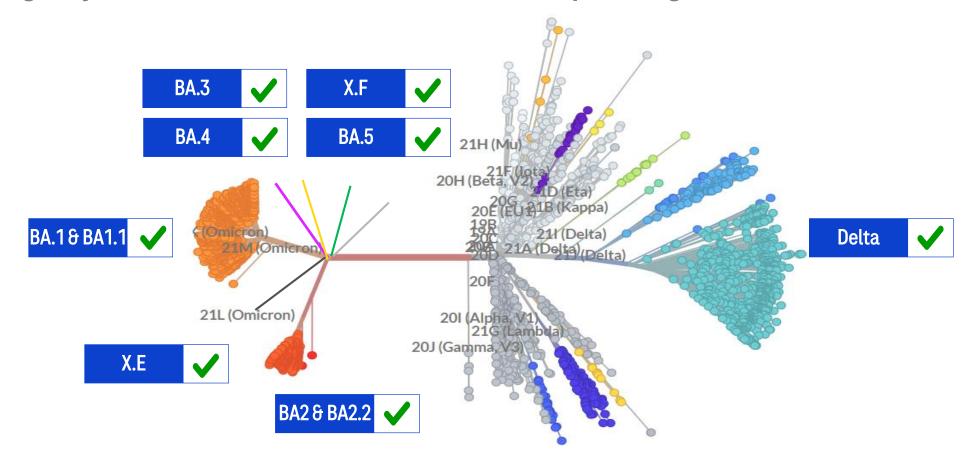


- Provide qualitative result of SARS-CoV-2 detection combined with the viral load result traceable to the WHO international standard in IU/mL
- Supports scalable testing on the fully automated cobas® 5800/6800/8800 systems and their broad menu



TIB-Molbiol SARS-Cov-2 menu for tracking virus evolution

Detecting major variants in hours vs a week for sequencing



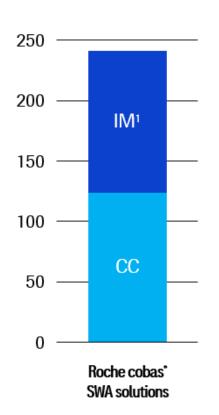
>10 tests to differentiate all relevant variants

Roche Serum Work Area menu expansion driving future growth



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

Broad IM + CC assay menu



Launched in 2021 & upcoming launches in 2022

Immuno chemistry assays					
EBV EBNA IgG (CE)	IGRA SARS-CoV-2 (CE)				
EBV VCA IgG (CE)	HCV Duo (CE)				
EBV IgM (CE)	Anti-HBs II ⁴ (US)				
Anti-p53 (CE)	Anti-HAV II ⁴ (CN)				
GAAD (CE)	HBsAg Confirmatory				
NT-proBNP claim	(US)				
extension ³ (CE)	AFP-L3 (CE)				
TnT-hs claim extension ³	Vit D total III4 (US, CN)				
(CE)	Androstendione (CN)				
PCT CE claim extension ³	Active B12 (US)				
(CE)	FT4 IV4 (CE, US)				
Vit D total III ⁴ (CE)	TG II ⁴ (US)				
Anti-HBe (US)	,				
HBsAg Confirmatory (CE)					

Clinical chemistry assays					
Fentanyl ⁵ (CE, US)	ASTP24 (US)				
sTfR Gen 2 ⁴ (CE)	ALTP24 (US)				
Sirolimus (CN)	Benz 2 ⁴ (US)				
CRP4 (CN)	A1MG Controls ⁵ (CE)				
	sTfR Gen 2 ⁴ (US, CN)				
	free PHNY2 (CE)				
	NH3L2 (CN)				

On market (Launched in 2021)

In development (to be launched in 2022)

Alzh CSF biomarkers (CE)

Alzheimer's disease IVD blood tests development





Enabling access to Alzheimer's disease modifying therapies

Patients undergoing initial evaluation for non-specific cognitive decline

Step 1: Triage

Elecsys® Amyloid Plasm

Non-AD patients¹

AD patients¹

Elecsys Amyloid Plasma Panel²

In-dev

Patients referred for amyloid confirmatory testing with further clinical and cognitive testing

Non-AD patients¹
AD patients¹

Step 2: Confirmation

Elecsys ° CSF AD assays³



Patients identified as amyloid positive may benefit from future anti-amyloid therapies



Step 3: Therapy

Anti-Amyloid

In-dev

- pTau 181 and ApoE4 have been selected based on clinical performance and robustness
- Clinical study results leading to the biomarkers selection will be published at AAIC (July 31st-Aug 4th)
- These biomarkers are used in the SKYLINE study (gantenerumab in pre-symptomatic Alzheimer's disease)
- Planned clinical validation to support IVD registration in major markets
- Launch of the Elecsys* amyloid plasma panel is planned together with gantenerumab

¹ Illustrative scheme; ² Mean of clinical performance data from retrospective cohorts measured with Elecsys Amyloid Plasma Panel; ³ Elecsys pTau / Amyloid Beta 42 ratio

Roche Analyst Event on Diagnostics Division at AACC 2022





Chicago, Palmer House hotel, July 26, 6-7:15pm CDT



AACC = Annual Scientific Meeting and Clinical Lab exposition

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Key launches 2022



Product Description Market

			<u> </u>	
	Pathology Lab	BenchMark ULTRA PLUS	Automated immunohistochemistry/in situ hybridization (ISH) advanced staining platform with enhanced software capabilities, workflow and testing efficiency	US & CE
		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
	Molecular Lab	cobas® 5800	Real-time PCR molecular testing for low volume labs	US
		Digital LightCycler	Novel digital PCR platform for lab developed tests (LDTs) and in-vitro diagnostics labs	WW
		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
		Elecsys pTau/AB42 ratio Gen2 (CSF)	Detect amyloid disease and enable a broader availability of testing for patients suspected of Alzheimer's Disease	US
	Molecular Lab	cobas® SARS-CoV-2 DUO	Automated RT-PCR assay for use on the cobas® 6800/8800 systems	US^2 & OUS^1
		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
	Lab Insights	Cervical Cancer Screening	Digital solution (mobile app and workflow) improving the management of screening programs for cervical cancer	CE
Digital	J	cobas® infinity edge suite	Portfolio of digital products to support decentralization of testing and data, to launch commercially with an open ecosystem	CE
Solutions		Lab Insights Platform	Data integration platform for laboratory customers across disciplines	CE
	Diabetes Care	RocheDiabetes Care Platform Payer Dashboard	Population-level insights via dashboard for HCPs, Admins and Payers	OUS ³
	Diabetes Care	mySugr Pump Control	Extended functionalities (e.g. temporary basal rate import from a connected insulin pump), expanded smartphone compatibility	OUS ³

CE: European Conformity, US: FDA approval, WW: Worldwide including CE, US and China, OUS: Outside the US; PCR: Polymerase Chain Reaction; RT: Real Time; Research Use Only; EUA: Emergency Use Authorization; Only selected countries





Finance

Alan Hippe Chief Financial Officer

Q1 2022: Highlights



Sales

- Group sales growth of +11% due to strong performance in Pharmaceuticals and Diagnostics division
- Pharma delivering well across entire portfolio; Diagnostics continuing with strong results in double-digit range

Currency impact on sales

Slightly negative currency impact mainly due to EUR and JPY, partially offset by USD

Share repurchase of Roche from Novartis

- CHF 19bn bridge loan largely refinanced and repaid
- Roche issued in total USD 11bn and CHF 3bn of bonds since December 2021 at an average initial yield of 1.56% for an average maturity of 8.8 years

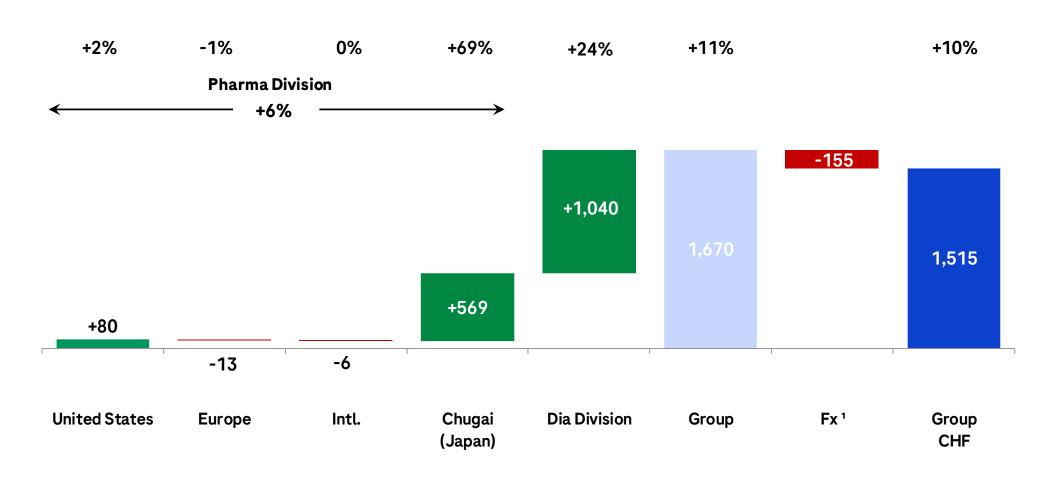
Patent settlement*

- USD 775m (CHF 765m @CER) revenue recorded as 'Income from out-licensing agreements' as part of core net income
- This revenue is taxable at Chugai's tax rate and partly attributable to Chugai's non-controlling interests

Q1 2022: Group Sales



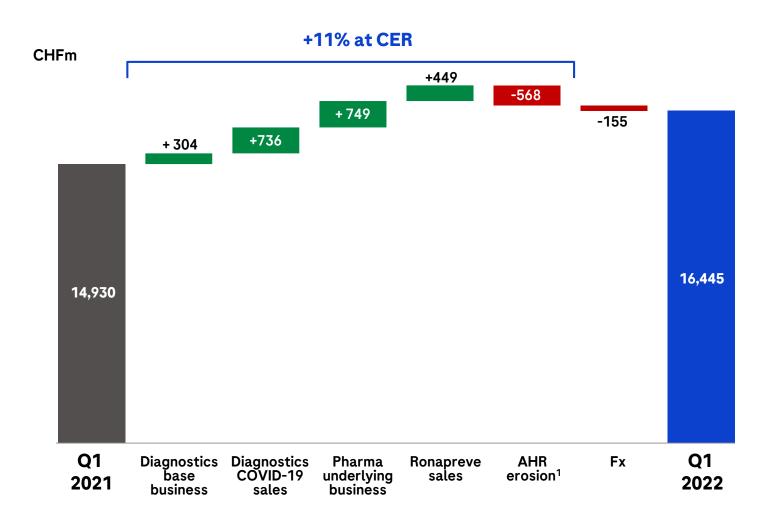
CER Group sales increase of +11% driven by Diagnostics Division & Chugai (Ronapreve)





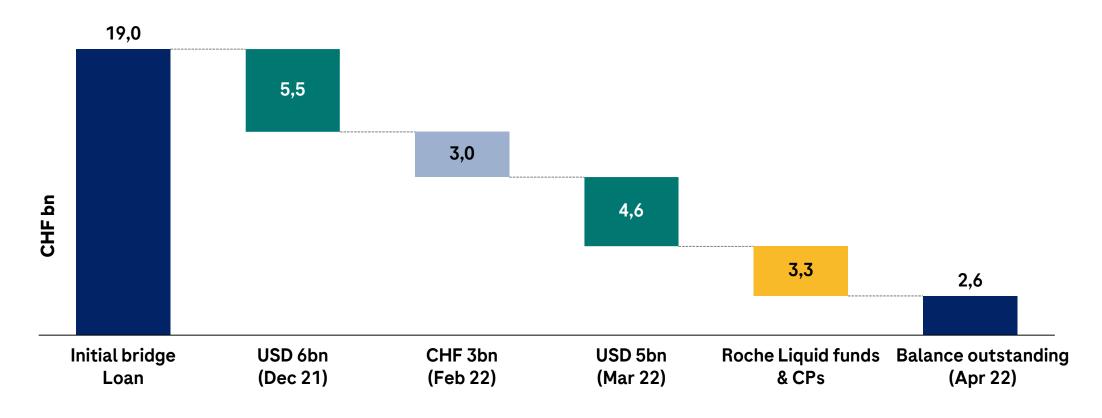


2022 outlook on COVID-19 related sales (+5bn) and AHR erosion (-2.5bn) confirmed



Roche

Novartis share repurchase: CHF 19bn bridge loan largely refinanced and repaid



 Roche issued in total USD 11bn and CHF 3bn of bonds since December 2021 at an average initial yield of 1.56% for an average maturity of 8.8 years

Exchange rate impact on sales growth

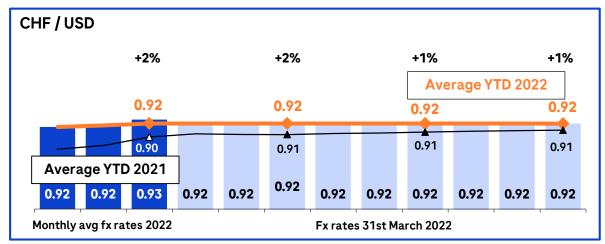


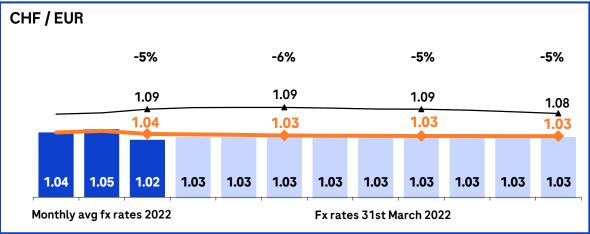
Slightly negative impact mainly from EUR, JPY and TRY partially offset by USD



2022 currency impact







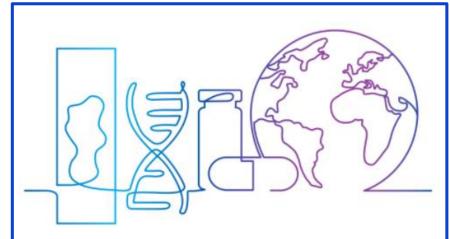
Assuming the 31 March 2022 exchange rates remain stable until end of 2022, 2022 impact¹ is expected to be (%p):

	Q1	HY	Sep YTD	FY
Sales	-1	-2	-2	-2
Core operating profit		-2		-2 to -3
Core EPS		-2		-2 to -3

¹On group growth rates

First Roche ESG event focusing on access to healthcare





Roche ESG Event on May 16 Access to Healthcare

15:00 - 16:30 CEST / 14:00 - 15:30 BST 09:00 - 10:30 am EDT / 6:00 - 7:30 am PDT

Our 10-year ambitions to be achieved by 2030



Pharmaceuticals: Double medical advances at less costs to society



Diagnostics: Double patient access to novel, high-medical-value diagnostics solutions

2022 outlook



Group sales growth¹

• Stable to low-single digit

Core EPS growth¹

• Low- to mid-single digit (including accretion of 4.4%p from share repurchase)

Dividend outlook

Further increase dividend in Swiss francs

¹At Constant Exchange Rates (CER)

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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



Q1 2022 update

New to phase I	New to phase II	New to phase III	New to registration
6 NMEs: RG6344 BRAF inhibitor (3) – solid tumors RG6333 CD19xCD28 + glofitamab – r/r NHL RG6163 NME – psychiatric disorders RG6156 EGFRVIIIxCD3 – glioblastoma RG6319 LepB inhibitor – complicated urinary tract infection RG7880 efmarodocokin alfa – aGVHD (new lead indication)	1 NME: RG6084 PDL1 LNA – HBV 2 Als: RG6107 crovalimab – sickle cell disease RG6026 glofitamab + chemo – 1L ctDNA high risk DLBCL		1 NME (EU): RG6026 glofitamab – 3L+ DLBCL 1AI (EU): RG6413+RG6412 Ronapreve – SARS-CoV-2 hospitalised
Removed from phase I	Removed from phase II	Removed from phase III	Approvals
1 NME: RG6115 TLR7 agonist (4) - hepatocellular carcinoma 1 Al: RG7601 Venclexta + gilteritinib - r/r AML	2 NMEs: RG7769 PD1xTIM3 – solid tumors RG7880 efmarodocokin alfa – inflammatory bowel disease (continues in phase I in aGVHD)	1 Al: RG6058 tiragolumab + Tecentriq - 1L SCLC	
I I I I I I I I I I I I I I I I I I I			

Status as of April 25, 2022

Roche Group development pipeline



Phase I (49 NMEs + 11 Als)

	RG6007	HLA-A2-WT1 x CD3	AML	C	:HU	FIXa x FX	haemophilia
	RG6026	glofitamab monotherapy & combos	heme tumors	C	:HU	glypican-3 x CD3	solid tumors
	RG6058	tiragolumab combos	heme & solid tumors	C	HU	codrituzumab	НСС
	RG6076	CD19-4-1BBL	heme tumors	C	:HU	CD137 switch antibod	ly solid tumors
	RG6129	HLA-A2-MAGE-A4 x CD3	solid tumors	C	HU	LUNA18	solid tumors
	RG6160	cevostamab (FcRH5 x CD3)	r/r MM	C	:HU	SPYK04	solid tumors
	RG6171	giredestrant (SERD)	solid tumors	S	QZ	PBMC vaccine	solid tumors
	RG6114	inavolisib (mPI3K alpha inh)	solid tumors	RG	6287	-	IBD
	RG6156	EGFRvIII x CD3	glioblastoma	RG	6341	-	asthma
	RG6180	autogene cevumeran±T	solid tumors	RG	6418	selnoflast (NLRP3 inh)	inflammation
	RG6185	belvarafenib (pan-RAF inh)+Cotellic	solid tumors	RG	6315	-	immunologic disorders
	RG6189	FAP-CD40	solid tumors		7828	mosunetuzumab	systemic lupus erythematosus
	RG6194	runimotamab (HER2 x CD3)	ВС	RG	7880	efmarodocokin alfa	aGVHD
	RG6234	-	multiple myeloma	RG	6006	Abx MCP	bacterial infections
	RG6279	PD1-IL2v	solid tumors	RG	6319	LepB inhibitor co	omplicated urinary tract infection
	RG6286	-	colorectal cancer	RG	6338	-	metabolic diseases
	RG6290	MAGE-A4 ImmTAC	solid tumors	RG	6035	BS-CD20 MAb	multiple sclerosis
	RG6292	CD25 MAb ± T	solid tumors	RG	6091	rugonersen (UBE3A LN	NA) Angelman syndrome
	RG6323	IL15/IL15Ra-Fc	solid tumors	RG	6163	-	psychiatric disorders
	RG6330	KRAS G12C	solid tumors	RG	6182	-	neurodegenerative diseases
	RG6333	CD19 x CD28 + glofitamab	r/r NHL	RG	6237	latent myostatin	neuromuscular disorders
	RG6344	BRAF inhibitor (3)	solid tumors	RG	6289	-	Alzheimer´s
	RG6392	-	oncology	RG	7637	-	neurodevelopmental disorders
	RG6433	SHP2i	solid tumors	RG	6120	VEGF-Ang2 DutaFab	nAMD
	RG6440	TGFβ (SOF10)	solid tumors	RG	6312	-	geographic atrophy
Ī	RG7440	ipatasertib + rucaparib	mCRPC, solid tumors		5501*	OpRegen	geographic atrophy
	NG/440	ipatasertib prosta	ate cancer, pretreated		7921	-	nAMD
	RG7446	Morpheus platform	solid tumors	C	:HU	AMY109	endometriosis
ĺ	RG7601	Venclexta ± azacitidine	r/r MDS			lecular Entity (NME)	Metabolism
	RG7802	cibisatamab ± T	solid tumors			nal Indication (AI)	Neuroscience
	RG7827	FAP-4-1BBL + combos	solid tumors		Immuno	gy/Hematology blogy	Ophthalmology Other
ı	DC7020		haa hamatumasa			97	5 t5.

heme tumors

¹combination platform T=Tecentriq, BS=Brain shuttle

Infectious Diseases

RG-No - Roche/Genentech CHU - Chugai managed

IONIS - IONIS managed SQZ - SQZ Biotechnology managed *Lineage Cell Therapeutics managed

Phase II (22 NMEs + 13 Als)

RG6026	glofitamab+chemo	1L ctDNA high risk DLBCL
	tiragolumab + T	NSCLC
	tiragolumab+T+chemo	1L non-squamous NSCLC
RG6058	tiragolumab+T+chemo	neoadj-adj NSCLC
	tiragolumab + T	cervical cancer
	tiragolumab + T	1L PD-L1+ mSCCHN
RG6107	crovalimab	sickle cell disease
RG6139	PD1 x LAG3	solid tumors
RG6171	giredestrant (SERD)	neoadjuvant ER+ BC
1100171	giredestrant (SERD)	2/3L ER+/HER2- mBC
RG6180	autogene cevumeran + pembrol	lizumab 1L melanoma
RG6354	zinpentraxin alfa (PRM-151)	myelofibrosis
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016 hemophilia	A with 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
RG6173	anti-tryptase	asthma
IONIS	ASO factor B	IgA nephropathy
RG7854/RG79 07/RG6346/ RG6084 ¹	TLR7 ago(3)/CpAM (2)/ siRNA/PDL1 LNA	нву
RG6359	SPK-3006	Pompe disease
RG6100	semorinemab	Alzheimer's
RG6102	BS-gantenerumab	Alzheimer's
RG6416	bepranemab	Alzheimer's
RG7412	crenezumab far	milial 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
IONIS	ASO factor B	geographic atrophy

mosunetuzumab monotherapy + combos

RG7828

Roche Group development pipeline



Phase III (10 NMEs + 40 Als)

RG3502	Kadcyla + T	2L+ HER-2+ PD-L1+ mBC	RG7601	Venclexta	r/r MM	t(11:14)
Kadcyla + T		HER-2+ eBC high-risk	1107001	Venclexta + azacitidine		1L MDS
RG6026	glofitamab + chemo	2L+ DLBCL	RG7828	mosunetuzumab+lenal	lidomide	2L+ FL
	tiragolumab + T	1L PD-L1+ NSCLC	RG7853	Alecensa	ALK+ NS	SCLC adj
RG6058	tiragolumab+T locally advan	ced esophageal cancer	RG3648	Xolair	foo	d allergy
1100030	tiragolumab + T	1L esophageal cancer	RG6354	zinpentraxin alfa (PRM-	151)	IPF
tiragolumab + T stage III		ınresectable 1L NSCLC		Gazyva	lupus i	nephritis
RG6107 crovalimab		PNH	RG7159	Gazyva	membranous neph	ropathy
NG0 107	crovalimab	aHUS		Gazyva	systemic lupus erythe	matosus
RG6114	inavolisib (mPI3K alpha inh)	1L HR+ mBC	RG6152	Xofluza	influenza, pediatric (C)-1 year)
RG6171	giredestrant (SERD)	ER+/HER2- mBC	NG0 132	Xofluza	influenza direct tran	smission
NG0 17 1	giredestrant (SERD)	adj ER+ BC	RG1450	gantenerumab Alzh		heimer's
RG6268	Rozlytrek ROS1+	1L NSCLC	RG1594	Ocrevus higher dose RMS & PP		S & PPMS
RG7440	ipatasertib + abiraterone	1L CRPC	RG6042	tominersen Huntingto		tington's
	Tecentriq + platinum chemo	NSCLC neoadj	RG6168	Enspryng myasthenia gra		ia gravis
	Tecentriq	NMIBC, high risk	RG6356	delandistrogene moxep	parvovec (SRP-9001)	DMD
	Tecentriq	RCC adj	RG7845	fenebrutinib		RMS
	Tecentriq + cabozantinib	advanced RCC	RG7845	fenebrutinib		PPMS
	Tecentriq + cabozantinib	2L NSCLC		Susvimo (PDS)		DME
	T ± chemo	SCCHN adj	RG6321	Susvimo (PDS)		DR
RG7446	RG7446 T + capecitabine or carbo/gem			Susvimo (PDS)	wAMD,	36-week
	T+paclitaxel TNBC adj		RG7716	Vabysmo (faricimab)		BRVO
	T + Avastin	HCC adj	NG//10	Vabysmo (faricimab)		CRVO
	T ± chemo	1L mUC				
	Tecentriq	SC NSCLC				

ctDNA+ high-risk MIBC

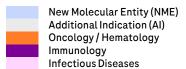
1L maintenance SCLC

T=Tecentriq PDS=Port Delivery System with ranibizumab

Registration US & EU (4 NMEs + 9 Als)

RG6013	Hemlibra ¹	mild to moderate hemophilia A
RG6026	glofitamab ¹	3L+ DLBCL
RG6396	Gavreto ²	RET+ MTC, TC
RG7446	Tecentriq ²	NSCLC adj
RG7596	Polivy ¹	1L DLBCL
RG7828	mosunetuzumab	3 L+ FL
RG6321	Susvimo (PDS)	wAMD
RG7716	Vabysmo (faricimab) ³	DME
NG//10	Vabysmo (faricimab) ³	wAMD
RG6152	Xofluza	influenza, pediatric
RG56413+	Ronapreve	SARS-CoV-2 hospitalised
RG6412	·	•
RG1569	Actemra ⁴	COVID-19 pneumonia
RG7916	Evrysdi	SMA pediatric <2months

¹ Filed in the EU





Status as of April 25, 2022

Tecentriq

T+ lurbinectedin

² Approved in US

³ Approved in US, filed in EU

⁴ Approved in EU

NME submissions and their additional indications



semorinemab

Alzheimer's

RG6100

Projects in phase II and III

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



Inte	Infectious Diseases						cancer	
						RG6058	tiragolumab + T locally adv esophageal cancer	
RG6026	glofitamab 3L+ DLBCL √					RG6058	tiragolumab + T 1L non-sq NSCLC	
RG6058	tiragolumab + T 1L PD-L1+ NSCLC					RG6058	tiragolumab + T 1L PD-L1+ mSCCHN	ı
RG6058	tiragolumab + T 1L esophageal cancer (CN)			RG6058	tiragolumab + T Stage III unresectable 1L NSCLC	RG6058	tiragolumab+T+/- chemo neoadj/adj NSCLC	ı
RG6107	crovalimab PNH(CN)			RG6107	crovalimab aHUS	RG6107	crovalimab sickle cell disease	ı
RG6171	giredestrant (SERD) 2L/3L ER+/HER2- mBC	RG6321	Susvimo (PDS) DME	RG6114	inavolisib (mPI3K alpha inh) 1L HR+ BC	RG6139	PD1xLAG3 solid tumors	ı
RG7440	ipatasertib+ abiraterone 1L CRPC	RG6321	Susvimo (PDS) DR (US)	RG6354	zinpentraxin alfa (PRM-151) IPF	RG6171	giredestrant (SERD) 1L ER+/HER2- mBC	
RG1450	gantenerumab Alzheimer's	RG7716	Vabysmo (faricimab) BRVO/CRVO	RG6356	delandistrogene moxeparvovec (SRP-9001) DMD	RG6171	giredestrant (SERD) Adj ER+ BC	

					Alzheimer's
RG6026	glofitamab + chemo 2L DLBCL			RG6102	brain shuttle gantenerumab Alzheimer's
RG6026	glofitamab + chemo 1L ctDNA+ high risk DLBCL			RG6416	bepranemab Alzheimer's
RG6058	tiragolumab + T 1L PD-L1+ cervical cancer			RG7816	alogabat (GABA Aa5 PAM) ASD
RG6058	tiragolumab + T locally adv esophageal cancer			RG7845	fenebrutinib RMS
RG6058	tiragolumab + T 1L non-sq NSCLC			RG7845	fenebrutinib PPMS
RG6058	tiragolumab + T 1L PD-L1+ mSCCHN	RG6180	autogene cevumeran 1L melanoma	RG7906	ralmitaront schizophrenia
RG6058	tiragolumab+T+/- chemo neoadj/adj NSCLC	RG6354	zinpentraxin alfa (PRM-151) myelofibrosis	RG7935	prasinezumab Parkinson's
RG6107	crovalimab sickle cell disease	RG7828	mosunetuzumab + lenalidomide 2L FL	RG6321	Susvimo (PDS) wAMD, 36-week refill
RG6139	PD1xLAG3 solid tumors	RG6149	astegolimab (anti-ST2) COPD	RG6147	galegenimab (HtrA1) geographic atrophy
RG6171	giredestrant (SERD) 1L ER+/HER2- mBC	RG6173	anti-tryptase asthma	RG6179	NME DME
RG6171	giredestrant (SERD) Adj ER+ BC	RG7907/ RG7854/ RG6346/ RG6084	TLR7 ago (3)/CpAM (2) /siRNA/ PDL1 LNA HBV	RG7774	NME retinal disease

2022

2023

2024

2025 and beyond

Al submissions for existing products



Projects in phase II and III

		RG3648	Xolair food allergy
		RG6152	Xofluza direct transmission
		RG6152	Xofluza influenza, pediatric (0-1 year)
		RG6396	Gavreto Tumour agnostic
		RG7446	Tecentriq SC NSCLC
		RG7446	Tecentriq + cabozantinib 2L NSCLC
RG6413+ RG6412	Ronapreve** SARS-CoV-2 hospitalized (EU) √	RG7446	Tecentriq + cabozantinib adv RCC
RG1569	Actemra COVID-19 pneumonia¹√	RG7446	Tecentriq + Avastin HCC adj
RG7446	Tecentriq RCC adj	RG7446	Tecentriq² NSCLC neo adj
RG7446	Tecentriq ± chemo 1L mUC	RG7601	Venclexta r/r MM t(11:14)
RG7596	Polivy 1L DLBCL (US)	RG7446	Tecentriq + capecitabine or carbo/gem TNBC
RG6268	Rozlytrek (BFAST)	RG7853	Alecensa

RG7853

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



RG7446	Tecentriq ctDNA+ high-risk MIBC	RG3502	Kadcyla + Tecentriq 2L+ HER-2+ PD-L1+ mBC
RG7446	Tecentriq SCCHN adj	RG3502	Kadcyla + Tecentriq HER-2+ eBC high-risk
RG7601	Venclexta + azacitidine 1L MDS	RG7446	Tecentriq + paclitaxel TNBC adj
RG7159	Gazyva lupus nephritis	RG7446	Tecentriq High risk NMIBC
RG6168	Enspryng myasthenia gravis	RG7446	Tecentriq+ lurbinectedin 1l maintenance SCLC

RG7159	Gazyva membranous nephropathy
RG7159	Gazyva systemic lupus erythematosus
RG1594	Ocrevus higher dose RMS & PPMS

2022

1L NSCLC ROS1+

2023

²filing timeline based on data from interim analysis

2024

2025 and beyond

Status as of April 25, 2022

ALK+ NSCLC adj

Major pending approvals 2022



US			
RG6152	Xofluza influenza pediatric Filed March 2020		
RG7916	Evrysdi SMA presymptomatic pediatric <2mo Filed Nov 2021		
RG7828	mosunetuzumab 3L+ FL Filed Dec 2021		
RG1569	Actemra COVID-19 pneumonia Filed Jan 2022		

	EU
RG6321	Susvimo (PDS) wAMD Filed April 2021
RG7716	Vabysmo (faricimab) DME Filed May 2021
RG7716	Vabysmo (faricimab) wAMD Filed May 2021
RG7446	Tecentriq NSCLC adj Filed June 2021
RG6013	Hemlibra mild to moderate hemophilia A Filed Oct 2021
RG6396	Gavreto RET+ MTC, TC Filed Nov 2021
RG6152	Xofluza influenza pediatric Filed Nov 2021
RG7916	Evrysdi SMA presymptomatic pediatric <2mo Filed Nov 2021
RG7596	Polivy 1L DLBCL Filed Dec 2021
RG7828	mosunetuzumab 3L+FL Filed Dec 2021
RG6413+ RG6412	Ronapreve** SARS-CoV-2 hospitalized Filed Jan 2022
RG6026	glofitamab 3L+ DLBCL Filed April 2022

China		Japan-Chugai		
RG6268	Rozlytrek ROS1+ NSCLC Filed Oct 2021	RG7446	Tecentriq NSCLC adj Filed July 2021	
RG6268	Rozlytrek NTRK+ solid tumors Filed Nov 2021	RG6013	Hemlibra acquired Haemophilia A Filed Nov 2021	
RG7596	Polivy 1L DLBCL Filed Nov 2021	RG7596	Polivy 1L DLBCL Filed Dec 2021	
RG7596	Polivy R/R DLBCL Filed Dec 2021	RG7159	Gazyva 1L CLL Filed March 2022	





PDS=Port Delivery System with ranibizumab

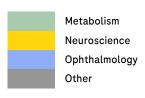
^{**}Ronapreve (casirivimab+imdevimab also known as REGEN-COV in the US) developed in collaboration with Regeneron Pharmaceuticals

Major granted approvals 2022



	US	EU		China	J	lapan-Chugai
RG7716	Vabysmo (faricimab) DME Jan 2022		RG7446	Tecentriq NSCLC adj March 2022	RG1569	Actemra COVID-19 pneumonia Jan 2022
RG7716	Vabysmo (faricimab) wAMD Jan 2022		RG1569	Actemra RA SC April 2022	RG7716	Vabysmo (faricimab) DME March 2022
RG1569	Actemra GCA IV Feb 2022				RG7716	Vabysmo (faricimab) wAMD March 2022
					RG1273	Perjeta + Herceptin HER-2+ CRC March 2022

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



Status as of April 25, 2022 **58**



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, dosi	
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	 Number of bleeds over 24 weeks 	 Number of bleeds over 24 weeks 	
Status	 FPI Q3 2016, recruitment completed Q2 2017 Study met primary and key secondary endpoints Q4 2017 FDA granted Breakthrough Therapy Designation April 2018 Data presented at WFH 2018 Filed in US (priority review) and EU in Q2 2018 Data published in NEJM 2018; 379: 811-822 	 FPI Q1 2017, recruitment completed Q2 2017 Pharmacokinetic run-in data at ASH 2017 Positive interim analysis outcome reported Q4 2017 Data presented at WFH 2018 Interim data filed in US and EU in Q2 2018 Data published in Lancet Haematology 2019 Jun;6(6):e295-e305 	
	•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	 Number of bleeds over 24 weeks 	Safety and efficacy	
Status	 FPI Q2 2018 Recruitment completed Q1 2019 Filed in China Q2 2020 Approved in China Q2 2021 	 FPI Q1 2020 Recruitment completed Q1 2021 Interim data presented at ASH 2021 Filed in EU Q4 2021 	
CT Identifier	NCT03315455	NCT04158648	

Alecensa

Roche

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	- ARM A: Alecensa 600mg BID - ARM B: Crizotinib 250mg BID	 ARM A: Alecensa 600mg BID ARM B: Platinum-based chemotherapy 	
Primary endpoint	Progression-free survival	Disease-free survival	
Status	 Recruitment completed Q3 2015 Primary endpoint met Q1 2017 Data presented at ASCO 2017, 2018, ESMO 2017, 2018 Data published in NEJM 2017; 377:829-838 CNS data presented at ESMO 2017 Final PFS and updated OS presented at ESMO 2019 Approved in US Q4 2017 (priority review) and in EU Q4 2017 	 FPI Q3 2018 Recruitment completed Q4 2021 	
CT Identifier	NCT02075840	NCT03456076	

Kadcyla



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	ARM A: Kadcyla 3.6mg/kg q3wARM B: Herceptin	 ARM A: Kadcyla plus Tecentriq ARM B: Herceptin plus placebo 	 ARM A: Kadcyla plus Tecentriq ARM B: Kadcyla plus placebo
Primary endpoint	 Invasive disease-free survival 	 Progression-free survival and overall survival 	 Invasive disease-free survival
Status	 Recruitment completed Q4 2015 Stopped at pre-planned interim data analysis for efficacy Q4 2018 Data presented at SABCS 2018 BTD granted by FDA in Q1 2019 US filling completed under RTOR Q1 2019 and filed in EU Q1 2019 Approved in US Q2 2019 and in EU Q4 2019 Data published in NEJM 2019; 380:617-628 	• FPI Q1 2021	• FPI Q2 2021
CT Identifier	NCT01772472	NCT04740918	NCT04873362

In collaboration with ImmunoGen, Inc.

Perjeta

Roche

First-in-class HER2 dimerization inhibitor

Indication	Adjuvant HER2-positive breast cancer (BC)	HER2-positive early breast cancer (BC) subcutaneous co-formulation	
Phase/study	Phase III APHINITY	Phase III FeDeriCa	Phase II PHranceSCa
# of patients	N=4,803	N=500	N=160
Design	 ARM A: Perjeta (840mg loading dose, 420mg q3w) plus Herceptin for 52 weeks plus chemotherapy (6-8 cycles) ARM B: Placebo plus Herceptin (52 weeks) plus chemotherapy (6-8 cycles) 	FDC of Perjeta and Herceptin for SC administration in combination with chemotherapy in neoadjuvant/adjuvant setting • ARM A: Perjeta IV plus Herceptin IV plus chemotherapy • ARM B: FDC of Perjeta and Herceptin SC plus chemotherapy	ARM A: Perjeta and Herceptin IV followed by FDC SC ARM B: Perjeta and Herceptin FDC SC followed by IV
Primary endpoint	 Invasive disease-free survival 	 Trough Serum Concentration (Ctrough) of Perjeta during cycle 7 	 Percentage of patients who preferred Perjeta and Herceptin FDC SC
Status	 Primary endpoint met Q1 2017 Data presented at ASCO 2017 and published in NEJM 2017; 377:122-131 Filed in US and EU Q3 2017 Approved in US Q4 2017 (priority review) and EU Q2 2018 	 Primary endpoint met Q3 2019 Data presented at SABCS 2019 Data published in Lancet Oncology 2021 Jan;22(1):85-97 	 FPI Q4 2018 Final analysis completed, 85% patients preferred FDC SC Data presented at ESMO 2020 Data published in <i>Eur J Cancer</i> 2021 Jul;152:223-232 PUS Q2 2020 and EU Q4 2020
	 Six year IDFS data presented at SABCS 2019 	Filed in US Dec 2019 & in EU Jan 2020; Approved in US Q2 2020 and EU Q4 2020	
CT Identifier	NCT01358877	NCT03493854	NCT03674112



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	 ARM A: Tecentriq plus platinum-based chemotherapy ARM B: Platinum-based chemotherapy
Primary endpoint	Disease-free survival	Event-free survival
Status	 Trial amended from PD-L1+ selected patients to all-comers FPI for all-comer population Q4 2016 Recruitment completed Q3 2018 Study met primary endpoint Q1 2021 Data presented at ASCO, WCLC and ESMO 2021 Filed in US (priority review) and EU Q2 2021 Approved in US Q4 2021 	 FPI Q2 2018 Recruitment completed Q3 2021
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 ¹	Phase III CONTACT-01
# of patients	N=450	N=366
Design	 ARM A:Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin ARM B:Platinum-etoposide + Tecentriq followed by maintenance Tecentriq 	 ARM A: Tecentriq plus cabozantinib ARM B: Docetaxel
Primary endpoint	Progression-free survival and overall survival	Overall survival
Status	• FPI Q4 2021	 FPI Q3 2020 Recruitment completed Q4 2021
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 Ib/III IMscin001 ¹
# of patients	Modular design	N=371
Design	 Cohort A: ALK+ (Alecensa) Cohort B: RET+ (Alecensa) Cohort C: bTMB-high (Tecentriq) Cohort D: ROS1+ (Rozlytrek) Cohort E: BRAF+ (Zelboraf plus Cotellic plus Tecentriq) Cohort F: EGFR Exon 20+ (Tecentriq, Avastin, carboplatin, pemetrexed) 	 Phase Ib Dose finding, Tecentriq SC followed by Tecentriq IV Phase III 2L NSCLC non inferiority of Tecentriq SC vs Tecentriq IV
Primary endpoint	 Cohort A/B/D: Objective response rate Cohort C: Progression-free survival Cohort E: Time in response Cohort F: Investigator-assessed objective response rate 	Observed concentration of Tecentriq in serum at cycle 1
Status	 FPI Q3 2017 Recruitment completed for cohort A Q3 2018 and cohort C Q3 2019 Cohort A: primary endpoint met Q3 2019; approved in US Q1 2021 Cohort C: did not show statistical significance for primary endpoint, data presented at ESMO 2021 Cohort F: FPI Q2 2021 	 FPI Q4 2018 FPI in phase III part Q4 2020 Recruitment completed Q1 2022
CT Identifier	NCT03178552	NCT03735121

¹SC 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)	First-line BRAFv600 mutation-positive metastatic or unresectable locally advanced melanoma
Phase/study	Phase III IMvoke010	Phase III IMspire150 TRILOGY ¹
# of patients	N=406	N=514
Design	 ARM A: Tecentriq 1200mg q3w ARM B: Placebo 	Double-blind, randomized, placebo-controlled study • ARM A: Tecentriq plus Cotellic plus Zelboraf ² • ARM B: Placebo plus Cotellic plus Zelboraf ²
Primary endpoint	Event-free survival and overall survival	Progression-free survival
Status	 FPI Q1 2018 Recruitment completed Q1 2020 	 FPI Q1 2017 Recruitment completed Q2 2018 Primary endpoint met Q4 2019 Data presented at AACR 2020 Data published in Lancet;395(10240):1835-1844 Filed in US Q2 2020 under Project Orbis³ Approved in US Q3 2020
CT Identifier	NCT03452137	NCT02908672



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	 ARM A: Tecentriq plus gemcitabine and carboplatin or cisplatin ARM B: Tecentriq monotherapy ARM C: Placebo plus gemcitabine and carboplatin or cisplatin 	 ARM A: BCG induction and maintenance ARM B: Tecentriq plus BCG induction and maintenance 	 ARM A: Tecentriq monotherapy ARM B: Placebo
Primary endpoint	 Progression-free survival, overall survival and safety 	Recurrence-free survival	Recurrence-free survival
Status	 FPI Q3 2016 FPI for arm B (amended study) Q1 2017 Recruitment completed Q3 2018 Study met co-primary endpoint of PFS Q3 2019 Data presented at ESMO 2019 and AACR 2021 Data published in Lancet 2020 May 16;395(10236):1547-1557 	■ 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 ¹
# of patients	N=778	N=500
Design	 ARM A: Tecentriq monotherapy ARM B: Placebo 	 ARM A: Tecentriq plus cabozantinib ARM B: Cabozantinib
Primary endpoint	 Investigator-assessed disease-free survival 	Progression-free survival and overall survival
Status	 FPI Q1 2017 Recruitment completed Q1 2019 	 FPI Q3 2020 Recruitment completed Q4 2021
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	 FPI Q1 2018 Recruitment completed Q1 2019 Data presented at ESMO Asia 2019 US filing completed under RTOR Q1 2020; filed in EU Q1 2020 Data published in NEJM 2020;382:1894-1905 Approved in US Q2 2020 and EU Q4 2020 	 FPI Q4 2019 Recruitment completed Q4 2021
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	 ARM A: Tecentriq plus nab-paclitaxel ARM B: Placebo plus nab-paclitaxel 	 ARM A: Tecentriq plus capecitabine or carbo/gem ARM B: Placebo plus capecitabine or carbo/gem
Primary endpoint	 Progression-free survival and overall survival (co-primary endpoint) 	Overall survival
Status	 Study met co-primary endpoint of PFS in both PD-L1+ and ITT populations Q3 2018 Primary PFS and interim OS data presented at ESMO 2018 and ASCO 2019 Data published in NEJM 2018; 379:2108-2121 US accelerated approval Q1 2019 – US indication voluntarily withdrawn Q3 2021 Approved in EU Q3 2019 Final OS presented at ESMO Asia 2020 	• FPI Q1 2018
CT Identifier	NCT02425891	NCT03371017

Tecentriq



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	 ARM A: Tecentriq plus nab-paclitaxel ARM B: Placebo plus nab-paclitaxel 	 ARM A: Tecentriq plus paclitaxel followed by AC followed by Tecentriq plus AC, followed by Tecentriq maintenance ARM B: Placebo plus paclitaxel followed by AC followed by placebo
Primary endpoint	 Percentage of participants with pathologic complete response 	■ Invasive disease-free survival
Status	 FPI Q3 2017 Recruitment completed Q2 2018 Study met primary endpoint Q2 2020 Data presented at ESMO 2020 Data published in Lancet 2020;396 (10257):1090-1100 Filed in EU Q4 2020 - application withdrawn Q3 2021 	• 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	 ARM A: Venclexta plus Gazyva ARM B: Chlorambucil plus Gazyva 	 ARM A: Venclexta plus Rituxan ARM B: Rituxan plus bendamustine 	 ARM A: Venclexta plus Gazyva ARM B: Fludarabine plus cyclophosphamide plus Rituxan or bendamustine plus Rituxan
Primary endpoint	■ Progression-free survival	 Progression-free survival 	 MRD negativity rate in peripheral blood at 15 months
Status	 Study met primary endpoint at pre-specified interim analysis Q4 2018 BTD granted by FDA Q1 2019 US filing completed under RTOR Q1 2019 Filed in EU Q2 2019 Data presented at ASCO 2019, ASH 2019, ASH 2020 and EHA 2021 Data published in NEJM 2019; 380:2225-2236 Approved US Q2 2019 and EU Q1 2020 	 Study met primary endpoint at interim analysis Data presented at ASH 2017 Filed in US Q4 2017 and EU Q1 2018 Data published in NEJM 2018; 378:1107-20 Updated data presented at ASCO 2018, ASH 2019 and ASH 2020 Approved in US Q2 2018 (priority review) EU approval Q4 2018 	• 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	 Dose escalation cohort: Venclexta dose escalation Safety expansion cohort (t11;14): Venclexta expansion Combination: Venclexta plus dexamethasone 	 Venclexta plus carfilzomib plus dexamethasone in t(11;14) positive r/r MM 	 Venclexta plus dexamethazone vs pomalidomide plus dexamethasone in t(11;14) positive r/r MM
Primary endpoint	 Safety and maximum tolerated dose 	 Safety, objective response rate, Pharmacokinetics, Pharmacodynamics 	 Progression-free survival
Status	 FPI Q4 2012 Data presented at ASCO 2015 Updated data presented at ASCO 2016 and ASH 2016 Data published in Blood 2017; 130(22):2401-2409 and Am J Hematol 2021 Apr 1;96(4):418-427 	 FPI Q1 2017 Data published Blood Adv 2021 Oct 12;5(19):3748-3759 	• 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	 Dose escalation cohort: Venclexta plus azacitidine dose escalation Safety expansion cohort 	ARM A: Venclexta plus azacitidine ARM B: Placebo plus azacitidine
Primary endpoint	 Safety, efficacy, Pharmacokinetics and Pharmacodynamics 	 Safety, Pharmacokinetics, RPTD 	 Complete remission rate and overall survival
Status	 FPI Q1 2017 Recruitment completed Q1 2022 	 FPI Q1 2017 Data presented at ASH 2019 Updated data presented at ASH 2020 BTD granted by FDA July 2021 Recruitment completed Q1 2022 	• 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	 FPI Q4 2017 Recruitment completed Q2 2019 Study met primary endpoint Q3 2021 Data presented at ASH 2021 Filed in EU, Japan and China Q4 2021 Published in NEJM 2022 Jan 27;386(4):351-363
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	 Maximum tolerated dose and RPTD
	FPI Q1 2016Data presented at WCLC 2018	FPI Q1 2016Data presented at ESMO 2018	 FPI Q2 2016 Initial data presented at ASCO 2019
Status	 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 Filed in US Q4 2018 and EU Q1 2019 Approved in US Q3 2019 and EU Q3 2020 Published in Lancet Oncol. 2020 Feb;21(2):261-271 and 271-282 		
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	 Part 1: Gavreto 30-600mg dose escalation Part 2: Gavreto 400mg dose expansion 	 Arm A: Gavreto 400mg Arm B: Platinum-based chemotherapy +/- pembrolizumab
Primary endpoint	Safety and efficacy	Progression-free survival
Status	 Data presented at ASCO (NSCLC) and ESMO ((MTC) 2020 Filed in US and EU for RET fusion-positive NSCLC and US for RET-mutant MTC and RET fusion-positive thyroid cancer Approved in US Q3 2020 in RET fusion-positive NSCLC, in Q4 2020 in RET-mutant MTC and RET fusion-positive thyroid cancer Updated data presented at ASCO 2021 Data published in Lancet Oncol 2021 Jul;22(7):959-969 Approved in EU for RET fusion-positive NSCLC Q4 2021 	• Study initiated in Q1 2020
CT Identifier	NCT03037385	NCT04222972

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 Phase III OPERA I OPERA II		Phase III ORATORIO
# of patients	N=821	N=835	N=732
Design	 96-week treatment period: ARM A: Ocrevus 2x300mg IV followed by 600mg IV every 24 weeks ARM B: Interferon β-1a (Rebif) 	 96-week treatment period: ARM A: Ocrevus 2x300mg IV followed by 600mg IV every 24 weeks ARM B: Interferon β-1a (Rebif) 	120-week treatment period: • ARM A: Ocrevus 2x300mg IV every 24 weeks • ARM B: Placebo
Primary endpoint	 Annualized relapse rate at 96 weeks versus Rebif 	 Annualized relapse rate at 96 weeks versus Rebif 	 Sustained disability progression versus placebo by EDSS
Status	 Primary endpoint met Q2 2015, OLE ongoing Primary data presented at ECTRIMS 2015 Updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 Data published in NEJM 2017; 376:221-234 Data published on COVID-19 in Mult Scler Relat Disord on Ocrevus treated people with MS, doi.org/10.1016/j.msard.2020.102725 		 Primary endpoint met Q3 2015 Primary data presented at ECTRIMS 2015, updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 Data published in NEJM 2017; 376:209-220
	- Approved in US Q1 2017 and EU Q1 2018		018
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=1225	N ~ 1000
Design	 Substudy of ongoing phase IIIb, open-label, single-arm ENSEMBLE study Shorter two-hour infusion time 	120-week treatment period: • ARM A: Ocrevus 600mg IV q24w • ARM B: Placebo
Primary endpoint	 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) 	Time to upper limb disability progression confirmed for at least 12 weeks
Status	 Filed in US and EU Q1 2020 Approved in EU Q2 2020 and US Q4 2020 Data published Neurol, Neuroimmunol and Neuroinflamm Sept 2020; 7(5), e807 	• 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)	
Phase/study	Phase IIIb GAVOTTE	Phase IIIb MUSETTE	
# of patients	N~699	N~786	
Design	 120-week treatment period: ARM A: Ocrevus 600mg IV every 24 weeks ARM B: Ocrevus 1200mg if body weight <75kg or 1800mg if body weight > or equal to 75kg every 24 weeks 	 120-week treatment period: ARM A: Ocrevus 600mg IV every 24 weeks ARM B: Ocrevus 1200mg if body weight <75kg or 1800mg if body weight > or equal to 75kg every 24 weeks 	
Primary endpoint	 Superiority of Ocrevus higher dose versus approved dose on cCDP 	 Superiority of Ocrevus higher dose versus approved dose on cCDP 	
Status	• FPI Q4 2020	 FPI Q4 2020 Recruitment completed Q4 2021 	
CT Identifier	NCT04548999	NCT04544436	

Evrysdi (risdiplam, RG7916)

Roche

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)		
Phase/study	Phase II/III Phase II/III Phase II FIREFISH SUNFISH 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 adult and pediatric patients with type 2 or type • Part 1 (dose-finding): At least 12 weeks • Part 2 (confirmatory): 24 months	
Primary endpoint	Safety, tolerability, PK/PD and efficacy	Safety, tolerability, PK/PD and efficacy	Safety, tolerability, PK/PD
Status	 12 month data from Part 1 presented at AAN, CureSMA and EAN 2019; 16 month data presented at WMS 2019 Study met primary endpoint in part 2 Q1 2020 Part 2 1-year data presented at AAN 2020, part 1 2-year data at WMS 2020 Part 1 data published in NEJM 2021;384:915-923 Part 2 2-year data presented at AAN 2021 Part 2 1-year data published in NEJM 2021;385:427-43 	 12 month data from Part 1 presented at AAN and EAN 2019; 16 month data presented at W Study met primary endpoint in part 2 Q4 201 Part 2 1-year data presented at SMA Europe year data at MDA 2021 and 3 year data at MD Part 2 data 1 year published in Lancet Neuro 	* Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, 2019, CureSMA 2020 and 2021 * Recruitment completed Q1 2020 ** **The complete of the complete
	 Orphan drug designation granted by FDA Q1 2017 and EU Q1 2019, PRIME designation in Q4 2018 Approved in US Q3 2020 and EU Q1 2021 		Edesignation in Q4 2018
CT Identifier	NCT02913482	NCT02908685	NCT03032172

Evrysdi (risdiplam, RG7916)

Roche

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	 Proportion of participants with two copies of the SMN2 gene (excluding the known SMN2 gene modifier mutation c.859G>C) and baseline CMAP>=1.5 millivolt who are sitting without support 	 Change from baseline in revised hammersmith scale (RHS) score after week 72 of treatment Safety, PK/PD and muscle biomarkers
Status	 FPI Q3 2019 Recruitment completed Q1 2022 Initial data presented at CureSMA, WMS 2021 and MDA 2022 Filed in US and EU Q4 2021 	 FPI expected Part 1 Q2 2022 Orphan Drug Designation granted by FDA in Q4 2021 for GYM329
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: • Group A: Enspryng 120mg SC monthly • Group B: Placebo SC monthly	Add-on therapy of Enspryng: • Group A: Enspryng 120mg SC monthly • Group B: Placebo SC monthly Both arms on top of baseline therapies: azathioprine, mycophenolate mofetil or oral corticosteroids	
Primary endpoint	•Efficacy (time to first relapse), safety and PK/PD	 Efficacy (time to first relapse), safety and PK/PD 	
Status	 Primary endpoint met Q4 2018 Data presented at ECTRIMS 2019 Published in Lancet Neurology 2020; 19(5): 402-412 	 FPI Q3 2017 Primary endpoint met Q3 2018 Data presented at ECTRIMS 2018 and AAN 2019 Published in NEJM 2019; 381:2114-2124 	
	 BTD granted by FDA Q4 2018 Filed in EU Q3 2019; US acceptance of filing Q4 2019, Approved in US Q3 2020 and EU Q2 2021 		
CT Identifier	NCT02073279	NCT02028884	

^{*}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	 Group A: Enspryng plus standard of care Group 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	 Mean change from baseline in total MG-ADL score at week 24 in AChR+ population 	Time from randomization to the first occurrence of a MOGAD relapse
Status	 Orphan Drug Designation granted in US Q1 2021 FPI Q4 2021 	• FPI expected Q2 2022
CT Identifier	NCT04963270	NCT05271409

Gazyva (obinutuzumab)

Roche

Immunology development program

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

Gazyva (obinutuzumab)

Roche

Immunology development program

Indication	Systemic lupus erythematosus (SLE)
Phase/study	Phase III ALLEGORY
# of patients	N=200
Design	• ARM A: Gazyva 1000mg IV on Day 1 and Weeks 2, 24 and 26. • ARM B: Placebo IV
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 ¹	Phase III REMDACTA ²
# of patients	N=450	N=650
Design	 Arm A: Actemra plus standard of care Arm B: Placebo plus standard of care 	 Arm A: Remdesivir plus Actemra Arm B: Remdesivir plus placebo
Primary endpoint	 Clinical status assessed using 7-Category Ordinal Scale (Day 28) 	Time to hospital discharge or ready for discharge
Status	 FPI Q1 2020 Recruitment completed Q2 2020 Primary endpoint not met Q3 2020 Published in NEJM 2021; 384:1503-1516 FPI Q2 2020 Recruitment completed Q1 2021 Primary endpoint not met Q1 2021 Published in Intensive Care Med 2021 doi: 10.1007/s00134-021-0650 Filed in the EU Q3 2021 Approved in EU Q4 2021 	
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	Arm A: 8 mg/kg Actemra plus standard of care Arm B: 4mg/kg Actemra plus standard of care	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	 Cumulative proportion of participants requiring mechanical ventilation by day 28
Status		 FPI Q2 2020 Primary endpoint met Q3 2020 Published in NEJM 2021 Jan 7;384(1):20-30 EU Q3 2021 in EU Q4 2021
CT Identifier	NCT04363736	NCT04372186

Xolair



Humanized monoclonal antibody that selectively binds to IgE

Indication	Food allergy	
Phase/study	Phase III OUtMATCH ¹	
# 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	

Susvimo (PDS)



First eye implant to achieve sustained delivery of a biologic medicine

Indication	Wet age-related macular degeneration (wAMD)		
Phase/study	Phase III Phase II+III extension Archway Portal		Phase IIIb Velodrome
# of patients	N=418	N=1,000	N=442
Design	 ARM A: Port delivery system with ranibizumab q24w ARM B: Intravitreal ranibizumab q4w 	 Patients from LADDER or Archway will receive refills of 100mg/mL ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills) 	 ARM A: Port delivery system with ranibizumab q36w ARM B: Port delivery system with ranibizumab q24w
Primary endpoint	 Change in BCVA from baseline at the average of week 36 and week 40 	 Safety and long term efficacy 	 Change in BCVA from baseline averaged over weeks 68 and 72
Status	 FPI Q3 2018 Recruitment completed Q2 2019 Study met primary endpoint Q2 2020 Primary endpoint data presented at ASRS 2020, 44/48 week data at Angiogenesis 2021 and 2-year data at Angiogenesis 2022 Filed in US (PRIME) and EU Q2 2021 Approved in US Q4 2021 	• 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 	 Arm A: Intravitreal ranibizumab (X2) followed by PDS implant (refill q36w) Arm B: Q4w comprehensive clinical monitoring until participants receive PDS (refill q36w)
Primary endpoint	 Change in BCVA from baseline at the average of week 48 and week 52 	 Percentage of participants with a ≥2-step improvement from baseline on the ETDRS-DRSS at Week 52
Status	 FPI Q3 2019 Recruitment completed Q2 2021 	 FPI Q3 2020 Recruitment completed Q3 2021
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	 ARM A: Faricimab q8w ARM B: Faricimab PTI up to q16w ARM C: Aflibercept, q8w 		 ARM A: Faricimab q8w ARM B: Faricimab PTI up to q16w ARM C: Aflibercept, q8w 	
Primary endpoint	 Change from baseline in BCVA at 1 year 		 Change from baseline in BCVA at 1 year 	
Status	 FPI Q3 2018 Recruitment completed Q3 2019 Study met primary endpoint Q4 2020 Data presented at Angiogenesis 2021 		 FPI Q4 2018 Recruitment completed Q3 2019 Study met primary endpoint Q4 2020 Data presented at Angiogenesis 2021 	
Status		 Filed in US and EU Q2 2021 Published in the Lancet 2022 Feb 19;399(10326):741-755. 2-year data presented at Angiogenesis 2022 Approved in US Q1 2022 		
CT Identifier	NCT03622580		NCT0362259	3

Vabysmo (faricimab)



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

Indication	Neovascular age related macular degeneration (nAMD)	
Phase/study	Phase III TENAYA	Phase III LUCERNE
# of patients	N=671	N=658
Design	 ARM A: Faricimab 6.0mg q16w flexible after 4 IDs ARM B: Aflibercept 2.0mg q8w after 3 IDs 	 ARM A: Faricimab 6.0mg q16w flexible after 4 IDs ARM B: Aflibercept 2.0mg q8w after 3 IDs
Primary endpoint	 Change from baseline in BCVA week 40, 44 & 48 	 Change from baseline in BCVA week 40, 44 & 48
Status	 FPI Q1 2019 Recruitment completed Q4 2019 Study met primary endpoint Q1 2021 Data presented at Angiogenesis 2021 	 FPI Q1 2019 Recruitment completed Q4 2019 Study met primary endpoint Q1 2021 Data presented at Angiogenesis 2021
	 Filed in US and EU Q2 2021 Published in Lancet 2022 Feb 19;399(10326):729-740 Approved in US Q1 2022 	
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	 ARM A: Faricimab, q4w/PTI ARM B: Aflibercept, q4w 	 ARM A: Faricimab, q4w/PTI ARM B: Aflibercept, q4w
Primary endpoint	 Change from baseline in BCVA at week 24 	 Change from baseline in BCVA at week 24
Status	FPI Q1 2021Recruitment completed Q1 2022	 FPI Q1 2021 Recruitment completed Q1 2022
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	- Safety	 Percentage of household contacts who are PCR- positive for influenza by day 5 post randomization of index patients
Status	• FPI Q1 2019	 Primary endpoint met Q2 2019 Data presented at OPTIONS X 2019 Filed in US Q1 2020 Data published in <i>Pediatric Infectious Disease</i> 2020 Aug;39(8):700-705 Not approved in the US, determining path forward with the FDA Filed in EU Q4 2021 	■ 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)

Roche

Highly selective small molecule inhibitor of Akt

Indication	1L castration-resistant prostate cancer (CRPC)	Advanced prostate cancer (PC) and solid tumors	Prostate cancer (PC) previously treated with androgen receptor-targeted therapy
Phase/study	Phase III IPATential 150	Phase Ib	Phase Ib
# of patients	N=1,100	N=54	N=50
Design	 ARM A: Ipatasertib plus abiraterone ARM B: Placebo plus abiraterone 	 Ipatasertib plus rucaparib Stage 1: Dose escalation in advanced breast, ovarian and prostate cancer Stage 2: Dose expansion in prostate cancer 	■ Ipatasertib plus Tecentriq plus docetaxel
Primary endpoint	 rPFS in patients with PTEN loss tumors and overall population 	Safety and efficacy	Safety and efficacy
Status	 FPI Q2 2017 Recruitment completed Q1 2019 Study met co-primary endpoint in rPFS in patients with PTEN loss tumors Q2 2020 Data presented at ESMO 2020 Published in Lancet 2021; 398:131-142 	• FPI Q2 2019	• FPI Q3 2020
CT Identifier	NCT03072238	NCT03840200	NCT04404140



Indication	1L NSCLC PD-L1 TPS>50%	1L ES-SCLC	Stage III unresectable 1L NSCLC
Phase/study	Phase III SKYSCRAPER-01	Phase III SKYSCRAPER-02	Phase III SKYSCRAPER-03
# of patients	N=500-560	N=470	N=800
Design	 Arm A: Tiragolumab plus Tecentriq Arm B: Placebo plus Tecentriq 	 Arm A: Tiragolumab plus Tecentriq, carboplatin and etoposide Arm B: Placebo plus Tecentriq, carboplatin and etoposide 	 Arm A: Tiragolumab plus Tecentriq for up to 12 months Arm B: Durvalumab for up to 12 months
Primary endpoint	 Overall survival and progression-free survival 	 Overall survival and progression-free survival 	Progression-free survival
Status	 FPI Q1 2020 Recruitment completed Q3 2021 	 FPI Q1 2020 Recruitment completed Q1 2021 Study did not meet its primary endpoint Q1 2022 	■ FPI Q3 2020
CT Identifier	NCT04294810	NCT04256421	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	 Arm A: (PD-L1 high) neoadjuvant Tiragolumab plus Tecentriq followed by adjuvant tiragolumab plus Tecentriq or adjuvant chemotherapy Arm B: (PD-L1 all-comers) neoadjuvant tiragolumab plus Tecentriq plus chemo followed by adjuvant tiragolumab plus Tecentriq 	 Arm A: Tiragolumab plus Tecentriq plus pemetrexed plus chemo followed by maintenance tiragolumab plus Tecentriq plus pemetrexed Arm B: Placebo plus pembrolizumab plus pemetrexed plus chemo followed by maintenance placebo plus pembrolizumab plus pemetrexed
Primary endpoint	Objective response rate	 Pathologic complete response, major pathological response and safety 	 Objective response rate, progression-free survival and overall survival
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	 Arm A: Tiragolumab plus Tecentriq Arm B: Tecentriq plus placebo Arm C: Placebo plus placebo 	 Arm A: Tiragolumab plus Tecentriq plus cisplatin and paclitaxel Arm B: Placebo plus placebo plus cisplatin and paclitaxel 	 Arm A: Tiragolumab plus Tecentriq Arm B: Tecentriq plus placebo
Primary endpoint	 Progression-free survival (A vs C) Overall survival (A vs C, hierarchical, B vs C hierarchical) 	 Overall survival and progression-free survival 	Objective response rate
Status	• FPI Q3 2020	 FPI Q4 2020 Recruitment completed Q4 2021 	• FPI Q1 2021
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 l
# of patients	N=540	N=135	N=52
Design	 Phase Ia: Dose escalation and expansion of tiragolumab Phase Ib: Dose escalation and expansion of tiragolumab in combination with Tecentriq and/or other anti-cancer therapies 	 Arm A: Tecentriq plus tiragolumab Arm B: Tecentriq monotherapy 	 Phase Ia: Tiragolumab monotherapy Phase Ib: Tiragolumab plus daratumumab (r/r MM) or rituximab (r/r NHL)
Primary endpoint	 Safety, tolerability, PK variability and preliminary efficacy 	 Overall response rate and progression-free survival 	 Safety, tolerability, PK/PD and preliminary efficacy
Status	 FPI Q2 2016 Data presented at AACR 2020 	 FPI Q3 2018 Recruitment completed Q2 2019 Data presented at ASCO 2020 and WCLC and ESMO IO 2021 BTD granted by FDA Q4 2020 	■ FPI Q2 2019
CT Identifier	NCT02794571	NCT03563716	NCT04045028

Glofitamab (CD20-TCB, RG6026)



Indication	Relapsed or refractory Non-Hodgkin's lymphoma (NHL)		
Phase/study	Phase I	Phase Ib	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	 FPI Q1 2017 Data presented at ASH 2018, ICML and ASH 2019; EHA and ASH 2020; ASCO, EHA, ICML and ASH 2021 Data published online March 2021 J Clin Oncology 39:18:1959-1970 Filed in EU April 2022 	 Arm A: FPI Q2 2018 Data presented at ASH 2019 and ASH 2021 Arm B: FPI Q4 2020 	• FPI Q3 2021
CT Identifier	NCT03075696	NCT03533283	ISRCTN17975931

Glofitamab (CD20-TCB, RG6026)



Indication	Non-Hodgkin's lymphoma (NHL)	Relapsed or refractory DLBCL and high-grade large B-cell lymphoma	2L+ SCT-ineligible DLBCL
Phase/study	Phase Ib	Phase Ib	Phase III STARGLO
# of patients	Part I: 15-60 Part II: ~66-104	N=20	N=270
Design	 Part I: Dose-finding for the combination of glofitamab plus G/R-CHOP in r/r indolent NHL Part II: Dose expansion glofitamab plus G/R-CHOP or R-CHOP in 1L DLBCL Part III: Glofitamab plus R-CHP plus Polivy 	 Glofitamab plus gemcitabine and oxaliplatin, followed by up to 4 cycles of glofitamab monotherapy A single dose of Gazyva will be administered 7 days prior to the first dose of glofitamab 	 Arm A: Glofitamab plus gemcitabine and oxaliplatin, followed by up to 4 cycles of glofitamab monotherapy Arm B: Rituxan in combination with gemcitabine and oxaliplatin A single dose of Gazyva will be administered 7 days prior to the first dose of glofitamab
Primary endpoint	■ Safety	- Safety	Overall survival
Status	Part I: FPI Q1 2018Part II: FPI Q1 2021Data presented at ASH 2021	• FPI Q2 2020	• FPI Q1 2021
CT Identifier	NCT03467373	NCT04313608	NCT04408638

Glofitamab (CD20-TCB, RG6026)



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

Mosunetuzumab (CD20/CD3, RG7828)



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	 Dose escalation study of mosunetuzumab as single agent and in combination with Tecentriq Expansion cohorts for r/r FL, r/r DLBCL and SC in r/r NHL 	 Mosunetuzumab plus CHOP Mosunetuzumab plus CHP plus Polivy Mosunetuzumab plus CHP-Polivy vs Rituximab plus CHP-Polivy 	 Mosunetuzumab plus Polivy Randomised cohorts ARM A: Mosunetuzumab SC plus Polivy ARM B: Rituximab plus Polivy
Primary endpoint	 Safety, tolerability, dose/schedule, PK and response rates 	 Safety/tolerability and response 	 Safety/tolerability and response
Status	 FPI Q3 2015 Data in r/r NHL presented at ASH 2018 and 2019, and in r/r FL at ASH 2020 and ASH 2021 BTD granted by FDA Q2 2020 SC cohort FPI Q2 2021 Filed in EU and rolling submission submitted in US Q4 2021 	 FPI Q1 2019 Data for mosunetuzumab plus CHOP presented at ASH 2020 	 FPI Q3 2018 Initial data presented at ASCO and ASH 2021
CT Identifier	NCT02500407	NCT03677141	NCT03671018

Mosunetuzumab (CD20/CD3, RG7828)



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	 Cohort A: Mosunetuzumab monotherapy (after a response to prior systemic chemotherapy) Cohort B: Mosunetuzumab monotherapy (1L treatment in elderly/frail) Cohort C: Mosunetuzumab SC plus Polivy in 1L elderly/unfit 	 Mosunetuzumab plus lenalidomide safety run-in for phase III Mosunetuzumab SC plus lenalidomide 	
Primary endpoint	Safety/tolerability and response	Safety/tolerability and response	
Status	 FPI Q2 2019 – Cohort B FPI Q3 2019 – Cohort A Initial data presented at ASH 2020 (cohort B) Cohort C: FPI Q1 2021 	 FPI Q3 2020 Initial data presented at ASH 2021 	
CT Identifier	NCT03677154	NCT04246086	

Mosunetuzumab (CD20/CD3, RG7828)



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

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: Mosunetuzumab plus lenalidomide ARM B: Rituxan plus lenalidomide	 Arm A: Mosunetuzumab plus tiragolumab Arm B: Mosunetuzumab plus tiragolumab plus Tecentriq Dose escalation phase Dose expansion phase 	Mosunetuzumab monotherapy (3L+ CLL)
Primary endpoint	Progression-free survival	 Phase Ib: Dose-limiting toxicity, Phase II: Best complete response 	 Safety, dose-limiting toxicity and RPTD
Status	• FPI Q4 2021	• FPI expected Q2 2022	• FPI Q1 2022
CT Identifier	NCT04712097	NCT05315713	

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	 Arm A: Inavolisib plus palbociclib plus fulvestrant Arm B: Placebo plus palbociclib plus fulvestrant 	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	 FPI Q4 2016 Preclinical/molecule discovery data presented at AACR 2017 Data presented at SABCS 2019, 2020 and 2021
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	 Dose escalation and expansion at RPTD Giredestrant monotherapy and in combination with palbociclib and/or LHRH agonist 	 Open-label, pre-operative administration Dose escalation 	 ARM A: Giredestrant followed by giredestrant plus palbociclib ARM B: Anastrazole followed by anastrazole plus palbociclib
Primary endpoint	 Safety 	Safety, tolerability and PK/PD	 Safety, tolerability and PK/PD
Status	 FPI Q4 2017 Data presented at SABCS 2019, ASCO 2020, ASCO 2021 and SABCS 2021 	 FPI Q3 2019 Data presented at ASCO 2021 	 FPI Q3 2020 Data presented at ESMO and SABCS 2021
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	 Arm A: Giredestrant monotherapy Arm B: Endocrine monotherapy (fulvestrant or aromatase inhibitor) 	 Arm A: Giredestrant plus palbociclib Arm B: Letrozole plus palbociclib 	 Arm A: Giredestrant monotherapy Arm B: Tamoxifen or aromatase inhibitor
Primary endpoint	 Progression-free survival 	 Progression-free survival 	 Invasive disease-free survival
Status	 FPI Q4 2020 Recruitment completed Q4 2021 	■ FPI Q4 2020	■ FPI Q3 2021
CT Identifier	NCT04576455	NCT04546009	NCT04961996

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	 Randomized, double-blind, placebo-controlled trial: 4-week screening period, 24-week randomized treatment period, 4-week follow-up visit (week 28) Zinpentraxin alfa at days 1, 3 and 5, then every 4 weeks vs placebo 	 Randomized, double-blind, placebo-controlled trial: 4-week screening period, 52-week randomized treatment period Zinpentraxin alfa at days 1, 3 and 5, then every 4 weeks vs placebo 	Multiple dose study of zinpentraxin alfa
Primary endpoint	 Least-squares mean change in FVC percentage of predicted value from baseline to week 28 	•Absolute change from baseline to week 52 in FVC	Bone marrow response rate
Status	 Study met primary endpoint Data published in JAMA 2018;319(22):2299-2307 and Lancet Respir Med 2019 Aug;7(8):657-664 	• 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 	 Arm A: Crovalimab Arm B: Eculizumab Arm C: Patients switching to crovalimab from ravulizumab, higher than labeled doses of eculizumab & C5 SNP patients (descriptive-arm)
Primary endpoint	■ Safety, PK, PD	 Non-inferiority of crovalimab compared to eculizumab - mean % change in LDH level (measure of haemolysis) from baseline to week 25
Status	 Part 1: FPI Q4 2016 Part 2/3: FPI Q2 2017 Part 4: FPI Q2 2019 Nonclinical data published in Scientific Reports 2017 Apr; 7(1):1080 Data presented for Part 2 and 3 at ASH 2018 and 2019 	• 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	 Crovalimab loading dose IV on Day 1, followed by weekly crovalimab SC doses for 4 weeks 	
Primary endpoint	 Non-inferiority of crovalimab compared to eculizumab: % patients with transfusion avoidance from baseline through week 25 % patients with haemolysis control, as measured by LDH <= 1.5ULN from week 5-25 	 Percentage of patients with transfusion avoidance from baseline through week 25 Mean percentage of participants with hemolysis control (week 5 through week 25) 	
Status	• FPI Q4 2020	 FPI Q1 2021 Recruitment completed Q3 2021 Co-primary endpoints met Q1 2022 	
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	 Cohort 1+3: proportion of patients with complete TMA response anytime between baseline and week 25 Cohort 2: proportion of patients with maintained TMA control from baseline through week 25 	 Cohort 1: proportion of patients with complete TMA response anytime between baseline and week 25 Cohort 2: proportion of patients with maintained TMA control from baseline through week 25
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	 VOC rate, up to 48 weeks
Status	■ FPI Q1 2022	■ FPI Q1 2022
CT Identifier	NCT04912869	NCT05075824

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

Mosunetuzumab (CD20/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	 ARM A: Mosunetuzumab SC on either Day 1 or on Days 1 and 8 ARM B: fractionated (divided) dose of mosunetuzumab SC on Days 1 and 8
Primary endpoint	- Safety
Status	• FPI January 2022
CT Identifier	NCT05155345

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	 ARM A: PSEN1 E280A mutation carriers receive crenezumab SC ARM B: PSEN1 E280A mutation carriers receive placebo ARM C: non-mutation carriers receive placebo 	
Primary endpoint	 Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score at 260 weeks treatment Annualized rate of change in an Episodic Memory Measure: Free and Cued Selective Reminding Task (FCSRT) 	
Status	FPI Q4 2013 Recruitment completed Q1 2017	
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	 Change in CDR-SOB at 27 months 	 Change in CDR-SOB at 27 months 	 Change from baseline in deposited amyloid (PET centiloid levels)
Status	 FPI Q2 2018 Recruitment completed Q2 2020 BTD grant 	 FPI Q3 2018 Recruitment completed Q2 2020 red by FDA Sep 2021 	 FPI Q4 2020 Recruitment completed Q3 2021
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	Early Alzheimer's disease
Phase/study	Phase II/III SCarlet RoAD ¹	Phase III Marguerite RoAD ¹	Phase III SKYLINE ²
# of patients	N=799	N=389	N=1200
Design	104-week SC treatment period: - ARM A: Gantenerumab (225 mg) - ARM B: Gantenerumab (105 mg) - ARM C: Placebo	104-week SC treatment period: - ARM A: Gantenerumab - ARM B: Placebo	 ARM A: Gantenerumab q1w or q2w (patient preference) ARM B: Placebo
Primary endpoint	 Change in CDR-SOB at 2 years Sub-study: change in brain amyloid by PET at 2 years 	 Change in ADAS-Cog and CDR-SOB at 2 years (co- primary) 	Cognitive composite (PACC5)
Status	 Phase I PET data: Archives of Neurology, 2012 Feb;69(2):198-207 Recruitment completed Q4 2013 Dosing stopped due to futility Q4 2014 FPI in open label extension study Q4 2015 Published in Alzheimers Res Ther 2017 Dec 8;9(1):95 	 FPI Q1 2014 Recruitment stopped Q4 2015 FPI Q1 2016 for open label extension 	• FPI expected Q2 2022
	■ 36 OLE data published in .	J Prev Alzheimers Dis 2021;8(1):3-6	
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	 Longer term safety, tolerability and PK/PD 					
Status	 FPI Q3 2015 Data presented at CHDI 2018 and AAN 2018 PRIME designation granted 2018 Published in NEJM 2019; 380:2307-2316 	 FPI Q1 2018 PK/PD data presented at AAN 2019 Update presented at CHDI 2020 Study completed, patients moved to GEN-EXTEND OLE 					
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	 ARM A: Tominersen 120mg q2w ARM B: Tominersen 120mg q4m ARM C: Placebo q2w 	OLE study in patients participating in prior Roche and Genentech sponsored studies • Arm A: Tominersen 120mg q2w • Arm B: Tominersen 120mg q4m					
Primary endpoint	cUHDRS globallyTFC USA only	 Long term safety, tolerability 					
Status	 FPI Jan 2019 Q1 2019 protocol modified to allow for bi-monthly vs four-monthly dosing, FPI for new protocol July 2019 Recruitment completed Q2 2020 Dosing stopped in Q1 2021 based on IDMC recommendation regarding the potential benefit/risk profile for study participants. No new safety signals identified. Data presented at EHDN and CHDI 2022 	• 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	iple sclerosis (RMS)		
Phase/study	Phase III FENtrepid	Phase III FENhance 1	Phase III FENhance 2		
# of patients	N=946	N=736	N=736		
Design	 ARM A: Fenebrutinib twice daily oral Arm B: Ocrevus 2x300mg IV q24w 	 Arm A: Fenebrutinib twice daily oral Arm B: Teriflunomide once daily oral 	 Arm A: Fenebrutinib twice daily oral Arm B: Teriflunomide once daily oral 		
Primary endpoint	Time to onset of cCDP12	 Time to onset of cCDP12 and annualized relapse rate 	 Time to onset of cCDP12 and annualized relapse rate 		
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	1	~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/RB cell non-Hodgkin's lymphoma	ı	~207	Part I: FPI Q3 2019 Part II: FPI Q3 2020	NCT04077723		
PD1-IL2v (RG6279)	Solid tumors	1	440	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	1	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	I	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	1	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 April 2022	NCT05187624		

pRED neuroscience development programs



Molecule	Indication	Phase	# of patients	Status	CT Identifier		
Neuroscience Neuroscience							
Brain Shuttle-gantenerumab (BS-gantenerumab, RG6102)	Alzheimer's disease	lla	~120	FPI Q1 2021	NCT04023994		
Brain Shuttle-CD20 (BS-CD20, RG6035)	Multiple sclerosis	I	30	FPI Q3 2021	ISRCTN16295 177		
		II	36	FPI Q4 2018; Recruitment completed Q3 2019			
ralmitaront (partial TAAR1 agonist, RG7906)	Schizophrenia	П	247	FPI Q4 2019	NCT03669640 (TWAIN I)		
(F)		П	308	FPI Q3 2020	NCT04512066 (TWAIN II)		
prasinezumab¹ (anti-αSynuclein, RG7935, PRX002)	Parkinson's disease	II	316	Study did not meet its primary objective, but showed signals of efficacy on core motor signs in PD. Key study data presented at MDS 2020, ADPD and MDS 2021. Part 3 (OLE) ongoing	NCT03100149 (PASADENA)		
i iixoozi		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	l	66	FPI Q3 2020	NCT04428281		
NME (RG6182)	Neurodegenerative disorder	I	30	FPI Q4 2020			

Partner: ¹Prothena; 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	1	84	FPI Q1 2022			

Partner: ¹Prothena; BS=Brain Shuttle





Molecule	Indication	Phase	# of patients	Status	CT Identifier	
Immunology						
selnoflast (NLRP3i, RG6418)	Inflammation	lb	18	FPI Q4 2021		

		Ophthaln	nology		
NME (RG6179) ¹		1	90	FPI Q3 2019	DOVETAIL
	DME	II	160	FPI Q4 2021	NCT05151744 (BARDERNAS)
		II	320	FPI Q4 2021	NCT05151731 (ALLUVIUM)
VEGF-Ang2 DutaFab (RG6120)	nAMD	1	~50	FPI Q4 2020	NCT04567303
NME (RG7774)	Retinal disease	II	135	FPI Q2 2020	NCT04265261 (CANBERRA)

Partner: ¹Sesen Bio

pRED infectious diseases development programs



Molecule	Indication	Phase	# of patients	Status	CT Identifier		
Infectious Diseases							
TLR7 agonist (3) (RG7854)	Chronic hepatitis B	1	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	11	275	FPI Q3 2020	NCT04225715 (PIRANGA)		
PDL1 LNA (RG6084)	Chronic hepatitis B	I	35	FPI Q1 2019 Part la completed, part lb initiated			
Abx MCP (RG6006)	A. baumannii infections	I	204	FPI Q4 2020	NCT04605718		

Abx MCP=antibiotic macrocyclic peptide



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Molecule	Indication	Phase	# of patients	Status	CT Identifier			
Oncology								
KRAS G12C (RG6330)	Metastatic solid tumors with KRAS G12C mutation	1	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	1	440	FPI Q2 2018	NCT03448042			
NME (RG6286)	Locally advanced or metastatic colorectal cancer	I	67	FPI Q3 2020	NCT04468607			
IL15/IL15Ra-Fc (RG6323) ¹	Solid tumors	1/11	250	FPI Q1 2020	NCT04250155			
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) ²	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: ¹Xencor, ²BioNTech, ³Hanmi

gRED immunology and ophthalmology development programs



Molecule	Indication	Phase	# of patients	Status	CT Identifier
		Immuno	ology		
efmarodocokin alfa (IL-22Fc, RG7880)	aGVHD	lb	18	FPI Q4 2020	NCT04539470
NME (RG6287, GDC-8264)	Inflammatory bowel disease	I	68	FPI Q1 2020 Recruitment completed Q3 2021	EUDRACT2019 -002613-19
	Inflammatory diseases	I	16	FPI Q4 2021	
anti-tryptase	Asthma	I	70	FPI Q1 2018 Recruitment completed Q4 2018	
(RG6173, MTPS9579A)	Asthma	lla	134	FPI Q4 2019 Recruitment completed Q1 2021	NCT04092582
NME (RG6315, MTBT1466A)	Immunologic disorders	I	~24	FPI Q3 2020	
astegolimab (Anti-ST2, (RG6149, AMG 282, MSTT1041A) ¹	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				

Partner: ¹Amgen





Molecule	Indication	Phase	# of patients	Status	CT Identifier				
Neuroscience									
comorinamah (PG4100)1	Prodromal to mild Alzheimer's disease	II 457		FPI Q4 2017 Primary endpoint not met Q3 2020 Data presented at CTAD 2020	NCT03289143 (TAURIEL)				
semorinemab (RG6100) ¹	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	NCT03828747 (LAURIET)				

Metabolic Diseases									
NME (RG6338)	Metabolic diseases	la/lb	116	FPI Q2 2021					

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

Partner: ¹AC Immune



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Hemophilia A

Spark Roche Roche

Unique gene therapy platform

Molecule	The state of the s	K-8011 G6357)	SPK-8016 (RG6358)
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	 Long term follow up study of patients who have received SPK-8011 in any prior Spark- sponsored SPK-8011 study 	 Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8011 	 Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8016 in individuals with FVIII inhibitors
Primary endpoint	■ Safety	 Safety and changes from baseline in FVIII activity levels at week 52 	 Safety; peak and steady state FVIII activity levels at week 52
Status	- Ongoing	 FPI Q1 2017 Updated data presented at ISTH 2020 and 2021 Recruitment completed Q1 2021 Data published in NEJM 2021; 385:1961-1973 	• FPI Q1 2019
CT Identifier	NCT03432520	NCT03003533	NCT03734588

Pompe disease

Spark 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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Foreign exchange rates information





CHFm	Q1 2021	Q1 2022	% change CER
Pharmaceuticals Division	10,600	11,159	+6
United States	5,292	5,489	+2
Europe	2,175	2,072	-1
Japan	852	1,337	+69
International	2,281	2,261	0
Diagnostics Division	4,330	5,286	+24
United States	947	1,465	+51
Europe	1,708	1,600	-2
Japan	158	223	+51
International	1,517	1,998	+33
Group	14,930	16,445	+11
United States	6,239	6,954	+9
Europe	3,883	3,672	-1
Japan	1,010	1,560	+66
International	3,798	4,259	+13

Pharma Division sales Q1 2022



Top 20 products

	Global		US	US		pe	Jap	an	Internat	tional
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	1,449	18	1,050	12	280	34	-	-	119	29
Perjeta	993	1	362	-1	228	-21	59	-1	344	32
Hemlibra	853	30	520	28	170	31	84	15	79	63
Tecentriq	825	8	446	10	183	14	107	-5	89	0
Actemra / RoActemra	792	3	380	22	220	-4	87	12	105	-30
Herceptin	607	-19	144	-26	122	-13	15	-30	326	-18
Ronapreve	587	272	-	-	62	-61	483	-	42	-
Avastin	581	-32	178	-39	58	-56	131	-12	214	-23
MabThera	564	-21	347	-20	54	-19	8	-15	155	-23
Kadcyla	511	9	204	0	172	8	32	28	103	26
Xolair	456	9	456	9	-	-	-	-	-	-
Alecensa	361	23	99	25	75	5	54	7	133	45
Lucentis	256	-26	256	-26	-	-	-	-	-	-
TNKase / Activase	247	-20	234	-21	-	-	-	-	13	-3
Esbriet	241	-6	170	-4	62	-5	-	-	9	-36
Evrysdi	226	189	109	36	68	*	17	-	32	*
Gazyva	165	7	75	0	46	-5	15	8	29	75
Phesgo	146	410	60	187	76	*	-	-	10	*
Pulmozyme	136	-3	87	0	26	-11	-	11	23	-4
CellCept	134	-12	10	-15	34	-7	14	-8	76	-14
Pharma Division	11,159	6	5,489	2	2,072	-1	1,337	69	2,261	0

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

Pharma Division sales Q1 2022

Roche

Product sales Pharmaceuticals Division

	Globa	al	US	US		pe	Jap	an	Internat	ional
	CHFm	% CER	CHFm 9	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	1,449	18	1,050	12	280	34	-	-	119	29
Perjeta	993	1	362	-1	228	-21	59	-1	344	32
Hemlibra	853	30	520	28	170	31	84	15	79	63
Tecentriq	825	8	446	10	183	14	107	-5	89	0
Actemra / RoActemra	792	3	380	22	220	-4	87	12	105	-30
Herceptin	607	-19	144	-26	122	-13	15	-30	326	-18
Ronapreve	587	272	-	-	62	-61	483	-	42	-
Avastin	581	-32	178	-39	58	-56	131	-12	214	-23
MabThera	564	-21	347	-20	54	-19	8	-15	155	-23
Kadcyla	511	9	204	0	172	8	32	28	103	26
Xolair	456	9	456	9	-	-	-	-	-	-
Alecensa	361	23	99	25	75	5	54	7	133	45
Lucentis	256	-26	256	-26	-	-	-	-	-	-
TNKase / Activase	247	-20	234	-21	-	-	-	-	13	-3
Esbriet	241	-6	170	-4	62	-5	-	-	9	-36
Evrysdi	226	189	109	36	68	*	17	-	32	*
Gazyva	165	7	75	0	46	-5	15	8	29	75
Phesgo	146	410	60	187	76	*	-	-	10	*
Pulmozyme	136	-3	87	0	26	-11	-	11	23	-4
CellCept	134	-12	10	-15	34	-7	14	-8	76	-14
Polivy	81	89	34	75	22	4	21	-	4	40
Erivedge	63	6	40	2	15	2	-	-	8	37
Enspryng	41	216	13	*	2	-	25	141	1	425
Vabysmo	21	-	21	-	-	-	-	-	-	-
Rozlytrek	16	78	11	66	2	88	2	49	1	413
Cotellic	12	20	4	31	4	-9	-	-	4	55
Gavreto	5	-	4	-	1	-	-	-	-	-
Xofluza	2	-	1	*	-	-	-	-	1	-
Susvimo	1	-	1	-	-	-	-	-	-	-
Other Products	787	-12	173	-10	90	-21	183	4	341	-18
Pharma Division	11,159	6	5,489	2	2,072	-1	1,337	69	2,261	0

Pharma Division CER sales growth¹ in %

Roche

Global top 20 products

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

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

Pharma Division CER sales growth¹ in %



Top 20 products by region

	US				Europe				Japa	an		International				
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Ocrevus	28	0	23	12	40	36	26	34	-	-	-	-	41	35	51	29
Perjeta	-3	2	-2	-1	2	-8	-8	-21	-2	0	-3	-1	34	16	24	32
Hemlibra	49	36	33	28	123	26	53	31	21	29	30	15	92	138	55	63
Tecentriq	19	10	2	10	20	16	41	14	86	75	34	-5	56	62	24	0
Actemra / RoActemra	3	143	67	22	20	10	18	-4	15	25	5	12	27	-14	-55	-30
Herceptin	-55	-52	-34	-26	-25	-20	-3	-13	-37	-37	-36	-30	-22	-7	17	-18
Ronapreve	-	-	-	-	-	-	-	-61	-	-	-	-	-	-	-	-
Avastin	-46	-50	-45	-39	-69	-69	-49	-56	0	5	0	-12	-20	-11	-24	-23
MabThera	-37	-49	-32	-20	-21	-33	-13	-19	-34	-30	-17	-15	-30	-25	-15	-23
Kadcyla	6	0	3	0	29	16	16	8	57	59	42	28	35	16	38	26
Xolair	3	8	14	9	-	-	-	-	-	-	-	-	-	-	-	-
Alecensa	13	9	18	25	19	7	9	5	10	11	5	7	59	40	25	45
Lucentis	2	-10	2	-26	-	-	-	-	-	-	-	-	-	-	-	-
TNKase / Activase	2	2	22	-21	-	-	-	-	-	-	-	-	6	17	7	-3
Esbriet	0	-2	-7	-4	9	0	0	-5	-	-	-	-	-7	-73	-36	-36
Evrysdi	-	*	112	36	-	-	*	*	-	-	-	-	-	-	*	*
Gazyva	28	3	11	0	19	10	2	-5	-17	10	-7	8	23	43	56	75
Phesgo	-	*	236	187	-	-	-	*	-	-	-	-	-	-	*	*
Pulmozyme	-21	-10	6	0	-7	-10	-15	-11	-9	-18	22	11	40	12	45	-4
CellCept	-18	-18	-31	-15	17	-2	3	-7	-7	-7	-9	-8	-8	13	3	-14

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

CER sales growth (%)



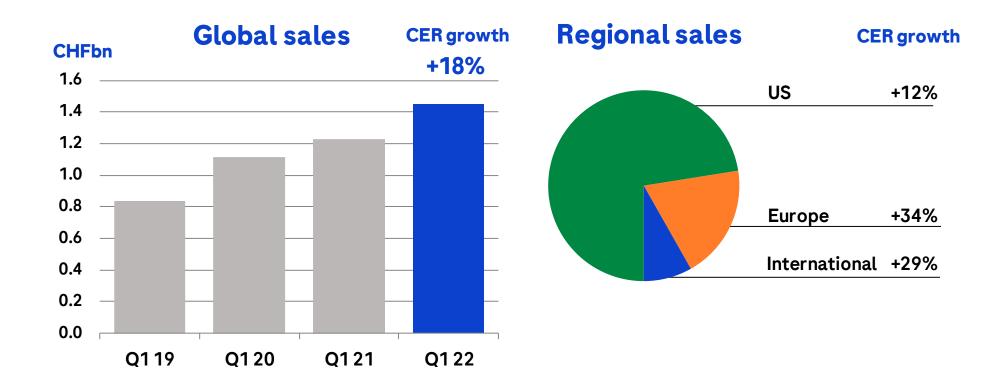
Quarterly development

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

Ocrevus



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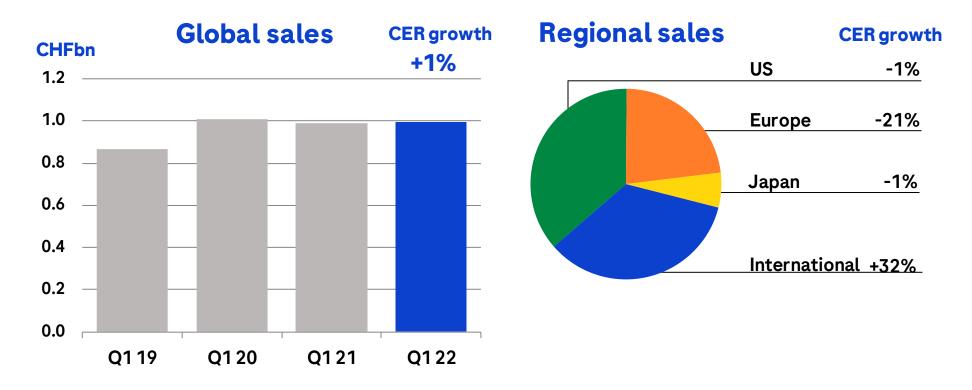


Q1 2022 sales of CHF 1,449m

- 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



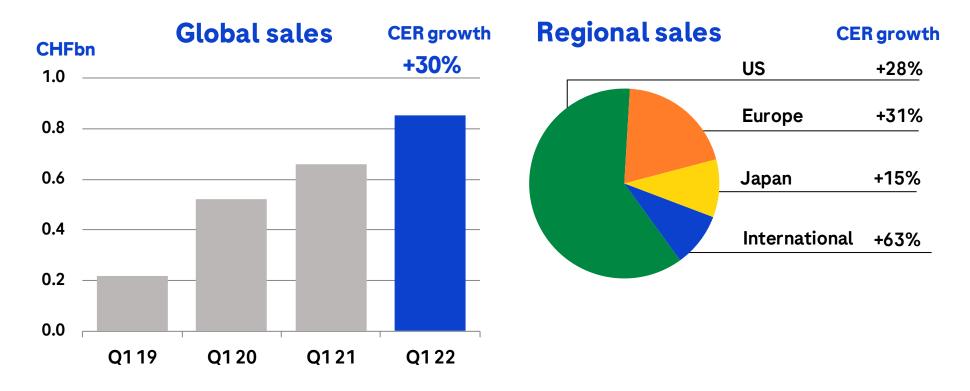


Q1 2022 sales of CHF 993m

- US: Cannibalization from Phesgo
- EU: Cannibalization from Phesgo
- International: Patients with residual disease being switched to Kadcyla; Accelerated growth in all regions

Hemlibra



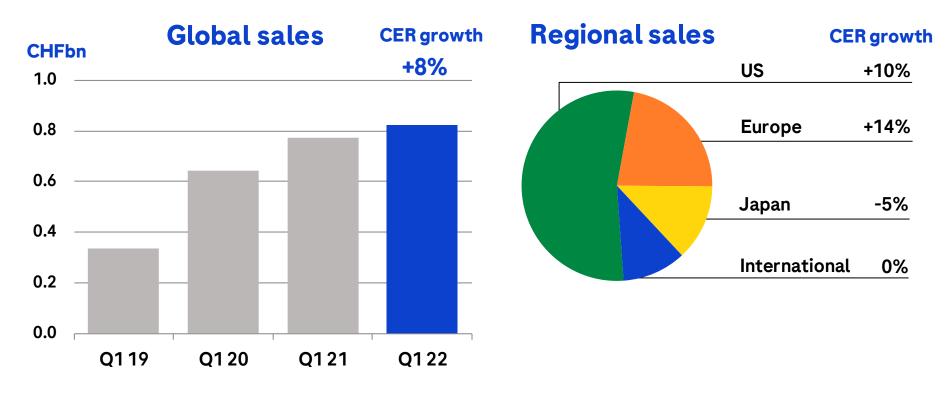


Q1 2022 sales of CHF 853m

- US: Continued share gains in non-inhibitor patients
- EU: Continued share gains in non-inhibitor severe patients with market shares > 40% in France and UK
- Japan: Strong uptake in non-inhibitor patients
- International: Accelerating momentum due to on-going launches

Tecentriq



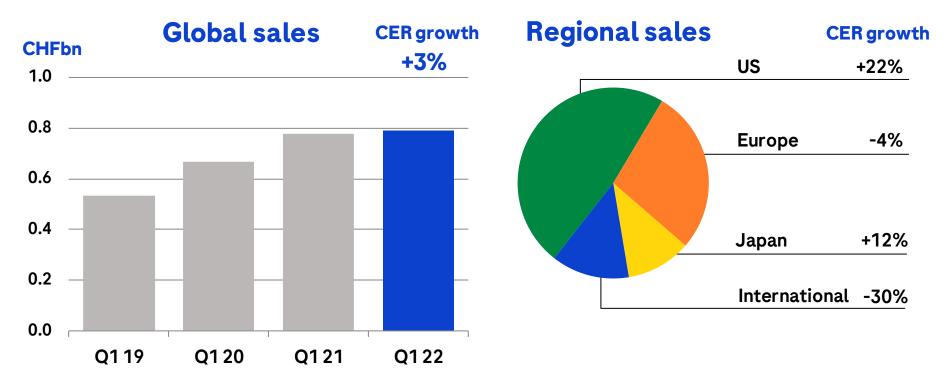


Q1 2022 sales of CHF 825m

- US: Growth driven by first-in-class launches in 1L HCC, 1L SCLC and adjuvant PDL1+ NSCLC
- EU: Growth driven by first-in-class launches in 1L HCC and 1L SCLC
- Japan: Volume growth driven by first-in-class launches in 1L HCC, 1L SCLC and 1L TNBC; mandatory price cut impacting sales

Actemra / RoActemra



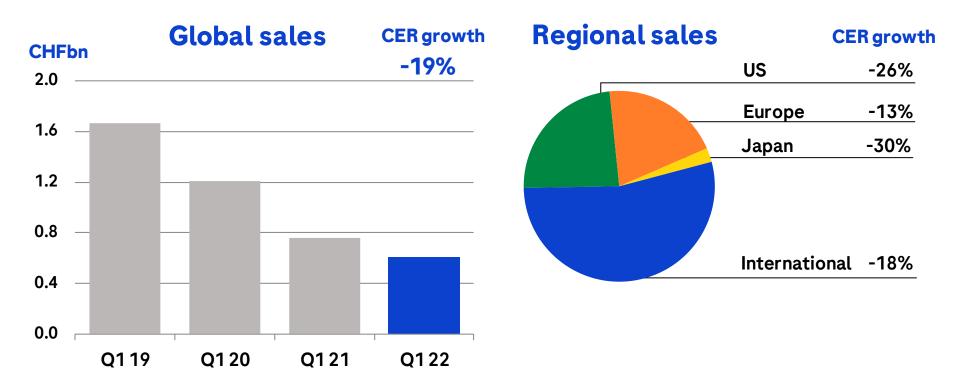


Q1 2022 sales of CHF 792m

- US: Increased demand for SC formulation (home administration); Slowing demand for COVID-19
- EU: Market leadership in 1L RA monotherapy maintained; Slowing demand for COVID-19
- International: Slowing demand for COVID-19

Herceptin



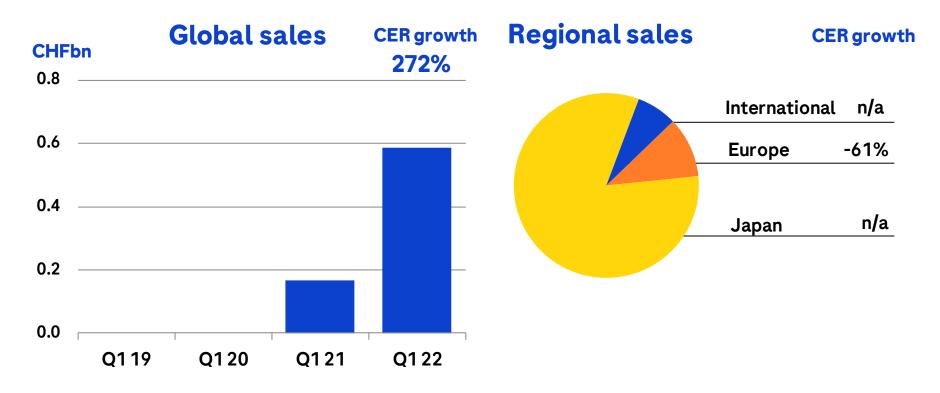


Q1 2022 sales of CHF 607m

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

Ronapreve





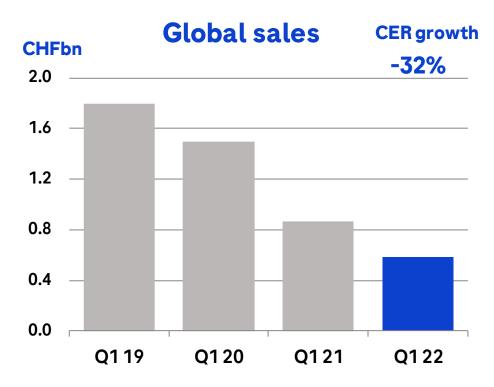
Q1 2022 sales of CHF 587m

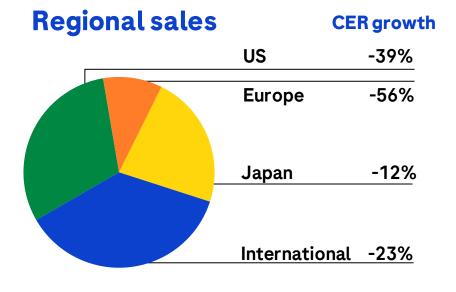
EU: Slowing sales as Ronapreve has limited activity against Omicron variant

• Japan: Additional sales to the government

Avastin





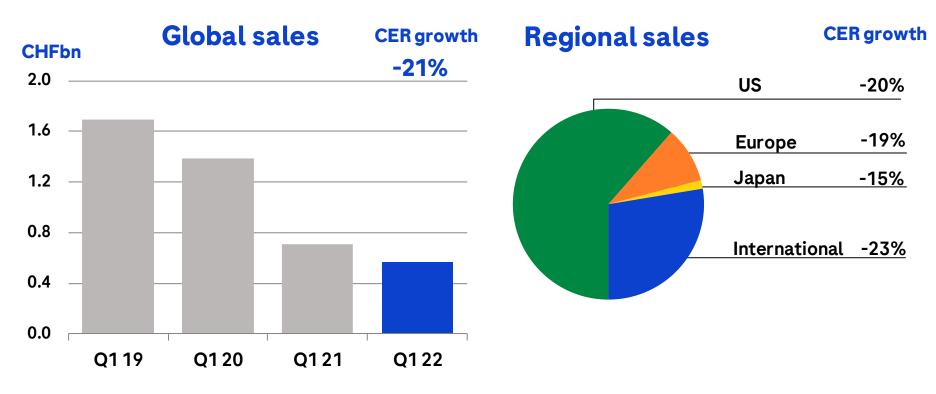


Q1 2022 sales of CHF 581m

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

Rituxan / MabThera



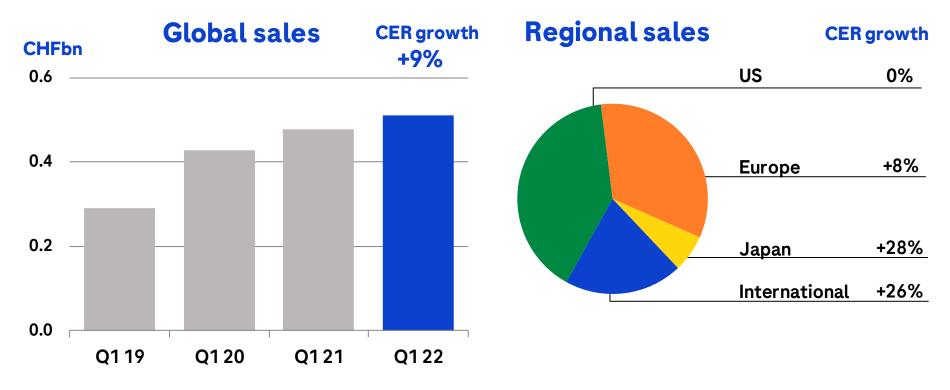


Q1 2022 sales of CHF 564m

- US: Decline due to biosimilars; erosion momentum slowing
- EU: Decline due to biosimilars; erosion momentum slowing
- Japan: Decline due to biosimilars
- International: Decline due to biosimilars

Kadcyla



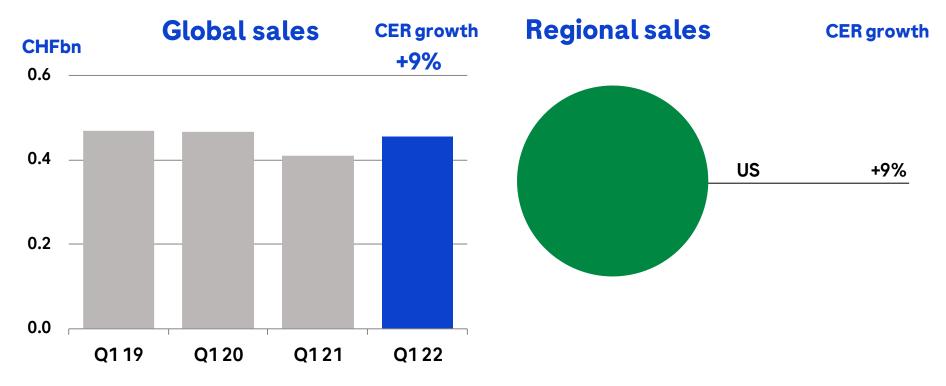


Q1 2022 sales of CHF 511m

- 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



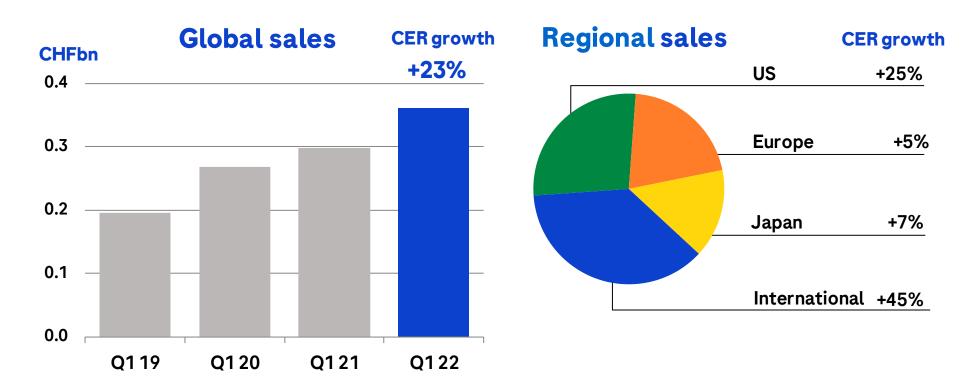


Q1 2022 sales of CHF 456m

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

Alecensa



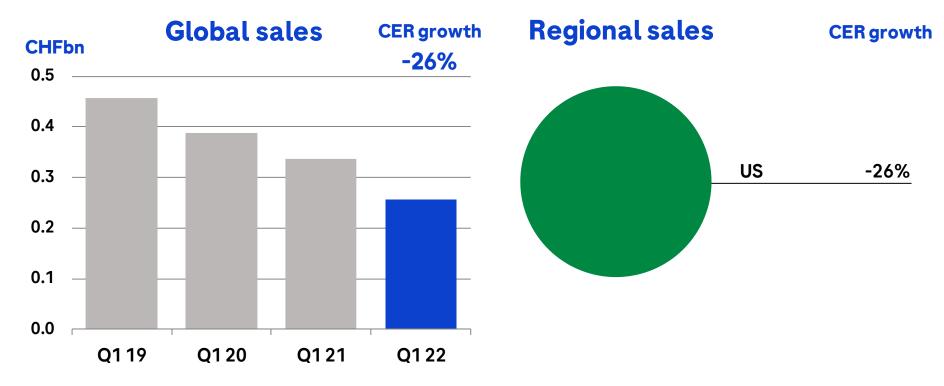


Q1 2022 sales of CHF 361m

- 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

Lucentis





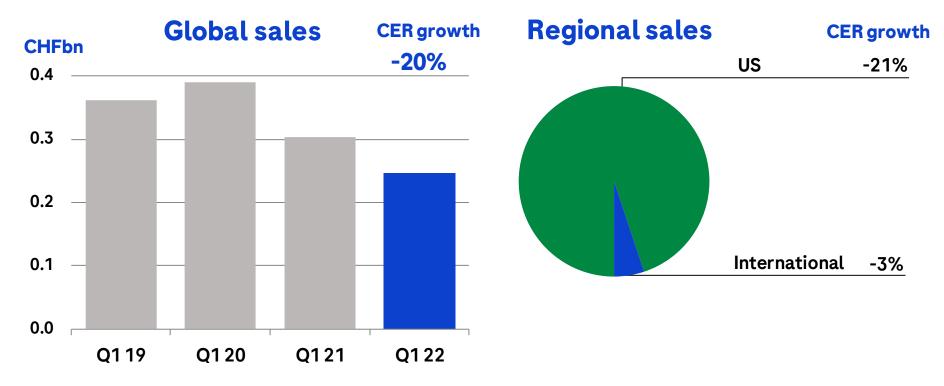
Q1 2022 sales of CHF 256m

Declining market share as market dynamics impacted by new entrances and upcoming biosimilars

• First biosimilar expected by mid 2022

TNKase / Activase



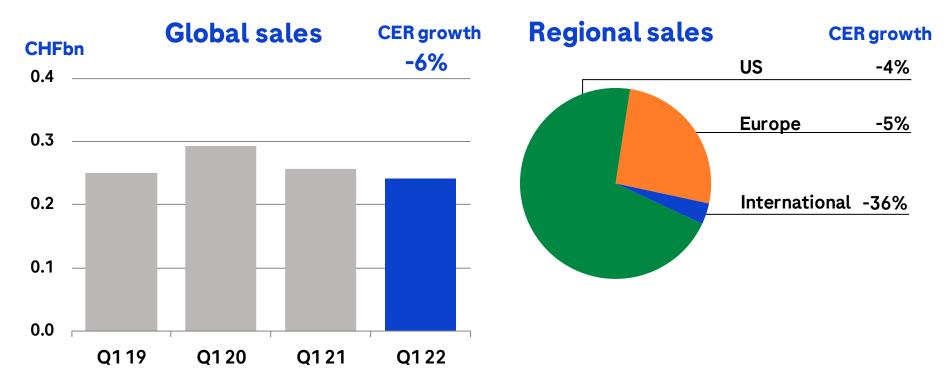


Q1 2022 sales of CHF 247m

US: Sales impacted by COVID-19 and purchasing patterns

Esbriet





Q1 2022 sales of CHF 241m

US: Reduction in new patients being diagnosed and initiated due to COVID-19

• EU: Reduction in new patients being diagnosed and initiated due to COVID-19



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 ³										
	Glob CHFm %		EME CHFm %			NOA APAC CHFm %CER CHFm %CEF			LATAM R CHFm %CER		Global CHFm %CER		EMEA¹ CHFm %CER		NOA CHFm %CER		APAC CHFm %CER		LATA	
Core Lab ^{2,3}	1,873	8	657	8	347	3	736	9	133	15	1,896	8	679	8	348	3	736	9	133	15
Point of Care ³	1,302	84	414	-23	639	>1000	199	344	50	-6	1,466	84	452	-21	726	541	236	396	52	-4
Molecular Lab³	1,376	26	520	26	492	14	323	58	41	-2	1,189	21	460	26	404	8	286	42	39	-4
Diabetes Care	417	-7	233	-3	58	-39	71	9	55	17	417	-7	233	-3	58	-39	71	9	55	17
Pathology Lab	318	14	78	12	169	10	66	23	5	39	318	14	78	12	169	10	66	23	5	39
Diagnostics Division	5,286	24	1,902	2	1,705	59	1,395	34	284	9	5,286	24	1,902	2	1,705	59	1,395	34	284	9

Diagnostics Division quarterly sales and CER growth¹



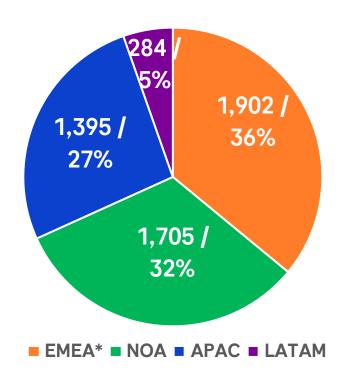
	Reported									Restatement ³											
	Q12 CHFm %		Q22		Q3 2 CHFm %		Q4 2 CHFm %		Q1 2		CI	Q1 2 HFm %		Q2 2		Q3 2		Q42 CHFm%		Q12 CHFm %	
Core Lab ^{2,3}	1,765	31	1,961	36	1,884	12	1,863	10	1,873	8		1,786	31	1,984	36	1,907	12	1,883	9	1,896	8
Point of Care ³	716	281	900	424	442	143	525	-2	1,302	84		806	255	992	464	617	222	719	15	1,466	84
Molecular Lab ³	1,107	86	1,109	19	1,238	21	1,358	15	1,376	26		996	87	994	9	1,040	5	1,144	7	1,189	21
Diabetes Care	460	13	434	7	400	-7	396	-2	417	-7		460	13	434	7	400	-7	396	-2	417	-7
Pathology Lab	282	9	308	32	299	4	313	7	318	14		282	9	308	32	299	4	313	7	318	14
Diagnostics Division	4,330	55	4,712	48	4,263	18	4,455	8	5,286	24	4	4,330	55	4,712	48	4,263	18	4,455	8	5,286	24

Q1 2022: Diagnostics Division regional sales

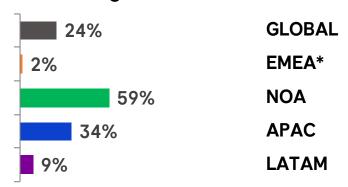


Growth driven by North America and Asia Pacific

Sales YTD CHFm & % of total sales Total YTD Sales = 5,286

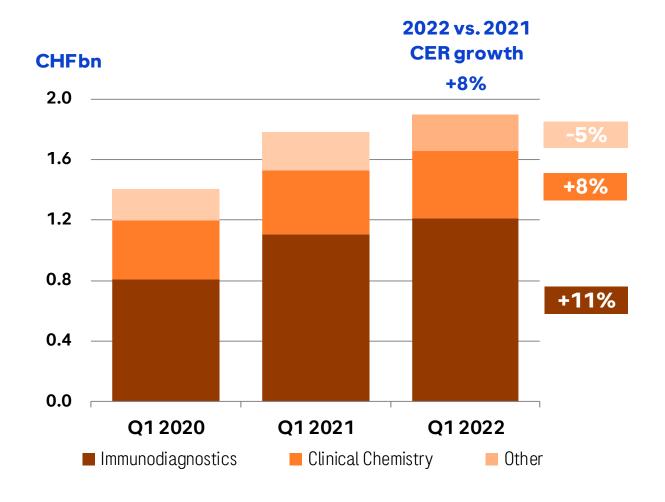


Sales growth at CER Diagnostics Division



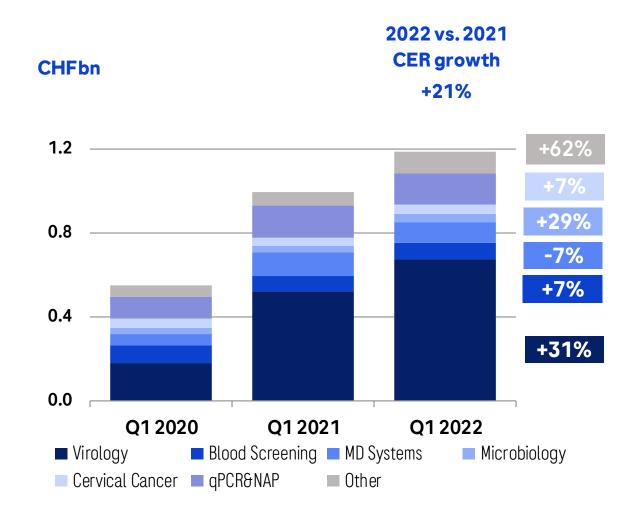
Core Lab





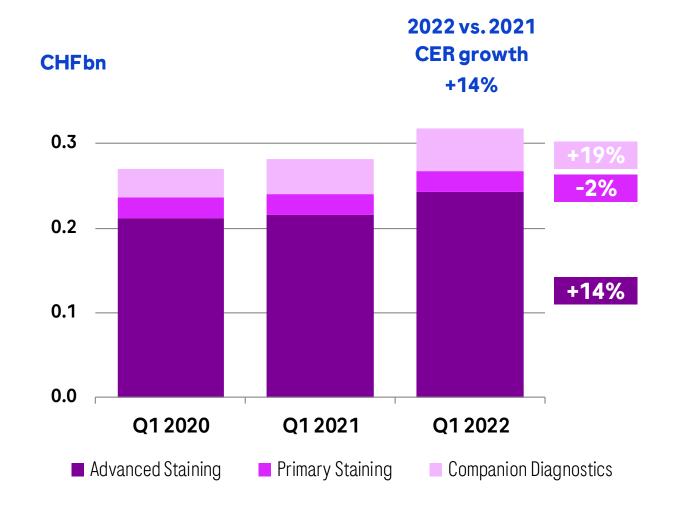
Molecular Lab





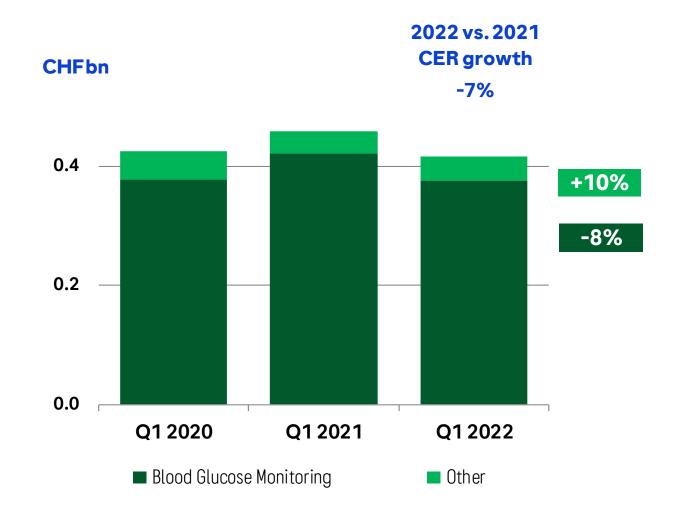
Pathology Lab





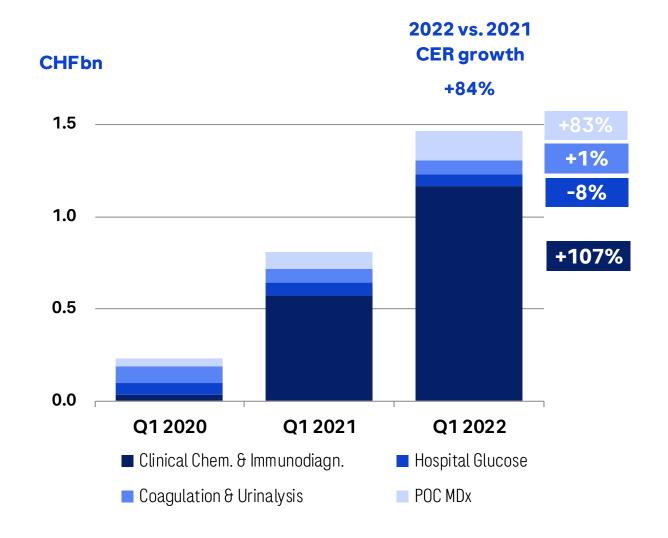
Diabetes Care





Point of Care







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

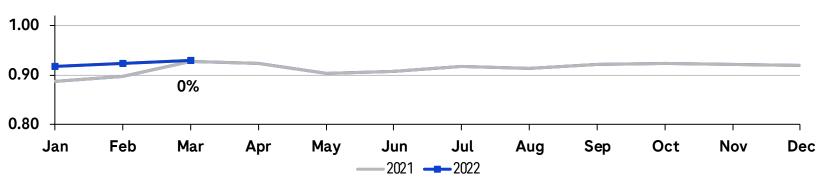
Diagnostics sales appendix

Foreign exchange rates information

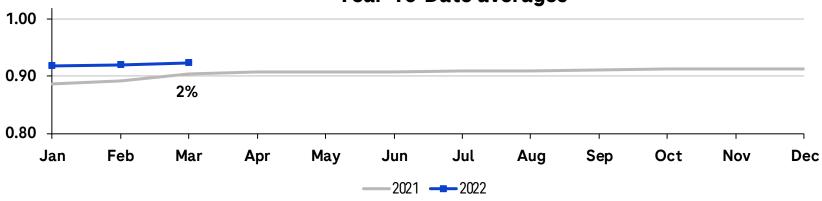
CHF/USD





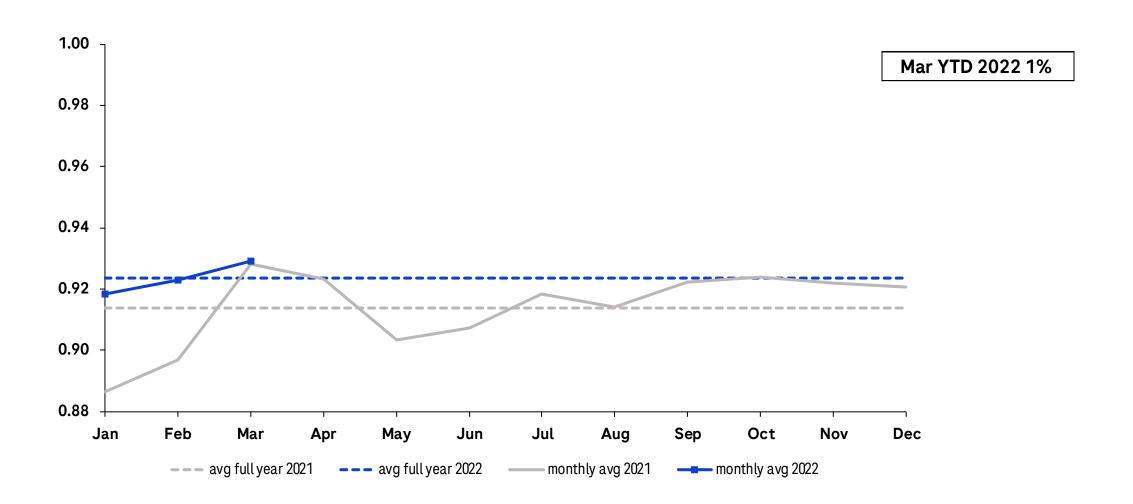


Year-To-Date averages



CHF/USD

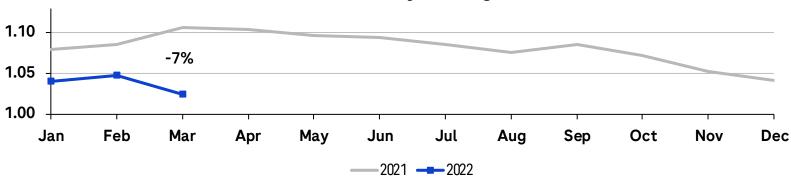


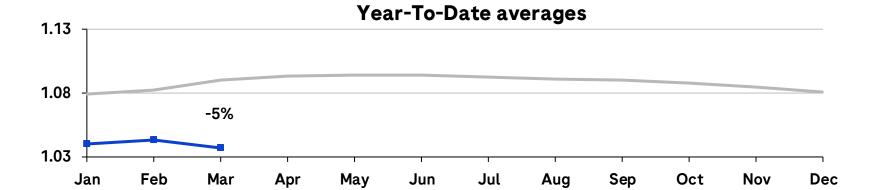


CHF/EUR





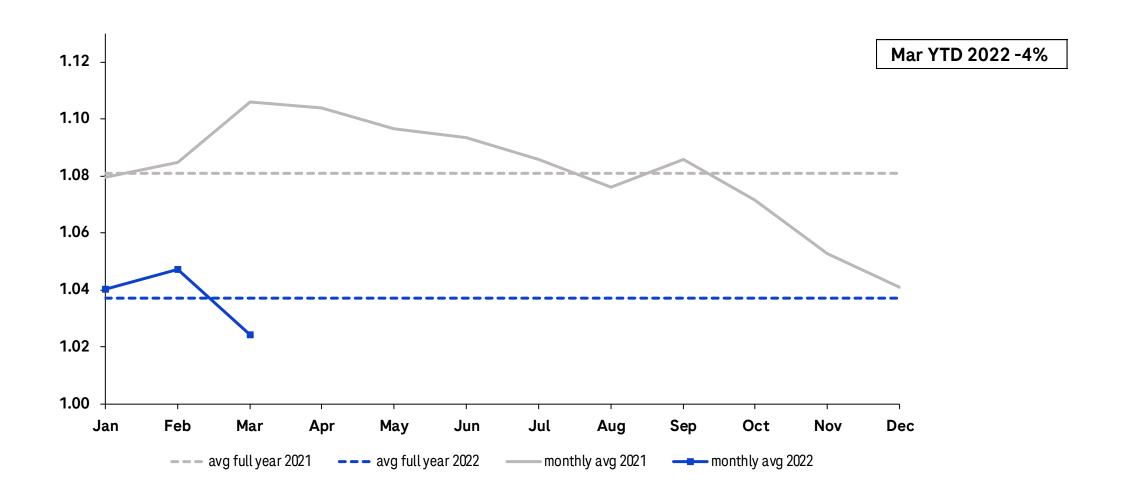




——2021 **——**2022

CHF/EUR

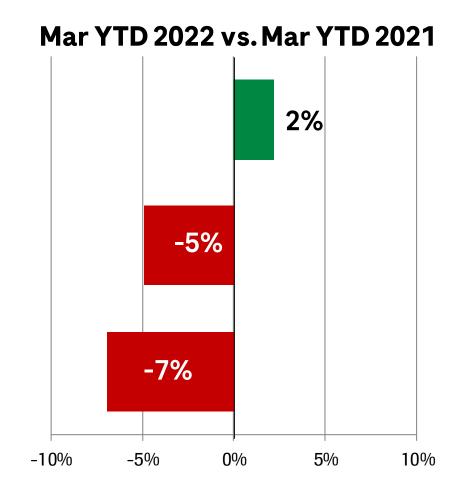




Average CHF Exchange Rates



	Mar YTD 2022	Mar YTD 2021
USD	0.92	0.90
EUR	1.04	1.09
JPY	0.80	0.85

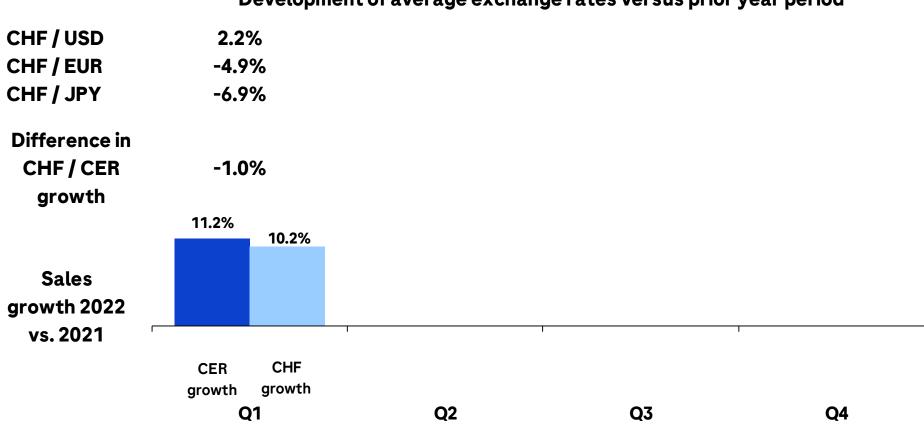






Q1 2022: negative impact of JPY and EUR, positive impact of USD

Development of average exchange rates versus prior year period



CER=Constant Exchange Rates (avg full year 2021)

Doing now what patients need next