
Roche

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4 fluctuations in currency exchange rates and general financial market conditions;
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Roche

HY 2023 results

Basel, 27 July 2023

Group

Thomas Schinecker
Chief Executive Officer

HY 2023 performance

Outlook

HY 2023: Strong base business growth in both divisions

Group sales -2% at CER due to expected COVID-19 sales decline

- Strong Pharma growth (+8% at CER) driven by Vabysmo, Ocrevus, Hemlibra, Evrysdi, Phesgo, Tecentriq and Polivy
- Strong Diagnostics base business growth (+6% at CER)
- COVID-19 sales decline in line with guidance

Profitability impacted by base effect in first HY; FY guidance confirmed

- Core EPS down -5% due to COVID-19 sales decline and Ultomiris patent settlement in 2022

Pharma milestones achieved in Q2; New partnerships strengthening pipeline

- Pharma approvals: Columvi (glofitamab) in 3L+ DLBCL in the US / EU; Elevidys (delandistrogene moxeparvovec) in the US*
- Positive Phase III (OCARINA II) results for Ocrevus 6m SC in RMS / PPMS, positive Phase II (FENopta) results for fenebrutinib in RMS, and positive Phase I/II (MORPHEUS) results for tiragolumab + Tecentriq + Avastin in 1L HCC
- Partnering: In-licensed zilebesiran (AGT-targeting siRNA) for mild-moderate hypertension and KSQ-4279 (USP1 inhibitor) for solid tumors

Upcoming newsflow 2023

- Pharma late-stage read-outs: Ph III (EMBARK) for Elevidys in DMD; line extensions for Tecentriq, Venclexta, Alecensa, Xolair, Phesgo
- Diagnostics: CCM Vertical, LightCycler Pro, Anti-HEV IgG/IgM, HBeAg Quant, and IL-6 Neonatal sepsis

Growth rates at CER (Constant Exchange Rates); CCM=cobas connection module; DLBCL=diffuse large B-Cell lymphoma; RMS=relapsing multiple sclerosis; PPMS=primary-progressive multiple sclerosis; HCC=hepatocellular carcinoma; NME=new molecular entity; AGT=angiotensinogen; siRNA=small interfering RNA; DMD=Duchenne muscular dystrophy; *Accelerated US approval by partner company Sarepta

HY 2023: Strong base business impacted by COVID-19 sales decline

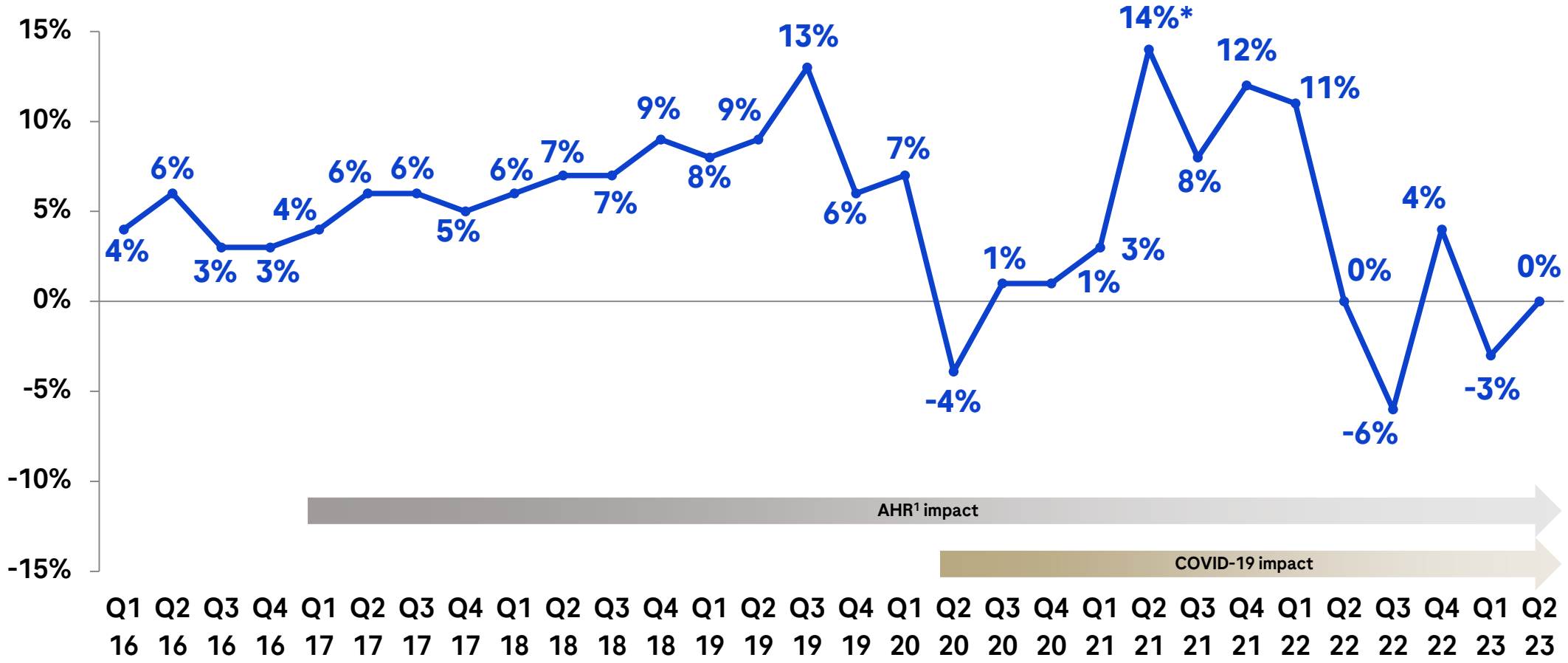
Currency headwinds further increased in Q2

	2023 CHFbn	2022 CHFbn	Change in % CHF	Change in % CER	Excl. C19[1]
Pharmaceuticals Division	22.7	22.3	1	8	8
Diagnostics Division	7.1	9.9	-29	-23	6
Roche Group	29.8	32.3	-8	-2	8

CER=Constant Exchange Rates; totals may include differences due to rounding; [1] Pharmaceuticals Division sales excluding Ronapreve, Diagnostics Division base business

Quarterly sales: COVID-19 and AHR impact as expected

Q4 2023 to be impacted by Ronapreve base effect of roughly CHF 1.1bn

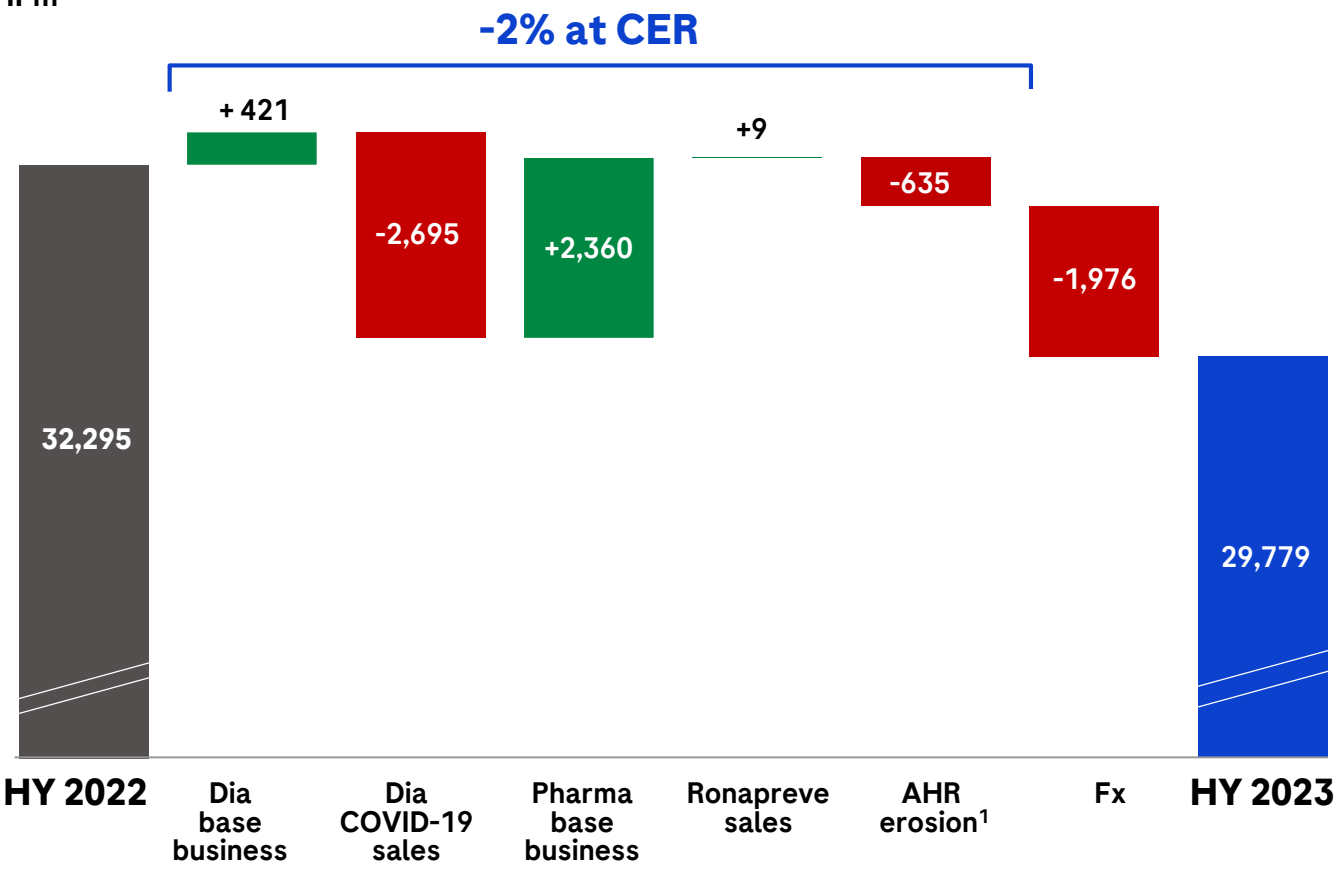


YoY growth rates at CER (Constant Exchange Rates); *Q2 2020 sales severely impacted by COVID-19 pandemic onset; [1] AHR: Avastin, Herceptin, Rituxan/MabThera

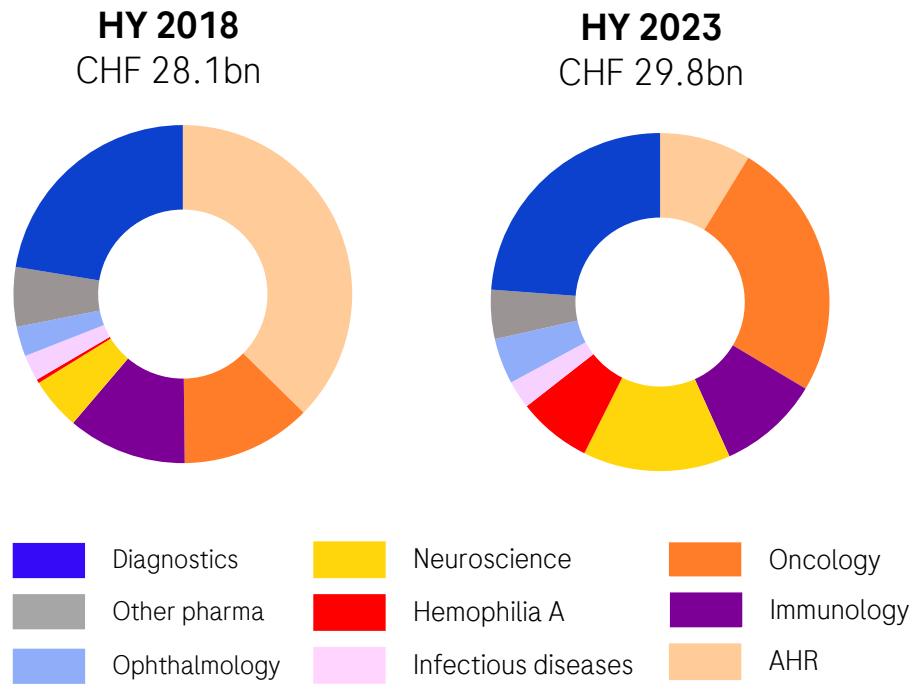
HY 2023: Base business largely compensates for COVID-19 impact

Portfolio diversification progresses as ophthalmology franchise gains momentum

CHFm



Diversification of Roche portfolio

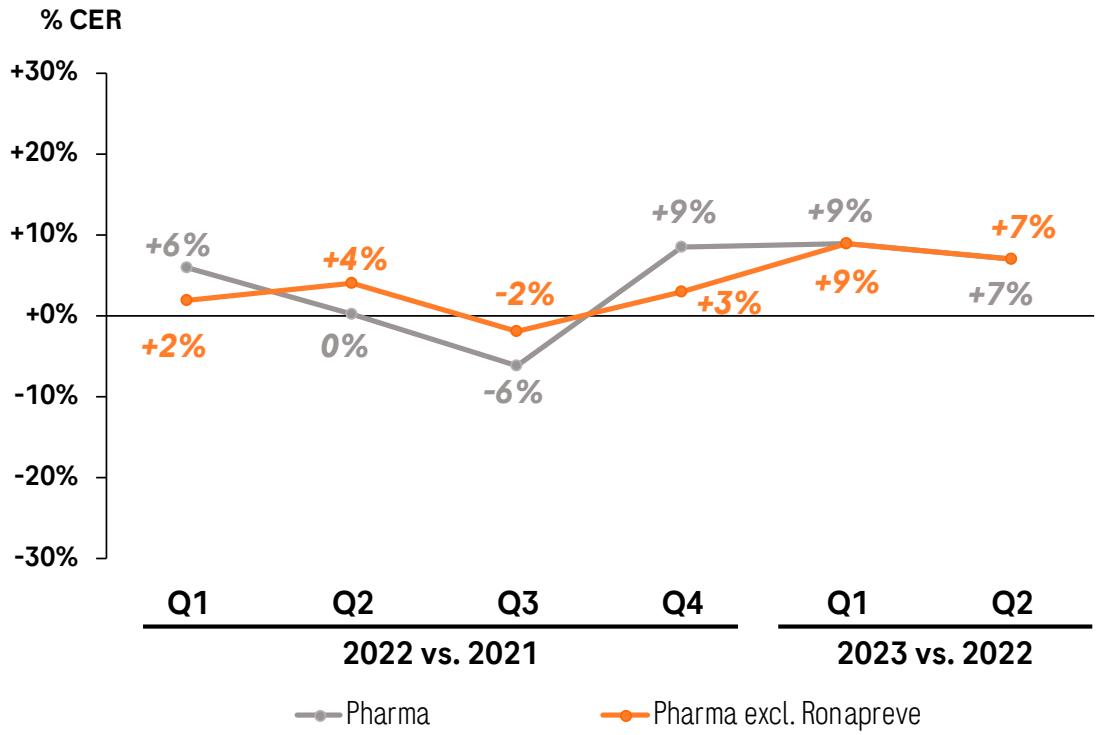


CER=Constant Exchange Rates; [1]AHR: Avastin, Herceptin, Rituxan/MabThera

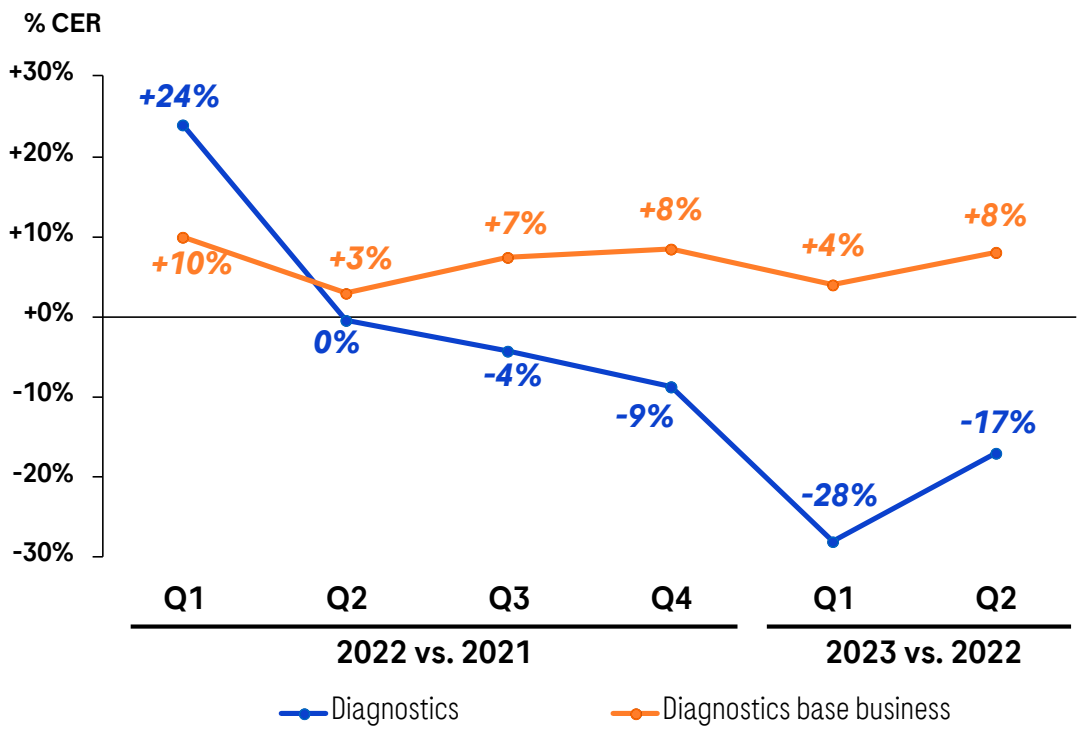
HY 2023: Base businesses in both divisions grow high single digit

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

Pharma
Quarterly sales evolution 2022-2023



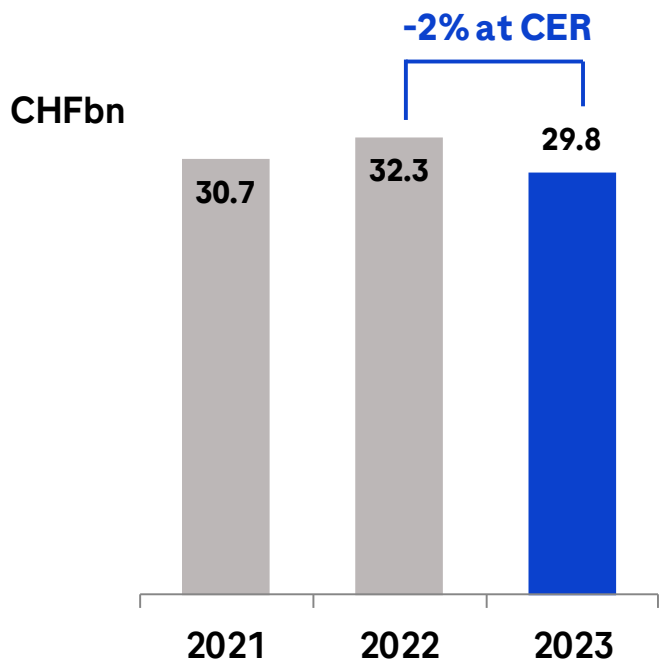
Diagnostics
Quarterly sales evolution 2022-2023



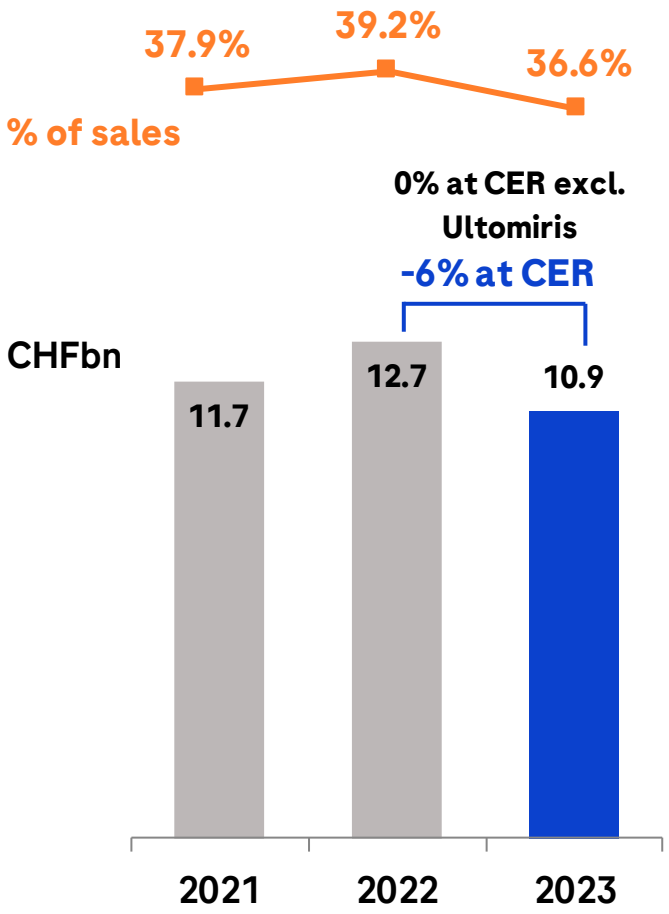
Growth rates at CER (Constant Exchange Rates)

HY 2023: Results impacted by Ultomiris settlement and COVID-19

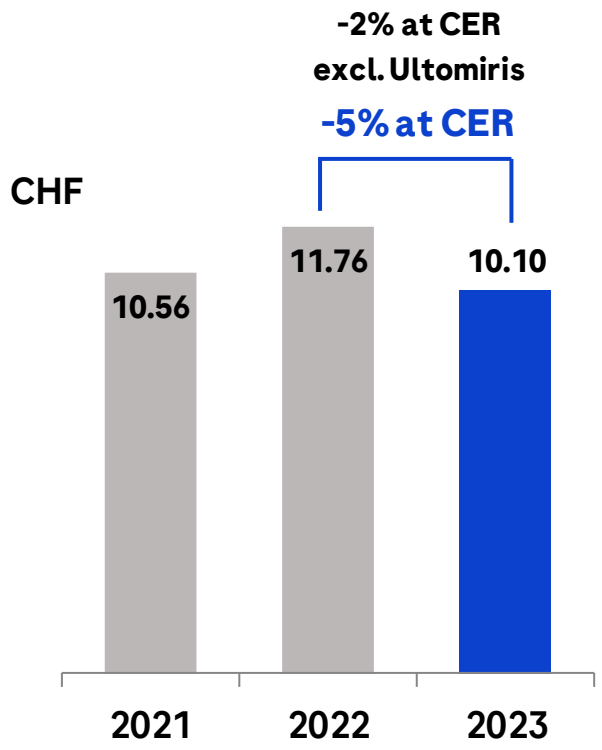
Group sales



Core operating profit



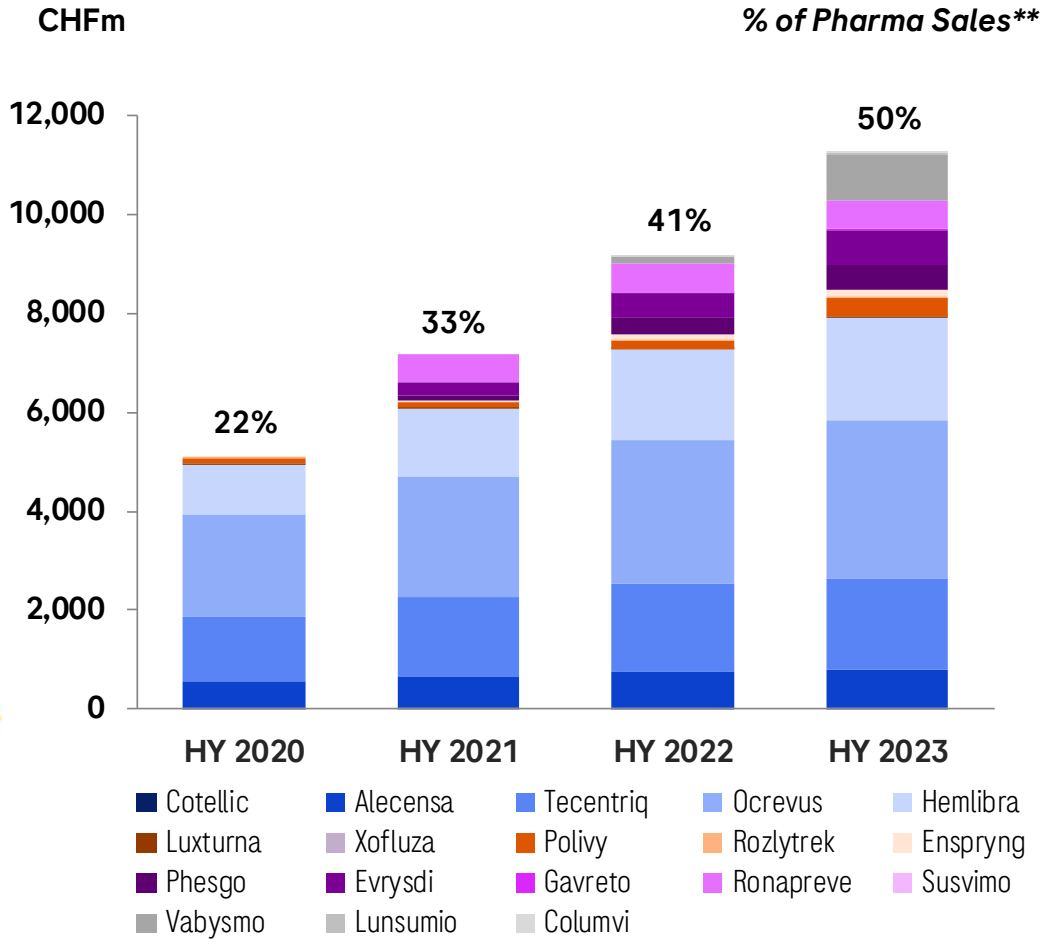
Core EPS



CER=Constant Exchange Rates

Young portfolio: New launches exceed 50% of sales

Keeping historic launch momentum with two NMEs approved in 2023

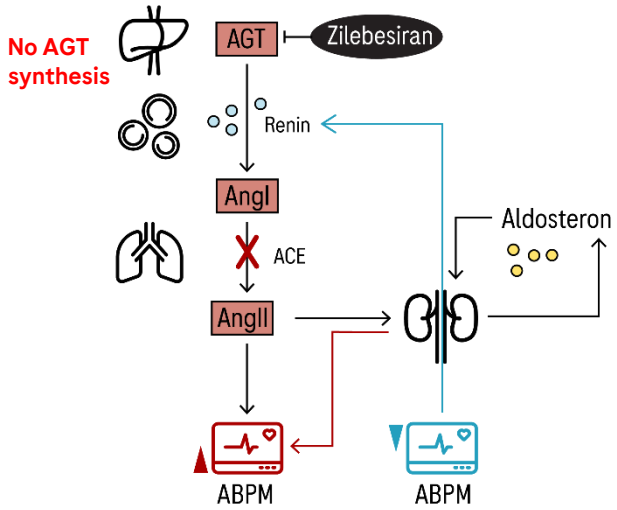


Young portfolio defined as all launches since end of 2015; * Elevidys: Accelerated US approval by partner company Sarepta; ** Venclexta sales booked by AbbVie and therefore not included

New partnerships signed to strengthen Pharma pipeline

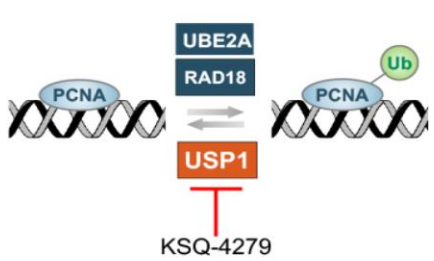
Entering hypertension and adding to the early portfolio in DNA damage response (DDR)

Zilebesiran (angiotensinogen siRNA)

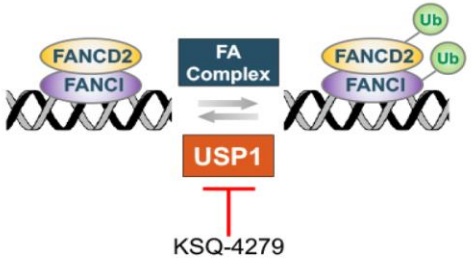


- siRNA targeting angiotensinogen, the precursor protein of all angiotensin peptides
- Consistent and durable blood pressure control with potential for improved adherence[1]
- Currently in two Ph II (KARDIA-1/2); data expected in mid-2023 and early 2024, respectively

KSQ-4279 (USP1 inhibitor)



Translesion synthesis



Inter-strand crosslink repair

- First-in-class small molecule inhibitor of ubiquitin-specific protease 1 (USP1)
- USP1 is involved in DNA damage response mechanisms, which are distinct from PARPi and other targeted therapies
- Currently in Ph I in patients with advanced solid tumors

[1] Desai et al. N Engl J Med 2023;389:228-38; HTN=hypertension; siRNA=small interfering RNA; AGT=angiotensinogen; SC=subcutaneous; PARPi=poly (ADP-ribose) polymerase; zilebesiran in partnership with Alnylam Pharmaceuticals; KSQ-4279 in partnership with KSQ Therapeutics

Invitation to Roche Pharma Day 2023

Additional IR events: ECTRIMS 2023, Digitalization Day and ASH 2023

Roche Pharma Day on Sep 11

London / hybrid event

11:30 - 15:30 CEST / 10:30 – 14:30 BST
05:30 – 09:30 am EDT / 02:30 – 06:30 am PDT

Presenters include:

- **Thomas Schinecker**, CEO Roche Group
- **Teresa Graham**, CEO Roche Pharmaceuticals
- **Levi Garraway**, Chief Medical Officer and Head of Global Product Development
- **Charlie Fuchs**, Senior Vice President and Global Head of Oncology and Hematology
- **Paulo Fontoura**, Senior Vice President and Global Head of Neuroscience, Immunology, Ophthalmology, Infectious and Rare Diseases Clinical Development
- **Christopher Brittain**, Vice President and Global Head Product Development Ophthalmology

Angiogenesis 2023 ✓	**Roche ESG Day** ✓	**EHA 2023** ✓	**Roche Pharma Day**	**ECTRIMS 2023**	**Roche Digitalization Day**	**ASH 2023**
Virtual	Virtual	Virtual	London	Virtual	Virtual	Virtual
Monday, 13 February	Tuesday, 23 May	Monday, 12 June	Monday, 11 September	October	Wednesday, 29 November	December
16:30 to 18:00 CET	15:30 to 17:00 CEST	16:30 to 17:30 CEST	10:30 to 14:30 BST	TBA	TBA	TBA

2023 performance

Outlook

2023: Upcoming newsflow

Pharma

Tiragolumab + Tecentriq in 1L PDL1+ NSCLC	**Q4 2023/ Q1 2024**
Tiragolumab + Tecentriq + chemo in 1L Esophageal	**2024**
Tecentriq + Avastin in adjuvant HCC	✓
Tecentriq in adjuvant SCCHN	
Tecentriq + chemo in adjuvant TNBC	✗
Tecentriq neoadjuvant/adjuvant TNBC	**2024**
Phesgo OBI in HER2+ BC	
Alecensa in adjuvant ALK+ NSCLC	
Venclexta + azacitidine in 1L high risk MDS	
Venclexta + dexamethasone in R/R MM (t11;14)	
Columvi + GemOx in 2L+ DLBCL	**2024**
Lunsumio + Polivy in 2L+ DLBCL	**2024**
Crovalimab in PNH	✓
Elevidys (delandistrogene moxeparvovec) in DMD	
Ocrevus 6m SC in RMS / PPMS	✓
TNKase in Stroke	✗
Susvimo in DME	✓
Susvimo in DR	✓
Xolair in Food allergy	

Neuroscience
Oncology/Hematology
Ophthalmology
Immunology

Diagnostics

CCM Vertical	Modular transportation system, integrated into existing cobas connection modules
LightCycler Pro	Flexible real-time PCR instrument with dual IVD and Research mode
Anti-HEV IgG and Anti-HEV IgM	Anti-HEV IgM: Immunoassay aiding in diagnosis of acute HEV infection in clinic. Anti-HEV IgG: Immunoassay aiding in detection of a recent or past HEV infection
HBeAg Quant	Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B
IL-6 Neonatal sepsis (claim extension)	Immunoassay with dedicated claim aiding in diagnosis of sepsis in neonates

DME=diabetic macular edema; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer; HCC=hepatocellular carcinoma; MM=multiple myeloma; PCR=polymerase chain reaction; SC=subcutaneous; DR=diabetic retinopathy; RMS=relapsing MS; PPMS=primary progressive MS; PNH=Paroxysmal nocturnal hemoglobinuria; TNBC=triple negative breast cancer; SCCHN=squamous cell carcinoma of head and neck; DMD=Duchenne muscular dystrophy; OBI=on-body injector; BC=breast cancer; MDS=Myelodysplastic syndrome; R/R=relapsed / refractory; IVD=in vitro diagnostics; HEV=Hepatitis E Virus

2023 sales outlook confirmed

Sales drivers[1]

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

Diagnostics: Base business with solid growth

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

AHR[2] sales expected to erode by roughly CHF 1.6bn

Group sales growth[1]	Low single digit decline

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

2023 outlook confirmed

Group sales growth[1]	Low single digit decline
Core EPS growth[1]	Broadly in line with sales decline
Dividend outlook	Further increase dividend in Swiss francs

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Teresa Graham
CEO Roche Pharmaceuticals

HY 2023: Pharmaceuticals Division sales

All regions delivering strong growth, intensifying currency headwinds in Q2

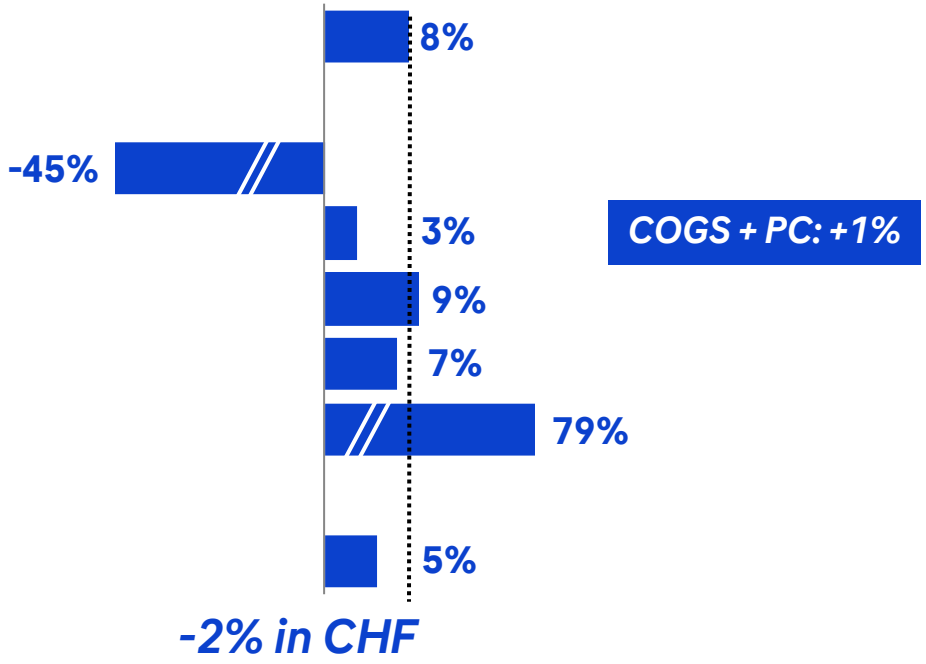
	2023 CHFm	2022 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**22,681**	**22,347**	**1**	**8**
United States	11,743	11,363	3	7
Europe	4,105	4,104	0	5
Japan	2,210	2,202	0	14
International	4,623	4,678	-1	9

CER=Constant Exchange Rates

HY 2023: Pharmaceuticals Division

Core operating profit impacted by Ultomiris patent settlement

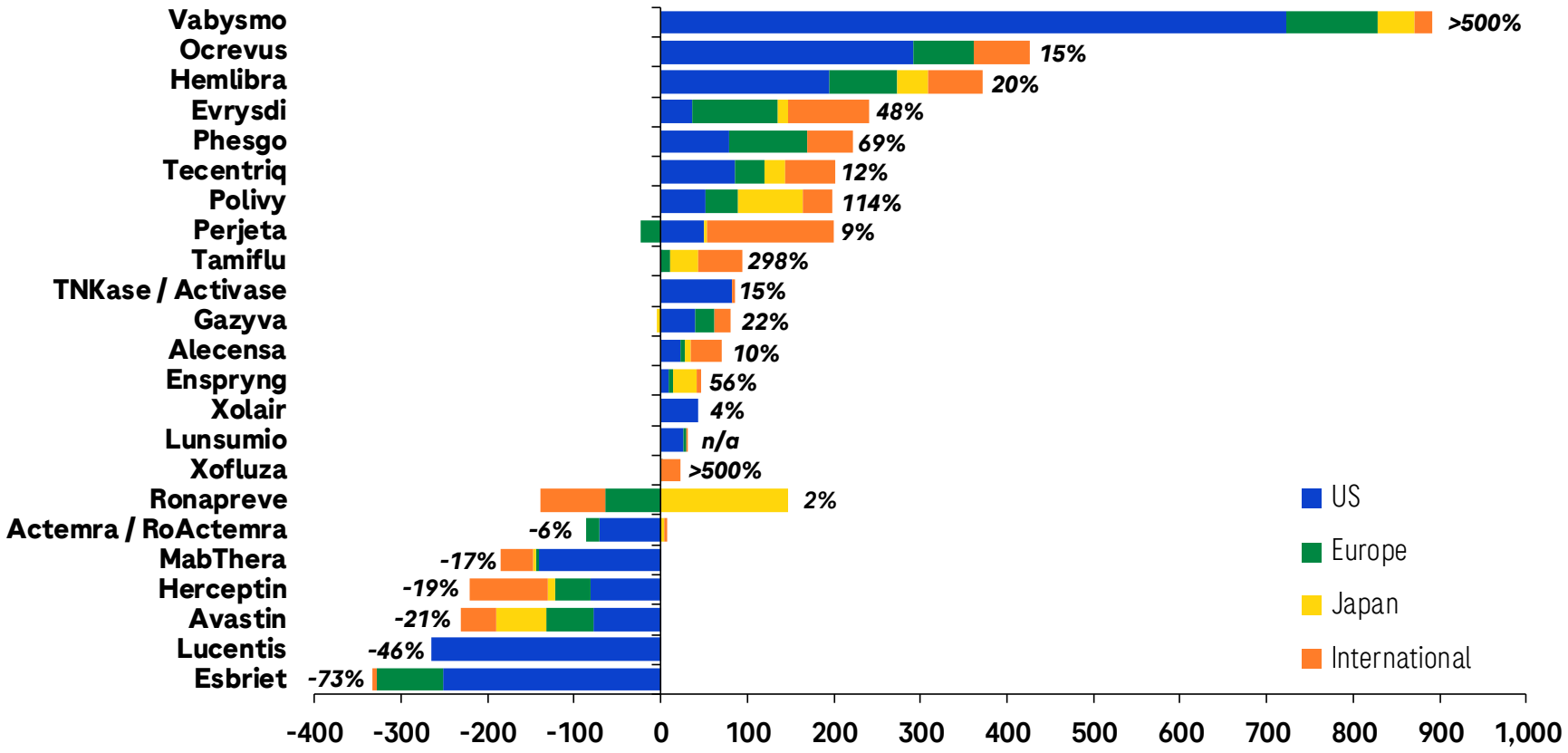
	2023 CHFm	2023 % sales
Sales	**22,681**	**100.0**
Other revenue	806	3.6
Cost of sales	-4,107	-18.0
R&D	-5,617	-24.8
SG&A	-3,444	-15.3
OOI&E	699	3.1
Core operating profit	**11,018**	**48.6**



CER=Constant Exchange Rates; COGS=costs of goods sold; PC=period costs; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense

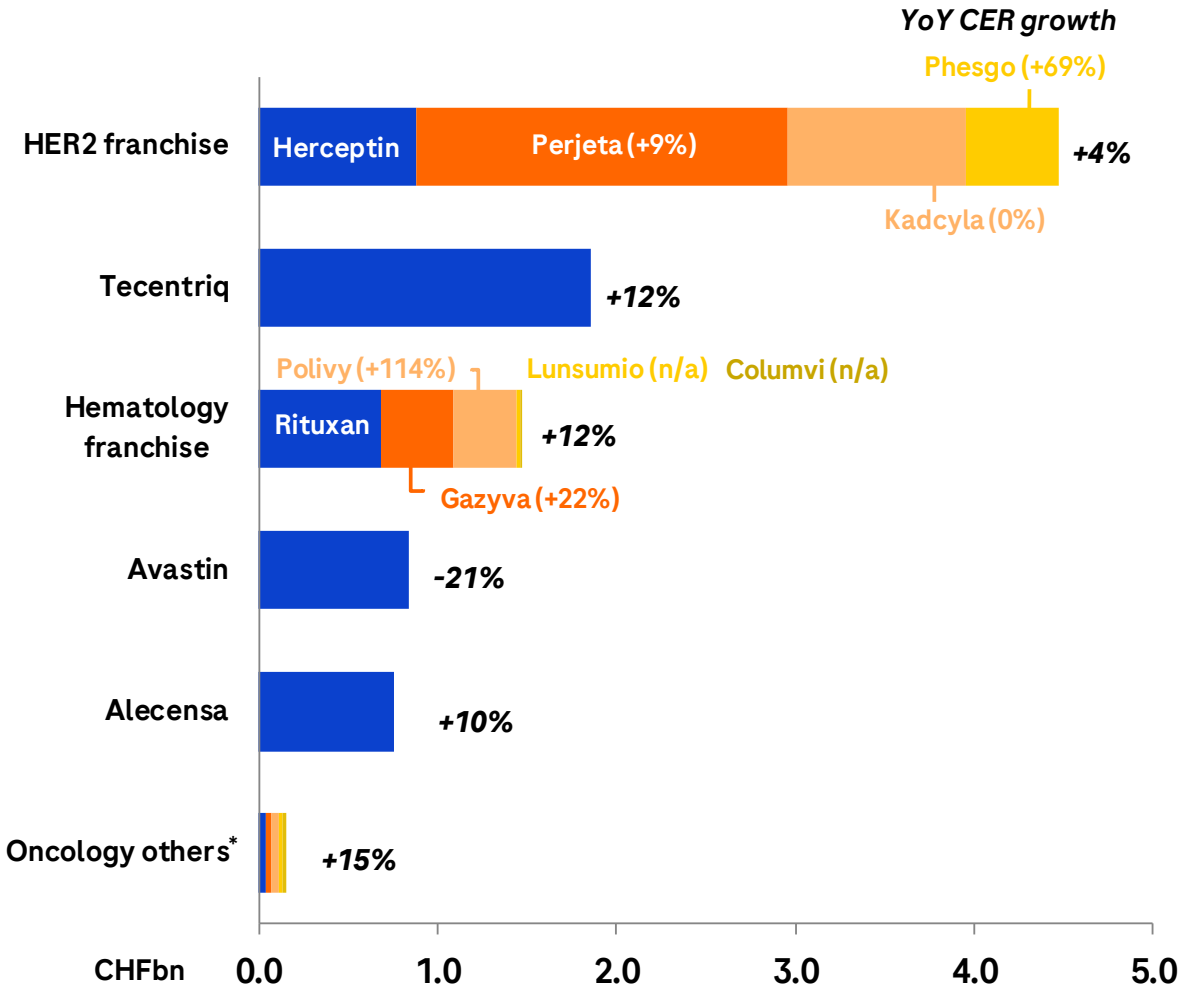
HY 2023: Strong momentum for key growth drivers

Vabysmo nearing CHF 1bn in H1; Polivy with strong launch in 1L DLBCL



Absolute values and growth rates at Constant Exchange Rates (CER); DLBCL=diffuse large B cell lymphoma

HY 2023: Oncology portfolio growing +4%



HER2 franchise

- Kadcyla (0%) growth in International compensating for US/EU
- Perjeta (+9%) driven by US and International
- Phesgo (+69%): 35% conversion in early launch countries**

Tecentriq

- Growth (+12%) driven by adjuvant NSCLC and 1L HCC

Hematology franchise

- Gazyva (+22%): Growth driven by 1L CLL
- Polivy (+114%): Strong 1L DLBCL uptake, especially in US, EU and JP
- Lunsumio: 3L+ FL launch and geographic expansion ongoing
- Columvi: US/EU launch in 3L+ DLBCL ongoing

Alecensa

- Strong growth (+10%) and 1L ALK+ NSCLC leadership in all markets

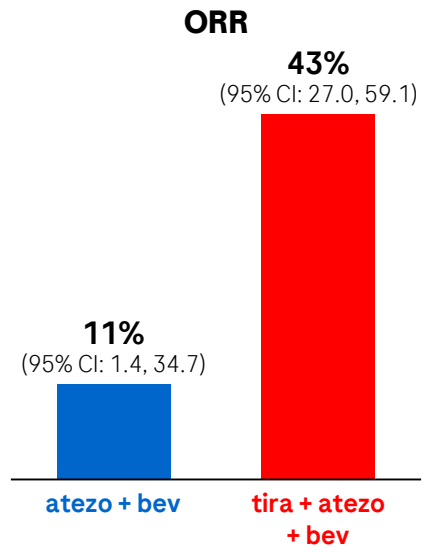
HY 2023 Oncology sales: CHF 9.8bn, CER growth +4%; CER=Constant Exchange Rates; * Includes sales of Zelboraf, Cotellic, Rozlytrek, Gavreto and Tarceva; ** Phesgo conversion rate is based on volumes (vials) and includes all launch countries after the 2nd quarter after the launch (38 countries); HCC=hepatocellular carcinoma; NSCLC=non-small cell lung cancer; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; ALK=anaplastic lymphoma kinase; Polivy in collaboration with Seagen

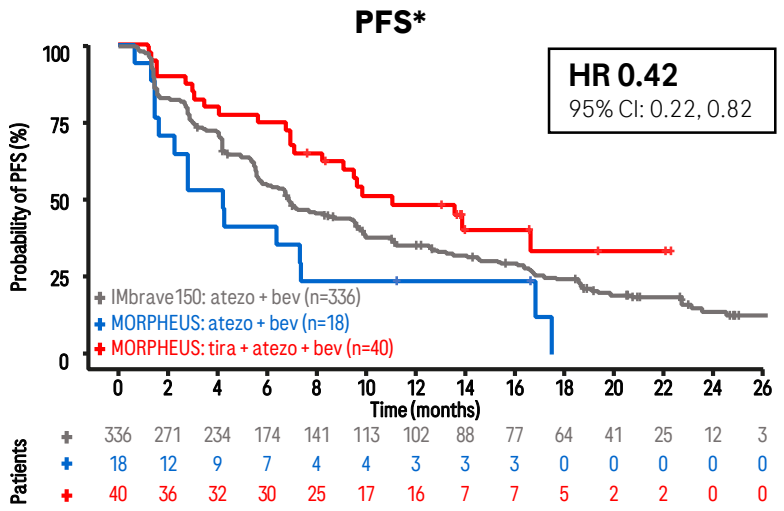
Tiragolumab: Positive early results in 1L HCC

Ph III in 1L HCC initiated

Ph I/II (MORPHEUS) results in 1L HCC

2023 ASCO ANNUAL MEETING





- Tiragolumab + Tecentriq + Avastin with PFS benefit of 58% (HR=0.42) and ORR of 43%
- Treatment benefit of tiragolumab supported by benchmarking vs IMbrave150 data
- No new safety signals

Development program

Indication	Ph I / Ph II / Ph III	
1L NSCLC: PD-L1 high	SKYSCRAPER-01	*Results in Q4 / Q1*
Stage III unres. NSCLC	SKYSCRAPER-03	
Neoadj/Adj NSCLC	SKYSCRAPER-05	
1L NSq NSCLC	SKYSCRAPER-06	
NSCLC	CITYSCAPE	
Locally advanced ESCC	SKYSCRAPER-07	
1L ESCC (China)	SKYSCRAPER-08	*Results in H1 2024*
2L+ PD-L1+CC	SKYSCRAPER-04	*Results in H2 2023*
SCCHN	SKYSCRAPER-09	
1L uHCC	SKYSCRAPER-14	
Solid tumors		
R/R MM or R/R NHL		

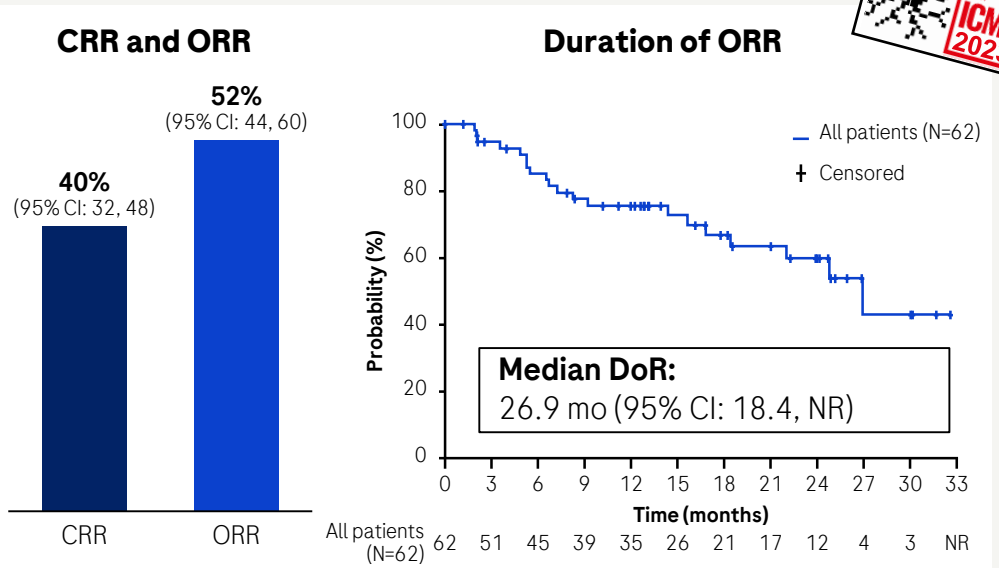
- Readout of SKYSCRAPER-01 in 1L NSCLC is event-driven and expected for Q4 / Q1
- Ph III (SKYSCRAPER-14) in 1L HCC initiated

Finn R, et al. J Clin Oncol 2023;41 (16 Suppl):4010; Cheng A-L. et al. J Hepatol 2022;76(4):862-873; *per RECIST v 1.1; SCLC=small cell lung cancer; NSCLC=non small cell lung cancer; ESCC=esophageal squamous cell carcinoma; NSq=non squamous; HR=hazard ratio; CI=confidence interval; PFS=progression free survival; ORR=objective response rate; CC=cervical cancer; SCCHN=squamous cell head and neck carcinoma; HCC=hepatocellular carcinoma; R/R=relapsed/refractory; MM=multiple myeloma; NHL=Non-Hodgkins lymphoma

Columvi: Approval in 3L+ DLBCL in US and EU achieved

First and only bispecific offering fixed-duration treatment in 3L+ DLBCL

Ph II results for Columvi in 3L+ DLBCL



- CRR / ORR of 40% / 52% with a median DoR of 26.9 months
- Off-the-shelf treatment option that provides durable response rates
- NCCN guideline inclusion as category 2A achieved

CD20 x CD3 development program

Regimen	Indication	Ph I / Ph II / Ph III	
Columvi	3L+ DLBCL		✓ US/EU approved
Columvi + GemOx	2L+ DLBCL (SCT-ineligible)	STARGLO	Readout 2024
Columvi + CD19x4-1BBL	r/r NHL		
Columvi + CD19xCD28	r/r NHL		
Columvi + Polivy + R-CHP	1L DLBCL		Ph III to initiate in 2023

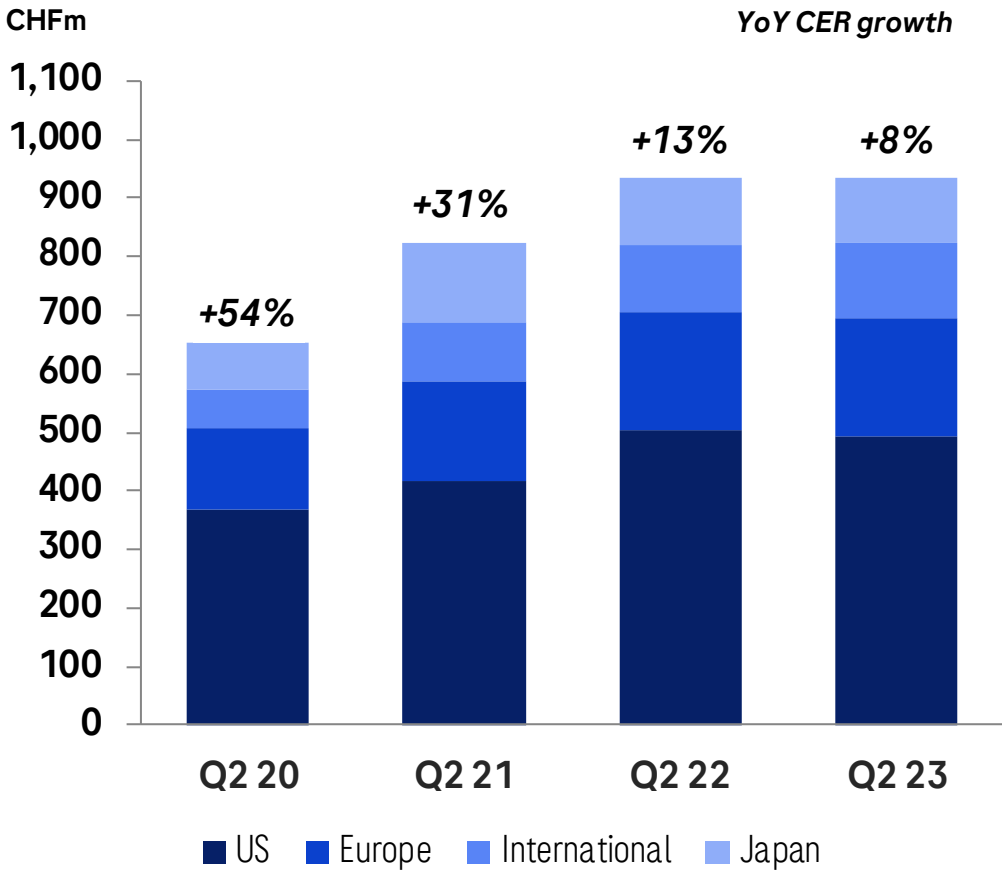
Regimen	Indication	Ph I / Ph II / Ph III	
Lunsumio	3L+ FL		✓ US/EU approved
Lunsumio + Polivy	2L+ DLBCL (SCT-ineligible)	SUNMO	Readout 2024
Lunsumio + lenalidomide	2L+ FL	CELESTIMO	Interim analysis 2024
Lunsumio	r/r CLL		
Lunsumio	1L DLBCL (elderly/unfit)		
Lunsumio + Polivy	1L DLBCL (elderly/unfit)		

- Ph III (STARGLO) Columvi + GemOx in 2L+ DLBCL readout now expected 2024

Dickinson M, et al. Hematol. Oncol. 2023;41 (S2):144-6; CRR=complete response rate; ORR=overall response rate; DoR=durability of response; NR=not reached; HR=hazard ratio; CI=confidence interval; R/R=relapsed refractory; FL=follicular lymphoma; DLBCL=diffuse large B-cell lymphoma; CLL=chronic lymphocytic leukemia; SCT=stem cell transplantation; NHL=non-Hodgkin's lymphoma; GemOx=gemcitabine oxaliplatin; R-CHP=rituxan + cyclophosphamide + hydroxydaunorubicin + prednisone; NCCN=national comprehensive cancer network

Tecentriq: First PD-(L)1 with pivotal SC results filed in US and EU

US PDUFA set for September 15th



Q2 update

Lung franchise (NSCLC, SCLC)

- US/EU: Adjuvant NSCLC launch ongoing

GI franchise (HCC)

- US/ROW: Further growth in 1L HCC, nearing peak penetration

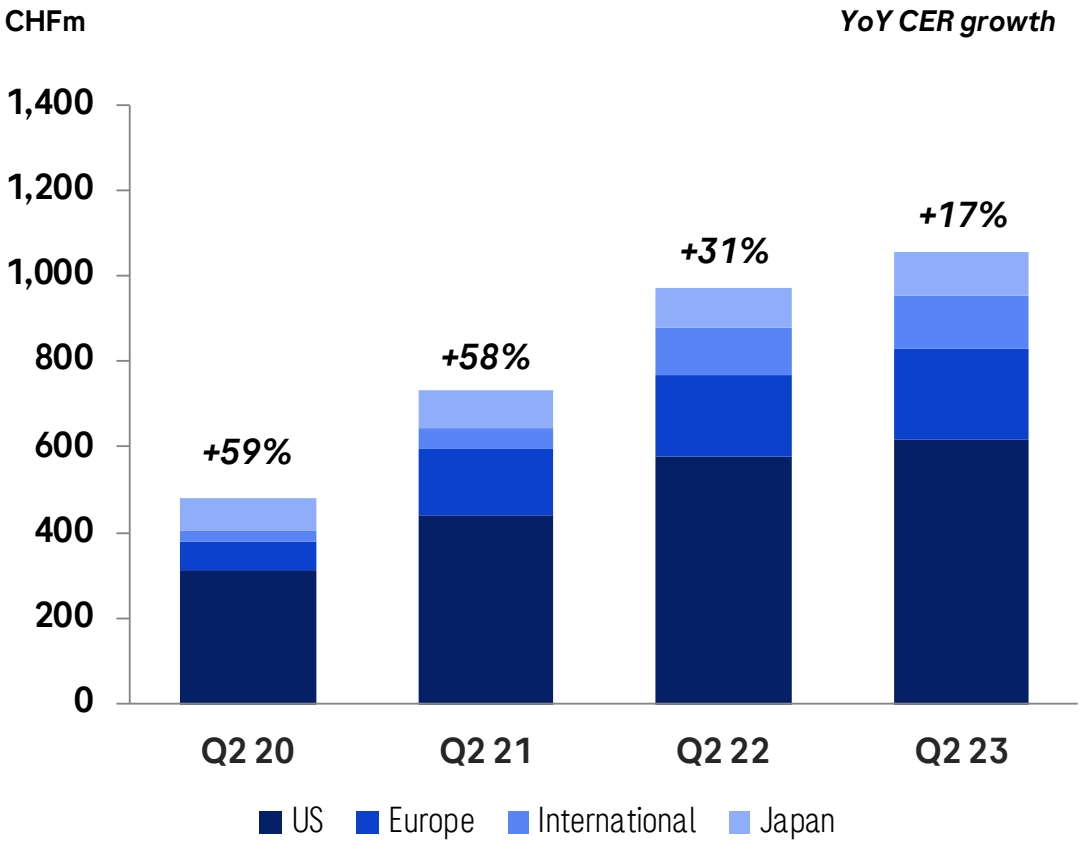
Outlook 2023

- US/Great Britain approvals for Tecentriq SC expected
- Ph III (IMvoke010) results in adjuvant SCCHN expected in Q4
- Ph III (SKYSCRAPER-01) Tecentriq + tiragolumab in 1L PD-L1+ NSCLC final OS results expected in Q4 / Q1

CER=Constant Exchange Rates; SC=subcutaneous; NSCLC=non-small cell lung cancer; HCC=hepatocellular cancer; SCLC=small cell lung cancer; SCCHN=squamous cell carcinoma of head and neck; PDUFA=prescription drug user fee act; OS=overall survival; ROW=rest of world

Hemophilia A: Hemlibra, the global SoC, keeps expanding

US/EU-5 patient share reached 39%



Q2 update

- ~21,000 patients treated globally
- Hemlibra continues to penetrate across all approved patient segments
- SPK-8011 pivotal Ph III gene therapy initiated
- Key data at ISTH 2023 presented:
  - Strong Hemlibra prophylaxis and QoL results
  - Ph I/II safety data for NXT-007
  - Ph I/II 3-year QoL and joint health data for SPK-8011

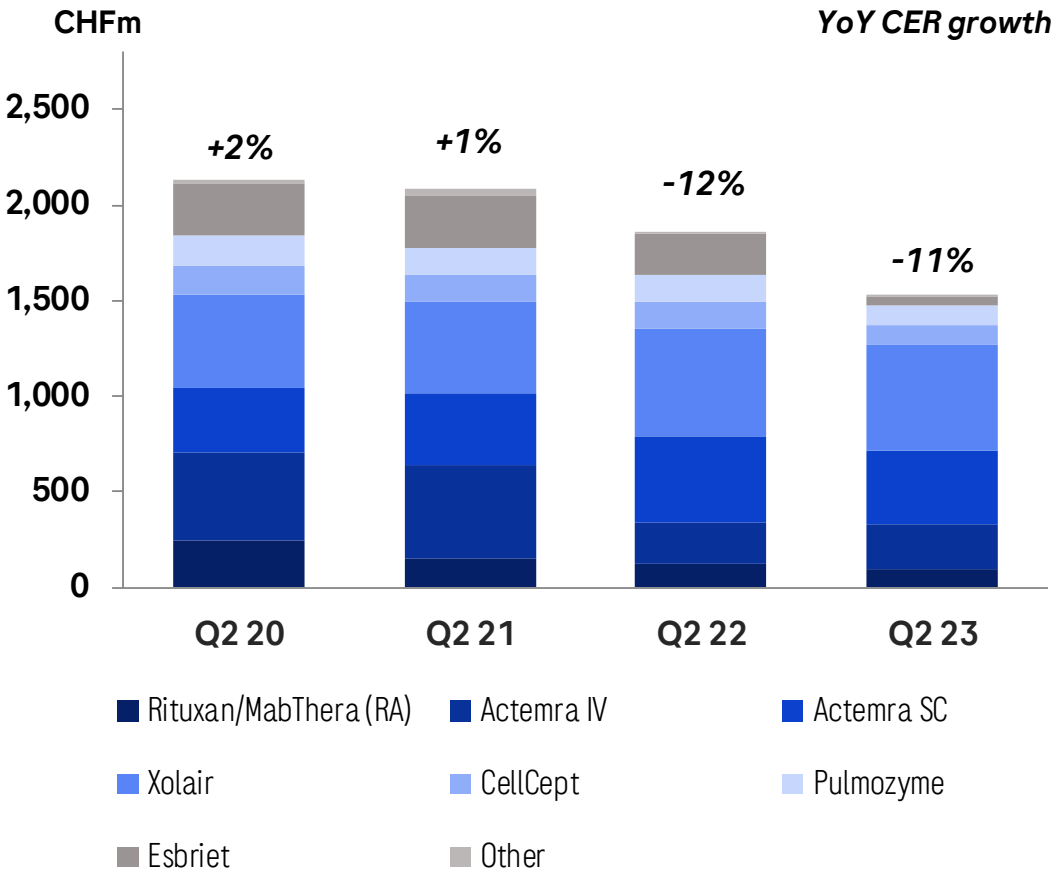
Outlook 2023

- US/EU: Further patient share gains in non-inhibitors

CER=Constant Exchange Rates; QoL=quality of life; SoC=standard of care

Immunology: Sales impacted by Esbriet erosion

Ph III (OUtMATCH) Xolair in food allergy readout expected in H2 2023



Q2 update

- Ph III (ARNASA) astegolimab in COPD initiated
- Ph III (IMAGINATION) ASO factor B in IgA nephropathy initiated

Actemra (+2%)

- No COVID-19 related sales
- Shift from IV to SC ongoing, SC share at ~60%

Esbriet (-78%)

- Generic competition in US/EU

Xolair (+4%)

- Growth driven by CSU

Outlook 2023

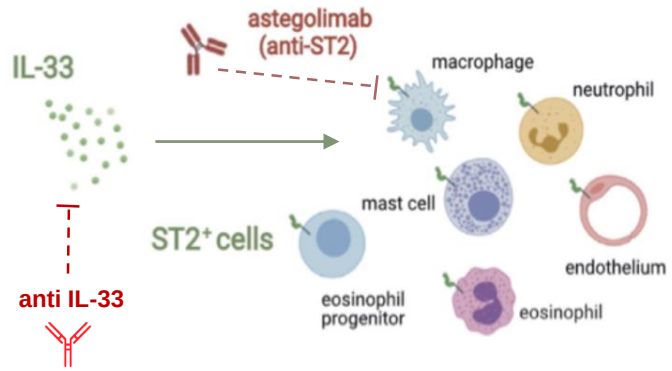
- Ph III (OUtMATCH) Xolair in food allergy results expected
- US approval of Xolair autoinjector expected

CER=Constant Exchange Rates; RA=rheumatoid arthritis; IV=intravenous; SC=subcutaneous; COPD=chronic obstructive pulmonary disease; CSU=chronic spontaneous urticaria; ASO=antisense oligonucleotide; IgA nephropathy =immunoglobulin A nephropathy

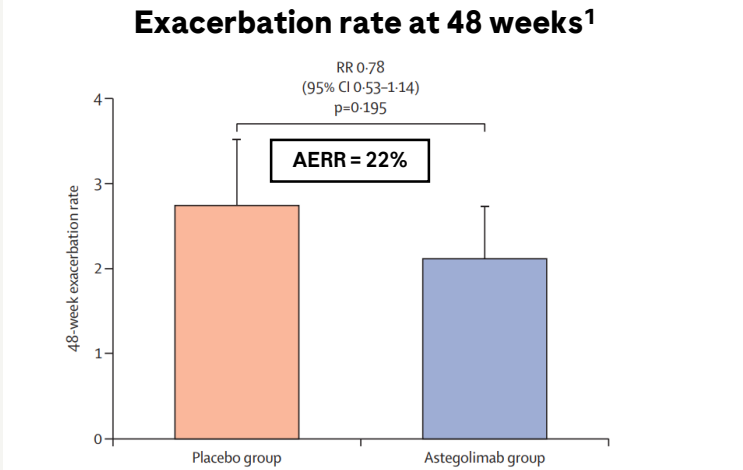
Astegolimab: First in class anti-ST2 mAb in COPD enters Ph III

Early results show benefit in key endpoints throughout broad patient population

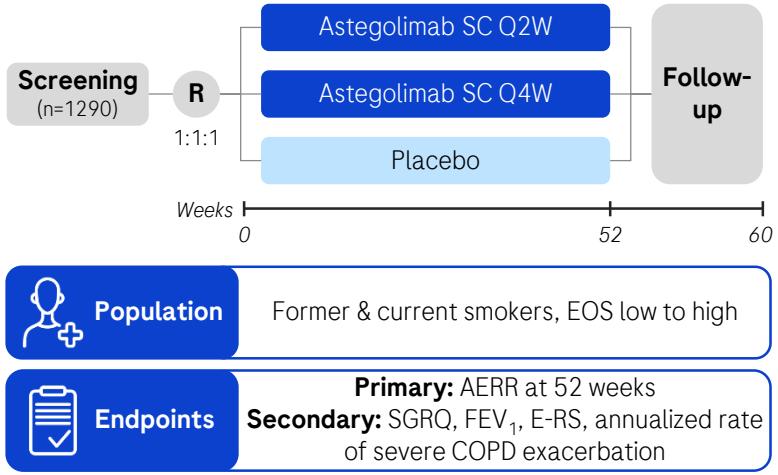
Astegolimab (anti-ST2 mAb)



Ph IIa (COPD-ST2OP) results



Ph III (ARNASA) trial design



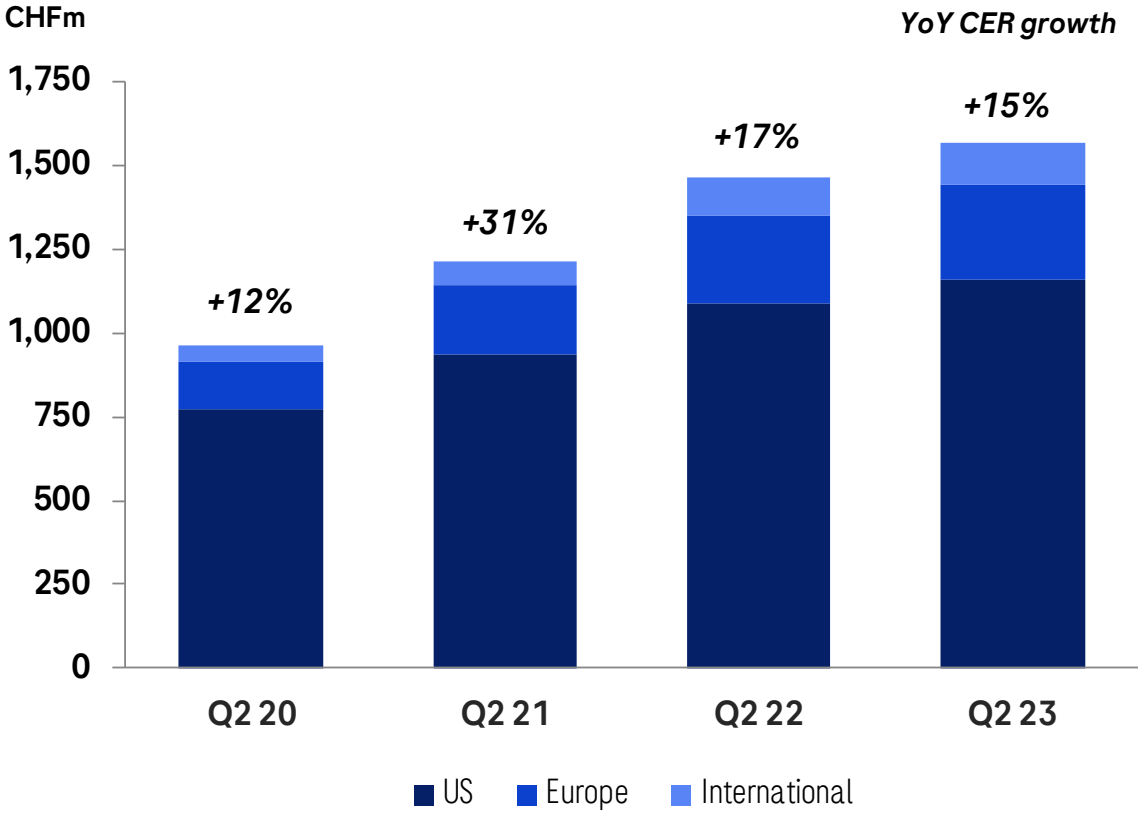
- Astegolimab binds both soluble ST2 and membrane bound ST2 (IL-33) receptor
- IL-33 blockade may impact airway remodeling in COPD patients
- No biologics currently approved in COPD

- Ph IIa (COPD-ST2OP): AER reduction of -22% (-37% in EOS low), reduction in SGRQ of -3.3 and increased FEV_1 by +40 ml
- Pivotal Ph III program includes up-scaled Ph IIb (ALIENTO) and newly initiated Ph III (ARNASA); results expected in 2025
- Broad patient population including former and current smokers, and EOS low to high

[1] Yousuf AJ, et al. Lancet Respir. Med. 2022;10 (5):469-77; mAb=monoclonal antibody; ST2=suppression of tumorigenicity 2; IL-33=interleukin-33; COPD=chronic obstructive pulmonary disease; R=randomization; SC=subcutaneous; Q2W/Q4W=every 2/4 weeks; EOS=eosinophils; RR=rate reduction; AERR=annualized exacerbation rate reduction; SGRQ=St. George's respiratory questionnaire; FEV_1=forced expiratory value; E-RS=evaluating respiratory systems

Multiple Sclerosis: Positive Ph III results for Ocrevus 6m SC

Twice a year, 10 min injection to further improve treatment experience and expand usage



Q2 update

- Ocrevus with 22% patient share globally (>300k pts treated)
- Market leader in US and EU-5
- Higher retention rate than other MS medicines
- Ph III (OCARINA II) for Ocrevus 6m SC met all primary and secondary endpoints
- Ph III (GAVOTTE/MUSETTE) high-dose Ocrevus fully recruited
- Positive Ph II (FENopta) results for fenebrutinib in RMS

Outlook 2023

- US/EU: Further market share gains expected
- Ph III (OCARINA II) results to be filed globally

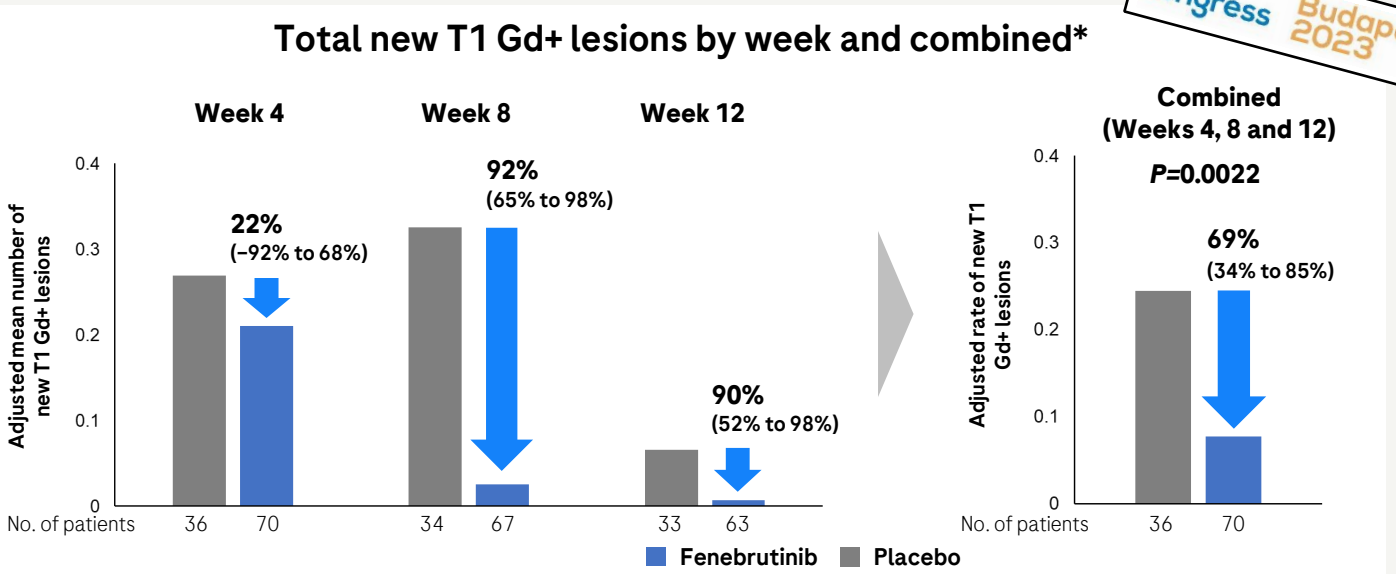
CER=Constant Exchange Rates; MS=multiple sclerosis; SC=subcutaneous; 6m=every 6 months; RMS=relapsing MS

Fenebrutinib: Strong Ph II data highlight potential in MS

Highly selective and the only reversible, non-covalent BTKi in Ph III

Ph II (FENopta) results in RMS

ean congress Budapest 2023



Ph III program

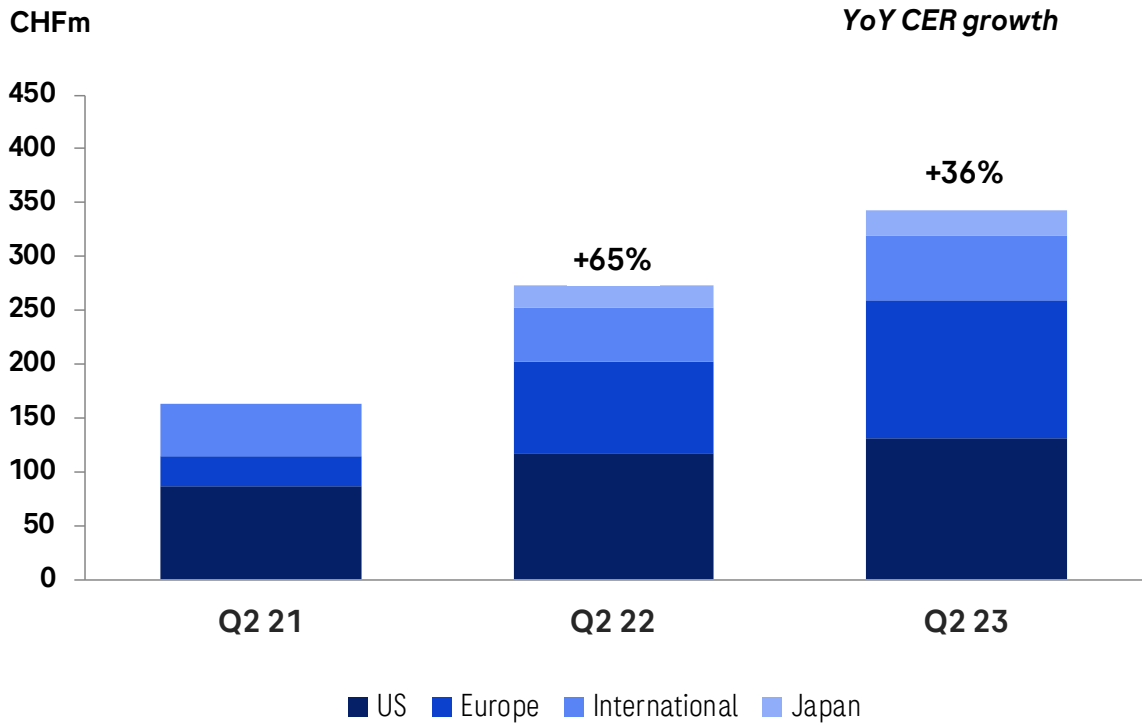
Indication	Trial design	Ph I	Ph II	Ph III
RMS	*vs placebo*	FENopta		✓
RMS	*vs teriflunomide*	FENhance 1/2		
PPMS	*vs Ocrevus*	FENtrepid		

- Significantly reduced brain lesions in RMS patients, meeting primary and secondary endpoints, with patients on fenebrutinib 4x more likely to be free from new T1 Gd+ and N/E T2 lesions at weeks 4, 8 and 12 vs placebo
- Safety profile consistent with previous and ongoing trials across >2,400 patients
- Ph III trials (FENhance 1/2) in RMS and (FENtrepid) in PPMS ongoing

Hua LH et al., EAN 2023; *Results were estimated from a negative binomial model controlling for baseline T1 Gd+ lesion status (presence or absence) and included log number of scans as an offset. Arrows indicate relative reduction (95% CI) of lesions; MS=multiple sclerosis; BTKi=Bruton's tyrosine kinase inhibitor; RMS=relapsing multiple sclerosis; PPMS=primary progressive multiple sclerosis; Gd+=gadolinium-enhancing; N/E T2 = new/enlarging T2-weighted; CI=confidence interval

Spinal muscular atrophy: Evrysdi on track to become global #1

4 year follow-up data confirm strong efficacy and safety profile in infants



Q2 update

- >8,500 patients treated worldwide; retention rate in first 12 months of ~90% globally
- US: Market leader with growth driven by switch and naive patient starts, including patients <2 months old
- Ex-US: Continued strong growth and share gains in all major markets; #1 in Japan
- Ph II/III (FIREFISH) 4 year follow-up data confirming strong efficacy / safety profile in infants shown at CURE SMA

Outlook 2023

- Continued growth and market share gains
- EU: Positive CHMP opinion for Ph II (RAINBOWFISH) in <2 months old infants; EU label extension expected

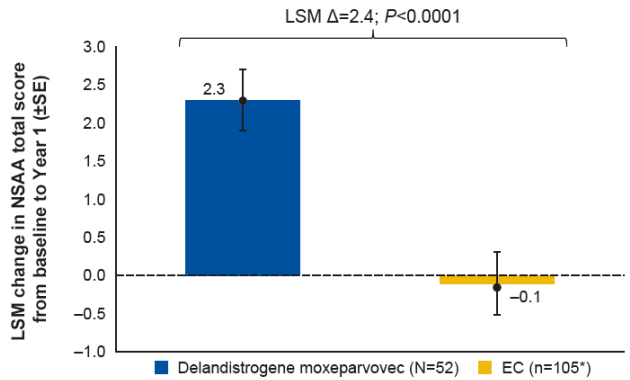
CER=Constant Exchange Rates; SMA=spinal muscular atrophy

Elevidys: US approval for first DMD gene therapy by partner Sarepta

Ph III (EMBARK) results in Q4, needed for EU filing & US label extension

Pooled analysis of studies 101/102/103*

Change from baseline in NSAA total score over 1 year**



- Positive functional and clinically meaningful results up to 4 years after treatment with consistent safety profile in >50 patients
- US accelerated approval in 4 and 5 year old ambulatory patients achieved by Sarepta in Q2
- Roche planning to file in selected countries referencing to the US approval

Development program

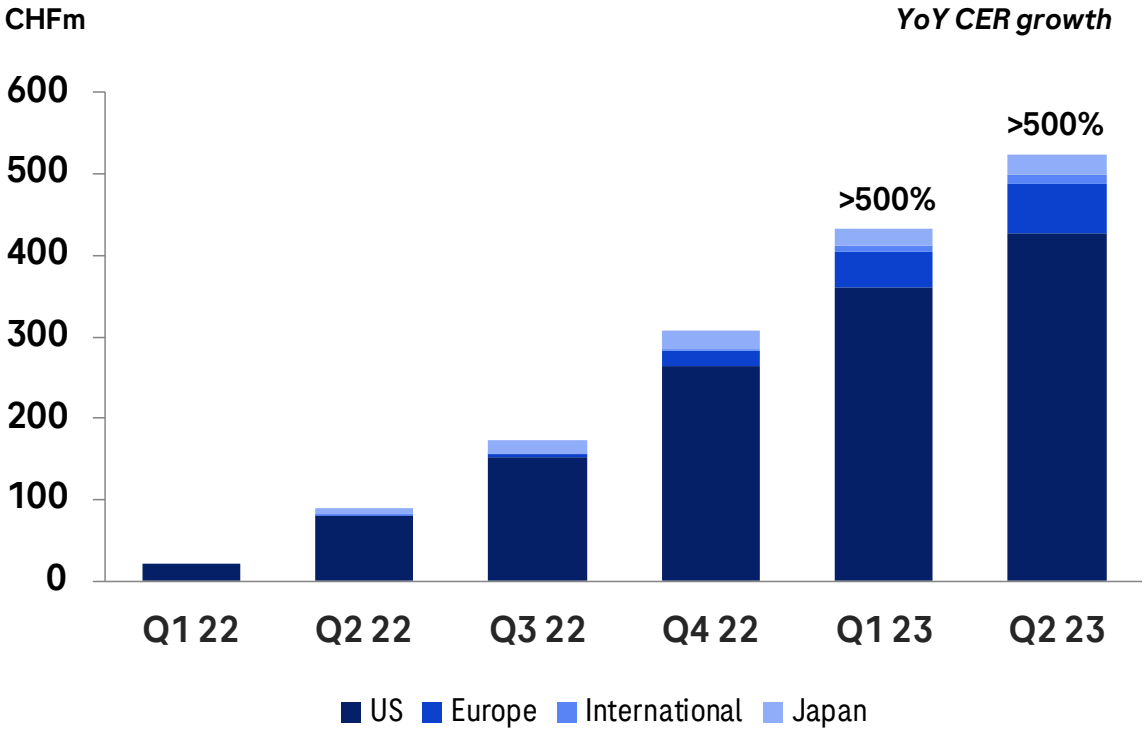
Study	DMD subgroup	Ph I / Ph II / Ph III	Comment
101	Ambulatory, 4-7 yrs.	Ph I	✓ US approval (Sarepta)
102	Ambulatory, 4-7 yrs.	Ph I / Ph II	✓ US approval (Sarepta)
103 (ENDEAVOR)	Ambulatory, 3-18 yrs Non-ambulatory, all ages	Ph I	✓ US approval (Sarepta)*
301 (EMBARK)	Ambulatory, 4-7 yrs.	Ph I / Ph II / Ph III	EU filing and US label extension
302 (ENVOL)	Ambulatory, 0-3 yrs.	Ph I / Ph II	Expansion to younger DMD pts
303 (ENVISION)	Ambulatory, 8-18 yrs Non-ambulatory, all ages	Ph I / Ph II / Ph III	Expansion to older ambulatory and non-ambulatory DMD pts

- Ph III (ENVISION) in older ambulatory and all ages non-ambulatory patients started in Q2 2023
- Ph II (ENVOL) in 0-3 year old ambulatory patients to initiate in H2 2023
- Ph III (EMBARK) results in Q4 2023; data to be filed in the EU and to facilitate non-age-restricted expansion of the US label

Elevidys (delandistrogene moxeparvovec) accelerated US approval by partner Sarepta Therapeutics; [1] Zaidman, et al. MDA 2023; *For study 103 (ENDEAVOR) only cohort 1 was used; **Functional data from patients who received the $1.33x10^{14}$ vg/kg dose of delandistrogene moxeparvovec and the propensity-score-weighted EC cohort were compared; DMD=Duchenne muscular dystrophy; NSAA=North Star Ambulatory Assessment; LSM=least-squares mean; EC=external control; SE=standard error

Ophthalmology: Vabysmo nearing CHF 1 bn sales in H1

*US market share reaches 15% in nAMD and 9% in DME**



Q2 update

- US: ~30% naive patients, ~70% switches (mostly from aflibercept)
- JP/UK/CH/AUS: Double-digit market share in early launch countries
- Filed for third indication RVO in US

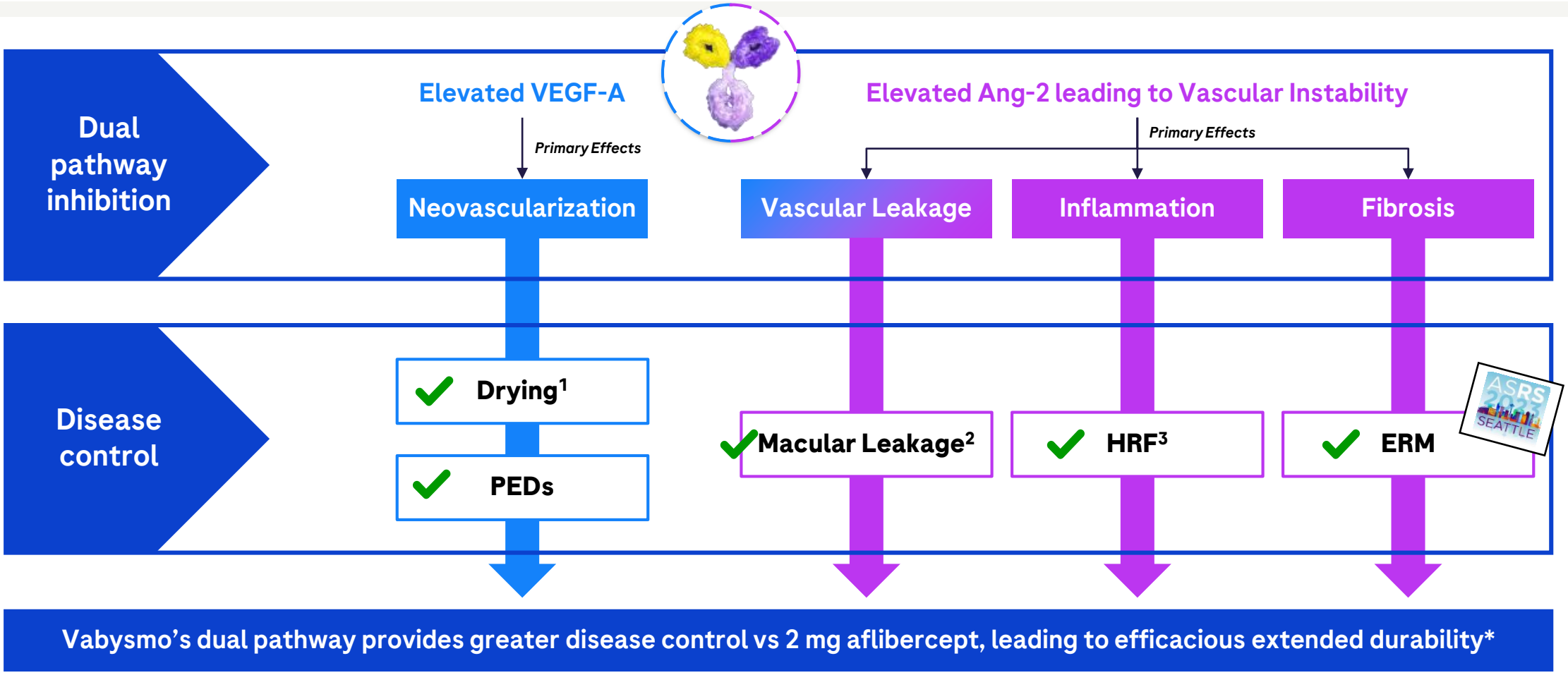
Outlook 2023

- Continued launches in EU and ROW countries and global market share gains in nAMD and DME
- US PDUFA for Vabysmo in RVO set for 22nd December; EU filing expected in Q3
- New Vabysmo data to be presented at ASRS 2023:
  - Post-hoc data indicates less fibrosis vs. aflibercept in DME
  - Real-world data reinforcing 1L benefits in nAMD and DME
  - New clinical results on positive anatomical outcomes in nAMD and DME

*Based on May 2023 patient claims data; CER=constant exchange rate; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; RVO=retinal vein occlusion; RWO=rest of world; PDUFA=prescription drug user fee act; Eylea (aflibercept) is a registered trademark/product of Regeneron

Vabysmo: Benefits of dual pathway supported by anatomic results

Latest results on ERM endpoint to be presented at ASRS 2023

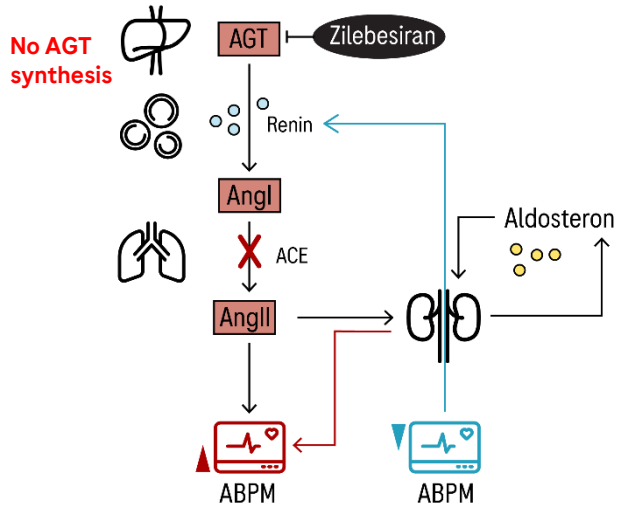


[1] Dhoot et al. Macula Society 2023 Annual Meeting; [2] Goldberg et al. ARVO 2023 Annual Meeting; [3] Maunz et al. ARVO 2023; *Based on results from head-to-head matched-dose loading phase in Vabysmo Ph III clinical trials; PEDs, Macular Leakage, HRF and ERM based on post-hoc, exploratory analysis with nominal p-value statistical testing; PED=pigment epithelial detachment; Ang-2=angiopoietin-2; VEGF-A=vascular endothelial growth factor A; HRF=hyper-reflective foci; ERM=epiretinal membrane; Eylea (aflibercept) is a registered trademark/product of Regeneron

Zilebesiran: Roche enters partnership with Alnylam in hypertension

New MoA with tight upstream blockade of AGT pathway and best in disease potential

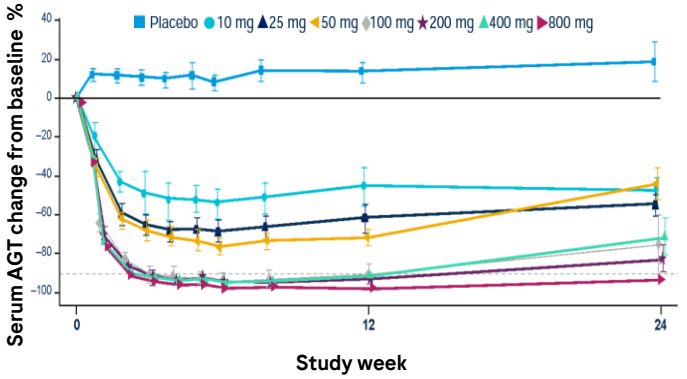
Zilebesiran (angiotensinogen siRNA)



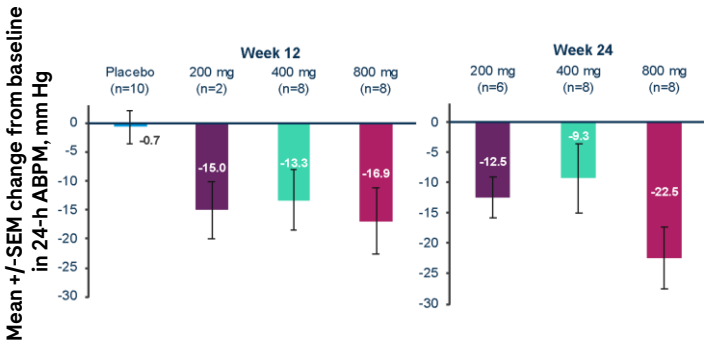
- siRNA targeting angiotensinogen, the precursor of all angiotensin peptides
- Consistent and durable blood pressure control with potential for improved adherence
- Liver-specific activity may avoid RAAS escape

Ph I results in hypertension[1]

Change in serum angiotensinogen



Mean change in 24-h ambulatory systolic blood pressure



- Positive Ph I results: >90% reduction of serum angiotensinogen for up to 6 mos at single SC dose of zilebesiran ≥100mg; >20 mmHg blood pressure reduction for 3-6 mos
- Two Ph II studies (KARDIA-1/2): Monotherapy study in mild/moderate hypertension and add-on study to SoC in uncontrolled hypertension; data expected in mid-2023 and early 2024, respectively

[1] Desai et al. N Engl J Med 2023;389:228-38; MoA=mode of action; SC=subcutaneous; RAAS=renin angiotensin aldosterone system; siRNA=small interfering RNA; AGT=angiotensinogen; AngI/II=angiotensin I/II; ACE=angiotensin-converting enzyme; ABPM=ambulatory blood pressure monitoring; SoC=standard of care; zilebesiran in partnership with Alnylam Pharmaceuticals

2023: Key late-stage newsflow*

	Compound	Indication	Milestone	
Regulatory	**Hemlibra**	Moderate hemophilia A	EU approval	✓
	Polivy + R-CHP	1L DLBCL	US approval	✓
	Vabysmo	RVO	US approval/EU filing	
	Tecentriq	Subcutaneous administration	US approval/EU filing	✓ EU filing
	Columvi (glofitamab)	3L+ DLBCL	US/EU approval	✓
	Xofluza	Influenza (paediatric 1+ yrs.)	EU approval	✓
Phase III / pivotal readouts	**Tecentriq + Avastin**	Adjuvant HCC	Ph III IMbrave050	✓
	Tecentriq + chemo	Neoadjuvant / adjuvant TNBC	Ph III GeparDouze/NSABP B-59	*2024*
	Tecentriq	Adjuvant SCCHN	Ph III IMvoke010	
	Tecentriq + chemo	Adjuvant TNBC	Ph III IMpassion030	✗
	Tiragolumab + Tecentriq	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	*Q4 2023 / Q1 2024*
	Tiragolumab + Tecentriq + chemo	1L esophageal cancer	Ph III SKYSCRAPER-08 (China only)	*2024*
	Venclexta + dexamethasone	t(11;14) R/R MM	Ph III CANOVA	
	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA	
	Alecensa	Adjuvant ALK+ NSCLC	Ph III ALINA	
	Phesgo OBI (on body injector)	HER2+ BC	Ph I *(pivotal)*	
	Crovalimab	PNH	Ph III COMMODORE 1/2	✓
	Columvi + GemOx	2L+ DLBCL	Ph III STARGLO	*2024*
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO	*2024*
	Elevidys (Delandistrogene moxeparvovec)	DMD	Ph III EMBARK	
	Ocrevus 6m SC	RMS / PPMS	Ph III OCARINA II	✓
	TNKase	Stroke patients 4.5-24h	Ph III TIMELESS	✗
	Susvimo	DME	Ph III PAGODA	✓
	Susvimo	DR	Ph III PAVILION	✓
	Xolair	Food allergy	Ph III OUtMATCH	

Additional 2023 newsflow:

- **Fenebrutinib**: Positive Ph II (FENopta) results in RMS
- **Elevidys** US approval in DMD for 4 and 5 years old (Sarepta)
- **Tiragolumab + Tecentriq + Avastin**: Positive Ph I/II (MORPHEUS) results in 1L HCC

* Outcome studies are event-driven: timelines may change

Diagnostics Division

Matt Sause
CEO Roche Diagnostics

HY 2023: Diagnostics Division sales

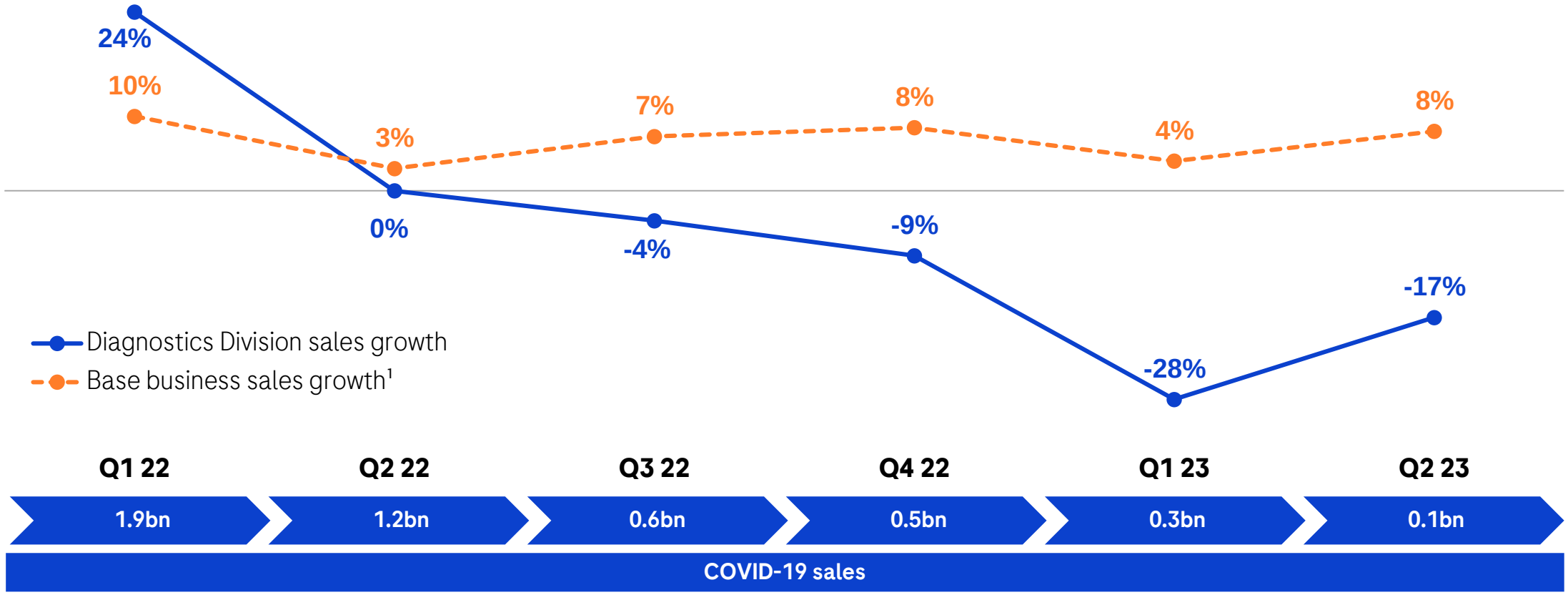
Good base business growth, partially offsetting COVID-19 sales decrease

	2023 CHFm	2022 CHFm	Change in % CHF	Change in % CER	Excl. C19[1]
Diagnostics Division	**7,098**	**9,948**	**-29**	**-23**	**6**
Core Lab	3,935	3,875	2	10	
Molecular Lab	1,118	1,980	-44	-40	
Diabetes Care	723	832	-13	-5	
Pathology Lab	687	652	5	12	
Point of Care	635	2,609	-76	-74	

CER=Constant Exchange Rates; [1] Diagnostics Division base business

Diagnostics Division sales growth by quarter

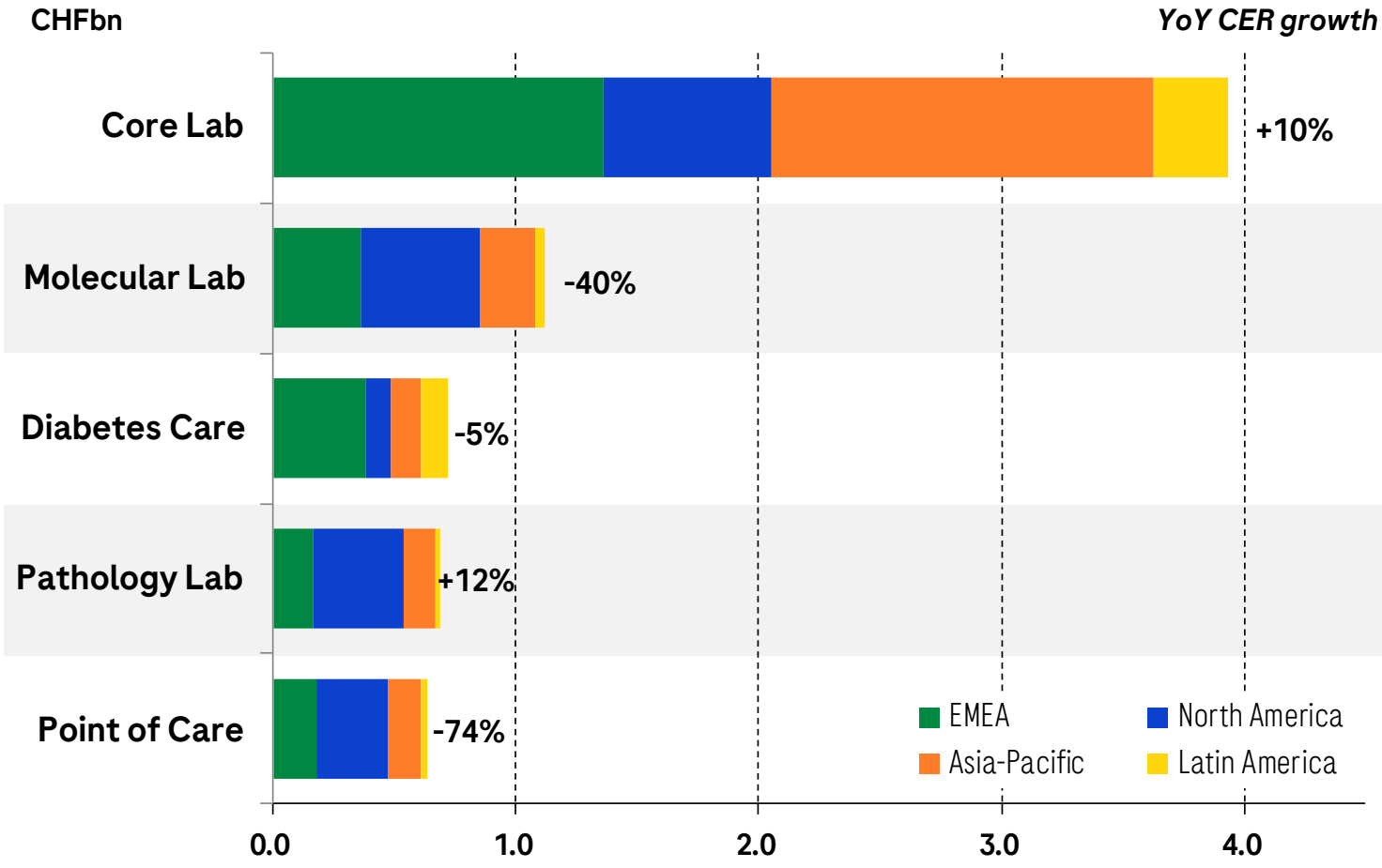
Good base business growth



Growth rates and absolute values at CER (Constant exchange Rates) of the respective year; [1]Quarterly sales growth excluding COVID-19 sales

HY 2023: Diagnostics Division highlights

Good base business growth, partially offsetting COVID-19 sales decrease



- Immunodiagnostics (+11%)
- Clinical Chemistry (+10%)
- Custom biotech (-8%)

- Cervical Cancer (+24%)
- Blood Screening (+13%)
- Virology base business (+5%)
- COVID-19 (-88%)

- Blood glucose monitoring (-3%)
- Insulin delivery systems (-29%)

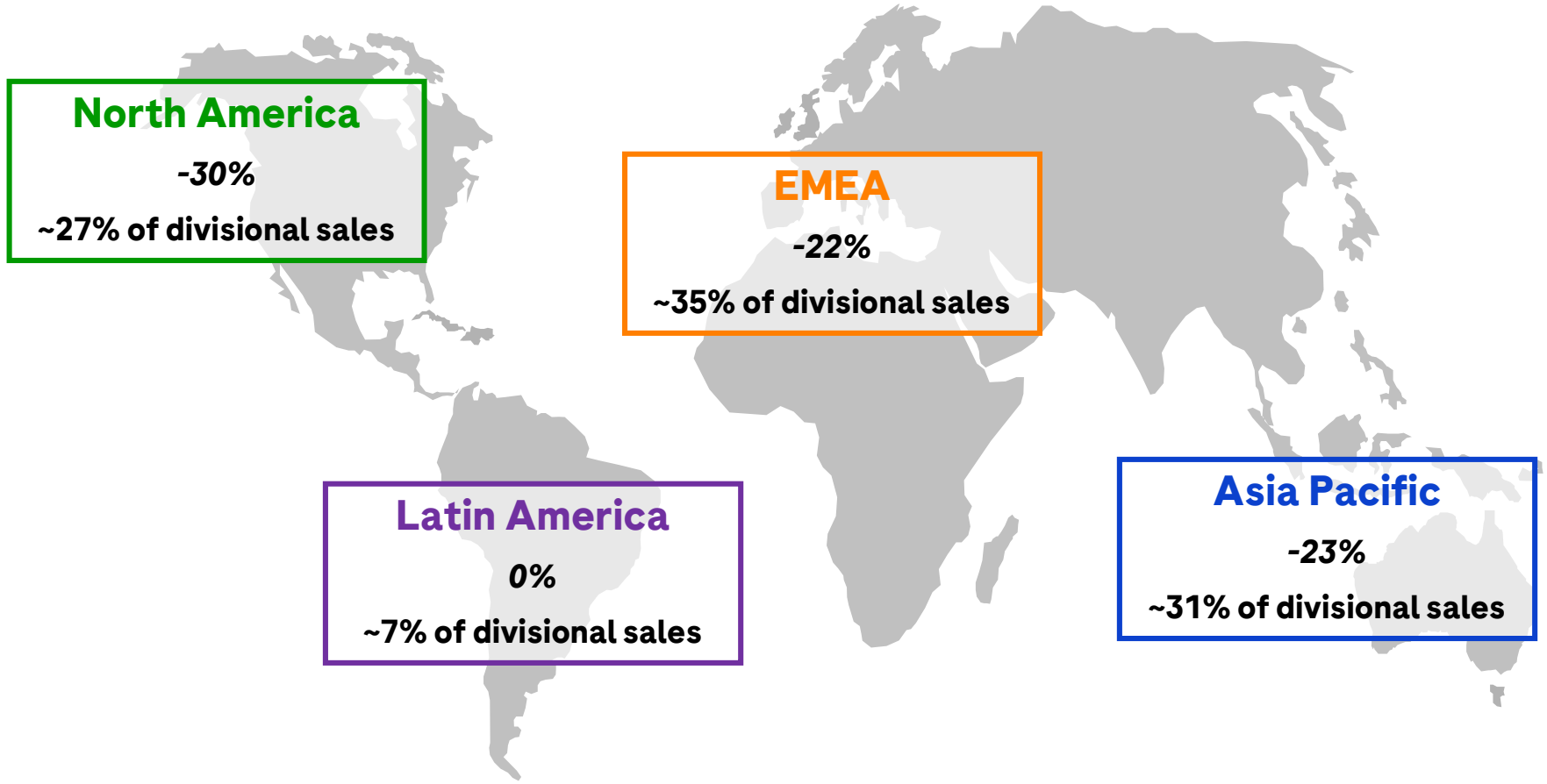
- Advanced staining (+10%)
- Companion diagnostics (+20%)

- POC Immunodiagnostics (-89%)
- POC Molecular (-40%)

CER=Constant Exchange Rates; POC=point of care; EMEA=Europe, Middle East and Africa

HY 2023: Diagnostics Division regional sales

Good base business growth across all regions impacted by lower COVID-19 sales

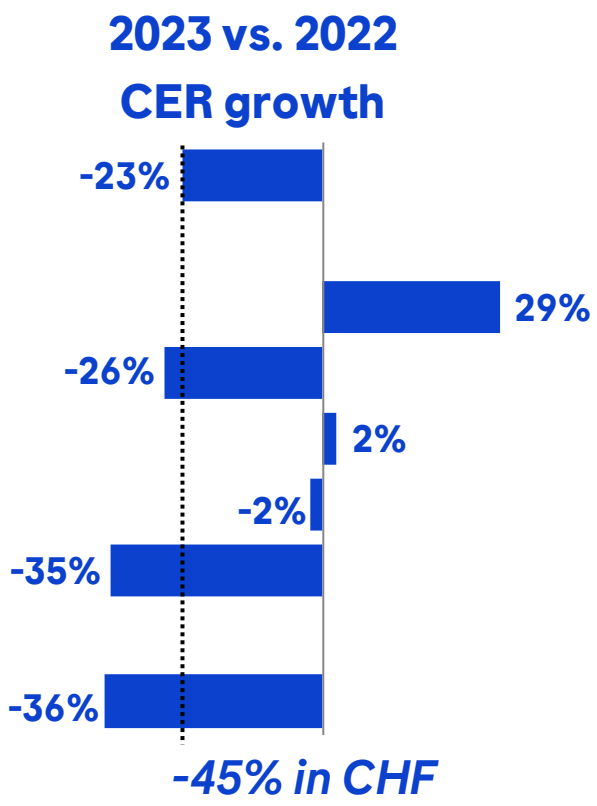


Growth rates at CER (Constant exchange Rates); EMEA=Europe, Middle East and Africa

HY 2023: Diagnostics Division

Core operating profit decline due to drop in COVID-19 sales

	2023 CHFm	2023 % sales
Sales	**7,098**	**100.0**
Other revenue	31	0.4
Cost of sales	-3,349	-47.2
R&D	-832	-11.7
SG&A	-1,342	-18.9
OOI&E	13	0.2
Core operating profit	**1,619**	**22.8**



CER=Constant Exchange Rates; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense

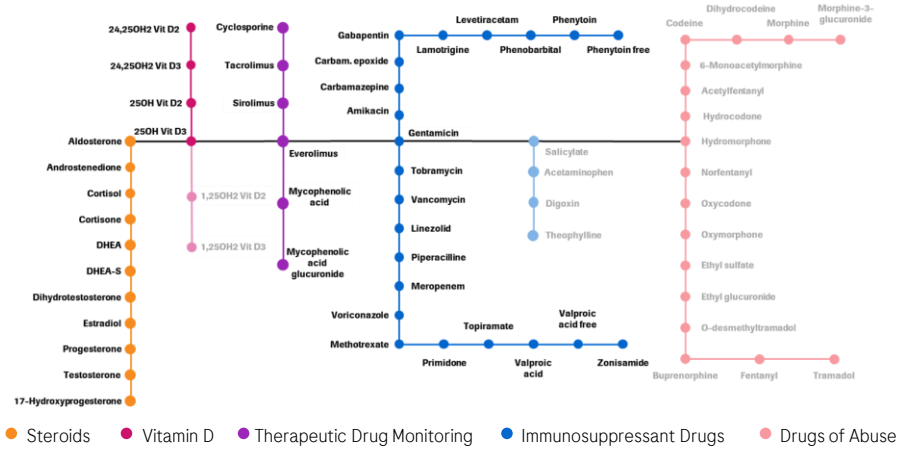
cobas® i601 analytical mass spectrometry unit and assay menu

Fully integrated and automated solution with more than 40 IVD assays at launch

Seamless integration into cobas® pro integrated solutions

- **Fully automated** solution reduces need for specialized labor
- **High throughput** of up to 100 samples / hr in random access

IVD assay menu of more than 60 assays in 2 launch waves[1]



- Launch menu complimentary to immunoassay offering
- Mass spec technology offering high sensitivity and specificity
- CE launch planned for end of 2024 (FDA approval expected in 2025)

Fully automated and integrated solution with IVD kits replacing labor intensive LDT mass spectrometry

[1]More than 40 IVD assays in established areas for clinical mass spec testing (steroids, therapeutic drug monitoring & vitamin D) at launch, more than 20 add. assays to follow in wave 2; LDT=Laboratory Developed Test

Driving access to essential diagnostics

WHO prequalification for HPV molecular test expands access in LMICs

WHO 2030 cervical cancer elimination goals[2]

- 90% of girls fully vaccinated against HPV by age 15
- 70% of women screened for HPV by age 35 and again at age 45
- 90% of women identified with lesions receive treatment

Implications for LMICs and Roche

- WHO PQ enables LMICs requiring PQ to use cobas® HPV test in cervical cancer elimination programs
- Affiliates covering WHO PQ countries leverage cobas® 6800/8800 installed base for cervical cancer screening tenders
- Roche to strengthen partnerships with governments and drive policy on HPV and multi-disease testing

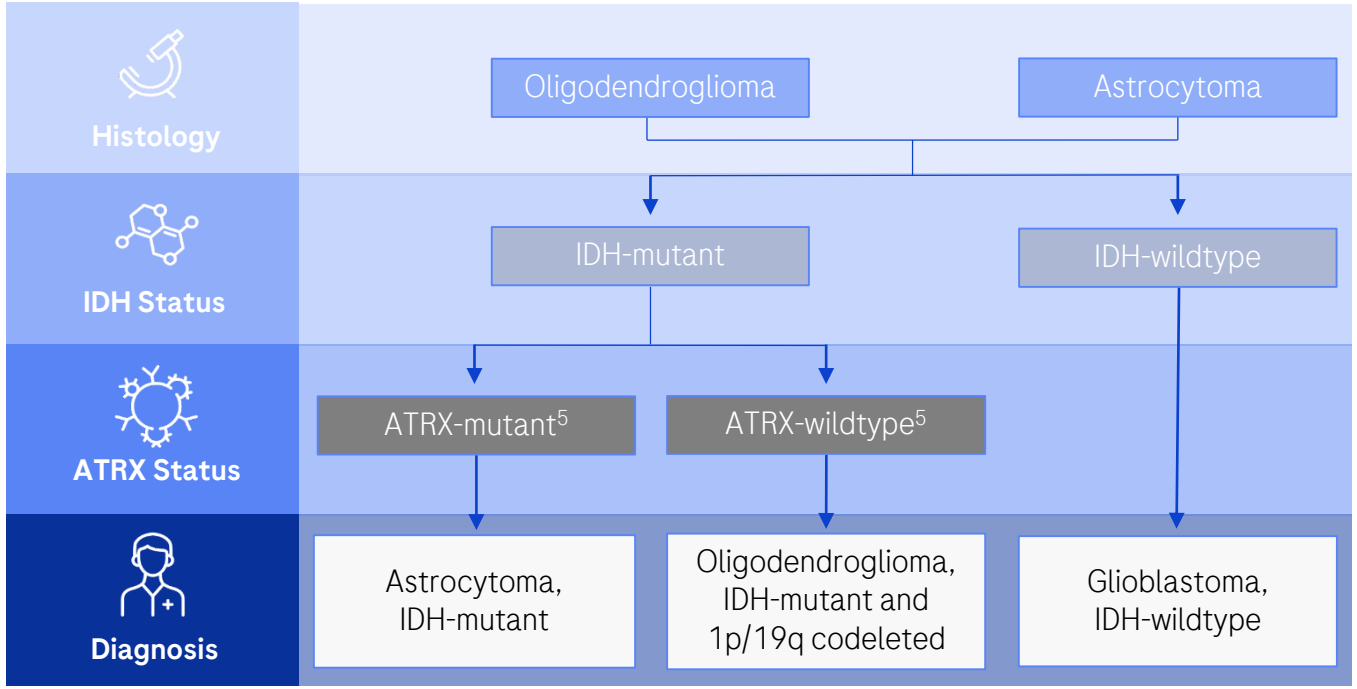
Achieving the WHO goals will help prevent 74 million new cases of cervical cancer in 78 LMICs

HPV is the cause of more than 99% of cervical cancer; WHO=World Health Organization; HPV=Human papillomavirus; LMIC=Low- and middle-income countries; PQ=prequalification; [1] Canfell et al. (2020) The Lancet; [2] Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: WHO (2020)

IDH1 R132H & ATRX (Glioma) assays[1]

Enable better treatment decisions for patients with brain cancer

Classification pathway of adult-type diffuse gliomas[2]



- Globally more than 340k patients estimated in 2025 with brain cancer, of which ~75% are malignant gliomas[3]
- Testing IDH1 & ATRX mutation status enables clinicians to:
  - Provide personalized care and a more informed prognosis
  - Select targeted therapies and determine eligibility for clinical trials
  - Enable rapid diagnosis and access to testing[4]
- Tests run on automated BenchMark series of instruments
- Expands Roche neuropathology portfolio to 29 biomarkers

[1]Only available in the US; aligned with the WHO guidelines for glioma classification; [2]Simplified overview based on 2021 WHO Classification of CNS Tumors; [3]WHO GCO statistics and Wood et al. (2019) Diagnostic Pathology; [4]IDH1/2 Mutations in Glioma: ESMO Biomarker Factsheet (2016); [5]Diagnosis can be made without 1p/19q testing if diffuse astrocytic-appearing WHO grade 2/3 tumor has IDH-mutation and loss of ATRX nuclear expression and/or strong, diffuse p53 immunopositivity

Diagnostics key launches 2023

	Area	Product	Description	Markets	Status
Instruments Automation	Core Lab	CCM Vertical	Modular transportation system, integrated into the existing cobas connection modules, allowing for overhead sample transportation over different work areas or different floors enabling effective use of lab space	Global	
		cobas pro integrated solutions	Scalable and modular serum work area analyzer for mid to high volume clinical chemistry and immunochemistry testing	China	
		cobas pure integrated solutions	Serum work area analyzer for low to mid volume clinical chemistry and immunochemistry testing on a footprint of two square meters	China	
	Molecular Lab	LightCycler Pro	Flexible real-time PCR instrument with dual IVD and research mode as well as enhanced system features	US & CE	
	Point of Care	cobas pulse	Handheld device combining professional glucose meter and a digital platform to host digital clinical decision support applications (from Roche and third parties)	US	
Tests	Pathology Lab	IDH1 R132H (IDH Glioma)	Neuropathology Immunohistochemistry (IHC) solution supporting the detection of tumor cells with the IDH1 R132H mutation aiding pathologists to render a diagnosis of gliomas	US	✓
	Core Lab	Anti-HEV IgG and Anti-HEV IgM	Anti-HEV IgM: Immunoassay aiding in the diagnosis of acute HEV infection in clinical settings; Anti-HEV IgG: Immunoassay aiding in the detection of a recent or past HEV infection and enabling accurate seroprevalence determinations. The two assays expand the hepatitis panel (HAV, HBV, HCV, HEV) on the same analytical platform	CE	
		HBeAg Quant	Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B viral infection	CE	
		IL-6 Neonatal sepsis (claim extension)	Only immunoassay available on the market with dedicated claim and supporting evidence aiding in diagnosis of sepsis in neonates, with potential to reduce newborn mortality	CE	
		RUO Amyloid Plasma Assays (pTau181 & ApoE4)	Two qualitative immunoassays measuring the phosphorylated Tau 181 protein and apolipoprotein E4 in human plasma for research use only	US	
Digital Solutions	Pathology Lab	RUO Digital Pathology Algorithm: PD-L1 SP142	Digital pathology algorithm aiding pathologists in scoring PD-L1 (SP142) breast samples, ensuring a standardized approach and an adjunctive tool to augment diagnostic confidence for research use only	Global	
	Lab Insights	navify Algorithm Suite	Digital solution providing access to an open library of certified IVD-based clinical algorithms	Selected markets[1]	✓
		Menu for navify Algorithm Suite	Certified clinical algorithms for oncology applications such as colon and liver cancers	Selected markets[1]	
		cobas infinity lab 3.05	Next-generation lab middleware enabling ecosystem of cloud-based solutions for quality control and instrument maintenance	Global	
		navify Marketplace	Digital marketplace offering lab customers full range of innovative applications (from Roche and third parties)	Selected markets[1]	✓
		navify Sample Tracking	Open digital solution offering sample tracking beyond the lab setting (from IVD-sample creation to lab reception) to improve testing traceability and quality	Selected markets[1]	

[1]Selected markets: 14 countries with first releases; CE=European conformity; RUO=research use only; PCR=polymerase chain reaction; IVD=in vitro diagnostic; IDH=isocitrate dehydrogenase; HEV=Hepatitis E virus; HAV=Hepatitis A virus; HBV=Hepatitis B virus; HCV=Hepatitis C virus

Finance

Alan Hippe
Chief Financial Officer

HY 2023: Highlights

Business

- Group sales -2% due to COVID-19 sales erosion in Diagnostics
- Pharma with strong momentum for key growth drivers; Strong Diagnostics base business growth (+6%)
- Core operating profit down by -6% and Core EPS -5% due to base effect from Ultomiris patent settlement in 2022

Cash flow

- Operating Free Cash Flow of CHF 8.0bn, -8% due to lower operating profit, partly offset by positive net working capital movement
- Net debt increased by CHF 2.3bn vs. YE 2022

Net financial result

- Core net financial result worsened by -75m driven by higher interest expenses

IFRS

- Net income -9% driven by the COVID-19 sales decline and Ultomiris patent settlement in 2022

Currency impact on results

- Negative currency impact of -6%p on sales, -8%p on core operating profit and -9%p on Core EPS

Growth rates and variances at CER (Constant exchange Rates)

New Income Statement Presentation effective Jan 2023

Improving comparability, reducing complexity, reinforcing alignment

Changes in Income Statement presentation

- Improve external comparability and simplify messaging by using **"Selling, General & Administration"** costs, from merging "Marketing & Distribution" and "General & Administration".
- Reinforcing alignment with latest developments on Revenue by using **"Other revenues"**, instead of "Royalties and Other Operating Income". Introducing a line **"Other operating income / expense"** for non-revenue income and expenses that do not fall into the regular functional costs.
- Simplify and standardise reporting by **removing allocations** from Corporate to the Divisions and various reporting lines for functions with global accountability such as informatics, human resources, and finance.

Consequences

- Sales, Group Operating Profit and EPS **metrics are unaffected**.
- No change to Core Reporting Concept.
- Allocation changes will reduce costs allocated to Divisions and **increase Divisional margins** (around 4.0-5.0 %points).

HY 2023: Group performance

Sales decline of -2% and Core EPS decline of -5%

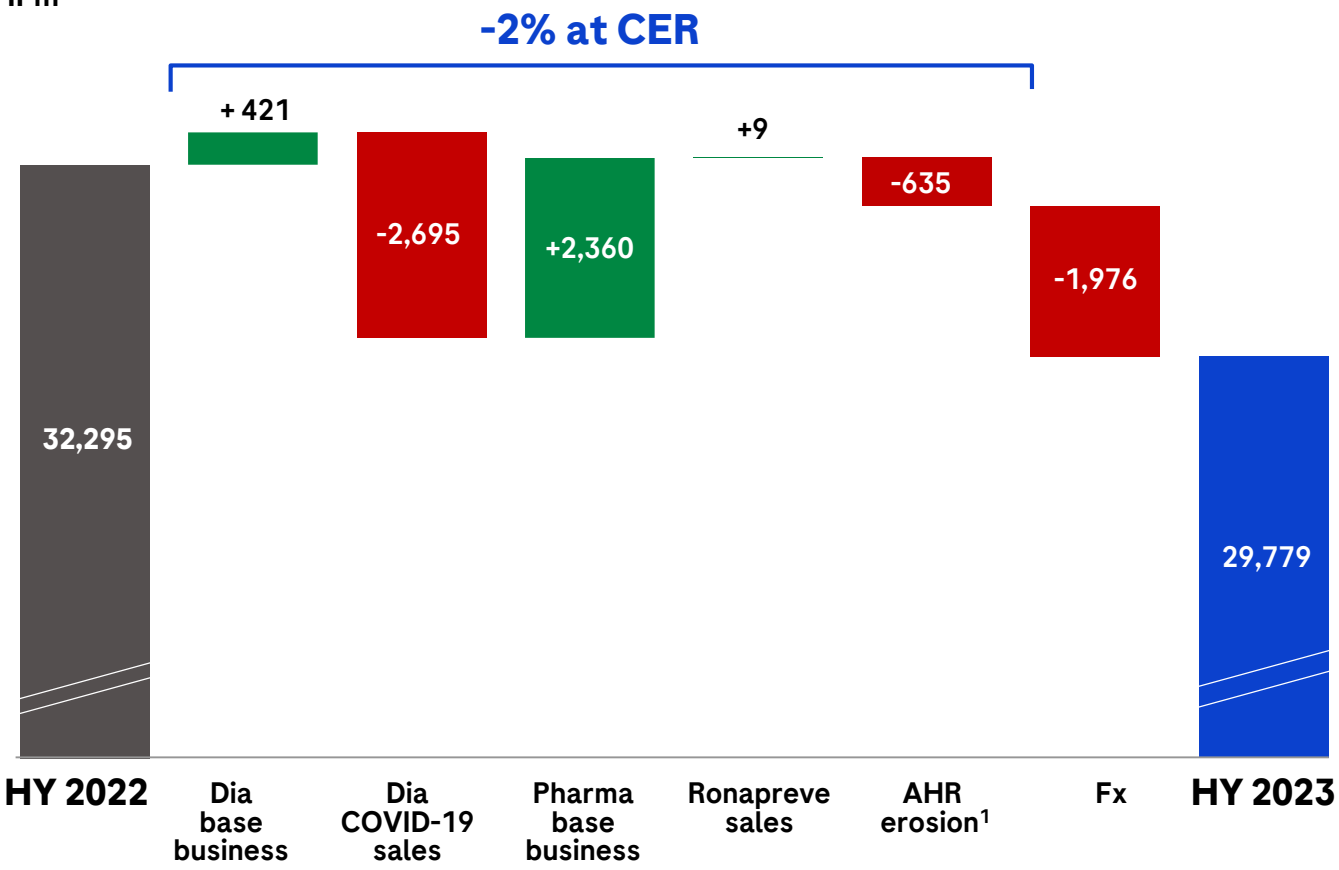
	2023 CHFm	2022 CHFm	Change in % CHF	Change in % CER
Sales	**29,779**	**32,295**	**-8**	**-2**
Core operating profit	**10,911**	**12,668**	**-14**	**-6**
as % of sales	*36.6*	*39.2*		
Core net income	**8,587**	**10,160**	**-15**	**-7**
as % of sales	*28.8*	*31.5*		
Core EPS (CHF)	**10.10**	**11.76**	**-14**	**-5**
IFRS net income	**7,563**	**9,161**	**-17**	**-9**
as % of sales	*25.4*	*28.4*		
Operating free cash flow	**8,031**	**9,782**	**-18**	**-8**
as % of sales	*27.0*	*30.3*		
Free cash flow	**6,128**	**7,097**	**-14**	**-2**
as % of sales	*20.6*	*22.0*		

CER=Constant Exchange Rates; All numbers in CHFm, except Core EPS in CHF

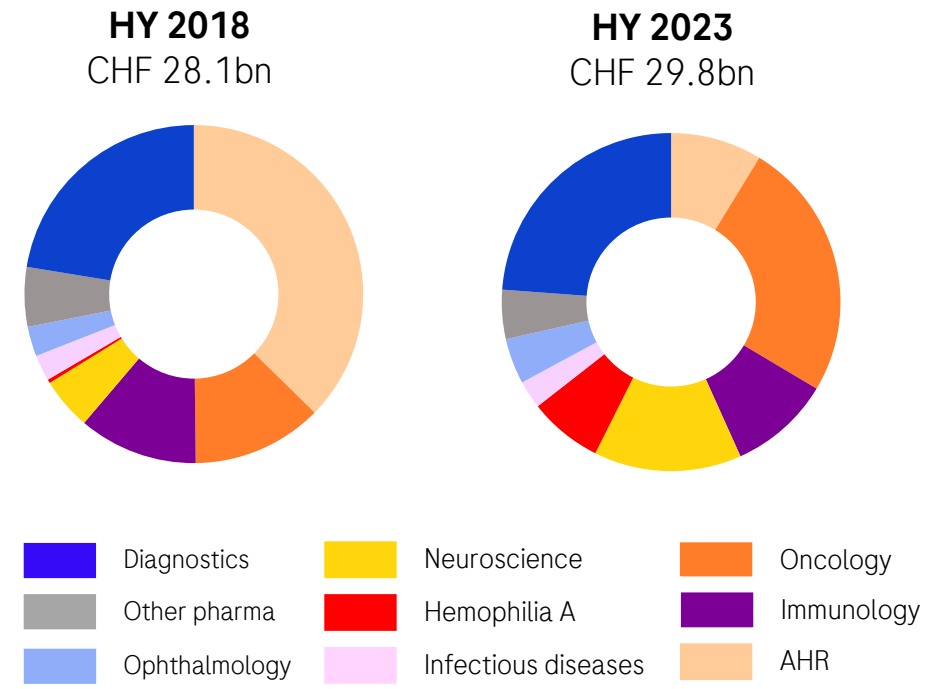
HY 2023: Base business largely compensates for COVID-19 impact

Portfolio diversification progresses as ophthalmology franchise gains momentum

CHFm



Diversification of Roche portfolio

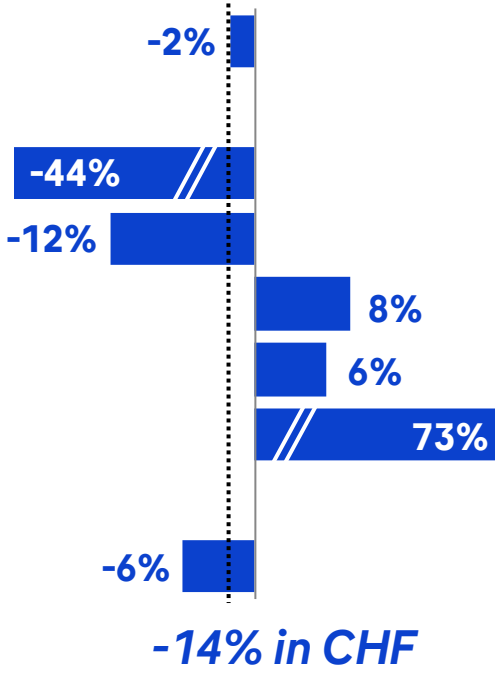


CER=Constant Exchange Rates; [1]AHR: Avastin, Herceptin, Rituxan/MabThera

HY 2023: Group operating performance

Core operating profit lower by -6% driven by the Ultomiris patent settlement

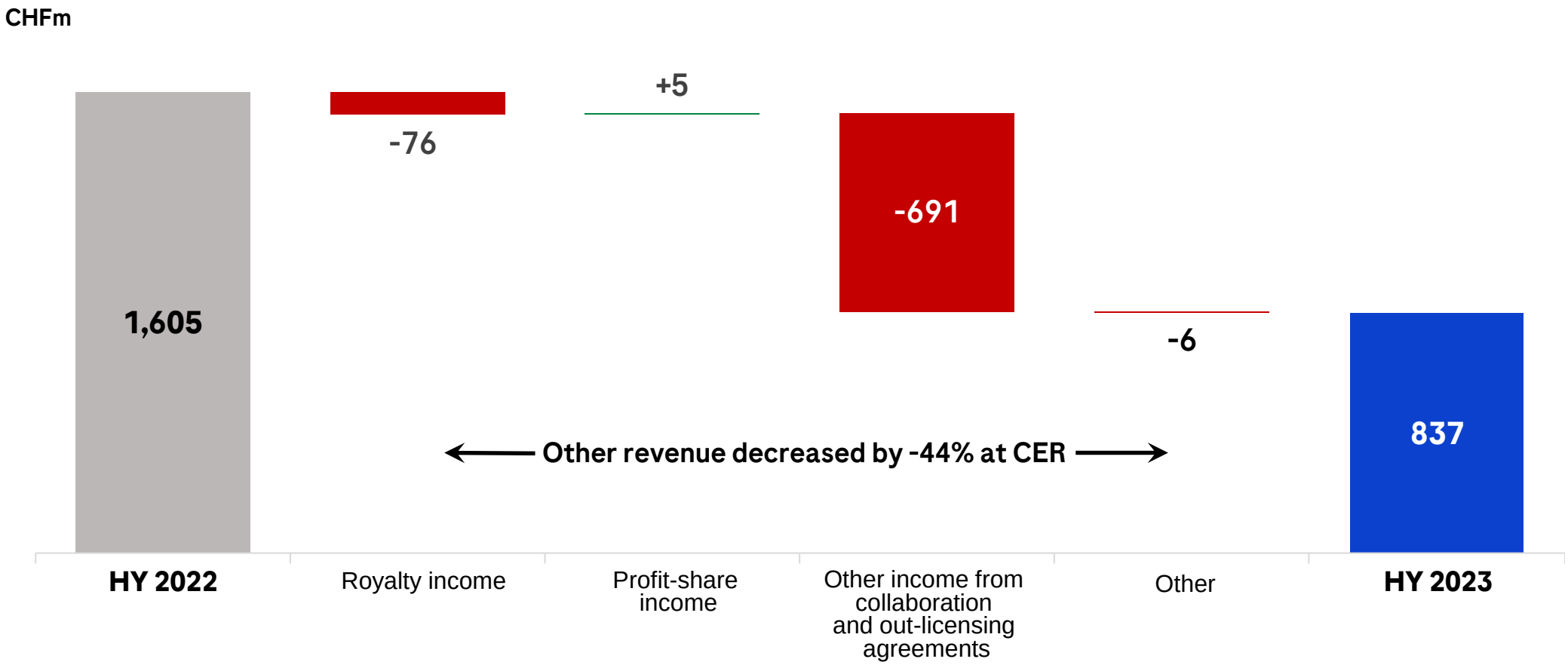
	2023 CHFm	2023 abs. CER
Sales	**29,779**	**-540**
Other revenue	837	-685
Cost of sales	-7,456	+1,093
R&D	-6,449	-486
SG&A	-6,505	-392
OOI&E	705	+305
Core operating profit	**10,911**	**-704**



CER=Constant Exchange Rates; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense

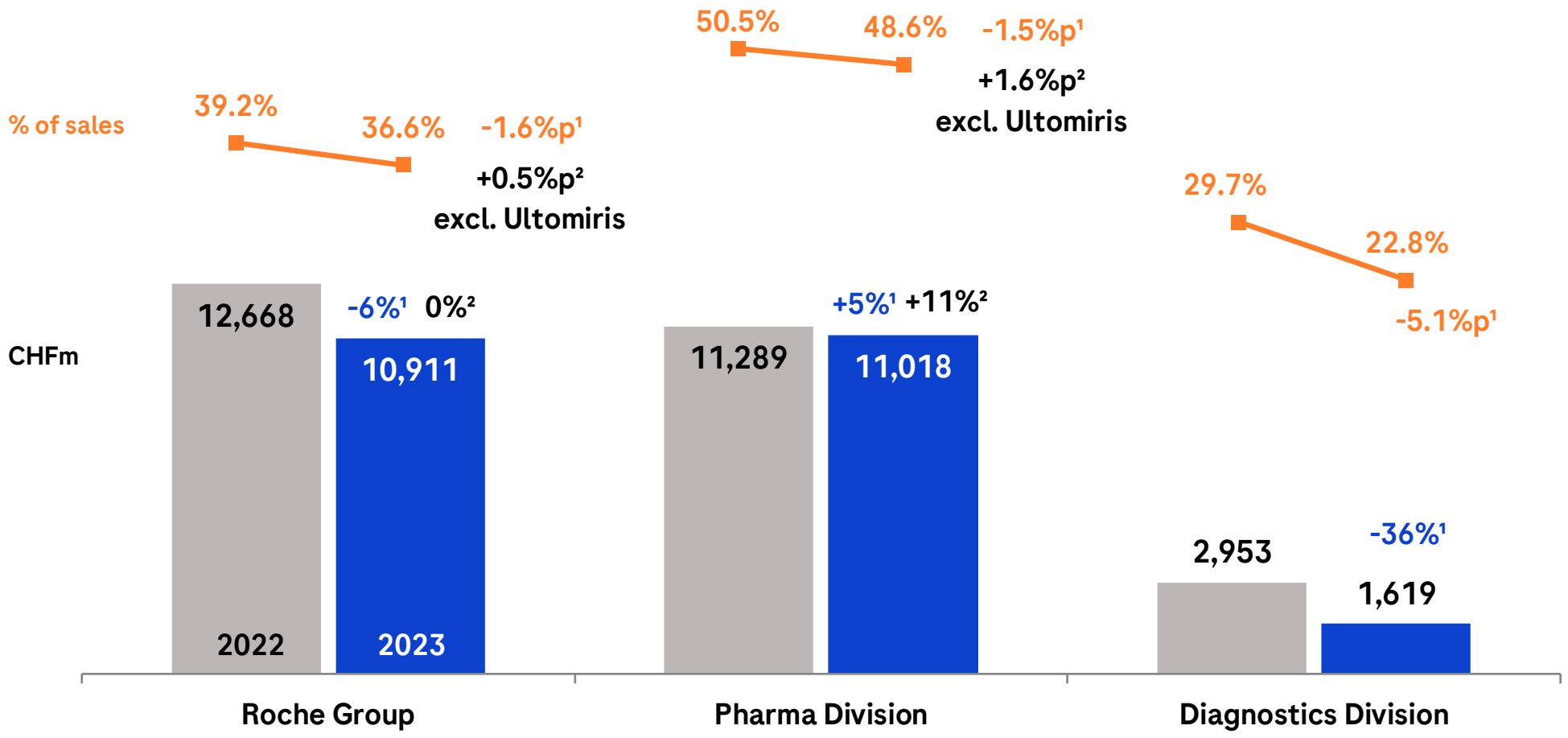
HY 2023: Other revenue

Lower revenue driven by base effect of the Ultomiris patent settlement in 2022



CER=Constant Exchange Rates

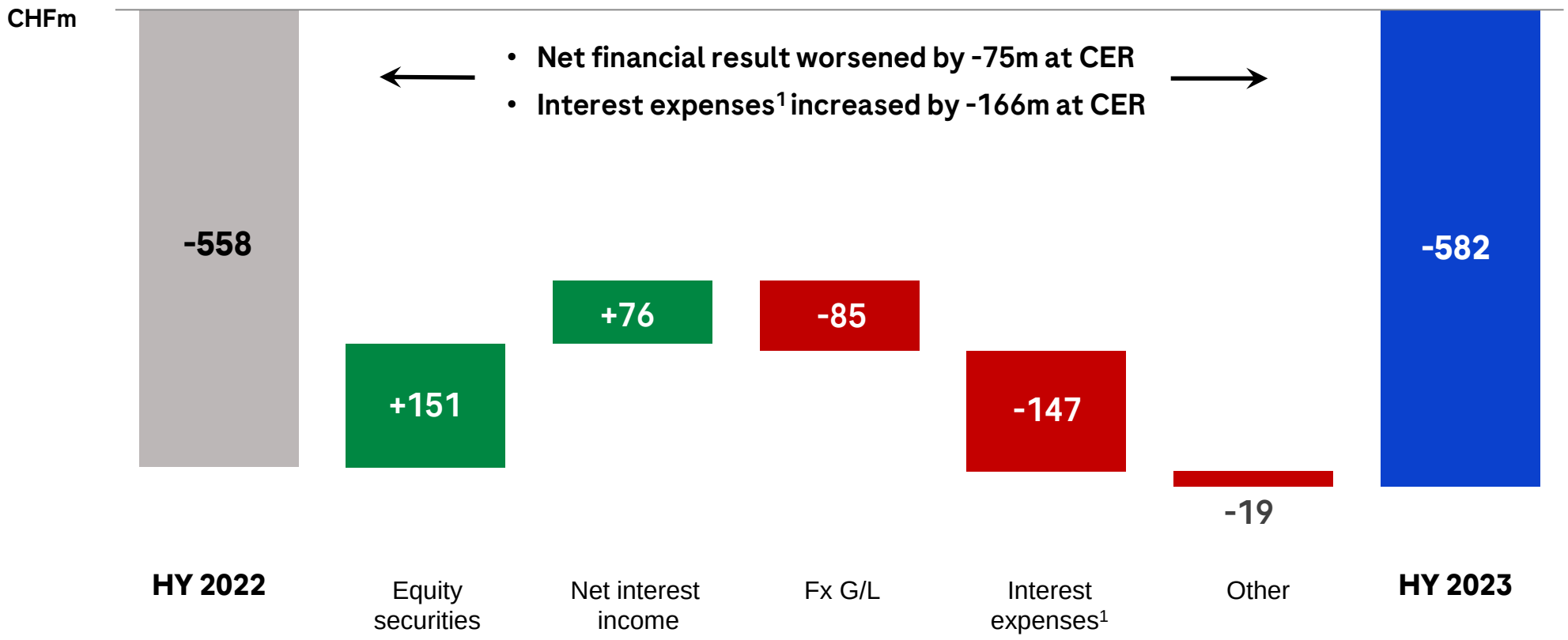
HY 2023: Core operating profit and margin



[1] At CER=Constant Exchange Rates; [2] At CER excluding 2022 Ultomiris patent settlement

HY 2023: Core net financial result

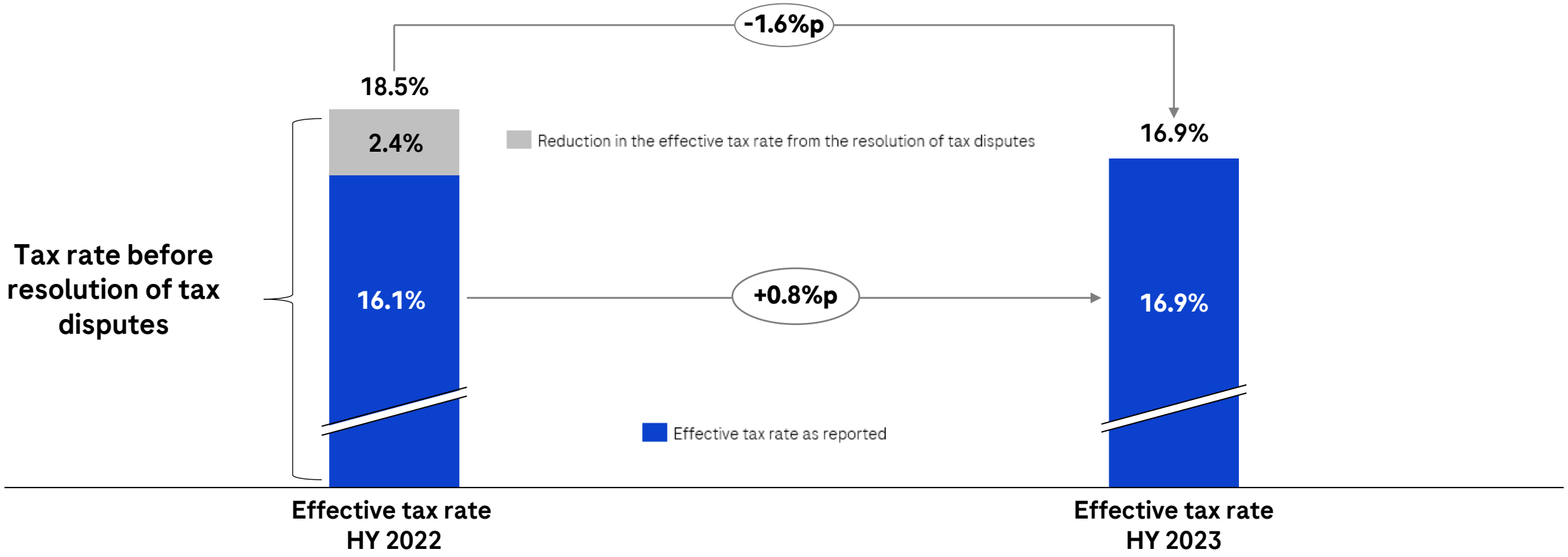
Worsening driven by higher interest expenses and Fx losses



CER=Constant Exchange Rates; Fx G/L=exchange rate gains and losses [1] incl. amortization of debt discount and net gains on interest rate derivatives

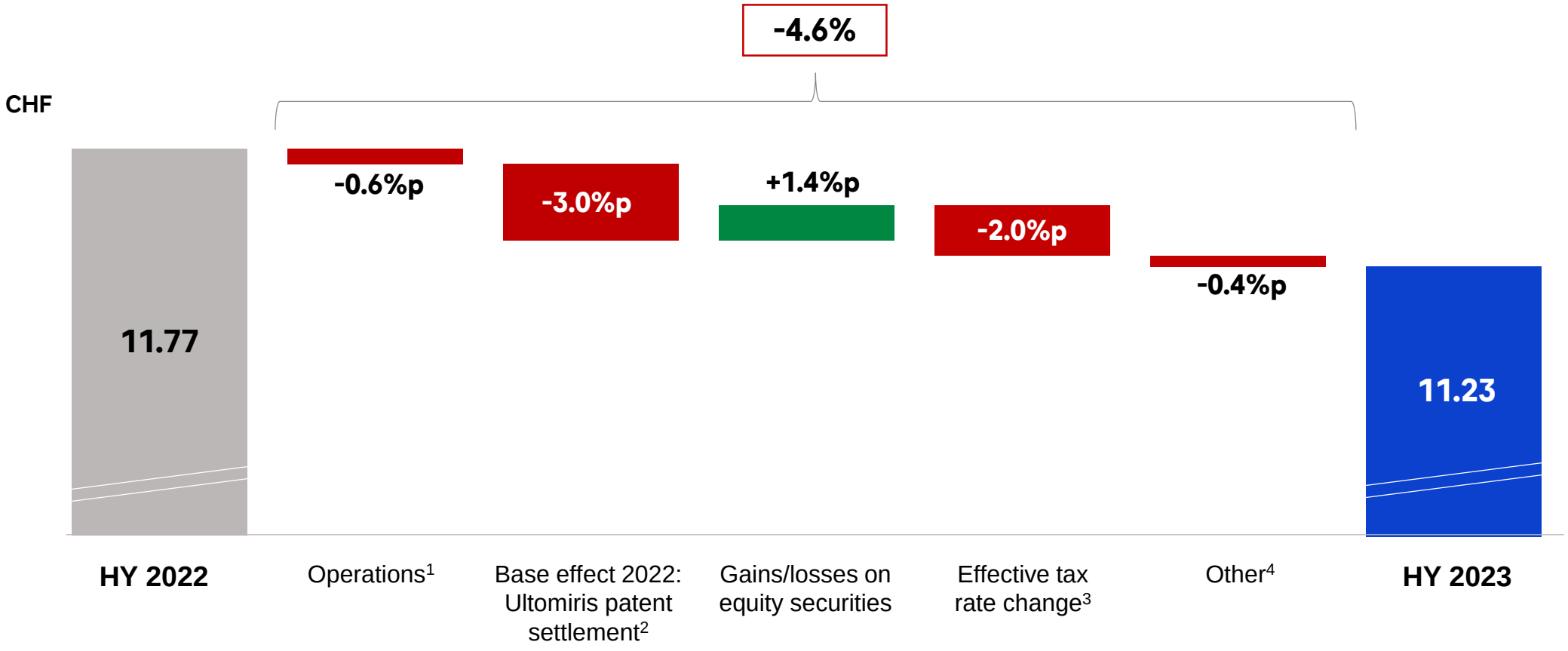
HY 2023: Group Core tax rate

Increase in core tax rate mainly due to the impact from the resolution of tax disputes in HY 2022 partially offset by lower profits in high tax jurisdictions in 2023



HY 2023: Core EPS development

Decrease of -4.6% driven by base effect of the Ultomiris patent settlement in 2022



At Constant Exchange Rates (CER); [1] Core operating profit excl. impacts from Ultomiris patent settlement; [2] Net impact from the Ultomiris patent settlement: gross income, net of income tax and non-controlling interests; [3] Excluding the effects of the Ultomiris patent settlement on the 2022 tax rate; [4] Other (net) include effects from changes in: financial income/expense (excl. equity securities), non-controlling interests and diluted number of shares

HY 2023: Non-core and IFRS income

Non-core operating expenses broadly in line with prior year

	2022	2023		Change in %	
	CHFm	CHFm	CHFm	CHF	CER
Core operating profit	**12,668**	**10,911**	**-1,756**	**-14**	**-6**
Global restructuring plans	-266	-678	-412		
Amortisation of intangible assets	-468	-358	110		
Impairment of intangible assets[1]	-423	-260	163		
M&A and alliance transactions	17	-1	-18		
Legal & Environmental[2]	19	150	131		
Total non-core operating items	-1,121	-1,147	-26		
IFRS Operating profit	**11,547**	**9,764**	**-1,784**	**-15**	**-7**
Total financial result & taxes	-2,386	-2,201	185		
IFRS net income	**9,161**	**7,563**	**-1,599**	**-17**	**-9**

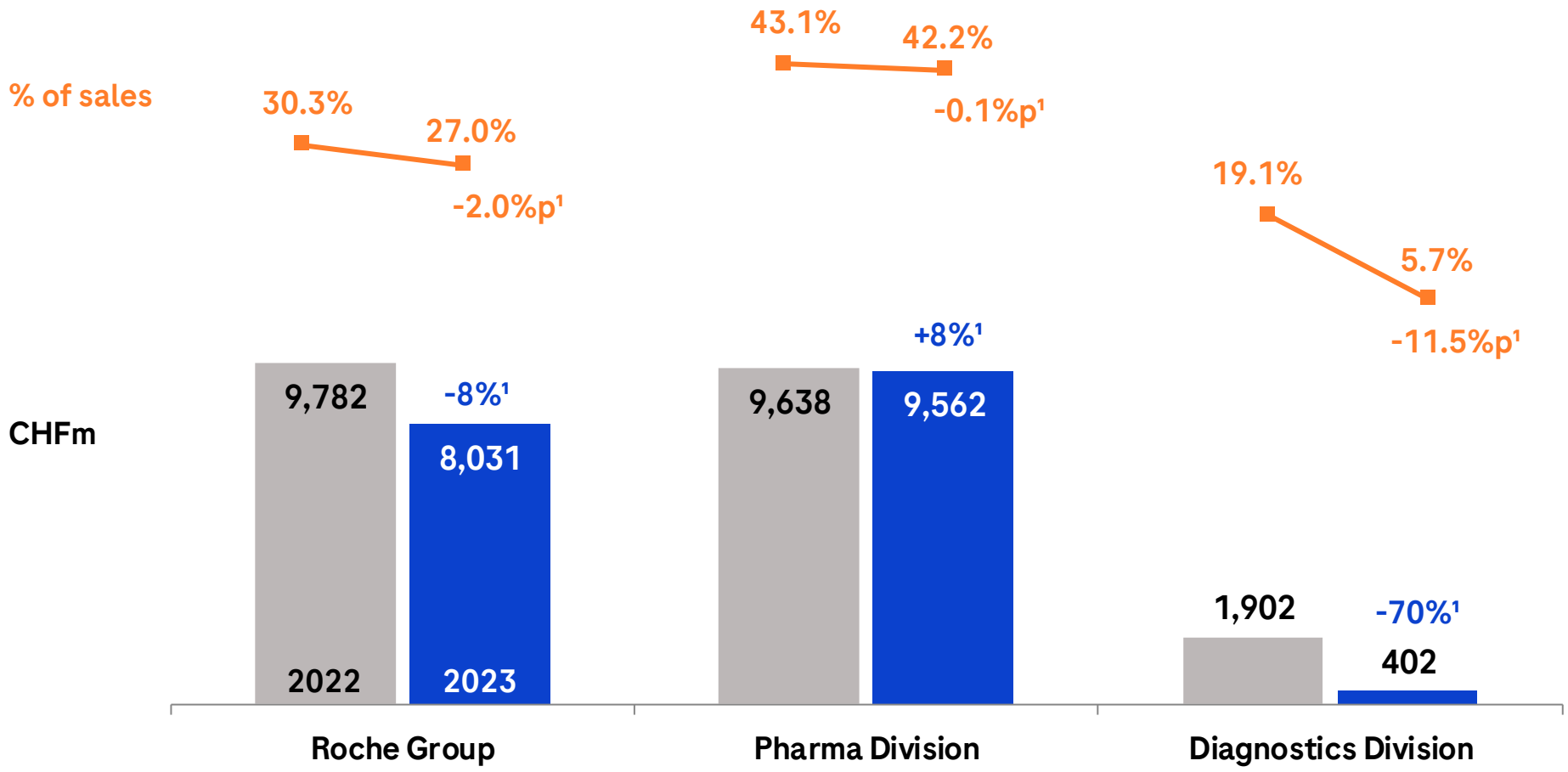
CER = Constant Exchange Rates; [1] incl. goodwill; [2] incl. pension plan settlements

2023 results

Focus on cash and balance sheet

Outlook

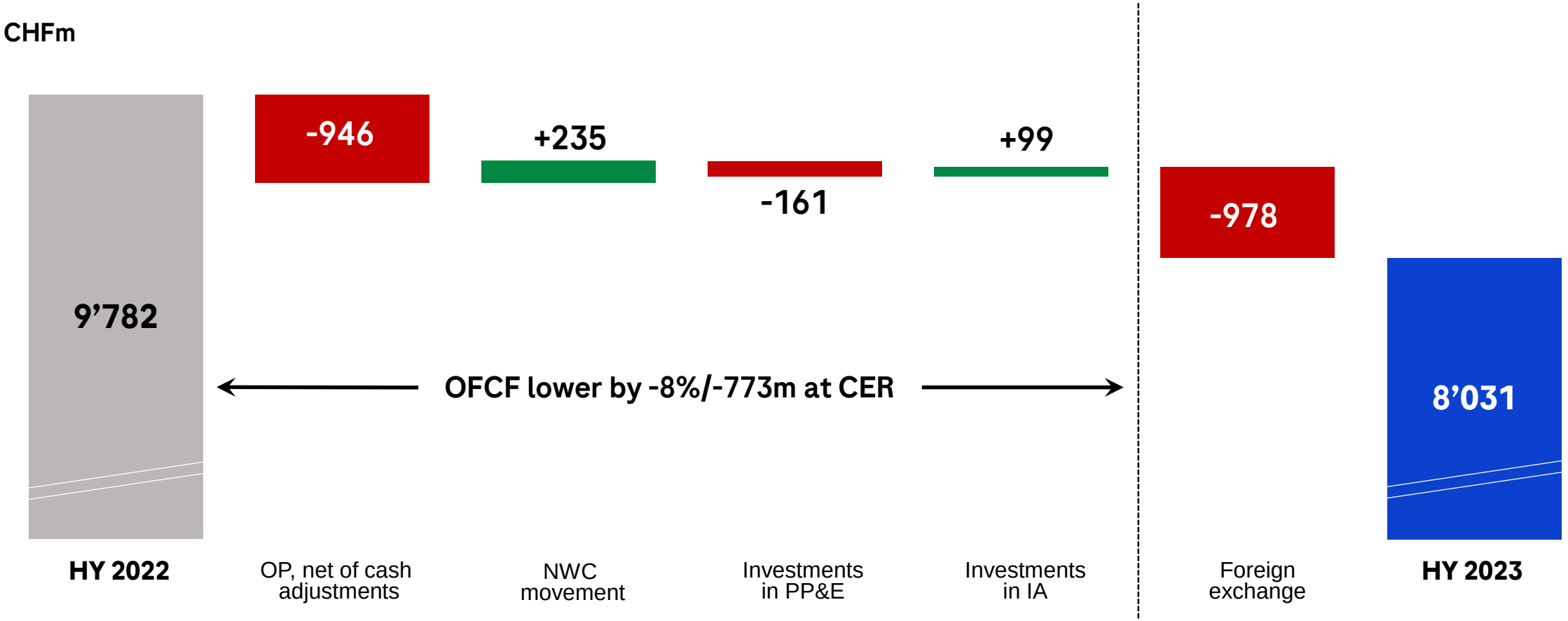
HY 2023: Operating free cash flow and margin



[1] At CER=Constant Exchange Rates

HY 2023: Group Operating Free Cash Flow

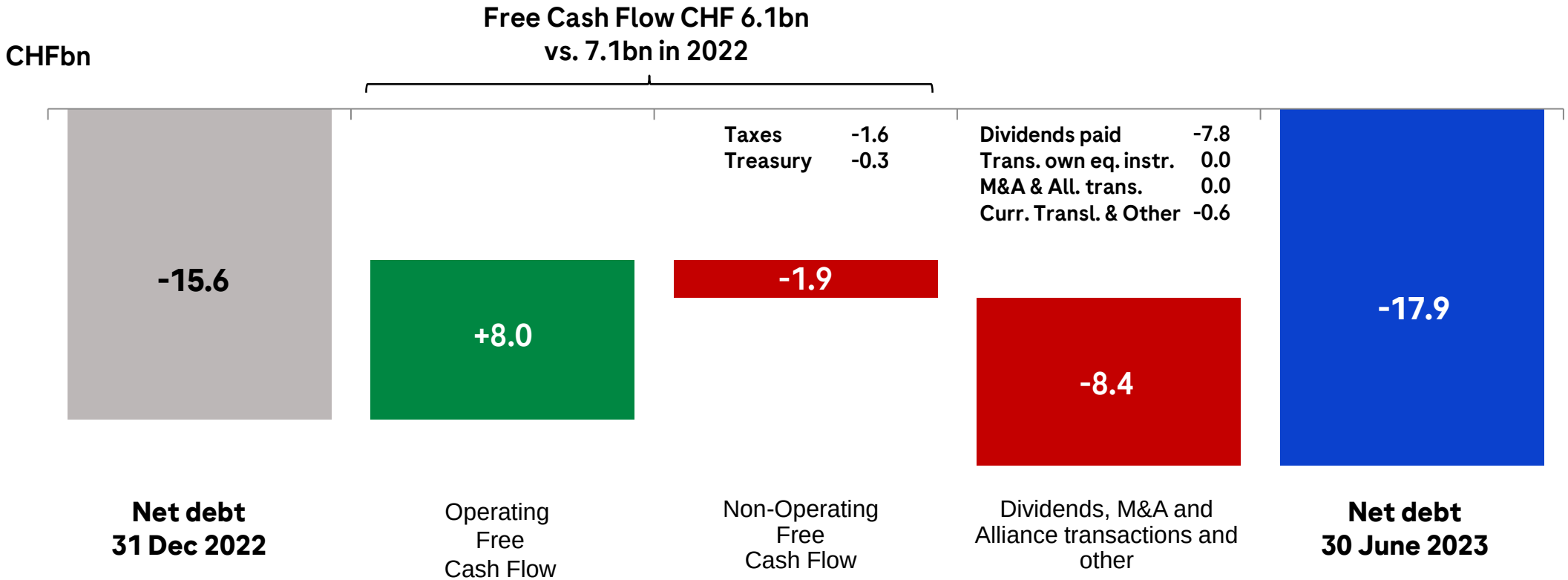
OFCF down -8% driven by lower Core operating profit due to base effect from Ultomiris patent settlement in 2022, partly offset by positive NWC movement



CER=Constant Exchange Rates; OP=Operating Profit; NWC=Net Working Capital; PP&E=Property, Plant & Equipment incl. increase of lease liability paid; IA=Intangible Assets

HY 2023: Group net debt development

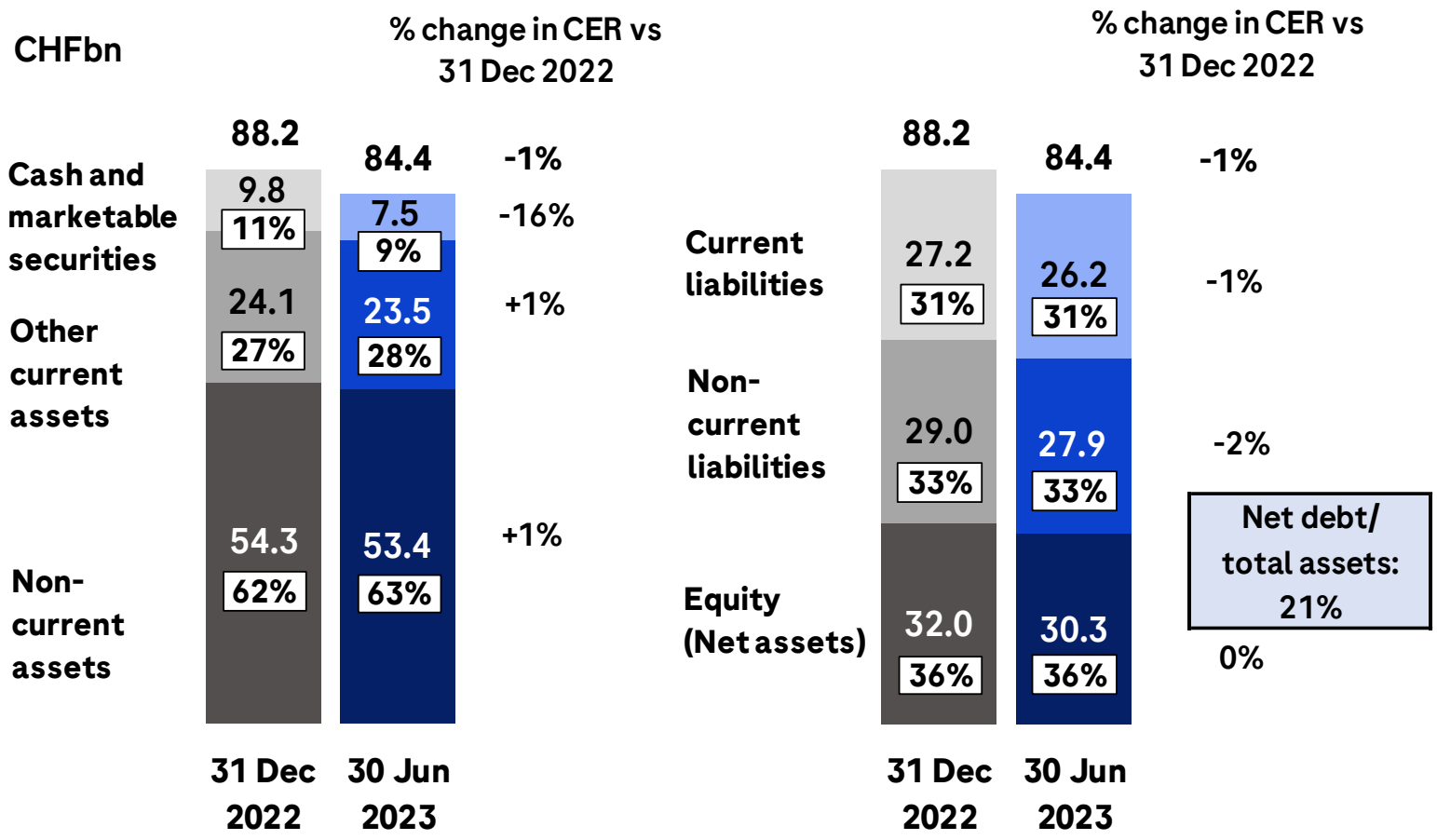
Net debt higher by CHF -2.3bn vs. year end 2022



Thereof investments in innovation:		Intangible Asset	Equity	M&A	Total
	2023	-0.2	0.0	0.0	-0.2
	2022	-0.3	0.0	0.0	-0.3

Balance sheet 30 June 2023

Equity ratio at 36% (31 Dec 22: 36%); net debt to assets at 21% (31 Dec 22: 18%)



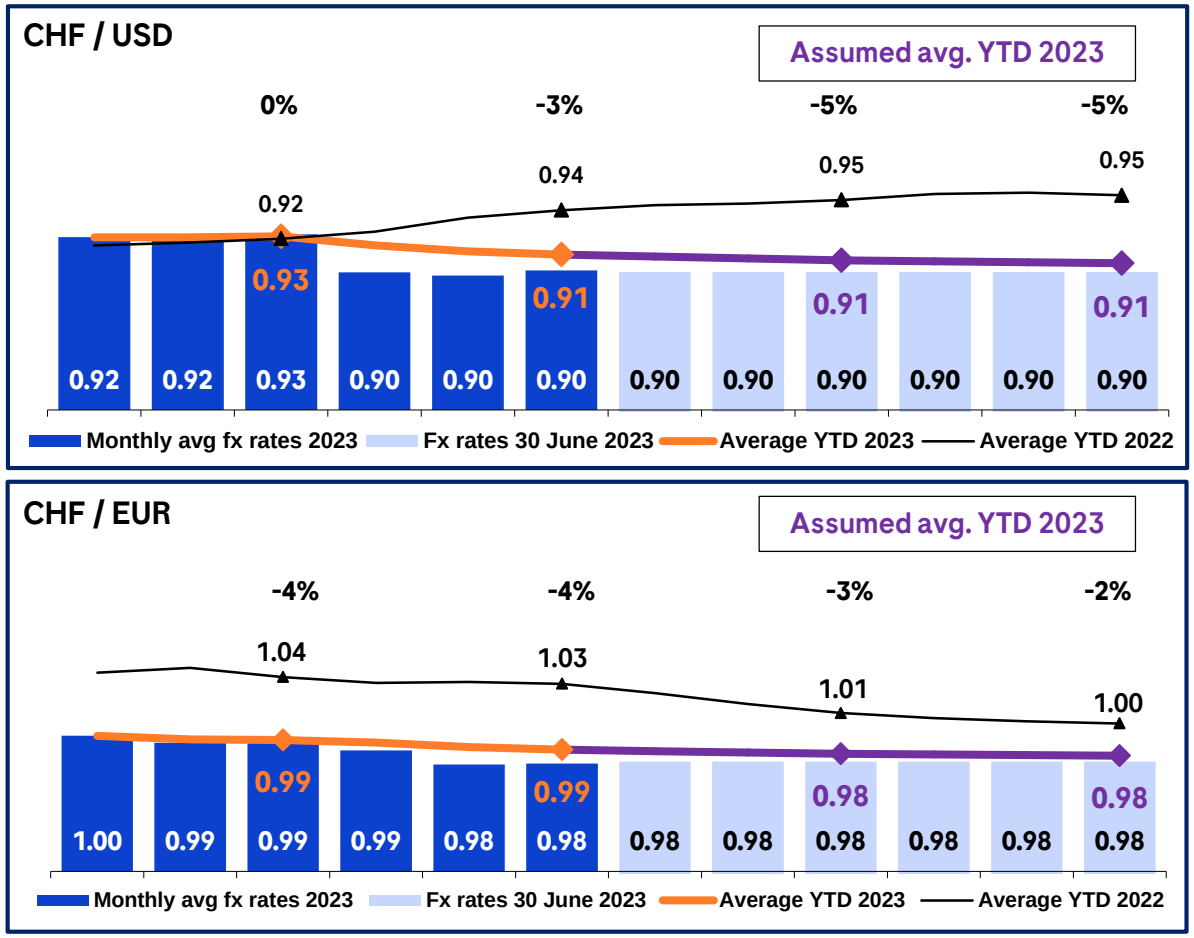
CER=Constant Exchange Rates

2023 results

Focus on cash and balance sheet

Outlook

Expected 2023 currency impact



Assuming the 30 June 2023 exchange rates remain stable until end of 2023, 2023 impact[1] is expected to be (%p):

	Q1	HY	Sep YTD	FY
Sales	-4	-6	-6	-7
Core operating profit		-8		-9
Core EPS		-9		-10

[1] On group growth rates

2023 outlook confirmed

Group sales growth[1]	Low single digit decline
Core EPS growth[1]	Broadly in line with sales decline
Dividend outlook	Further increase dividend in Swiss francs

[1] At Constant Exchange Rates (CER)

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

Q2 2023 update

New to phase I

4 NMEs:
RG6449 HBsAg MAb – chronic hepatitis B
RG6353 HLA-G CD3 TCB – solid tumors
RG6537 AR degrader – mCRPC
CHU SAIL66 – solid tumors

New to phase II

1 NME:
RG6536 vixarelimab – IPF & SSc-ILD

1 AI:
RG6171 giredestrant – endometrial cancer

New to phase III

1 AI:
RG6114 inavolisib - post CDKi HR+ BC

New to registration

1 NME (US & EU)
RG6107 crovalimab – PNH*

1 AI (US):
RG7716 Vabysmo – BRVO/CRVO

Removed from phase I

4 NMEs:
RG6007 HLA-A2-WT1 x CD3 – AML
RG7637 – psychiatric disorders
RG6392 – oncology
SQZ PBMC vaccine – solid tumors

Removed from phase II

1 NME:
RG6358 SPK-8016 – hemophilia A with inhibitors to factor VIII

Removed from phase III

1 AI:
RG3625 TNKase – stroke

Approvals

1 NME (US & EU):
RG6026 Columvi (glofitamab) – 3L+ DLBCL

*US filing acceptance pending

Status as of July 27, 2023

Roche Group development pipeline

Phase I (49 NMEs + 12 AIs)

RG6026	Columvi (glofitamab) monotherapy + combos	heme tumors
RG6058	tiragolumab combos	heme & solid tumors
RG6076	englumafusp alfa (CD19-4-1BBL) combos	heme tumors
RG6114	inavolisib	solid tumors
RG6156	EGFRvIII x CD3	glioblastoma
RG6160	cevostamab	r/r multiple myeloma
RG6171	giredestrant monotherapy + combos	solid tumors
RG6180	autogene cevumeran ± T	solid tumors
RG6185	belvarafenib + Cotellic ± T	solid tumors
RG6189	FAP-CD40 ± T	solid tumors
RG6194	runimotamab	BC
RG6234	forimtamig	multiple myeloma
RG6264	Phesgo OBI	HER2+ BC
RG6279	eciskafusp alfa (PD1-IL2v) ± T	solid tumors
RG6286	-	colorectal cancer
RG6292	CD25 MAb combos	solid tumors
RG6323	IL15/IL15Ra-Fc ± T	solid tumors
RG6330	divarasib (KRAS G12C) monotherapy + combos	solid tumors
RG6333	CD19 x CD28 + Columvi (glofitamab)	r/r NHL
RG6344	BRAF inhibitor (3)	solid tumors
RG6353	HLA-G CD3 TCB	solid tumors
RG6411	-	solid tumors
RG6433	SHP2i combos	solid tumors
RG6440	Anti-latent TGF-β1 (SOF10)	solid tumors
RG6512	FIXa x FX	hemophilia
RG6524	DLL3 trispecific	solid tumors
RG6526[1]	camonsertib	solid tumors
RG6537	AR degrader	mCRPC
RG6538[2]	P-BCMA-ALLO1	multiple myeloma
RG7446	Morpheus platform	solid tumors
RG7601	Venclexta ± azacitidine	r/r MDS
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL monotherapy + combos	solid tumors
RG7828	Lunsumio monotherapy + combos	heme tumors
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
CHU	CD137 switch antibody	solid tumors
CHU	RAS inhibitor	solid tumors
CHU	SPYK04	solid tumors
CHU	SAIL66	CLDN6+ solid tumors
RG6107	crovalimab	lupus nephritis
RG6287	-	aGVHD
RG6315	-	immunologic disorders
RG6421	TMEM16A potentiator	cystic fibrosis
RG7828	Lunsumio	SLE
CHU	anti-HLA-DQ2.5 x gluten peptides	celiac disease
CHU	RAY121	immunology
RG6006	zosurabalpin (Abx MCP)	bacterial infections
RG6319	LepB inhibitor	complicated urinary tract infection
RG6449	HBsAg MAb	chronic hepatitis B
RG6035	BS-CD20 MAb	multiple sclerosis
RG6091	rugonersen	Angelman syndrome
RG6163	-	psychiatric disorders
RG6182	MAGLi	multiple sclerosis
RG6289	-	Alzheimer´s
RG6418*	selnoflast	inflammation
RG6120	zifibancimig (VEGF-Ang2 DutaFab)	nAMD
RG6209	-	retinal disease
RG6351	-	retinal disease
RG7921	-	RVO
CHU	anti-IL-8 recycling antibody	endometriosis

Status as of July 27, 2023

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

Phase II (23 NMEs + 10 AIs)

RG6026	Columvi (glofitamab) + chemo	1L ctDNA high risk DLBCL
RG6058	tiragolumab + T	NSCLC
	tiragolumab + T + chemo	NSCLC neoadj-adj
	tiragolumab + T	cervical cancer
	tiragolumab + T	1L PD-L1+ mSCCHN
RG6107	crovalimab	sickle cell disease
RG6139	tobemstomig (PD1 x LAG3)	solid tumors
RG6171	giredestrant	endometrial cancer
RG6180	autogene cevumeran + pembrolizumab	1L melanoma
RG6357	dirloctogene samoparvovec (SPK-8011)	hemophilia A
RG6299[3]	ASO factor B	IgA nephropathy
RG6341	-	chronic cough
RG6536	vixarelimab	IPF/SSc-ILD
RG7854/ RG6346/ RG6084**	ruzotolimod/xalnesiran/PDL1 LNA	HBV
RG6359	SPK-3006	Pompe disease
RG1662	basmisanil	Dup15q syndrome
RG6042	tominersen	Huntington's
RG6100	semorinemab	Alzheimer's
RG6102	trontinemab	Alzheimer's
RG6237	latent myostatin + Evrysdi	SMA
	latent myostatin	FSHD
RG6416	bepranemab	Alzheimer's
RG7314	balovaptan	post-traumatic stress disorder
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7816	alogabat	ASD
RG7906	ralmitaront	schizophrenia
RG7935	prasinezumab	Parkinson's
RG6179	anti-IL-6	DME
RG6299[3]	ASO factor B	geographic atrophy
RG6501	OpRegen	geographic atrophy
RG7774	vicasinabin	DR

RG-No - Roche/Genentech; CHU - Chugai managed; [1]Repare Therapeutics managed; [2]Poseida Therapeutics managed; [3]IONIS managed; T=Tecentriq; BS=Brain Shuttle; OBI=On-Body Delivery System; *also developed in Immunology; **combination platform

Roche Group development pipeline

Phase III (8 NMEs + 38 AIs)

RG3502	Kadcyla + T	HER-2+ eBC high-risk
RG6026	Columvi (glofitamab) + chemo	2L+ DLBCL
RG6058	tiragolumab + T	1L PD-L1 high NSCLC
	tiragolumab + T	1L esophageal cancer
	tiragolumab + T	locally advanced esophageal cancer
	tiragolumab + T	stage III unresectable 1L NSCLC
	tiragolumab + T	1L non-squamous NSCLC
RG6107	crovalimab	aHUS
RG6114	inavolisib	1L HR+ mBC
	inavolisib	post CDKi HR+ BC
RG6171	giredestrant	1L ER+/HER2- mBC
	giredestrant	ER+ BC adj
	giredestrant + Phesgo	1L ER+/HER2+ BC
RG6330	divarasib (KRAS G12C)	2L NSCLC
RG7446	Tecentriq + platinum chemo	NSCLC periadj
	Tecentriq	NMIBC, high-risk
	Tecentriq ± chemo	SCCHN adj
	Tecentriq + capecitabine or carbo/gem	1L TNBC
	Tecentriq + Avastin	HCC adj
	Tecentriq	ctDNA+ high-risk MIBC
	Tecentriq + lurbinectedin	1L maintenance SCLC
RG7601	Venclexta	r/r MM t(11:14)
	Venclexta + azacitidine	1L MDS
RG7828	Lunsumio + lenalidomide	2L+ FL
	Lunsumio + Polivy	2L+ DLBCL
RG7853	Alecensa	ALK+ NSCLC adj
RG3648	Xolair	food allergy
RG6149	astegolimab	COPD
RG7159	Gazyva	lupus nephritis
	Gazyva	membranous nephropathy
	Gazyva	systemic lupus erythematosus
	Gazyva	childhood onset idiopathic nephrotic syndrome**
RG6152	Xofluza	influenza, pediatric (0-1 year)
	Xofluza	influenza direct transmission
RG1594	Ocrevus higher dose	RMS & PPMS
	Ocrevus SC	RMS & PPMS
RG6168	Enspryng	myasthenia gravis
	Enspryng	MOG-AD
	Enspryng	autoimmune encephalitis
RG6356	Elevidys (delandistrogene moxeparvovec)	DMD
RG7845	fenebrutinib	RMS
	fenebrutinib	PPMS
RG6179	anti-IL-6	UME
RG6321	Susvimo	DME
	Susvimo	DR
	Susvimo	wAMD, 36-week

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

Metabolism
Neuroscience
Ophthalmology
Other

Registration US & EU (1 NME + 4 AIs)

RG6107*	crovalimab[1]	PNH
RG7446	Tecentriq SC	all approved indications
RG7916	Evrysdi[2]	SMA pediatric <2months
RG7716	Vabysmo[3]	BRVO
	Vabysmo[3]	CRVO

[1]US filing acceptance pending
[2]Approved in US, filed in EU
[3]Filed in US

T=Tecentriq
*First filed in China in Q3 2022
**also known as pediatric nephrotic syndrome (PNS)

Status as of July 27, 2023

NME submissions and their additional indications

Projects in phase II and III

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
T=Tecentriq
*First filed in China
[1]IONIS managed

2023

RG6107	**crovalimab*** PNH (EU, US) ✓

2024

RG6026	**Columvi (glofitamab) + chemo** 2L DLBCL
RG6058	**tiragolumab + T** 1L PD-L1 high NSCLC
RG6058	**tiragolumab + T** 1L esophageal cancer (CN)
RG6114	**inavolisib** 1L HR+ BC
RG6356	**Elevidys (delandistrogene moxeparvovec)** DMD (EU)
RG6321	**Susvimo** DME (US)
RG6321	**Susvimo** DR (US)

2025

RG6058	**tiragolumab + T** Stage III unresectable 1L NSCLC
RG6107	**crovalimab** aHUS
RG6321	**Susvimo** wAMD, DME, DR (EU)

2026 and beyond

RG6026	**Columvi (glofitamab) + chemo** 1L ctDNA+ high risk DLBCL
RG6058	**tiragolumab + T** 1L PD-L1+ cervical cancer
RG6058	**tiragolumab + T** locally adv esophageal cancer
RG6058	**tiragolumab + T** 1L non-sq NSCLC
RG6058	**tiragolumab + T** 1L PD-L1+ mSCCHN
RG6058	**tiragolumab+T+/- chemo** NSCLC neoadj/adj
RG6107	**crovalimab** sickle cell disease
RG6114	**inavolisib** post CDKi HR+ BC
RG6139	**tobemstomig (PD1xLAG3)** solid tumors
RG6171	**giredestrant** 1L ER+/HER2- mBC
RG6171	**giredestrant** ER+ BC adj
RG6171	**giredestrant + Phesgo** 1L ER+/HER2+ BC
RG6171	**giredestrant** endometrial cancer
RG6180	**autogene cevumeran** 1L melanoma
RG6330	**divarasib (KRAS G12 C)** 2L NSCLC
RG6149	**astegolimab** COPD
RG6299[1]	**ASO factor B** IgA nephropathy
RG6341	**NME** chronic cough
RG6536	**vixarelimab** IPF & SSc-ILD
RG7854/ RG6346/ RG6084	**ruzotolimod/xalnesiran/ PDL1 LNA** HBV
RG1662	**basmisanil** Dup15q syndrome
RG6042	**tominersen** Huntington's
RG6100	**semorinemab** Alzheimer's
RG6102	**trontinemab** Alzheimer's
RG6237	**latent myostatin + Evrysdi** SMA
RG6237	**latent myostatin** FSHD
RG6416	**bepranemab** Alzheimer's
RG7314	**balovaptan** post-traumatic stress disorder
RG7816	**alogabat** ASD
RG7845	**fenebrutinib** RMS &PPMS
RG7935	**prasinezumab** Parkinson's
RG6179	**anti-IL-6** UME & DME
RG6299[1]	**ASO factor B** geographic atrophy
RG6321	**Susvimo** wAMD, 36-week refill
RG6501	**OpRegen** geographic atrophy
RG7774	**vicasinabin** DR

Status as of July 27, 2023

AI submissions for existing products

Projects in phase II and III

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
OBI=On-Body Delivery System, [1]filing timeline based on data from interim analysis
*also known as pediatric nephrotic syndrome (PNS)

2023

RG7446	**Tecentriq + Avastin** HCC adj
RG7601	**Venclexta** r/r MM t(11:14)
RG7853	**Alecensa** ALK+ NSCLC adj
RG1594	**Ocrevus SC** RMS & PPMS
RG3625	**TNKase** stroke
RG3648	**Xolair** food allergy
RG7716	**Vabysmo** BRVO/CRVO ✓

2024

RG6264	**Phesgo OBI** HER2+ BC
RG7446	**Tecentriq**[1] NSCLC periadj
RG7446	**Tecentriq** SCCHN adj
RG7446	**Tecentriq + capecitabine or carbo/gem** TNBC
RG7446	**Tecentriq** ctDNA+ high-risk MIBC
RG7601	**Venclexta + azacitidine** 1L MDS
RG7159	**Gazyva** lupus nephritis
RG6168	**Enspryng** myasthenia gravis
RG6152	**Xofluza** direct transmission
RG6152	**Xofluza** influenza, pediatric (0-1 year)

2025

RG7828	**Lunsumio + lenalidomide** 2L FL+
RG7828	**Lunsumio + Polivy** 2L+ DLBCL (US)
RG7446	**Tecentriq+ lurbinectedin** 1l maintenance SCLC
RG1594	**Ocrevus higher dose** RMS & PPMS
RG6168	**Enspryng** autoimmune encephalitis

2026 and beyond

RG3502	**Kadcyla + Tecentriq** HER-2+ eBC high-risk
RG7446	**Tecentriq** High-risk NMIBC
RG7159	**Gazyva** membranous nephropathy
RG7159	**Gazyva** systemic lupus erythematosus
RG7159	**Gazyva** childhood onset idiopathic nephrotic syndrome*
RG6168	**Enspryng** MOG-AD

Status as of July 27, 2023

Major pending approvals 2023

US		EU		China		Japan-Chugai	
RG7446	**Tecentriq SC** all approved indications Filed Nov 2022	RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo Filed Nov 2021	RG6264	**Phesgo** HER-2+ BC Filed July 2022	RG6264	**Phesgo** HER-2+ BC/CC Filed Sept 2022
RG7716	**Vabysmo** BRVO/CRVO Filed May 2023	RG1569	**Actemra** SS-ILD Filed Aug 2022	RG6107	**crovalimab** PNH Filed Aug 2022	RG1569	**Actemra** Cytokine release syndrome (CRS) Filed Feb 2023
RG6107*	**crovalimab** PNH Filed June 2023	RG7446	**Tecentriq SC** all approved indications Filed Nov 2022	RG6026	**Columvi (glofitamab)** 3L+ DLBCL Filed Dec 2022	RG7716	**Vabysmo** BRVO/CRVO Filed April 2023
		RG6107	**crovalimab** PNH Filed June 2023	RG7716	**Vabysmo** nAMD/DME Filed June 2023	RG6107	**crovalimab** PNH Filed June 2023

Status as of July 27, 2023

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

Metabolism
Neuroscience
Ophthalmology
Other

SC=Subcutaneous
*US filing acceptance pending

Major granted approvals 2023

US		EU		China		Japan-Chugai
RG7596	**Polivy** 1L DLBCL (US) April 2023	RG6152	**Xofluza** influenza pediatric Jan 2023	RG7596	**Polivy** 1L DLBCL Jan 2023	
RG6026	**Columvi (glofitamab)** 3L+ DLBCL June 2023	RG6013	**Hemlibra** moderate hemophilia A Jan 2023	RG7596	**Polivy** r/r DLBCL Jan 2023	
		RG6413+ RG6412	**Ronapreve*** SARS-CoV-2 hospitalized May 2023	RG6152	**Xofluza** influenza pediatric 5 to <12 years March 2023	
		RG6026	**Columvi (glofitamab)** 3L+ DLBCL July 2023	RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo June 2023	

Status as of July 27, 2023

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Metabolism
Neuroscience
Ophthalmology
Other

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 (emicizumab, RG6013)

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, dosing every 4 weeks
Phase/study	**Phase III HAVEN 3**	**Phase III HAVEN 4**
# of patients	N=135	N=46
Design	Patients on FVIII episodic treatment prior to study entry: ▪ **ARM A:** Hemlibra prophylaxis qw ▪ **ARM B:** Hemlibra prophylaxis q2w ▪ **ARM C:** Episodic FVIII treatment; switch to Hemlibra prophylaxis possible after 24 weeks Patients on FVIII prophylaxis prior to study entry: ▪ **ARM D:** Hemlibra prophylaxis qw	▪ **Part I:** Pharmacokinetic run-in part (N=6); Hemlibra q4w ▪ **Part II:** Expansion part (N=40); Hemlibra q4w
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 24 weeks
Status	▪ 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	▪ 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

In collaboration with Chugai

ASH=American Society of Hematology; WFH=World Federation of Hemophilia; NEJM=New England Journal of Medicine

Hemlibra (emicizumab, RG6013)

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)	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 and primary data presented at ISTH 2022 ▪ Filed in EU Q4 2021 ▪ Data presented at ASH 2022 ▪ Approved in EU for moderate Hemophilia A Q1 2023
CT Identifier	NCT03315455	NCT04158648

In collaboration with Chugai
ASH=American Society of Hematology; ISTH=International Society on Thrombosis and Haemostasis

Alecensa (alectinib, RG7853)

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=257
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	▪ Data presented at ASCO 2017, 2018, ESMO 2017, 2018 and 2019 (final PFS and updated OS) ▪ Data published in *NEJM* 2017; 377:829-838 ▪ Approved in US Q4 2017 (priority review) and in EU Q4 2017	▪ FPI Q3 2018 ▪ Recruitment completed Q4 2021
CT Identifier	NCT02075840	NCT03456076

In collaboration with Chugai

ALK=anaplastic lymphoma kinase; CNS= Central nervous system; NSCLC=non-small cell lung cancer; OS=Overall survival, PFS=Progression-free survival; ASCO=American Society of Clinical Oncology; *NEJM*=New England Journal of Medicine; ESMO=European Society for Medical Oncology

Kadcyla (trastuzumab emtansine, RG3502)

First ADC for HER2-positive breast cancer

Indication	HER2-positive early breast cancer (BC) high-risk patients	HER2-positive early breast cancer (BC) high-risk patients
Phase/study	**Phase III KATHERINE**	**Phase III ASTEFANIA**
# of patients	N=1,484	N=1,700
Design	▪ **ARM A:** Kadcyla 3.6mg/kg q3w ▪ **ARM B:** Herceptin	▪ **ARM A:** Kadcyla plus Tecentriq ▪ **ARM B:** Kadcyla plus placebo
Primary endpoint	▪ Invasive disease-free survival	▪ Invasive disease-free survival
Status	▪ Stopped at pre-planned interim data analysis for efficacy Q4 2018 ▪ Data presented at SABCS 2018 ▪ BTD granted by FDA in Q1 2019 ▪ Filed in US (under RTOR) and EU Q1 2019 ▪ Approved in US Q2 2019 and in EU Q4 2019 ▪ Data published in *NEJM* 2019; 380:617-628	▪ FPI Q2 2021
CT Identifier	NCT01772472	NCT04873362

In collaboration with ImmunoGen, Inc.

ADC=antibody drug conjugate; BTD=Breakthrough therapy designation; HER2=Human Epidermal growth factor Receptor 2; SABCS=San Antonio Breast Cancer Symposium; RTOR=Real time oncology review; *NEJM*=New England Journal of Medicine

Phesgo (pertuzumab/trastuzumab, RG6264)

FDC of Perjeta and Herceptin for subcutaneous administration

Indication	HER2-positive early breast cancer (BC)		HER2-positive breast cancer (BC)
Phase/study	**Phase III FeDeriCa**	**Phase II PHranceSCa**	**Pivotal Phase I[1]**
# of patients	N=500	N=160	N=144
Design	Phesgo in combination with chemotherapy in neoadjuvant/adjuvant setting ▪ **ARM A:** Perjeta IV plus Herceptin IV plus chemotherapy ▪ **ARM B:** Phesgo plus chemotherapy	▪ **ARM A:** Perjeta and Herceptin IV followed by Phesgo ▪ **ARM B:** Phesgo followed by IV	▪ **ARM A:** Phesgo administered using a handheld syringe with hypodermic needle (SC) ▪ **ARM B:** Phesgo administered using the on-body delivery system (OBI)
Primary endpoint	▪ Trough Serum Concentration (Ctrough) of Perjeta during cycle 7	▪ Percentage of patients who preferred Phesgo	▪ AUC0-62*, Cmax**
Status	▪ Primary endpoint met Q3 2019 ▪ Data presented at SABCS 2019 ▪ Data published in Lancet Oncology 2021 Jan;22(1):85-97	▪ Final analysis completed, 85% patients preferred Phesgo ▪ Data presented at ESMO 2020 ▪ Data published in *Eur J Cancer* 2021 Jul;152:223-232	▪ FPI Q2 2022
	▪ Filed in US Q4 2019 & in EU Q1 2020; Approved in US Q2 2020 and EU Q4 2020		
CT Identifier	NCT03493854	NCT03674112	NCT05275010

SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase; [1]In collaboration with West Pharmaceuticals;*AUC0-62=comparability of area under the time-concentration curve from the start of dosing to 63 days; **Cmax=maximum serum concentration for pertuzumab and trastuzumab within Phesgo; FDC=Fixed-dose combination; Phesgo=FDC of Perjeta and Herceptin for SC administration; HER2=Human Epidermal growth factor Receptor 2, IV=intravenous; SC=Subcutaneous; SABCS=San Antonio Breast Cancer Symposium; Eur J Cancer=European Journal of Cancer; ESMO=European Society for Medical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	Adjuvant NSCLC	Periadjuvant 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	▪ 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 and EU Q2 2022	▪ FPI Q2 2018 ▪ Recruitment completed Q3 2021
CT Identifier	NCT02486718	NCT03456063

NSCLC=non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; WCLC=World Conference on Lung Cancer

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L maintenance extensive-stage SCLC	Stage IV NSCLC
Phase/study	**Phase III** **IMforte**[1]	**Phase Ib/III** **IMscin001**[2]
# of patients	N=450	N=371
Design	▪ **ARM A:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin ▪ **ARM B:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq	**Phase Ib** ▪ Dose finding, Tecentriq SC followed by Tecentriq IV **Phase III** ▪ 2L NSCLC non inferiority of Tecentriq SC vs Tecentriq IV
Primary endpoint	▪ Progression-free survival and overall survival	▪ Observed concentration of Tecentriq in serum at cycle 1
Status	▪ FPI Q4 2021	▪ FPI Phase Ib Q4 2018 and FPI Phase III Q4 2020 ▪ Recruitment completed Q1 2022 ▪ Study met its primary end point Q3 2022 ▪ Data presented at ESMO-IO 2022 ▪ Filed in US and EU Q4 2022
CT Identifier	NCT05091567	NCT03735121

[1]In collaboration with Jazz Pharma, [2]SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase

NSCLC=non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; SCLC=small cell lung cancer, SC=Subcutaneous, IV=Intravenous; ESMO-IO=European Society for Medical Oncology-Immuno-Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – SCCHN

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

SCCHN=squamous cell carcinoma of the head and neck

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – urothelial carcinoma

Indication	High-risk non-muscle-invasive bladder cancer (NMIBC)	ctDNA+, high-risk muscle-invasive bladder cancer (MIBC)
Phase/study	**Phase III ALBAN**	**Phase III IMvigor011**
# of patients	N=516	N=495
Design	▪ **ARM A:** BCG induction and maintenance ▪ **ARM B:** Tecentriq plus BCG induction and maintenance	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Placebo
Primary endpoint	▪ Recurrence-free survival	▪ Recurrence-free survival
Status	▪ FPI Q4 2018	▪ FPI Q2 2021
CT Identifier	NCT03799835	NCT04660344

BCG=Bacille Calmette-Guérin; PD-L1=Programmed cell death-ligand 1

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – hepatocellular carcinoma

Indication	Adjuvant hepatocellular carcinoma (HCC)
Phase/study	**Phase III** **IMbrave050**
# of patients	N=668
Design	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Active surveillance
Primary endpoint	▪ Recurrence-free survival
Status	▪ FPI Q4 2019 ▪ Recruitment completed Q4 2021 ▪ Study met its primary endpoint Q1 2023 ▪ Data presented at AACR 2023 and ASCO 2023 (PROs)
CT Identifier	NCT04102098

PD-L1=Programmed cell death-ligand 1; AACR=American Association for Cancer Research; PROs=Patient-reported outcomes

Tecentriq (atezolizumab, RG7446)

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

Carbo/gem=gemcitabine and carboplatin; ITT=Intention to treat; PD-L1=Programmed cell death-ligand 1; PFS=Progression-free survival; OS=Overall survival; ESMO=European Society for Medical Oncology; ASCO=American Society of Clinical Oncology; NEJM=New England Journal of Medicine

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Neoadjuvant triple negative breast cancer (TNBC)
Phase/study	**Phase III** **IMpassion031**
# of patients	N=333
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel
Primary endpoint	▪ Percentage of participants with pathologic complete response
Status	▪ 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
CT Identifier	NCT03197935

PD-L1=Programmed cell death-ligand 1; ESMO=European Society for Medical Oncology, IDMC=Independent Data Monitoring Committee

Venclexta (venetoclax, RG7601)

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

Indication	Untreated chronic lymphocytic leukemia (CLL) patients with coexisting medical conditions	Untreated fit chronic lymphocytic leukemia (CLL) patients
Phase/study	**Phase III** **CLL14**	**Phase III** **CristaLLo**
# of patients	N=445	N=165
Design	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Chlorambucil plus Gazyva	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Fludarabine plus cyclophosphamide plus Rituxan or bendamustine plus Rituxan
Primary endpoint	▪ Progression-free survival	▪ MRD negativity rate in peripheral blood at 15 months
Status	▪ Study met primary endpoint Q4 2018 ▪ BTD granted by FDA Q1 2019 ▪ Filed in US (under RTOR) Q1 2019 and EU Q2 2019 ▪ Data presented at ASCO 2019, ASH 2019, 2020 and EHA 2021, 2022; 6-year data presented at EHA and ICML 2023 ▪ Data published in *NEJM* 2019; 380:2225-2236 ▪ Approved US Q2 2019 and EU Q1 2020	▪ FPI Q2 2020 ▪ Recruitment completed Q1 2023
CT Identifier	NCT02242942	NCT04285567

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

Bcl-2=B-cell lymphoma 2; BTD=Breakthrough therapy designation; MRD=Minimal Residual Disease; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology; EHA=European Hematology Association; RTOR=Real time oncology review; NEJM=New England Journal of Medicine

Venclexta (venetoclax, RG7601)

Novel small molecule Bcl-2 selective inhibitor – multiple myeloma

Indication	Relapsed or refractory multiple myeloma (MM)	
Phase/study	**Phase I**	**Phase III CANOVA**
# of patients	N=117	N=244
Design	▪ **Dose escalation cohort:** Venclexta dose escalation ▪ **Safety expansion cohort (t11;14):** Venclexta expansion ▪ **Combination cohort:** Venclexta plus dexamethasone	▪ **ARM A:** Venclexta plus dexamethazone ▪ **ARM B:** Pomalidomide plus dexamethasone in t(11;14) positive r/r MM
Primary endpoint	▪ Safety and maximum tolerated dose	▪ Progression-free survival
Status	▪ Data presented at ASCO 2015, 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 Q4 2018 ▪ Recruitment completed Q3 2022
CT Identifier	NCT01794520	NCT03539744

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

Bcl-2=B-cell lymphoma 2; MM=multiple myeloma; r/r=Relapsed or refractory ; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology

Venclexta (venetoclax, RG7601)

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:** ▪ 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	▪ Overall survival
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q1 2022 ▪ Data published in *Am J Hematol* 2023 Feb;98(2):272-281	▪ FPI Q1 2017 ▪ Data presented at ASH 2019, 2020 and ASCO 2021 ▪ BTD granted by FDA July 2021 ▪ Recruitment completed Q1 2022	▪ FPI Q4 2020 ▪ Recruitment completed Q3 2022
CT Identifier	NCT02966782	NCT02942290	NCT04401748

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

Bcl-2=B-cell lymphoma 2; BTD=Breakthrough therapy designation; RPTD=Recommended phase II dose ; ASH=American Society of Hematology

Polivy (polatuzumab vedotin, RG7596)

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	▪ Data presented at ASH 2021 and 2022 ▪ Filed in EU, Japan and China Q4 2021 and in the US Q3 2022 ▪ Published in *NEJM* 2022 Jan 27;386(4):351-363 ▪ Approved in EU Q2 2022, Japan Q3 2022, China Q1 2023 and US April 2023
CT Identifier	NCT03274492

In collaboration with Seagen Inc.

DLBCL=diffuse large B cell lymphoma; R-CHP=Rituxan, cyclophosphamide, hydroxydoxorubicin, prednisone; R-CHOP=Rituxan, cyclophosphamide, doxorubicin, vincristine, and prednisone; ASH=American Society of Hematology, NEJM=New England Journal of Medicine

Gavreto (pralsetinib, RG6396)

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 I:** Gavreto 30-600mg dose escalation ▪ **Part II:** Gavreto 400mg dose expansion	▪ **ARM A:** Gavreto 400mg ▪ **ARM B:** Platinum-based chemotherapy +/- pembrolizumab
Primary endpoint	▪ Safety and efficacy	▪ Progression-free survival
Status	▪ 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 and 2022 ▪ Data published in Lancet Oncol 2021 Jul;22(7):959-969 and Lancet Diabetes & Endocrinology Aug 2021;9(8):491-501 ▪ Approved in EU for RET fusion-positive NSCLC Q4 2021 ▪ Filing withdrawn in EU Q4 2022 for RET-mutant MTC and RET fusion-positive thyroid cancer ▪ US Approval withdrawn Q2 2023 for RET-mutant medullary thyroid cancer	▪ Study initiated in Q1 2020
CT Identifier	NCT03037385	NCT04222972

In collaboration with Blueprint Medicines

NSCLC=non-small cell lung cancer; MTC=medullary thyroid cancer; RET=Rearranged during transfection; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

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

Indication	3L+ FL, 3L+ DLBCL & other relapsed or refractory NHL	1L DLBCL	Relapsed or refractory DLBCL
Phase/study	**Phase I/II**	**Phase Ib/II**	**Phase Ib/II**
# of patients	N=746	N=160	N=262
Design	▪ Dose escalation of Lunsumio monotheraphy and in combination with Tecentriq ▪ Expansion cohorts for r/r FL, r/r DLBCL and SC in r/r NHL	▪ Lunsumio plus CHOP ▪ Lunsumio plus CHP plus Polivy ▪ Lunsumio plus CHP-Polivy vs Rituximab plus CHP-Polivy	Lunsumio plus Polivy, randomised cohorts ▪ **ARM A:** Lunsumio 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	▪ Data in r/r NHL presented at ASH 2018, 2019, and in r/r FL at ASH 2020, 2021 and 2022 ▪ BTD granted by FDA Q2 2020 ▪ Filed in EU and rolling submission in US Q4 2021; Filed in US (priority review) Q2 2022 ▪ Approved in EU Q2 2022 and US Q4 2022 ▪ DLBCL data published in *J. Clin. Oncol.* 40(5)481-491 and *Blood Advances* 2023 Apr 17: doi:10.1182/bloodadvances.2022009260 ▪ FL data published in the *Lancet Oncology* 2022 Aug;23(8):1055-1065	▪ FPI Q1 2019 ▪ Recruitment completed Q2 2021 ▪ Data for Lunsumio plus CHOP presented at ASH 2020	▪ FPI Q3 2018 ▪ Recruitment completed Q1 2023 ▪ Initial data presented at ASCO 2021 and ASH 2021, 2022
CT Identifier	NCT02500407	NCT03677141	NCT03671018

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; r/r=relapsed/refractory; NHL=non-Hodgkin's lymphoma; R=Rituximab; SC=subcutaneous; CHOP=cyclophosphamide, doxorubicin, vincristine, and prednisone; CHP=cyclophosphamide, doxorubicin, and prednisone; PK=Pharmacokinetics; BTD=Breakthrough Therapy Designation; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

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

Indication	1L DLBCL & 2L DLBCL following 1L induction	Relapsed or refractory 2L+ FL
Phase/study	**Phase I**	**Phase Ib**
# of patients	N=188	N=27
Design	▪ **Cohort A:** Lunsumio monotherapy (after a response to prior systemic chemotherapy) ▪ **Cohort B:** Lunsumio monotherapy (1L treatment in elderly/frail) ▪ **Cohort C:** Lunsumio SC plus Polivy in 1L elderly/unfit	▪ Lunsumio plus lenalidomide safety run-in for phase III ▪ Lunsumio SC plus lenalidomide
Primary endpoint	▪ Safety/tolerability and response	▪ Safety/tolerability and response
Status	▪ FPI Q2 2019 – Cohort B ▪ FPI Q3 2019 – Cohort A ▪ FPI Q1 2021 – Cohort C ▪ Recruitment completed Q1 2023 ▪ Initial data presented at ASH 2020 (Cohort B) and ASH 2022	▪ FPI Q3 2020 ▪ Initial data presented at ASH 2021 and 2022 ▪ Recruitment completed Q2 2023
CT Identifier	NCT03677154	NCT04246086

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; SC=subcutaneous; ASH=American Society of Hematology

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

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

Indication	2L+ FL	Relapsed or refractory CLL
Phase/study	**Phase III CELESTIMO**	**Phase Ib/II**
# of patients	N=400	N=56
Design	▪ **ARM A**: Lunsumio plus lenalidomide ▪ **ARM B:** Rituxan plus lenalidomide	▪ Lunsumio monotherapy (3L+ CLL)
Primary endpoint	▪ Progression-free survival	▪ Safety, dose-limiting toxicity and RPTD
Status	▪ FPI Q4 2021	▪ FPI Q1 2022
CT Identifier	NCT04712097	NCT05091424

FL=follicular lymphoma; r/r=relapsed/refractory; RPTD=Recommended Phase II Dose; CLL=Chronic lymphocytic leukemia

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

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

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

DLBCL=diffuse large B cell lymphoma; SCT=stem cell transplant; R=Rituxan/MabThera; GemOx=Gemcitabin und Oxaliplatin

Columvi (glofitamab, CD20-TCB, RG6026)

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

Indication	Relapsed or refractory Non-Hodgkin's lymphoma (NHL)		
Phase/study	**Phase I**	**Phase 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:** Columvi plus Gazyva (i.e. continuous treatment with Gazyva)	Dose escalation and expansion ▪ **ARM A:** Columvi plus Tecentriq ▪ **ARM B:** Columvi plus Polivy	Columvi SC ▪ Part 1 dose escalation
Primary endpoint	▪ Efficacy, safety, tolerability and PK	▪ Safety	▪ Safety
Status	▪ Data presented at ASH 2018, 2020, 2021, 2022, ICML 2019, 2021, EHA 2020, 2021, 2022 and ASCO 2021, 2022 and 2023 ▪ Data published in *J Clin Oncology* 2021; 39:18:1959-1970 and *NEJM* 2022; 387:2220-2231 ▪ Filed in EU Q2 2022 and US Q4 2022 ▪ Approved in Canada Q1 2023, US Q2 2023 and EU July 2023	▪ **ARM A:** FPI Q2 2018 ▪ **ARM B:** FPI Q4 2020 ▪ Recruitment completed Q2 2022 ▪ Data presented at ASH 2019, 2021	▪ FPI Q3 2021
CT Identifier	NCT03075696	NCT03533283	ISRCTN17975931

DLBCL=diffuse large B cell lymphoma; FL=Follicular lymphoma; r/r=Relapsed or refractory; SC=subcutenous; PK=Pharmacokinetics; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology; EHA=European Hematology Association; ICML=International Conference on Malignant Lymphoma; NEJM=New England Journal of Medicine

Columvi (glofitamab, CD20-TCB, RG6026)

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

Indication	Non-Hodgkin's lymphoma (NHL)	2L+ SCT-ineligible DLBCL	1L ctDNA high risk DLBCL
Phase/study	**Phase Ib**	**Phase III STARGLO**	**Phase II**
# of patients	Part I: 15-60 Part II: ~66-104	N=270	N=40
Design	▪ **Part I:** Dose-finding for the combination of Columvi plus G/R-CHOP in r/r indolent NHL ▪ **Part II:** Dose expansion Columvi plus G/R-CHOP or R-CHOP in 1L DLBCL ▪ **Part III:** Columvi plus R-CHP plus Polivy	▪ **ARM A:** Columvi plus gemcitabine and oxaliplatin, followed by up to 4 cycles of Columvi 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 Columvi	▪ Columvi plus R-CHOP (Columvi is introduced as a consolidation to R-CHOP at cycle 3-8 in patients ctDNA+ at cycle 2)
Primary endpoint	▪ Safety	▪ Overall survival	▪ EOT PET-CR
Status	▪ Part I: FPI Q1 2018 ▪ Part II: FPI Q1 2021 ▪ Recruitment completed Q1 2023 ▪ Data presented at ASH 2021, 2022 and ASCO 2023	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2023	▪ FPI Q1 2022
CT Identifier	NCT03467373	NCT04408638	NCT04980222

DLBCL=diffuse large B cell lymphoma; SCT=stem cell transplant; CHOP=cyclophosphamide, doxorubicin, vincristine and prednisone; R=Rituxan/MabThera; G=Gazyva; NHL=Non-Hodgkin's lymphoma; ctDNA=circulating tumor DNA; ASH=American Society of Hematology; EOT PET-CR=End of treatment PET-complete response rate

Columvi (glofitamab, CD20-TCB, RG6026)

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

Indication	2L+ SCT-eligible DLBCL	2L+ SCT-ineligible DLBCL
Phase/study	**Phase Ib**	**Phase Ib**
# of patients	N=40	N=112
Design	▪ Columvi plus R-ICE (single-arm study)	▪ Columvi IV plus CELMoD (CC-220 and CC-99282) ▪ Lunsumio SC plus CELMoD (CC-220 and CC-99282)
Primary endpoint	▪ Objective response rate within 3 cycles	▪ Safety, DLT, RPTD
Status	▪ FPI Q4 2022	▪ FPI Q4 2022
CT Identifier	NCT05364424	NCT05169515

DLBCL=diffuse large B cell lymphoma; DLT=Dose-limiting toxicity, RPTD=Recommended Phase II Dose; R-ICE= Rituxan plus ifosfamide, carboplatin, and etoposide; IV=Intravenous; SC=Subcutaneous

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Relapsing multiple sclerosis (RMS)		Primary progressive multiple sclerosis (PPMS)
Phase/study	**Phase III OPERA I**	**Phase III OPERA II**	**Phase III ORATORIO**
# of patients	N=821	N=835	N=732
Design	96-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV followed by 600mg IV q24w ▪ **ARM B:** Interferon β-1a (Rebif)	96-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV followed by 600mg IV q24w ▪ **ARM B:** Interferon β-1a (Rebif)	120-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV q24w ▪ **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 ▪ Data presented at ECTRIMS 2015, 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 ▪ Data presented at ECTRIMS 2015, 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		
CT Identifier	NCT01247324	NCT01412333	NCT01194570

IV=intravenous; EDSS=Expanded Disability Status Scale; OLE=Open label extension; ECTRIMS=European Committee for Treatment and Research in Multiple Sclerosis; AAN=Annual Meeting of the American Academy of Neurology; EAN=European Academy of Neurology; NEJM=New England Journal of Medicine

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Relapsing and primary progressive multiple sclerosis (RMS & PPMS)	Primary progressive multiple sclerosis (PPMS)
Phase/study	**Phase IIIb** **ENSEMBLE PLUS**	**Phase IIIb** **ORATORIO-HAND**
# of patients	N=1,225	N ~ 1,000
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	▪ 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)	PPMS & RMS
Phase/study	**Phase IIIb GAVOTTE**	**Phase IIIb MUSETTE**	**Phase III Ocarina II[1]**
# of patients	N ~ 699	N ~ 786	N ~ 232
Design	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV q24w ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg q24w	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV q24w ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg q24w	▪ **ARM A:** Ocrevus IV ▪ **ARM B:** Ocrevus SC
Primary endpoint	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Serum Ocrevus area under the concentration-time curve (AUCW1-12) at week 12
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2023	▪ FPI Q4 2020 ▪ Recruitment completed Q4 2021	▪ FPI Q2 2022 ▪ Recruitment completed Q4 2022 ▪ Study met it's primary endpoint July 2023
CT Identifier	NCT04548999	NCT04544436	NCT05232825

[1]SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase
cCDP=composite confirmed disability progression; IV=intravenous; SC=Subcutaneous

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)		
Phase/study	**Phase II/III FIREFISH**	**Phase II/III SUNFISH**	**Phase II JEWELFISH**
# of patients	N=21 (Part 1), 41 (Part 2)	N=51 (Part 1), 180 (Part 2)	N=174
Design	Infants with type 1 SMA ▪ **Part I (dose-finding):** ≥4 weeks ▪ **Part II (confirmatory):** 24 months	Adult & pediatric patients with type 2 or 3 SMA: ▪ **Part I (dose-finding):** At least 12 weeks ▪ **Part II (confirmatory):** 24 months	▪ Adult and pediatric patients with previously treated SMA type 1, 2 and 3
Primary endpoint	▪ Safety, tolerability, PK/PD and efficacy	▪ Safety, tolerability, PK/PD and efficacy	▪ Safety, tolerability, PK/PD
Status	▪ Part I 12-month data presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019 ▪ Part II 1-year data presented at AAN 2020, Part I 2-year data at WMS 2020 ▪ Part I data published in *NEJM* 2021;384:915-923 ▪ Part II 2-year data presented at AAN 2021 ▪ Part II 1-year data published in *NEJM* 2021;385:427-435 ▪ 3-year data presented at EPNS 2022 and 4-year data presented at Cure SMA and EAN 2023	▪ Part I 12-month data presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019 ▪ Part II 1-year data presented at SMA Europe 2020, 2-year data at MDA 2021, 3-year data at MDA 2022 and 4-year data at MDA and EAN 2023 ▪ Part II 1-year data published in Lancet Neurology, 2022; 21 (1) 42-52	▪ Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, WMS 2019, CureSMA 2020 and 2021 ▪ 2-year data presented at WMS 2022
	▪ ODD granted by FDA Q1 2017 and EU Q1 2019, PRIME designation in Q4 2018 ▪ Approved in US Q3 2020 and EU Q1 2021		
CT Identifier	NCT02913482	NCT02908685	NCT03032172

In collaboration with PTC Therapeutics and SMA Foundation

SMA=Spinal muscular atrophy; SMN=survival motor neuron; PK/PD=Pharmacokinetics/Pharmacodynamics; PRIME=priority medicines; AAN=American Academy of Neurology; WMS=World Muscle Society; EAN=European Academy of Neurology; NEJM=New England Journal of Medicine; MDA=Muscular Dystrophy Association; CureSMA=Annual SMA Conference; EPNS=European Paediatric Neurology Society; ODD=Orphan drug designation

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)
Phase/study	**Phase II** **RAINBOWFISH**
# of patients	N=25
Design	▪ Infants aged from birth to 6 weeks who have been genetically diagnosed with SMA but are not yet presenting with symptoms
Primary endpoint	▪ Proportion of participants with two copies of the SMN2 gene and baseline CMAP>=1.5 millivolt who are sitting without support
Status	▪ FPI Q3 2019 ▪ Recruitment completed Q1 2022 ▪ Initial data presented at CureSMA , WMS 2021, MDA and WMS 2022 ▪ Filed in US and EU Q4 2021 ▪ Approved in US Q2 2022
CT Identifier	NCT03779334

In collaboration with PTC Therapeutics and SMA Foundation

SMN=survival motor neuron; CMAP=compound muscle action potential; WMS=World Muscle Society; CureSMA=Annual SMA Conference; MDA=Muscular Dystrophy Association;

Enspryng (satralizumab, RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Neuromyelitis optica spectrum disorder (NMOSD)	
Phase/study	**Phase III** **SAkuraStar**	**Phase III** **SAkuraSky**
# of patients	N=95	N=83
Design	Enspryng monotherapy: ▪ **ARM A:** Enspryng 120mg SC monthly ▪ **ARM B:** Placebo SC monthly	Add-on therapy of Enspryng: ▪ **ARM A:** Enspryng 120mg SC monthly ▪ **ARM 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	▪ 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)

BTD=Breakthrough therapy designation; PK/PD=Pharmacokinetics/Pharmacodynamics; SC=Subcutaneous; ECTRIMS=European Committee for Treatment and Research in Multiple Sclerosis; AAN=American Academy of Neurology; NEJM=New England Journal of Medicine

Enspryng (satralizumab, RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Generalised myasthenia gravis (MG)	Myelin oligodendrocyte glycoprotein antibody disease (MOG-AD)	Autoimmune encephalitis (AIE)
Phase/study	**Phase III Luminesce**	**Phase III METEOROID**	**Phase III CIELO**
# of patients	N=240	N=152	N=152
Design	▪ **ARM A:** Enspryng plus standard of care ▪ **ARM B:** Placebo plus standard of care	▪ **ARM A**: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses q4w ▪ **ARM B:** Placebo	▪ **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 MOG-AD relapse	▪ Efficacy (proportion of participants with mRS score improvement ≥ 1 from baseline and no use of rescue therapy at week 24) and safety
Status	▪ ODD granted in US Q1 2021 ▪ FPI Q4 2021	▪ FPI Q3 2022 ▪ ODD granted by FDA in Q4 2021	▪ FPI Q3 2022 ▪ ODD granted for NMDAR AIE in US Q3 22
CT Identifier	NCT04963270	NCT05271409	NCT05503264

In collaboration with Chugai

MG-ADL= Myasthenia Gravis Activities of Daily Living; AChR=Acetylcholine receptor; MOG-AD=Myelin Oligodendrocyte Glycoprotein Antibody Disease, mRS=Modified Rankin Scale; AIE=Autoimmune encephalitis; NMDAR AIE= Anti-N-Methyl-D-Aspartic Acid Receptor Autoimmune Encephalitis; ODD=Orphan drug designation

TNKase (RG3625, tenecteplase)

Small molecule tissue plasminogen activator

Indication	Stroke patients between 4.5 and 24 hours
Phase/study	**Phase III** **TIMELESS**
# of patients	N=456
Design	▪ **ARM A:** Tenecteplase (0.25 mg/kg, maximum 25 mg) single bolus injection ▪ **ARM B:** Placebo
Primary endpoint	▪ Ordinal modified Rankin scale (mRS) score after 90 days
Status	▪ FPI Q1 2019 ▪ Recruitment completed Q4 2022 ▪ Study did not meet it's primary endpoint Q2 2023
CT Identifier	NCT03785678

Gazyva (obinutuzumab, RG7159)

Immunology development program

Indication	Lupus nephritis		Membranous nephropathy
Phase/study	**Phase II NOBILITY**	**Phase III REGENCY**	**Phase III MAJESTY**
# of patients	N=126	N=252	N=140
Design	▪ **ARM A:** Gazyva 1000mg IV plus MFF / mycophenolic acid ▪ **ARM B:** Placebo IV plus MFF/ mycophenolic acid	▪ **ARM A:** Gazyva 1000mg IV (6 doses through Week 52) plus MFF ▪ **ARM B:** Gazyva1000 mg IV (5 doses through Week 52) plus MFF ▪ **ARM C:** Placebo IV plus MFF	▪ **ARM A:** Gazyva 1000mg IV on top of renin-angiotensin inhibitors ▪ **ARM B:** Tacrolimus treatment for 12 months
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of patients who achieve complete remission at week 104
Status	▪ Primary endpoint met Q2 2019 ▪ BTD granted by the FDA Q3 2019 ▪ Data presented at ASN and ACR 2019 ▪ Published in *Ann Rheum Dis* 2022 Jan;81(1):100-107	▪ FPI Q3 2020 ▪ Recruitment completed Q1 2023	▪ FPI Q2 2021
CT Identifier	NCT02550652	NCT04221477	NCT04629248

In collaboration with Biogen

BTD=Breakthrough therapy designation; IV=Intravenous; ASN=American Society of Nephrology; ACR=American College of Rheumatology; MFF=mycophenolate mofetil

Gazyva (obinutuzumab, RG7159)

Immunology development program

Indication	Systemic lupus erythematosus (SLE)	Childhood onset idiopathic nephrotic syndrome*
Phase/study	**Phase III** **ALLEGORY**	**Phase III** **INShore**
# of patients	N=200	N=80
Design	▪ **ARM A:** Gazyva 1000mg IV on Day 1 and Weeks 2, 24 and 26. ▪ **ARM B:** Placebo IV	▪ **ARM A:** Gazyva plus oral steroids ▪ **ARM B:** Mycophenolate mofetil (MMF) plus oral steroids
Primary endpoint	▪ Percentage of participants who achieve Systemic Lupus Erythematosus Responder Index (SRI) at week 52	▪ Percentage of participants with sustained complete remission at 1 year
Status	▪ FPI Q4 2021	▪ FPI Q1 2023
CT Identifier	NCT04963296	NCT05627557

In collaboration with Biogen
*also known as pediatric nephrotic syndrome (PNS); IV=Intravenous

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

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

Indication	Systemic lupus erythematosus (SLE)
Phase/study	**Phase I**
# of patients	N=50
Design	▪ **ARM A:** Lunsumio SC on either Day 1 or on Days 1 and 8 ▪ **ARM B:** Fractionated (divided) dose of Lunsumio SC on Days 1 and 8
Primary endpoint	▪ Safety
Status	▪ FPI Q1 2022
CT Identifier	NCT05155345

In collaboration with Biogen
SC=subcutaneous

Xolair (omalizumab, RG3648)

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

In collaboration with Novartis; [1] Sponsor of the study is the National Institute of Allergy and Infectious Diseases (NIAID)
IgE=Immunoglobulin E; SC=Subcutaneous

Susvimo (PDS, RG6321)

First eye implant to achieve sustained delivery of a biologic medicine

Indication	Wet age-related macular degeneration (wAMD)		
Phase/study	**Phase III Archway**	**Phase II+III extension Portal**	**Phase IIIb Velodrome**
# of patients	N=418	N=1,000	N=442
Design	▪ **ARM A:** PDS q24w ▪ **ARM B:** Intravitreal ranibizumab q4w	▪ Patients from LADDER or Archway receive refills of ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)	▪ **ARM A:** PDS q36w ▪ **ARM B:** PDS 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	▪ Study met primary endpoint Q2 2020 ▪ 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 Q2 2021
CT Identifier	NCT03677934	NCT03683251	NCT04657289

BCVA=best corrected visual acuity; wAMD=wet age-related macular degeneration; ASRS=American Society of Retinal Specialists; PDS=Port Delivery System with ranibizumab; PRIME=Priority review

Susvimo (PDS, RG6321)

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:** PDS 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 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023	▪ FPI Q3 2020 ▪ Recruitment completed Q3 2021 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023
CT Identifier	NCT04108156	NCT04503551

BCVA=best corrected visual acuity; ETDRS=Early Treatment Diabetic Retinopathy Study; DRSS=Diabetic Retinopathy Severity Scale; PDS=Port Delivery System with ranibizumab

Vabysmo (faricimab, RG7716)

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	▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021	▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021
	▪ 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 and EU Q3 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03622580	NCT03622593

Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor; PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity, ARVO=Association for Research in Vision and Ophthalmology

Vabysmo (faricimab, RG7716)

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

Indication	Wet age related macular degeneration (wAMD)	
Phase/study	**Phase III TENAYA**	**Phase III LUCERNE**
# of patients	N=671	N=658
Design	▪ **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	▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021	▪ 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 and EU Q3 2022 ▪ 2-year data presented at ASRS 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03823287	NCT03823300

BCVA=best corrected visual acuity; Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor; IDs=initiating doses; ASRS=American Society of Retina Specialists, ARVO=Association for Research in Vision and Ophthalmology

Vabysmo (faricimab, RG7716)

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 2021 ▪ Recruitment completed Q1 2022 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023 ▪ Filed in US Q2 2023	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2022 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023 ▪ Filed in US Q2 2023
CT Identifier	NCT04740905	NCT04740931

PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity; Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor

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	Healthy pediatric patients from birth to <1 year with influenza-like symptoms receive Xofluza on Day 1	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 and EU Q4 2021 ▪ Data published in *Pediatric Infectious Disease* 2020 Aug;39(8):700-705 ▪ Approved in the US (age 5 years and older) Q3 2022 , EU Jan 2023 and China (age 5 years and older) Q1 2023	▪ FPI Q4 2019
CT Identifier	NCT03653364	NCT03629184	NCT03969212

In collaboration with Shionogi & Co., Ltd.
CAP=Catabolite Activating Protein

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

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	1L NSCLC PD-L1 TPS>50%	Stage III unresectable 1L NSCLC
Phase/study	**Phase III** **SKYSCRAPER-01**	**Phase III** **SKYSCRAPER-03**
# of patients	N=500-560	N=800
Design	▪ **ARM A:** Tiragolumab plus Tecentriq ▪ **ARM B:** Placebo plus Tecentriq	▪ **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	▪ Progression-free survival
Status	▪ FPI Q1 2020 ▪ Recruitment completed Q3 2021 ▪ Study did not meet one of its primary endpoints, PFS, Q2 2022	▪ FPI Q3 2020 ▪ Recruitment completed Q2 2023
CT Identifier	NCT04294810	NCT04513925

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; TPS=Tumor Proportion Score; PFS=Progression-free survival

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

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 III SKYSCRAPER-06**
# of patients	N=172	N=82	N=540
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 chemotherapy followed by maintenance tiragolumab plus Tecentriq plus pemetrexed ▪ **ARM B:** Placebo plus pembrolizumab plus pemetrexed plus chemotherapy 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

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

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 ▪ Recruitment completed Q2 2022
CT Identifier	NCT04543617	NCT04540211	NCT04665843

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	**Locally advanced, recurrent or metastatic solid tumors**
Phase/study	**Phase II** **SKYSCRAPER-11**
# of patients	N=60
Design	▪ Tiragolumab plus Tecentriq IV FDC
Primary endpoint	▪ Safety
Status	▪ FPI Q2 2023
CT Identifier	NCT05661578

NSCLC=Non-small cell lung cancer; FDC=Fixed-dose combination; IV=Intravenous

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	Solid tumors	NSCLC	Relapsed or refractory multiple myeloma (MM) or r/r B-cell NHL
Phase/study	**Phase I**	**Phase II CITYSCAPE**	**Phase I**
# of patients	N=540	N=135	N=52
Design	▪ **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	▪ Data presented at AACR 2020	▪ Data presented at ASCO 2020 and WCLC and ESMO IO 2021 ▪ BTD granted by FDA Q4 2020 ▪ Data published in *Lancet Oncol* 2022 Jun;23(6):781-792	▪ FPI Q2 2019
CT Identifier	NCT02794571	NCT03563716	NCT04045028

BTD=Breakthrough therapy designation; MM=Multiple myeloma; NSCLC=Non-small cell lung cancer; r/r=Relapsed refractory; NHL=Non-Hodgkin's lymphoma; PK=Pharmacokinetics; PD=Pharmacodynamics; ASCO=American Society of Clinical Oncology; AACR=American Association for Cancer Research; WCLC=World Conference on Lung Cancer; ESMO IO=European Society for Medical Oncology - Immuno-Oncology

Inavolisib (RG6114, GDC-0077)

A potent, orally available, and selective PI3Kα inhibitor

Indication	PIK3CA-mutant HR-positive metastatic breast cancer (mBC)	post CDKi HR-positive breast cancer	PIK3CA mutant solid tumors and metastatic ER+ HER2-negative breast cancer
Phase/study	**Phase III INAVO120**	**Phase III INAVO121**	**Phase I**
# of patients	N=400	N=400	N=256
Design	▪ **ARM A:** Inavolisib plus palbociclib plus fulvestrant ▪ **ARM B:** Placebo plus palbociclib plus fulvestrant	▪ **ARM A:** Inavolisib plus fulvestrant ▪ **ARM B:** alpelisib 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	▪ Progression-free survival	▪ Safety, tolerability and pharmacokinetics
Status	▪ FPI Q1 2020	▪ FPI Q2 2023	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017 ▪ Data presented at SABCS 2019, 2020 and 2021
CT Identifier	NCT04191499	NCT05646862	NCT03006172

ER=Estrogen receptor; HR=Hormon receptor; HER2=Human Epidermal growth factor Receptor 2; PI3K=Phosphoinositide 3-Kinase; AACR=American Association for Cancer Research; SABCS=San Antonio Breast Cancer Symposium; CDKi= Cyclin-dependent kinase inhibitor

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

A selective estrogen receptor degrader or downregulator

Indication	ER+ HER2-negative metastatic breast cancer (mBC)	ER+ HER2-negative Stage I-III operable breast cancer (BC)	Neoadjuvant ER-positive 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, 2021 and ASCO 2020, 2021	▪ FPI Q3 2019 ▪ Data presented at ASCO 2021	▪ FPI Q3 2020 ▪ Data presented at ESMO and SABCS 2021; ASCO 2022 ▪ Data (biomarker subgroup analysis) presented at ESMO 2022
CT Identifier	NCT03332797	NCT03916744	NCT04436744

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor; RPTD=Recommended phase II dose; LHRH=Luteinizing hormone–releasing hormone; PK/PD=Pharmacokinetics/Pharmacodynamics; SABCS=San Antonio Breast Cancer Symposium; ASCO=American Society of Clinical Oncology

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

A selective estrogen receptor degrader or downregulator

Indication	1L ER-positive metastatic breast cancer (mBC)	Adjuvant ER-positive breast cancer (BC)
Phase/study	**Phase III** **persevERA Breast Cancer**	**Phase III** **lidERA Breast Cancer**
# of patients	N=978	N=4,100
Design	▪ **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	▪ Invasive disease-free survival
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q1 2023	▪ FPI Q3 2021
CT Identifier	NCT04546009	NCT04961996

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor

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

A selective estrogen receptor degrader or downregulator

Indication	1L ER-positive/HER2-positive breast cancer (BC)	Grade 1 endometrial cancer
Phase/study	**Phase III** **heredERA**	**Phase II** **endomERA**
# of patients	N=812	N=45
Design	Induction Phesgo plus taxane followed by maintenance with either: ▪ **ARM A:** Giredestrant plus Phesgo ▪ **ARM B:** Phesgo	▪ Giredestrant once a day (QD) on days 1 to 28 of each 28-day cycle for 6 cycles
Primary endpoint	▪ Progression-free survival	▪ Percentage of participants who have regression by 6 months
Status	▪ FPI Q2 2022	▪ FPI Q2 2023
CT Identifier	NCT05296798	NCT05634499

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor; Phesgo=FDC of Perjeta and Herceptin for SC administration

Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)

A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein

Indication	Advanced or metastatic solid tumors with a KRAS G12C mutation	2L NSCLC	2L, 1L metastatic colorectal cancer (mCRC)
Phase/study	**Phase I**	**Phase II/III B-FAST***	**Phase Ib INTRINSIC**
# of patients	N=438	Modular design	Modular design
Design	Monotherapy and combinations of divarasib with other anti-cancer therapies	**Cohort G (KRAS G12C)** ▪ **ARM A:** divarasib ▪ **ARM B:** Docetaxel	▪ **ARM E** (1L CRC): divarasib + cetuximab + FOLFOX ▪ **ARM F** (2L CRC): divarasib + cetuximab
Primary endpoint	▪ Safety	▪ Progression-free survival	▪ Safety
Status	▪ FPI Q3 2020 ▪ Data presented at WCLC 2022, ESMO 2022	▪ BTD granted by FDA Q3 2022 ▪ FPI Q4 2022	▪ FPI Q1 2023
CT Identifier	NCT04449874	NCT03178552	NCT04929223

*Only cohorts with active recruitment shown; NSCLC=Non-small cell lung cancer; WCLC=World Conference on Lung Cancer; ESMO=European Society for Medical Oncology; BTD=Breakthrough therapy designation, CRC=Colorectal cancer

Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)

A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein

Indication	1L NSCLC
Phase/study	**Phase Ib** **KRASCENDO 170**
# of patients	N=60
Design	▪ Combination of divarasib and pembrolizumab in 1L PD-L1+ metastatic NSCLC
Primary endpoint	▪ Safety, tolerability
Status	▪ FPI Q2 2023
CT Identifier	NCT05789082

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand

Crovalimab (RG6107, SKY59)

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=89 (ARMs A/B)
Design	Healthy volunteers and treatment naïve and pretreated patients with PNH: ▪ **Part I:** Single ascending dose study in healthy subjects ▪ **Part II:** Intra-patient single ascending dose study in PNH patients ▪ **Part III:** Multiple-dose study in PNH patients ▪ **Part IV:** 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	▪ Safety
Status	▪ 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 ▪ Study results in Q1 2023 supported the favorable benefit-risk profile of crovalimab, as seen in the pivotal COMMODORE 2 study ▪ Data presented at EHA 2023 ▪ Filed in US and EU Q2 2023
CT Identifier	NCT03157635	NCT04432584

In collaboration with Chugai

ASH=American Society of Hematology; PNH=Paroxysmal nocturnal hemoglobinuria; PK/PD=Pharmacokinetics/Pharmacodynamics

Crovalimab (RG6107, SKY59)

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=204	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 ▪ Recruitment completed Q2 2022 ▪ Study met its primary endpoint Q1 2023 ▪ Data presented at EHA 2023 ▪ Filed in US and EU Q2 2023	▪ FPI Q1 2021; Recruitment completed Q3 2021 ▪ Study met its co-primary endpoints Q1 2022 ▪ Filed in China (priority review) Q3 2022 ▪ Data presented at ASH 2022
CT Identifier	NCT04434092	NCT04654468

In collaboration with Chugai

LDH=Lactate Dehydrogenase; ULN=Upper Limit of Normal; IV=Intravenous; SC=Subcutaneous, ASH=American Society of Hematology

Crovalimab (RG6107, SKY59)

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 ▪ **Cohort 3:** previously treated with C5i (includes participants with known C5 polymorphism)
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

In collaboration with Chugai
aHUS=Atypical Hemolytic Uremic Syndrome; C5i=C5 inhibitor; TMA=thrombotic microangiopathy

Crovalimab (RG6107, SKY59)

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

VOC=Vaso-occlusive crises

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Lupus nephritis (LN)
Phase/study	**Phase I**
# of patients	N=15
Design	▪ Single-arm study of patients with active class III, IV, or V lupus nephritis and urine protein-to-creatinine ratio >=1.5 g/g ▪ All patients to receive crovalimab IV loading dose and subsequent crovalimab SC q1w (Day 1, Week 1,2 and 3) followed by corvalimab SC q4w
Primary endpoint	▪ PK, safety
Status	▪ FPI Q1 2023
CT Identifier	ISRCTN12809537

In collaboration with Chugai
IV=Intravenous, SC=Subcutaneous, PK=Pharmacokinetics

Astegolimab (RG6149, Anti-ST2)

A monoclonal antibody that selective binds to ST2

Indication	Chronic obstructive pulmonary disease (COPD)		
Phase/study	**Phase II** **COPD-ST2OP**	**Phase IIb** **ALIENTO**	**Phase III** **ARNASA**
# of patients	N=81	N=1,290	N=1,290
Design	▪ Astegolimab SC 490mg q4w for 48 weeks	▪ **ARM A:** SC astegolimab q2w ▪ **ARM B:** SC astegolimab q4w ▪ **ARM C:** SC placebo q2w	▪ **ARM A:** SC astegolimab q2w ▪ **ARM B:** SC astegolimab q4w ▪ **ARM C:** SC placebo q2w
Primary endpoint	▪ Number of moderate to severe exacerbation	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period
Status	▪ Published in Lancet Respir Med 2022;10(5):469-477. doi: 10.1016/S2213-2600(21)00556-7	▪ FPI Q4 2021	▪ FPI Q1 2023
CT Identifier	NCT03615040	NCT05037929	NCT05595642

In collaboration with Amgen
COPD=Chronic obstructive pulmonary disease, SC=Subcutaneous

Crenezumab (RG7412)

Humanized monoclonal antibody targeting all forms of Aß

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 or IV ▪ **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	▪ Study did not meet its co-primary endpoints Q2 2022 ▪ Data presented at AAIC 2022 ▪ All carriers receive crenezumab
CT Identifier	NCT01998841

In collaboration with AC Immune

Ab=amyloid-beta; SC=Subcutaneous; IV=Intravenous

Tominersen (RG6042, HTT ASO)

Antisense oligonucleotide (ASO) targeting human HTT mRNA

Indication	Huntington's disease
Phase/study	**Phase II** **GENERATION HD2**
# of patients	N=360
Design	Patients aged 25 to 50 years with prodromal (very early subtle signs of HD) or early manifest HD ▪ **ARM A:** Tominersen 60mg q16w via a lumbar puncture ▪ **ARM B:** Tominersen 100mg q16w via a lumbar puncture ▪ **ARM C:** Placebo q16w via a lumbar puncture
Primary endpoint	▪ Safety, biomarkers and efficacy
Status	▪ FPI Q1 2023
CT Identifier	NCT05686551

In collaboration with Ionis Pharmaceuticals
HD=Huntington's Disease; HTT=Huntingtin

Fenebrutinib (RG7845, GCD-0853)

Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple 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

IV=Intravenous; cCDP12=Composite 12-week confirmed disability progression

Fenebrutinib (RG7845, GCD-0853)

Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Relapsing multiple sclerosis (RMS)
Phase/study	**Phase II (Biomarker study)** **FENopta**
# of patients	N=109
Design	▪ **ARM A:** Fenebrutinib ▪ **ARM B:** Placebo
Primary endpoint	▪ Total number of new gadolinium-enhancing T1 lesions observed on MRI scans of the brain at 12 weeks
Status	▪ Data presented at EAN 2023
CT Identifier	NCT05119569

MRI=Magnetic resonance imaging; EAN=European Academy of Neurology

Balovaptan (RG7314)

Small molecule antagonist of the V1A vasopressin receptor

Indication	Post-traumatic stress disorder (PTSD)
Phase/study	**Phase II**
# of patients	N=30
Design	▪ **ARM A:** Balovaptan IV once a day for 12 weeks ▪ **ARM B:** Placebo
Primary endpoint	▪ Change from baseline in the Clinician-Administered PTSD Total Symptom Severity Score
Status	▪ FPI Q3 2022
CT Identifier	NCT05401565

PTSD=Post-traumatic stress disorder; IV=Intravenous

Latent myostatin (RG6237, GYM329)

Recycling and antigen-sweeping monoclonal anti-latent myostatin antibody

Indication	Facioscapulohumeral Muscular Dystrophy (FSHD)	Spinal muscular atrophy (SMA)
Phase/study	**Phase II** **MANOEUVRE**	**Phase II/III** **MANATEE**[1]
# of patients	N=48	N=180
Design	▪ **ARM A:** 4-week pre-treatment to collect baseline movement data with a wearable device, followed by latent myostatin ▪ **ARM B:** Placebo	**ARM A:** ▪ **Part I**: GYM329 plus Evrysdi for 24 weeks, followed by GYM329 plus Evrysdi for 72 weeks ▪ **Part II:** GYM329 plus Evrysdi for 72 weeks **ARM B:** ▪ Placebo plus Evrysdi
Primary endpoint	▪ Percent change in contractile muscle volume of quadriceps femoris muscles by MRI at week 52 and safety	▪ Change from baseline in RHS score after week 72 of treatment ▪ Safety, PK/PD and muscle biomarkers
Status	▪ FPI Q1 2023	▪ ODD granted by FDA in Q4 2021 for GYM329 ▪ FPI Part I ambulatory cohort Q2 2022; non-ambulatory cohort July 2023
CT Identifier	NCT05548556	NCT05115110

[1] In collaboration with PTC Therapeutics and SMA Foundation

PK/PD=Pharmacokinetics/Pharmacodynamics; ODD=Orphan drug designation; RHS=Revised hammersmith scale ; MRI=Magnetic Resonance Imaging

Anti-IL-6 (RG6179)

A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine

Indication	Diabetic macular edema (DME) and Uveitic macular edema (UME)	Diabetic macular edema (DME)	
Phase/study	**Phase I** **DOVETAIL**	**Phase II** **BARDENAS**	**Phase II** **ALLUVIUM**
# of patients	N=90	N=210-230	N=360-400
Design	▪ Part I: Multiple ascending dose study of intravitreal monotherapy ▪ Part II: monotherapy and in combination with anti-VEGF	▪ **ARM A:** Anti-IL-6 plus ranibizumab ▪ **ARM B:** Ranibizumab plus sham control	▪ **Arm A:** 0.25 mg anti-IL-6 q8w ▪ **Arm B:** 1.0 mg anti-IL-6 q8w ▪ **Arm C:** 1.0 mg anti-IL-6 q4w ▪ **Arm D**: 0.5 mg ranibizumab q4w
Primary endpoint	▪ Safety, tolerability, PK	▪ Mean change from baseline in BCVA averaged over week 44 and week 48	▪ Mean change from baseline in BCVA averaged over week 44 and week 48
Status	▪ FPI Q3 2019 ▪ Data presentation at ARVO 2023	▪ FPI Q4 2021	▪ FPI Q4 2021
CT Identifier		NCT05151744	NCT05151731

PK=Pharmacokinetics; BCVA=Best corrected visual acuity, ARVO=Association for Research in Vision & Ophthalmology

Anti-IL-6 (RG6179)

A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine

Indication	Uveitic macular edema (UME)	
Phase/study	**Phase III MEERKAT**	**Phase III SANDCAT**
# of patients	N=225	N=225
Design	▪ **ARM A:** Anti-IL-6 low-dose q4w to week 12, followed by PRN ▪ **ARM B:** Anti-IL-6 high-dose q4w to week 12, followed by PRN ▪ **ARM C:** Sham control q4w to week 12,followed by PRN	▪ **ARM A:** Anti-IL-6 low-dose q4w to week 12, followed by PRN ▪ **ARM B:** Anti-IL-6 high-dose q4w to week 12, followed by PRN ▪ **ARM C:** Sham control q4w to week 12,followed by PRN
Primary endpoint	▪ Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16	▪ Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16
Status	▪ FPI Q1 2023	▪ FPI Q1 2023
CT Identifier	NCT05642312	NCT05642325

BCVA=Best corrected visual acuity; PRN= Pro re nata

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Marketed products development programmes

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Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

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pRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
FAP-4-1BBL (RG7827)	Solid tumors	I	~150	FPI Q2 2018 Data presented at ESMO 2020 Recruitment completed Q2 2021	
	3L+ MSS mCRC	Ib	80	FPI Q3 2021 Combination study with cibisatamab	NCT04826003
cibisatamab (CEA x CD3, RG7802)	CEA-positive solid tumors	Ia	149	FPI Q4 2014 Data presented at ASCO 2017	NCT02324257
		Ib	228	FPI Q1 2016 Data presented at ASCO 2017	NCT02650713
	3L+ MSS mCRC	Ib	46	FPI Q1 2019	NCT03866239
tobemstomig PD1-LAG3 (RG6139)	Solid tumors	I	320	FPI Q4 2019 Data presented at ESMO 2022 Recruitment completed Q4 2022	NCT04140500
	advanced or metastatic esophageal squamous cell cancer	II	210	FPI Q2 2021 Randomized trial, compared with nivolumab	NCT04785820 TALIOS
	Untreated unresectable or metastatic melanoma	II	80	FPI Q3 2022	NCT05419388
	Non-small cell lung cancer	II	180	FPI Q1 2023	NCT05775289
	advanced and metastatic urothelial cancer	II	240	FPI Q2 2023	NCT05645692
	Metastatic renal cell carcinoma	II	210	FPI Q2 2023	NCT05805501

pRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
englumafusp alfa (CD19-4-1BBL, RG6076)	R/R B cell non-Hodgkin's lymphoma	I	362	Part I: FPI Q3 2019 Part II: FPI Q3 2020 Combination study with Columvi Data presented at ASH 2022 and ICML 2023	NCT04077723
eciskafusp alfa (PD1-IL2v, RG6279)	Solid tumors	Ib	348	Part I: FPI Q2 2020; recruitment completed Q4 2021 Part II: FPI Q1 2022 Part III: FPI Q1 2023	NCT04303858
CD25 (RG6292)	Solid tumors	I	110	FPI Q4 2019 PK/PD data presented at AACR 2023	NCT04158583
forimtamig (Anti-GPRC5D, RG6234)	Multiple myeloma	I	400	FPI Q4 2020 Data presented at EHA 2022 and ASH 2022	NCT04557150
FAP-CD40 (RG6189)	Solid tumors	I	280	FPI Q2 2021	NCT04857138
BRAFi (3) (RG6344)	Solid tumors	I	292	FPI Q1 2022	ISRCTN13713551
CD19xCD28 (RG6333)	R/R B cell non-Hodgkin's lymphoma	I	~200	FPI Q1 2022 Combination study with Columvi	NCT05219513
EGFRvIIIxCD3 (RG6156)	Glioblastoma	I	~200	FPI Q2 2022	NCT05187624
DLL3 trispecific (RG6524)	Solid tumors	I	168	FPI Q1 2023	NCT05619744
HLA-G CD3 TCB (RG6353)	Solid tumors	I	150	FPI Q2 2023	NCT05769959

pRED neuroscience development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
trontinemab (BS-gantenerumab, RG6102)	Alzheimer's disease	IIa	~120	FPI Q1 2021	NCT04639050
Brain Shuttle-CD20 (BS-CD20, RG6035)	Multiple sclerosis	I	30-63	FPI Q3 2021	ISRCTN16295177 NCT05704361
ralmitaront (partial TAAR1 agonist, RG7906)	Schizophrenia	II	36	FPI Q4 2018 Recruitment completed Q3 2019	
		II	247	FPI Q4 2019 An interim analysis of TWAIN I did not show evidence of clinical benefit in patients that have negative symptoms of schizophrenia.	NCT03669640 (TWAIN I)
prasinezumab[1] (anti-αSynuclein, RG7935, PRX002)	Parkinson's disease	II	316	The study did not meet its primary endpoint, but showed a reduced clinical decline of core motor signs (MDS UPDRS partIII). Data presented at MDS & ADPD 2020-22. The Open Label Extension is ongoing.	NCT03100149 (PASADENA)
		IIb	575	FPI Q2 2021 Recruitment completed Q1 2023	NCT04777331 (PADOVA)
alogabat (GABA-Aa5 PAM, RG7816)	Autism spectrum disorder	II	105	FPI Q1 2021	NCT04299464 (Aurora)

Partner: [1]Prothena
BS=Brain Shuttle

pRED neuroscience development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
rugonersen (UBE3A LNA, RG6091)	Angelman syndrome	I	66	FPI Q3 2020	NCT04428281
MAGLi (RG6182)	Multiple sclerosis	I	Up to 36	FPI July 2023	
NME (RG6289)	Alzheimer's disease	I	138	FPI Q4 2021	
NME (RG6163)	Psychiatric disorders	I	84	FPI Q1 2022	
selnoflast* (NLRP3i, RG6418)	Parkinson's disease	Ib	48	FPI Q3 2022	
basmisanil (GABA-Aa5 NAM, RG1662)	Dup15q syndrome	II	90	FPI Q4 2022	NCT05307679

*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022

pRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
selnoflast* (NLRP3i, RG6418)	Chronic obstructive pulmonary disease	Ib	102	FPI Q2 2022 Study closed Q3 2022	
Ophthalmology					
zifibancimig (VEGF-Ang2 DutaFab, RG6120)	nAMD	I	251	FPI Q4 2020	NCT04567303 (BURGUNDY)
vicasinabin (CB2 receptor agonist, RG7774)	DR	II	135	FPI Q2 2020 Recruitment completed Q3 2022	NCT04265261 (CANBERRA)
NME (RG6209)	retinal disease	I	~70 (Part I)	FPI Q4 2022	

*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022

pRED infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Infectious Diseases					
ruzotolimod (TLR7 agonist (3) RG7854)	Chronic hepatitis B	I	150	FPI Q4 2016 Data presented at APASL 2019	NCT02956850
ruzotolimod/ xalnesiran/ PDL1 LNA (RG7854/RG6346/RG6084)	Chronic hepatitis B	II	275	FPI Q3 2020	NCT04225715 (PIRANGA)
PDL1 LNA (RG6084)	Chronic hepatitis B	I	35	FPI Q1 2019 Part Ia: completed Part Ib: initiated	
zosurabalpin (Abx MCP, RG6006)	A. baumannii infections	I	204	FPI Q4 2020	NCT04605718
HBsAg MAb (RG6449)	Chronic hepatitis B	I	110	FPI Q2 2023	NCT05763576

Abx MCP=antibiotic macrocyclic peptide

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gRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
cevostamab (anti-FcRH5 x CD3; RG6160)	R/R multiple myeloma	I	300	FPI Q3 2017 Data presented at ASH 2020, 2021 & 2022	NCT03275103
	R/R multiple myeloma	I	120	FPI Q2 2021	NCT04910568
	BCMA-experienced R/R MM	I/II	140	FPI Q4 2022	NCT05535244
runimotamab (HER2 x CD3, RG6194)	Metastatic HER2-expressing cancers	I	440	FPI Q2 2018	NCT03448042
NME (RG6286)	Locally advanced or metastatic colorectal cancer	I	67	FPI Q3 2020	NCT04468607
IL15/IL15Ra-Fc (RG6323)[1]	Solid tumors	Ia/Ib	250	FPI Q1 2020	NCT04250155
	R/R multiple myeloma	I	60	FPI Q2 2022	NCT05243342
	R/R multiple myeloma	I	90	FPI Q1 2023 Combination study with cevostamab	NCT05646836
autogene cevumeran (Individualized Neoantigen-Specific Therapy (iNeST); RG6180)[2]	Solid tumors	Ia/Ib	272	FPI Q4 2017 Data presented at AACR 2020 Recruitment completed Q1 2022	NCT03289962
	1L advanced melanoma	II	131	FPI Q1 2019	NCT03815058 (IMcode001)

Partner: [1]Xencor, [2]BioNTech

gRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
SHP2i (RG6433)[1]	Solid tumors	Ib	~125	FPI Q3 2022	NCT05487235
	KRAS-G12C mutant solid tumors	Ib	~500	FPI Q4 2021 Arm F of a combination study investigating divarasib monotheraphy and combinations	NCT04449874
belvarafenib (RG6185)[2]	nRASmt CPI-experienced melanoma	Ib	83	FPI Q2 2021 Data presented at ESMO 2021	NCT04835805
NME (RG6411)	Solid tumors	I	110	FPI Q4 2022	NCT05581004
AR degrader (RG6537)[3]	mCRPC	I	~160	FPI Q2 2023	NCT05800665

Partner: [1]Relay, [2]Hanmi, [3]Jemincare

gRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
NME (RG6287, GDC-8264)	Acute graft versus host disease	Ib	40	FPI Q2 2023	NCT05673876
NME (RG6315, MTBT1466A)	Immunologic disorders	I	~24	FPI Q3 2020 Recruitment completed Q2 2022	
	Systemic sclerosis	Ib	100	FPI Q1 2023	NCT05462522
NME (RG6341, GDC-6599)	Asthma	Ia/Ib	84	FPI Q4 2021	
	Chronic cough	IIa	80	FPI Q1 2023	NCT05660850
TMEM16A potentiator (RG6421, GDC-6988)	Cystic fibrosis	Ib	30	FPI Q3 2022 Recruitment completed Q2 2023	ISRCTN15406513
Vixarelimab (RG6536)[1]	Idiopathic pulmonary fibrosis / Systemic sclerosis-sssociated interstitial lung disease	II	~290	FPI Q2 2023	NCT05785624
Ophthalmology					
NME (RG6351)	DME	I	42-78	FPI Q2 2022	ISRCTN14152148
OpRegen (RG6501)[2]	Geographic atrophy	II	60	FPI Q1 2023	NCT05626114

Partner: [1]Kiniksa Pharmaceuticals, [2]Lineage Cell Therapeutics

gRED neuroscience and infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
semorinemab (RG6100)[1]	Mild-to-moderate Alzheimer's disease	II	272	FPI Q1 2019 One of two co-primary endpoints met Q3 2021 Data presented at CTAD 2021 The Open Label Extension is ongoing	NCT03828747 (LAURIET)
Infectious Diseases					
LepB inhibitor (RG6319)	Complicated urinary tract infection	I	32	FPI Q1 2023	

Partner: [1]AC Immune

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Hemophilia A

Unique gene therapy platform

Molecule	Dirloctogene Samoparvovec (SPK-8011) (RG6357)	
Indication	**Hemophilia A**	
Phase/study	**Phase I**	**Phase I/II**
# of patients	N=100	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
Primary endpoint	▪ Safety	▪ Safety and changes from baseline in FVIII activity levels at week 52
Status	▪ Ongoing	▪ Updated data presented at ISTH 2020 and 2021 ▪ Recruitment completed Q1 2021 ▪ Data published in *NEJM* 2021; 385:1961-1973 ▪ 5-year data published at ASH 2022
CT Identifier	NCT03432520	NCT03003533

ISTH=International Society on Thrombosis and Haemostasis; NEJM=New England Journal of Medicine

Pompe disease

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 ▪ Recruitment completed Q2 2022
CT Identifier	NCT04093349

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Spark

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Foreign exchange rates information

Geographical sales split by Divisions and Group*

CHFm	HY 2022	HY 2023	% change CER
Pharmaceuticals Division	**22,347**	**22,681**	**+8**
United States	11,363	11,743	+7
Europe	4,104	4,105	+5
Japan	2,202	2,210	+14
International	4,678	4,623	+9
Diagnostics Division	**9,948**	**7,098**	**-23**
United States	2,511	1,745	-28
Europe	2,799	1,932	-27
Japan	380	287	-14
International	4,258	3,134	-19
Group	**32,295**	**29,779**	**-2**
United States	13,874	13,488	+1
Europe	6,903	6,037	-8
Japan	2,582	2,497	+10
International	8,936	7,757	-4

CER=Constant Exchange Rates; * Geographical sales split shown here does not represent operational organization

Pharma Division sales HY 2023

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	3'200	15	2'346	13	584	13	-	-	270	28
Hemlibra	2'087	20	1'247	18	419	22	192	21	229	34
Perjeta	2'082	9	763	7	413	-5	109	3	797	20
Tecentriq	1'853	12	1'000	9	398	9	214	11	241	28
Actemra / RoActemra	1'296	-6	574	-11	383	-4	157	3	182	1
Xolair	1'031	4	1'031	4	-	-	-	-	-	-
Kadcyla	1'001	0	386	-4	298	-10	52	-13	265	24
Vabysmo	957	*	788	*	103	*	46	*	20	*
MabThera	882	-17	534	-20	96	-4	13	-14	239	-13
Herceptin	878	-19	176	-31	183	-17	17	-32	502	-14
Avastin	837	-21	256	-23	57	-48	177	-23	347	-10
Alecensa	758	10	221	11	148	4	107	6	282	14
Evrysdi	705	48	255	16	241	66	45	34	164	105
TNKase / Activase	621	15	592	15	-	-	-	-	29	12
Ronapreve	550	2	-	-	-	-100	549	33	1	-99
Phesgo	517	69	209	57	240	57	-	-	68	216
Gazyva	402	22	194	25	111	24	20	-17	77	28
Polivy	353	114	124	65	80	84	108	182	41	339
Lucentis	299	-46	299	-46	-	-	-	-	-	-
Pulmozyme	238	-10	158	-11	39	-18	-	5	41	3
Pharma Division	**22'681**	**8**	**11'743**	**7**	**4'105**	**5**	**2'210**	**14**	**4'623**	**9**

CER=Constant Exchange Rates; *over 500%

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q1/22	Q2/22	Q3/22	Q4/22	Q1/23	Q2/23
Ocrevus	18	17	16	18	14	15
Hemlibra	30	31	23	24	24	17
Perjeta	1	9	5	4	11	6
Tecentriq	8	13	9	24	15	8
Actemra / RoActemra	3	-23	-42	-22	-12	2
Xolair	9	13	8	6	5	4
Kadcyla	9	18	6	-3	5	-5
Vabysmo	-	-	-	-	*	*
MabThera	-21	-20	-19	-20	-17	-17
Herceptin	-19	-11	-23	-22	-17	-22
Avastin	-32	-27	-28	-25	-24	-17
Alecensa	23	16	11	10	9	11
Evrysdi	189	65	93	59	62	36
TNKase / Activase	-20	1	-5	-27	23	9
Ronapreve	272	-91	-92	118	9	-98
Phesgo	410	168	76	73	72	67
Gazyva	7	9	9	9	24	20
Polivy	89	93	63	97	96	129
Lucentis	-26	-9	-39	-40	-35	-55
Pulmozyme	-3	2	-3	-15	-5	-15

CER (Constant exchange Rates) of the respective year; *over 500%; [1] Q1-Q4/22 vs Q1-Q4/21 at CER avg. full year 2021; Q1-Q2/23 vs Q1-Q2/22 at CER avg. full year 2022

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Ocrevus	17	15	13	14	11	26	11	16	-	-	-	-	26	29	32	23
Hemlibra	16	21	21	14	36	27	27	18	22	14	24	19	53	45	38	31
Perjeta	0	13	8	6	-15	-15	1	-12	-1	3	2	5	30	13	22	18
Tecentriq	3	20	14	5	17	23	11	7	0	6	12	11	30	70	34	23
Actemra / RoActemra	-61	-42	-22	6	-3	-14	-8	0	-4	6	0	5	-44	51	10	-9
Xolair	8	6	5	4	-	-	-	-	-	-	-	-	-	-	-	-
Kadcyla	-8	-4	-3	-5	3	-2	-6	-15	16	2	-8	-17	46	-3	42	11
Vabysmo	-	-	*	458	-	-	-	*	-	-	-	299	-	-	-	*
MabThera	-14	-15	-21	-19	-18	-21	0	-9	-13	-23	-13	-15	-32	-28	-12	-14
Herceptin	-29	-29	-37	-23	-18	-27	-17	-18	-28	-28	-30	-34	-22	-17	-7	-22
Avastin	-31	-26	-25	-20	-47	-56	-45	-51	-19	-21	-21	-25	-23	-16	-19	1
Alecensa	22	13	7	14	5	3	3	5	4	7	5	7	9	13	14	13
Evrysdi	13	20	13	19	216	116	74	61	*	83	47	25	231	73	189	39
TNKase / Activase	-6	-29	23	9	-	-	-	-	-	-	-	-	12	20	17	8
Ronapreve	-	-	-	-	-54	-100	-100	-100	-100	313	33	-	-99	-81	-100	-97
Phesgo	62	58	62	53	107	61	59	55	-	-	-	-	20	*	232	206
Gazyva	7	11	32	18	-9	-8	25	22	-17	-12	-35	1	91	62	27	29
Polivy	57	65	35	91	88	144	93	76	34	92	169	194	135	86	340	339
Lucentis	-39	-40	-35	-55	-	-	-	-	-	-	-	-	-	-	-	-
Pulmozyme	2	-17	-5	-16	-12	-13	-16	-20	-1	38	18	-4	-16	-9	10	-5

CER (Constant exchange Rates) of the respective year; *over 500%; [1] Q3-Q4/22 vs Q3-Q4/21 at CER avg. full year 2021; Q1-Q2/23 vs Q1-Q2/22 at CER avg. full year 2022

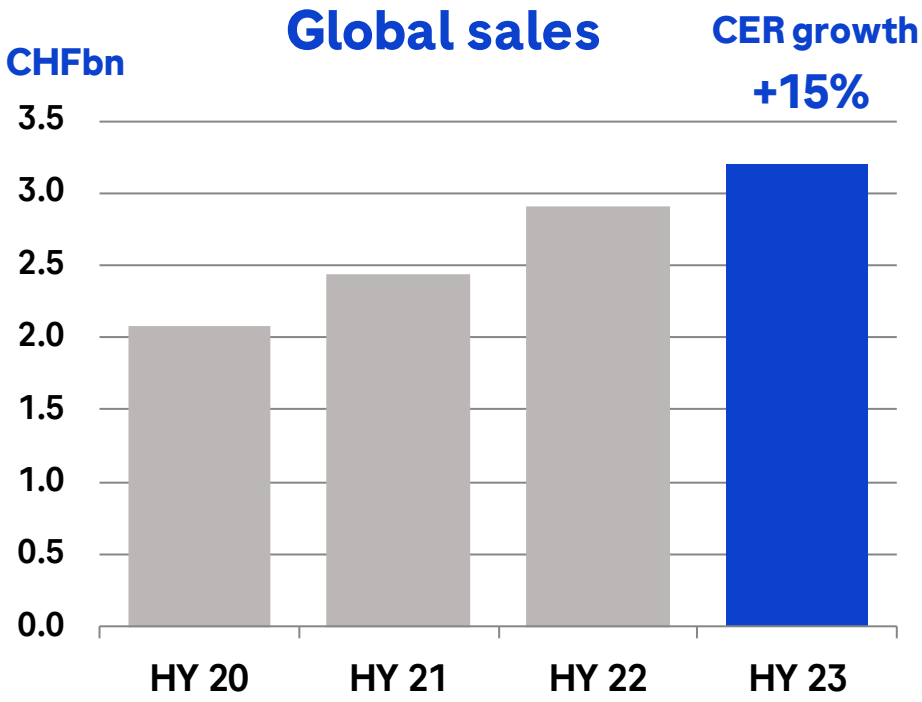
CER sales growth (%)

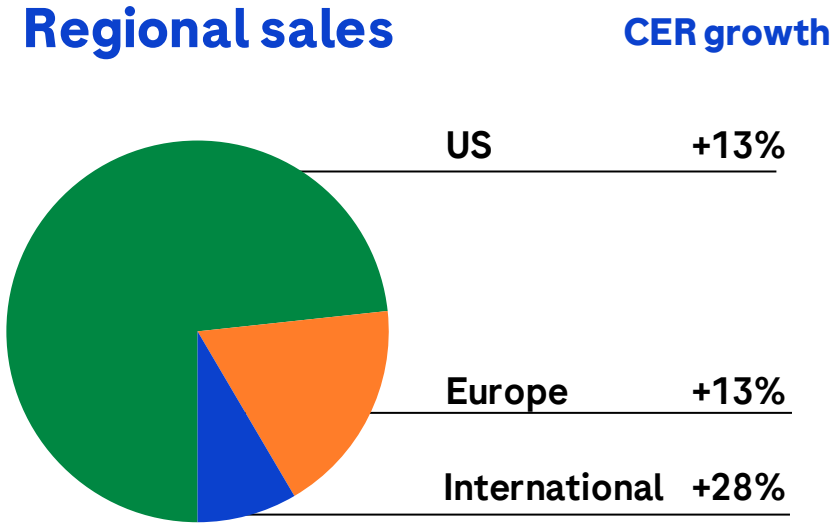
Quarterly development

	2022 vs. 2021				2023 vs. 2022	
	Q1	Q2	Q3	Q4	Q1	Q2
Pharmaceuticals Division	**6**	**0**	**-6**	**9**	**9**	**7**
United States	2	1	-6	1	6	7
Europe	-1	-6	4	-3	5	5
Japan	69	3	-27	69	18	8
International	0	4	-3	4	13	6
Diagnostics Division	**24**	**0**	**-4**	**-9**	**-28**	**-17**
Roche Group	**11**	**0**	**-6**	**4**	**-3**	**0**

CER (Constant exchange Rates) of the respective year

Ocrevus



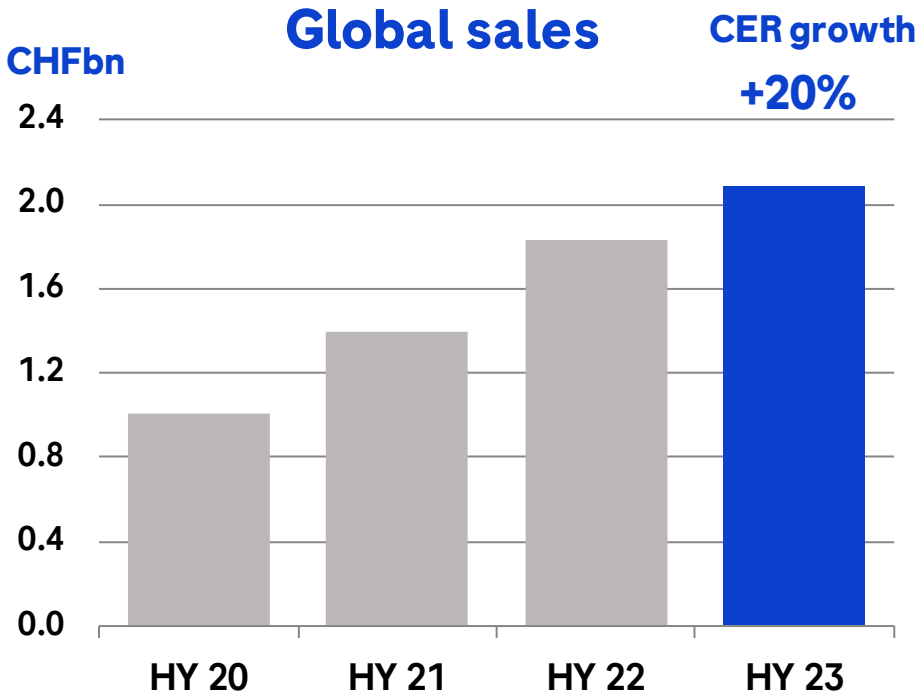


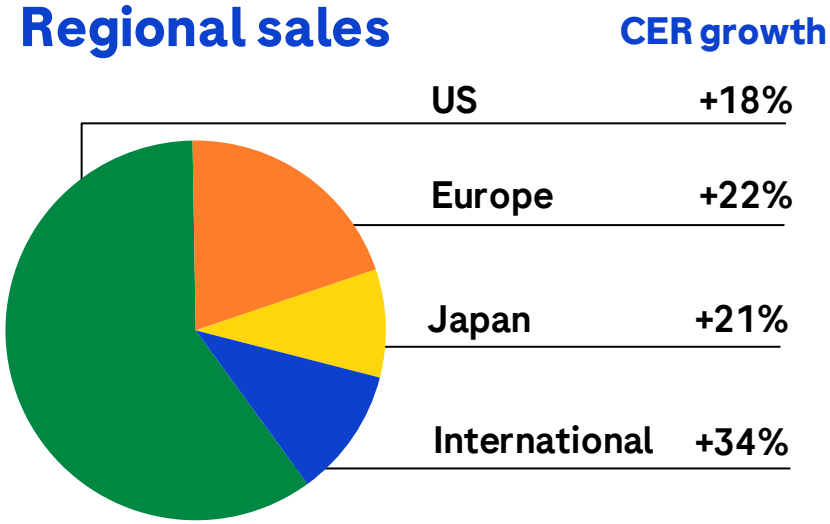
HY 2023 sales of CHF 3,200m

- US: Moving into earlier lines displacing orals; #1 in US for both dynamic and total share
- EU: Moving into earlier lines displacing orals; #1 in EU5 for both dynamic and total share

CER=Constant Exchange Rates

Hemlibra



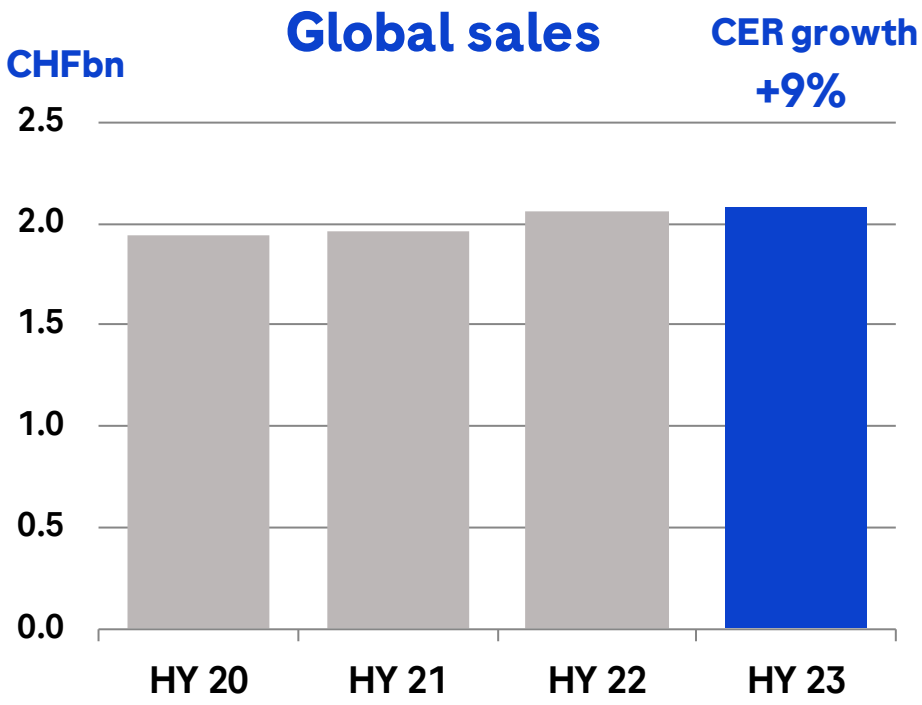


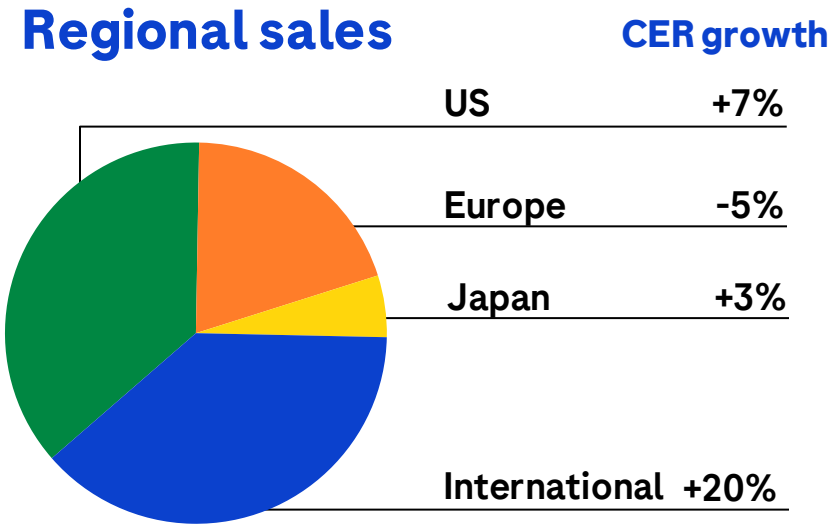
HY 2023 sales of CHF 2,087m

- US: Continued share gains in non-inhibitor patients
- EU: Continued share gains in non-inhibitor severe patients, label extension including moderate patients granted in Q1
- Japan: Strong uptake in non-inhibitor patients
- International: Accelerating momentum in all regions (LATAM, APAC, EEMEA)

CER=Constant Exchange Rates

Perjeta





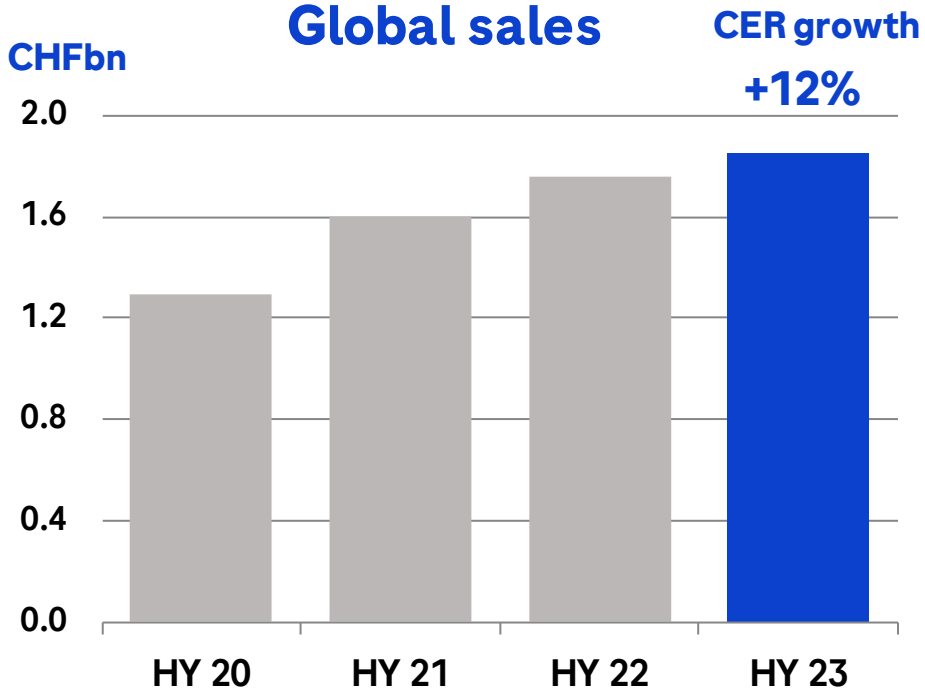
HY 2023 sales of CHF 2,082m

- US: Growth driven by eBC; increasing conversion to Phesgo
- EU: Conversion to Phesgo
- International: Strong growth in all regions (LATAM, APAC, EEMEA)

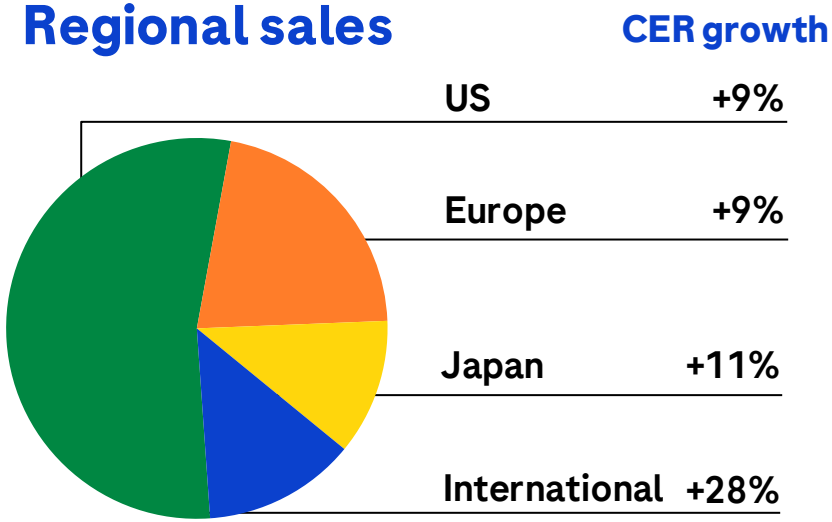
CER=Constant Exchange Rates

Tecentriq

Global sales



Regional sales

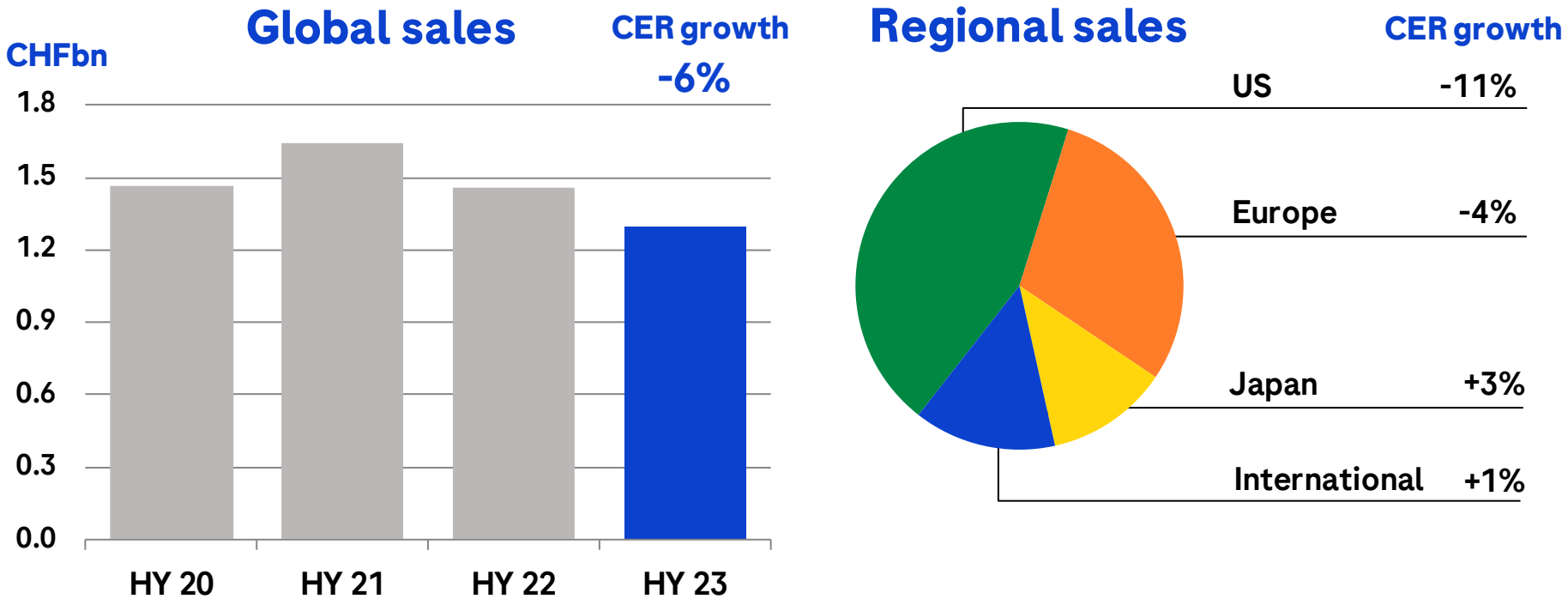


HY 2023 sales of CHF 1,853m

- US: Growth driven by adj NSCLC; 1L HCC nearing peak penetration
- EU: Growth drive by adj NSCLC and 1L HCC
- Japan: Growing share in adj NSCLC

CER=Constant Exchange Rates

Actemra / RoActemra

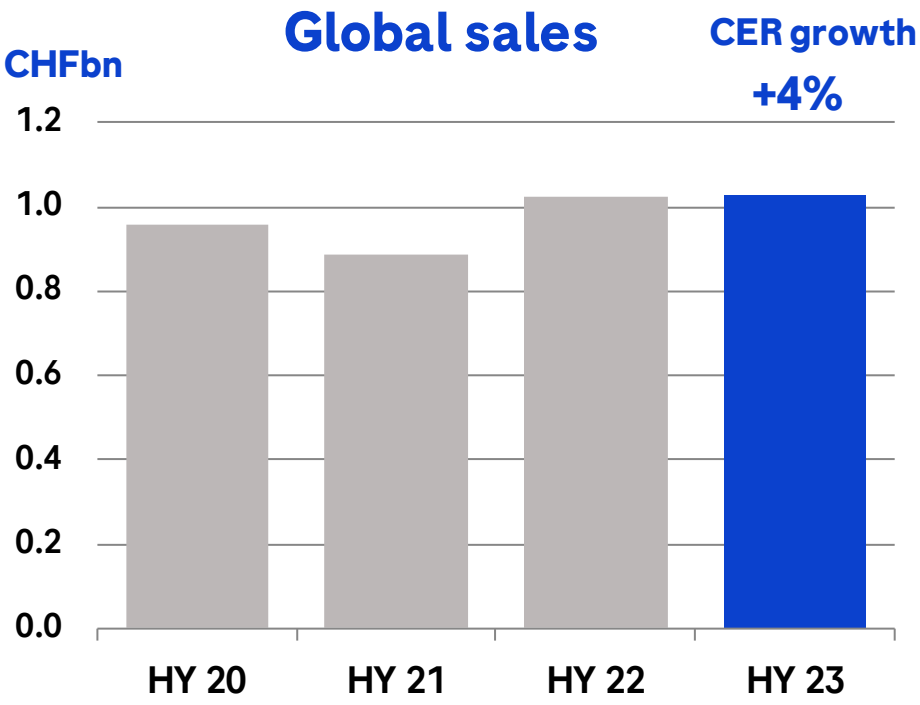


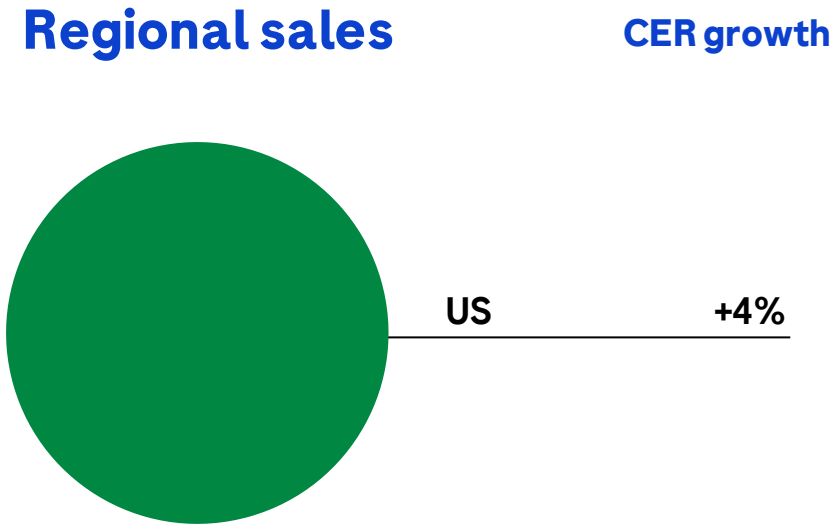
HY 2023 sales of CHF 1,296m

- US: Ongoing patient shift from Actemra IV to SC in RA; COVID-19 sales completely washed out as of Q2
- EU: Stable share of Actemra SC in RA; COVID-19 sales completely washed out as of Q2

CER=Constant Exchange Rates

Xolair



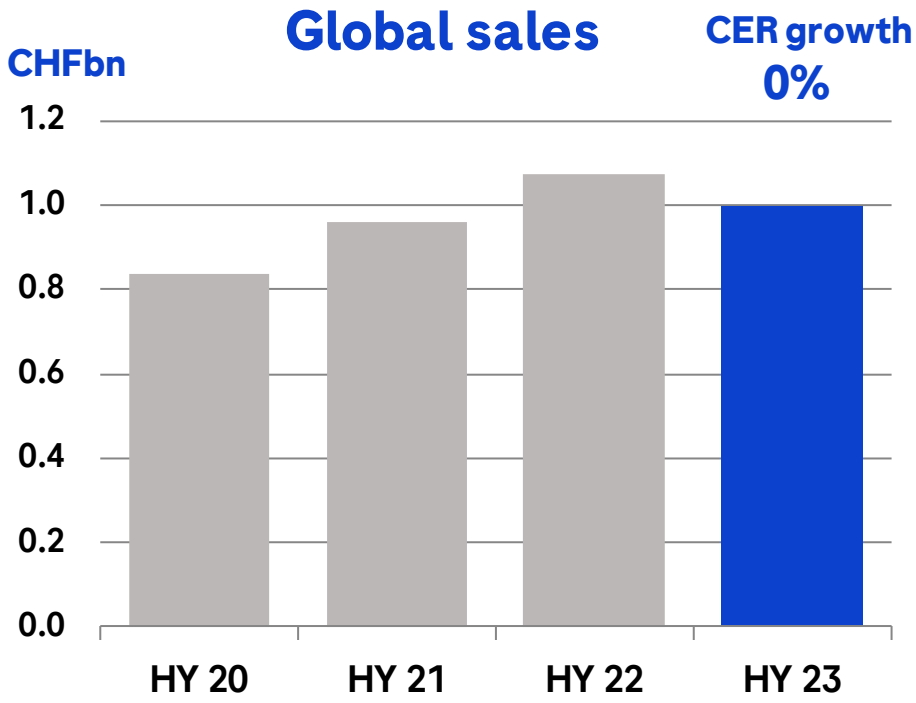


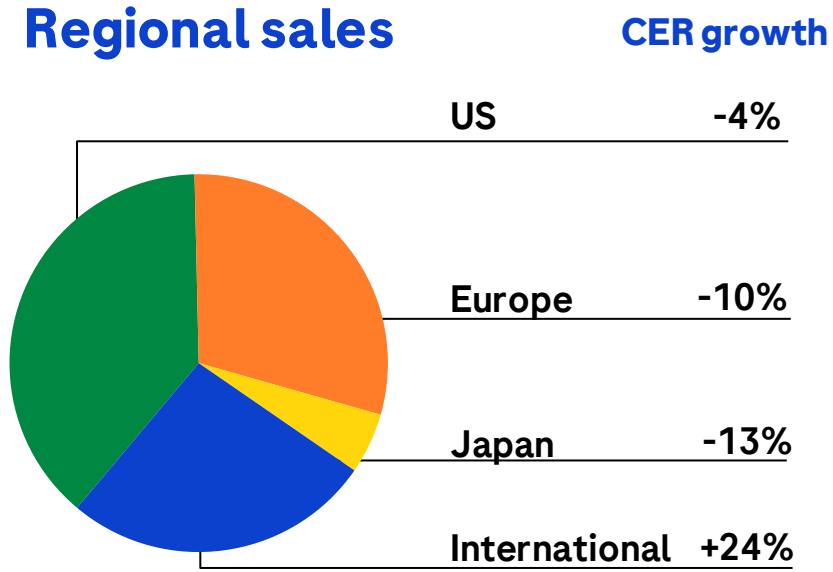
HY 2023 sales of CHF 1,031m

- US: Growth driven by growth in CSU

CER=Constant Exchange Rates

Kadcyla



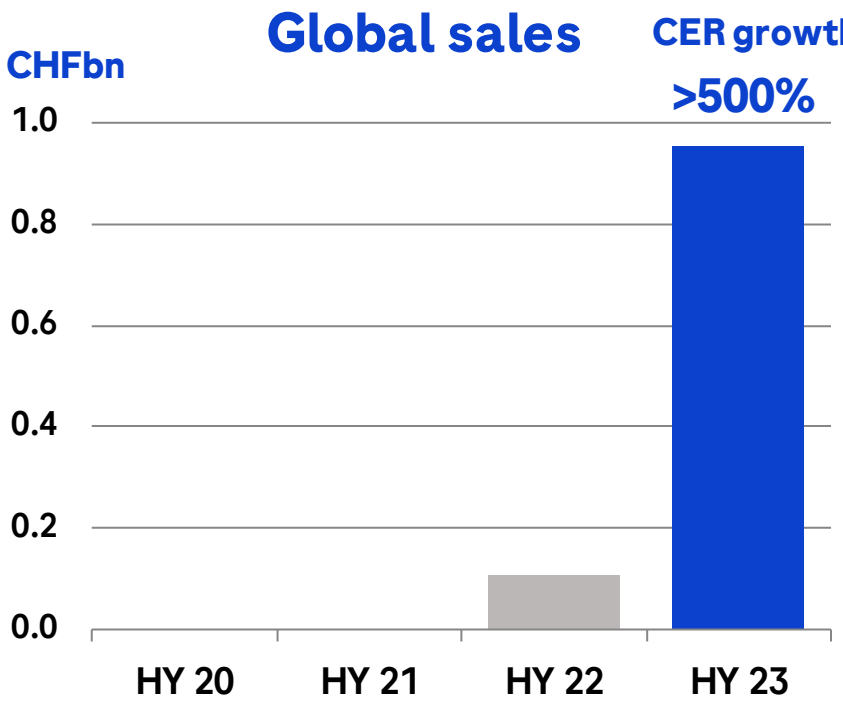


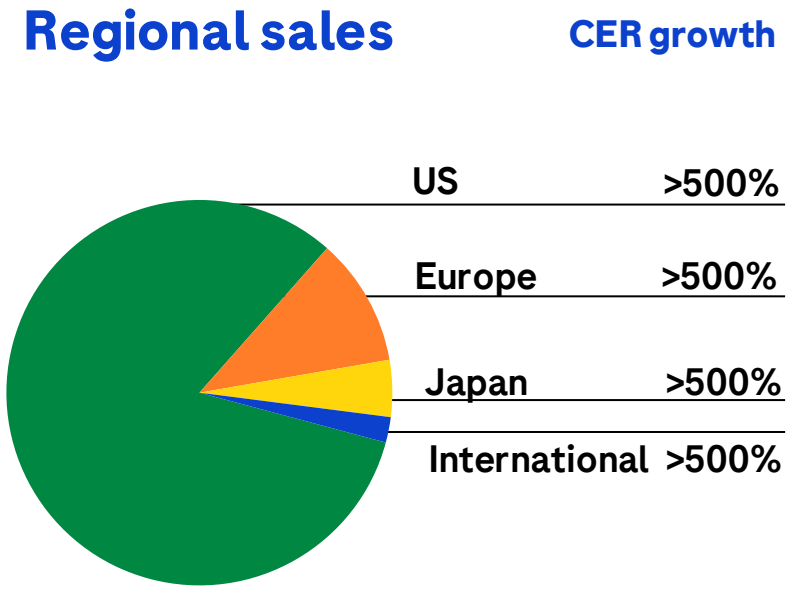
HY 2023 sales of CHF 1,001m

- US: Share decline in metastatic BC due to competition
- EU: Share decline in metastatic BC due to competition
- Japan: Share decline in metastatic BC due to competition
- International: Growth driven by uptake in eBC all regions (LATAM, EEMEA, APAC)

CER=Constant Exchange Rates

Vabysmo



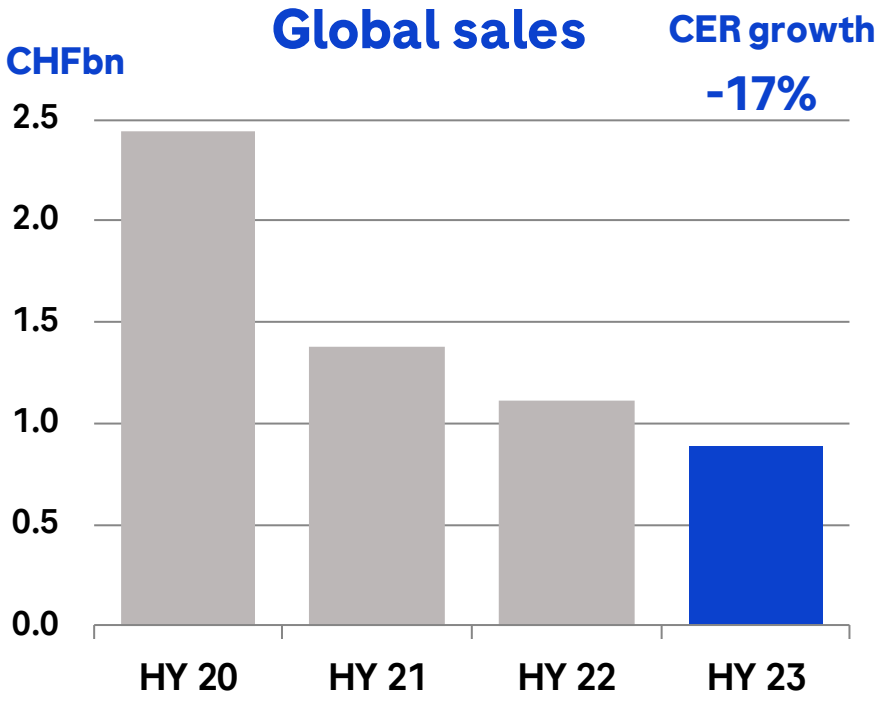


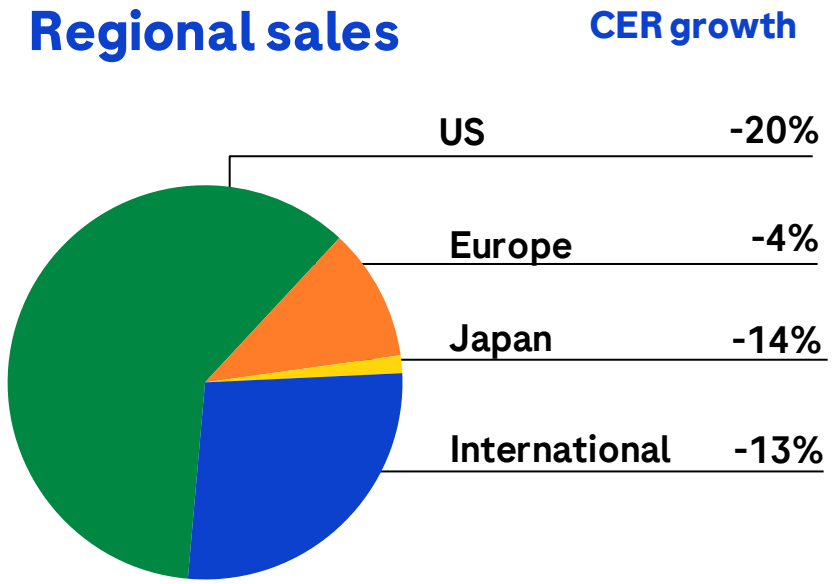
HY 2023 sales of CHF 957m

- US: Strong uptake with ~30% naïve patients, ~70% switches (mostly from aflibercept)
- EU: Similar uptake dynamics in first launch countries as seen in the US
- Japan: Double-digit market share with ~40% naïve patients

CER=Constant Exchange Rates

Rituxan / Mabthera



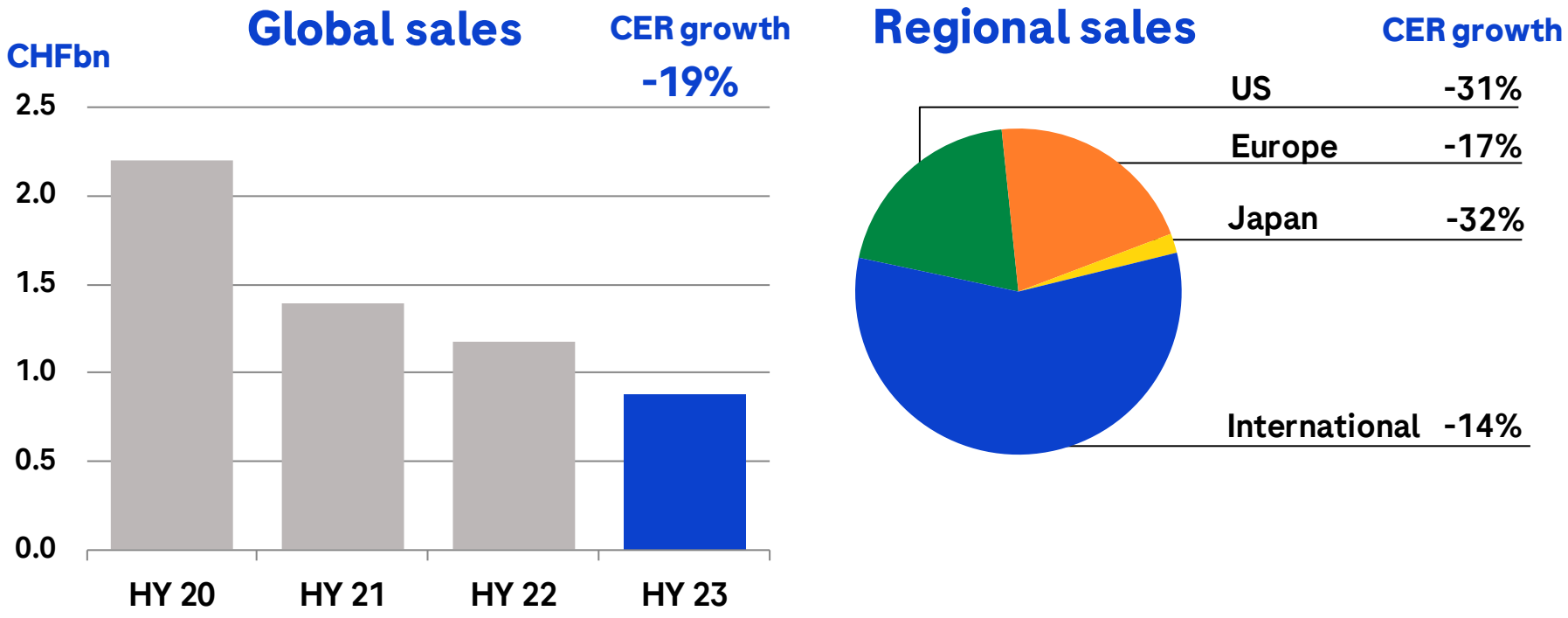


HY 2023 sales of CHF 882m

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

CER=Constant Exchange Rates

Herceptin



HY 2023 sales of CHF 878m

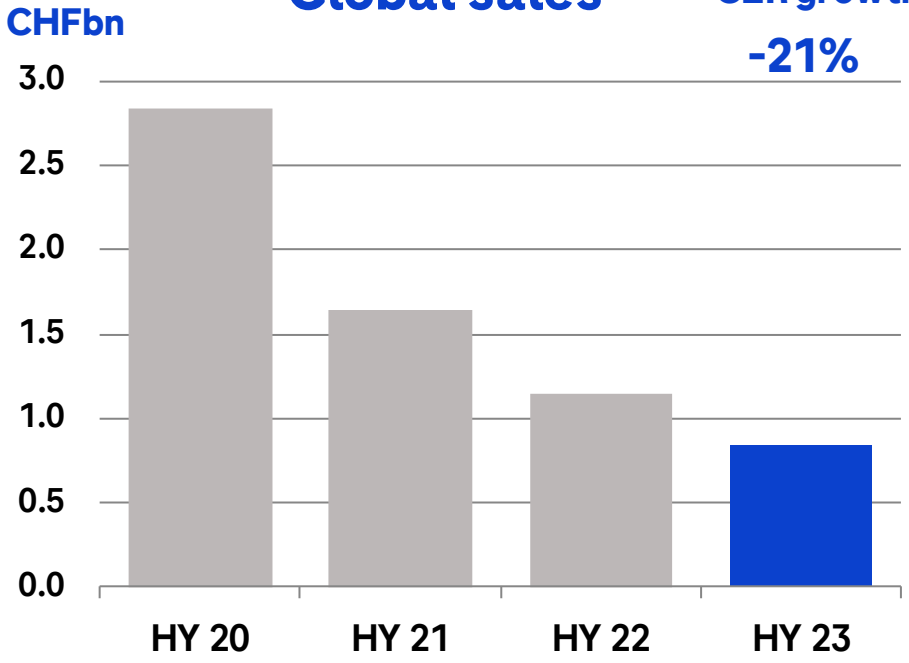
- US: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Conversion to Phesgo
- EU: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Conversion to Phesgo
- Japan: Decline due to biosimilars
- International: Decline due to biosimilars;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

CER=Constant Exchange Rates

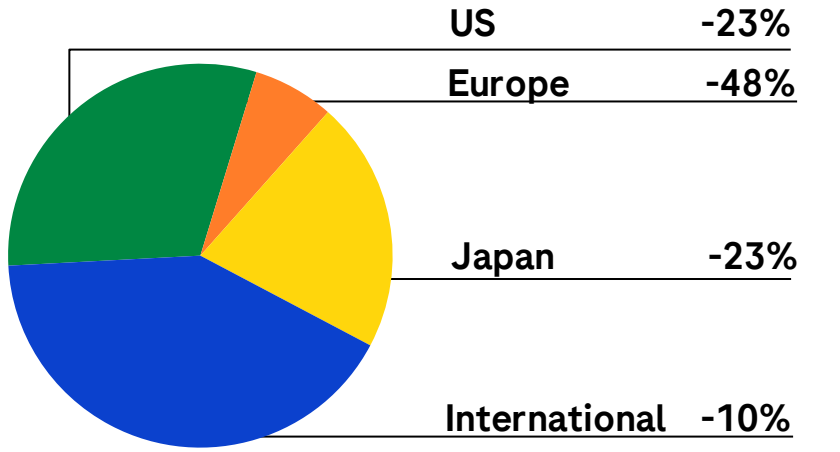
Avastin

Global sales

CER growth -21%



Regional sales

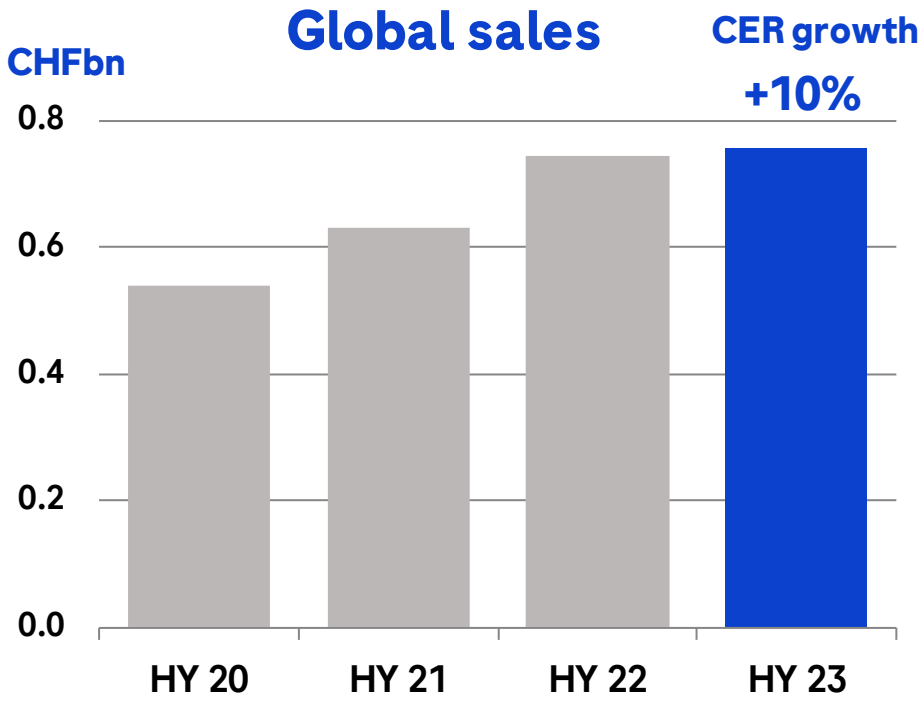


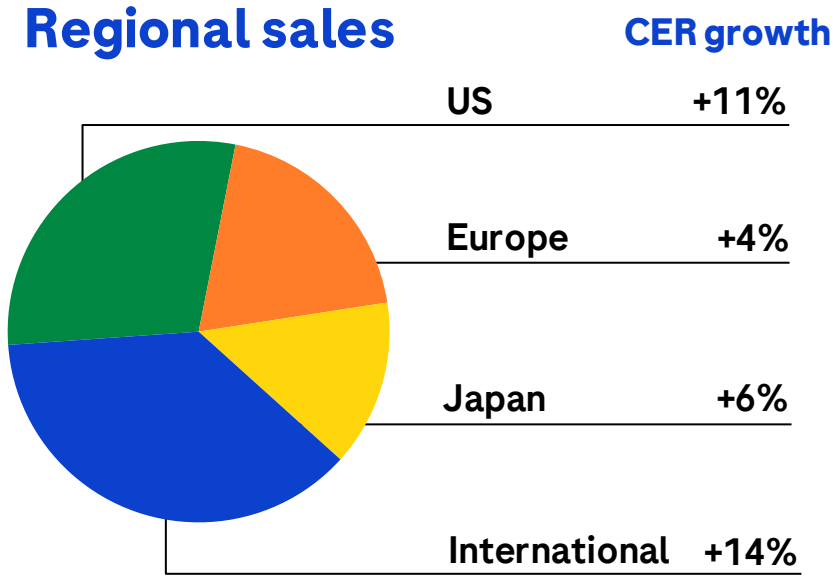
HY 2023 sales of CHF 837m

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

CER=Constant Exchange Rates

Alecensa





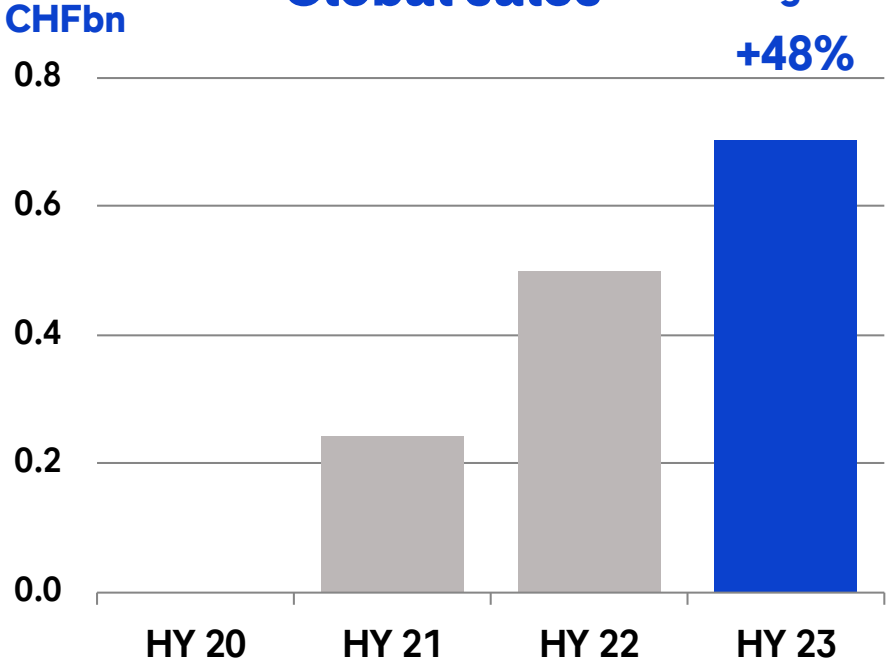
HY 2023 sales of CHF 758m

- US: Market leadership in 1L ALK+ NSCLC is maintained
- EU: Market leadership in 1L ALK+ NSCLC is maintained
- Japan: Market leadership in 1L ALK+ NSCLC is maintained
- International: Strong growth driven by all regions

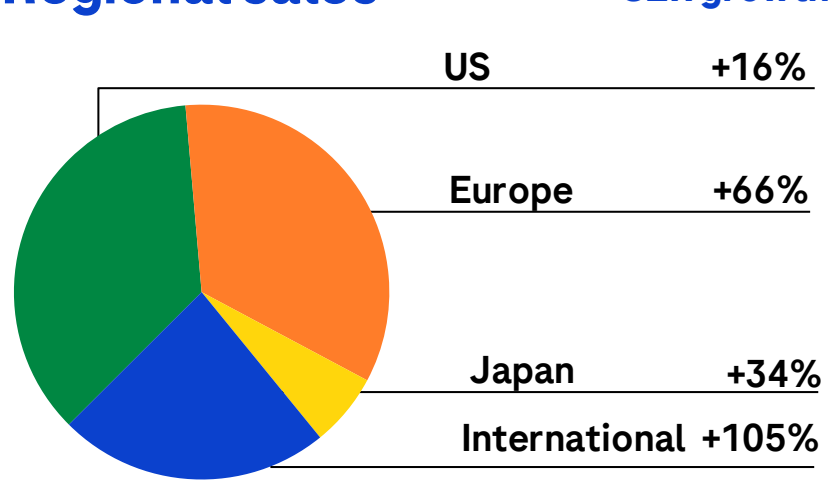
CER=Constant Exchange Rates

Evrysdi

Global sales



Regional sales

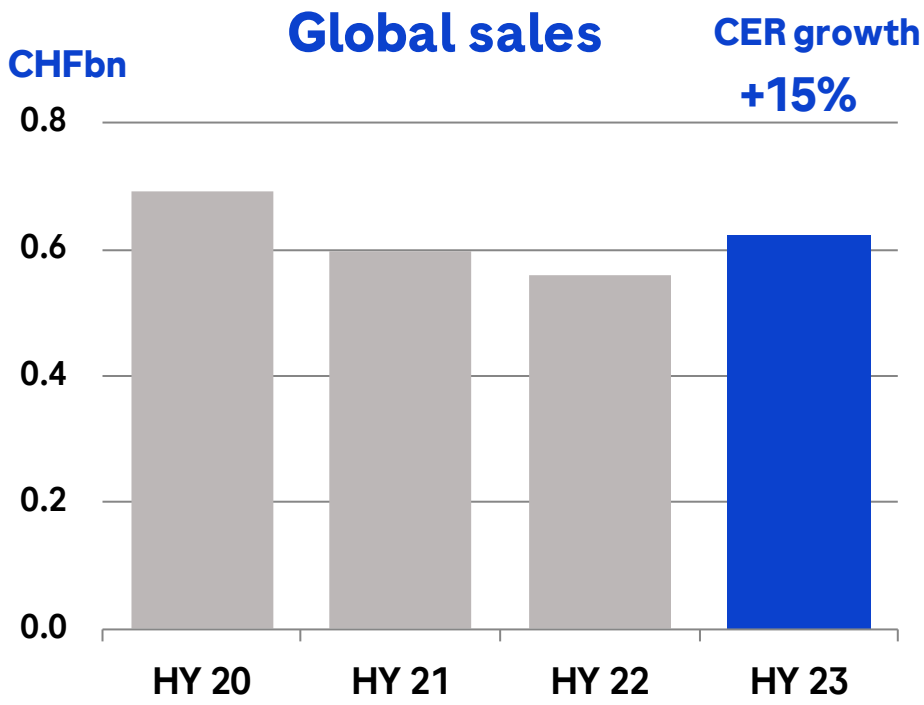


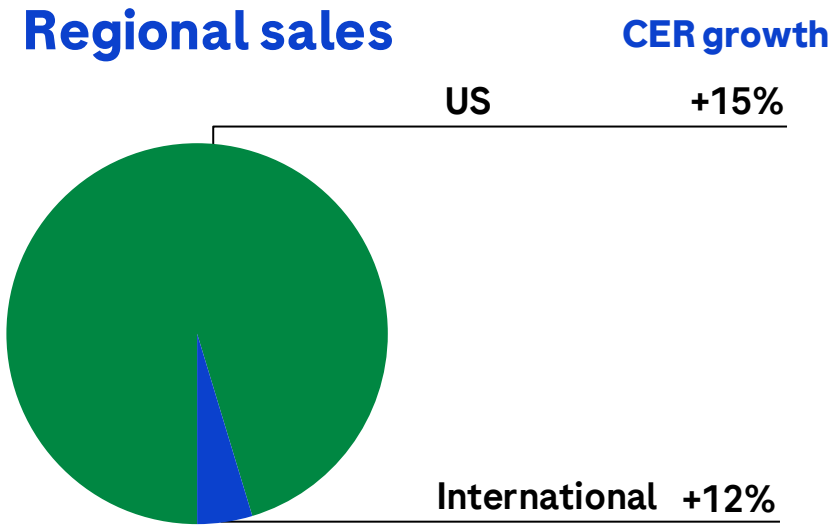
HY 2023 sales of CHF 705m

- US: Strong uptake across all patient segments; including treatment-naïve patients; leading market share with >25%
- EU: Continued strong growth and share gains, especially in Germany, UK and Italy
- Japan: Market leading position with >50%
- International: Strong growth in all regions

CER=Constant Exchange Rates

TNKase / Activase



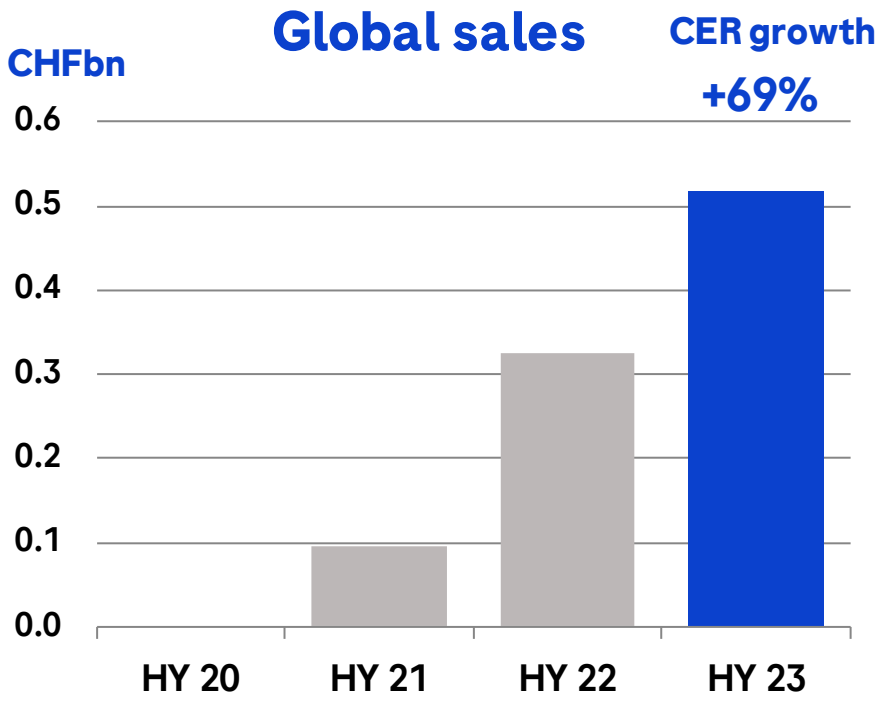


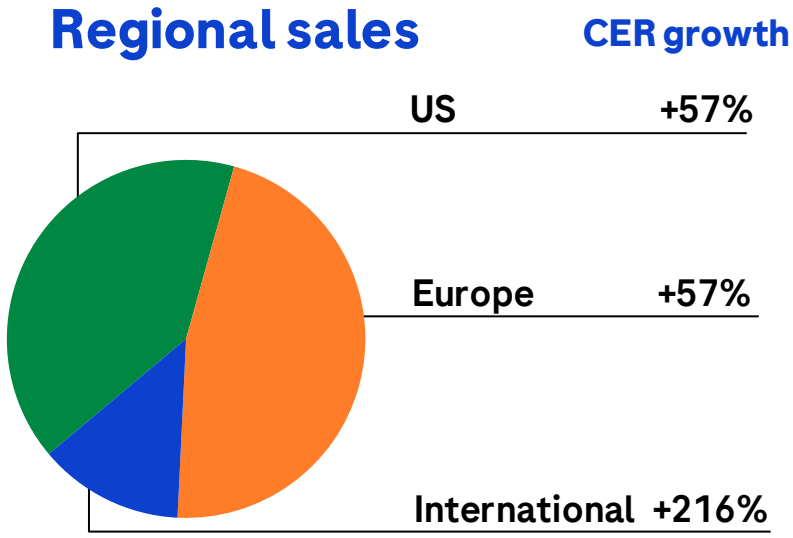
HY 2023 sales of CHF 621m

- Spontaneous TNKase use in AIS early time window

CER=Constant Exchange Rates

Phesgo



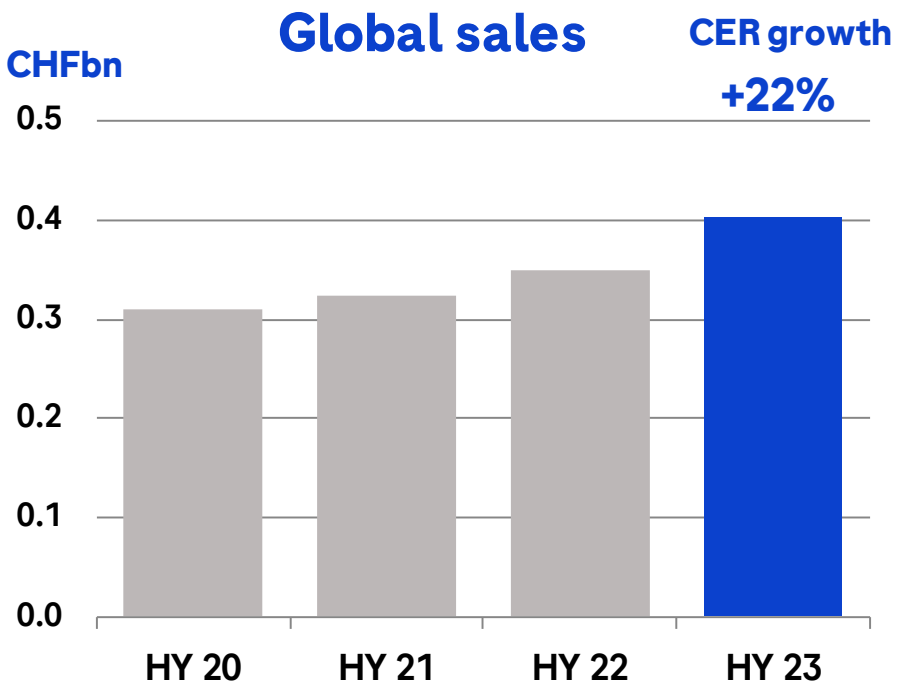


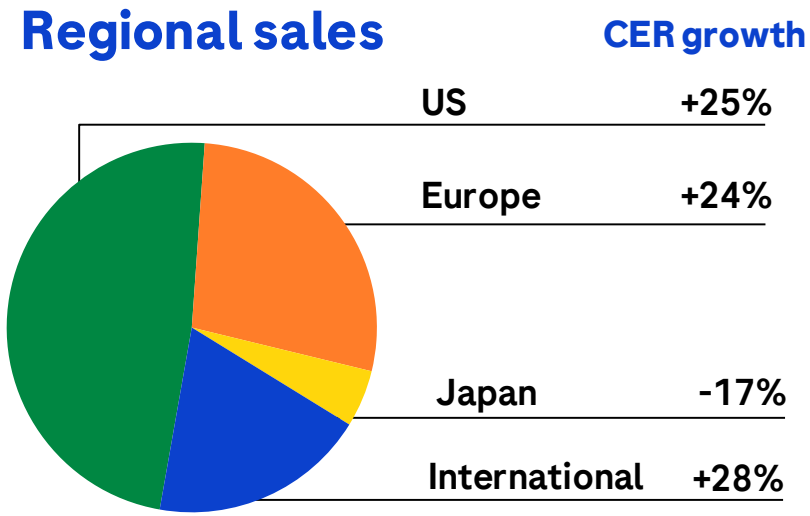
HY 2023 sales of CHF 517m

- US: Strong growth driven by eBC, switching of patients from Perjeta+Herceptin to Phesgo
- EU: Strong growth in all regions, mainly UK, France, Germany and Italy
- International: Strong uptake in all regions

CER=Constant Exchange Rates

Gazyva



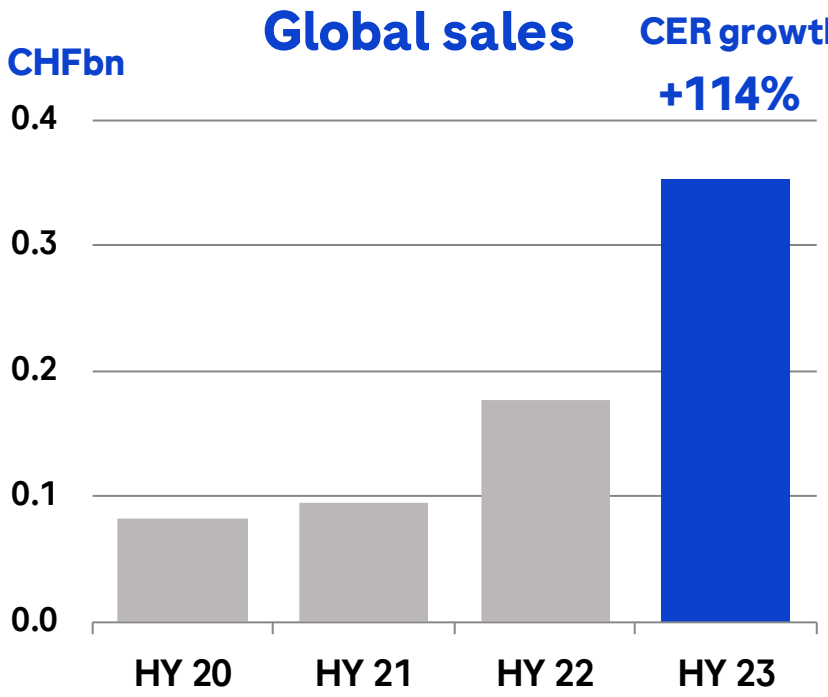


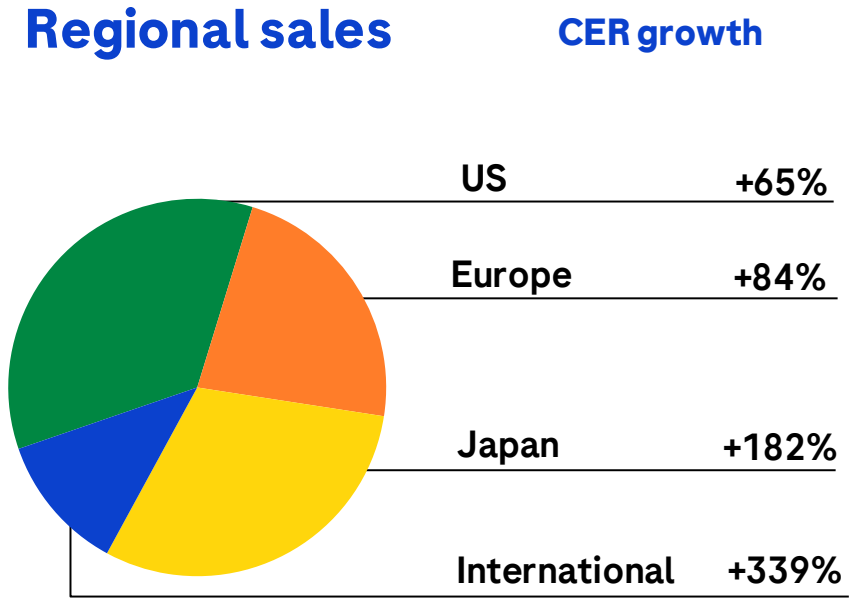
HY 2023 sales of CHF 402m

- US: Strong growth driven by combination therapies in 1L CLL
- EU: Strong growth driven by combination therapies in 1L CLL
- International: Continued growth in all key markets

CER=Constant Exchange Rates

Polivy





HY 2023 sales of CHF 353m

- US: Strong growth following approval in 1L DLBCL and inclusion to the NCCN guidelines as Category I
- EU: Strong growth following approval in 1L DLBCL
- JP: Strong growth following approval in 1L DLBCL
- International: Strong growth following approval in 1L DLBCL

CER=Constant Exchange Rates

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

HY 2023: Diagnostics Division CER growth

By Region and Customer Area (vs. 2022)

	Global		EMEA[1]		North America		Asia-Pacific		Latin America	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Core Lab[2]	3,935	10	1,362	8	691	0	1,575	15	307	16
Molecular Lab	1,118	-40	363	-46	489	-29	227	-46	39	-34
Diabetes Care	723	-5	380	-12	103	-7	129	-1	111	18
Pathology Lab	687	12	169	13	369	10	134	12	15	43
Point of Care	635	-74	182	-70	288	-69	140	-83	25	-63
Diagnostics Division	**7,098**	**-23**	**2,456**	**-22**	**1,940**	**-30**	**2,205**	**-23**	**497**	**0**

CER (Constant exchange Rates) of the respective year; [1] Europe, Middle East and Africa; [2] incl. Roche Information Solutions

Diagnostics Division quarterly sales and CER growth[1]

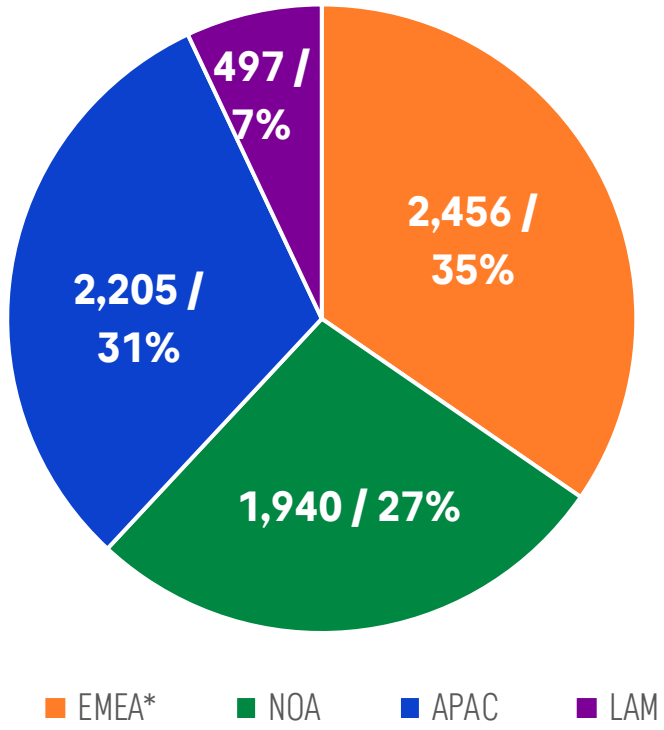
	Q1 22		Q2 22		Q3 22		Q4 22		Q1 23		Q2 23	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Core Lab[2]	1,896	8	1,979	1	1,958	7	1,942	9	1,928	7	2,007	12
Molecular Lab	1,189	21	791	-20	755	-24	715	-35	593	-48	525	-27
Diabetes Care	417	-7	415	-3	387	2	379	1	376	-5	347	-6
Pathology Lab	318	14	334	7	323	10	343	12	329	7	358	17
Point of Care	1,466	84	1,143	15	477	-16	503	-26	397	-72	238	-77
Diagnostics Division	**5,286**	**24**	**4,662**	**0**	**3,900**	**-4**	**3,882**	**-9**	**3,623**	**-28**	**3,475**	**-17**

CER (Constant exchange Rates) of the respective year; [1] versus same period of prior year; [2] incl. Roche Information Solutions

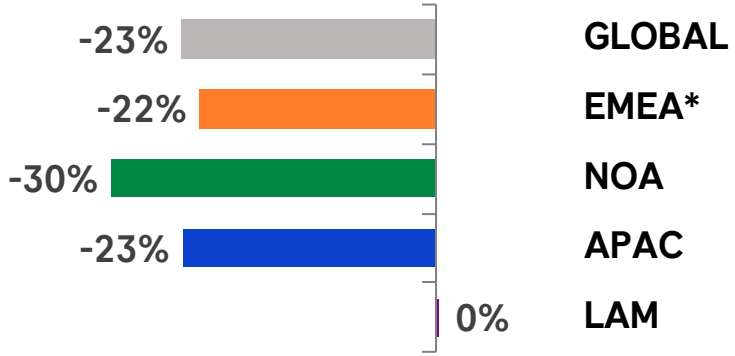
HY 2023: Diagnostics Division regional sales

Decline in most regions

Sales YTD CHFm & % of total sales
Total YTD Sales = 7,098

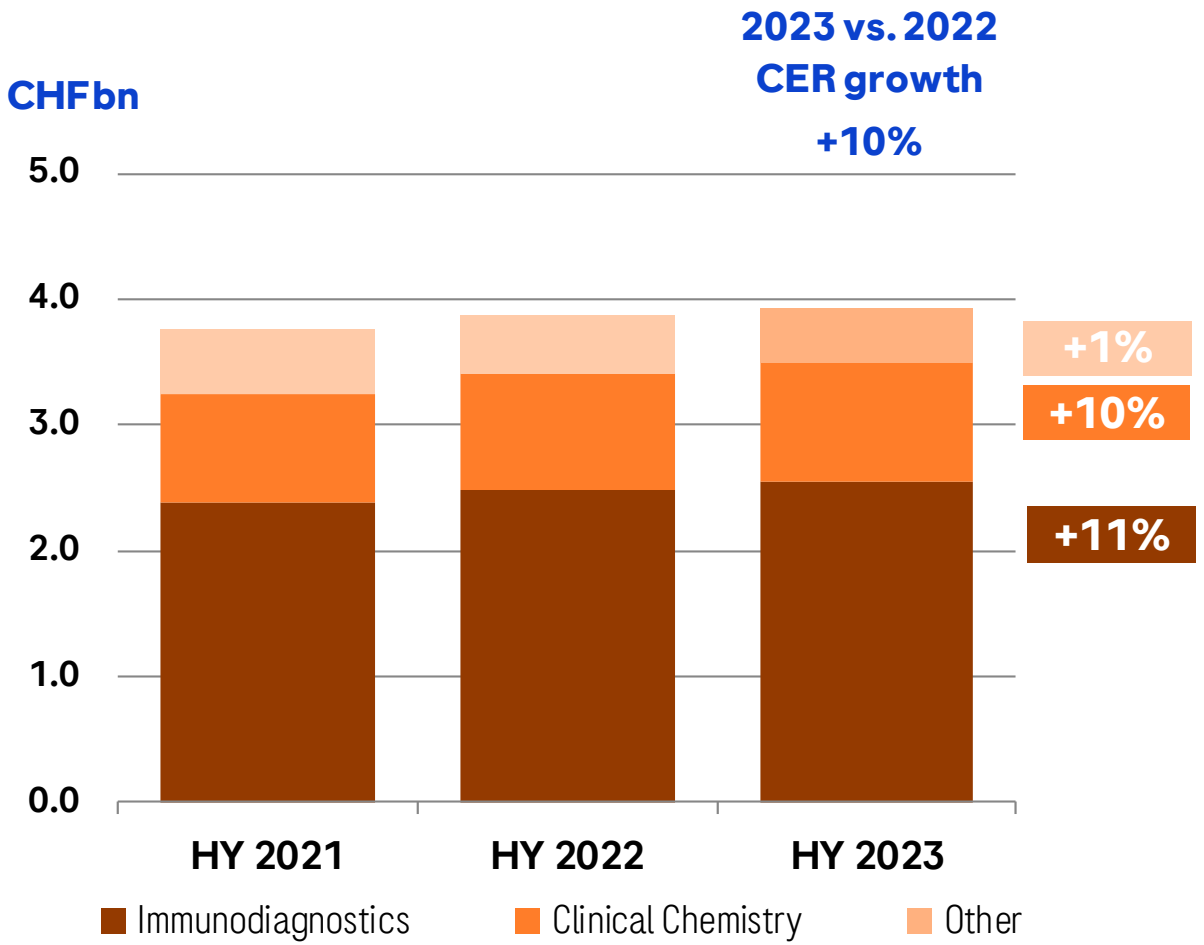


Sales growth at CER
Diagnostics Division



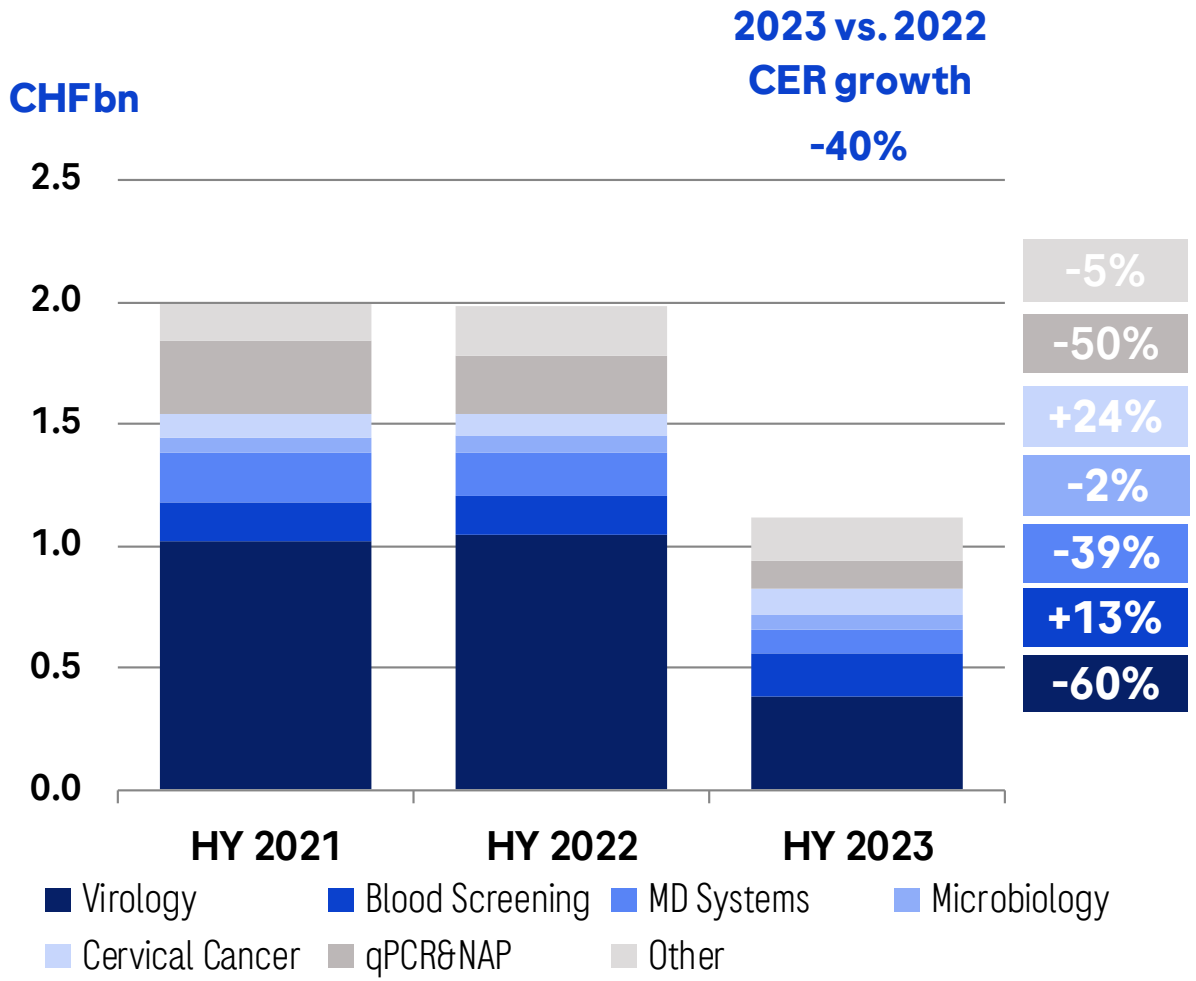
CER=Constant Exchange Rates; * Europe, Middle East and Africa

Core Lab[1]



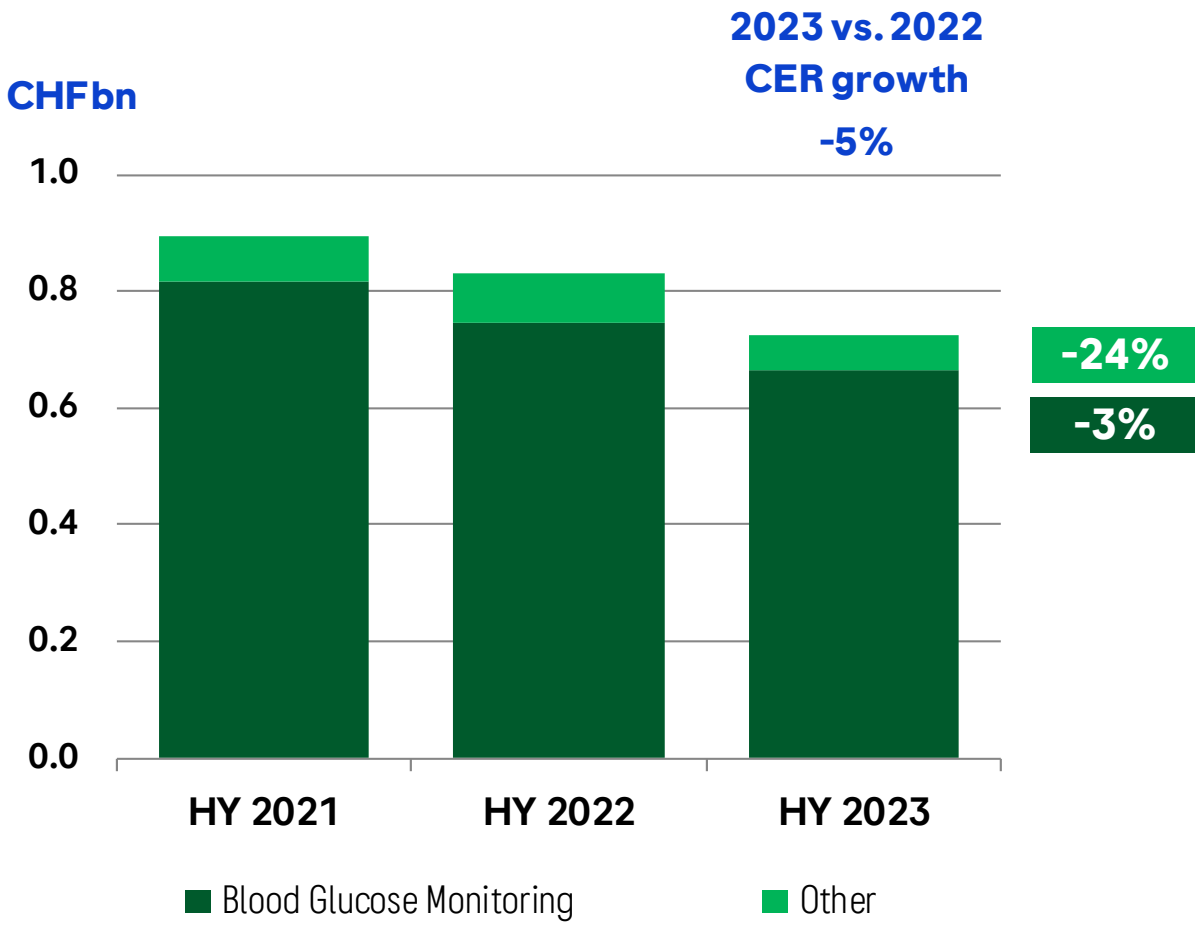
CER=Constant Exchange Rates; [1] incl. Roche Information Solutions; underlying growth of Core Lab excluding Roche Information Solutions: +9%

Molecular Lab



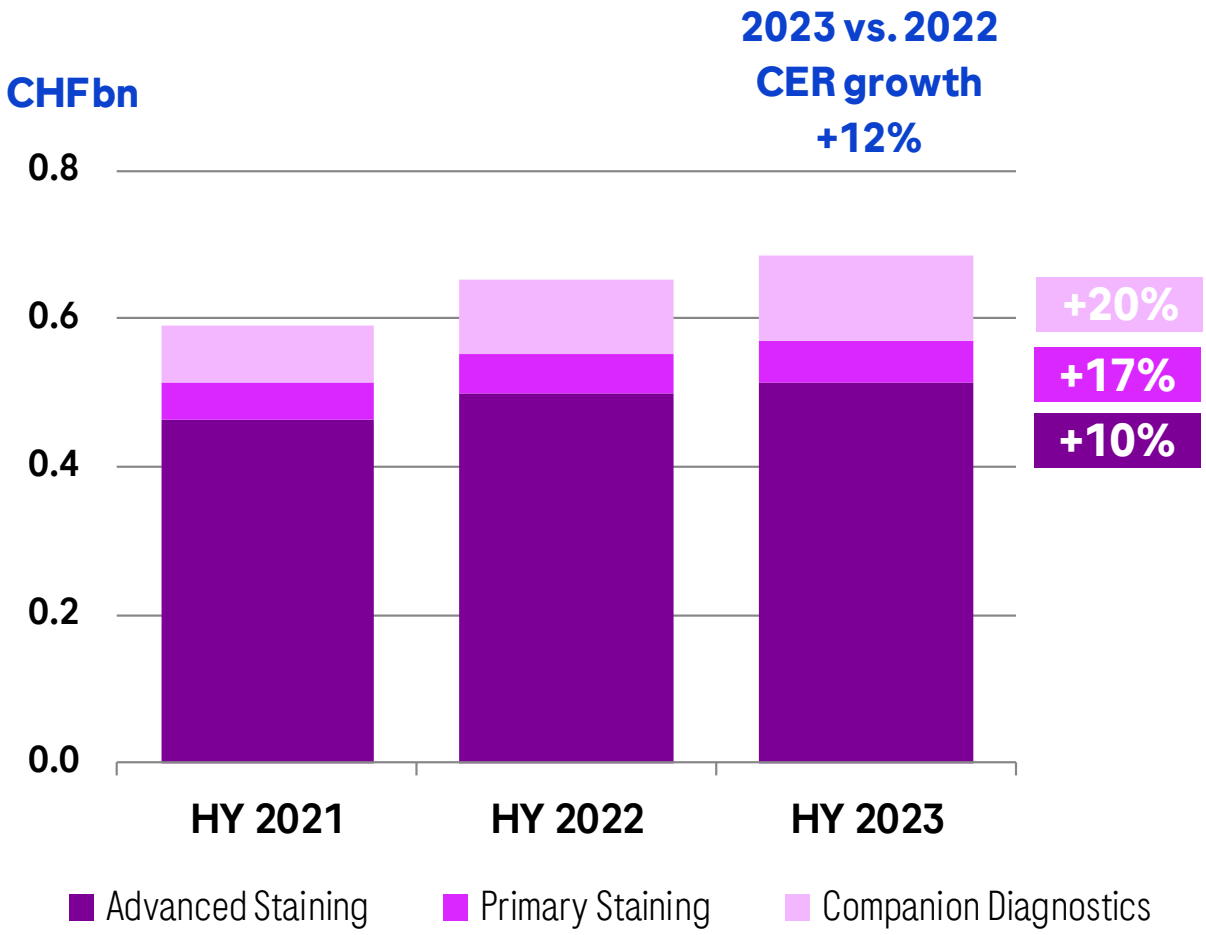
CER=Constant Exchange Rates

Diabetes Care



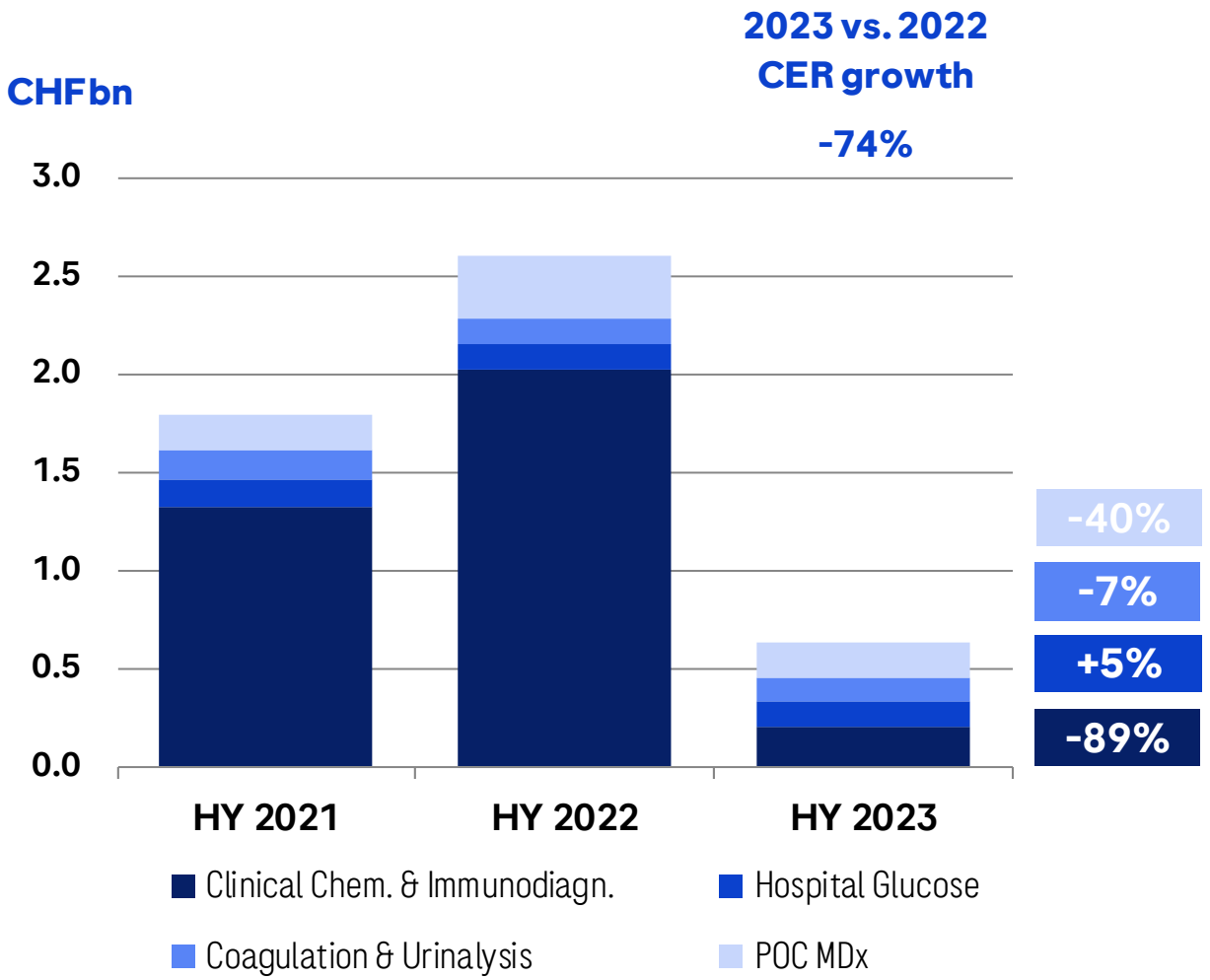
CER=Constant Exchange Rates

Pathology Lab



CER=Constant Exchange Rates

Point of Care



CER=Constant Exchange Rates

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)

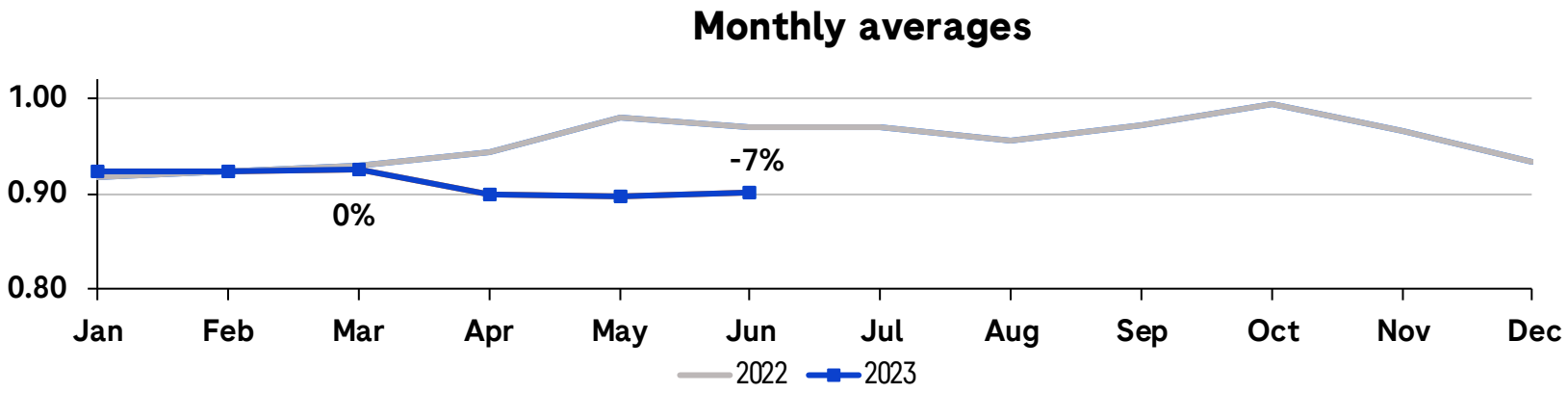
Spark

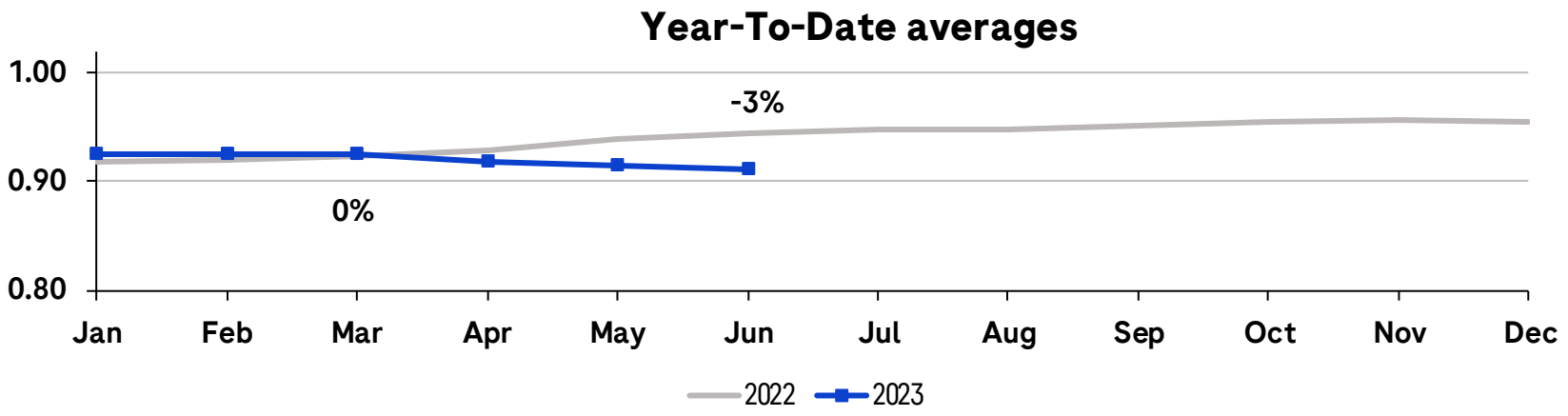
Pharma sales appendix

Diagnostics sales appendix

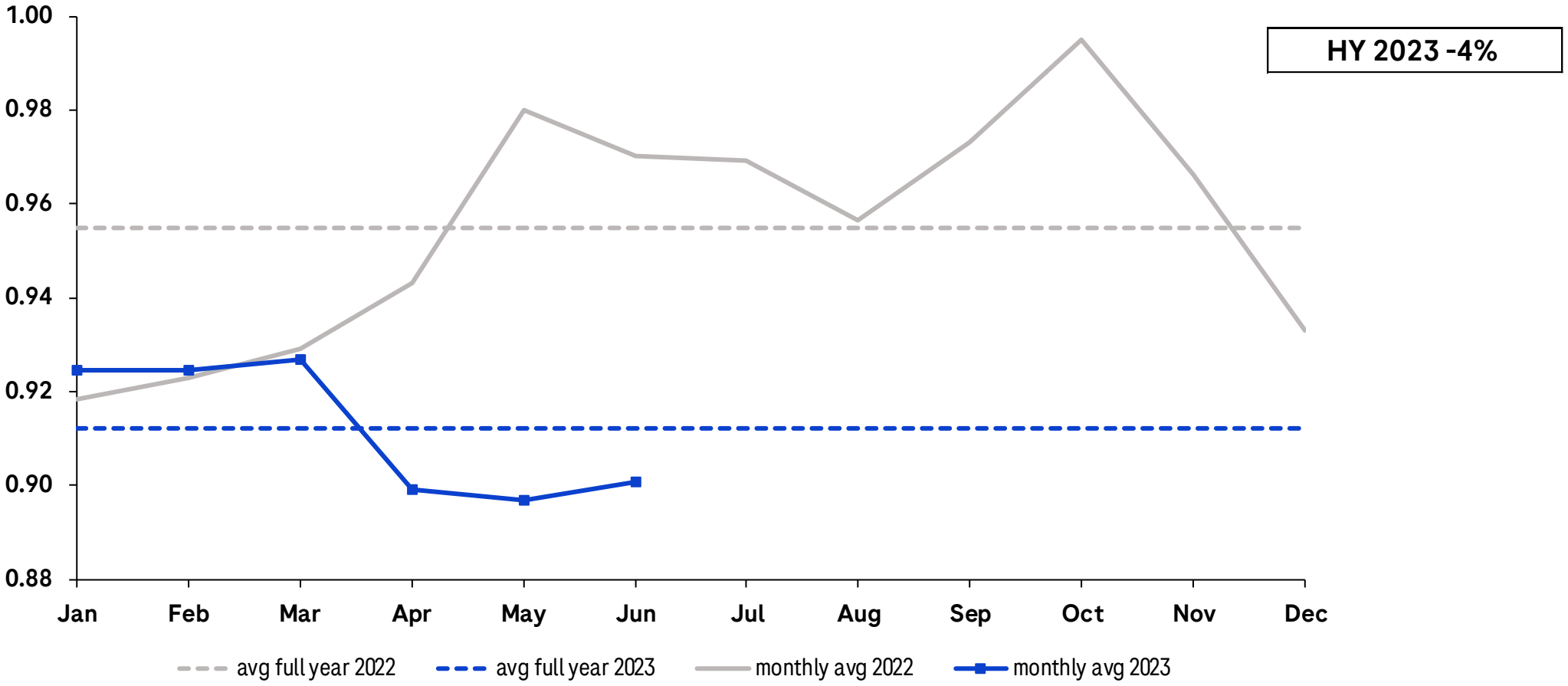
Foreign exchange rates information

CHF/USD

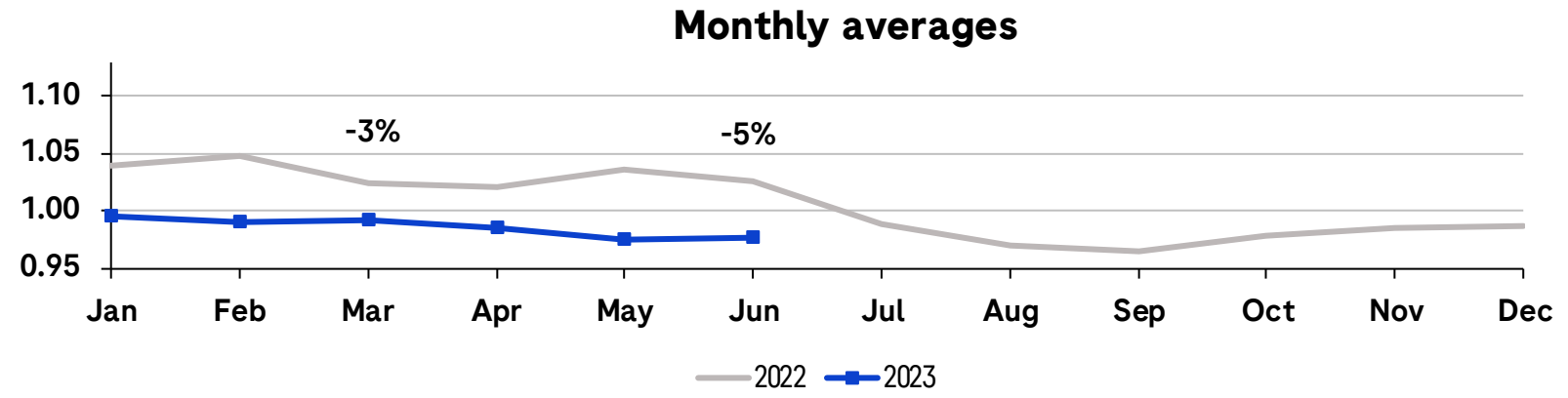

Monthly averages
1.00
0.90
0.80
-7%
0%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

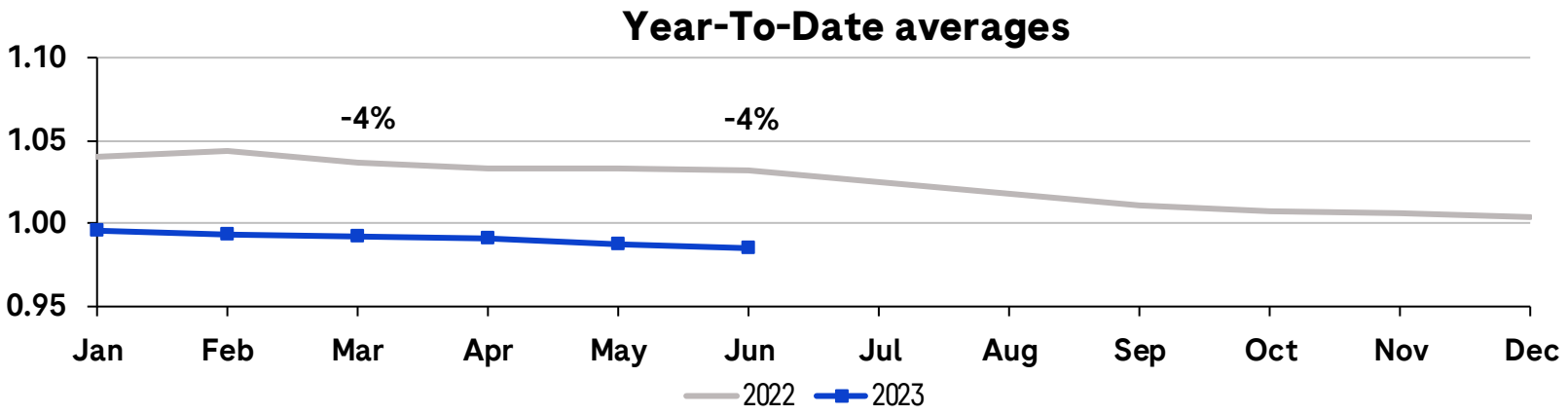

Year-To-Date averages
1.00
0.90
0.80
-3%
0%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

CHF/USD

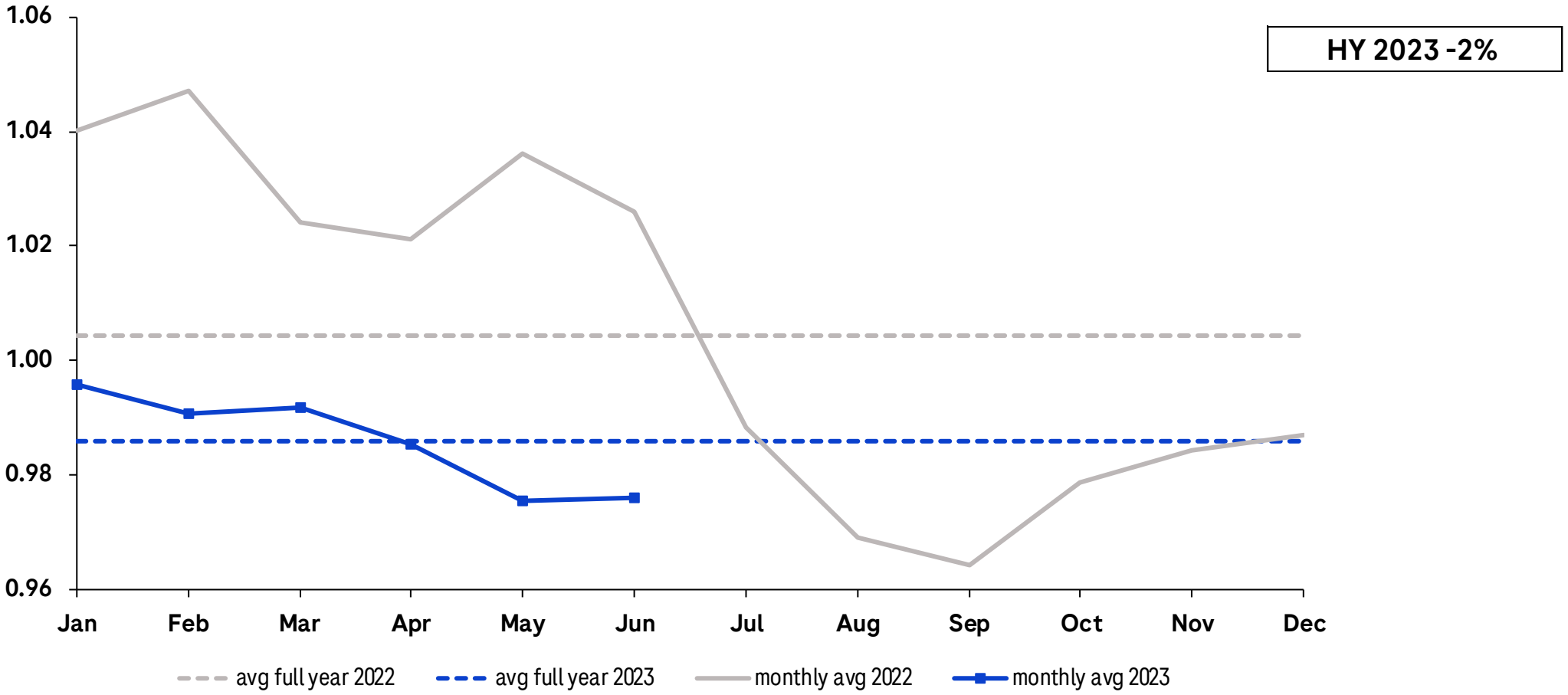

HY 2023 -4%
1.00
0.98
0.96
0.94
0.92
0.90
0.88
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
avg full year 2022
avg full year 2023
monthly avg 2022
monthly avg 2023

CHF/EUR


Monthly averages
1.10
1.05
1.00
0.95
-3%
-5%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

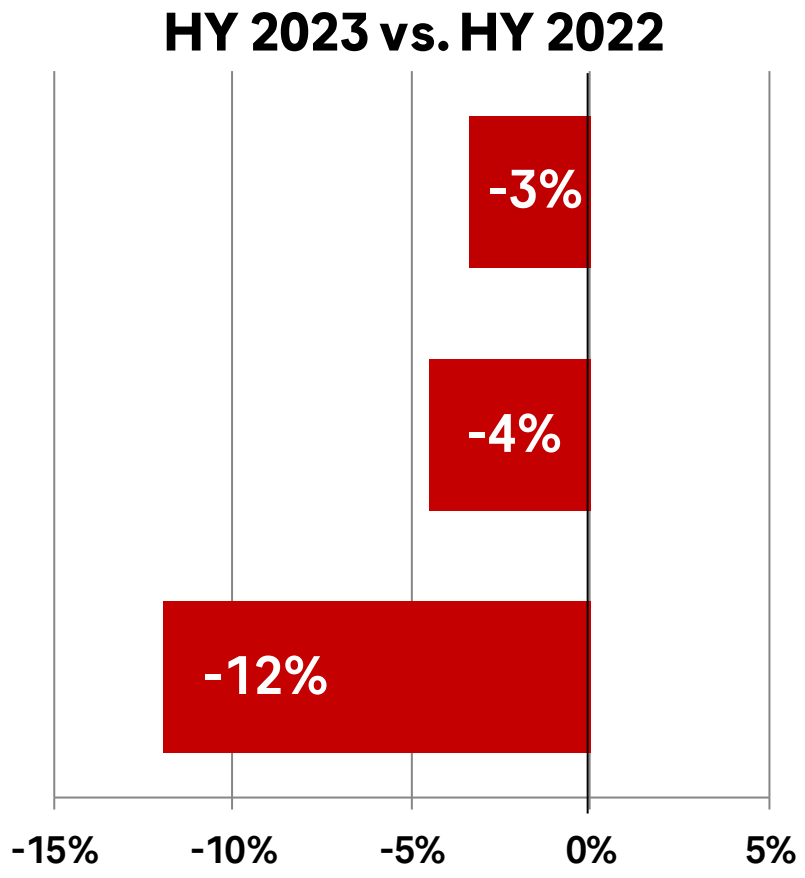

Year-To-Date averages
1.10
1.05
1.00
0.95
-4%
-4%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

CHF/EUR


HY 2023 -2%
1.06
1.04
1.02
1.00
0.98
0.96
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
avg full year 2022
avg full year 2023
monthly avg 2022
monthly avg 2023

Average CHF Exchange Rates

	HY 2023	HY 2022
USD	0.91	0.94
EUR	0.99	1.03
JPY	0.68	0.77



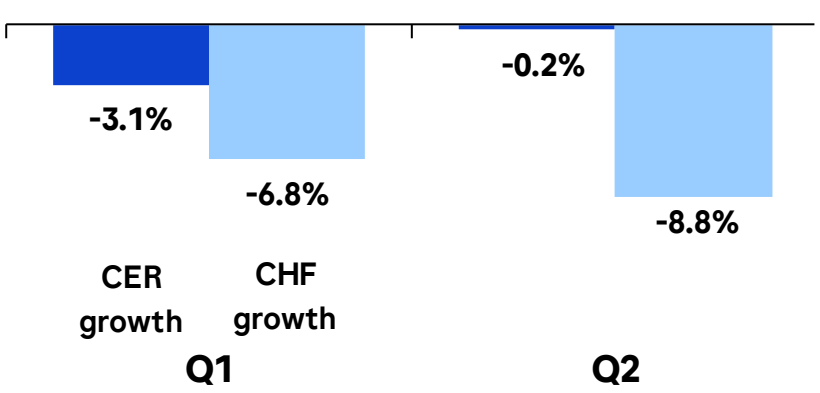
Exchange rate impact on sales growth

Q2 2023: negative impact of JPY, USD and EUR

Development of average exchange rates versus prior year period

CHF / USD	**0.2%**	**-6.8%**
CHF / EUR	**-4.3%**	**-4.8%**
CHF / JPY	**-12.1%**	**-12.0%**
Difference in CHF / CER growth	**-3.7%**	**-8.6%**

Sales growth 2023 vs. 2022



CER=Constant Exchange Rates

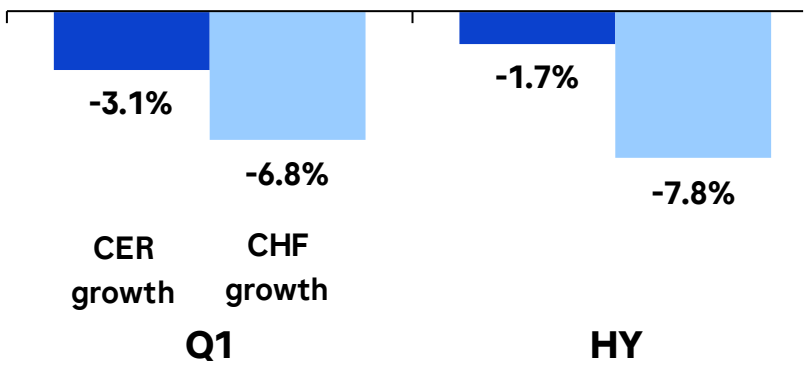
Exchange rate impact on sales growth

HY 2023: negative impact of JPY, EUR and USD

Development of average exchange rates versus prior year period

CHF / USD	**0.2%**	**-3.4%**
CHF / EUR	**-4.3%**	**-4.5%**
CHF / JPY	**-12.1%**	**-11.9%**
Difference in CHF / CER growth	**-3.7%**	**-6.1%**

Sales growth 2023 vs. 2022



CER=Constant Exchange Rates

Doing now what patients need next