
Roche

This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as ‘believes’, ‘expects’, ‘anticipates’, ‘projects’, ‘intends’, ‘should’, ‘seeks’, ‘estimates’, ‘future’ or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

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2 legislative and regulatory developments and economic conditions;
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4 fluctuations in currency exchange rates and general financial market conditions;
5 uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
6 increased government pricing pressures;
7 interruptions in production;
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10 loss of key executives or other employees; and
11 adverse publicity and news coverage.

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Roche

YTD September 2022 sales

Basel, 18 October 2022

Group

Severin Schwan
Chief Executive Officer

YTD Sep 2022 performance

Outlook

YTD Sep 2022: Group sales +2% despite COVID-19 decline in Q3

Group sales +2% driven by Diagnostics division

- Pharma with stable performance, key products compensating for LOEs and declining COVID-19 sales
- Diagnostics with good growth momentum (+6%) including good base business growth (+6%)

Key products growing strongly; new launches with significant sales potential

- Pharma growth drivers Ocrevus, Hemlibra, Evrysdi, Phesgo, Vabysmo and Tecentriq with strong momentum
- Promising new launches with Vabysmo in ophthalmology and Polivy & Lunsumio in hematology
- New launches of next generation of SARS-CoV-2 rapid antigen test 2.0, Prame immunohistochemistry assay for melanoma and Digital LightCyler

Upcoming late-stage newsflow in 2022

- Pharma: Gantenerumab in Alzheimer's disease; Venclexta in MM (t11;14); Vabysmo in RVO; Susvimo in DME & DR
- Diagnostics: Elecsys® pTau/AB42 ratio Gen2 CSF (FDA), cobas® 5800 (FDA)

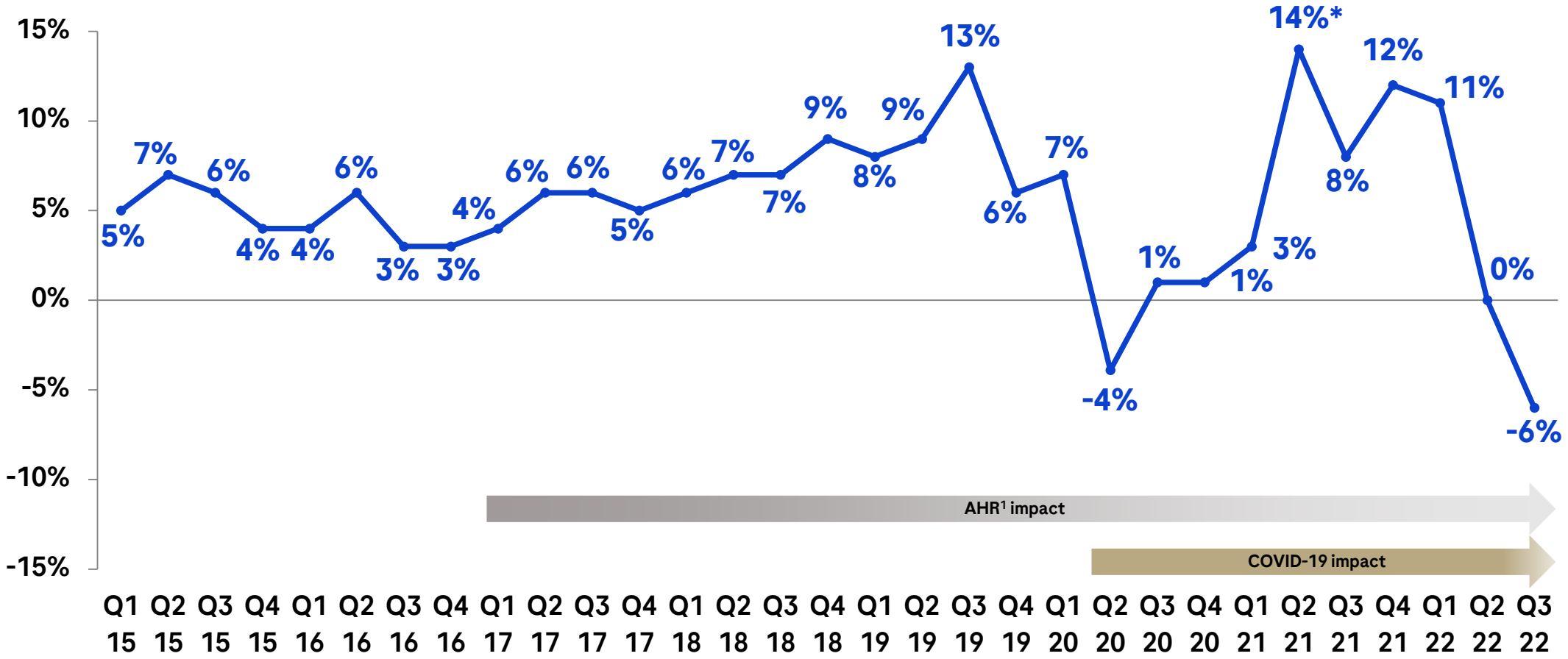
Growth rates at CER (Constant exchange Rates); LOE=loss-of-exclusivity

YTD Sep 2022: Group sales growth driven by Diagnostics Division

	2022 CHFbn	2021 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	33.2	33.4	-1	0
Diagnostics Division	13.8	13.3	4	6
Roche Group	47.0	46.7	1	2

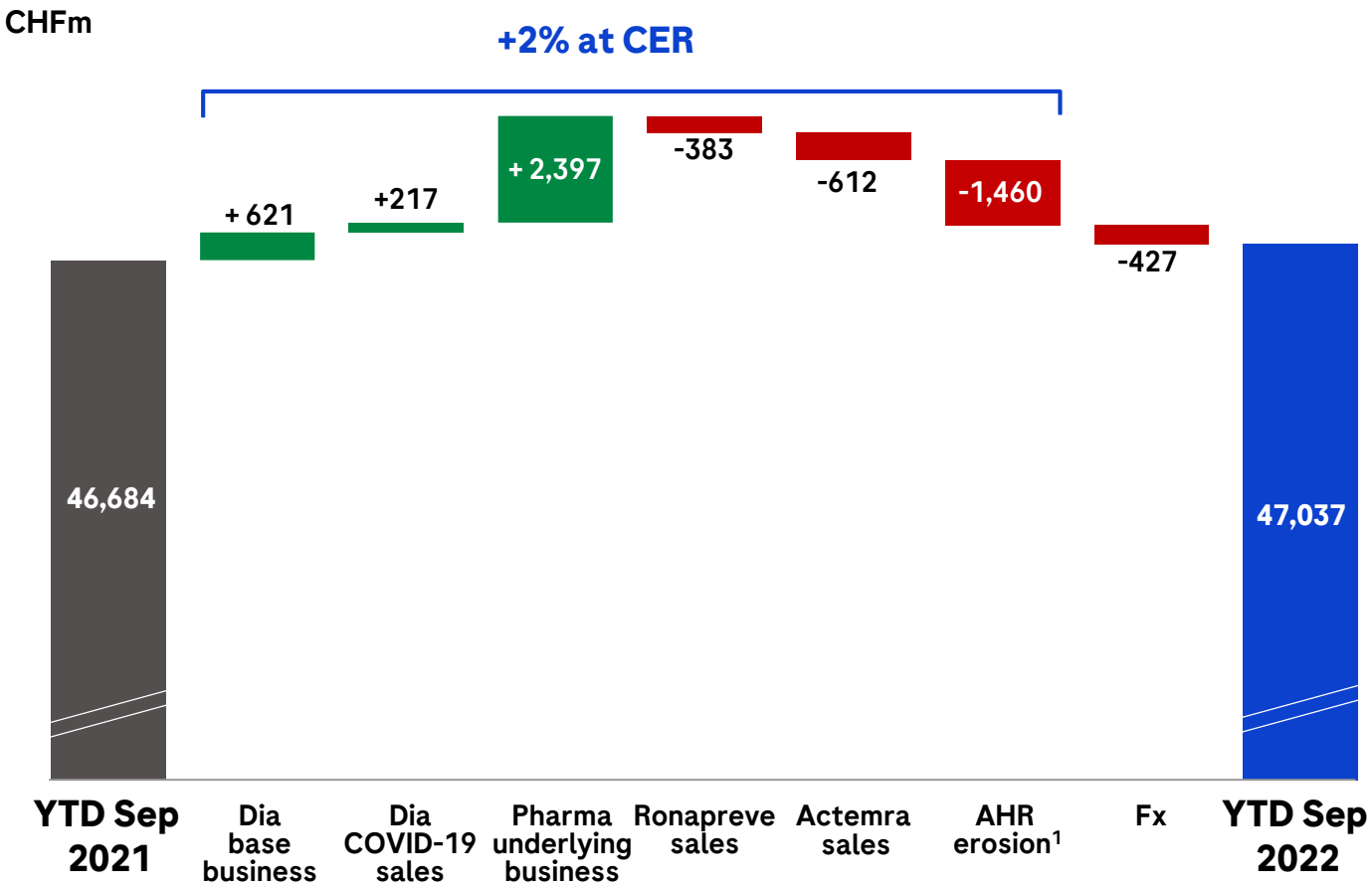
CER=Constant Exchange Rates; totals may include differences due to rounding

Quarterly sales performance: COVID-19 sales coming down

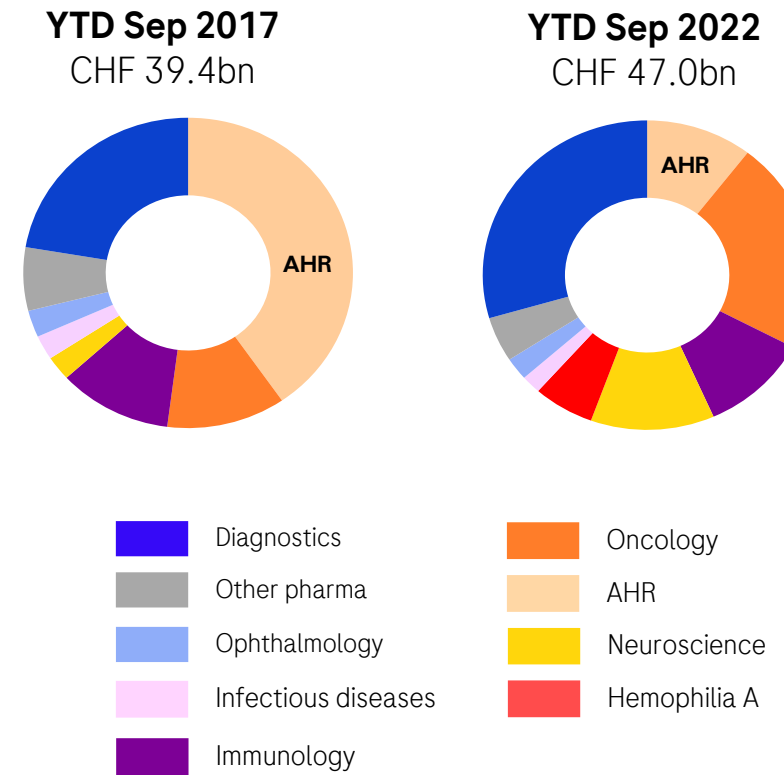


Growth rates at CER (Constant Exchange Rates); * Q2 2020 sales severely impacted by COVID-19 pandemic onset; [1]AHR: Avastin, Herceptin, Rituxan/MabThera

YTD Sep 2022: Portfolio rejuvenation ongoing



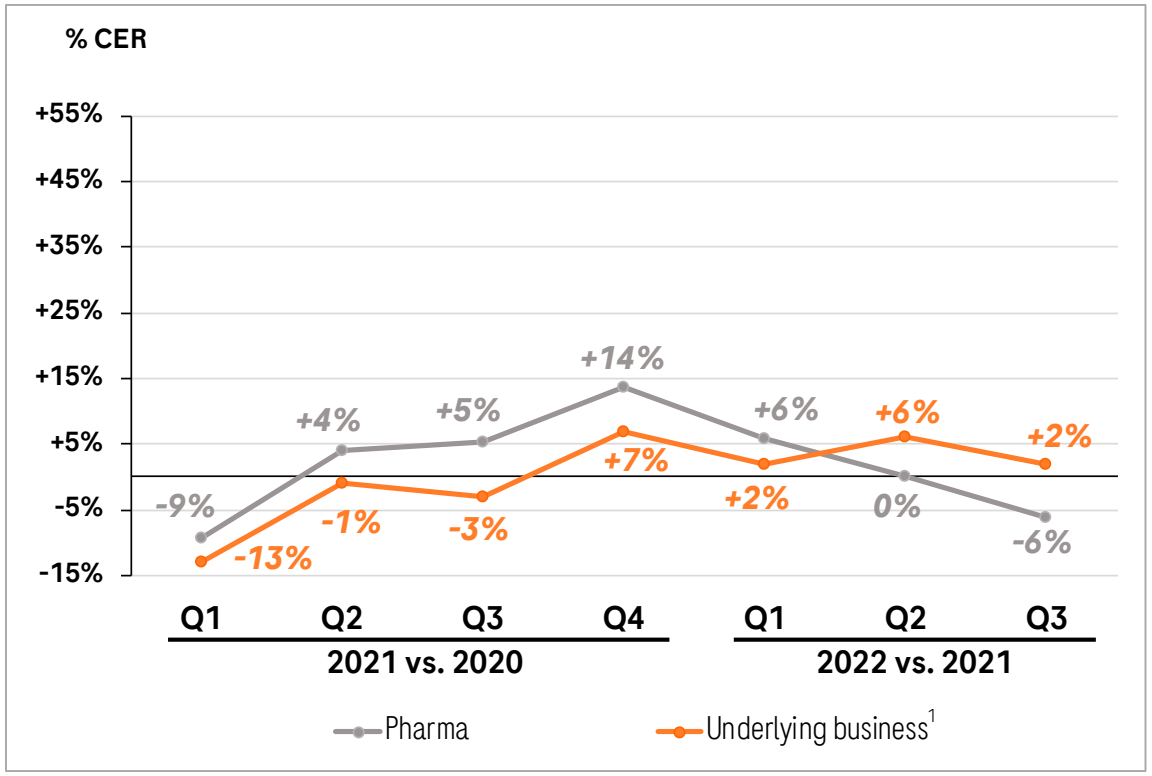
Diversification of Roche business



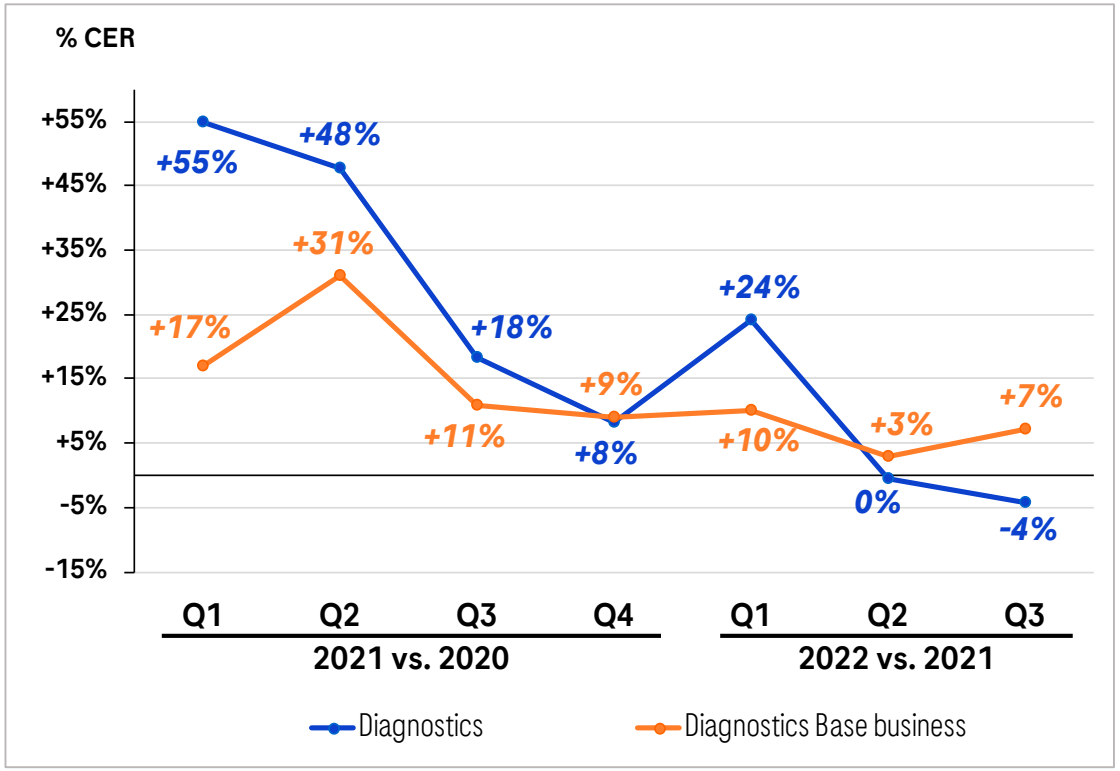
YTD Sep 2022 values in reported CHFm, variances in CERm; [1] AHR: Avastin, Herceptin, Rituxan/MabThera sales erosion

YTD Sep 2022: Solid underlying sales growth in both divisions

Pharma
Quarterly sales evolution 2021-2022



Diagnostics
Quarterly sales evolution 2021-2022



Growth rates at CER (Constant Exchange Rates); [1] Excl. Ronapreve and Actemra

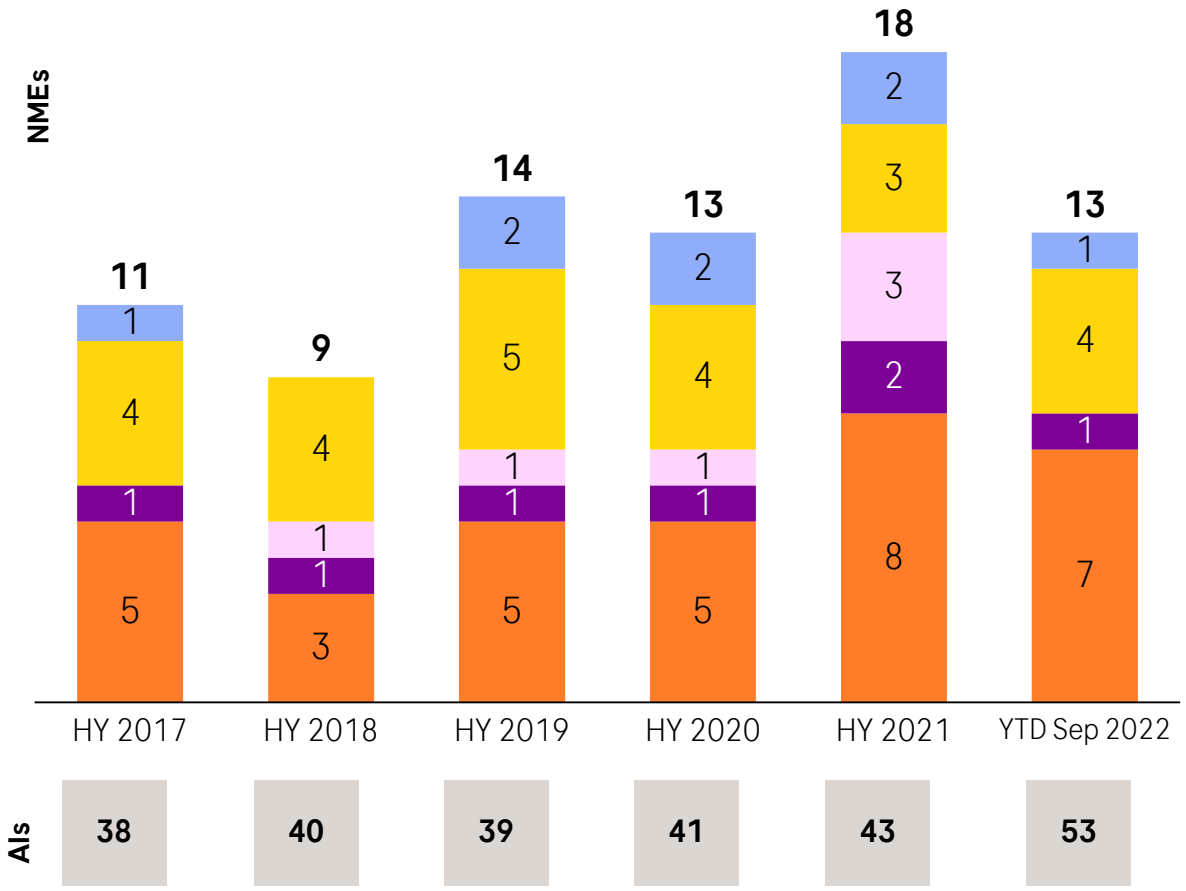
YTD Sep 2022 performance

Outlook

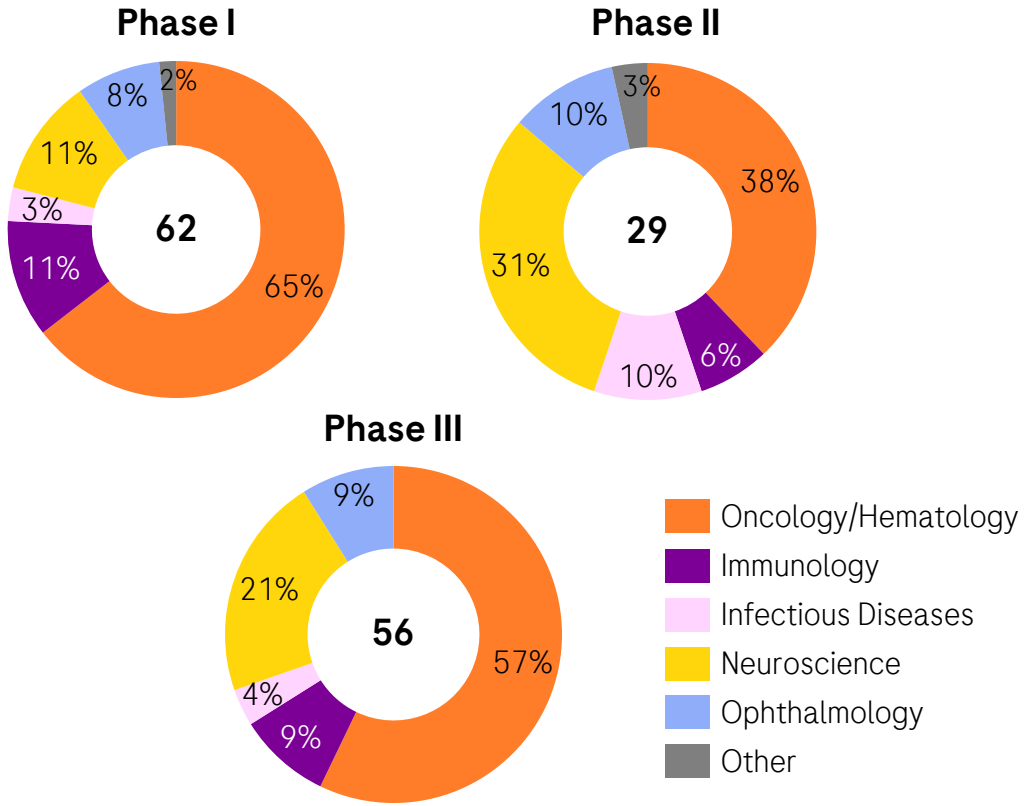
Continuous increase in pipeline breadth and depth

All-time high for Ph III AIs and industry-leading number of NMEs in the clinic

Projects in Ph III & registration



Record number of NMEs and AIs (YTD Sep 2022)



NME=new molecular entity; AI=additional indication

2022/23: Upcoming Pharma newsflow

2022	2023
Vabysmo in RVO	**Tiragolumab + Tecentriq** in 1L PDL1+ NSCLC
Susvimo in DME	**Tiragolumab + Tecentriq** in 1L Esophageal
Susvimo in DR	**Tecentriq** in adjuvant HCC
Venclexta in R/R MM (t11;14)	**Tecentriq** in adjuvant SCCHN
Gantenerumab in Alzheimer's disease	**Tecentriq + chemo** in adjuvant TNBC
	Tecentriq neoadjuvant/adjuvant TNBC
	Tecentriq periadjuvant NSCLC
	Phesgo OBI in HER2+ BC
	Alecensa in adjuvant ALK+ NSCLC
	Venclexta in 1L high risk MDS
	Crovalimab in PNH
	Glofitamab in 2L+ DLBCL*
	Lunsumio in 2L+ DLBCL*
	Delandistrogene moxeparvovec in DMD
	Ocrevus SC in RMS / PPMS
	TNKase in Stroke
	Xolair in Food allergy

Neuroscience
Oncology
Ophthalmology
Immunology

DME=diabetic macular edema; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer; HCC=hepatocellular carcinoma; MM=multiple myeloma; RVO=retinal vein occlusion; CSF=cerebrospinal fluid; PCR=polymerase chain reaction; SC=subcutaneous; *Results are event-driven, read-outs expected 2023/24

R&D focus area Alzheimer's disease

Clinical results for gantenerumab and blood-based biomarkers to be presented at CTAD

Pharmaceuticals

FDA BTD

gantenerumab

- Nearly two decades of scientific investigation with nearly 7000 patient years on treatment
- GRADUATE I/II: Patients with early AD (FDA BTD)
- SKYLINE: Patients at risk of, or at the earliest stages of AD

Brain shuttle gantenerumab

- Improve transport of gantenerumab across the blood brain barrier
- Promising Ph I PK data
- Platform technology: Ph I trial in MS with a CD20

Anti-tau mABs

- Different MoA, targeting tau protein tangles instead of Aß plaques
- Two assets (semorinemab & bepranemab) in Ph II trials

Diagnostics

FDA BDD

Blood-based biomarker

- Elecsys Amyloid Plasma Panel (FDA BDD)
- A minimally invasive test to help pre-select patients for confirmatory testing
- Runs on serum work area platforms

CSF-based biomarker

- Elecsys Aß and pTau CSF
- Confirmatory test equivalent to PET scan
- Runs on serum work area platforms

Multiple Real World Data (RWD) studies*

*Topics include natural history, predictors of progression in early AD, QoL across the AD continuum and more; Latest RWD study: Delphi study CONCORD-AD 2.0, connecting cohorts to diminish AD
AD=Alzheimer's disease; PK=pharmacokinetics; MS=multiple sclerosis; Aß=amyloid beta; BDD=breakthrough device designation; CSF=Cerebrospinal fluid; QoL=quality of life

2022 outlook confirmed

Group sales growth[1]	• Stable to low-single digit
Core EPS growth[1]	• Low- to mid-single digit
Dividend outlook	• Further increase dividend in Swiss francs

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Bill Anderson
CEO Roche Pharmaceuticals

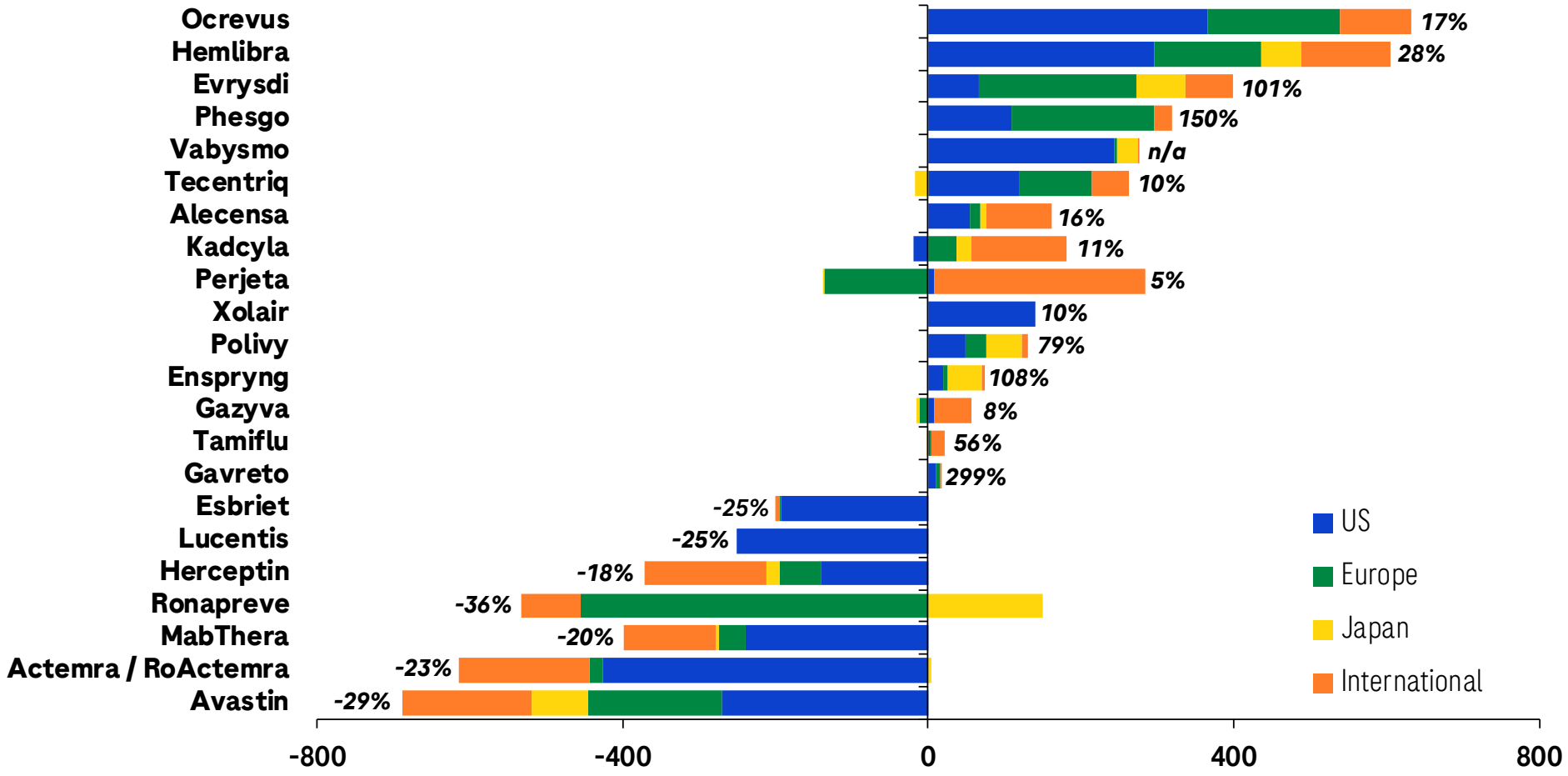
YTD Sep 2022: Pharmaceuticals Division sales

New products compensate for loss-of-exclusivity and COVID-19 sales decline

	2022 CHFm	2021 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**33,189**	**33,379**	**-1**	**0**
United States	17,199	16,707	3	-1
Europe	6,100	6,610	-8	-1
Japan	3,029	3,186	-5	7
International	6,861	6,876	0	0

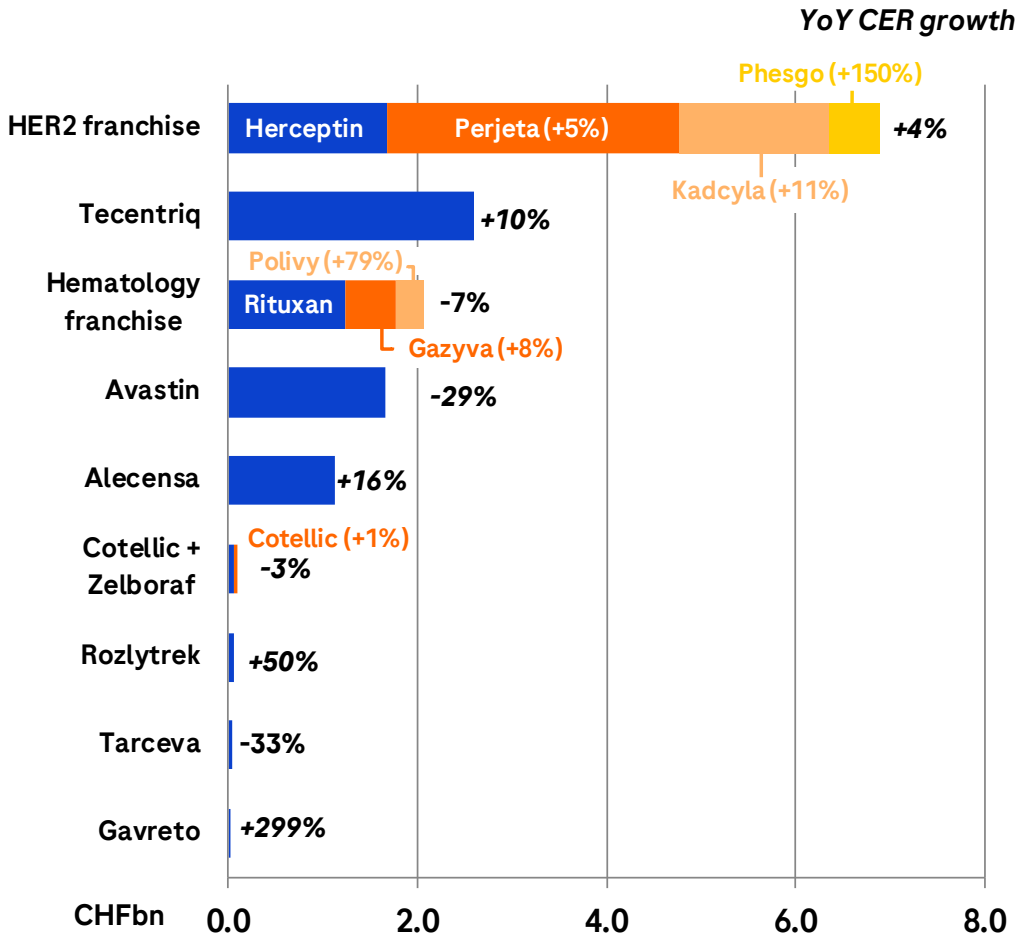
CER=Constant Exchange Rates

YTD Sep 2022: Portfolio diversification accelerating



Absolute values and growth rates at Constant Exchange Rates (CER)

YTD Sep 2022: Oncology portfolio rejuvenation on-going



HER2 franchise

- Kadcyla (+11%) with growth ex-US due to adjuvant BC
- Perjeta (+5%) driven by International, especially APAC
- Phesgo (CHF 526m): 30% conversion in early launch countries

Tecentriq

- Growth (+10%) driven by adjuvant NSCLC, 1L HCC and 1L SCLC

Hematology franchise

- Venclexta*: Expanding patient share in 1L AML & R/R CLL
- Gazyva (+8%): Growth due to 1L FL and in 1L CLL
- Polivy (+79%): Strong 1L DLBCL uptake in early launch countries; PDUFA date for 1L DLBCL (POLARIX) set for Apr 2nd
- Lunsumio: Approved in EU with strong early launch in Germany and Austria; PDUFA set for Dec 29th

Alecensa

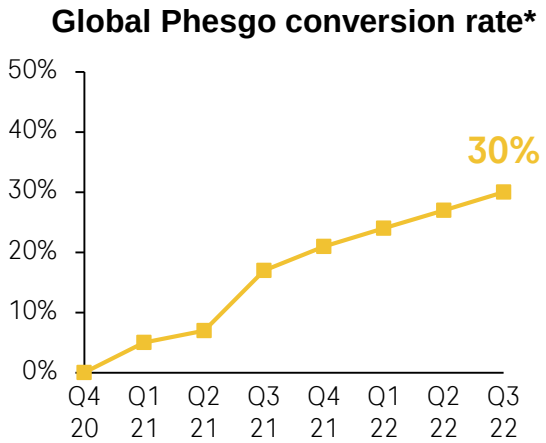
- Strong growth (+16%) and 1L ALK+ NSCLC leadership in major markets

YTD Sep 2022 Oncology sales: CHF 15.0bn; CER growth -1%; CER=Constant Exchange Rates; * Venclexta sales booked by AbbVie and therefore not included; Polivy in collaboration with Seagen; BC=breast cancer; HCC=hepatocellular carcinoma; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; AML=acute myeloid leukemia; R/R CLL=relapsed/refractory chronic lymphocytic leukemia; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; PDUFA=Prescription Drug User Fee Act; ALK=anaplastic lymphoma kinase

HER2+ franchise: Continued growth

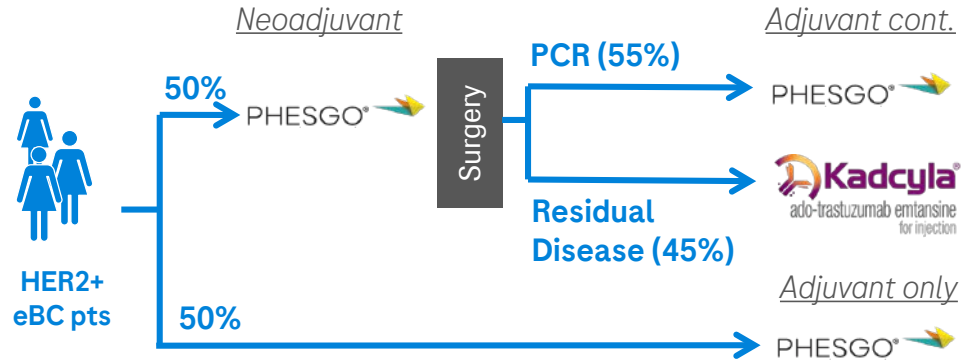
Multiple Ph III combination trials initiated

Phesgo's strong global launch continues



- Phesgo conversion rate at 30% in early launch countries
- Phesgo significantly cuts healthcare costs and resource use
- P+H in eBC (APHINITY): 8-year follow up data presented at ESMO Virtual Plenary showing a 28% reduction in the risk of recurrence or death for high risk, lymph-node positive patients
- Ph III (heredERA) Phesgo + giredestrant in 1L HER2+/HR+ mBC initiated

Kadcyla growth driven by adjuvant setting



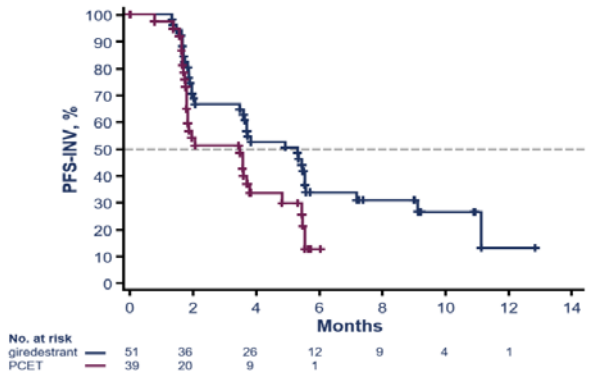
- Continued growth enabled by global expansion in the adjuvant setting
- Kadcyla remains SoC in adjuvant patients with residual disease (KATHERINE) with > 60% of sales in the adjuvant setting
- Ph III (KATE-3) Kadcyla + Tecentriq in 2L+ HER2+/PD-L1+ mBC initiated
- Ph III (ASTEFANIA) Kadcyla + Tecentriq in HER2+/PD-L1+ eBC initiated

P=Perjeta; H=Herceptin; HR=Hormone receptor; HER2=Human epidermal growth factor receptor 2; BC=Breast cancer; eBC=Early breast cancer; mBC=Metastatic breast cancer; PCR=pathologic complete response; SoC=standard of care; ESMO=European Society for Medical Oncology; *Phesgo conversion rate is based on volumes (vials) and includes all launch countries after the 2nd quarter after the launch (25 countries); Phesgo in collaboration with Halozyme

Giredestrant: Early data support continued development in ER+ BC

Ph III (persevERA) interim results in 1L ER+ BC expected for 2024

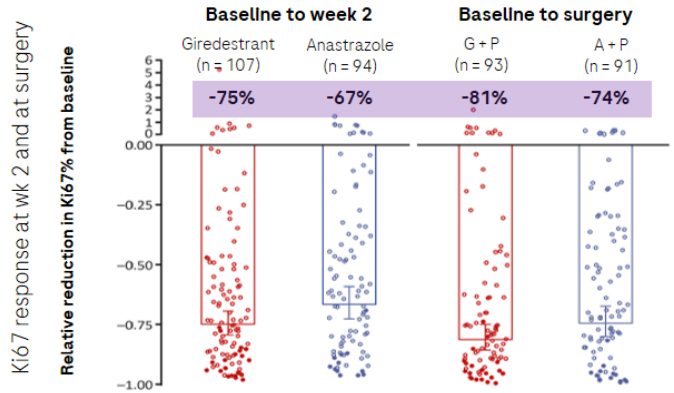
Ph II (acelERA) results in 2/3L ER+/HER- BC



	giredestrant (n = 51)	PCET (n = 39)
HR (95% CI)	**0.60** (0.35, 1.03)	
p-value (log-rank)	0.0610	
mPFS, months	5.3	3.5

- PFS benefit was more pronounced in patients with *ESR1* mutations (HR of 0.81 in all-comers vs HR of 0.60 in patients with *ESR1* mutations)
- In 2L/3L setting patients have received multiple cycles of ET
- The activity observed in patients whose tumours still depend on estrogen receptor activity for viability is encouraging for earlier lines, where nearly all ER+ tumours are dependent on ER activity

Ph II (coopERA) results in neoadjuvant ER+/HER- BC



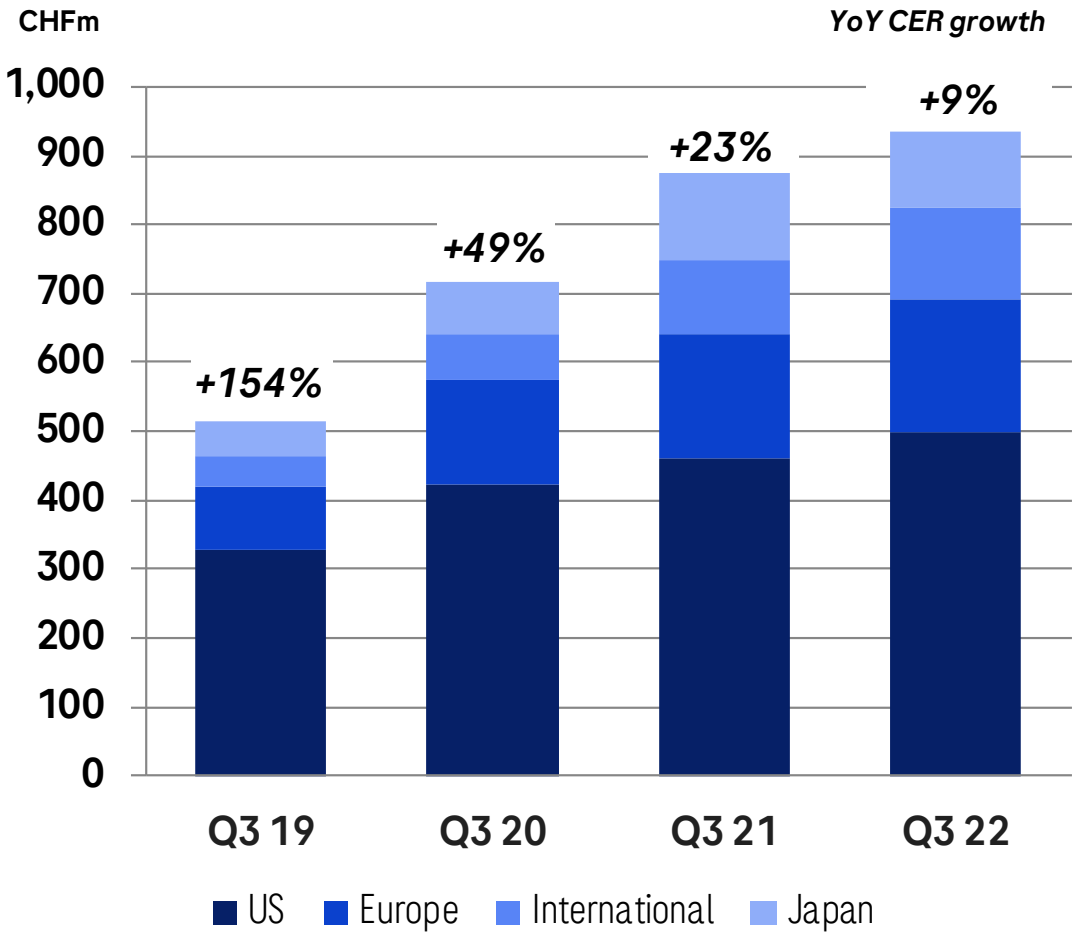
G+P, Giredestrant + Palbociclib; A+P, Anastrozole + Palbociclib

- First randomized study to show superior activity of an oral SERD (giredestrant) over an aromatase inhibitor (anastrozole) in ER+/HER2– eBC
- Final analysis confirmed greater suppression of Ki67 and rates of complete cell cycle arrest with giredestrant vs. anastrazole at time of surgery
- Ki67 is a biomarker of proliferation associated with improved long-term efficacy outcomes in early stage disease
- Safety data consistent with known safety profile

Fasching P et al., ASCO 2022; Martin M et al., ESMO 2022; Clinical cutoff: 18 Feb 2022; median follow-up 7.89 months; SERD=Selective estrogen receptor degrader; BC=Breast cancer; ER=estrogen receptor; ESR1=estrogen receptor 1; ET=estrogen therapy; PFS-INV=progression-free survival by investigator assessment; HR=hazard ratio; PCET=physician's choice of endocrine therapy; HER2=Human epidermal growth factor receptor 2

Tecentriq overview: Adjuvant key trials now to read out in 2023

First PD-(L)1 with pivotal SC results to be filed in 2022



Tecentriq Q3 update

- Positive Ph III (IMscin001) results for SC administration

Lung franchise (NSCLC, SCLC)

- EU: Strong launch in adj. NSCLC; 1L SCLC with continued growth
- US: Continued strong launch in adj. NSCLC

GI franchise (HCC)

- US/EU/Japan: Further growth in 1L HCC

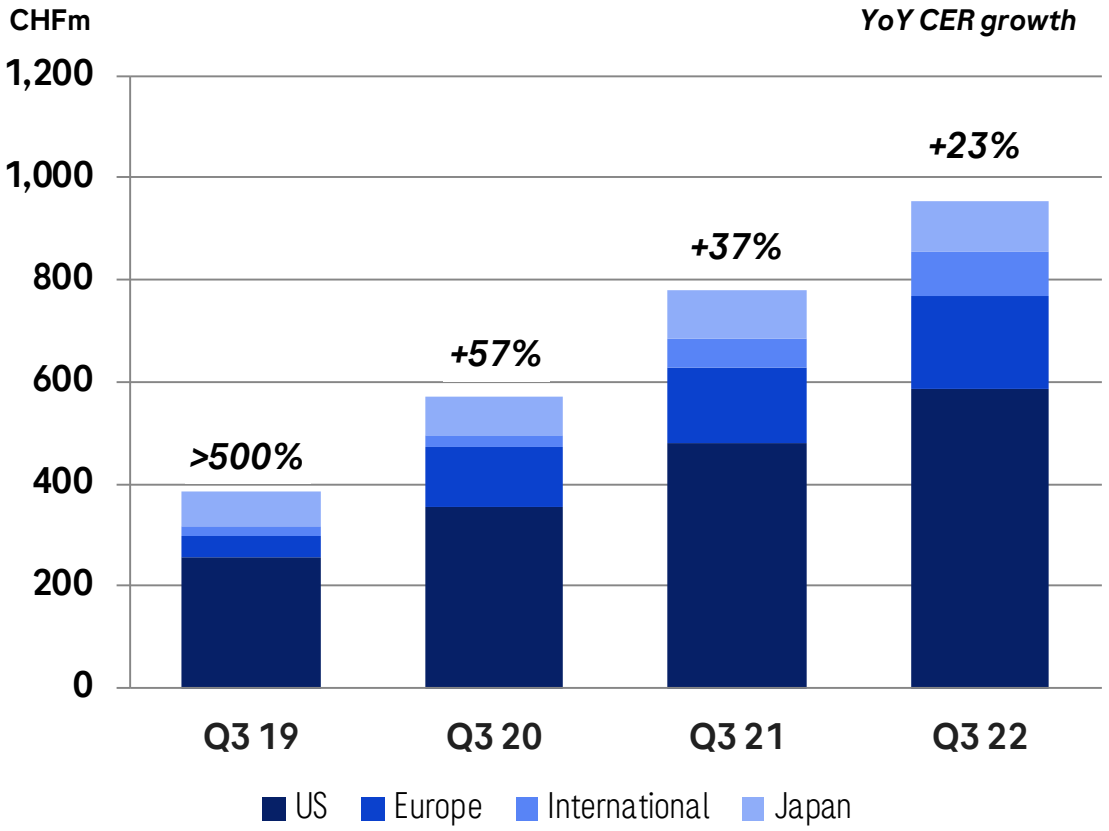
Outlook 2022

- Further growth due to first-to-market indications

CER=Constant Exchange Rates; SC=subcutaneous; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; HCC=hepatocellular cancer

Hemophilia A franchise: Hemlibra new global standard of care

36% US/EU-5 patient share reached



Hemophilia Q3 update

- >18,000 patients treated globally
- Hemlibra continues to penetrate across all approved patient segments
- 2nd generation FIXa x FX bi-specific (NXT007) to be taken into Roche clinical development

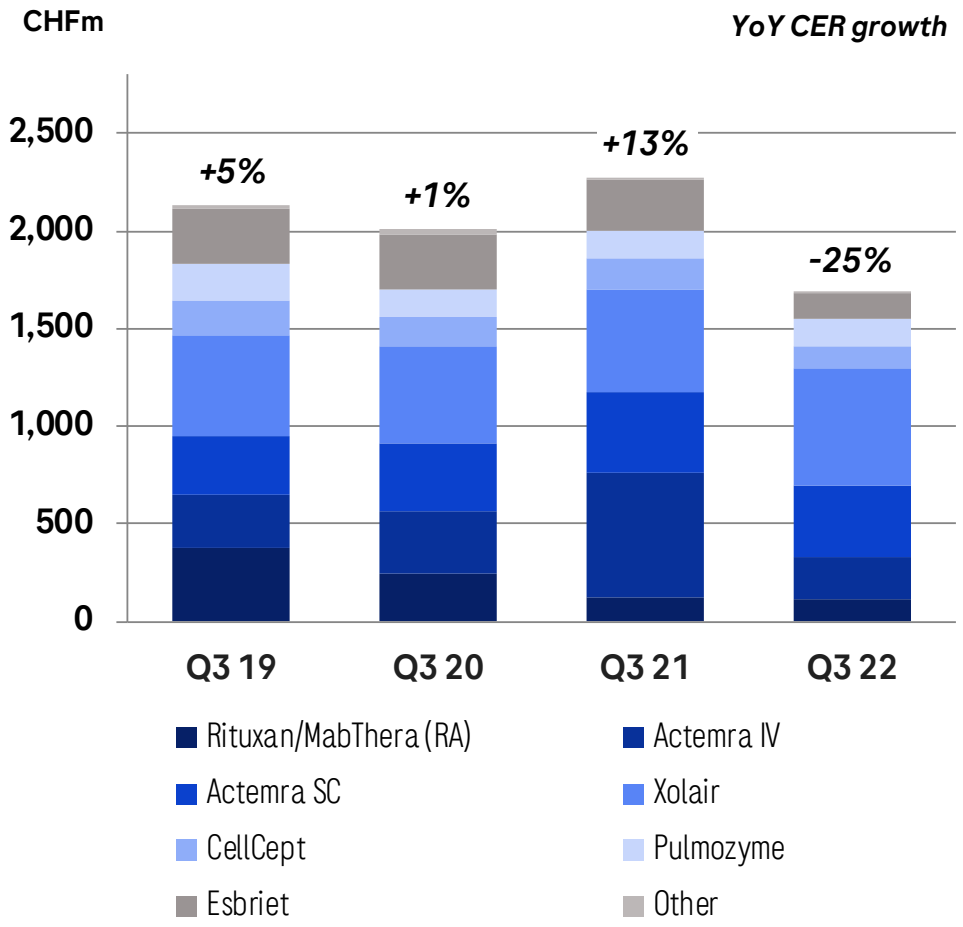
Outlook 2022

- US/EU: Further patient share gains in non-inhibitors
- EU: Label expansion to include mild/moderate patients (HAVEN 6) expected
- Ph III (HAVEN 7) in infants (0-1 year) submitted for presentation at ASH 2022

CER=Constant Exchange Rates

Immunology franchise

Actemra COVID-19 sales declining and Esbriet generic competition



Immunology Q3 updates

Actemra (-42%)

- COVID-19 demand completely washed out in Q3
- Submitted to EMA for approval in SSC-ILD
- Shift from IV to SC ongoing

Xolair (+8%)

- Market leader in asthma biologics and strong growth in CSU
- Autoinjector submitted to FDA for approval

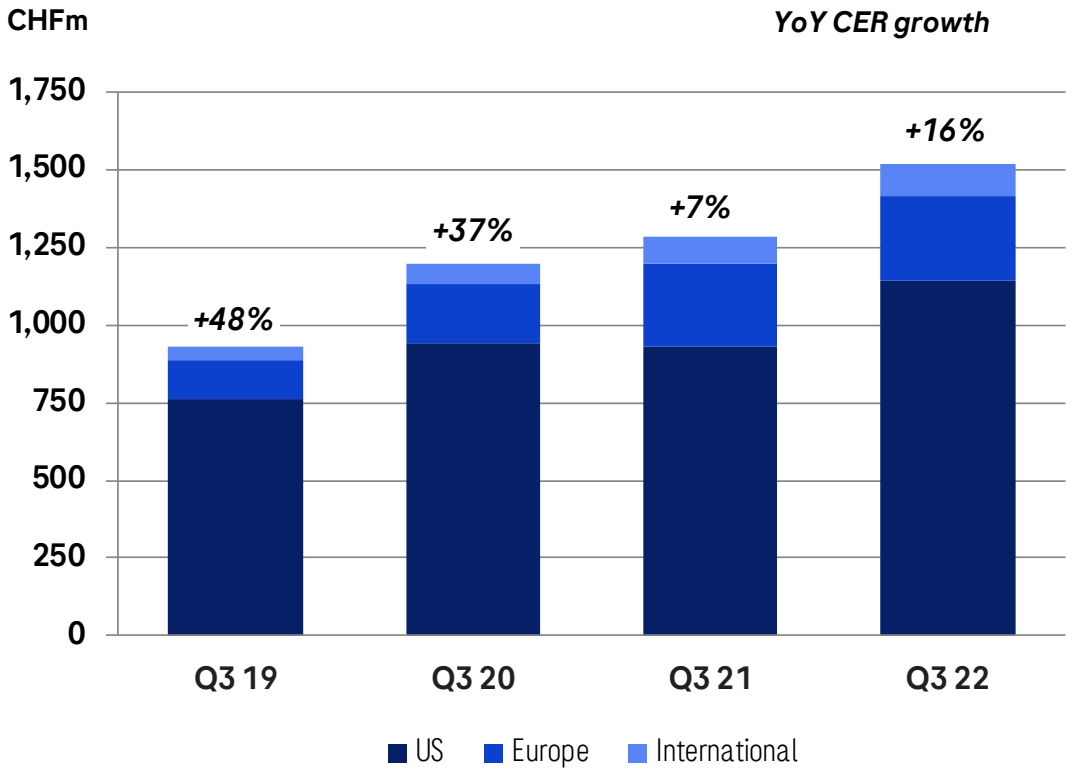
Esbriet (-48%)

- US: Generic competition

CER=Constant Exchange Rates; RA=rheumatoid arthritis; IV=intravenous; SC=subcutaneous; CSU=chronic spontaneous urticaria; SSc-ILD=systemic sclerosis-interstitial lung disease

MS franchise: Ocrevus #1 treatment in US and now also in EU-5

MS development programs well on track



Q3 update

- >250.000 patients treated globally
- #1 treatment in US and EU-5, both in total share and new to brand share
- Higher persistence than other MS medicines
- Ph III program (FENhance I/II, FENtrepid) for fenebrutinib in RMS and PPMS on track
- Ph III (OCARINA II) Ocrevus SC with strong recruitment; results expected in 2023

Outlook 2022

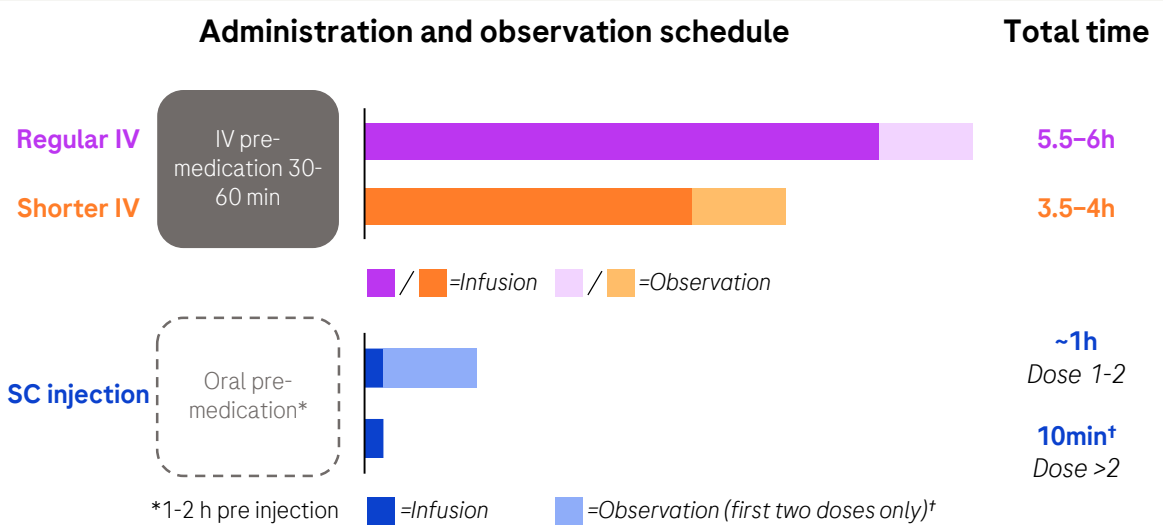
- US/EU: Further market share gains expected

CER=Constant Exchange Rates; MS=multiple sclerosis; SC=subcutaneous; RMS=relapsing MS; PPMS=primary progressive MS

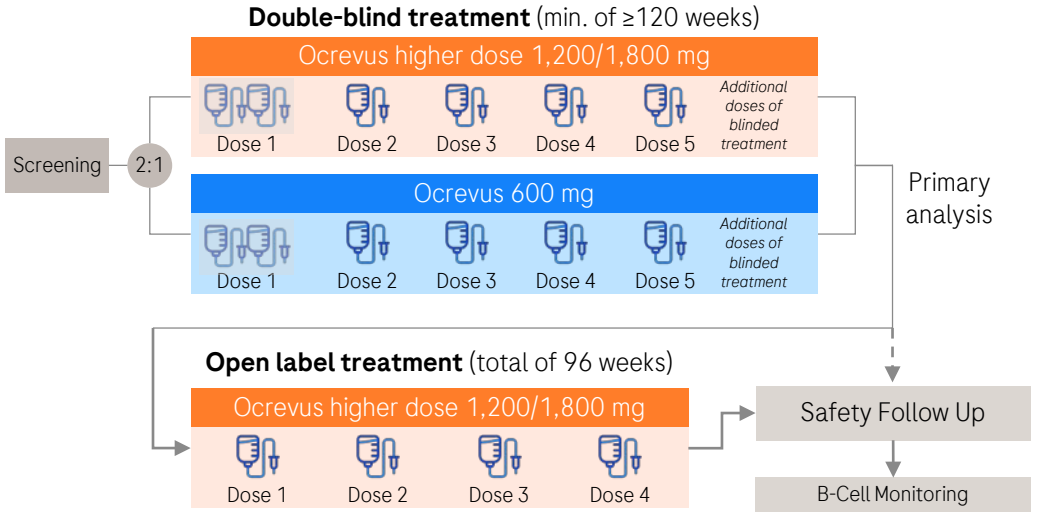
MS franchise: Subcutaneous dosing and higher dose Ocrevus

Q6M SC dosing readout expected in 2023

Ocrevus SC will retain Q6M dosing



Ocrevus higher dose vs 600 mg in RMS and PPMS



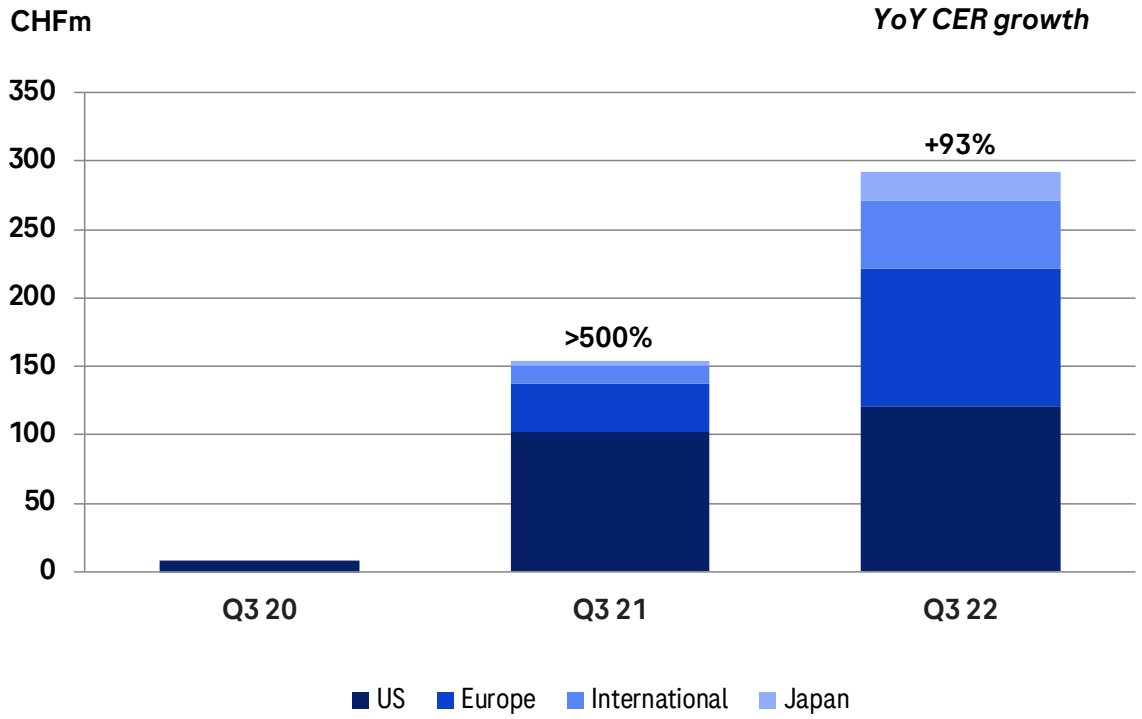
- Ph III (OCARINA II) evaluating subcutaneous Q6M dosing of Ocrevus for non-inferiority vs Ocrevus IV in RMS & PPMS with data expected in 2023
- Increases potential for Ocrevus use in centers with IV capacity constraints

- Two double-blind, randomized Ph III studies were designed to test higher dose Ocrevus (MUSETTE in RMS and GAVOTTE in PPMS)[1]
- Exposure/response analysis of Ph III data suggests a higher dose could lower the risk of disability progression without compromising safety

[1] Hauser S.L. et al, ACTRIMS-ECTRIMS 2020; †Expected, but may vary based on clinical results; MS=multiple sclerosis; IV=intra-venous; SC=Subcutaneous; RMS=relapsing multiple sclerosis; PPMS=primary progressive MS; Q6M=dosing every 6 months

SMA franchise: Evrysdi with strong global momentum

Well-positioned to become #1 worldwide



Q3 update

- >7,000 patients treated worldwide (commercial, clinical trials, compassionate use)
- Retention rate in first 12 months of ~90% globally
- US: 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
- Positive Ph II (JEWELFISH) 2 year data presented at WMS; largest SMA study in previously treated patients

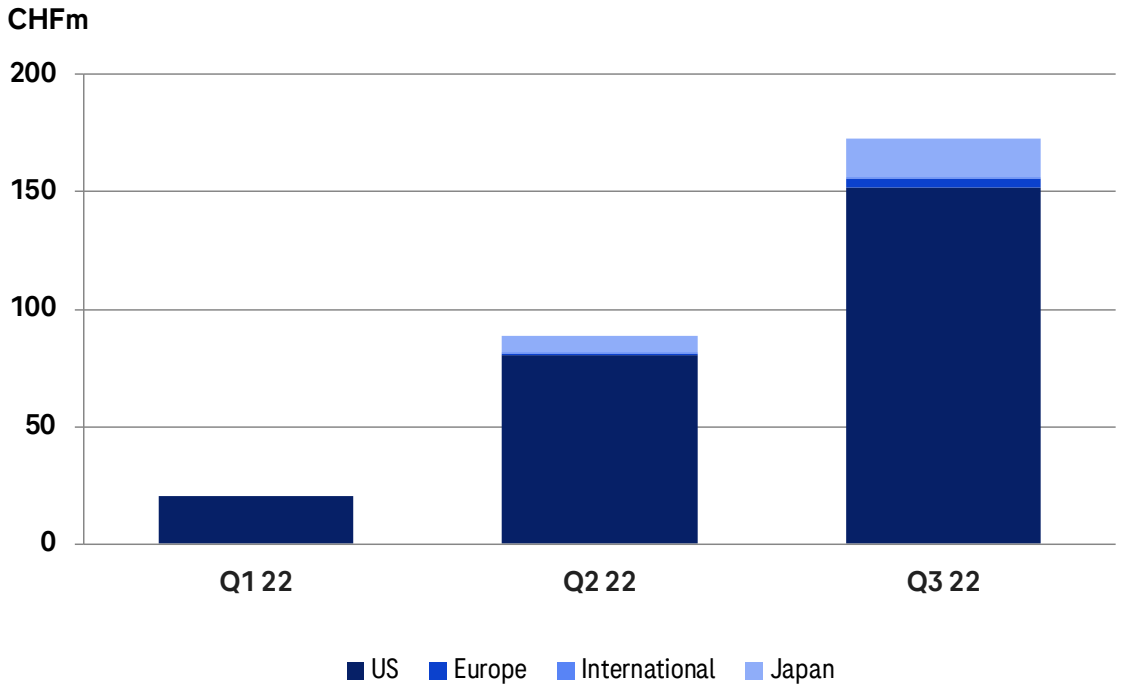
Outlook 2022

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

CER=Constant Exchange Rates; SMA=spinal muscular atrophy

Ophthalmology franchise: Excellent Vabysmo launch

More than 165k vials shipped in the US in the first 7 months



Q3 update

Vabysmo

- US: Strong uptake with switches primarily from aflibercept and first naïve patient starts
- US: Permanent J-code granted on October 1st
- EU: Approval granted in DME and nAMD
- Ph III (TENAYA/LUCERNE) 2 year data in nAMD presented at ASRS
- Real-world study (TRUCKEE*) update presented at AAO supporting efficacy and safety profile

Susvimo

- Voluntary recall due to manufacturing issue

Outlook 2022

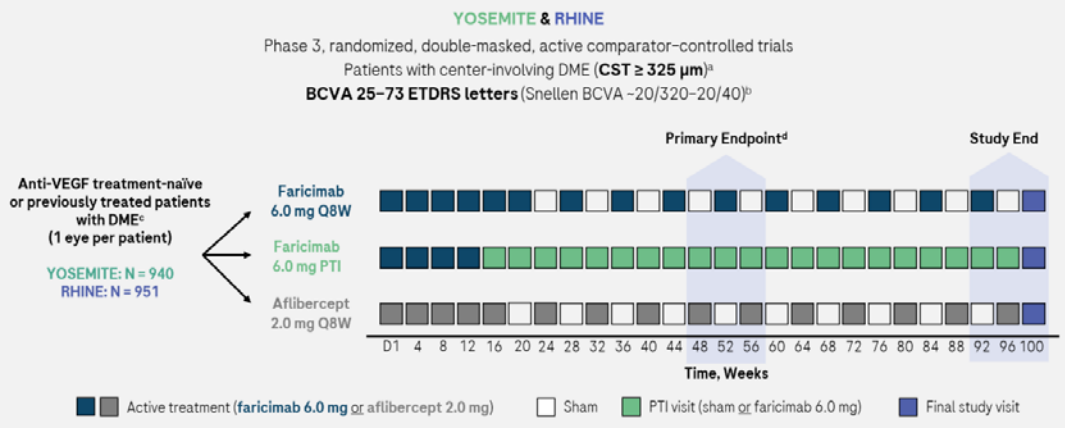
- Ph III (BALATON / COMINO) results for Vabysmo in RVO expected
- Ph III (PAGODA/PAVILLION) results for Susvimo in DME/DR expected
- Ph III (MEERKAT/SANDCAT) IL-6 mAb in UME to be initiated

*Investigator initiated study; DME=diabetic macular edema; nAMD=neovascular age-related macular degeneration; RVO=retinal vein occlusion; DR=diabetic retinopathy; UME=uveitic macular edema; mAb=monoclonal antibody; Eylea (aflibercept) is a registered trademark/product of Regeneron

Vabysmo: Improved overall disease control in DME

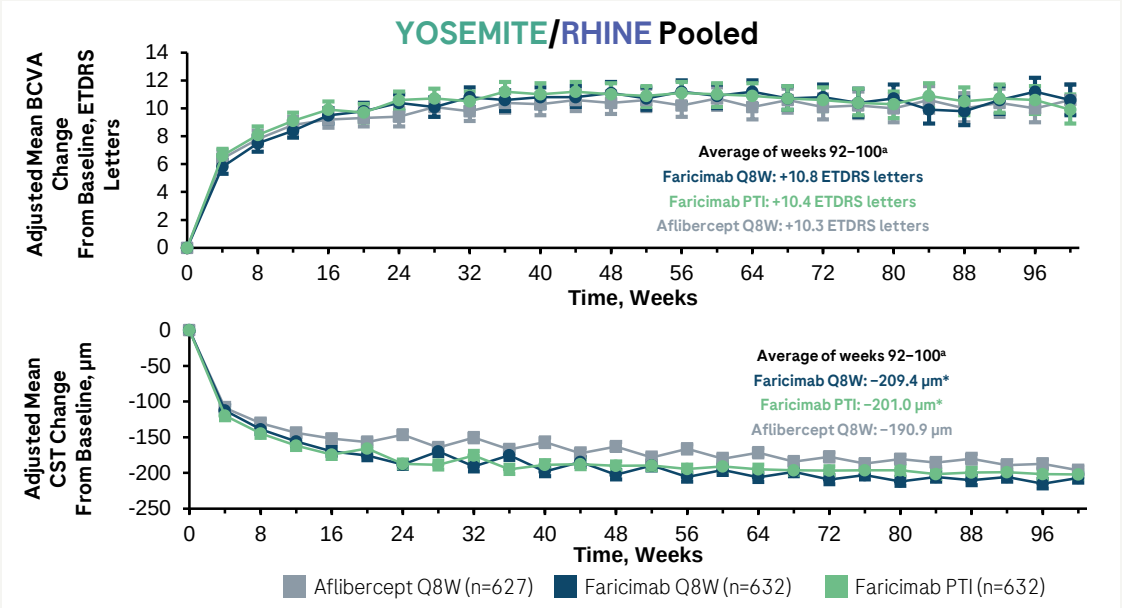
Treat & extend study design well-aligned with clinical practice

Ph III trial design in DME (YOSEMITE/RHINE)



- First time treat & extend principals were consistently applied in a randomized Ph III setting aligned with clinical practice
- Share of patients on ≥Q12W dosing at 78% in year 2, with share of patients on Q16W dosing improving to 62% from 52% in year 1

Ph III (YOSEMITE/RHINE) 2 year results



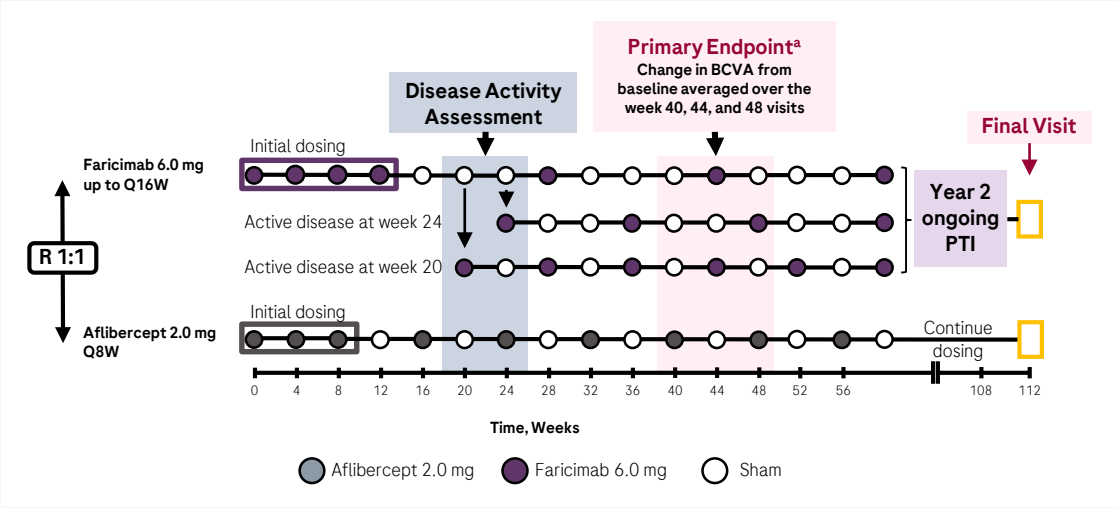
- Improved disease control seen in anatomic outcomes vs aflibercept Q8W, maintained over two years
- Comparable BCVA gains vs aflibercept over two years, maintained with fewer injections in Vabysmo PTI arm

YOSEMITE (NCT03622580)/RHINE (NCT03622593). Test for superiority: * Nominal P < 0.05 versus aflibercept Q8W. P values are nominal and not adjusted for multiplicity; [a] CST was measured as the distance from the internal limiting membrane to Bruch's membrane. [b] BCVA was measured using the ETDRS visual acuity at a starting distance of 4 m. [c] Previously anti-VEGF-treated eyes (treated>= 3 months before day 1) were limited to 25% of the total enrolment. [d] Primary efficacy endpoint: adjusted mean BCVA change from baseline at year 1, averaged over weeks 48, 52 and 56. BCVA=best corrected visual acuity; CST=central subfield thickness; DME=diabetic macular edema; ETDRS=early diabetic retinopathy study; PTI=personalized treatment interval; Q8W=every 8 weeks; Eylea (aflibercept) is a registered trademark/product of Regeneron

Vabysmo: 2 year nAMD data presented at ASRS

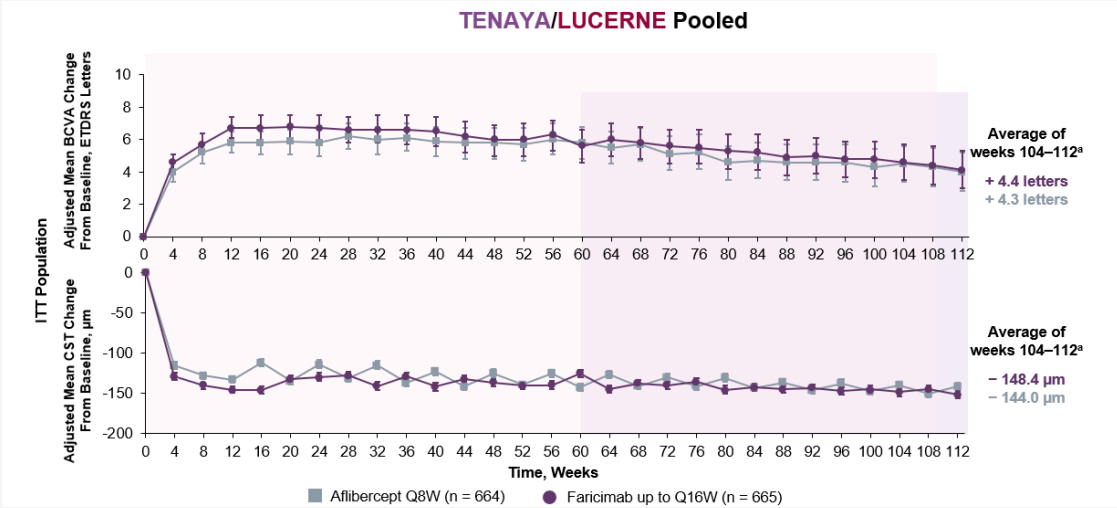
Strong BCVA and CST results sustained over 2 years

Ph III trial design in nAMD (TENAYA/LUCERNE)



- Disease activity criteria at week 20 and 24 used to allocate patients to treatment intervals (Q8W or Q12W or Q16W) for the remainder of year 1
- During year 2, Vabysmo patients were treated via a personalized treatment interval regimen
- Share of patients on ≥Q12W dosing at 78% in year 2, with share of patients on Q16W dosing improving to 63% from 45% in year 1

Ph III (TENAYA/LUCERNE) 2 year results



- Rapidly improved anatomy in more patients on VABYSMO vs aflibercept during the matched Q4W loading period
- Comparable BCVA and CST gains vs aflibercept over two years, maintained with fewer injections for Vabysmo

Khanani A.M. et al., ASRS conference 2022; TENAYA (NCT03823287)/LUCERNE (NCT03823300): [a] BCVA was measured using the ETDRS visual acuity chart at a starting distance of 4 m; BCVA=best-corrected visual acuity; nAMD=neovascular age-related macular degeneration; CST=central subfield thickness; ETDRS=early diabetic retinopathy study; Q8W=every 8 weeks; ITT=intention to treat; Eylea (aflibercept) is a registered trademark/product of Regeneron

Vabysmo: Disease criteria chosen impact patient allocation

Vabysmo nAMD trials use disease criteria reflective of clinical practice[1]

Different ≥Q12W disease criteria as applied to TENAYA/LUCERNE patients

Stringent criteria**

*Treatment change if **ANY** criteria are met (based on criteria used in pivotal trials)*

- **≥ 5 letters BCVA loss** vs avg. BCVA over previous 2 scheduled visits, due to nAMD*
- OR
- **≥ 10 letters BCVA loss** vs highest BCVA recorded over previous 2 scheduled visits, due to nAMD*
- OR
- **> 50 µm CST increase** vs avg. CST over previous 2 scheduled visits
- OR
- **≥ 75 µm CST increase** vs lowest CST recorded at either of previous 2 scheduled visits
- OR
- **Presence of new macular hemorrhage***, due to nAMD activity

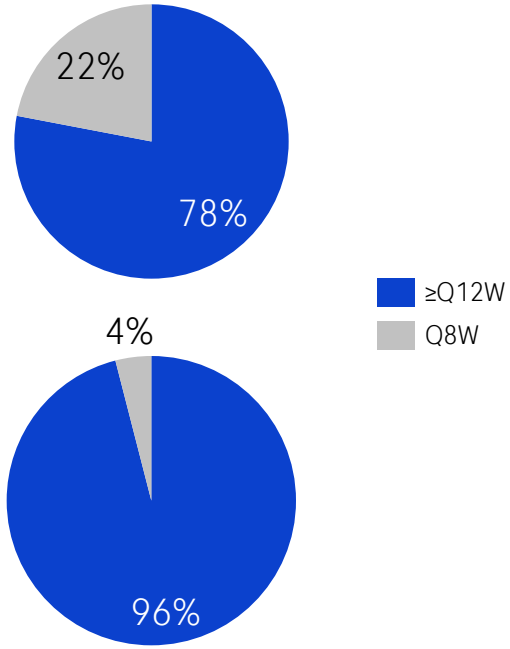
Less stringent criteria

*Treatment change if **ALL** criteria are met*

- **>5 letters BCVA loss** vs week 16 BCVA
- AND
- **> 25 µm CST increase** vs week 16 CST or new macular hemorrhage

Share of patients on ≥Q12W dosing

Assessment done at week 20



- Ph III TENAYA/LUCERNE trial with stringent patient-centric criteria resulted in 22% of patients being allocated to Q8W dosing
- Utilizing less stringent criteria only 4% of patients would have resulted in Q8W dosing (post hoc analysis)

[1]Heier et al. Lancet. 2022;399(10326):729-40; TENAYA (NCT03823287) & LUCERNE (NCT03823300); *per the investigator; **Additional patients with a missing Week 20 assessment were considered to have met disease activity criteria and were treated Q8W; Q8W=every 8 weeks; BCVA=best-corrected visual acuity; nAMD=neovascular age-related macular degeneration; CST=central subfield thickness

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

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

Virtual event Angiogenesis ✓	***Virtual event MDA*** ✓	***Roche ESG Day Access to Healthcare*** ✓	***Virtual event ASCO*** ✓	***Roche Pharma Day London*** ✓	***Virtual event ASH***
Monday, 14 Feb *16:30 to 17:45 CEST*	***Wednesday, 16 Mar*** *16:30 to 17:30 CEST*	***Monday, 16 May*** *15:00 to 16:30 CEST*	***Monday, 6 Jun*** *16:00 to 17:30 CEST*	***Monday, 12 Sep*** *10:30 to 15:00 BST*	***Wednesday, 14 Dec*** *16:00 to 17:30 CET*

* Outcome studies are event-driven: timelines may change; OS=overall survival; IA=interim analysis

Diagnostics Division

Thomas Schinecker
CEO Roche Diagnostics

YTD Sep 2022: Diagnostics Division sales

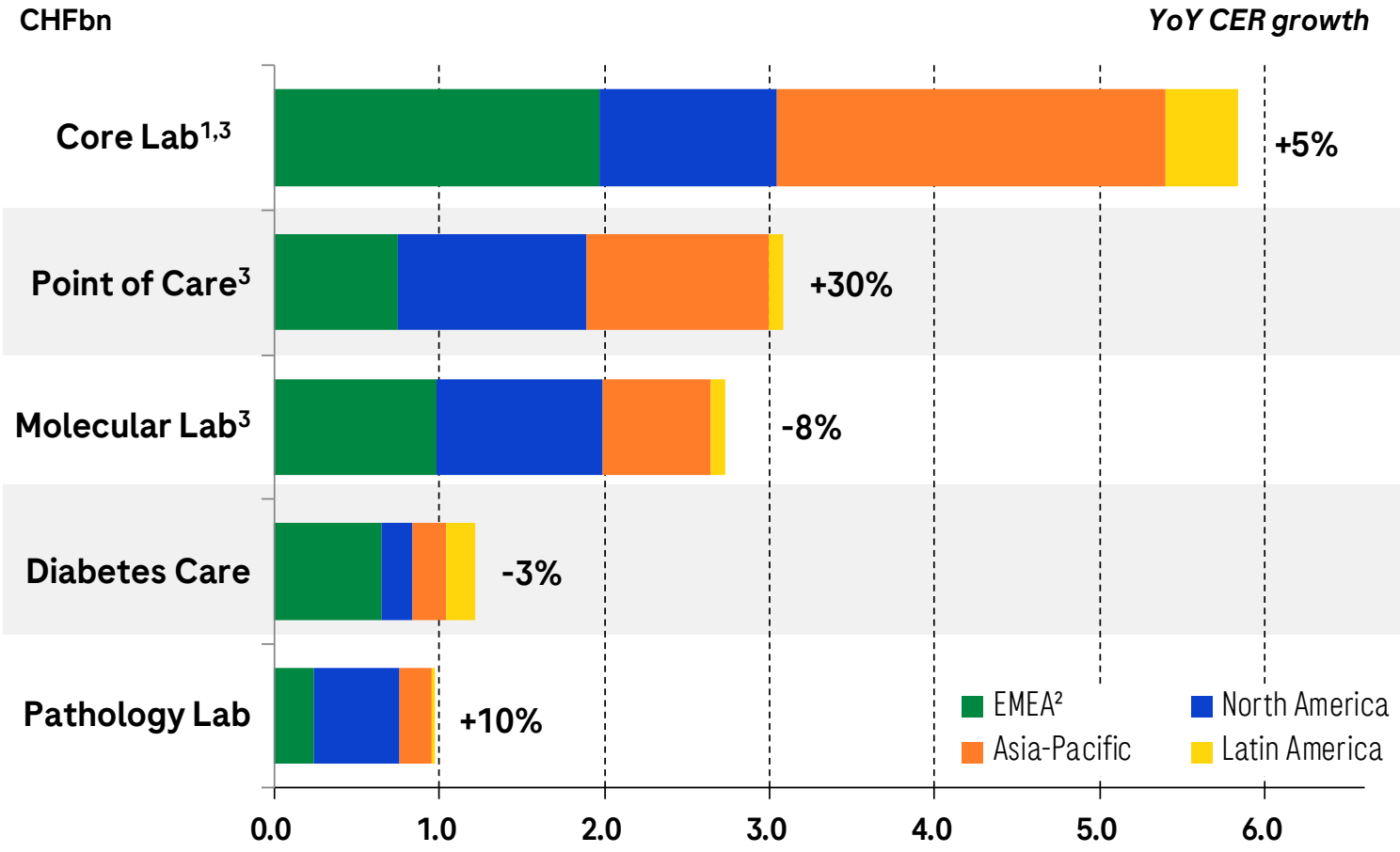
Sales increase of +6% driven by base business and COVID-19 testing

	2022 CHFm	2021 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**13,848**	**13,305**	**4**	**6**
Core Lab[1]	5,833	5,677	3	5
Point of Care[1]	3,086	2,415	28	30
Molecular Lab[1]	2,735	3,030	-10	-8
Diabetes Care	1,219	1,294	-6	-3
Pathology Lab	975	889	10	10

CER=Constant Exchange Rates; underlying growth of Core Lab excluding Roche Information Solutions: +5%; [1] Sales in the Point of Care customer area include sales from the Liat business (POC molecular), and sales in the Core Lab customer area include sales from the Life Science Alliances, both previously shown as part of Molecular Lab customer area. The comparative information for 2021 has been updated accordingly. In Q1 21 POC molecular sales = 90mCHF, Q2 21=92mCHF, Q3 21=175mCHF, Q4 21=194mCHF. In Q1 21 LS Alliances = 21mCHF, Q2 21=23mCHF, Q3 21=23mCHF, Q4 21=20mCHF.

YTD Sep 2022: Diagnostics Division highlights

Growing from a high base in 2021



- Immunodiagnostics (+6%)
- Clinical Chemistry (+8%)
- Custom biotech (-8%)[3]

- POC Immunodiagnostics (+39%)
- POC Molecular[3] (+33%)

- qPCR&NAP (-28%)
- Virology (-7%)

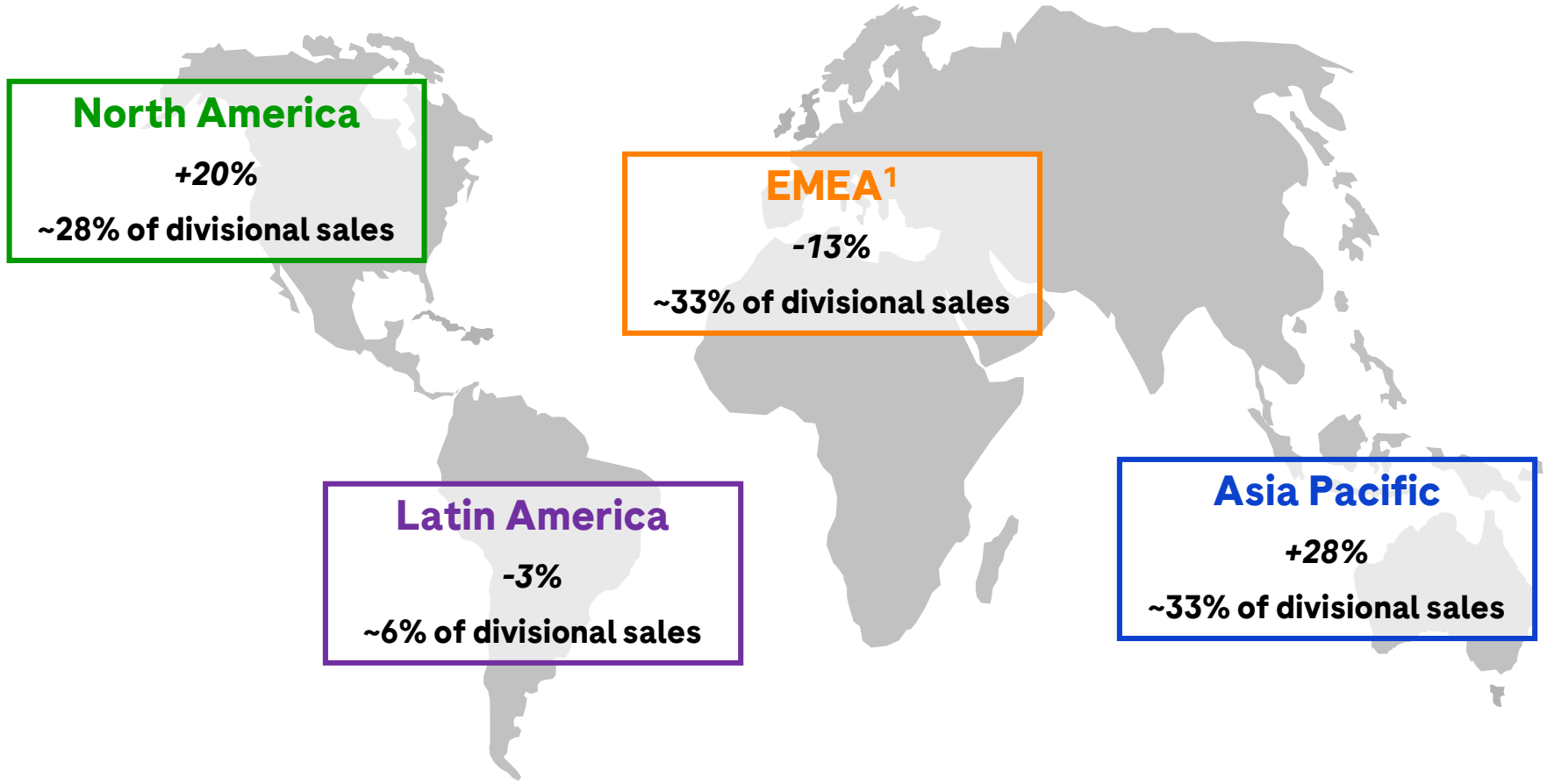
- Blood glucose monitoring (-4%)
- Insulin delivery systems (+9%)

- Advanced staining (+8%)
- Companion diagnostics (+28%)

CER=Constant Exchange Rates; POC=point of care; [1] Underlying growth of Core Lab excluding Roche Information Solutions: +5%; [2] EMEA=Europe, Middle East and Africa; [3] Sales in Point of Care customer area include sales from the Liat business (POC molecular), and sales in the Core Lab customer area include sales from the Life Science Alliances, both previously shown as part of Molecular Lab customer area. The comparative information for 2021 has been updated accordingly. In Q1 21 POC molecular sales = 90mCHF, Q2 21=92mCHF, Q3 21=175mCHF, Q4 21=194mCHF. In Q1 21 LS Alliances = 21mCHF, Q2 21=23mCHF, Q3 21=23mCHF, Q4 21=20mCHF.

YTD Sep 2022: Diagnostics Division regional sales

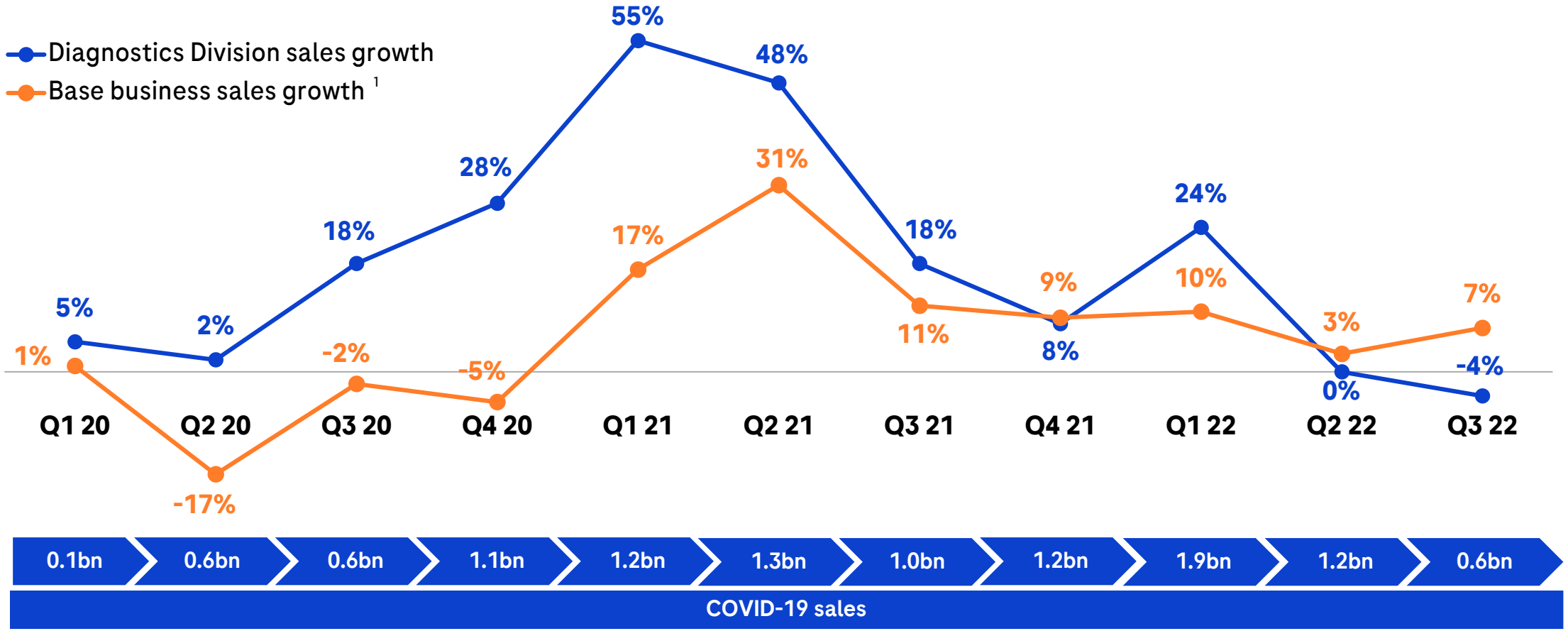
Strong base business growth across all regions



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

Diagnostics Division sales growth by quarter

Strong base business growth



Growth rates at CER (Constant exchange Rates); [1] Quarterly sales growth excluding COVID-19 sales

Our contribution against COVID-19

Roche has enabled access to >1.8 billion tests to fight the COVID-19 pandemic

20+ solutions

Broad portfolio of COVID-19 solutions

>1.8 billion COVID-19 tests

Conducted with our products since 2020

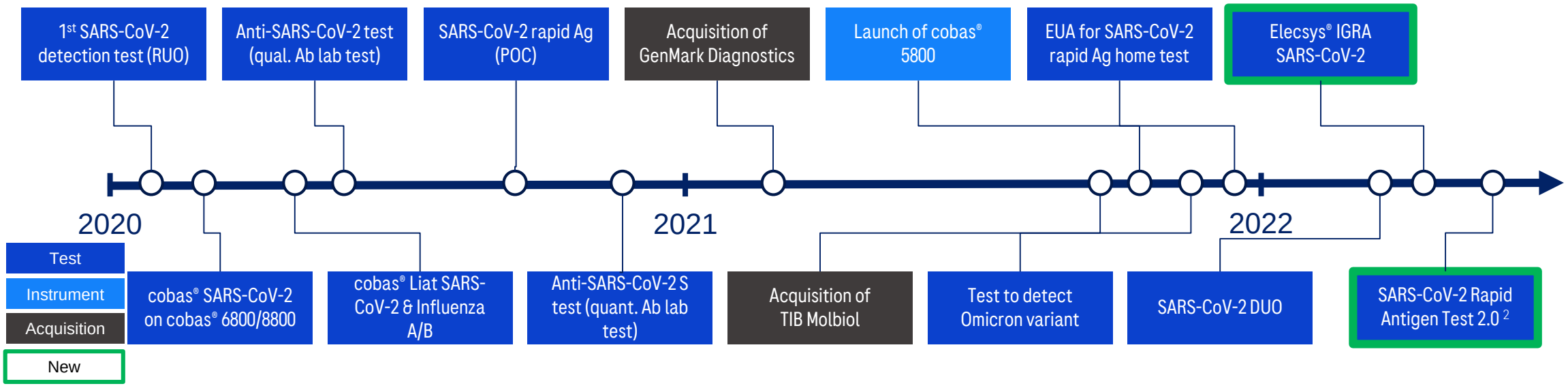
Responsible pricing to enable access

Costs should not be a barrier to access testing

~2'000 cobas® 6800/8800 instruments placed[1]

Increase over two-fold since the pandemic, enabling increased access to testing beyond COVID-19

Selected launches and acquisitions



[1] cobas® 6800/8800 instruments installed base per September 2022; [2] Elecsys® IGRA SARS-CoV-2 upcoming launch in end of July, 2022; [2] sensitivity of 99.00% (95% CI: 94.55 - 99.97%) and a relative specificity of 99.75% (95% CI: 98.62 - 99.99%); RUO: Research use only; POC: Point of care; EUA: Emergency Use Authorization; Ab: Antibody; Ag: Antigen

Roche Digital LightCycler®

Filling the gap between standard PCR and sequencing

Analyzer

Partition engine

Nanowell plates options:

1 

High sensitivity
~45µL sample, ~20k partitions

2 

Benchmark
~30µL sample, ~28k partitions

3 

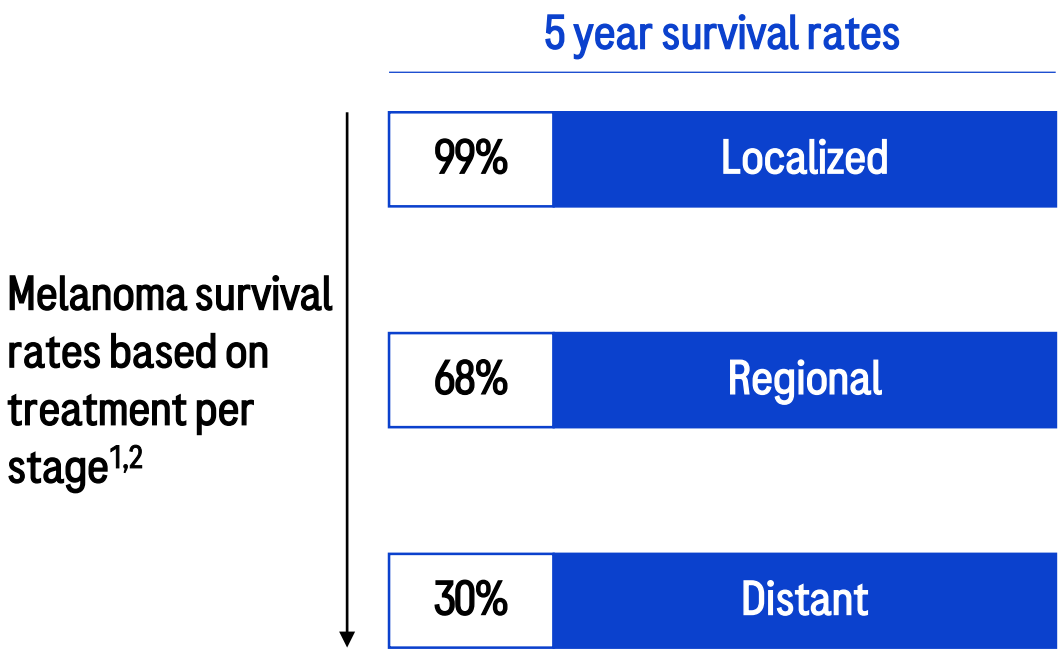
High resolution
~15µL sample , ~100k partitions

- Digital PCR system with IVD label & superior performance
- Key differentiators:
  - Powerful analytical software & simpler workflow - no more emulsions
  - Flexibility to tailor assays from high sensitivity to high resolution needs
  - Industry-leading multiplexing capabilities
- High-medical value applications:
  - Cancer treatment monitoring
  - Transplant rejection monitoring
  - COVID-19 / Infectious diseases environmental surveillance

PCR: Polymerase chain reaction; IVD: In-vitro diagnostic

PRAME immunohistochemistry assay

Enabling optimal patient prognosis via early & accurate diagnosis and treatment of melanoma



- >300k new cases and ~60k death per year caused by Melanoma cancer[3]
- Key immunohistochemistry assay to:
  - Help differentiate between benign and malignant lesions in skin cancer[4,5]
  - Evaluate tumor margins in known melanoma specimens[4,5]
  - Evaluate sentinel lymph nodes in known melanoma cases[6,7]
- Localized melanoma is highly curable with a simple surgical excision
- Roche's broad dermatology portfolio includes >50 biomarkers

[1] American Cancer Society. https://www.cancer.org/cancer/melanoma-skin-cancer/detection-diagnosis-staging/survival-rates-for-melanoma-skin-cancer-by-stage.html; [2] Definitions of stages: 'Localized': There is no sign that the cancer has spread beyond the skin where it started. 'Regional': The cancer has spread beyond the skin where it started to nearby structures or lymph nodes. 'Distant': The cancer has spread to distant parts of the body, such as the lungs, liver, or skin on other parts of the body. [3] Cazzato G. et al. Genes. 2022;13: 545; [4] Lezcano, C. et al. Am J Surg Pathol 2018;42(11):1456-1465; [5] Lezcano, C. et al. Surg Pathol Clin 2021 Jun;14(2):165-175; [6] Lezcano, C. et al. Am J Surg Pathol 2020;44(4):503-508; [7] NCCN Guidelines Version 3.2022. PRAME: Preferentially expressed Antigen in Melanoma

Elecsys® Amyloid Plasma Panel clinical results

Addressing the unmet need of early detection of Alzheimer's disease pathology

1 Triage
Patients undergoing initial evaluation for non-specific cognitive decline[1]

Elecsys® Amyloid Plasma Panel[2]
pTau181 + APOE4

FDA BDD

sensitivity > 85%
specificity > 65%

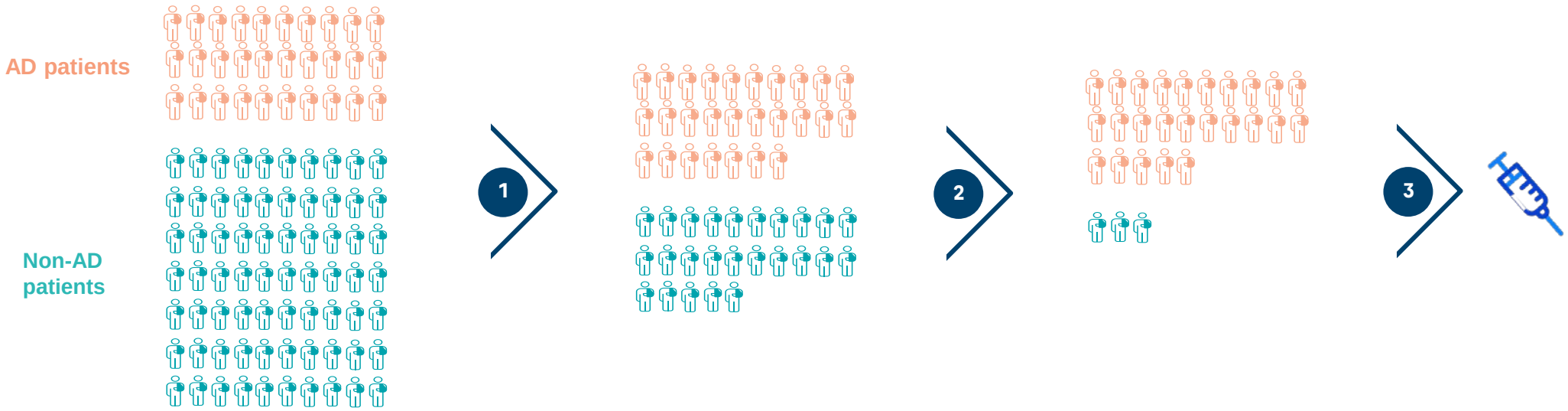
2 Confirmation
Patients referred for amyloid confirmatory testing[3]

Elecsys® CSF AD assays[4]
pTau/Abeta 42

sensitivity > 90%
specificity > 90%

3 Therapy
Patients identified for future therapies

Anti-amyloid antibodies



[1] Assumed prevalence of AD 30% in symptomatic patients; [2] Mean of clinical performance data from retrospective cohorts measured with Elecsys Amyloid Plasma Panel; [3] Alternative to PET scan; [4] FDA approval expected in Q4 2022

= 10 patients

Key launches 2022

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

CE: European Conformity, US: FDA approval, WW: Worldwide including CE, US and China, OUS: Outside the US; PCR: Polymerase Chain Reaction; RT: Real Time; [1]Research Use Only; [2] EUA: Emergency Use Authorization; [3]Only selected countries; *HER2 Low Breast received FDA approval on 4 Oct 2022; **PRAME launched on 11 Oct 2022

Finance

Alan Hippe
Chief Financial Officer

YTD Sep 2022: Highlights

Sales

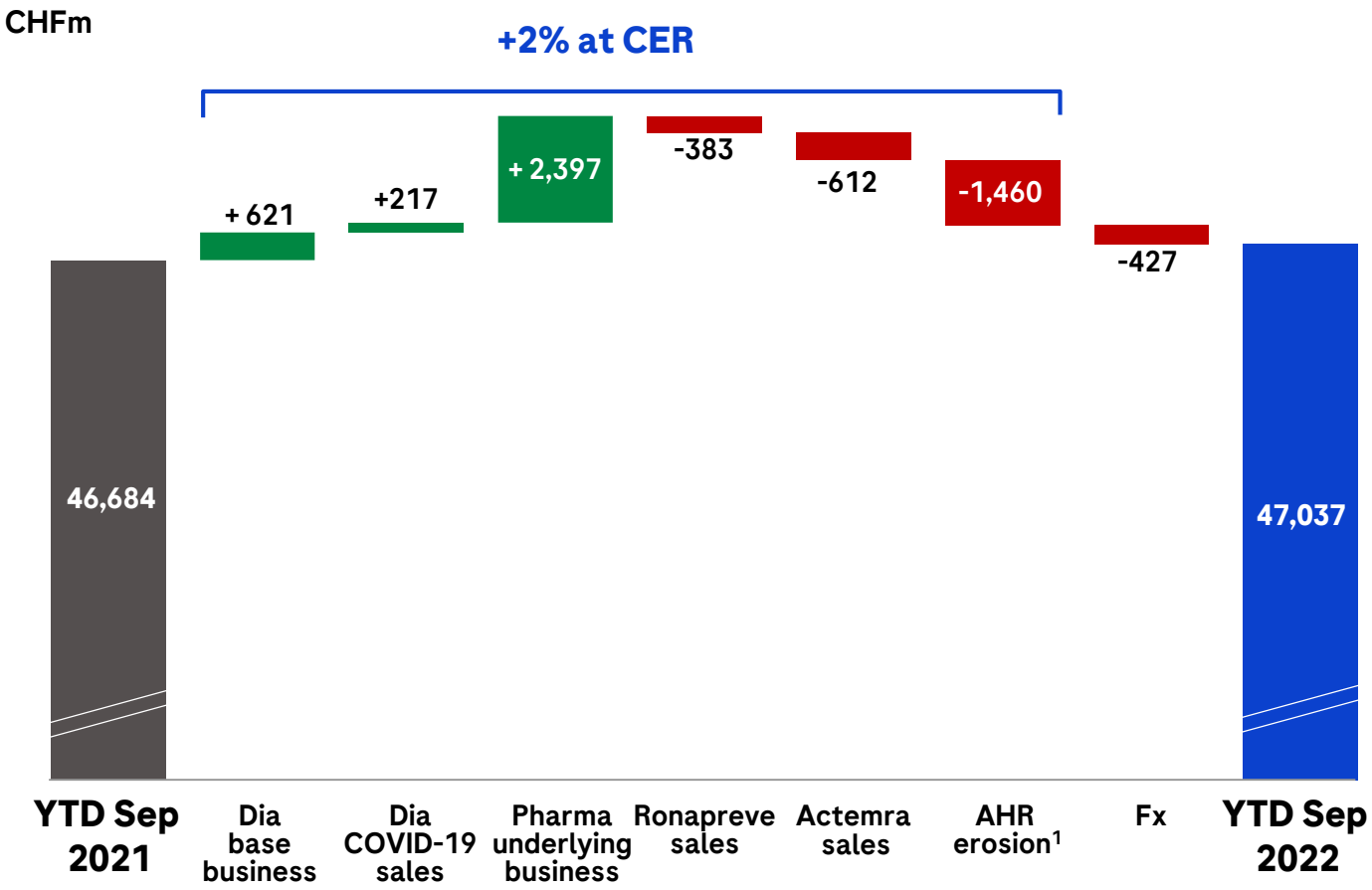
- Group sales growth of +2%
- Solid Pharma and Diagnostics underlying growth

Currency impact on sales

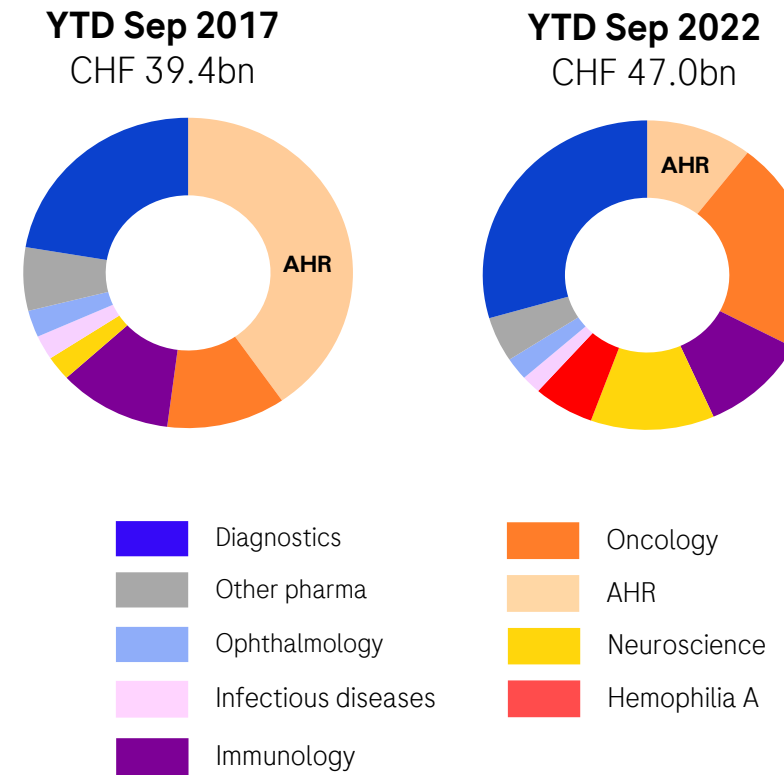
- Negative currency impact especially in Q3, particularly weaker EUR and JPY, only partially offset by stronger USD

Growth rates at CER (Constant exchange Rates)

YTD Sep 2022: Portfolio rejuvenation ongoing

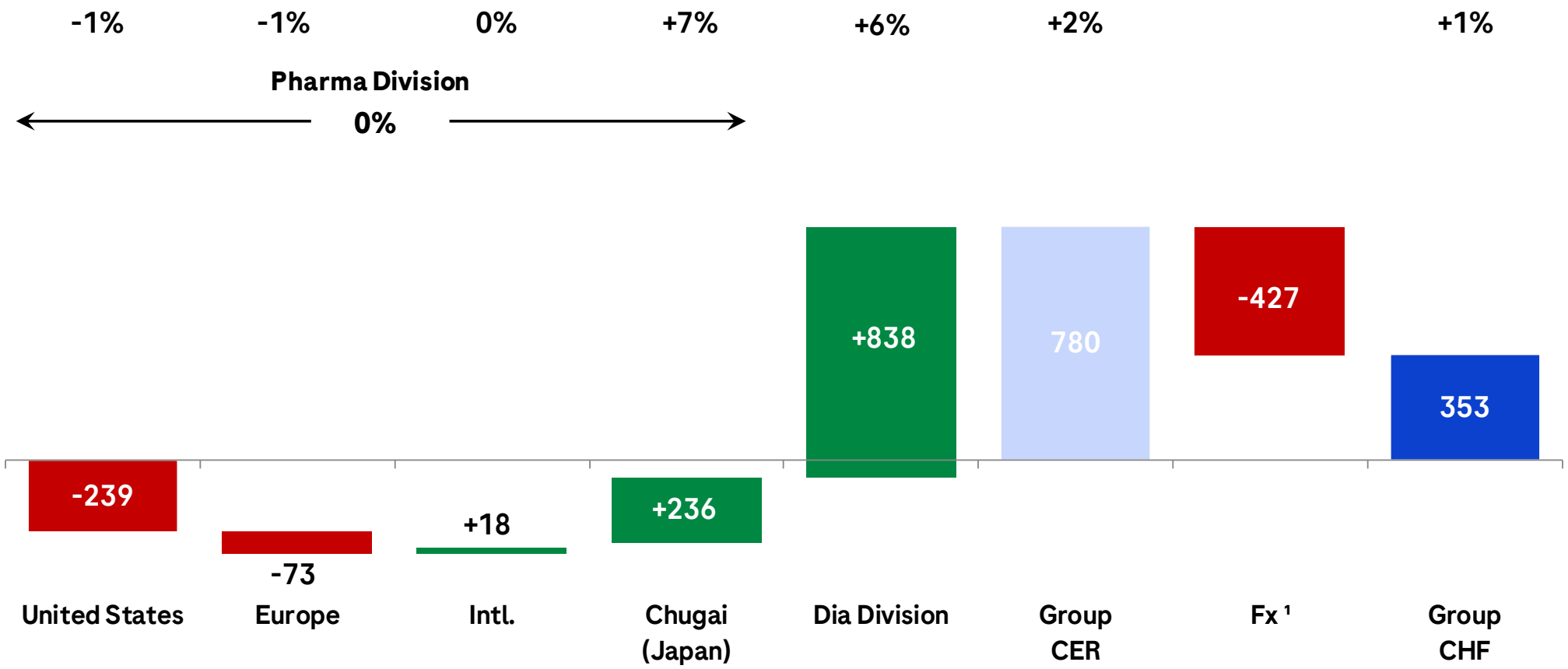


Diversification of Roche business



YTD Sep 2022 values in reported CHFm, variances in CERm; [1] AHR: Avastin, Herceptin, Rituxan/MabThera sales erosion

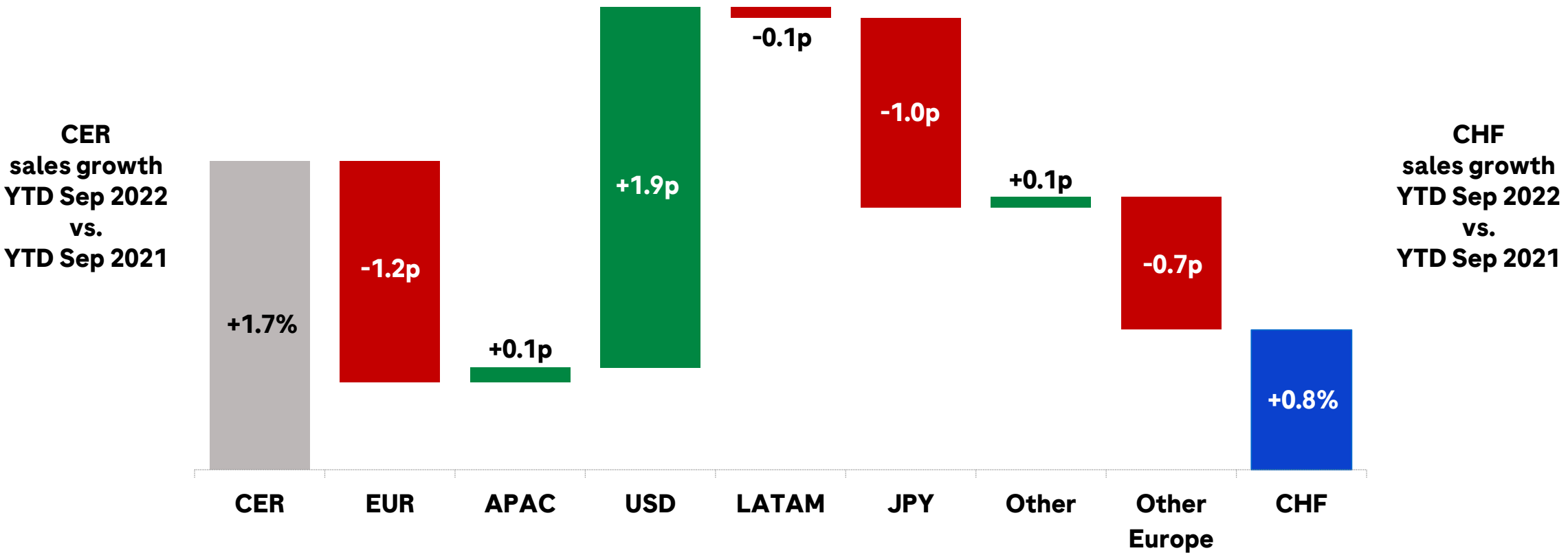
YTD Sep 2022: Regional sales development



Absolute values in CHFm at Constant Exchange Rates (avg full year 2021); [1] avg. full year 2021 to avg YTD September 2022 fx impact

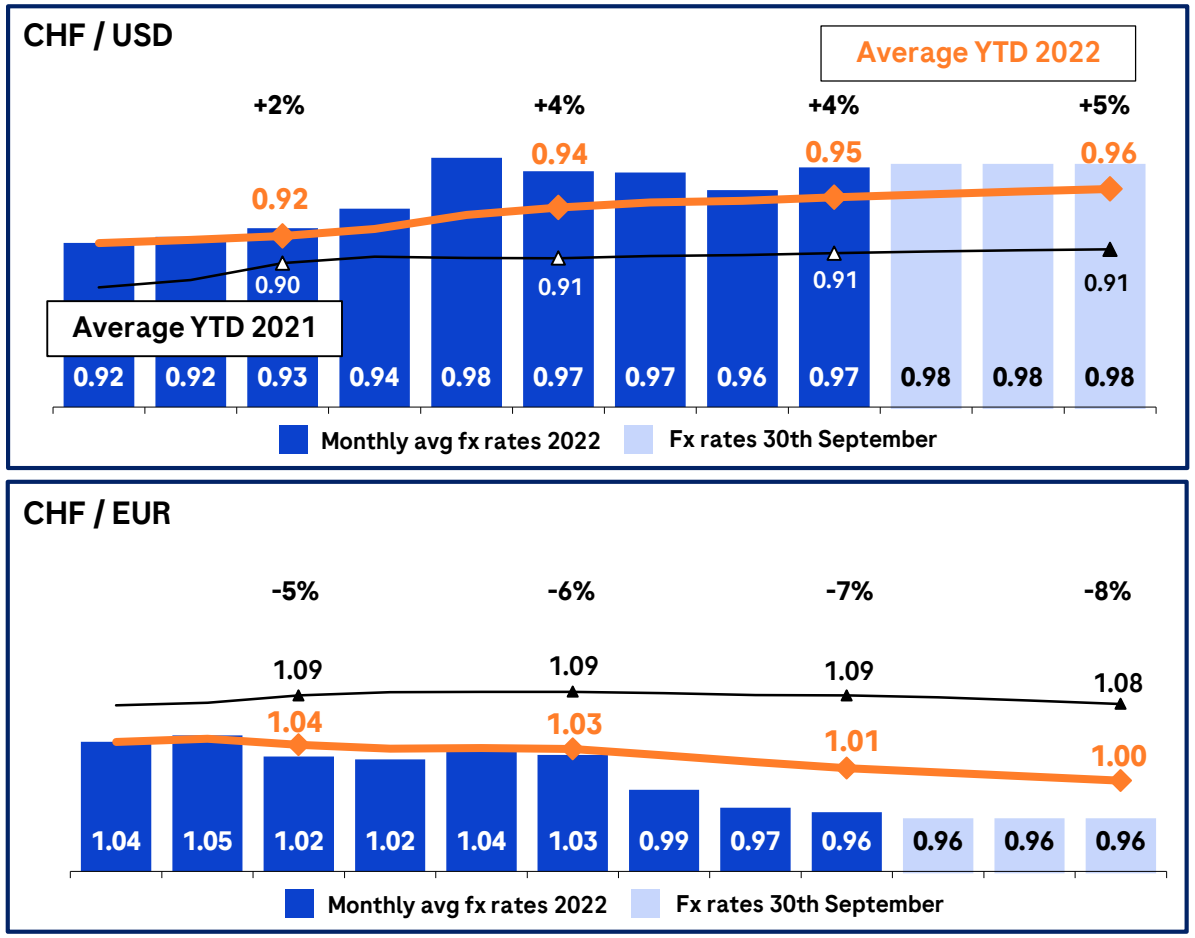
YTD exchange rate swings

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



CER = Constant Exchange Rates (avg full year 2021)

Expected currency impact 2022



Assuming the 30 September 2022 exchange rates remain stable until end of 2022, 2022 impact[1] is expected to be (%p):

	Q1	HY	Sep YTD	FY
Sales	-1	0	-1	-1
Core operating profit		0		-2
Core EPS		0		-2

[1] On group growth rates

2022 outlook

Group sales growth[1]	• Stable to low-single digit
Core EPS growth[1]	• Low- to mid-single digit
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

Q3 2022 update

New to phase I

2 NMEs:
RG6536 vixarelimab – immunology
RG6538 P-BCMA-ALLO1 – multiple myeloma

New to phase II

1 NME:
RG7314 balovaptan – post-traumatic stress disorder

New to phase III

4 AIs:
RG6168 Enspryng – MOG-AD
RG6168 Enspryng – autoimmune encephalitis
RG6058 tiragolumab – 1L non-squamous NSCLC (SKYSCRAPER-06)
RG3625 TNKase – stroke (FPI 2019)

New to registration

1 NME (First filed in China*):
RG6017 crovalimab - PNH

Removed from phase I

Removed from phase II

2 NMEs:
RG7907 CpAM (2) – HBV
RG6147 galegenimab (HtrA1) – geographic atrophy

1 AI (removed by Chugai):
CHU Oncolytic Type 5 adenovirus – esophageal cancer

Removed from phase III

1 AI:
RG7446 Tecentriq – RCC adj

Approvals

1 NME (EU):
RG7716 Vabysmo - DME

1 AI (EU):
RG7716 Vabysmo – wAMD

1 AI (US):
RG6512 Xofluza - influenza pediatric

Status as of October 18, 2022

*US/EU filing expected 2023

Roche Group development pipeline

Phase I (51 NMEs + 11 AIs)

RG6007	HLA-A2-WT1 x CD3	AML
RG6026	glofitamab monotherapy + combos	heme tumors
RG6058	tiragolumab combos	heme & solid tumors
RG6076	CD19-4-1BBL combos	heme tumors
RG6129	HLA-A2-MAGE-A4 x CD3	solid tumors
RG6160	cevostamab (FcRH5 x CD3)	r/r multiple myeloma
RG6171	giredestrant (SERD)	solid tumors
RG6114	inavolisib (mPI3K alpha inh)	solid tumors
RG6156	EGFRvIII x CD3	glioblastoma
RG6180	autogene cevumeran ± T	solid tumors
RG6185	belvarafenib (pan-RAF inh) + Cotellic ± T	solid tumors
RG6189	FAP-CD40 ± T	solid tumors
RG6194	runimotamab (HER2 x CD3)	BC
RG6234	GPRC5D x CD3	multiple myeloma
RG6264	Phesgo OBI	HER2+ BC
RG6279	PD1-IL2v ± T	solid tumors
RG6286	-	colorectal cancer
RG6290	MAGE-A4 ImmTAC ± T	solid tumors
RG6292	CD25 MAb combos	heme & solid tumors
RG6323	IL15/IL15Ra-Fc ± T	solid tumors
RG6330	KRAS G12C	solid tumors
RG6333	CD19 x CD28 + glofitamab	r/r NHL
RG6344	BRAF inhibitor (3)	solid tumors
RG6392	-	oncology
RG6433	SHP2i combos	solid tumors
RG6440	TGFβ (SOF10)	solid tumors
RG6512	FIXa x FX	hemophilia
RG6526[1]	camonsertib	solid tumors
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 (mosunetuzumab) monotheraphy + combos	heme tumors
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
CHU	CD137 switch antibody	solid tumors
CHU	LUNA18	solid tumors
CHU	SPYK04	solid tumors
SQZ	PBMC vaccine	solid tumors
RG6287	-	IBD
RG6341	-	asthma
RG6418	selnoflast (NLRP3 inh)	inflammation
RG6315	-	immunologic disorders
RG6536[3]	vixarelimab	immunology
RG7828	Lunsumio (mosunetuzumab)	SLE
RG7880	efmarodocokin alfa	aGVHD
RG6006	Abx MCP	bacterial infections
RG6319	LepB inhibitor	complicated urinary tract infection
RG6035	BS-CD20 MAb	multiple sclerosis
RG6091	rugonersen (UBE3A LNA)	Angelman syndrome
RG6163	-	psychiatric disorders
RG6182	-	neurodegenerative diseases
RG6237	latent myostatin	neuromuscular disorders
RG6289	-	Alzheimer´s
RG7637	-	psychiatric disorders
RG6120	VEGF-Ang2 DutaFab	nAMD
RG6312	-	geographic atrophy
RG6351	-	retinal disease
RG6501[4]	OpRegen	geographic atrophy
RG7921	-	nAMD
CHU	AMY109	endometriosis

Status as of October 18, 2022

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

Phase II (21 NMEs + 8 AIs)

RG6026	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	PD1 x LAG3	solid tumors
RG6180	autogene cevumeran + pembrolizumab	1L melanoma
RG6354	zinpentraxin alfa (PRM-151)	myelofibrosis
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016	hemophilia A with inhibitors to factor VIII
RG6149	astegolimab (Anti-ST2)	COPD
RG6299[5]	ASO factor B	IgA nephropathy
RG7854/ RG6346/ RG6084*	TLR7 ago(3)/siRNA/PDL1 LNA	HBV
RG6359	SPK-3006	Pompe disease
RG6100	semorinemab	Alzheimer's
RG6102	BS-gantenerumab	Alzheimer's
RG6237	latent myostatin + Evrysdi	SMA
RG6416	bepranemab	Alzheimer's
RG7314	balovaptan	post-traumatic stress disorder
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7816	alogabat (GABA Aa5 PAM)	ASD
RG7906	ralmitaront	schizophrenia
RG7935	prasinezumab	Parkinson's
RG6179	anti-IL-6	DME
RG7774	CB2 receptor agonist	DR
RG6299[5]	ASO factor B	geographic atrophy

RG-No - Roche/Genentech
CHU - Chugai managed
SQZ - SQZ Biotechnology managed
[1]Repare Therapeutics managed
[2]Poseida Therapeutics managed
[3]Kiniksa Pharmaceuticals managed
[4]Lineage Cell Therapeutics managed
[5]IONIS managed

*combination platform
T=Tecentriq
BS=Brain Shuttle
OBI=On-Body Delivery System

Roche Group development pipeline

Phase III (10 NMEs + 46 AIs)

RG3502	Kadcyla + T	2L+ HER-2+ PD-L1+ mBC
	Kadcyla + T	HER-2+ eBC high-risk
RG6026	glofitamab + chemo	2L+ DLBCL
RG6058	tiragolumab + T	1L PD-L1+ 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*	PNH
	crovalimab	aHUS
RG6114	inavolisib (mPI3K alpha inh)	1L HR+ mBC
RG6171	giredestrant (SERD)	1L ER+/HER2- mBC
	giredestrant (SERD)	ER+ BC adj
	giredestrant (SERD) + Phesgo	1L ER+/HER2+ BC
RG7440	ipatasertib + abiraterone	1L CRPC
RG7446	Tecentriq + platinum chemo	NSCLC periadj
	Tecentriq	NMIBC, high risk
	Tecentriq + cabozantinib	RCC adv
	Tecentriq + cabozantinib	2L NSCLC
	T ± chemo	SCCHN adj
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + Avastin	HCC adj
	T ± chemo	1L mUC
	Tecentriq SC	2L NSCLC
	Tecentriq	ctDNA+ high-risk MIBC
	T+ lurbinectedin	1L maintenance SCLC
RG7601	Venclexta	r/r MM t(11:14)
	Venclexta + azacitidine	1L MDS
RG7828	Lunsumio (mosunetuzumab) + lenalidomide	2L+ FL
	Lunsumio (mosunetuzumab) + Polivy	2L+ DLBCL
RG7853	Alecensa	ALK+ NSCLC adj
RG3648	Xolair	food allergy
RG6354	zinpentraxin alfa (PRM-151)	IPF
RG7159	Gazyva	lupus nephritis
	Gazyva	membranous nephropathy
	Gazyva	systemic lupus erythematosus
RG6152	Xofluza	influenza, pediatric (0-1 year)
	Xofluza	influenza direct transmission
RG1450	gantenerumab	prodromal to mild Alzheimer's
	gantenerumab	preclinical Alzheimer's
RG1594	Ocrevus higher dose	RMS & PPMS
	Ocrevus SC	RMS & PPMS
RG3625	TNKase	stroke
RG6042	tominersen	Huntington's
RG6168	Enspryng	myasthenia gravis
RG6168	Enspryng	MOG-AD
RG6168	Enspryng	autoimmune encephalitis
RG6356	delandistrogene moxeparvovec (SRP-9001)	DMD
RG7845	fenebrutinib	RMS
RG7845	fenebrutinib	PPMS
RG6321	Susvimo (PDS)	DME
	Susvimo (PDS)	DR
	Susvimo (PDS)	wAMD, 36-week
RG7716	Vabysmo (faricimab)	BRVO
	Vabysmo (faricimab)	CRVO

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

Registration US & EU (3 NMEs + 7AIs)

RG6013	Hemlibra[1]	mild to moderate hemophilia A
RG6026	glofitamab[2]	3L+ DLBCL
RG6396	Gavreto[1]	RET+ MTC, TC
RG7596	Polivy[3]	1L DLBCL
RG7828	Lunsumio (mosunetuzumab)[3]	3 L+ FL
RG6321	Susvimo (PDS)[1]	wAMD
RG6152	Xofluza[1]	influenza, pediatric
RG56413+ RG6412	Ronapreve[2]	SARS-CoV-2 hospitalised
RG1569	Actemra[3]	COVID-19 pneumonia
RG7916	Evrysdi[1]	SMA pediatric <2months

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

T=Tecentriq
PDS=Port Delivery System with ranibizumab
*First filed in China

Status as of October 18, 2022

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
PDS=Port Delivery System with ranibizumab
Mosun=mosunetuzumab
*First filed in China
[1]IONIS managed

2022

RG6026	**glofitamab** 3L+ DLBCL ✓
RG6107	**crovalimab*** PNH (CN) ✓
RG1450	**gantenerumab** prodromal to mild Alzheimer‘s

2023

RG6107	**crovalimab*** PNH (EU, US)
RG6058	**tiragolumab + T** 1L PD-L1+ NSCLC
RG6058	**tiragolumab + T** 1L esophageal cancer (CN)
RG6321	**Susvimo (PDS)** DME
RG6321	**Susvimo (PDS)** DR (US)
RG7716	**Vabysmo (faricimab)** BRVO/CRVO

2024

RG6026	**glofitamab + chemo** 2L DLBCL
RG6058	**tiragolumab + T** Stage III unresectable 1L NSCLC
RG6107	**crovalimab** aHUS
RG6114	**inavolisib (mPI3K alpha inh)** 1L HR+ BC
RG6354	**zinpentraxin alfa (PRM-151)** IPF
RG6356	**delandistrogene moxeparvovec (SRP-9001)** DMD (EU)

2025 and beyond

RG6026	**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
RG6139	**PD1xLAG3** solid tumors
RG6171	**giredestrant (SERD)** 1L ER+/HER2- mBC
RG6171	**giredestrant (SERD)** ER+ BC adj
RG6171	**giredestrant (SERD) + Phesgo** 1L ER+/HER2+ BC
RG6180	**autogene cevumeran** 1L melanoma
RG6354	**zinpentraxin alfa (PRM-151)** myelofibrosis
RG7828	**Lunsumio (mosun) + lenalidomide** 2L FL
RG7828	**Lunsumio (mosun) + Polivy** 2L+ DLBCL (US)
RG6149	**astegolimab (anti-ST2)** COPD
RG6299[1]	**ASO factor B** IgA nephropathy
RG7854/ RG6346/ RG6084	**TLR7 ago (3)/ siRNA/ PDL1 LNA** HBV
RG1450	**gantenerumab** preclinical Alzheimer‘s
RG6100	**semorinemab** Alzheimer’s
RG6102	**brain shuttle gantenerumab** Alzheimer’s
RG6237	**latent myostatin + Evrysdi** SMA
RG6416	**bepranemab** Alzheimer's
RG7314	**balovaptan** post-traumatic stress disorder
RG7816	**alogabat (GABA Aa5 PAM)** ASD
RG7845	**fenebrutinib** RMS
RG7845	**fenebrutinib** PPMS
RG7906	**ralmitaront** schizophrenia
RG7935	**prasinezumab** Parkinson’s
RG6321	**Susvimo (PDS)** wAMD, 36-week refill
RG6179	**anti-IL-6** DME
RG6299[1]	**ASO factor B** geographic atrophy
RG7774	**CB2 receptor agonist** DR

Status as of October 18, 2022

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

2022		2023		2024		2025 and beyond	
RG6413+ RG6412	**Ronapreve**** SARS-CoV-2 hospitalized (EU) ✓	RG6264	**Phesgo OBI** HER2+ BC	RG1594	**Ocrevus SC** RMS & PPMS	RG7446	**Tecentriq + paclitaxel** TNBC adj	RG3502	**Kadcyla + Tecentriq** 2L+ HER-2+ PD-L1+ mBC
RG1569	**Actemra** COVID-19 pneumonia[1] ✓	RG6396	**Gavreto** Tumor agnostic (US)	RG3625	**TNKase** stroke	RG7446	**Tecentriq** ctDNA+ high-risk MIBC	RG3502	**Kadcyla + Tecentriq** HER-2+ eBC high-risk
RG7446	**Tecentriq ± chemo** 1L mUC	RG7446	**Tecentriq + cabozantinib** 2L NSCLC	RG3648	**Xolair** food allergy	RG7601	**Venclexta + azacitidine** 1L MDS	RG7446	**Tecentriq** High risk NMIBC
RG7446	**Tecentriq SC** 2L NSCLC	RG7446	**Tecentriq + cabozantinib** RCC adv	RG6152	**Xofluza** direct transmission	RG7159	**Gazyva** lupus nephritis	RG7446	**Tecentriq+ lurbinectedin** 1l maintenance SCLC
RG7596	**Polivy** 1L DLBCL (US) ✓	RG7446	**Tecentriq + Avastin** HCC adj	RG6152	**Xofluza** influenza, pediatric (0-1 year)	RG6168	**Enspryng** myasthenia gravis	RG7159	**Gazyva** membranous nephropathy
		RG7446	**Tecentriq**[2] NSCLC periadj					RG7159	**Gazyva** systemic lupus erythematosus
		RG7446	**Tecentriq** SCCHN adj					RG1594	**Ocrevus higher dose** RMS & PPMS
		RG7601	**Venclexta** r/r MM t(11:14)					RG6168	**Enspryng** MOG-AD
		RG7446	**Tecentriq + capecitabine or carbo/gem** TNBC					RG6168	**Enspryng** autoimmune encephalitis
		RG7853	**Alecensa** ALK+ NSCLC adj						

Status as of October 18, 2022

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
[1]Approved in EU, filed in US
[2]filing timeline based on data from interim analysis

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

Major pending approvals 2022

US		EU		China		Japan-Chugai	
RG7828	**Lunsumio (mosunetuzumab)** 3L+ FL Filed Dec 2021	RG6321	**Susvimo (PDS)** wAMD Filed April 2021	RG7596	**Polivy** 1L DLBCL Filed Nov 2021	RG7159	**Gazyva** 1L CLL Filed March 2022
RG1569	**Actemra** COVID-19 pneumonia Filed Jan 2022	RG6013	**Hemlibra** mild to moderate hemophilia A Filed Oct 2021	RG7596	**Polivy** r/r DLBCL Filed Dec 2021	RG6264	**Phesgo** HER-2+ BC/CC Filed Sept 2022
RG7421	**Cotellic** histiocytosis Filed April 2022	RG6396	**Gavreto** RET+ MTC, TC Filed Nov 2021	RG6107	**crovalimab** PNH Filed Aug 2022		
RG7446	**Tecentriq** ASPS Filed June 2022	RG6152	**Xofluza** influenza pediatric Filed Nov 2021				
RG7596	**Polivy** 1L DLBCL (US) Filed Aug 2022	RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo Filed Nov 2021				
		RG6413+ RG6412	**Ronapreve*** SARS-CoV-2 hospitalized Filed Jan 2022				
		RG6026	**glofitamab** 3L+ DLBCL Filed April 2022				
		RG1569	**Actemra** SS-ILD Filed Aug 2022				

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

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

Status as of October 18, 2022

Major granted approvals 2022

US	
RG7716	**Vabysmo (faricimab)** DME Jan 2022
RG7716	**Vabysmo (faricimab)** wAMD Jan 2022
RG1569	**Actemra** GCA IV Feb 2022
RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo May 2022
RG6152	**Xofluza** influenza pediatric Aug 2022

EU	
RG7596	**Polivy** 1L DLBCL May 2022
RG7446	**Tecentriq** NSCLC adj June 2022
RG7828	**Lunsumio (mosunetuzumab)** 3L+ FL June 2022
RG7716	**Vabysmo (faricimab)** DME Sept 2022
RG7716	**Vabysmo (faricimab)** wAMD Sept 2022

China	
RG7446	**Tecentriq** NSCLC adj March 2022
RG1569	**Actemra** RA SC April 2022
RG6268	**Rozlytrek** NTRK+ solid tumors July 2022
RG6268	**Rozlytrek** ROS1+ NSCLC Aug 2022

Japan-Chugai	
RG1569	**Actemra** COVID-19 pneumonia Jan 2022
RG7716	**Vabysmo (faricimab)** DME March 2022
RG7716	**Vabysmo (faricimab)** wAMD March 2022
RG1273	**Perjeta + Herceptin** HER-2+ CRC March 2022
RG7446	**Tecentriq** NSCLC adj May 2022
RG6013	**Hemlibra** acquired Hemophilia A June 2022
RG105	**Rituxan** NMOSD June 2022
RG7596	**Polivy** 1L DLBCL Aug 2022

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

Status as of October 18, 2022

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	Multicenter, open-label, non-randomized study to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of Hemlibra administered every 4 weeks. ▪ **Part I:** Pharmacokinetic run-in part (N=6) ▪ **Part II:** Expansion part (N=40)
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 24 weeks
Status	▪ FPI Q3 2016, recruitment completed Q2 2017 ▪ Study met primary and key secondary endpoints Q4 2017 ▪ FDA granted Breakthrough Therapy Designation April 2018 ▪ Data presented at WFH 2018 ▪ Filed in US (priority review) and EU in Q2 2018 ▪ Data published in *NEJM* 2018; 379: 811-822	▪ FPI Q1 2017, recruitment completed Q2 2017 ▪ Pharmacokinetic run-in data at ASH 2017 ▪ Positive interim analysis outcome reported Q4 2017 ▪ Data presented at WFH 2018 ▪ Interim data filed in US and EU in Q2 2018 ▪ Data published in Lancet Haematology 2019 Jun;6(6):e295-e305
	▪ Approved in US Q4 2018 and EU Q1 2019	
CT Identifier	NCT02847637	NCT03020160

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)	Multicenter, open-label study to evaluate the safety, efficacy, pharmacokinetics, and pharmacodynamics of Hemlibra in patients with mild or moderate Hemophilia A without FVIII inhibitors ▪ Hemlibra qw (1.5mg/kg), q2w (3.0mg/kg) or q4w (6.0mg/kg) (patients preference)
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Safety and efficacy
Status	▪ FPI Q2 2018 ▪ Recruitment completed Q1 2019 ▪ Filed in China Q2 2020 ▪ Approved in China Q2 2021	▪ FPI Q1 2020 ▪ Recruitment completed Q1 2021 ▪ Interim data presented at ASH 2021 and primary data presented at ISTH 2022 ▪ Filed in EU Q4 2021
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=255
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Progression-free survival	▪ Disease-free survival
Status	▪ Recruitment completed Q3 2015 ▪ Primary endpoint met Q1 2017 ▪ Data presented at ASCO 2017, 2018, ESMO 2017, 2018 ▪ Data published in *NEJM* 2017; 377:829-838 ▪ CNS data presented at ESMO 2017 ▪ Final PFS and updated OS presented at ESMO 2019 ▪ Approved in US Q4 2017 (priority review) and in EU Q4 2017	▪ FPI Q3 2018 ▪ Recruitment completed Q4 2021
CT Identifier	NCT02075840	NCT03456076

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	2L+ HER-2 positive PD-L1 positive metastatic breast cancer (mBC)	HER2-positive early breast cancer (BC) high-risk patients
Phase/study	**Phase III KATHERINE**	**Phase III KATE 3**	**Phase III ASTEFANIA**
# of patients	N=1,484	N=320	N=1,700
Design	▪ **ARM A:** Kadcyla 3.6mg/kg q3w ▪ **ARM B:** Herceptin	▪ **ARM A:** Kadcyla plus Tecentriq ▪ **ARM B:** Kadcyla plus placebo	▪ **ARM A:** Kadcyla plus Tecentriq ▪ **ARM B:** Kadcyla plus placebo
Primary endpoint	▪ Invasive disease-free survival	▪ Progression-free survival and overall survival	▪ Invasive disease-free survival
Status	▪ Recruitment completed Q4 2015 ▪ Stopped at pre-planned interim data analysis for efficacy Q4 2018 ▪ Data presented at SABCS 2018 ▪ BTD granted by FDA in Q1 2019 ▪ US filling completed under RTOR Q1 2019 and filed in EU Q1 2019 ▪ Approved in US Q2 2019 and in EU Q4 2019 ▪ Data published in *NEJM* 2019; 380:617-628	▪ FPI Q1 2021	▪ FPI Q2 2021
CT Identifier	NCT01772472	NCT04740918	NCT04873362

In collaboration with ImmunoGen, Inc.

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

Perjeta (pertuzumab, RG1273)

First-in-class HER2 dimerization inhibitor

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

HER2=Human Epidermal growth factor Receptor 2, IDFS=Invasive disease-free survival; ASCO=American Society of Clinical Oncology; *NEJM*=New England Journal of Medcine; SABCS=San Antonio Breast Cancer Symposium

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**	**Phase I[1]**
# of patients	N=500	N=160	N=144
Design	FDC of Perjeta and Herceptin for SC administration (Phesgo) in combination with chemotherapy in neoadjuvant/adjuvant setting ▪ **ARM A:** Perjeta IV plus Herceptin IV plus chemotherapy ▪ **ARM B:** Phesgo plus chemotherapy	▪ **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 Perjeta and Herceptin FDC SC	▪ 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 FDC SC ▪ Data presented at ESMO 2020 ▪ Data published in *Eur J Cancer* 2021 Jul;152:223-232	▪ FPI Q2 2022
	▪ Filed in US Dec 2019 & in EU Jan 2020; Approved in US Q2 2020 and EU Q4 2020		
CT Identifier	NCT03493854	NCT03674112	NCT05275010

[1]In collaboration with West Pharmaceuticals and Halozyme

*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; ASCO=American Society of Clinical Onclogy; NEJM=New England Journal of Medcine; SABCS=San Antonio Breast Cancer Symposium; Eur J Cancer=European Journal of Cancer; ESMO=European Society for Medical Oncology

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	▪ Trial amended from PD-L1+ selected patients to all-comers ▪ FPI for all-comer population Q4 2016 ▪ Recruitment completed Q3 2018 ▪ Study met primary endpoint Q1 2021 ▪ Data presented at ASCO, WCLC and ESMO 2021 ▪ Filed in US (priority review) and EU Q2 2021 ▪ Approved in US Q4 2021 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	2L NSCLC previously treated with an immune checkpoint inhibitor
Phase/study	**Phase III** **IMforte**[1]	**Phase III** **CONTACT-01**[2]
# of patients	N=450	N=366
Design	▪ **ARM A:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin ▪ **ARM B:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq	▪ **ARM A:** Tecentriq plus cabozantinib ▪ **ARM B:** Docetaxel
Primary endpoint	▪ Progression-free survival and overall survival	▪ Overall survival
Status	▪ FPI Q4 2021	▪ FPI Q3 2020 ▪ Recruitment completed Q4 2021
CT Identifier	NCT05091567	NCT04471428

[1]In collaboration with Jazz Pharma, [2]In collaboration with Exelixis
NSCLC=non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; SCLC=small cell lung cancer

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – lung cancer

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

[1]SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase

ALK=Anaplastic lymphoma kinase; BRAF=V-raf murine sarcoma viral oncogene homolog B; bTMB=Blood-based tumor mutational burden; EGFR=Epidermal growth factor receptor; IV=intravenous; NSCLC=non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; RET=Rearranged during transfection; ROS1=C-ros oncogene 1; SC=Subcutaneous, IV=Intravenous; ESMO=European Society for Medical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – SCCHN and melanoma

Indication	Adjuvant squamous cell carcinoma of the head and neck (SCCHN)
Phase/study	**Phase III** **IMvoke010**
# of patients	N=406
Design	▪ **ARM A:** Tecentriq 1200mg q3w ▪ **ARM B:** Placebo
Primary endpoint	▪ Event-free survival and overall survival
Status	▪ 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	1L metastatic urothelial carcinoma (UC)	High-risk non-muscle-invasive bladder cancer (MIBC)	ctDNA+, high-risk muscle-invasive bladder cancer (MIBC)
Phase/study	**Phase III IMvigor130**	**Phase III ALBAN**	**Phase III IMvigor011**
# of patients	N=1,200	N=516	N=495
Design	▪ **ARM A:** Tecentriq plus gemcitabine and carboplatin or cisplatin ▪ **ARM B:** Tecentriq monotherapy ▪ **ARM C:** Placebo plus gemcitabine and carboplatin or cisplatin	▪ **ARM A**: BCG induction and maintenance ▪ **ARM B:** Tecentriq plus BCG induction and maintenance	▪ **ARM A**: Tecentriq monotherapy ▪ **ARM B:** Placebo
Primary endpoint	▪ Progression-free survival, overall survival and safety	▪ Recurrence-free survival	▪ Recurrence-free survival
Status	▪ FPI Q3 2016 ▪ FPI for arm B (amended study) Q1 2017 ▪ Recruitment completed Q3 2018 ▪ Study met co-primary endpoint of PFS Q3 2019 ▪ Data presented at ESMO 2019 and AACR 2021 ▪ Data published in Lancet 2020 May 16;395(10236):1547-1557	▪ FPI Q4 2018	▪ FPI Q2 2021
CT Identifier	NCT02807636	NCT03799835	NCT04660344

BCG=Bacille Calmette-Guérin; PD-L1=Programmed cell death-ligand 1; PFS=Progression-free survival; AACR=American Association for Cancer Research; ESMO=European Society for Medical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – renal cell cancer

Indication	Advanced renal cell carcinoma (RCC) after immune checkpoint inhibitor treatment
Phase/study	**Phase III** **Contact-03**[1]
# of patients	N=500
Design	▪ **ARM A:** Tecentriq plus cabozantinib ▪ **ARM B:** Cabozantinib
Primary endpoint	▪ Progression-free survival and overall survival
Status	▪ FPI Q3 2020 ▪ Recruitment completed Q4 2021
CT Identifier	NCT04338269

[1]In collaboration with Exelixis
PD-L1=Programmed cell death-ligand 1; DFS=Disease-free survival

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
CT Identifier	NCT04102098

PD-L1=Programmed cell death-ligand 1; ESMO=European Society for Medical Oncology; NEJM=New England Journal of Medicine; RTOR=Real time oncology review

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

PD-L1=Programmed cell death-ligand 1; ESMO=European Society for Medical Oncology

Venclexta (venetoclax, RG7601)

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

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

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

Bcl-2=B-cell lymphoma 2; BTD=Breakthrough therapy designation; CLL=chronic lymphocytic leukemia; 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:** ▪ Venclexta plus dexamethasone	▪ Venclexta plus dexamethazone vs pomalidomide plus dexamethasone in t(11;14) positive r/r MM
Primary endpoint	▪ Safety and maximum tolerated dose	▪ Progression-free survival
Status	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016 and ASH 2016 ▪ Data published in Blood 2017; 130(22):2401-2409 and Am *J Hematol* 2021 Apr 1;96(4):418-427	▪ FPI Q4 2018
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:** ▪ **ARM A:** Venclexta plus azacitidine **Study expansion:** ▪ Venclexta or Venclexta plus azacitidine	**Dose escalation cohort:** ▪ Venclexta plus azacitidine dose escalation **Safety expansion cohort**	▪ **ARM A:** Venclexta plus azacitidine ▪ **ARM B:** Placebo plus azacitidine
Primary endpoint	▪ Safety, efficacy, Pharmacokinetics and Pharmacodynamics	▪ Safety, Pharmacokinetics, RPTD	▪ Complete remission rate and overall survival
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q1 2022	▪ FPI Q1 2017 ▪ Data presented at ASH 2019, ASH 2020 and ASCO 201 ▪ BTD granted by FDA July 2021 ▪ Recruitment completed Q1 2022	▪ FPI Q4 2020
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	▪ FPI Q4 2017 ▪ Recruitment completed Q2 2019 ▪ Study met primary endpoint Q3 2021 ▪ Data presented at ASH 2021 ▪ Filed in EU, Japan and China Q4 2021 ▪ Published in *NEJM* 2022 Jan 27;386(4):351-363 ▪ Approved in EU Q2 2022 ▪ Filed in US Q3 2022
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	▪ Data presented at ASCO (NSCLC) and ESMO (MTC) 2020 ▪ Filed in US and EU for RET fusion-positive NSCLC and US for RET-mutant MTC and RET fusion-positive thyroid cancer ▪ Approved in US Q3 2020 in RET fusion-positive NSCLC, in Q4 2020 in RET-mutant MTC and RET fusion-positive thyroid cancer ▪ Updated data presented at ASCO 2021 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	▪ 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 study of Lunsumio as single agent 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 and 2019, and in r/r FL at ASH 2020 and ASH 2021 ▪ BTD granted by FDA Q2 2020 ▪ SC cohort FPI Q2 2021 ▪ Filed in EU and rolling submission in US Q4 2021 ▪ Approved in EU Q2 2022 ▪ Filed in US (priority review) Q2 2022 ▪ Data published in *J. Clin. Oncol.* 40(5)481-491 and in the *Lancet* July 2022: doi.org/10.1016/S1470-2045(22)00335-7	▪ FPI Q1 2019 ▪ Data for Lunsumio plus CHOP presented at ASH 2020	▪ FPI Q3 2018 ▪ Initial data presented at ASCO and ASH 2021
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=92 + 80 (cohort C)	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 ▪ Initial data presented at ASH 2020 (Cohort B) ▪ Cohort C: FPI Q1 2021	▪ FPI Q3 2020 ▪ Initial data presented at ASH 2021
CT Identifier	NCT03677154	NCT04246086

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; r/r=relapsed/refractory; 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 FL	Relapsed or refractory CLL
Phase/study	**Phase III CELESTIMO**	**Phase Ib/II**	**Phase Ib/II**
# of patients	N=400	N=118	N=56
Design	▪ **ARM A**: Lunsumio plus lenalidomide ▪ **ARM B:** Rituxan plus lenalidomide	▪ **ARM A**: Lunsumio plus tiragolumab ▪ **ARM B:** Lunsumio plus tiragolumab plus Tecentriq ▪ Dose escalation phase ▪ Dose expansion phase	▪ Lunsumio monotherapy (3L+ CLL)
Primary endpoint	▪ Progression-free survival	▪ Phase Ib: Dose-limiting toxicity ▪ Phase II: Best complete response	▪ Safety, dose-limiting toxicity and RPTD
Status	▪ FPI Q4 2021	▪ FPI Phase Ib Q2 2022	▪ FPI Q1 2022
CT Identifier	NCT04712097	NCT05315713	

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

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 every 24 weeks ▪ **ARM B:** Interferon β-1a (Rebif)	96-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV followed by 600mg IV every 24 weeks ▪ **ARM B:** Interferon β-1a (Rebif)	120-week treatment period: ▪ **ARM A:** Ocrevus 2x300mg IV every 24 weeks ▪ **ARM B:** Placebo
Primary endpoint	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Sustained disability progression versus placebo by EDSS
Status	▪ Primary endpoint met Q2 2015, OLE ongoing ▪ Primary data presented at ECTRIMS 2015 ▪ Updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM* 2017; 376:221-234 ▪ Data published on COVID-19 in *Mult Scler Relat Disord* on Ocrevus treated people with MS, doi.org/10.1016/j.msard.2020.102725		▪ Primary endpoint met Q3 2015 ▪ Primary data presented at ECTRIMS 2015, updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM* 2017; 376:209-220
	▪ Approved in US Q1 2017 and EU Q1 2018		
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 (frequency/severity assessed during and 24-hours post infusion)	▪ Time to upper limb disability progression confirmed for at least 12 weeks
Status	▪ Filed in US and EU Q1 2020 ▪ Approved in EU Q2 2020 and US Q4 2020 ▪ Data published *Neurol, Neuroimmunol* and *Neuroinflamm* Sept 2020; 7(5), e807	▪ FPI Q3 2019
CT Identifier	NCT03085810	NCT04035005

IV=intravenous; IRR=Infusion Related Reaction

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple sclerosis (RMS)	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 every 24 weeks ▪ **ARM B:** Ocrevus 1200mg if body weight <75kg or 1800mg if body weight > or equal to 75kg every 24 weeks	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV every 24 weeks ▪ **ARM B:** Ocrevus 1200mg if body weight <75kg or 1800mg if body weight > or equal to 75kg every 24 weeks	▪ **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	▪ FPI Q4 2020 ▪ Recruitment completed Q4 2021	▪ FPI Q2 2022
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	Open-label study in infants with type 1 SMA ▪ **Part I (dose-finding):** At least 4 weeks ▪ **Part II (confirmatory):** 24 months	Randomized, double-blind, placebo-controlled study in adult and pediatric patients with type 2 or type 3 SMA: ▪ **Part I (dose-finding):** At least 12 weeks ▪ **Part II (confirmatory):** 24 months	▪ Open-label single arm study in 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	▪ 12-month data from Part I presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019 ▪ Study met primary endpoint in Part II Q1 2020 ▪ 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	▪ Recruitment completed for part 2 Q3 2018 ▪ 12-month data from Part I presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019 ▪ Study met primary endpoint in Part II Q4 2019 ▪ Part II 1-year data presented at SMA Europe 2020, 2-year data at MDA 2021 and 3-year data at MDA 2022 ▪ Part II 1-year data published in Lancet Neurology, 2022; 21 (1) 42-52	▪ FPI Q1 2017 ▪ Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, WMS 2019, CureSMA 2020 and 2021 ▪ Recruitment completed Q1 2020
	▪ Orphan drug designation granted by FDA Q1 2017 and EU Q1 2019, PRIME designation in Q4 2018 ▪ Approved in US Q3 2020 and EU Q1 2021		
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

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

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

In collaboration with PTC Therapeutics and SMA Foundation

SMN=survival motor neuron; CMAP=compound muscle action potential; PK/PD=Pharmacokinetics/Pharmacodynamics; 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	▪ FPI Q3 2017 ▪ Primary endpoint met Q3 2018 ▪ Data presented at ECTRIMS 2018 and AAN 2019 ▪ Published in *NEJM* 2019; 381:2114-2124
	▪ BTD granted by FDA Q4 2018 ▪ Filed in EU Q3 2019; US acceptance of filing Q4 2019 ▪ Approved in US Q3 2020 and EU Q2 2021	
CT Identifier	NCT02073279	NCT02028884

*Trials managed by Chugai (Roche opted-in)

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 (AE)
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	▪ Orphan Drug Designation granted in US Q1 2021 ▪ FPI Q4 2021	▪ FPI Q3 2022 ▪ Orphan Drug Designation granted by FDA in Q4 2021	▪ FPI Q3 2022 ▪ Orphan Drug Designation 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; AE=Autoimmune encephalitis, mRS=Modified Rankin Scale; NMDAR AIE= Anti-N-Methyl-D-Aspartic Acid Receptor Autoimmune Encephalitis; PK/PD=Pharmacokinetics/Pharmacodynamics

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 mycophenolate mofetil / mycophenolic acid ▪ **ARM B:** Placebo IV plus mycophenolate mofetil / mycophenolic acid	▪ **ARM A:** Gazyva 1000mg IV (6 doses through Week 52) plus mycophenolate mofetil ▪ **ARM B:** Gazyva1000 mg IV (5 doses through Week 52) plus mycophenolate mofetil ▪ **ARM C:** Placebo IV plus mycophenolate mofetil	▪ **ARM A:** Gazyva 1000mg IV dosed at baseline and weeks 0, 2, 24, and 26 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	▪ Recruitment completed Q4 2017 ▪ Primary endpoint met Q2 2019 ▪ BTD granted by the FDA Q3 2019 ▪ Data presented at ASN and ACR 2019 ▪ Published in *Ann Rheum Dis* 2022 Jan;81(1):100-107	▪ FPI Q3 2020	▪ 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

Gazyva (obinutuzumab, RG7159)

Immunology development program

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

In collaboration with Biogen
IV=Intravenous

Actemra/RoActemra (tocilizumab, RG1569)

Interleukin 6 receptor inhibitor

Indication	Adult hospitalised with severe COVID-19 pneumonia	
Phase/study	**Phase III COVACTA[1]**	**Phase III REMDACTA[2]**
# of patients	N=450	N=650
Design	▪ **ARM A:** Actemra plus standard of care ▪ **ARM B:** Placebo plus standard of care	▪ **ARM A:** Remdesivir plus Actemra ▪ **ARM B:** Remdesivir plus placebo
Primary endpoint	▪ Clinical status assessed using 7-Category Ordinal Scale (Day 28)	▪ Time to hospital discharge or ready for discharge
Status	▪ FPI Q1 2020 ▪ Recruitment completed Q2 2020 ▪ Primary endpoint not met Q3 2020 ▪ Published in *NEJM* 2021; 384:1503-1516	▪ FPI Q2 2020 ▪ Recruitment completed Q1 2021 ▪ Primary endpoint not met Q1 2021 ▪ Published in *Intensive Care Med* 2021 doi: 10.1007/s00134-021-06507-x
	▪ Filed in EU Q3 2021 ▪ Approved in EU Q4 2021 ▪ Filed in US Q1 2022	
CT Identifier	NCT04320615	NCT04409262

[1]In collaboration with US Biomedical Advanced Research and Development Authority (BARDA); [2]In collaboration with Gilead Sciences, Inc.
NEJM=New England Journal of Medicine

Actemra/RoActemra (tocilizumab, RG1569)

Interleukin 6 receptor inhibitor

Indication	Adult hospitalised with severe COVID-19 pneumonia	
Phase/study	**Phase II** **MARIPOSA**	**Phase III** **EMPACTA**
# of patients	N=100	N=379
Design	▪ **ARM A:** 8 mg/kg Actemra plus standard of care ▪ **ARM B:** 4mg/kg Actemra plus standard of care	Conducted in sites known to provide critical care to underserved and minority populations that often do not have access to clinical trials ▪ **ARM A:** Actemra plus standard of care ▪ **ARM B:** Placebo plus standard of care
Primary endpoint	▪ Pharmacodynamics and pharmacokinetics	▪ Cumulative proportion of participants requiring mechanical ventilation by day 28
Status	▪ FPI Q2 2020 ▪ Recruitment completed Q2 2020 ▪ Published in *Open Forum Infect Dis* 2021 Dec 4;9(1)	▪ FPI Q2 2020 ▪ Primary endpoint met Q3 2020 ▪ Published in *NEJM* 2021 Jan 7;384(1):20-30 ▪ Filed in EU Q3 2021 ▪ Approved in EU Q4 2021 ▪ Filed in US Q1 2022
CT Identifier	NCT04363736	NCT04372186

NEJM=New England Journal of Medicine

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

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 January 2022
CT Identifier	NCT05155345

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:** Port delivery system with ranibizumab q24w ▪ **ARM B:** Intravitreal ranibizumab q4w	▪ Patients from LADDER or Archway will receive refills of 100mg/mL ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)	▪ **ARM A:** Port delivery system with ranibizumab q36w ▪ **ARM B:** Port delivery system with ranibizumab q24w
Primary endpoint	▪ Change in BCVA from baseline at the average of week 36 and week 40	▪ Safety and long term efficacy	▪ Change in BCVA from baseline averaged over weeks 68 and 72
Status	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2019 ▪ Study met primary endpoint Q2 2020 ▪ Primary endpoint data presented at ASRS 2020, 44/48 week data at Angiogenesis 2021 and 2-year data at Angiogenesis 2022 ▪ Filed in US (PRIME) and EU Q2 2021 ▪ Approved in US Q4 2021	▪ FPI Q3 2018	▪ FPI Q3 2021
CT Identifier	NCT03677934	NCT03683251	NCT04657289

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:** Port delivery system with ranibizumab q24w ▪ **ARM B:** Intravitreal ranibizumab q4w	▪ **ARM A:** Intravitreal ranibizumab (X2) followed by PDS implant (refill q36w) ▪ **ARM B:** Q4w comprehensive clinical monitoring until participants receive PDS (refill q36w)
Primary endpoint	▪ Change in BCVA from baseline at the average of week 48 and week 52	▪ Percentage of participants with a ≥2-step improvement from baseline on the ETDRS-DRSS at Week 52
Status	▪ FPI Q3 2019 ▪ Recruitment completed Q2 2021	▪ FPI Q3 2020 ▪ Recruitment completed Q3 2021
CT Identifier	NCT04108156	NCT04503551

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	▪ FPI Q3 2018 ▪ Recruitment completed Q3 2019 ▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021	▪ FPI Q4 2018 ▪ Recruitment completed Q3 2019 ▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021
	▪ 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	
CT Identifier	NCT03622580	NCT03622593

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

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	▪ FPI Q1 2019 ▪ Recruitment completed Q4 2019 ▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021	▪ FPI Q1 2019 ▪ Recruitment completed Q4 2019 ▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021
	▪ Filed in US and EU Q2 2021 ▪ Published in Lancet 2022 Feb 19;399(10326):729-740 ▪ Approved in US Q1 2022 and EU Q3 2022 ▪ 2-year data presented at ASRS 2022	
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

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	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2022
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	Xofluza on Day 1 (based on body weight and age) in healthy pediatric patients from birth to <1 year with influenza-like symptoms	Healthy pediatric patients 1 to <12 years of age with influenza-like symptoms ▪ **ARM A:** Xofluza ▪ **ARM B:** Tamiflu	Reduction of direct transmission of influenza from otherwise healthy patients to household contacts ▪ **ARM A:** Xofluza ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety	▪ Safety	▪ Percentage of household contacts who are PCR-positive for influenza by day 5 post randomization of index patients
Status	▪ FPI Q1 2019	▪ Primary endpoint met Q2 2019 ▪ Data presented at OPTIONS X 2019 ▪ Filed in US Q1 2020 ▪ Data published in *Pediatric Infectious Disease* 2020 Aug;39(8):700-705 ▪ Filed in EU Q4 2021 ▪ Approved in the US (age 5 years and older) Q3 2022	▪ 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

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L castration-resistant prostate cancer (CRPC)
Phase/study	**Phase III** **IPATential150**
# of patients	N=1,100
Design	▪ **ARM A:** Ipatasertib plus abiraterone ▪ **ARM B:** Placebo plus abiraterone
Primary endpoint	▪ rPFS in patients with PTEN loss tumors and overall population
Status	▪ FPI Q2 2017 ▪ Recruitment completed Q1 2019 ▪ Study met co-primary endpoint in rPFS in patients with PTEN loss tumors Q2 2020 ▪ Data presented at ESMO 2020 and interim OS at ASCO 2022 ▪ Published in Lancet 2021; 398:131-142
CT Identifier	NCT03072238

Akt=Protein Kinase B; PTEN=Phosphatase and Tensin homolog; rPFS=Radiographic progression-free survival ; ESMO=European Society for Medical Oncology, ASCO=American Society of Clinical Oncology

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
CT Identifier	NCT04294810	NCT04513925

NSCLC=Non-small cell lung cancer; ES-SCLC=Extensive stage 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 chemo followed by maintenance tiragolumab plus Tecentriq plus pemetrexed ▪ **ARM B:** Placebo plus pembrolizumab plus pemetrexed plus chemo followed by maintenance placebo plus pembrolizumab plus pemetrexed
Primary endpoint	▪ Objective response rate	▪ Pathologic complete response, major pathological response and safety	▪ Objective response rate, progression-free survival and overall survival
Status	▪ FPI Q2 2020	▪ FPI Q2 2021	▪ FPI Q4 2020
CT Identifier	NCT04300647	NCT04832854	NCT04619797

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	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	▪ FPI Q2 2016 ▪ Data presented at AACR 2020	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2019 ▪ Data presented at ASCO 2020 and WCLC and ESMO IO 2021 ▪ BTD granted by FDA Q4 2020 ▪ 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

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:** Glofitamab plus Gazyva (i.e. continuous treatment with Gazyva)	Dose escalation and expansion ▪ **ARM A:** Glofitamab plus Tecentriq ▪ **ARM B:** Glofitamab plus Polivy	Glofitamab SC ▪ Part 1 dose escalation
Primary endpoint	▪ Efficacy, safety, tolerability and pharmacokinetics	▪ Safety	▪ Safety
Status	▪ FPI Q1 2017 ▪ Data presented at ASH 2018, ICML and ASH 2019; EHA and ASH 2020; ASCO, EHA, ICML and ASH 2021; ASCO and EHA 2022 ▪ Data published online June 2021 *J Clin Oncology* 39:18:1959-1970 ▪ Filed in EU April 2022	▪ ARM A: FPI Q2 2018 ▪ Data presented at ASH 2019 and ASH 2021 ▪ ARM B: FPI Q4 2020	▪ FPI Q3 2021
CT Identifier	NCT03075696	NCT03533283	ISRCTN17975931

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

Glofitamab (CD20-TCB, RG6026)

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

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

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; r/r=Relapsed or refractory
ASH=American Society of Hematology

Glofitamab (CD20-TCB, RG6026)

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

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

ctDNA=circulating tumor DNA; DLBCL=diffuse large B cell lymphoma; R-CHOP=Rituxan, cyclophosphamide, doxorubicin, vincristine and prednisone; PET=positron emission tomography; EOT PET-CR=End of treatment PET-complete response rate

Inavolisib (RG6114, GDC-0077)

A potent, orally available, and selective PI3Kα inhibitor

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

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

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

A selective estrogen receptor degrader or downregulator

Indication	ER+ HER2-neg metastatic breast cancer (mBC)	ER+ HER2-neg Stage I-III operable breast cancer (BC)	Neoadjuvant ER+ breast cancer (BC)
Phase/study	**Phase I**	**Phase I**	**Phase II coopERA Breast Cancer**
# of patients	N=181	N=75	N=221
Design	▪ Dose escalation and expansion at RPTD ▪ Giredestrant monotherapy and in combination with palbociclib and/or LHRH agonist	▪ Open-label, pre-operative administration ▪ Dose escalation	▪ **ARM A:** Giredestrant followed by giredestrant plus palbociclib ▪ **ARM B:** Anastrazole followed by anastrazole plus palbociclib
Primary endpoint	▪ Safety	▪ Safety, tolerability and PK/PD	▪ Safety, tolerability and PK/PD
Status	▪ FPI Q4 2017 ▪ Data presented at SABCS 2019, ASCO 2020, ASCO 2021 and SABCS 2021	▪ FPI Q3 2019 ▪ Data presented at ASCO 2021	▪ FPI Q3 2020 ▪ Data presented at ESMO and SABCS 2021; 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+ metastatic breast cancer (mBC)	Adjuvant ER+ 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	▪ 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+/HER2-positive breast cancer (BC)
Phase/study	**Phase III** **heredERA**
# of patients	N=812
Design	Induction Phesgo plus taxane followed by maintenance with either: ▪ **ARM A:** Giredestrant plus Phesgo ▪ **ARM B:** Phesgo
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q2 2022
CT Identifier	NCT05296798

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

Zinpentraxin alfa (PRM-151, RG6354)

Recombinant human innate immunity protein pentraxin-2

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

FVC=Forced vital capacity, JAMA=Journal of the American Medical Association

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=250
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	▪ Non-inferiority of crovalimab compared to eculizumab - mean % change in LDH level (measure of haemolysis) from baseline to week 25
Status	▪ Part I: FPI Q4 2016 ▪ Part II/III: FPI Q2 2017 ▪ Part IV: FPI Q2 2019 ▪ Nonclinical data published in Scientific Reports 2017 Apr; 7(1):1080 ▪ Data presented for Part 2 and 3 at ASH 2018 and 2019	▪ FPI Q3 2020
CT Identifier	NCT03157635	NCT04432584

In collaboration with Chugai

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

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=200	N=51
Design	▪ **ARM A:** Crovalimab ▪ **ARM B:** Eculizumab	▪ Crovalimab loading dose IV on Day 1, followed by weekly crovalimab SC doses for 4 weeks
Primary endpoint	▪ Non-inferiority of crovalimab compared to eculizumab: ▪ % patients with transfusion avoidance from baseline through week 25 ▪ % patients with haemolysis control, as measured by LDH <=1.5ULN from week 5-25	▪ Percentage of patients with transfusion avoidance from baseline through week 25 ▪ Mean percentage of participants with hemolysis control (week 5 through week 25)
Status	▪ FPI Q4 2020	▪ FPI Q1 2021 ▪ Recruitment completed Q3 2021 ▪ Study met its co-primary endpoints Q1 2022 ▪ Filed in China (priority review) Q3 2022
CT Identifier	NCT04434092	NCT04654468

In collaboration with Chugai
LDH=Lactate Dehydrogenase; ULN=Upper Limit of Normal; IV=Intravenous; SC=Subcutaneous

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
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

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

Crenezumab (RG7412)

Humanized monoclonal antibody targeting all forms of Ab

Indication	Alzheimer's prevention initiative (API) Colombia
Phase/study	**Phase II** Cognition study
# of patients	N=252
Design	▪ **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	▪ FPI Q4 2013 ▪ Recruitment completed Q1 2017 ▪ Study did not meet its co-primary endpoints Q2 2022 ▪ Data presented at AAIC 2022
CT Identifier	NCT01998841

In collaboration with AC Immune

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

Gantenerumab (RG1450)

Fully human monoclonal antibody binding aggregated forms of Aß

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

In collaboration with MorphoSys AG

Aß=amyloid-beta; CDR-SOB=Clinical Dementia Rating Scale Sum of Boxes; SC=Subcutaneous; BTD=Breakthrough Therapy Designation; PET= positron emission tomography

Gantenerumab (RG1450)

Fully human monoclonal antibody binding aggregated forms of Aß

Indication	Prodromal Alzheimer's disease	Mild Alzheimer's disease	Cognitively unimpaired participants at risk for or at the earliest stages of Alzheimer's disease
Phase/study	**Phase II/III** **SCarlet RoAD[1]**	**Phase III** **Marguerite RoAD[1]**	**Phase III** **SKYLINE[2]**
# of patients	N=799	N=389	N=1,200
Design	104-week SC treatment period: ▪ **ARM A:** Gantenerumab (225 mg) ▪ **ARM B:** Gantenerumab (105 mg) ▪ **ARM C:** Placebo	104-week SC treatment period: ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo	▪ **ARM A:** Gantenerumab q1w or q2w (patient preference) ▪ **ARM B:** Placebo
Primary endpoint	▪ Change in CDR-SOB at 2 years ▪ Sub-study: change in brain amyloid by PET at 2 years	▪ Change in ADAS-Cog and CDR-SOB at 2 years (co-primary)	▪ Cognitive composite (PACC5)
Status	▪ Phase I PET data: *Archives of Neurology*, 2012 Feb;69(2):198-207 ▪ Recruitment completed Q4 2013 ▪ Dosing stopped due to futility Q4 2014 ▪ FPI in open label extension study Q4 2015 ▪ Published in *Alzheimers Res Ther* 2017 Dec 8;9(1):95	▪ FPI Q1 2014 ▪ Recruitment stopped Q4 2015 ▪ FPI Q1 2016 for open label extension	▪ FPI Q2 2022
	▪ 36 OLE data published in J Prev Alzheimers Dis 2021;8(1):3-6		
CT Identifier	NCT01224106	NCT02051608	NCT05256134

[1]In collaboration with MorphoSys AG; [2]In collaboration with Banner Alzheimer's Institute

Aß=amyloid-beta; CDR-SOB=Clinical Dementia Rating Scale Sum of Boxes; PET= positron emission tomography; ADAS-cog=Alzheimer's Disease Assessment Scale cognitive subscale; SC=Subcutaneous; OLE=Open Label Extension; PACC5=Preclinical Alzheimer's Cognitive Composite

Tominersen (RG6042, HTT ASO)

Antisense oligonucleotide (ASO) targeting human HTT mRNA

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

In collaboration with Ionis Pharmaceuticals

HTT=Huntingtin; PK/PD=Pharmacokinetics/Pharmacodynamics; PRIME=Priority medicines; OLE=Open Label Extension; AAN=American Academy of Neurology; NEJM=New England Journal of Medicine; CHDI=Huntington's Disease Association of Ireland

Tominersen (RG6042, HTT ASO)

Antisense oligonucleotide (ASO) targeting human HTT mRNA

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

In collaboration with Ionis Pharmaceuticals

cUHDRS=composite Unified Huntington's Disease Rating Scale; TFC=total function capacity; HTT=Huntingtin; OLE=Open Label Extension; IDMC=Independent Data Monitoring Committee; CHDI=Huntington's Disease Association of Ireland; EHDN=European Huntington's Disease Network

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

Balovaptan (RG7314)

Small molecule antagonist of the V1A vasopressin receptor

Indication	Post-traumatic stress disorder (PTSD)
Phase/study	**Phase II**
# of patients	N=252
Design	▪ **ARM A:** Balovaptan (IV) once a day for 12 weeks ▪ **ARM B:** Placebo matched control
Primary endpoint	▪ Change from baseline in the Clinician-Administered PTSD Total Symptom Severity Score
Status	▪ FPI Q3 2022
CT Identifier	NCT05401565

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
CT Identifier	NCT03785678

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

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
CD19-4-1BBL (RG6076)	R/R B cell non-Hodgkin's lymphoma	I	362	Part I: FPI Q3 2019 Part II: FPI Q3 2020	NCT04077723
PD1-IL2v (RG6279)	Solid tumors	I	348	Part I: FPI Q2 2020; recruitment completed Q4 2021 Part II: FPI Q1 2022	NCT04303858
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
PD1-LAG3 (RG6139)	Solid tumors	I	320	FPI Q4 2019 Data presented at ESMO 2022	NCT04140500
	Solid tumors	II	210	FPI Q2 2021 Randomized trial, compared with nivolumab	NCT04785820 TALIOS
	Untreated unresectable or metastatic melanoma	II	80	FPI Q3 2022	NCT05419388

pRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
CD25 (RG6292)	Solid tumors	I	110	FPI Q4 2019	NCT04158583
	Advanced and metastatic solid tumors	I	160	Part I: FPI Q1 2021 Part II: FPI Q4 2021	NCT04642365
Anti-GPRC5D (RG6234)	Multiple myeloma	I	240	FPI Q4 2020 Data presented at EHA 2022	NCT04557150
HLA-A2-WT1 x CD3 (RG6007)	AML	I	220	FPI Q4 2020	NCT04580121
FAP-CD40 (RG6189)	Solid tumors	I	280	FPI Q2 2021	NCT04857138
HLA-A2-MAGE-A4 x CD3 (RG6129)	Solid tumors	I	260	FPI Q1 2022	NCT05129280
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 glofitamab	NCT05219513
EGFRvIIIxCD3 (RG6156)	Glioblastoma	I	~200	FPI Q2 2022	NCT05187624

pRED neuroscience development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
Brain Shuttle-gantenerumab (BS-gantenerumab, RG6102)	Alzheimer's disease	IIa	~120	FPI Q1 2021	NCT04639050
Brain Shuttle-CD20 (BS-CD20, RG6035)	Multiple sclerosis	I	30	FPI Q3 2021	ISRCTN16295177
ralmitaront (partial TAAR1 agonist, RG7906)	Schizophrenia	II	36	FPI Q4 2018 Recruitment completed Q3 2019	
		II	247	FPI Q4 2019	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	NCT04777331 (PADOVA)
alogabat (GABA-Aa5 PAM, RG7816)	Autism spectrum disorder	II	105	FPI Q1 2021	NCT04299464 (Aurora)
NME (RG7637)	Psychiatric disorders	I	80	FPI Q3 2020	NCT04475848
rugonersen (UBE3A LNA, RG6091)	Angelman syndrome	I	66	FPI Q3 2020	NCT04428281
NME (RG6182)	Neurodegenerative disorder	I	30	FPI Q4 2020	

Partner: [1]Prothena
BS=Brain Shuttle

pRED neuroscience development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
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	

Partner: [1]Prothena; BS=Brain Shuttle

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	
Ophthalmology					
Anti-IL-6 (RG6179)	DME, UME	I	90	FPI Q3 2019	DOVETAIL
	DME	II	~210	FPI Q4 2021	NCT05151744 (BARDENAS)
		II	~360	FPI Q4 2021	NCT05151731 (ALLUVIUM)
VEGF-Ang2 DutaFab (RG6120)	nAMD	I	200	FPI Q4 2020	NCT04567303
CB2 receptor agonist (RG7774)	DR	II	135	FPI Q2 2020	NCT04265261 (CANBERRA)

pRED infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Infectious Diseases					
TLR7 agonist (3) (RG7854)	Chronic hepatitis B	I	150	FPI Q4 2016 Data presented at APASL 2019	NCT02956850
TLR7 agonist (3)/ siRNA/ 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	
Abx MCP (RG6006)	A. baumannii infections	I	204	FPI Q4 2020	NCT04605718

Abx MCP=antibiotic macrocyclic peptide

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)

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Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

gRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
KRAS G12C (RG6330)	Metastatic solid tumors with KRAS G12C mutation	I	270	FPI Q3 2020 Data presented at WCLC 2022, ESMO 2022	NCT04449874
cevostamab (anti-FcRH5 x CD3; RG6160)	R/R multiple myeloma	I	300	FPI Q3 2017 Data presented at ASH 2020, ASH 2021	NCT03275103
	R/R multiple myeloma	I	120	FPI Q2 2021	NCT04910568
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	I/II	250	FPI Q1 2020	NCT04250155
	R/R multiple myeloma	I	60	FPI Q2 2022	NCT05243342
autogene cevumeran (Individualized Neoantigen-Specific Therapy (iNeST); RG6180)[2]	Solid tumors	Ia/IIb	271	FPI Q4 2017 Data presented at AACR 2020 Recruitment completed Q1 2022	NCT03289962
	1L advanced melanoma	II	132	FPI Q1 2019	NCT03815058 (IMcode001)
SHP2i (RG6344)[3]	Solid tumors	Ia	~50	FPI Q1 2020	NCT04252339
	Solid tumors	Ib	~125	FPI Q3 2022	NCT05487235

Partner: [1]Xencor, [2]BioNTech, [3]Relay, [4]Hanmi

gRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
belvarafenib (RG6185)[4]	nRASmt CPI-experienced melanoma	Ib	83	FPI Q2 2021 Data presented at ESMO 2021	NCT04835805
NME (RG6392)	Oncology	I	60	FPI Q4 2021	ISRCTN92655801

Partner: [1]Xencor, [2]BioNTech, [3]Relay, [4]Hanmi

gRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
efmarodocokin alfa (IL-22Fc, RG7880)	aGVHD	Ib	18	FPI Q4 2020	NCT04539470
NME (RG6287, GDC-8264)	Inflammatory bowel disease	I	68	FPI Q1 2020 Recruitment completed Q3 2021	EUDRACT2019-002613-19
	Inflammatory diseases	I	16	FPI Q4 2021	
NME (RG6315, MTBT1466A)	Immunologic disorders	I	~24	FPI Q3 2020	
astegolimab (Anti-ST2, (RG6149, AMG 282, MSTT1041A)[1]	Chronic obstructive pulmonary disease	IIb	930	FPI Q4 2021	NCT05037929
NME (RG6341, GDC-6599)	Asthma	Ia/Ib	84	FPI Q4 2021	
Ophthalmology					
NME (RG6312)	Geographic atrophy	Ia	63	FPI Q4 2020	NCT04615325
NME (RG6351)	Retinal disease	I	42-78	FPI Q2 2022	

Partner: [1]Amgen

gRED neuroscience and infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neuroscience					
semorinemab (RG6100)[1]	Prodromal to mild Alzheimer's disease	II	457	FPI Q4 2017 Primary endpoint not met Q3 2020 Data presented at CTAD 2020	NCT03289143 (TAURIEL)
	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	56	FPI Q1 2022	

Partner: [1]AC Immune

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

Hemophilia A

Unique gene therapy platform

Molecule	SPK-8011 (RG6357)		SPK-8016 (RG6358)
Indication	**Hemophilia A**		**Hemophilia A with inhibitors to Factor VIII**
Phase/study	**Phase I**	**Phase I/II**	**Phase I/II**
# of patients	N=100	N=30	N=30
Design	▪ Long term follow up study of patients who have received SPK-8011 in any prior Spark-sponsored SPK-8011 study	▪ Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8011	▪ Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8016 in individuals with FVIII inhibitors
Primary endpoint	▪ Safety	▪ Safety and changes from baseline in FVIII activity levels at week 52	▪ Safety; peak and steady state FVIII activity levels at week 52
Status	▪ Ongoing	▪ FPI Q1 2017 ▪ Updated data presented at ISTH 2020 and 2021 ▪ Recruitment completed Q1 2021 ▪ Data published in *NEJM* 2021; 385:1961-1973	▪ FPI Q1 2019
CT Identifier	NCT03432520	NCT03003533	NCT03734588

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

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

Geographical sales split by Divisions and Group*

CHFm	YTD Sep 2021	YTD Sep 2022	% change CER
Pharmaceuticals Division	**33,379**	**33,189**	**0**
United States	16,707	17,199	-1
Europe	6,610	6,100	-1
Japan	3,186	3,029	+7
International	6,876	6,861	0
Diagnostics Division	**13,305**	**13,848**	**+6**
United States	2,845	3,471	+17
Europe	4,851	3,774	-17
Japan	505	691	+55
International	5,104	5,912	+17
Group	**46,684**	**47,037**	**+2**
United States	19,552	20,670	+1
Europe	11,461	9,874	-8
Japan	3,691	3,720	+14
International	11,980	12,773	+8

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

Pharma Division sales YTD Sep 2022

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	4,427	17	3,283	13	808	25	-	-	336	37
Perjeta	3,090	5	1,135	1	661	-16	175	-1	1,119	33
Hemlibra	2,778	28	1,684	22	542	32	277	20	275	76
Tecentriq	2,692	10	1,451	9	573	19	326	-5	342	16
Actemra / RoActemra	2,039	-23	914	-33	602	-3	256	1	267	-39
Herceptin	1,672	-18	376	-28	329	-13	40	-28	927	-15
Avastin	1,652	-29	497	-36	158	-51	378	-15	619	-21
Xolair	1,625	10	1,625	10	-	-	-	-	-	-
MabThera	1,596	-20	1,002	-20	156	-18	24	-10	414	-23
Kadcyla	1,590	11	619	-3	508	8	101	21	362	50
Alecensa	1,127	16	331	20	218	6	169	5	409	26
TNKase / Activase	881	-8	836	-9	-	-	-	-	45	5
Lucentis	800	-25	800	-25	-	-	-	-	-	-
Evrysdi	793	101	348	24	253	335	60	*	132	100
Ronapreve	631	-36	-	-	102	-81	452	42	77	-49
Esbriet	590	-25	381	-34	186	-1	-	-	23	-22
Gazyva	539	8	251	3	144	-7	39	-7	105	89
Phesgo	526	150	217	112	263	204	-	-	46	99
Pulmozyme	414	-1	280	2	73	-12	-	-	61	-2
CellCept	386	-12	30	-19	101	-6	43	-6	212	-14
Pharma Division	**33,189**	**0**	**17,199**	**-1**	**6,100**	**-1**	**3,029**	**7**	**6,861**	**0**

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

Pharma Division sales YTD Sep 2022

Product sales Pharmaceuticals Division

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	4,427	17	3,283	13	808	25	-	-	336	37
Perjeta	3,090	5	1,135	1	661	-16	175	-1	1,119	33
Hemlibra	2,778	28	1,684	22	542	32	277	20	275	76
Tecentriq	2,692	10	1,451	9	573	19	326	-5	342	16
Actemra / RoActemra	2,039	-23	914	-33	602	-3	256	1	267	-39
Herceptin	1,672	-18	376	-28	329	-13	40	-28	927	-15
Avastin	1,652	-29	497	-36	158	-51	378	-15	619	-21
Xolair	1,625	10	1,625	10	-	-	-	-	-	-
MabThera	1,596	-20	1,002	-20	156	-18	24	-10	414	-23
Kadcyla	1,590	11	619	-3	508	8	101	21	362	50
Alecensa	1,127	16	331	20	218	6	169	5	409	26
TNKase / Activase	881	-8	836	-9	-	-	-	-	45	5
Lucentis	800	-25	800	-25	-	-	-	-	-	-
Evrysdi	793	101	348	24	253	335	60	*	132	100
Ronapreve	631	-36	-	-	102	-81	452	42	77	-49
Esbriet	590	-25	381	-34	186	-1	-	-	23	-22
Gazyva	539	8	251	3	144	-7	39	-7	105	89
Phesgo	526	150	217	112	263	204	-	-	46	99
Pulmozyme	414	-1	280	2	73	-12	-	-	61	-2
CellCept	386	-12	30	-19	101	-6	43	-6	212	-14
Polivy	290	79	121	74	84	41	68	161	17	111
Vabysmo	282	-	253	-	4	-	24	-	1	-
Erivedge	200	2	126	-6	44	7	-	-	30	35
Enspryng	133	108	37	135	6	*	86	87	4	456
Rozlytrek	53	50	34	40	9	83	5	22	5	174
Cotellic	35	1	10	0	11	-9	-	-	14	13
Gavreto	20	299	15	200	5	*	-	-	-	-
Xofluza	6	-	2	-	-	-	-	-	4	34
Susvimo	3	-	3	-	-	-	-	-	-	-
Lunsumio	1	-	-	-	1	-	-	-	-	-
Other Products	2,318	-15	538	-20	259	-20	506	-10	1,015	-13
Pharma Division	**33,189**	**0**	**17,199**	**-1**	**6,100**	**-1**	**3,029**	**7**	**6,861**	**0**

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

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q1/21	Q2/21	Q3/21	Q4/21	Q1/22	Q2/22	Q3/22
Ocrevus	16	31	7	25	18	17	16
Perjeta	2	7	2	3	1	9	5
Hemlibra	33	58	37	38	30	31	23
Tecentriq	26	31	23	17	8	13	9
Actemra / RoActemra	22	12	57	21	3	-23	-42
Herceptin	-35	-35	-26	-6	-19	-11	-23
Avastin	-40	-40	-37	-30	-32	-27	-28
Xolair	-6	3	8	14	9	13	8
MabThera	-46	-34	-42	-26	-21	-20	-19
Kadcyla	17	21	11	16	9	18	6
Alecensa	14	25	18	15	23	16	11
TNKase / Activase	-17	3	3	22	-20	1	-5
Lucentis	-7	2	-10	2	-26	-9	-39
Evrysdi	-	-	*	347	189	65	93
Ronapreve	-	-	-	-	272	-91	-92
Esbriet	-8	1	-5	-7	-6	-21	-48
Gazyva	-2	18	10	10	7	9	9
Phesgo	-	-	*	*	410	168	76
Pulmozyme	-23	-13	-7	5	-3	2	-3
CellCept	-5	-3	3	-2	-12	-3	-20

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

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Ocrevus	23	12	10	17	26	34	34	11	-	-	-	-	51	29	62	26
Perjeta	-2	-1	4	0	-8	-21	-12	-15	-3	-1	-1	-1	24	32	37	30
Hemlibra	33	28	24	16	53	31	29	36	30	15	24	22	55	63	115	53
Tecentriq	2	10	15	3	41	14	24	17	34	-5	-9	0	24	0	17	30
Actemra / RoActemra	67	22	-31	-61	18	-4	-2	-3	5	12	-2	-4	-55	-30	-44	-44
Herceptin	-34	-26	-29	-29	-3	-13	-9	-18	-36	-30	-27	-28	17	-18	-3	-22
Avastin	-45	-39	-36	-31	-49	-56	-49	-47	0	-12	-13	-19	-24	-23	-17	-23
Xolair	14	9	13	8	-	-	-	-	-	-	-	-	-	-	-	-
MabThera	-32	-20	-24	-14	-13	-19	-16	-18	-17	-15	-2	-13	-15	-23	-13	-32
Kadcyla	3	0	-1	-8	16	8	12	3	42	28	20	16	38	26	81	46
Alecensa	18	25	14	22	9	5	8	5	5	7	5	4	25	45	29	9
TNKase / Activase	22	-21	1	-6	-	-	-	-	-	-	-	-	7	-3	4	12
Lucentis	2	-26	-9	-39	-	-	-	-	-	-	-	-	-	-	-	-
Evrysdi	112	36	28	13	*	*	227	216	-	-	-	*	*	*	-5	231
Ronapreve	-	-	-	-	-	-61	-99	-54	-	-	-	-100	-	-	-68	-99
Esbriet	-7	-4	-28	-67	0	-5	1	1	-	-	-	-	-36	-36	-36	109
Gazyva	11	0	3	7	2	-5	-8	-9	-7	8	-10	-17	56	75	101	91
Phesgo	236	187	134	62	-	*	188	107	-	-	-	-	*	*	278	20
Pulmozyme	6	0	5	2	-15	-11	-12	-12	22	11	44	-1	45	-4	14	-16
CellCept	-31	-15	-17	-25	3	-7	-7	-5	-9	-8	-9	-1	3	-14	3	-29

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

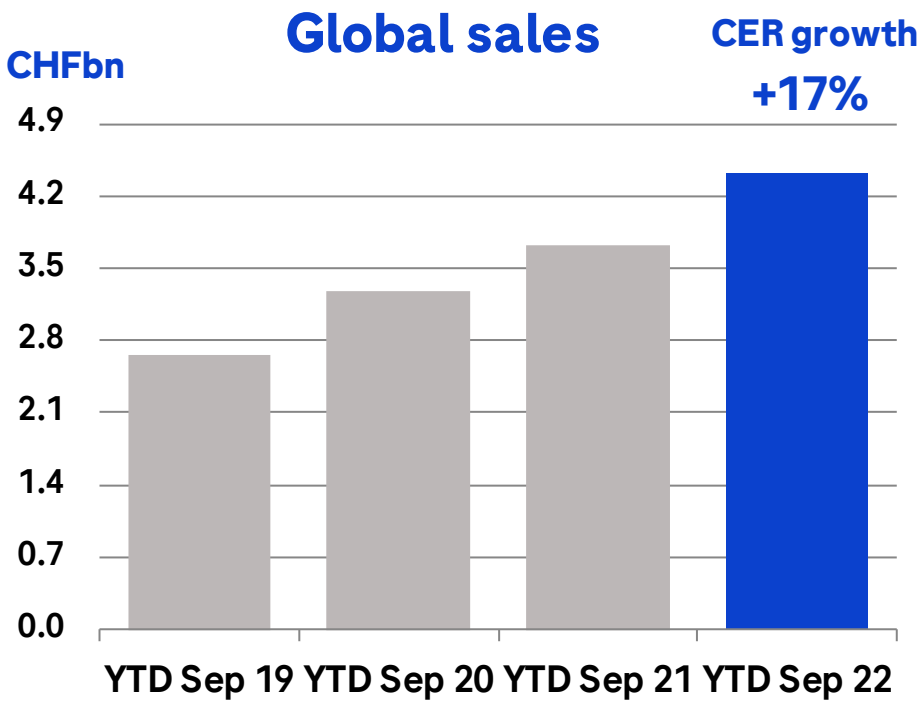
CER sales growth (%)

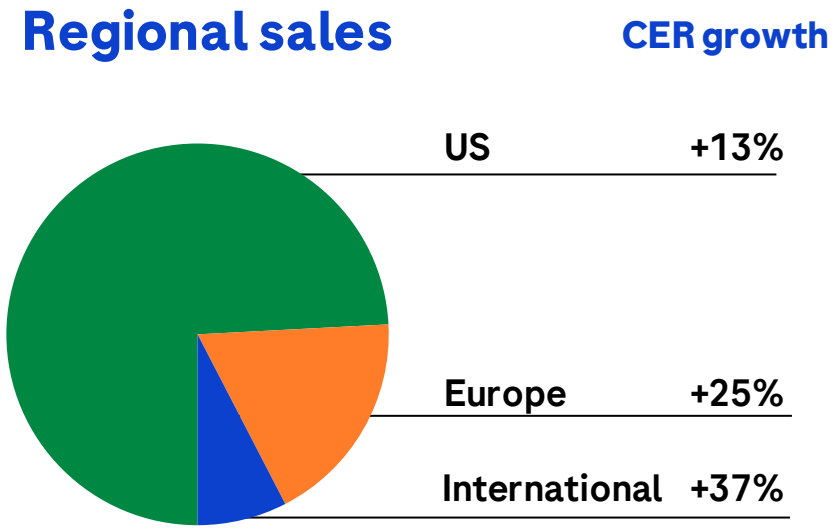
Quarterly development

	2021 vs. 2020				2022 vs. 2021		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Pharmaceuticals Division	**-9**	**4**	**5**	**14**	**6**	**0**	**-6**
United States	-14	0	0	8	2	1	-6
Europe	-6	15	1	19	-1	-6	4
Japan	-7	7	60	46	69	3	-27
International	0	4	2	9	0	4	-3
Diagnostics Division	**55**	**48**	**18**	**8**	**24**	**0**	**-4**
Roche Group	**3**	**14**	**8**	**12**	**11**	**0**	**-6**

CER=Constant Exchange Rates

Ocrevus



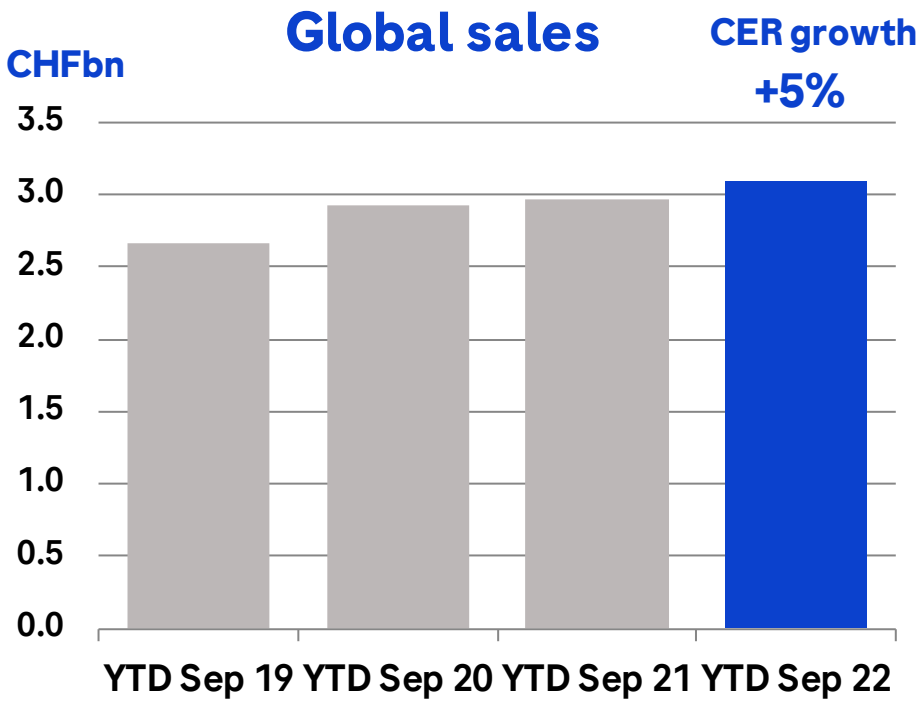


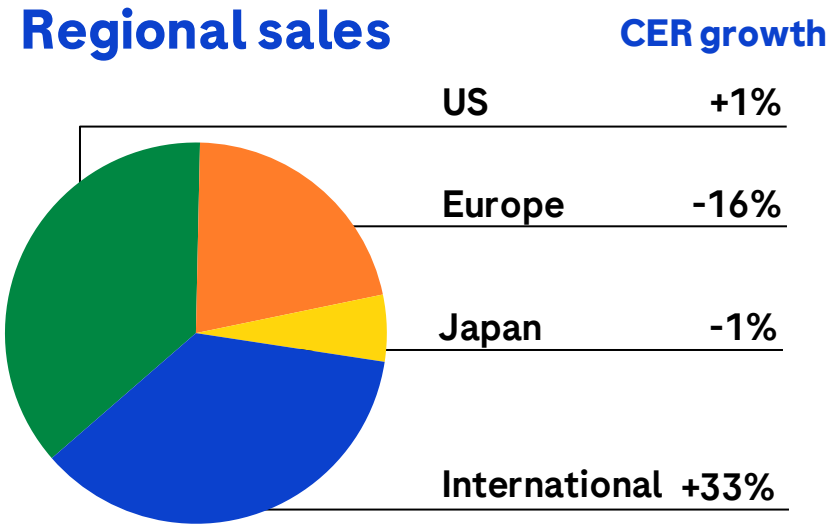
YTD Sep 2022 sales of CHF 4,427m

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

CER=Constant Exchange Rates

Perjeta



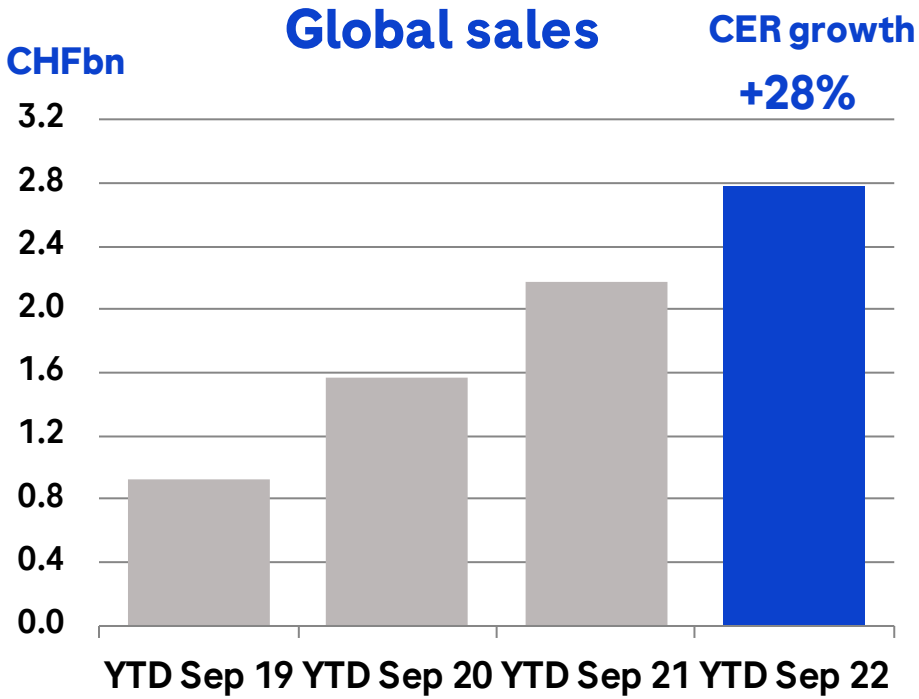


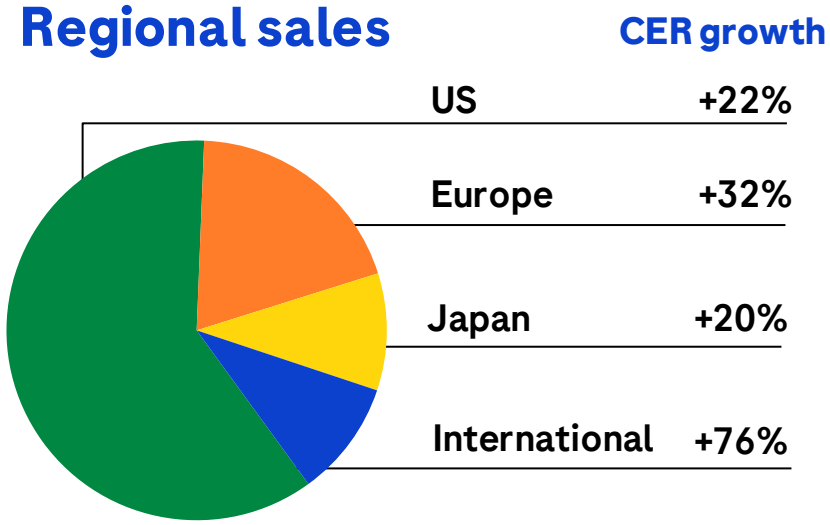
YTD Sep 2022 sales of CHF 3,090m

- US: Cannibalization from Phesgo
- EU: Cannibalization from Phesgo
- International: Accelerated growth in all regions (LATAM, APAC, EEMEA)

CER=Constant Exchange Rates

Hemlibra



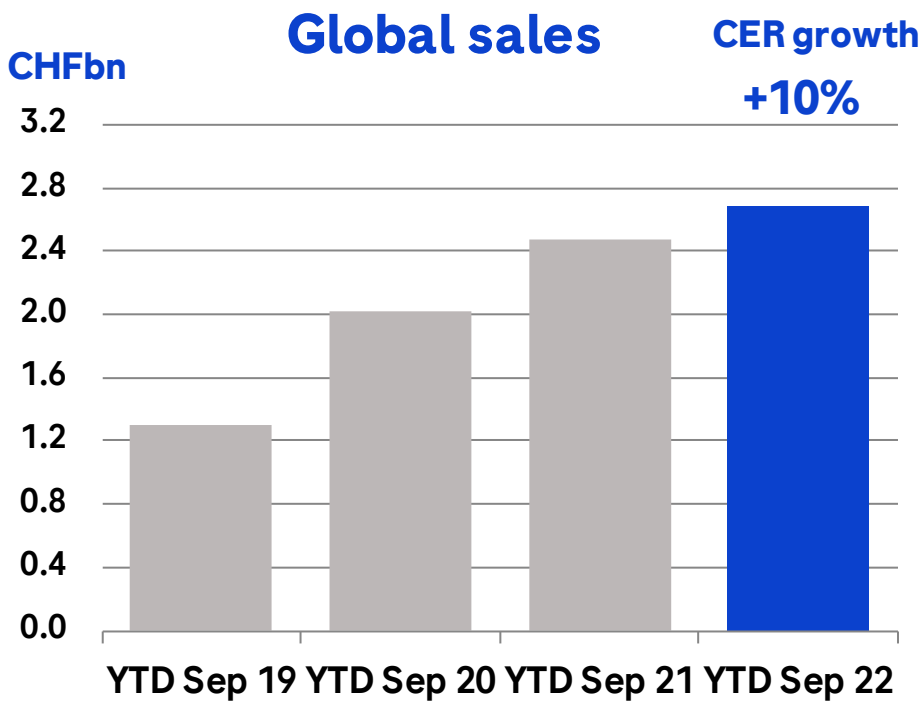


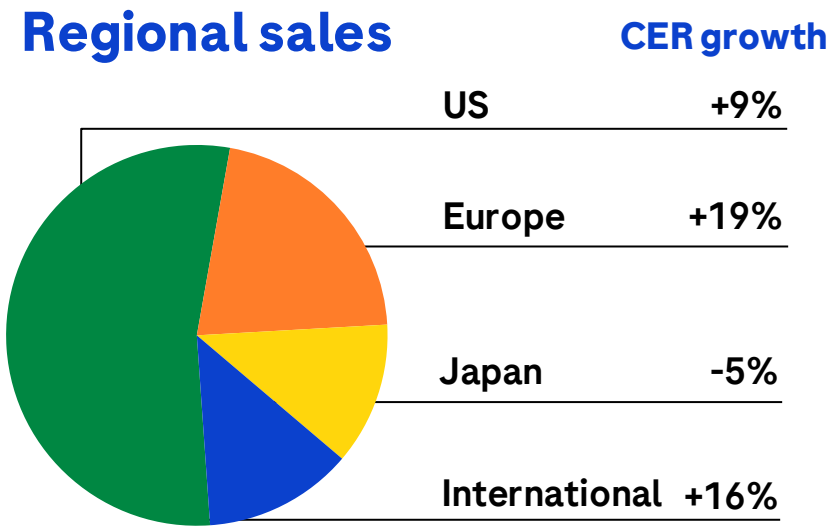
YTD Sep 2022 sales of CHF 2,778m

- US: Continued share gains in non-inhibitor patients
- EU: Continued share gains in non-inhibitor severe patients with market shares ~60% in France, UK and GER, Italy, Spain ~30%
- Japan: Strong uptake in non-inhibitor patients
- International: Accelerating momentum with strong growth from China

CER=Constant Exchange Rates

Tecentriq





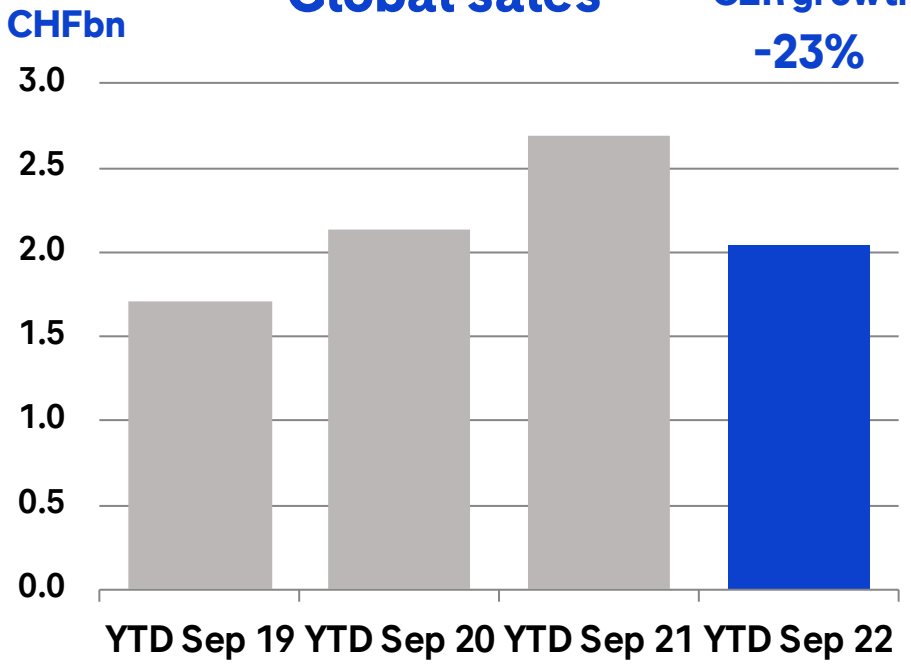
YTD Sep 2022 sales of CHF 2,692m

- US: Growth driven by first-in-class launches in adjuvant PDL1+ NSCLC, in 1L HCC and 1L SCLC
- EU: Growth driven by first-in-class launches in adjuvant PDL1+ NSCLC, in 1L HCC and 1L SCLC
- Japan: 11% price cut in Q2 2021

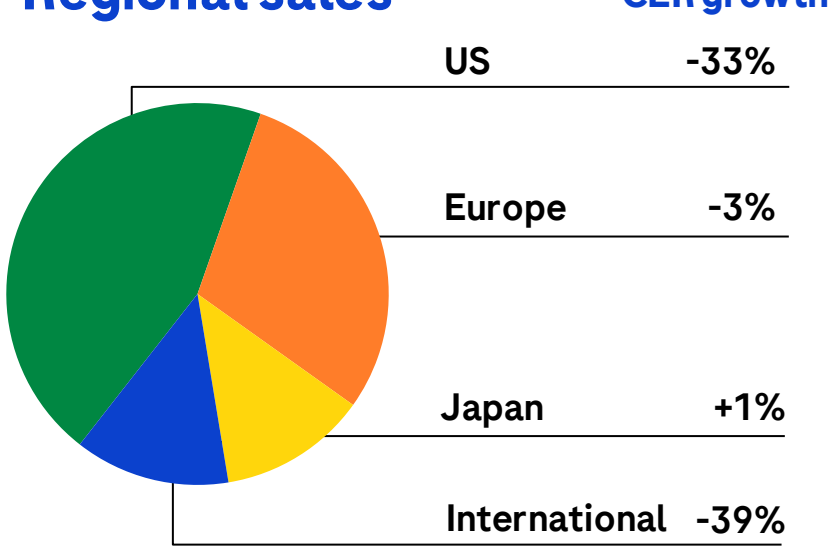
CER=Constant Exchange Rates

Actemra / RoActemra

Global sales



Regional sales



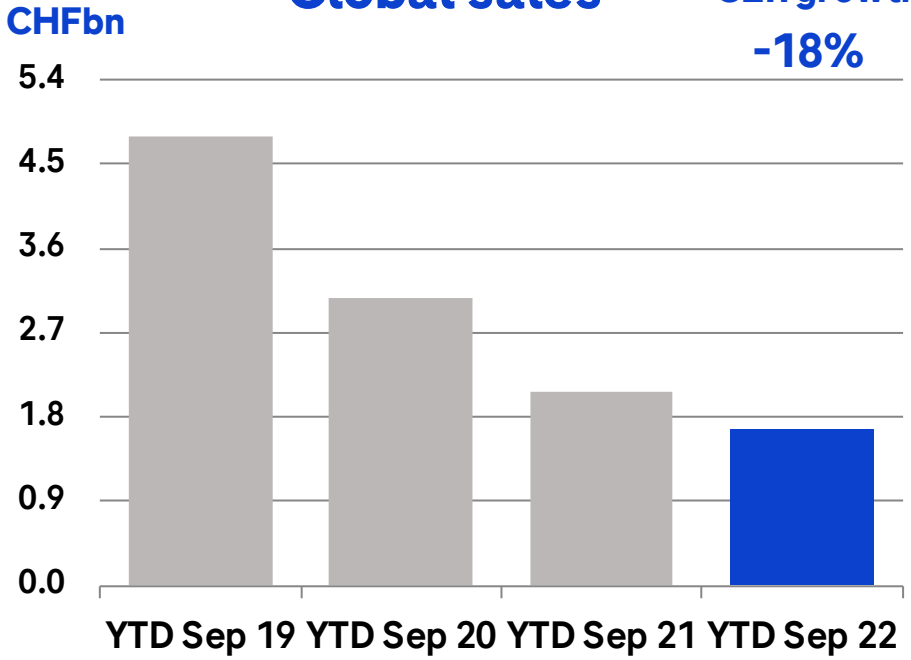
YTD Sep 2022 sales of CHF 2,039m

- US: Actemra SC share in RA keeps increasing; COVID-19 sales washed out as of Q3
- EU: Market leadership in 1L RA monotherapy maintained; COVID-19 sales washed out as of Q3
- International: COVID-19 sales washed out as of Q3

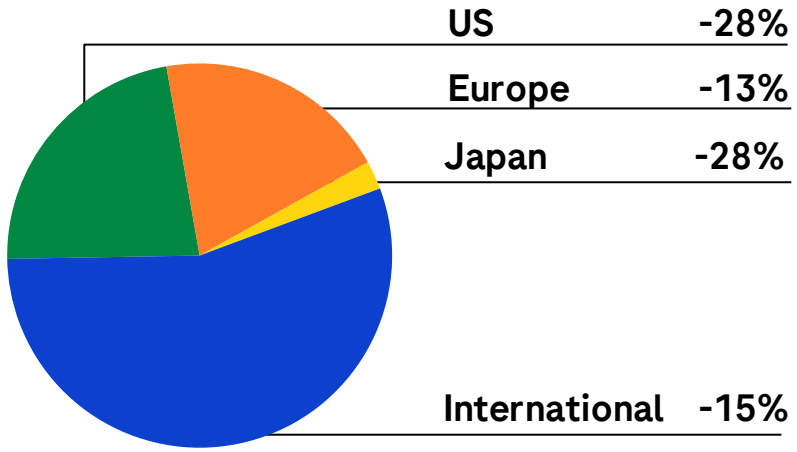
CER=Constant Exchange Rates

Herceptin

Global sales



Regional sales



YTD Sep 2022 sales of CHF 1,672m

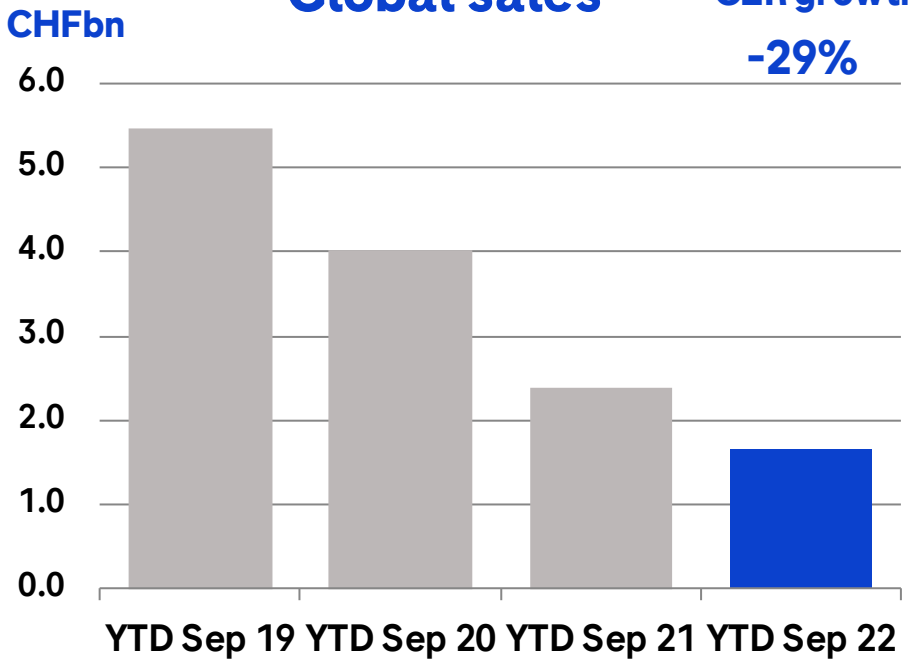
- US: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Cannibalization from Phesgo
- EU: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Cannibalization from Phesgo
- Japan: Decline due to biosimilars
- International: Decline due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

CER=Constant Exchange Rates

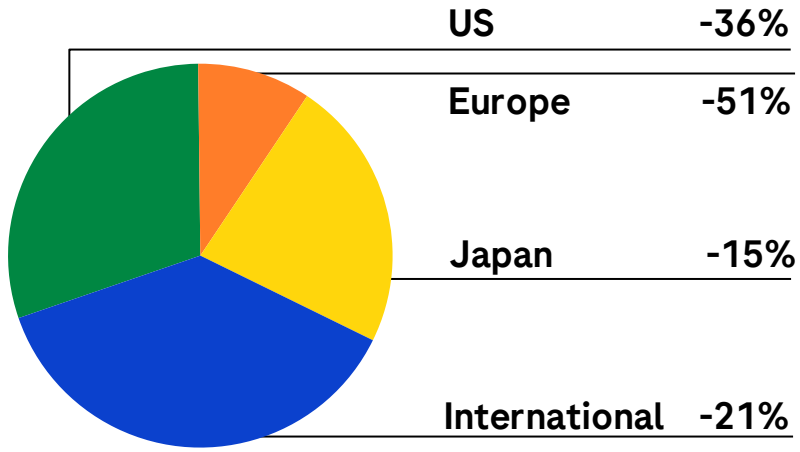
Avastin

Global sales

CER growth -29%



Regional sales

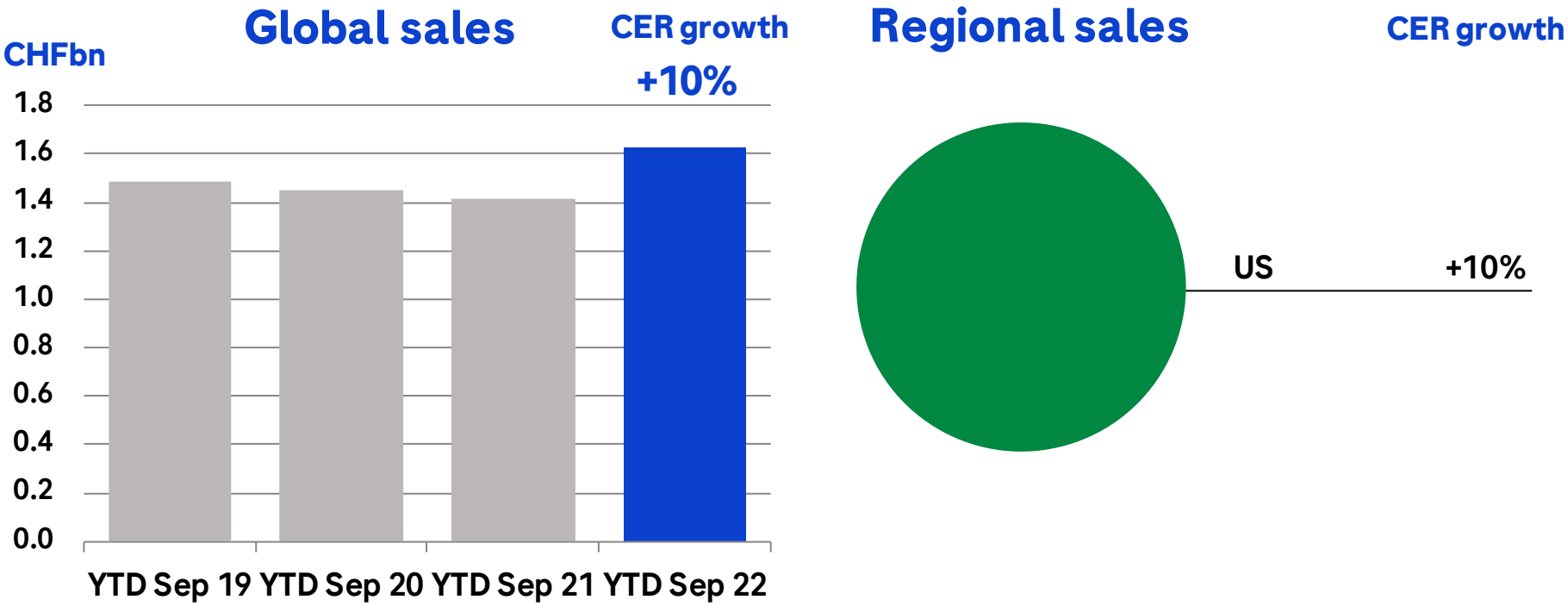


YTD Sep 2022 sales of CHF 1,652m

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

CER=Constant Exchange Rates

Xolair



YTD Sep 2022 sales of CHF 1,625m

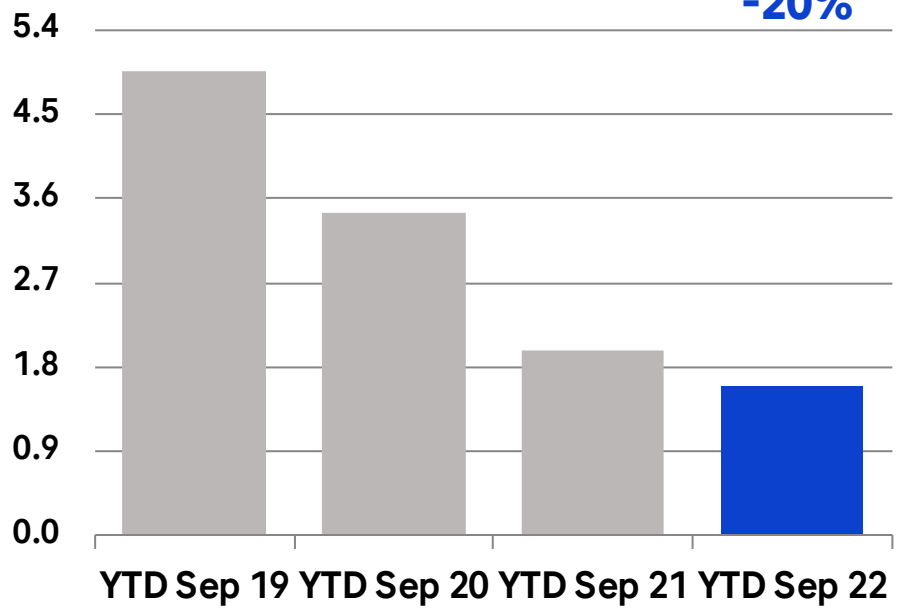
- US: Xolair remains market leader in growing biologics asthma market; Growth driven by chronic spontaneous urticaria (CSU)

CER=Constant Exchange Rates

Rituxan / Mabthera

Global sales

CHFbn

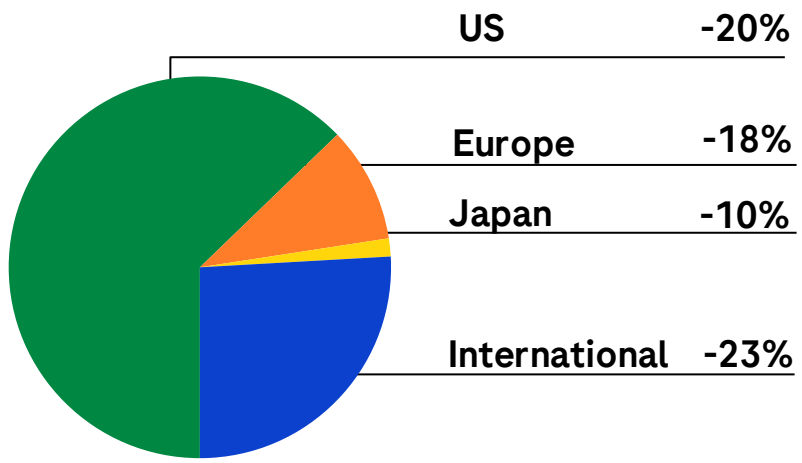


CER growth

-20%

Regional sales

CER growth

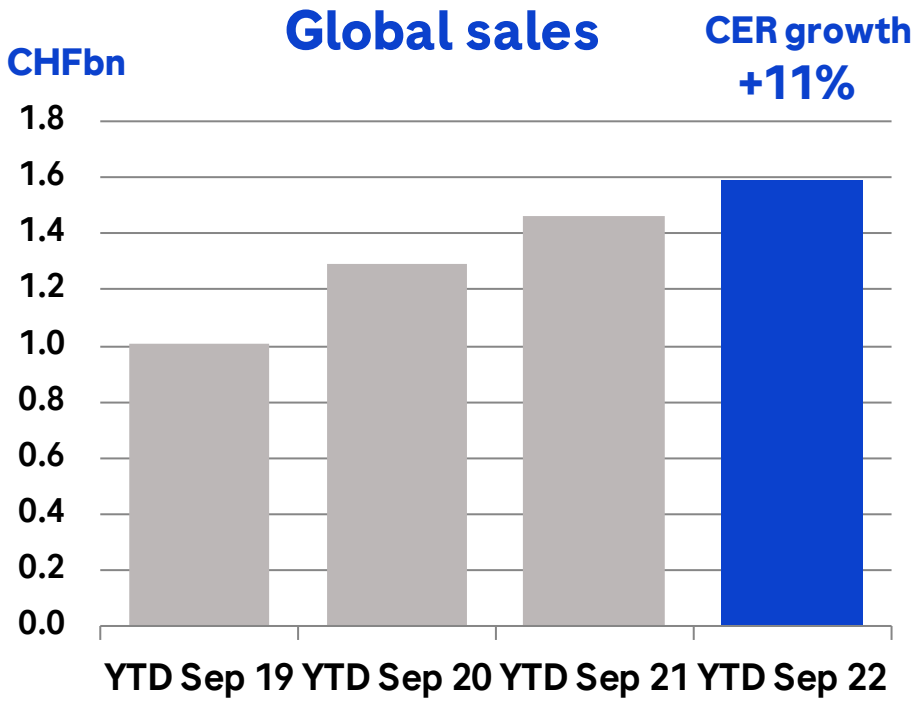


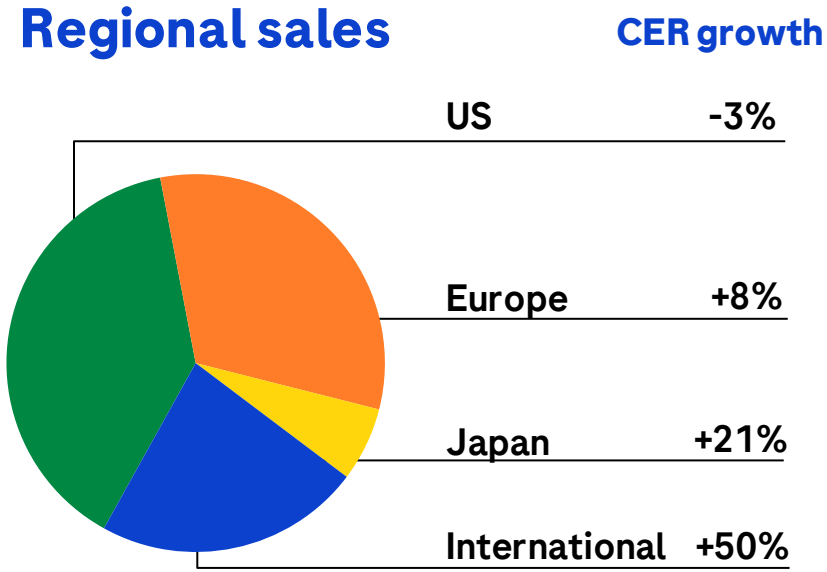
YTD Sep 2022 sales of CHF 1,596m

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

CER=Constant Exchange Rates

Kadcyla



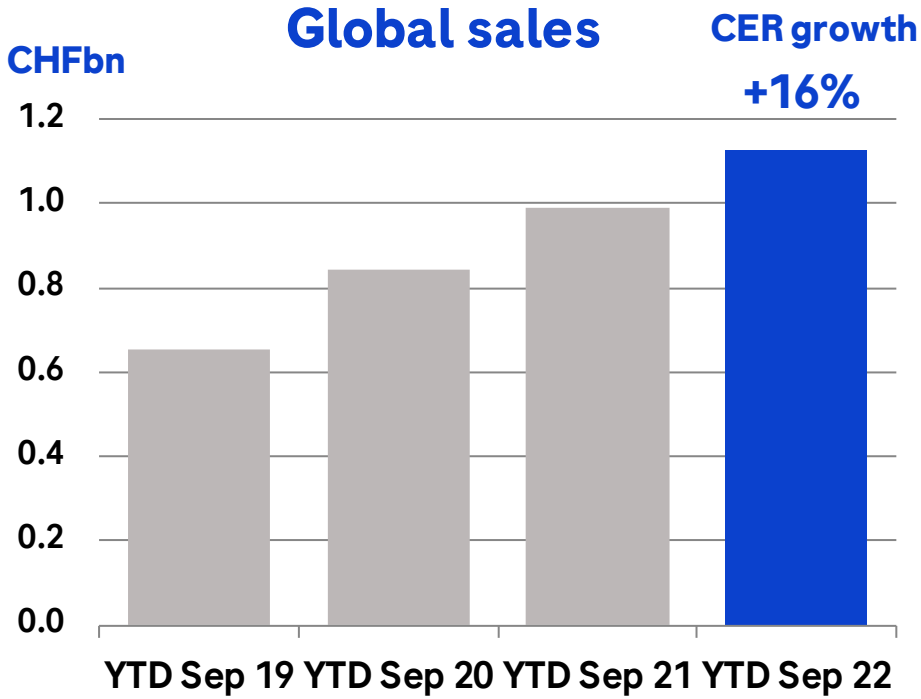


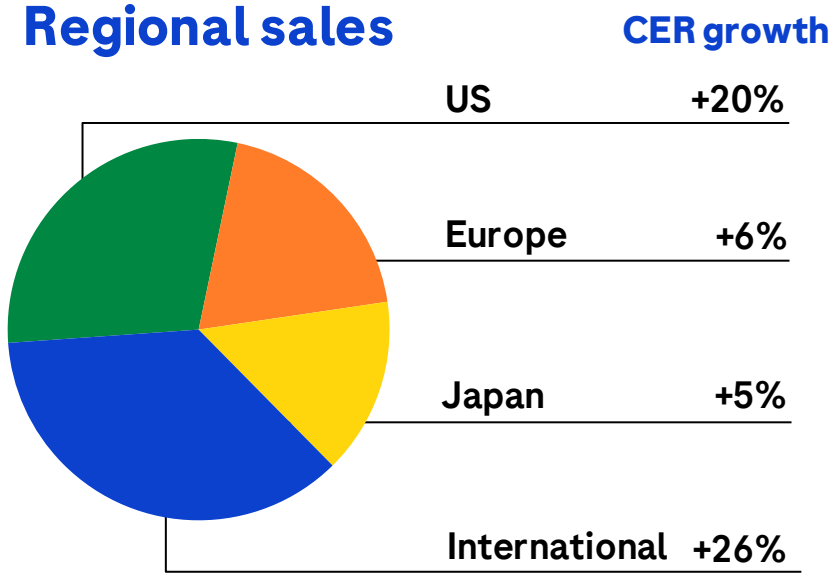
YTD Sep 2022 sales of CHF 1,590m

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

CER=Constant Exchange Rates

Alecensa



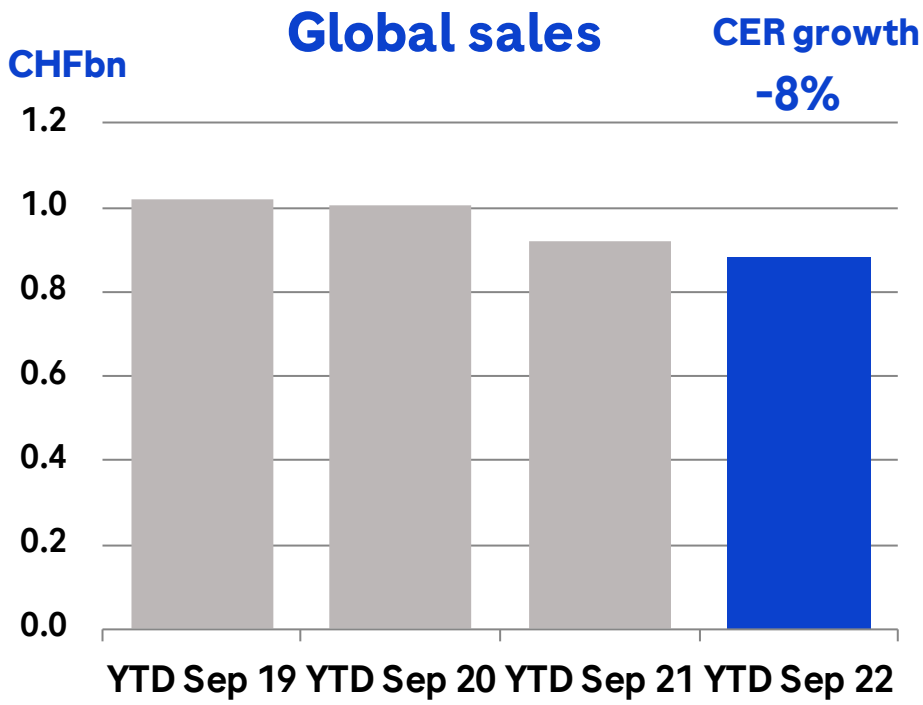


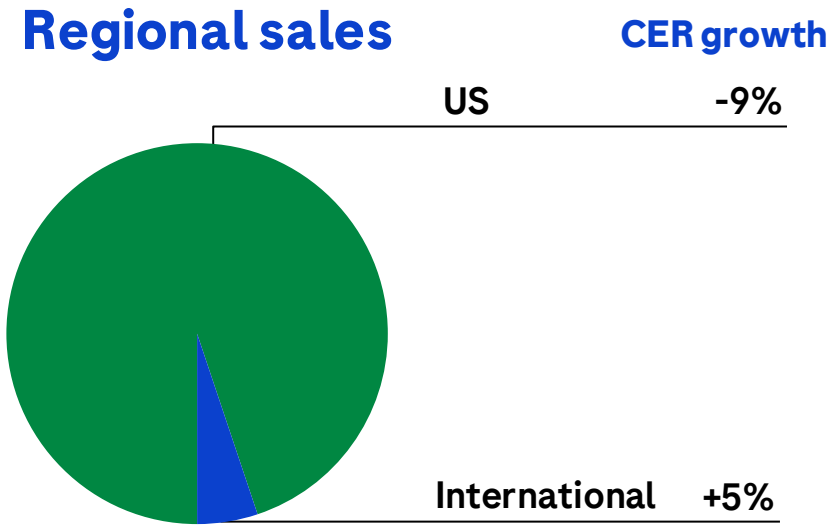
YTD Sep 2022 sales of CHF 1,127m

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

CER=Constant Exchange Rates

TNKase / Activase



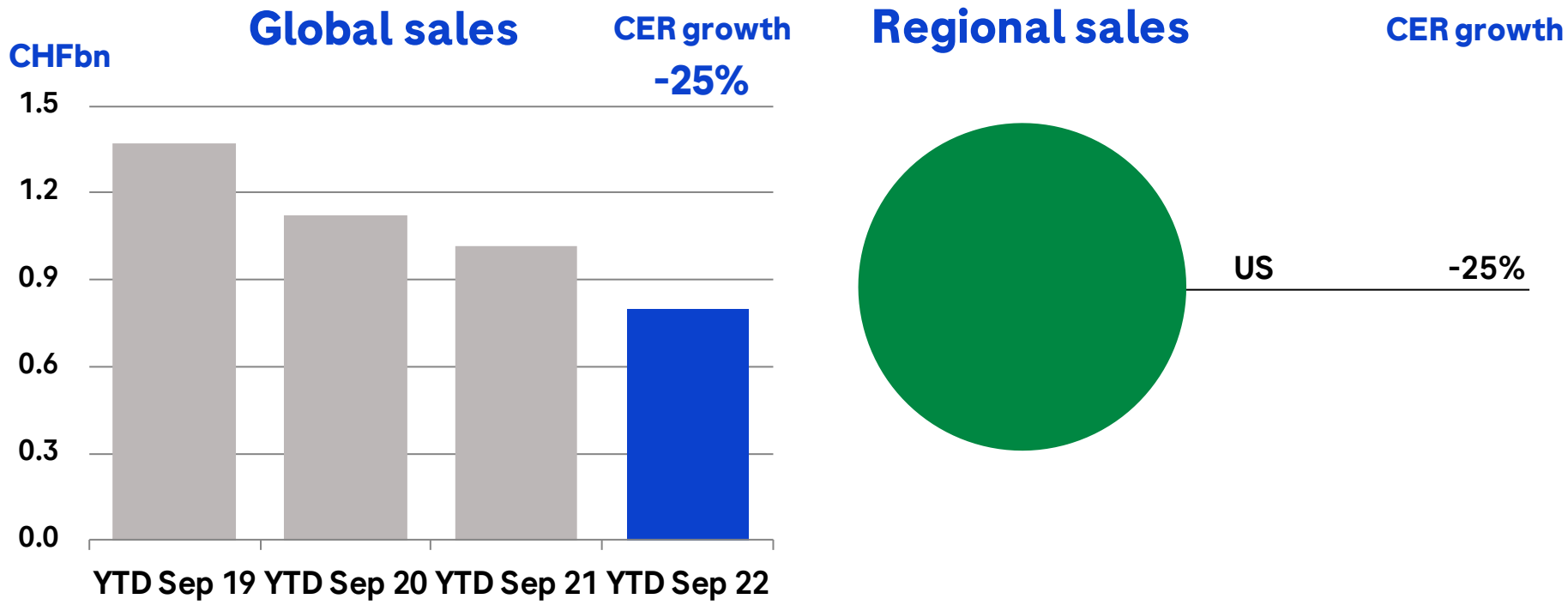


YTD Sep 2022 sales of CHF 881m

- US: Sales impacted by COVID-19 and purchasing patterns

CER=Constant Exchange Rates

Lucentis



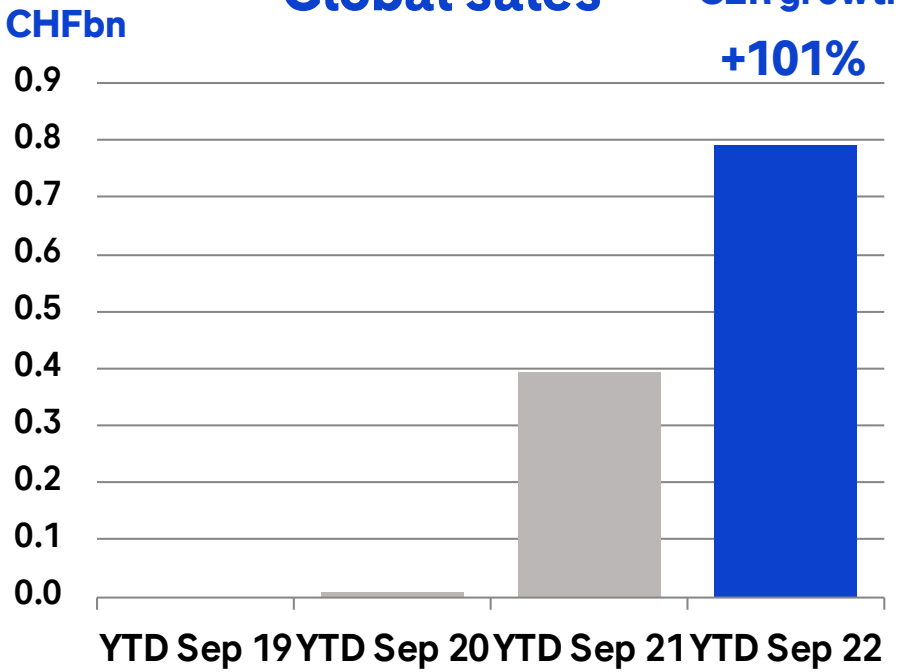
YTD Sep 2022 sales of CHF 800m

- Impacted by switching to Vabysmo, entrance of biosimilars and order patterns

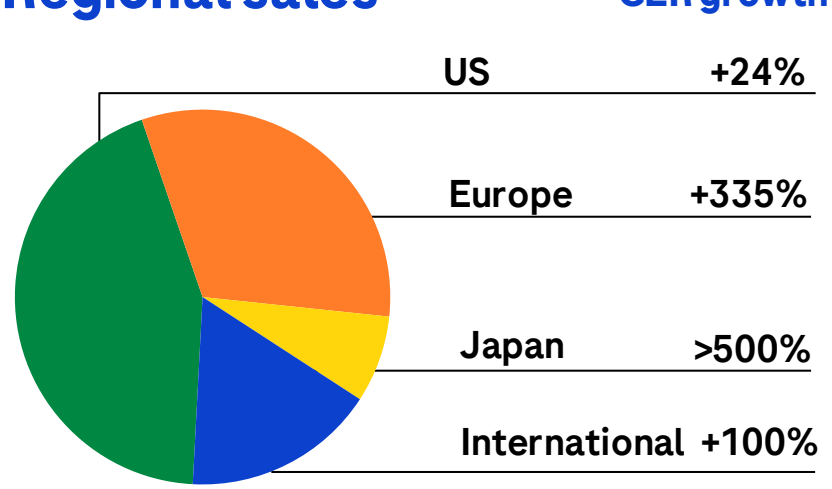
CER=Constant Exchange Rates

Evrysdi

Global sales



Regional sales

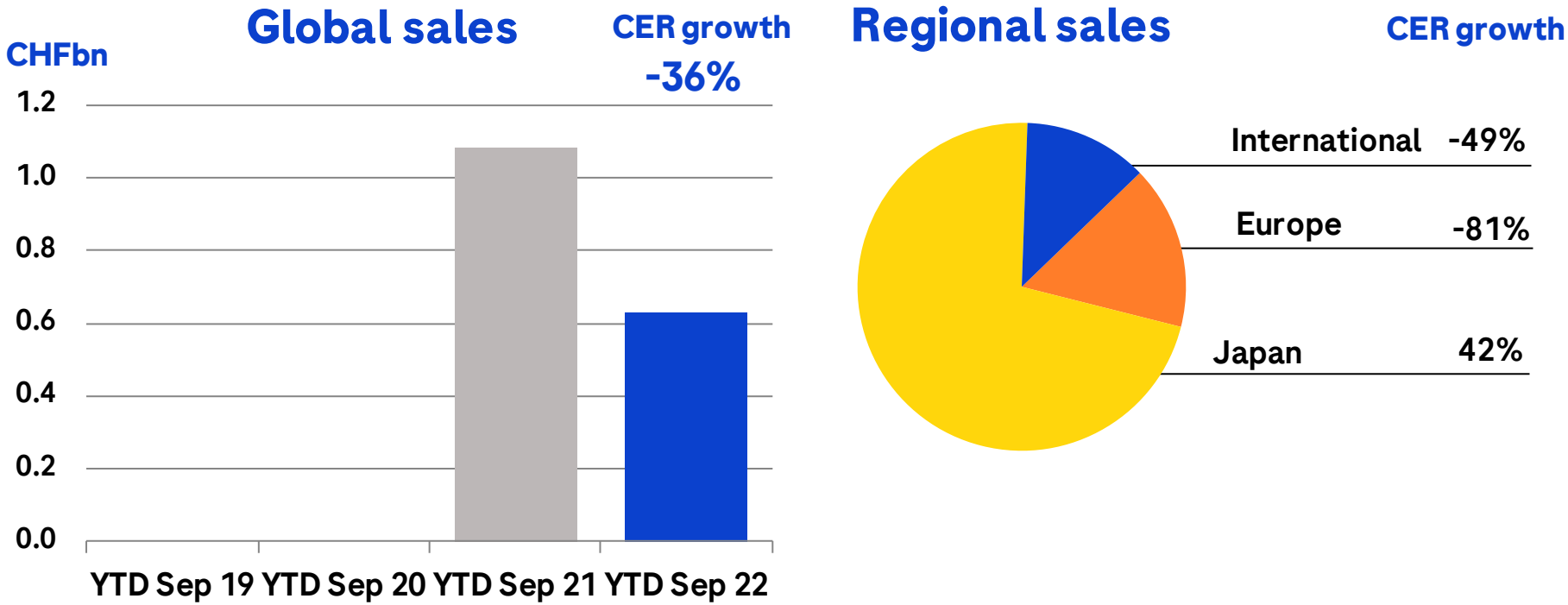


YTD Sep 2022 sales of CHF 793m

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

CER=Constant Exchange Rates

Ronapreve

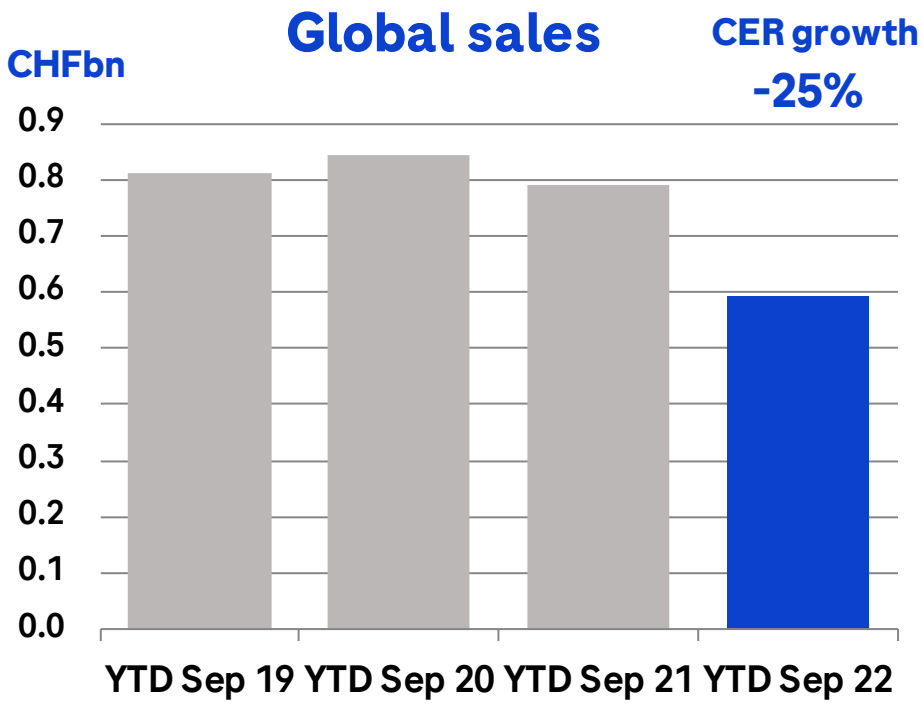


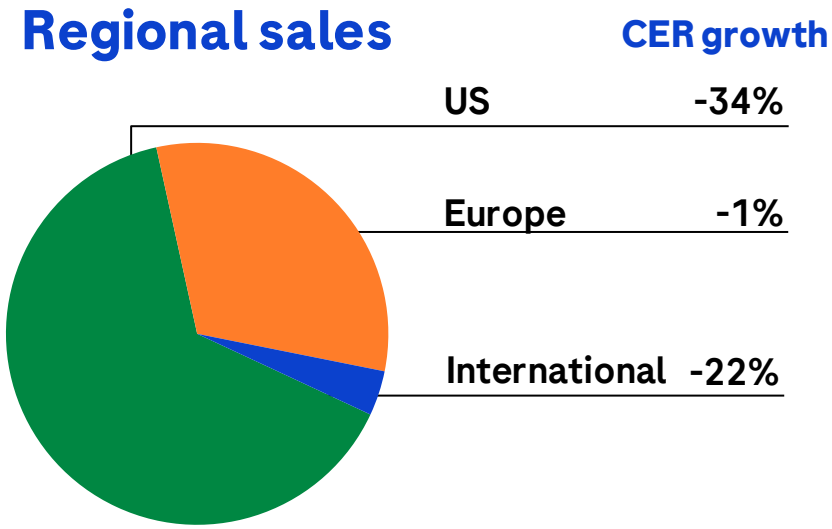
YTD Sep 2022 sales of CHF 631m

- EU: Limited sales potential left as Ronapreve has low activity against Omicron variants
- Japan: Additional sales of CHF 1.1 bn to the government expected in Q4 (overall CHF 1.6 bn for FY 2022)

CER=Constant Exchange Rates

Esbriet





YTD Sep 2022 sales of CHF 590m

- US: Generics have entered the market in Q2, rapid erosion expected
- EU: Generic entry expected in Q4

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

YTD Sep 2022: Diagnostics Division CER growth

By Region and Customer Area (vs. 2021)

	Reported										Restatement[3]									
	Global		EMEA[1]		NOA		APAC		LATAM		Global		EMEA[1]		NOA		APAC		LATAM	
	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER
Core Lab[2,3]	5,772	5	1,913	6	1,072	2	2,354	6	433	11	5,833	5	1,971	5	1,074	2	2,355	6	433	11
Point of Care[3]	2,610	29	660	-54	868	421	994	386	88	-45	3,086	30	753	-51	1,135	192	1,106	357	92	-43
Molecular Lab[3]	3,272	-3	1,133	-4	1,279	-5	769	4	91	-26	2,735	-8	982	-4	1,010	-10	656	-7	87	-28
Diabetes Care	1,219	-3	652	-3	181	-21	209	1	177	25	1,219	-3	652	-3	181	-21	209	1	177	25
Pathology Lab	975	10	237	11	523	9	196	13	19	29	975	10	237	11	523	9	196	13	19	29
Diagnostics Div.	**13,848**	**11**	**4,595**	**-14**	**3,923**	**34**	**4,522**	**28**	**808**	**-3**	**13,848**	**6**	**4,595**	**-13**	**3,923**	**20**	**4,522**	**28**	**808**	**-3**

CER=Constant Exchange Rates; [1] Europe, Middle East and Africa; [2] incl. Roche Information Solutions; [3] Sales in the Point of Care customer area include sales from the Liat business (POC molecular), and sales in the Core Lab customer area include sales from the Life Science Alliances, both previously shown as part of Molecular Lab customer area. The comparative information for 2021 has been updated accordingly. In Q1 21 POC molecular sales = 90mCHF, Q2 21=92mCHF, Q3 21=175mCHF, Q4 21=194mCHF. In Q1 21 LS Alliances = 21mCHF, Q2 21=23mCHF, Q3 21=23mCHF, Q4 21=20mCHF.

Diagnostics Division quarterly sales and CER growth[1]

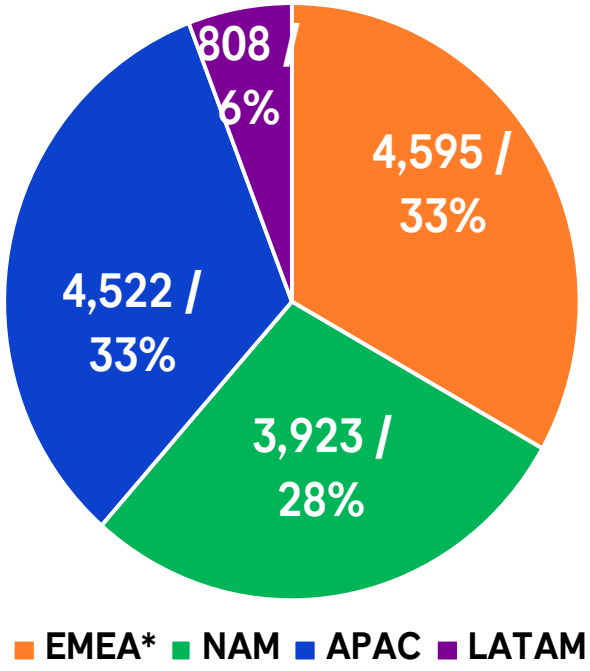
	Reported										Restatement[3]									
	Q3 21		Q4 21		Q1 22		Q2 22		Q3 22		Q3 21		Q4 21		Q1 22		Q2 22		Q3 22	
	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	%CER	CHFm	% CER
Core Lab[2,3]	1,884	12	1,863	10	1,873	8	1,961	1	1,938	7	1,907	12	1,883	9	1,896	8	1,979	1	1,958	7
Point of Care[3]	442	143	525	-2	1,302	84	987	10	321	-19	617	222	719	15	1,466	84	1,143	15	477	-16
Molecular Lab[3]	1,238	21	1,358	15	1,376	26	965	-13	931	-22	1,040	5	1,144	7	1,189	21	791	-20	755	-24
Diabetes Care	400	-7	396	-2	417	-7	415	-3	387	2	400	-7	396	-2	417	-7	415	-3	387	2
Pathology Lab	299	4	313	7	318	14	334	7	323	10	299	4	313	7	318	14	334	7	323	10
Diagnostics Div.	**4,263**	**18**	**4,455**	**8**	**5,286**	**24**	**4,662**	**0**	**3,900**	**-4**	**4,263**	**18**	**4,455**	**8**	**5,286**	**24**	**4,662**	**0**	**3,900**	**-4**

CER=Constant Exchange Rates; [1] versus same period of prior year; [2] incl. Roche Information Solutions; [3] Sales in the Point of Care customer area include sales from the Liat business (POC molecular), and sales in the Core Lab customer area include sales from the Life Science Alliances, both previously shown as part of Molecular Lab customer area. The comparative information for 2021 has been updated accordingly. In Q1 21 POC molecular sales = 90mCHF, Q2 21=92mCHF, Q3 21=175mCHF, Q4 21=194mCHF. In Q1 21 LS Alliances = 21mCHF, Q2 21=23mCHF, Q3 21=23mCHF, Q4 21=20mCHF.

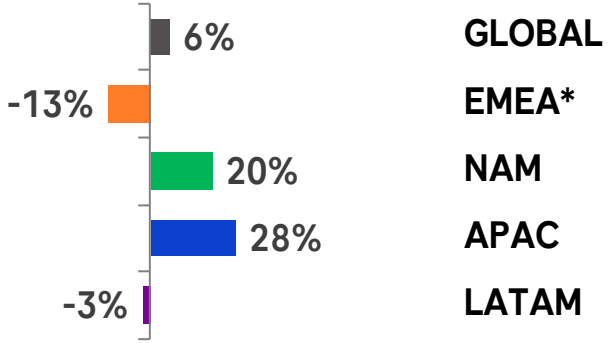
YTD Sep 2022: Diagnostics Division regional sales

Growth driven by Asia Pacific and North America

Sales YTD CHFm & % of total sales
Total YTD Sales = 13,848

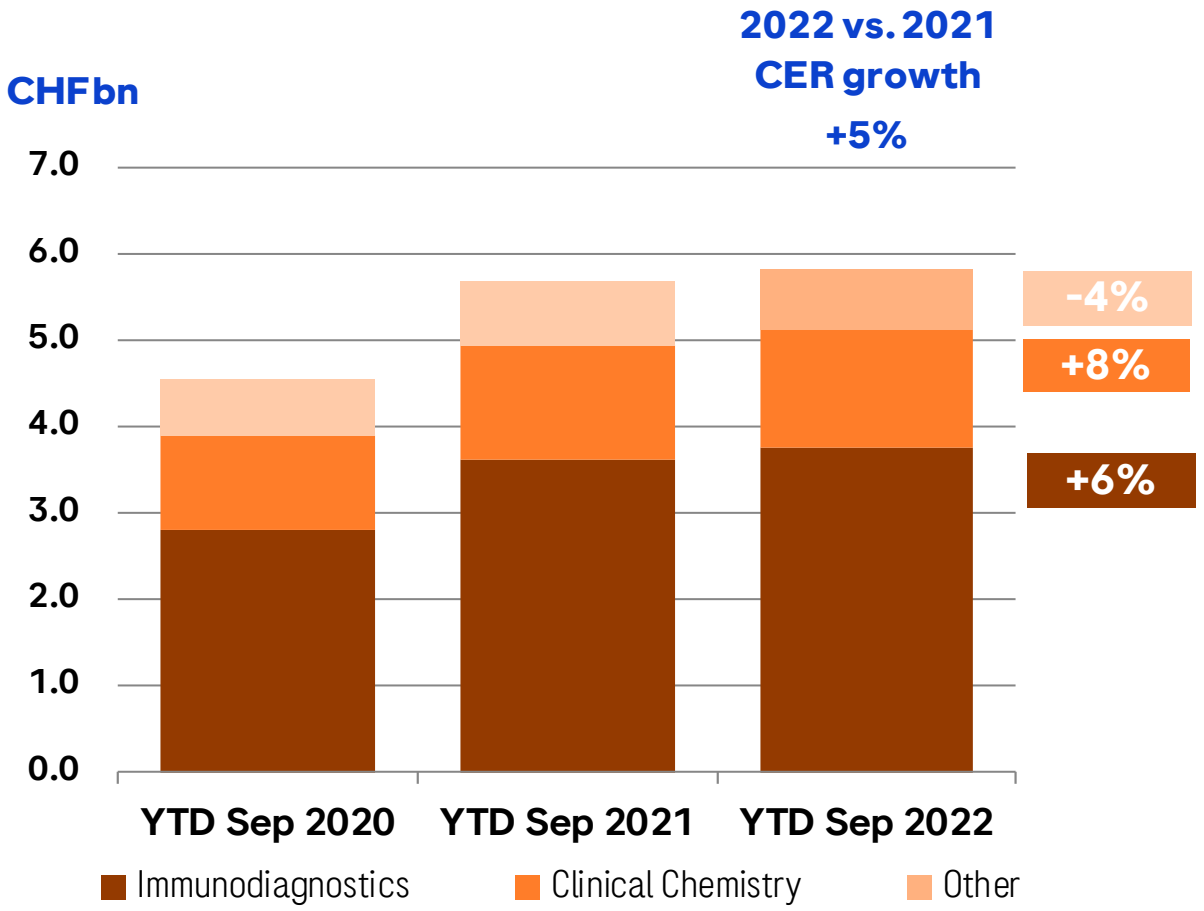


Sales growth at CER
Diagnostics Division



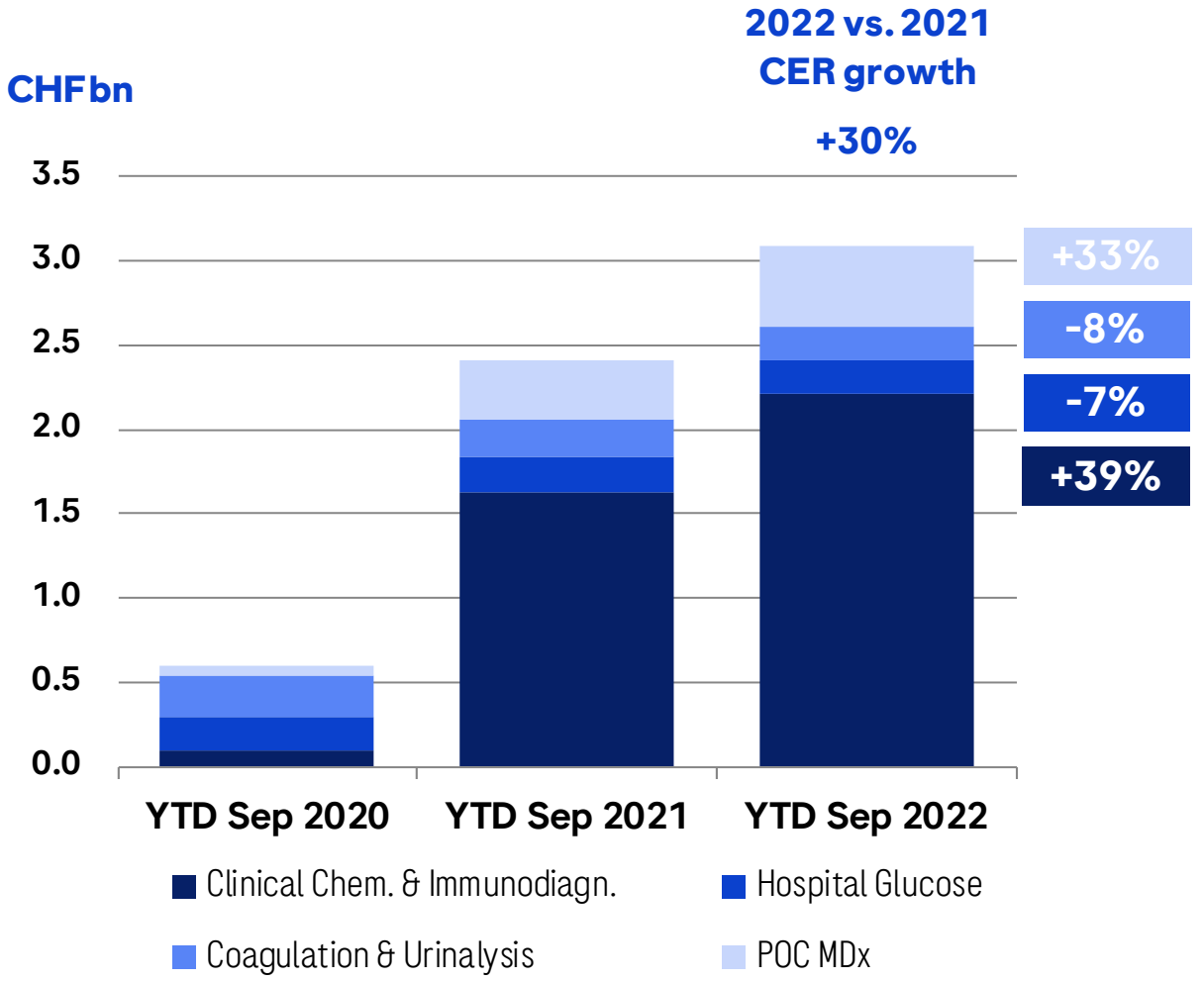
CER=Constant Exchange Rates (avg. full year 2021); * Europe, Middle East and Africa

Core Lab



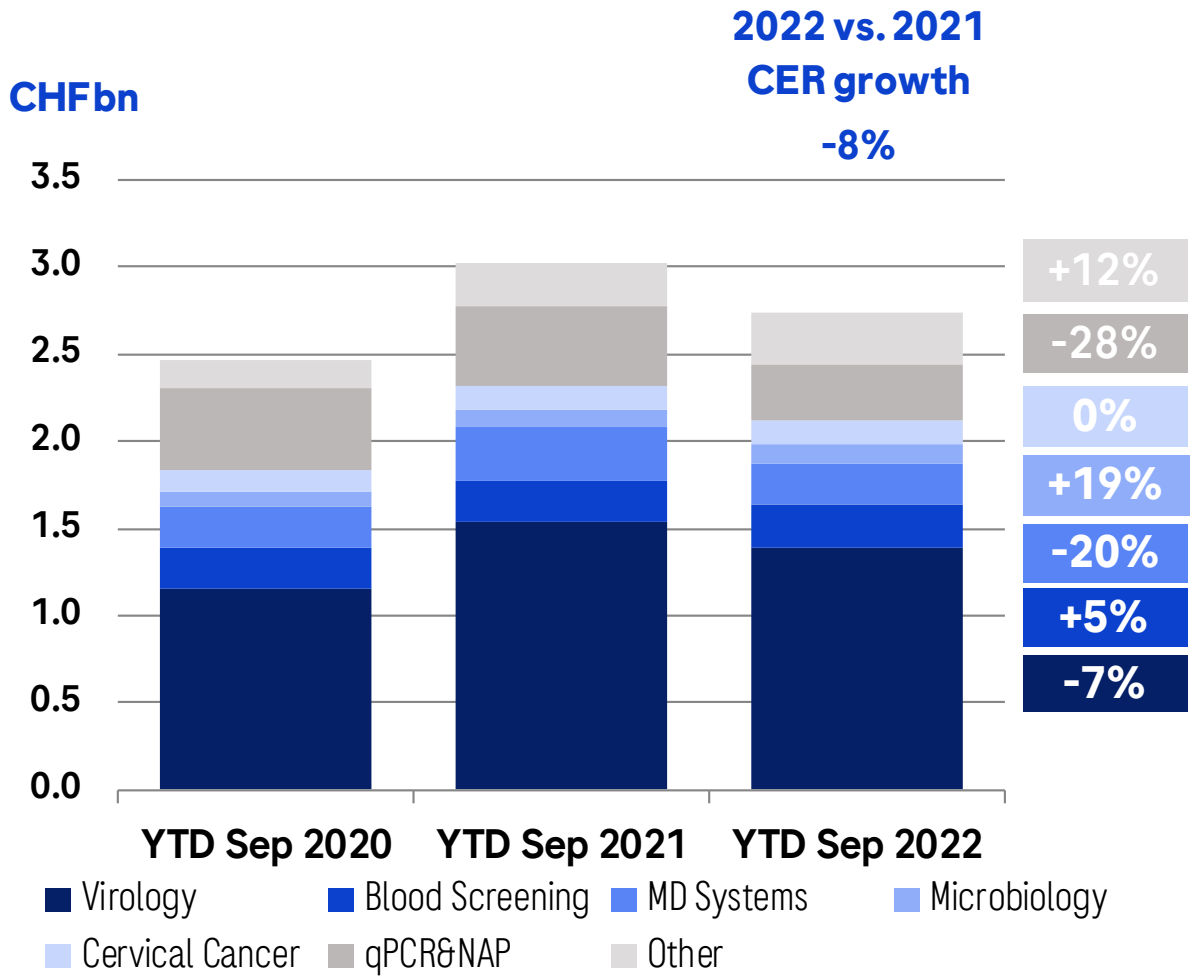
CER=Constant Exchange Rates; underlying growth of Core Lab excluding Roche Information Solutions: +5%

Point of Care



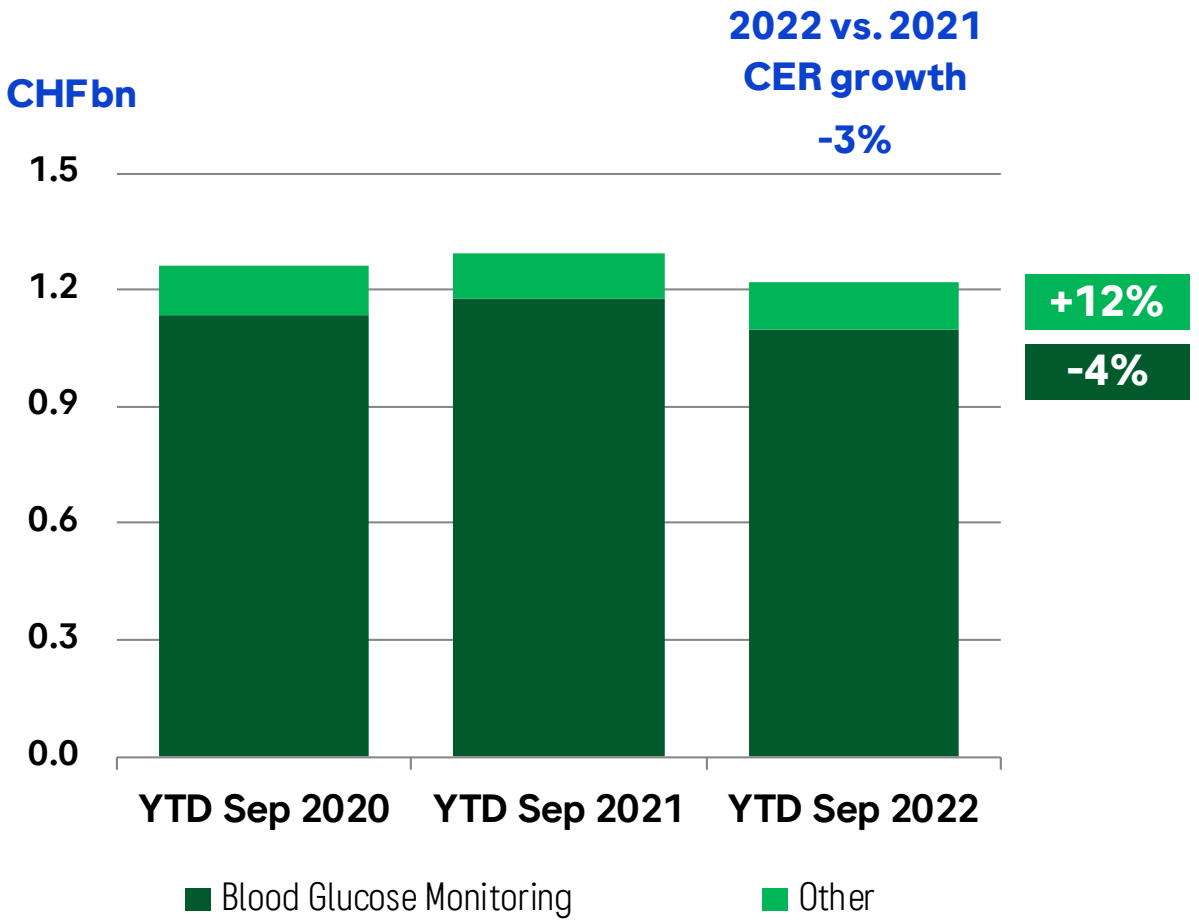
CER=Constant Exchange Rates

Molecular Lab



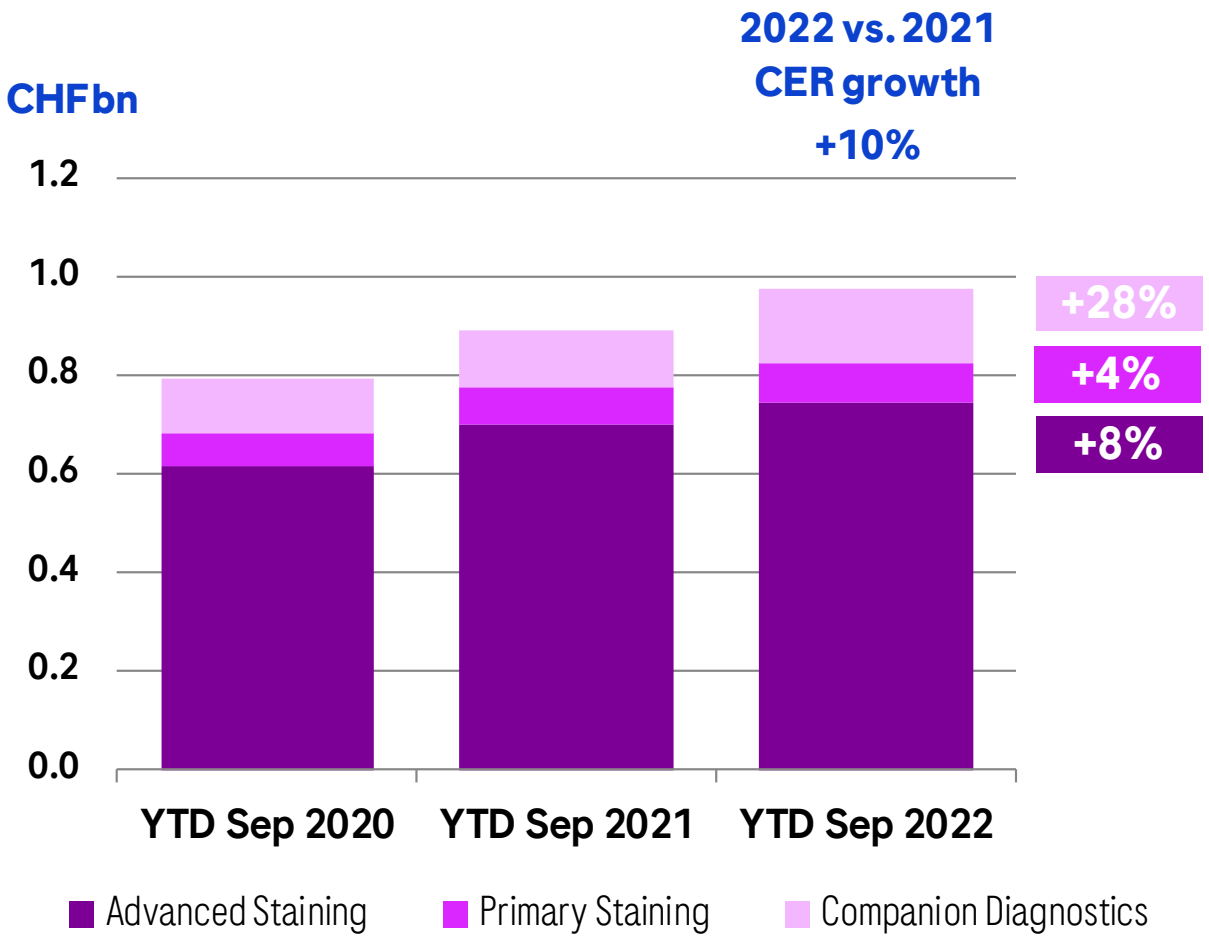
CER=Constant Exchange Rates

Diabetes Care



CER=Constant Exchange Rates

Pathology Lab



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)

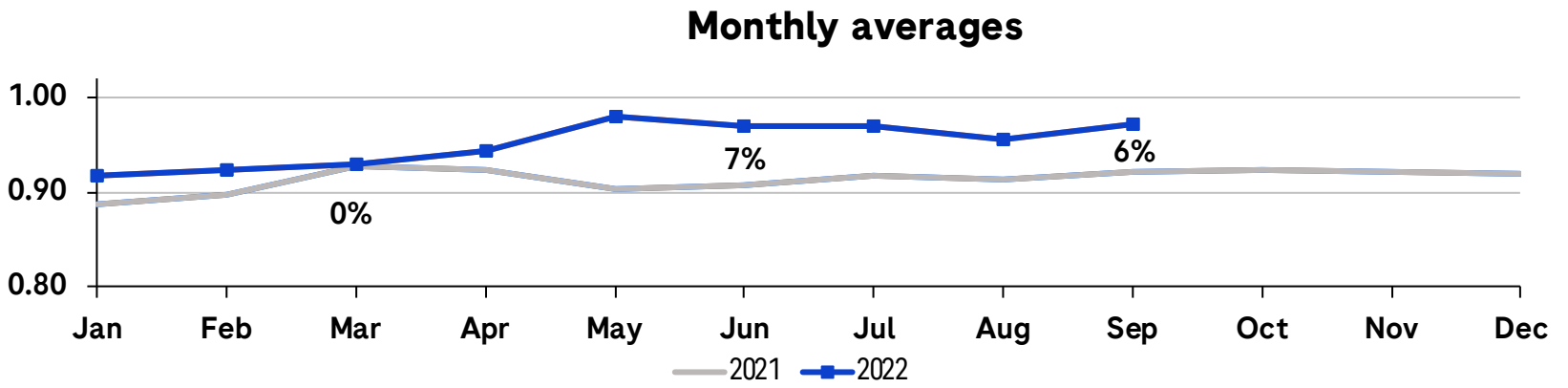
Spark

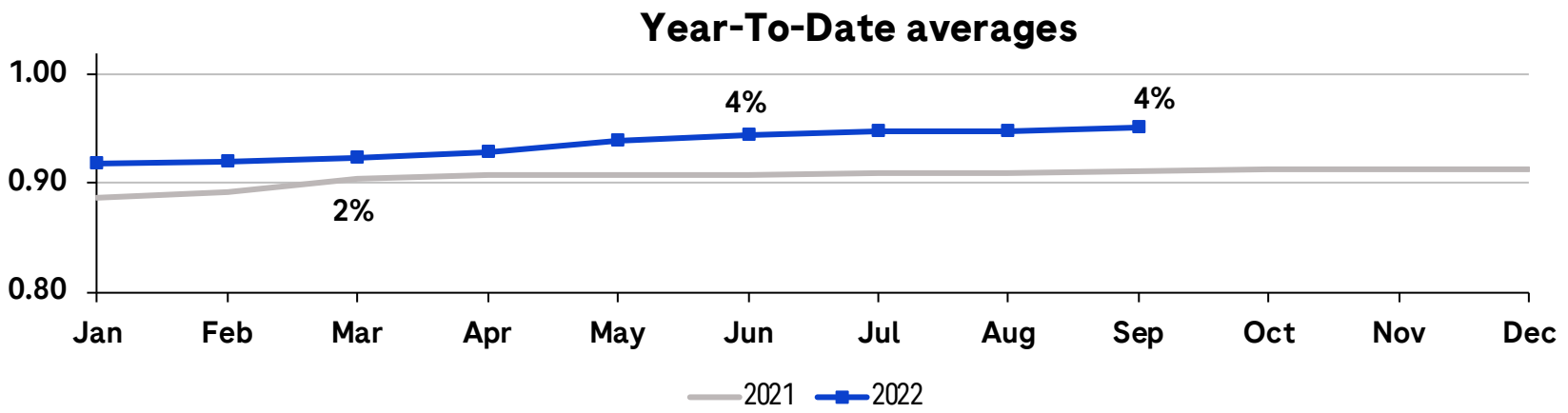
Pharma sales appendix

Diagnostics sales appendix

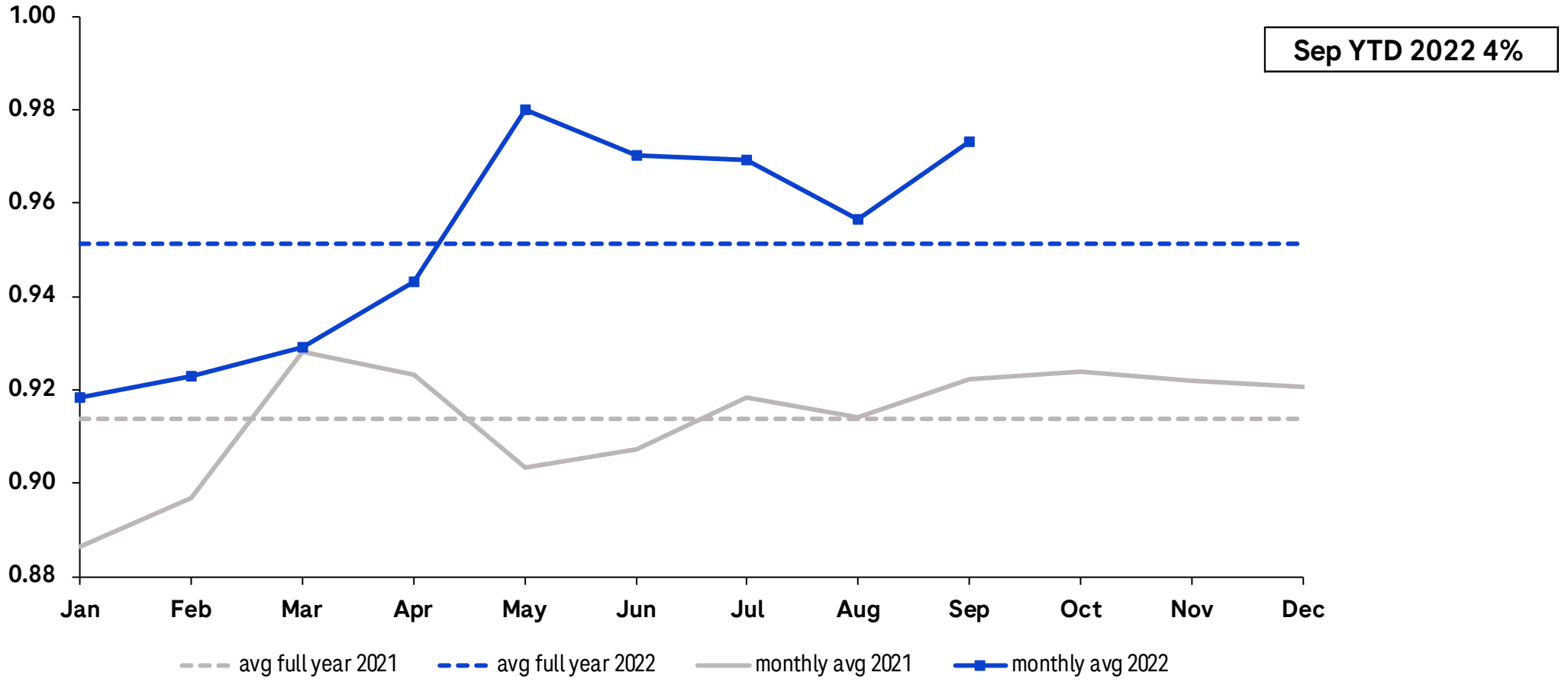
Foreign exchange rates information

CHF/USD

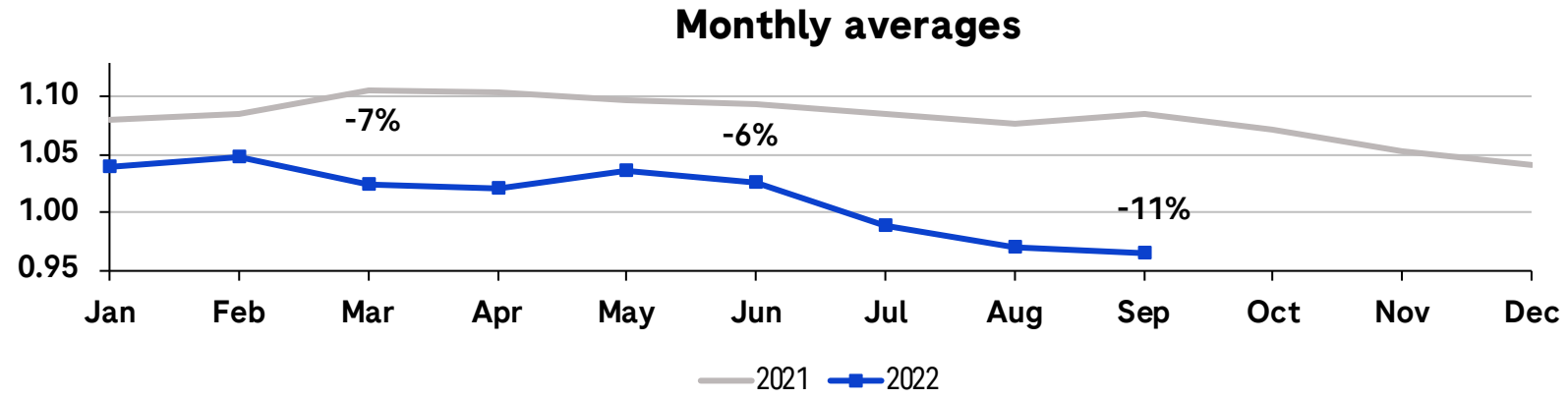

Monthly averages
1.00
0.90
0.80
0%
7%
6%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2021
2022

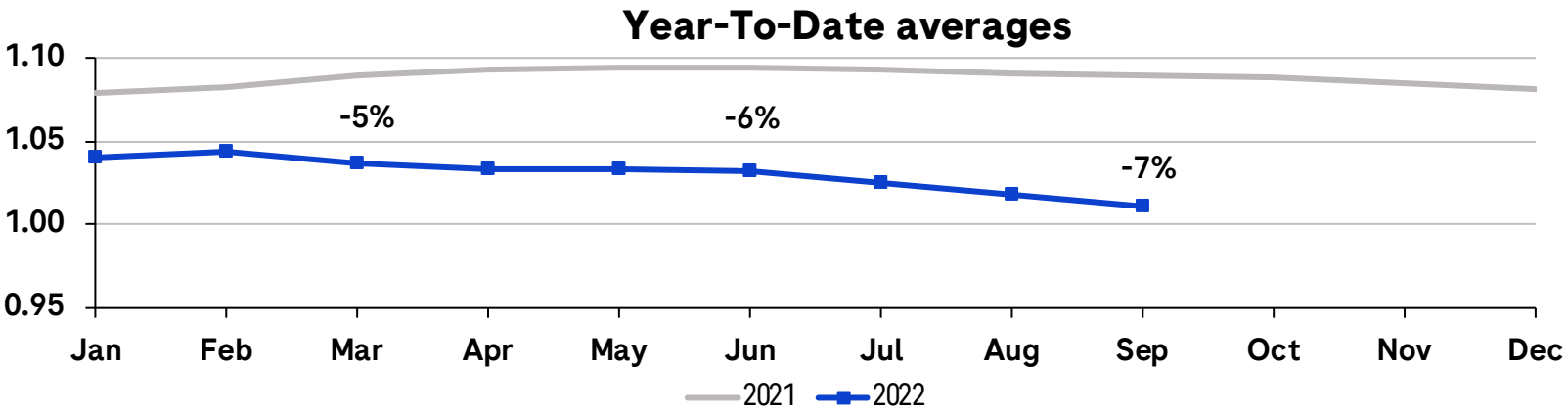

Year-To-Date averages
1.00
0.90
0.80
2%
4%
4%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2021
2022

CHF/USD

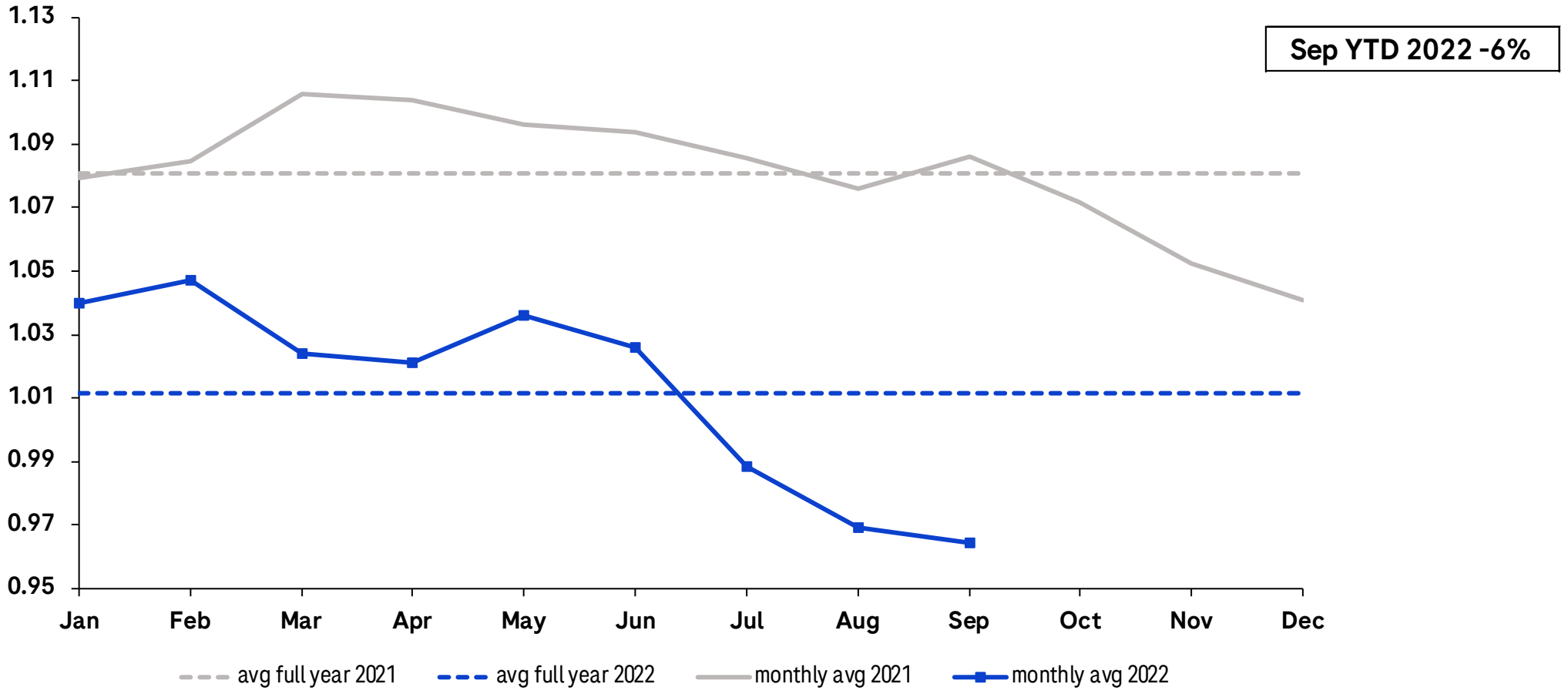

Sep YTD 2022 4%
1.00
0.98
0.96
0.94
0.92
0.90
0.88
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
avg full year 2021
avg full year 2022
monthly avg 2021
monthly avg 2022

CHF/EUR


Monthly averages
1.10
1.05
1.00
0.95
-7%
-6%
-11%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2021
2022

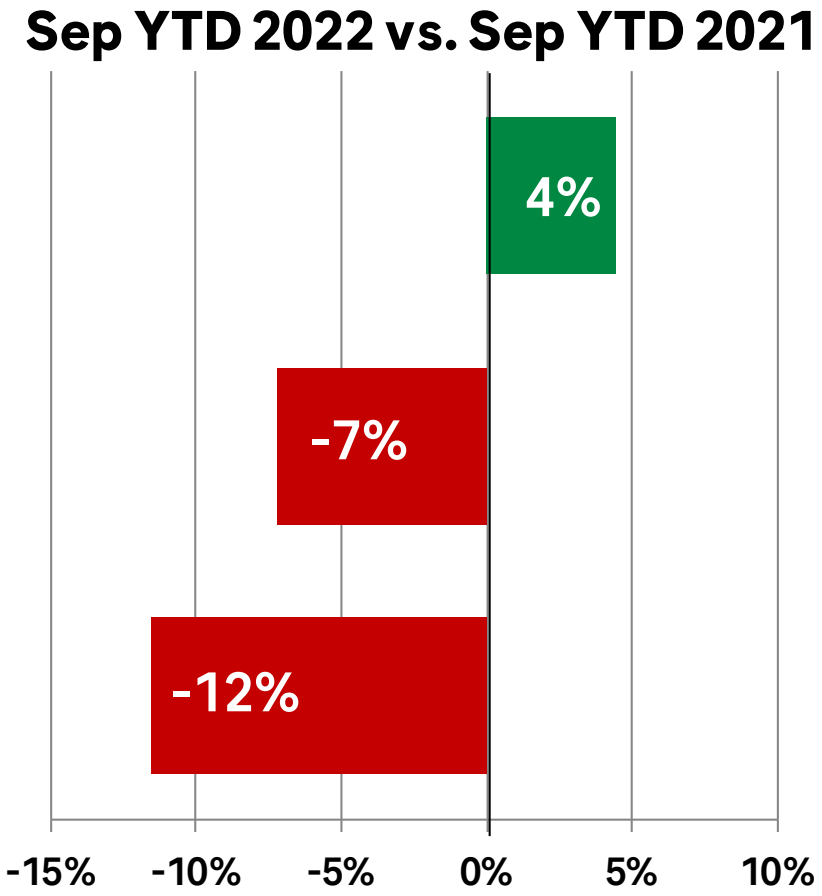

Year-To-Date averages
1.10
1.05
1.00
0.95
-5%
-6%
-7%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2021
2022

CHF/EUR


Sep YTD 2022 -6%
1.13
1.11
1.09
1.07
1.05
1.03
1.01
0.99
0.97
0.95
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
avg full year 2021
avg full year 2022
monthly avg 2021
monthly avg 2022

Average CHF Exchange Rates

	Sep YTD 2022	Sep YTD 2021
USD	0.95	0.91
EUR	1.01	1.09
JPY	0.74	0.84

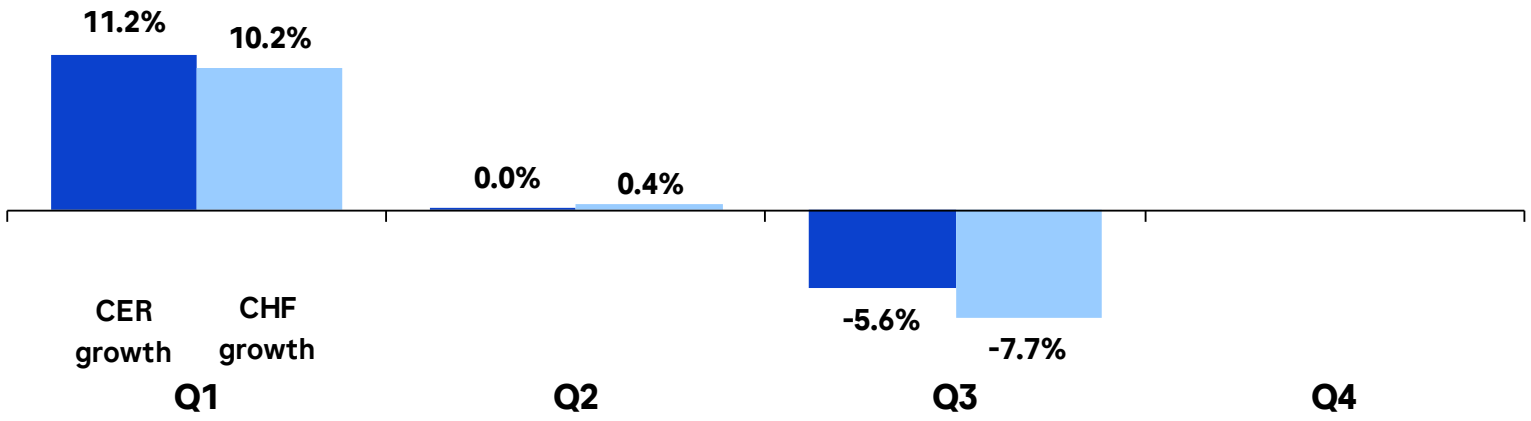


Exchange rate impact on sales growth

Q3 2022: negative impact of JPY and EUR, positive impact of USD

Development of average exchange rates versus prior year period

	Q1	Q2	Q3
CHF / USD	2.2%	5.9%	5.2%
CHF / EUR	-4.9%	-6.4%	-10.0%
CHF / JPY	-6.9%	-10.6%	-16.2%
Difference in CHF / CER growth	-1.0%	0.4%	-2.1%



CER = Constant Exchange Rates (avg full year 2021)

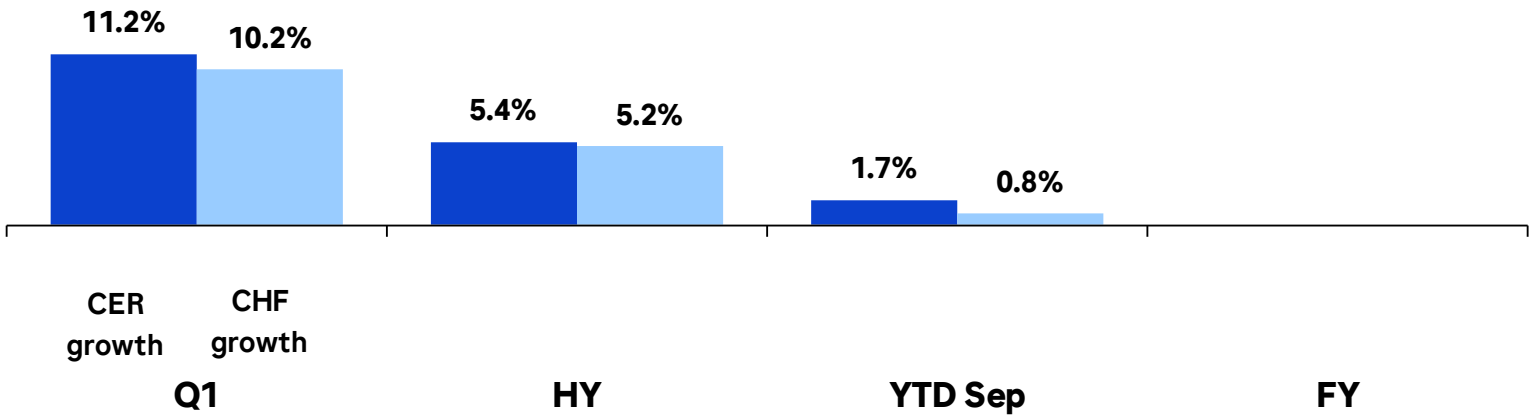
Exchange rate impact on sales growth

YTD Sep 2022: negative impact of JPY and EUR, positive impact of USD

Development of average exchange rates versus prior year period

CHF / USD	**2.2%**	**4.0%**	**4.4%**
CHF / EUR	**-4.9%**	**-5.7%**	**-7.2%**
CHF / JPY	**-6.9%**	**-8.9%**	**-11.5%**
Difference in CHF / CER growth	**-1.0%**	**-0.2%**	**-0.9%**

Sales growth 2022 vs. 2021



CER = Constant Exchange Rates (avg full year 2021)

Doing now what patients need next