
Roche

Roche

HY 2020 results

Basel, 23 July 2020

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

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Group

Severin Schwan
Chief Executive Officer

HY 2020 performance

Outlook

Significant COVID-19 impact

Pharmaceuticals

- Significant decline in May due to delay of HCP visits, recovering since June
- Launch of NMEs, readouts & pivotal trial starts largely on track
- Continued good growth momentum of new products (+37%), offsetting biosimilar erosion

Diagnostics

- Increase of COVID-19 testing offsetting negative impact on routine testing in Q2
- Ramping up of SARS-CoV-2 test manufacturing capacity will support growth in HY2
- Additional COVID-19 tests to be launched in Q3: PoC antibody test; multiplex SARS-CoV-2/flu

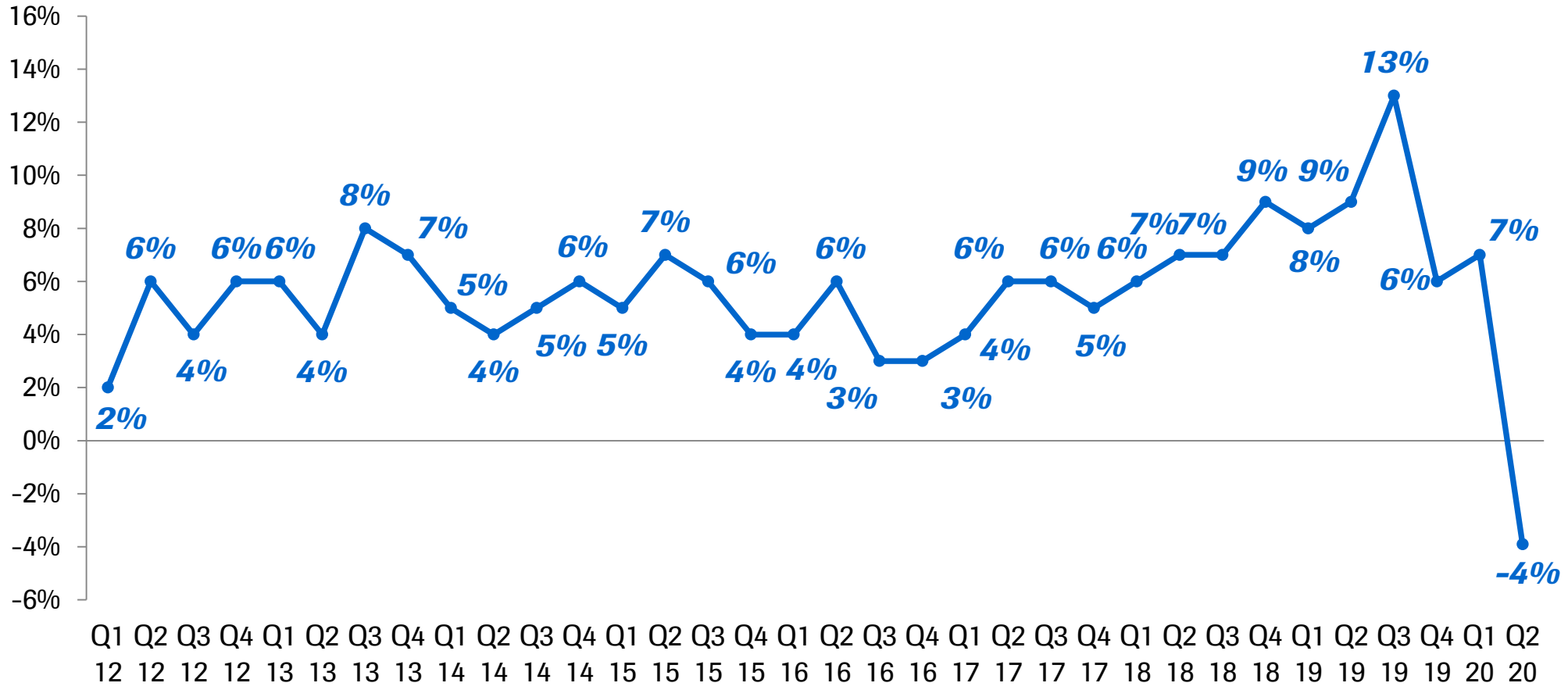
All growth rates at Constant Exchange Rates (CER), HCP=healthcare professionals; PoC=Point of Care

HY 2020: Sales growth despite COVID-19

	HY 2020 CHFbn	HY 2019 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	**23.2**	24.2	**-4**	**1**
Diagnostics Division	**6.1**	6.3	**-3**	**3**
Roche Group	**29.3**	30.5	**-4**	**1**

CER=Constant Exchange Rates

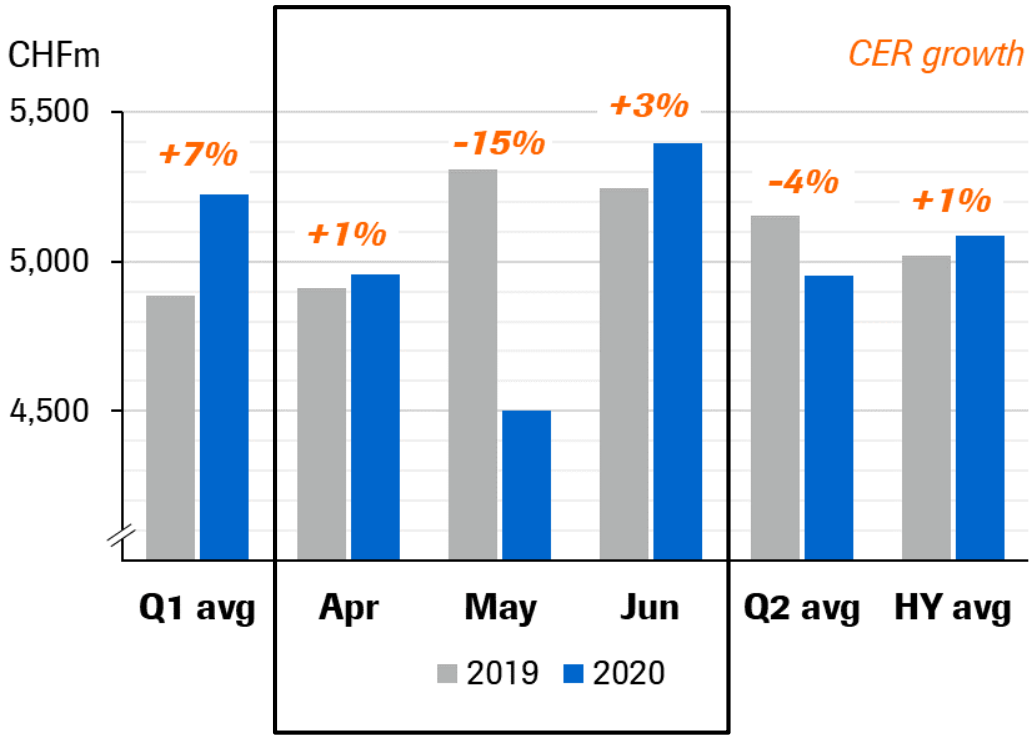
Q2 2020: Heavily impacted by COVID-19



All growth rates at Constant Exchange Rates (CER)

HY 2020: Group sales – May heavily impacted by COVID-19

Recovery started in June



Pharmaceuticals

- Impact in May driven by patients delaying appointments (mainly but not only chronic diseases)
- Recovery in the last weeks of the quarter

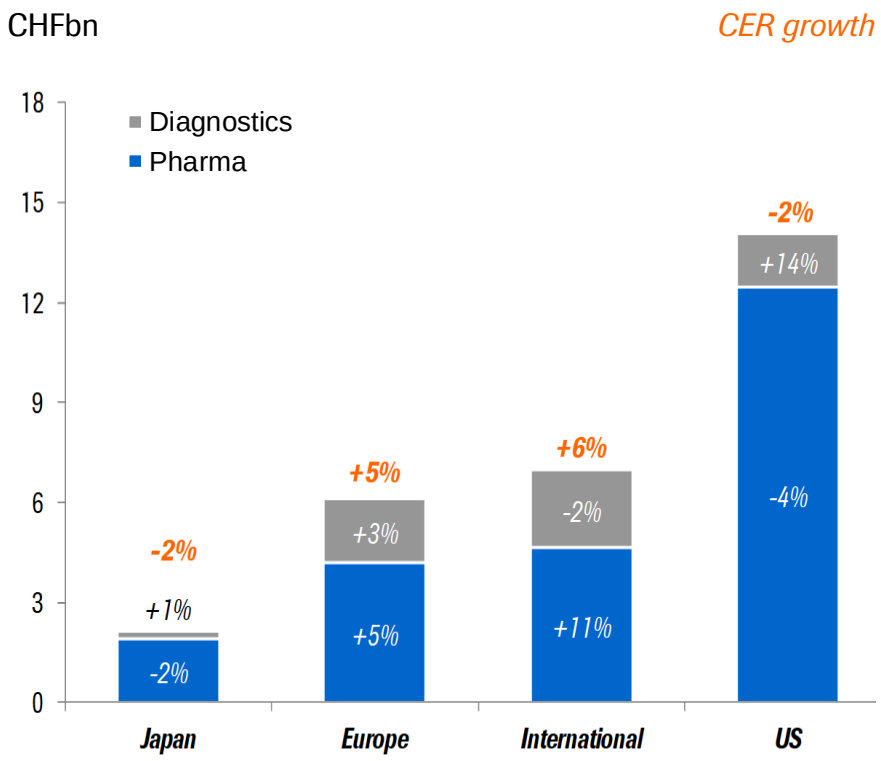
Diagnostics

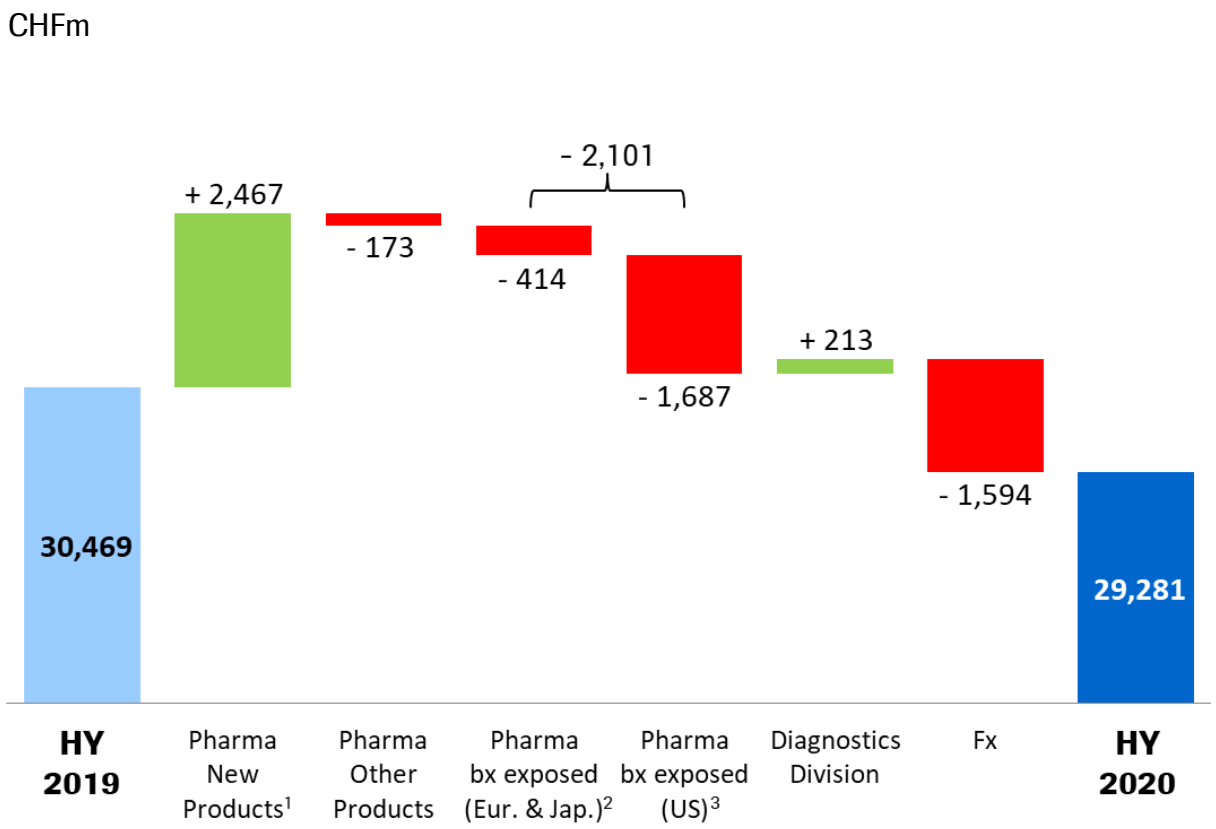
- Impact in April/May driven by decline in routine testing, partially compensated by COVID-19 testing
- Recovery started with easing of restrictions

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

HY 2020: Good sales growth in International and Europe

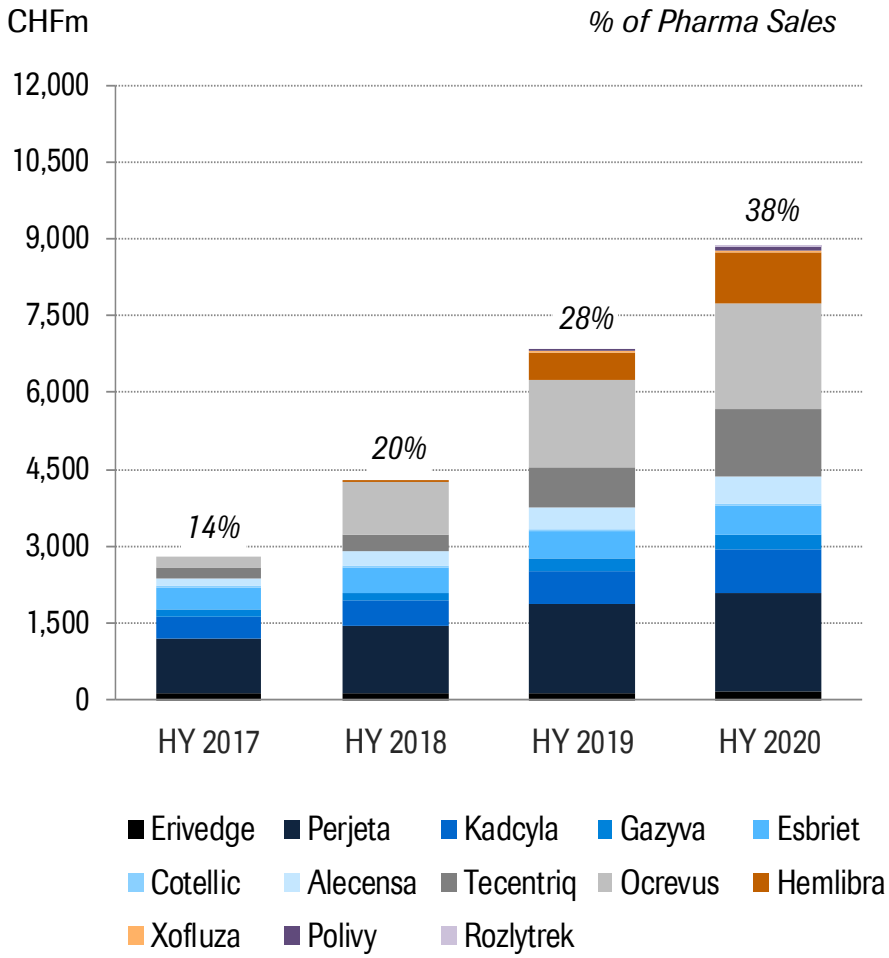
New products with strong momentum



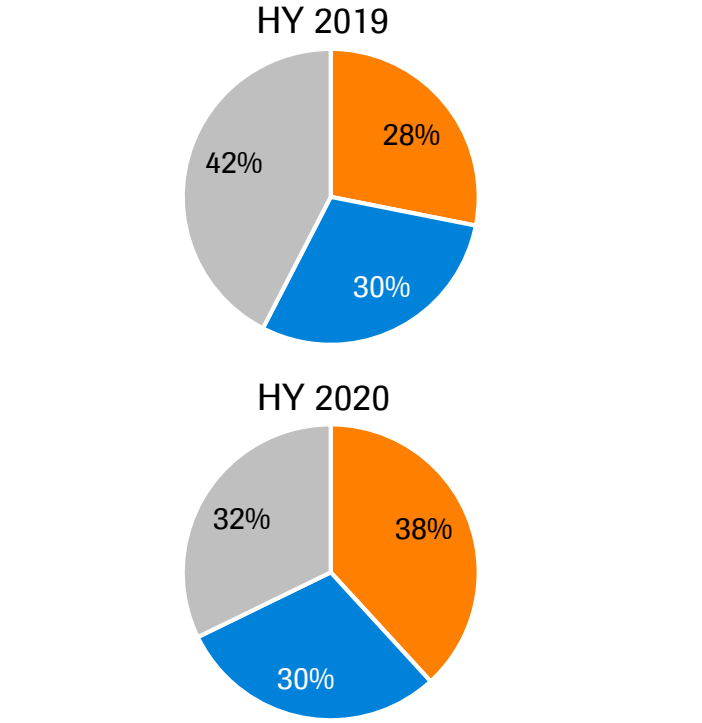


HY values reported in CHFm and variances in CERm; [1] Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy & Rozlytrek; [2] MabThera & Herceptin in Europe and MabThera, Herceptin & Avastin in Japan; [3] Herceptin, Avastin & MabThera in US

New products with strong momentum – accelerated rejuvenation



Pharma sales mix



All absolute values are presented in CHFm reported

Roche significantly advancing patient care

Pivotal trials on track despite difficult environment

34 *Breakthrough Therapy Designations (BTD) since 2013*

Year	Molecule	Indication
2020	mosunetuzumab	3L+ FL
	Tecentriq	unresectable or metastatic ASPS
	Esbriet	ulLD
2019	Cotellic	Histiocytic neoplasms
	Gazyva	Lupus nephritis
	PRM-151	IPF
	Venclexta + Gazyva	1L unfit CLL
	Kadcyla	Adjuvant HER2+ BC
2018	SPK-8011	Hemophilia A
	satralizumab	NMOSD
	Xolair	Food allergies
	Tecentriq + Avastin	1L HCC
	Hemlibra	Hemophilia A non-inhibitors
	Rozlytrek	NTRK+ solid tumors
2017	Polivy + BR	R/R DLBCL
	Venclexta + LDAC	1L unfit AML
	Zelboraf	BRAF-mutated ECD
	Rituxan	Pemphigus vulgaris

8 *Breakthrough Device Designations (BDD) since 2018*

Year	Device	Intended use
2020	Elecsys GALAD score	early stage HCC
2018	Elecsys β-Amyloid + p-Tau Cerebro Spinal Fluid assays	AD: PET concordance AD: Progression
	sFlt + PLGF	Preeclampsia: rule-out within 1w
	FACT CDx (liquid biopsy assay)	70 oncogenes + MSI + bTMB
	cobas EBV	EBV in transplant patients
	cobas BKV	BKV in transplant patients
	CoaguChek Direct-X	Patients on Factor Xa

Pivotal trial recruitment finished in HY1 2020

ipatasertib	1L TNBC (Ph III: IPATunity130)
risdiplam	SMA type 1/2/3 (Ph II: JEWELFISH)
gantenerumab	Alzheimer's disease (Ph III: GRADUATE 1 & 2)
tominersen	Huntington's disease (Ph III: Generation HD1)

New pivotal study starts in HY1 2020

tiragolumab	mNSCLC (Ph III: SKYSCRAPER-01), ES-SCLC (Ph III: SKYSCRAPER-02) Cervical cancer (Ph II: SKYSCRAPER-04)
PI3Ki	HR+ mBC (Ph III: INAVO120)
Venclexta+Gazyva	1L fit CLL (Ph III: CristaLLo)
Actemra	severe COVID-19 pneumonia (Ph III: COVACTA, REMDACTA, EMPACTA)

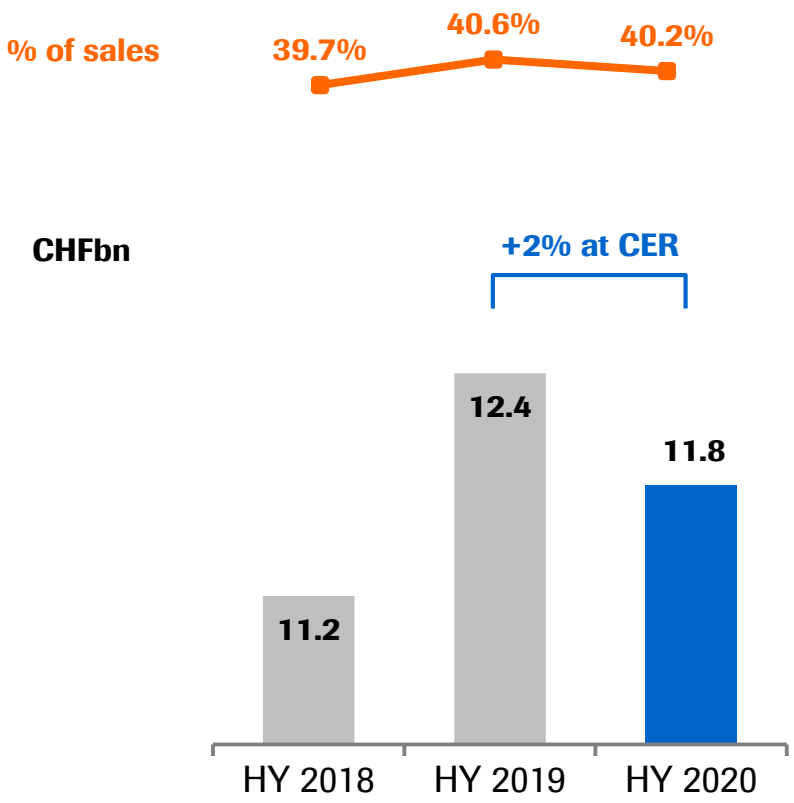
Oncology Neuroscience Immunology

Key Diagnostics news flow in HY1 2020

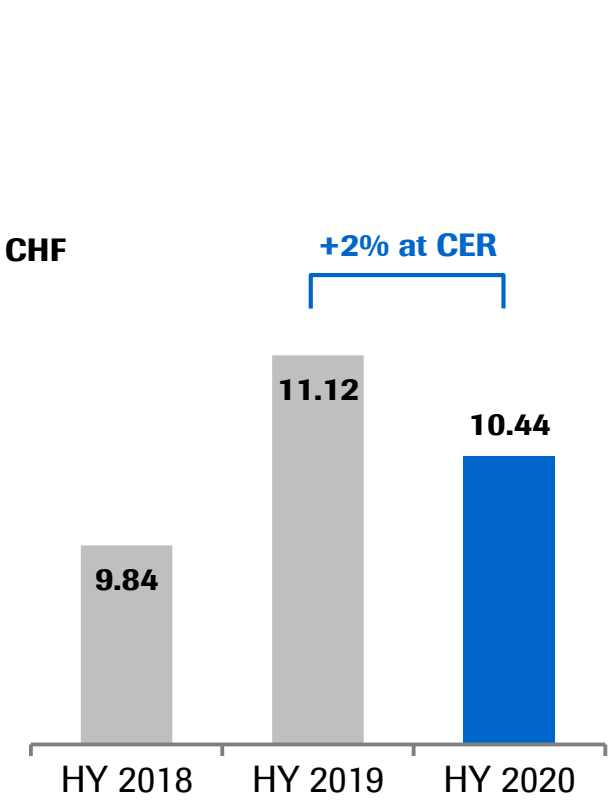
Instruments/Devices	Launch of cobas® prime pre-analytical system
Tests/Assays	Launch of SARS-CoV-2 antibody & PCR tests
Software	Launch of v-TAC digital algorithm for blood-gas monitoring

HY 2020: Core OP and Core EPS maintained at high levels

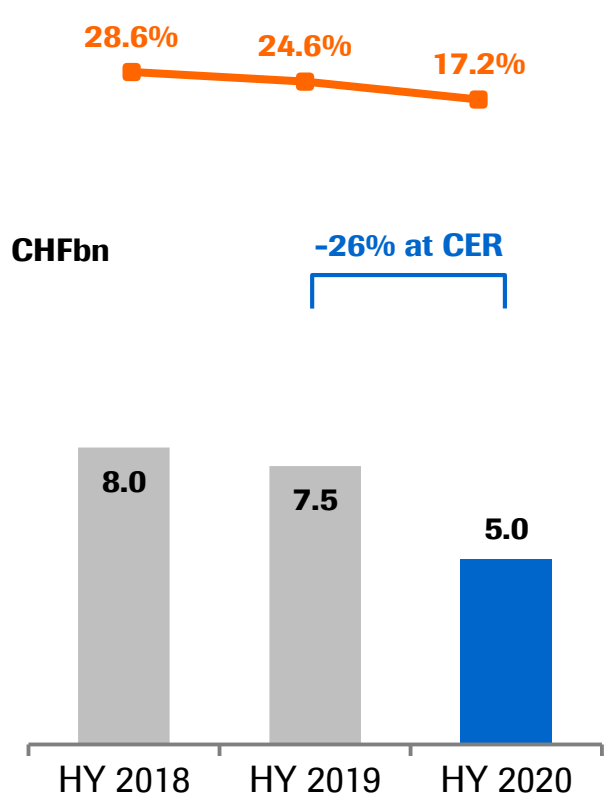
Core operating profit



Core EPS



Operating free cash flow



CER=Constant Exchange Rates

Outlook

Major pipeline advances and upcoming launches in HY2 2020

Pharma

3 Upcoming NME launches

- **risdiplam** in SMA
- **Enspryng (satralizumab)** in NMOSD
- **pralsetinib*** in RET+ NSCLC; Thyroid cancer

7 Upcoming pivotal trial starts

- **SERDi** (Ph III 1L HR+ mBC)
- **glofitamab** (Ph III r/r DLBCL)
- **PRM-151/pentraxin-2** (Ph III IPF)
- **Gazyva** (Ph III Lupus Nephritis)
- **crovalimab** (Ph III PNH in patients switching from a C5 inhibitor; Ph III PNH in C5 inhibitor-naive patients)
- **SRP-9001** (Ph III DMD; run by Sarepta)

Diagnostics

4 Upcoming key launches

- **cobas**® SARS-CoV-2 & Influenza A/B for use on the **cobas**® Liat® System
- **cobas**® SARS-CoV-2 & Influenza A/B for use on the **cobas**® 6800/8800 Systems
- SARS-CoV-2 Rapid Antibody test
- Elecsys® Anti-SARS-CoV-2 S

* subject to the expiration or termination of the waiting period under the HSR Act

2020 outlook confirmed

Further growing top and bottom line

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

[1] At Constant Exchange Rates (CER); based on the current assessment of the COVID-19 impact

Pharmaceuticals Division

Bill Anderson
CEO Roche Pharmaceuticals

Replace and extend the business: Further milestones achieved

Replace/extend existing businesses		Entering new franchises
MabThera/Rituxan	Gazyva, Venclexta, Polivy, mosunetuzumab, glofitamab	**Oncology:** Tecentriq (mUC, TNBC, SCLC, HCC, mM), ipatasertib (mCRPC), SERD (HR+ BC)
Herceptin	Perjeta, Kadcyla, Phesgo	**MS:** Ocrevus
		Hemophilia A: Hemlibra
Avastin	Tecentriq, Alecensa, Rozlytrek, tiragolumab	**CNS:** Enspryng (NMOSD), risdiplam (SMA), tominersen (Huntington), gantenerumab (AD), SRP-9001 (DMD)
Lucentis	Port delivery system (PDS) faricimab	**Immunology:** etrolizumab (UC, CD), Gazyva (lupus nephritis)
Tamiflu	Xofluza	

Achievements Q2 2020

Entering new franchises

Tecentriq: US approval in 1L HCC (with Avastin)

ipatasertib: Positive Ph III (IPATential150) results in patients with PTEN loss tumors in mCRPC

Enspryng: First approvals in Canada, Japan, CH in NMOSD

risdiplam: FIREFISH (SMA) part 2 results in Type 1 patients presented at AAN

SPARK: 2 to 3.3 year follow up efficacy/safety data for SPK-8011 hem A gene therapy presented at ISTH

Replace/extend existing businesses

Phesgo: US approval for P+H FDC-SC

tiragolumab: Randomized Ph II data presented at ASCO; Ph III trials in 1L NSCLC and 1L SCLC initiated

SERD: Clinical data showing excellent efficacy /safety profile presented at ASCO

glofitamab: Ph Ib data presented at EHA; Ph III in 2L+ DLBCL initiated

mosunetuzumab: BTD designation in 3L+ FL awarded

PDS: Positive Ph III (ARCHWAY) results in nAMD

mUC=metastatic urothelial carcinoma; TNBC=triple negative breast cancer; SCLC=small cell lung cancer; HCC=hepatocellular carcinoma; mM=metastatic melanoma; mCRPC=metastatic castration resistant prostate cancer; BC=breast cancer; NMOSD=neuromyelitis optica spectrum disorder; SMA=spinal muscular atrophy; AD=Alzheimer's disease; DMD=duchenne muscular dystrophy; UC=ulcerative colitis; CD=Crohn's disease; NSCLC=non-small cell lung cancer; FDC=fixed dose combination; NSCLC=non-small cell lung cancer; DLBCL=diffuse large B-cell lymphoma; FL=follicular lymphoma; nAMD=neovascular age-related macular degeneration

COVID-19 impact in May, but recovery starting in June

- Broad COVID-19 impact due to missed patient visits and postponed new patient starts (e.g. breast cancer franchise, hematology franchise, neuroscience franchise)
- Immunology franchise holds up well with strong adherence to therapy by patients with lung diseases (Xolair, Esbriet)
- Launches (risdiplam; Enspryng; pralsetinib*) on track
- Pivotal read-outs in 2020/21 on track
- Clinical studies broadly on track, some delays in early trial starts
- Ultimate impact will also depend on the length and severity of the pandemic

All values and growth rates at Constant Exchange Rates (CER); * subject to the expiration or termination of the waiting period under the HSR Act

HY 2020: Pharmaceuticals Division sales

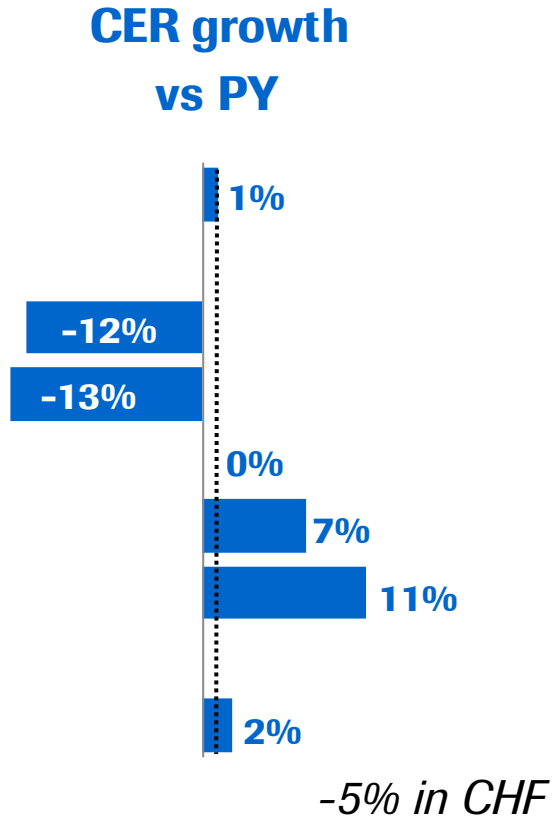
Growth in International and Europe

	HY 2020 CHFm	HY 2019 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**23,202**	**24,194**	**-4**	**1**
United States	12,464	13,370	-7	-4
Europe	4,190	4,221	-1	5
Japan	1,908	1,988	-4	-2
International	4,640	4,615	1	11

CER=Constant Exchange Rates

HY 2020: Pharma profitability maintained at high level

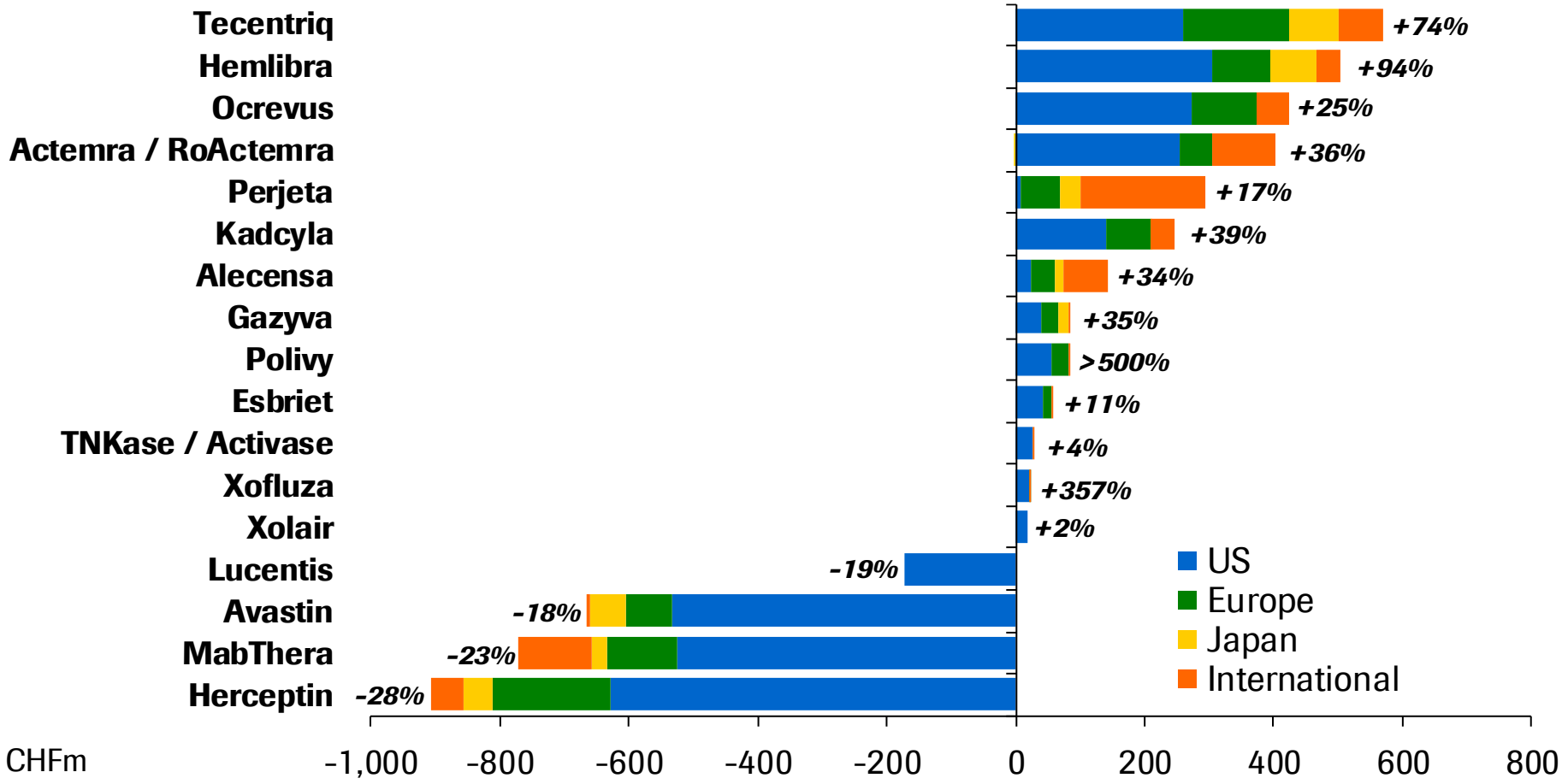
	2020 CHFm	abs. CER
Sales	**23,202**	**+193**
Royalties & other op. inc.	1,070	-150
Cost of sales	-4,175	+620
M & D	-3,266	-7
R & D	-5,077	-358
G & A	-793	-79
Core operating profit	**10,961**	**+220**
Core OP in % of sales	47.2%	



-5% in CHF

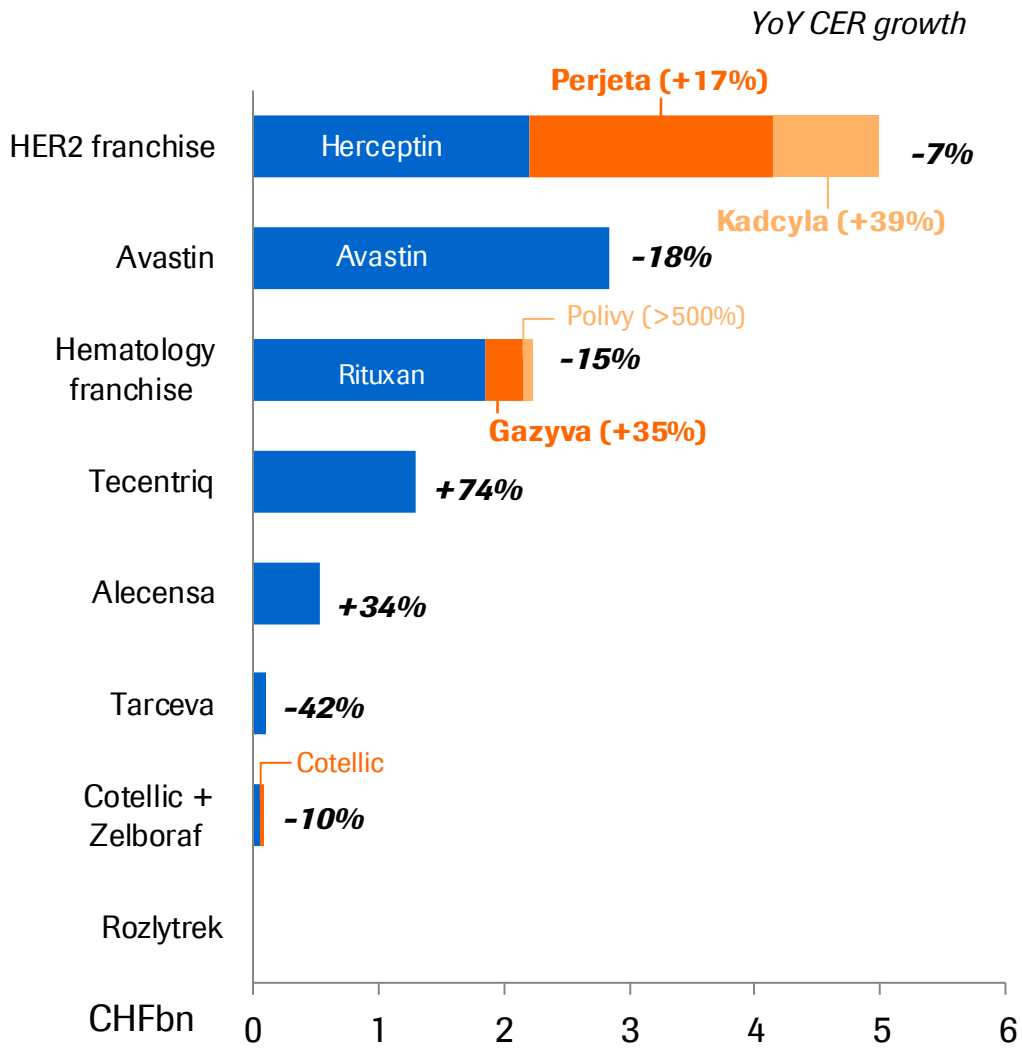
CER=Constant Exchange Rates

HY 2020: New medicines compensating for biosimilar erosion



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

HY 2020: Oncology sales -6% with COVID-19 impact in May



HER2 franchise

- Kadcyla and Perjeta with strong global uptake in adjuvant BC

Avastin franchise

- Biosimilar erosion in US/Japan; first biosimilars launched in EU

Hematology franchise

- Venclexta:* Strong growth in 1L AML and 1L CLL
- Gazyva: Growth in 1L CLL and 1L FL
- Polivy: Strong US launch in R/R DLBCL

Tecentriq

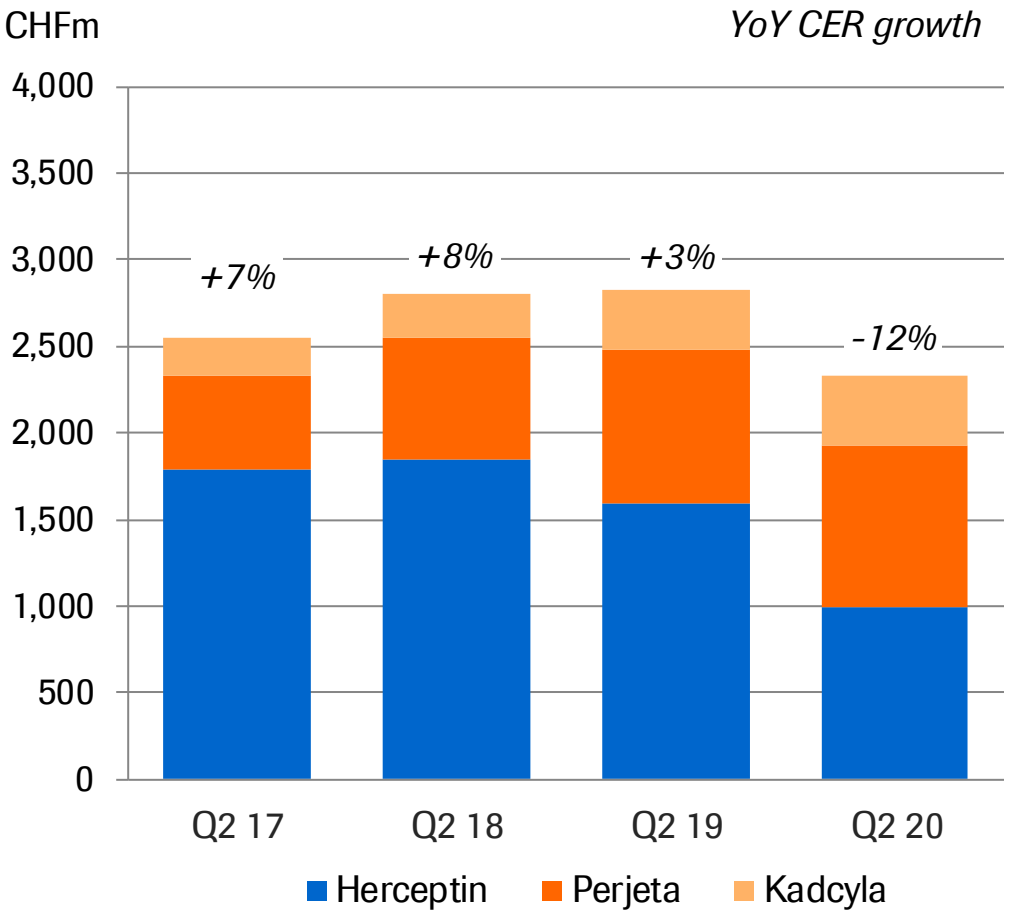
- Growth driven by 1L SCLC & 1L TNBC; 1L HCC launched in US

Alecensa

- Strong growth in China following NRDL listing

CER=Constant Exchange Rates; HY 2020 Oncology sales: CHF 12.5bn; CER growth -6%; * Venclexta sales booked by AbbVie and therefore not included; BC=breast cancer; AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; R/R DLBCL=relapsed/refractory diffuse large B cell lymphoma; SCLC=small cell lung cancer; TNBC=triple negative breast cancer; HCC=hepatocellular carcinoma; NRDL=national reimbursement drug list

HER2 franchise: Growth for Perjeta and Kadcyla, Phesgo approved



HER2 franchise Q2 update

- COVID-19 impact due to lower BC screening rates
- Perjeta (+12%): Global growth driven by eBC (APHINITY) and early uptake in China
- Kadcyla (+26%): Growth in adjuvant setting for patients with residual disease (KATHERINE); switching as planned
- Herceptin (-33%): Decline due to switching to Kadcyla and biosimilar erosion in the US as expected
- US approval for Phesgo (PH FDC SC) achieved

Outlook 2020

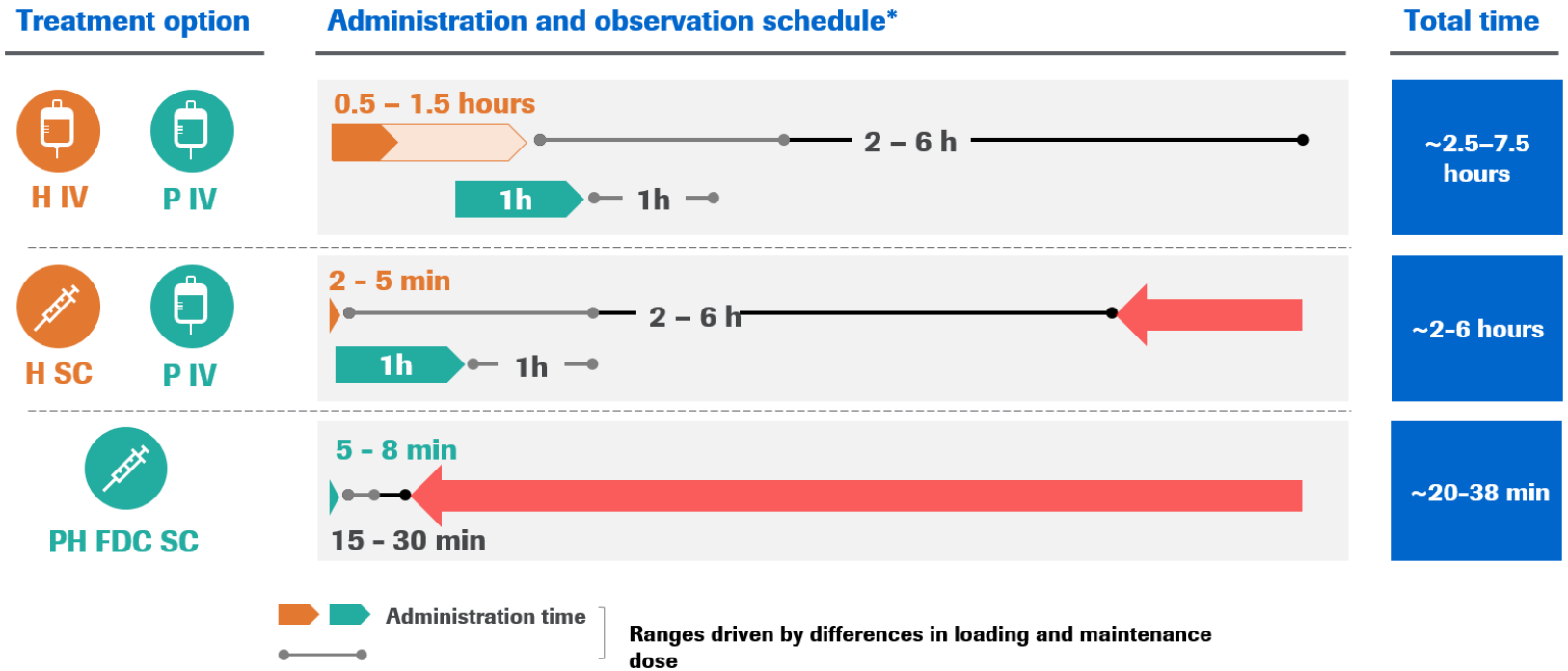
- Global Perjeta (including China) and Kadcyla uptake in eBC
- Continued Herceptin erosion in the US

CER=Constant Exchange Rates; eBC=early breast cancer; PH=Perjeta+Herceptin; FDC=fixed dose combination; SC=subcutaneous

HER2 franchise: Phesgo US approval

Significantly reduced healthcare costs and resource use

PHESGO™ pertuzumab/trastuzumab/hyaluronidase-zzxf SUBCUTANEOUS INJECTION / 1,200 mg/600 mg/30,000 units 600 mg/600 mg/20,000 units



- Phesgo (PH FDC SC) achieves equivalent serum concentrations as IV at cycle 7 in neoadjuvant HER2+ eBC
- 85% of patients prefer Phesgo compared to standard IV administration
- US approval achieved in June; filed in the EU

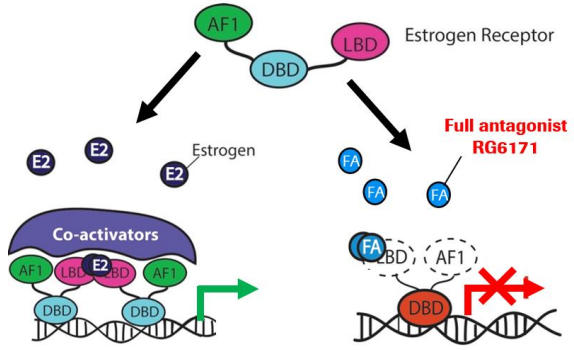
PH=Perjeta+Herceptin; FDC=fixed dose combination; SC=subcutaneous; IV=intravenous; *Ranges driven by differences in loading and maintenance dose; PH FDC SC in collaboration with Halozyme

HR+/HER2- franchise: Potentially best in class SERD (RG6171)

Strong efficacy as a single agent or in combination

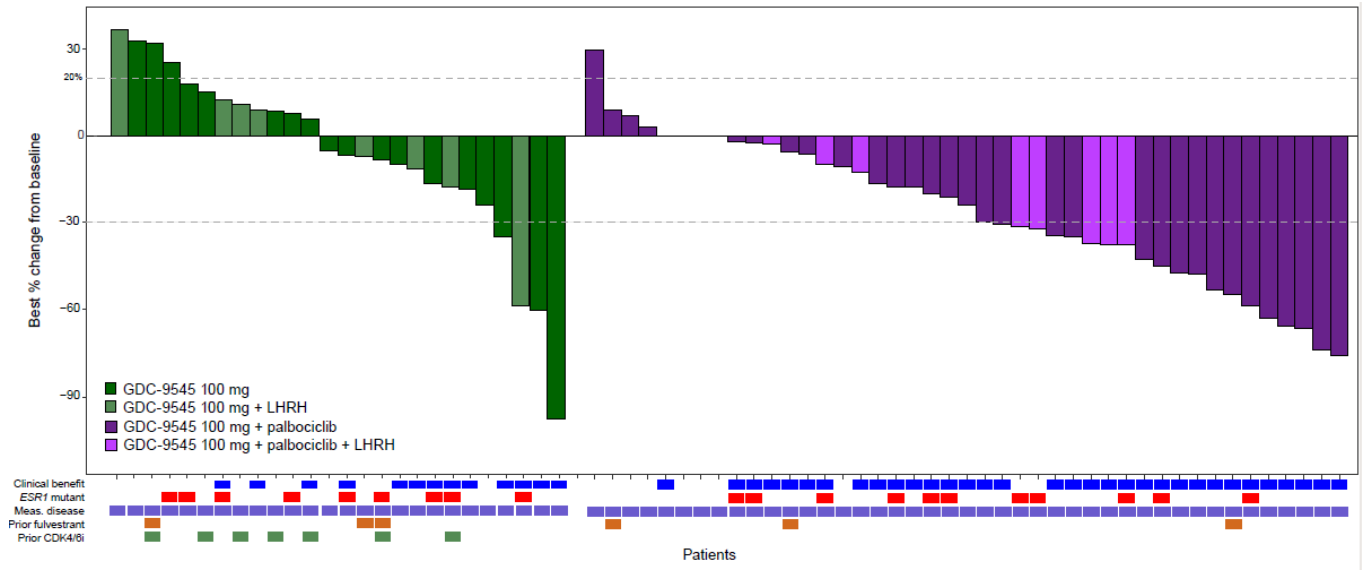
ASCO 20 Virtual

Selective ER degrader (SERD)



- 3rd generation oral SERD
- Highly potent in vitro and improved efficacy in vivo versus other SERDs
- High potency + minimal safety findings lead to wide nonclinical safety margins

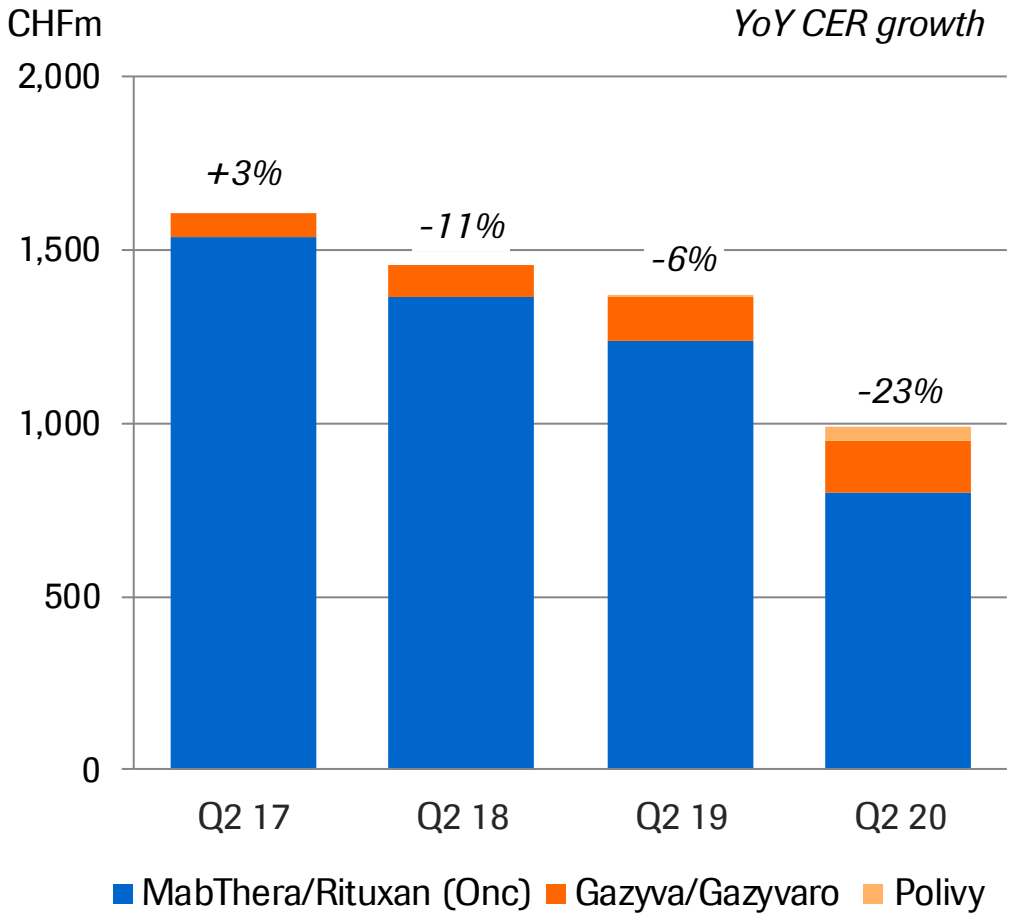
Ph Ib results: Tumor responses RG6171 +/- palbociclib



- Well-tolerated; strong efficacy as single agent or in combination in pre-treated ER+ patients, regardless of ESR1 mutation status
- Further evaluation at 30 mg daily expansion cohort given the promising efficacy with CBR of 50% and a safety profile observed at this dose level with no bradycardia events
- Ph III combination studies in HR+/HER2- mBC to be initiated

Lim E. *et al.*, ASCO 2020; Metcalfe C. *et al.*, SABCS 2018; HR=hormone receptor; mBC=metastatic breast cancer; ER=estrogen receptor; CBR=clinical benefit rate

Hematology franchise: Growth from Venclexta, Gazyva and Polivy



Hematology franchise Q2 update

CD20 franchise

- MabThera/Rituxan (-32%): Biosimilar erosion in US as expected and market contraction due to COVID-19
- Gazyva (+23%): Growth driven by 1L CLL (CLL14) and 1L FL

Venclexta*

- Strong growth driven by 1L unfit AML and 1L CLL (CLL14)

Polivy

- US: Uptake in 3L+ DLBCL

Outlook 2020

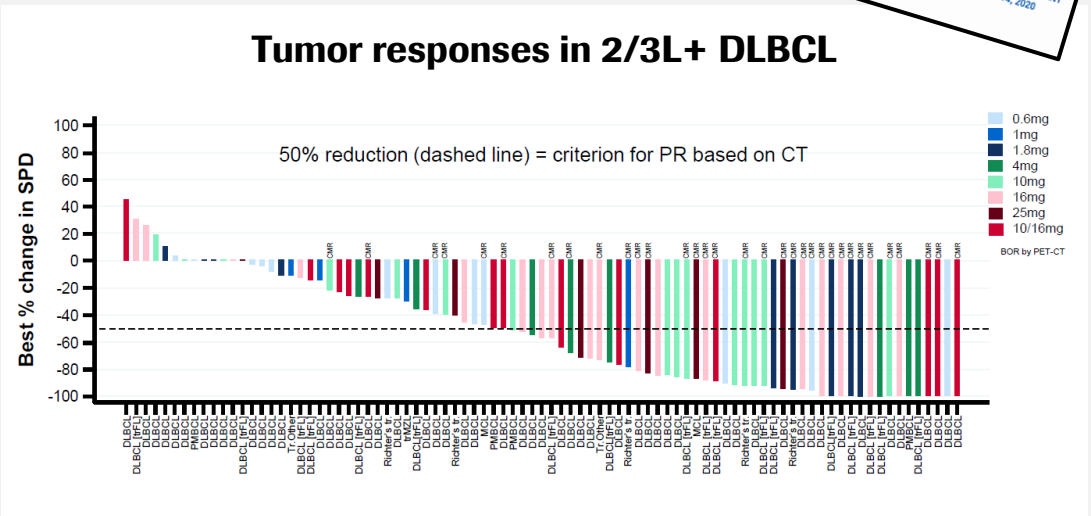
- Strong growth of new products and on-going Rituxan erosion
- Updates on the CD20 x CD3 program and Polivy combinations
- V+azacitidine in 1L unfit AML (Viale-A) US approval expected
- Ph III (POLARIX) Polivy in 1L DLBCL expected early 2021

CER=Constant Exchange Rates; * Venclexta in collaboration with AbbVie; Gazyva in collaboration with Biogen; Polivy in collaboration with Seattle Genetics; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; AML=acute myeloid leukemia; DLBCL=diffuse large B cell lymphoma

Hematology franchise: CD20 x CD3 program in NHL progresses

Improving the standard of care in DLBCL and FL

Glofitamab in R/R DLBCL



- The ≥10mg cohorts in R/R DLBCL showed an ORR of 49.4% and a CR rate of 34.1%; CRs appeared durable with the mDOR not reached after a median follow up of 10.2m
- Good safety profile with manageable CRS confined to cycle 1
- Dose optimization / trials with Tecentriq, Polivy, R-CHOP ongoing
- Ph III safety run-in for glofitamab in 2L+ DLBCL initiated

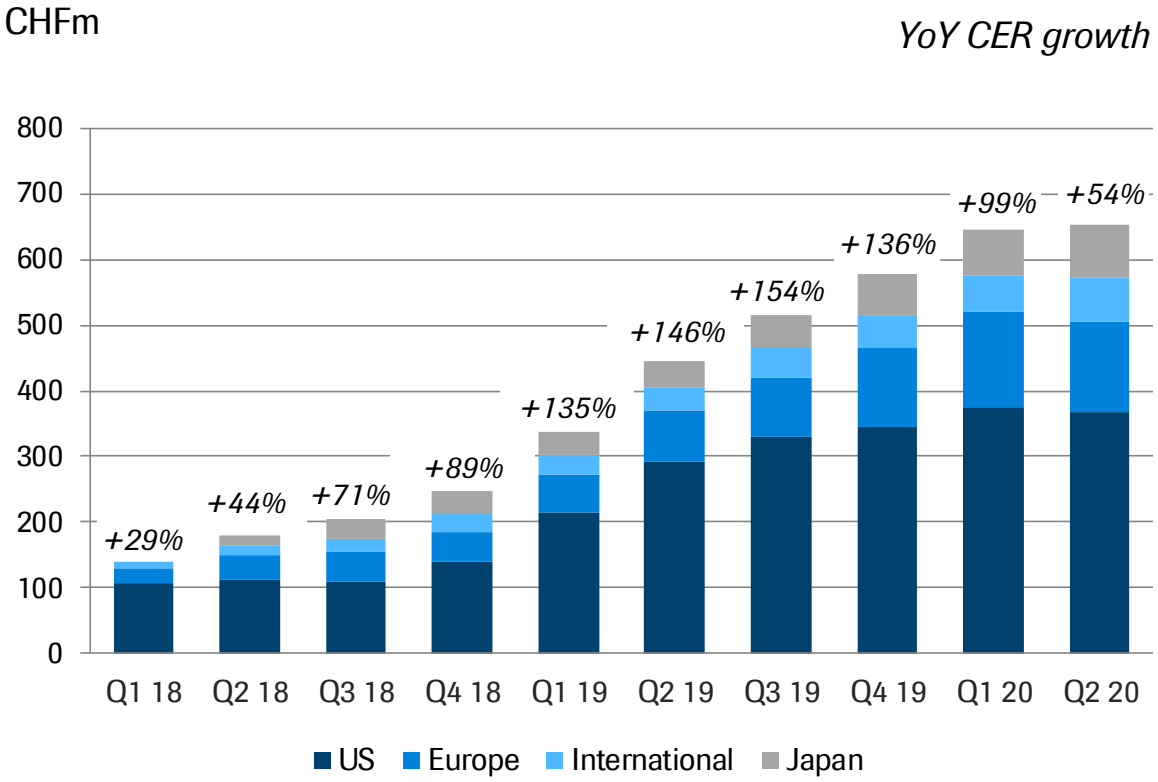
Mosunetuzumab in R/R FL

- Pooled data from 2.8mg to 13.5mg cohorts showed an ORR of 62.7% and CR of 43.3%; 82.8% pts remain in complete remission for up to 26m off initial treatment
- 95% of AEs in cycle 1; no cumulative or chronic toxicity; most CRS events mild-to-moderate with only 3 Gr ≥3 CRS events (1.1%)
- BTD for mosunetuzumab in 3L+ FL awarded; Ph III to be initiated

Dickinson. M.J. et al, EHA 2020; Shuster, S.J., et al, et al., ASH 2019; NHL=non-Hodgkin's lymphoma; DLBCL=diffuse large B cell lymphoma; FL=follicular lymphoma; R-CHOP=rituxan, cyclophosphamide, doxorubicin, vincristine, prednisone; ORR=overall response rate; CR=complete response; AE=adverse event; CRS=cytokine release syndrome; R/R=relapsed/refractory; mDOR=median duration of response

Tecentriq overview: Growth driven by first-in-class indications

1L HCC approved in the US; filed in EU/China



Tecentriq Q2 update

Lung franchise (NSCLC, SCLC)

- US/EU/Japan: Growth driven by 1L SCLC and 1L NSCLC
- US: Approval in 1L PDL1+ NSCLC achieved
- China: Approval in 1L SCLC achieved

Breast franchise (TNBC)

- US/EU: Growth driven by 1L PDL1+ TNBC
- Positive Ph III results in neoadjuvant TNBC

GI franchise (HCC)

- US: First-in-class 1L HCC approval achieved
- EU/China: 1L HCC filed

Outlook 2020

- US: First-in-class filing/approval in 1L BRAF+ melanoma
- Ph III data in neoadjuvant TNBC to be presented

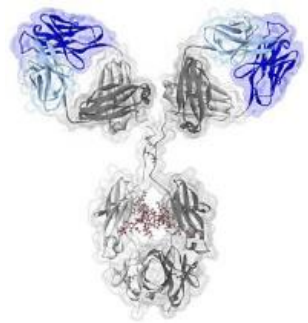
CER=Constant Exchange Rates; SCLC=small cell lung cancer; NSCLC=non small cell lung cancer; TNBC=triple negative breast cancer; HCC=hepatocellular cancer

Lung franchise: Tiragolumab + Tecentriq in 1L NSCLC

Meaningful efficacy improvement and excellent safety

ASCO 20 Virtual

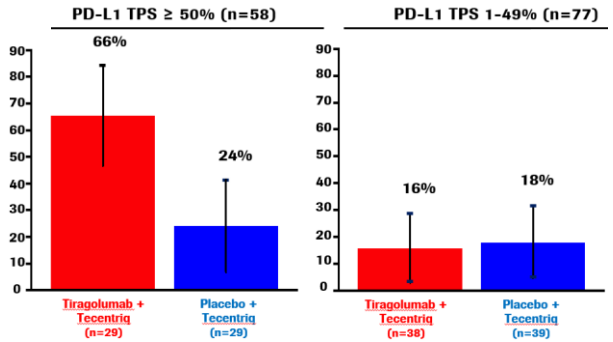
Anti-TIGIT antibody (tiragolumab)



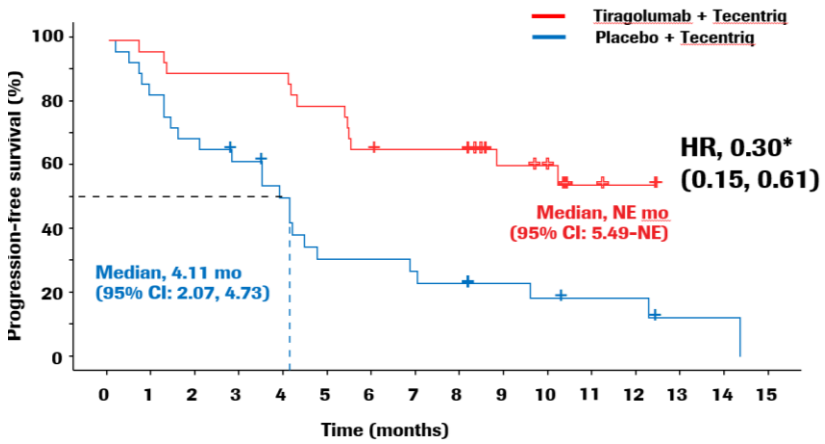
- Fully human IgG1/kappa Ab with intact Fc region that blocks the binding of TIGIT to its receptor PVR
- Could restore anti-tumor response and could complement the activity of anti-PD-L1/PD-1 Abs

Randomized Ph II (CITYSCAPE): Tiragolumab + Tecentriq in 1L NSCLC

ORR



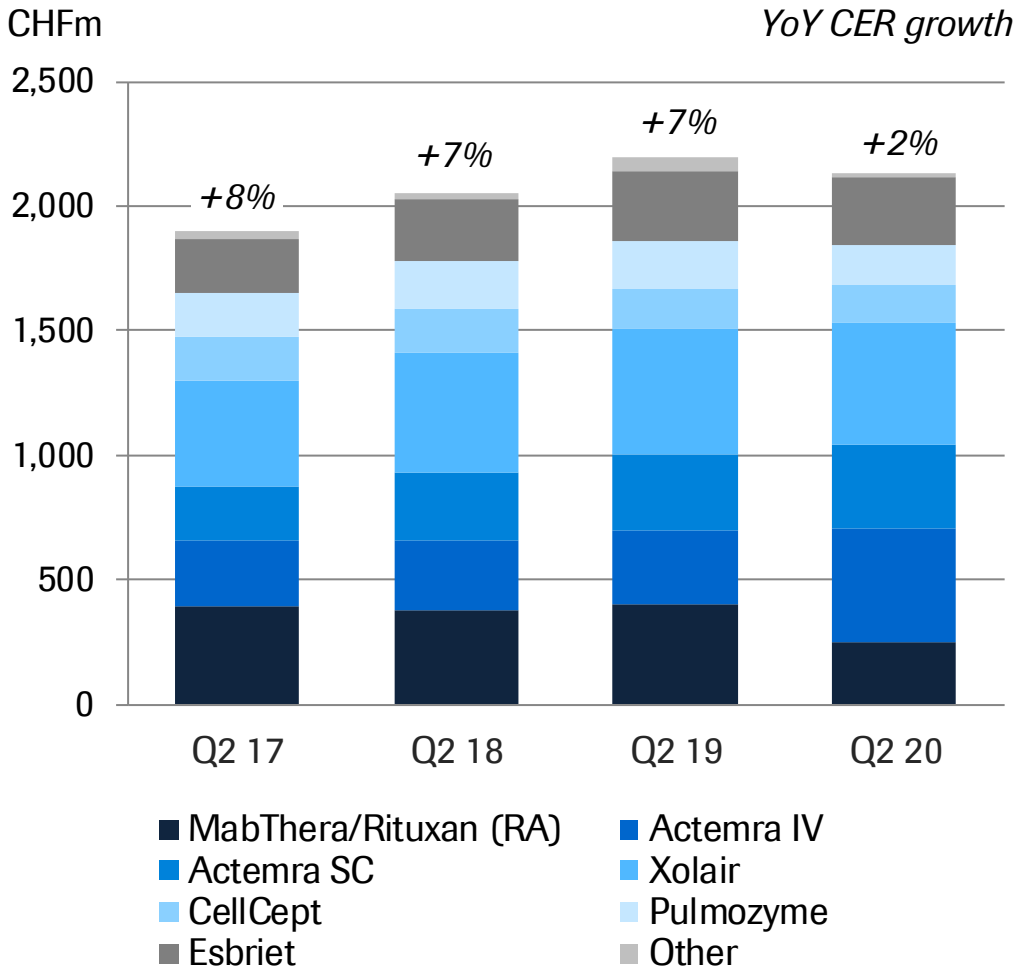
PFS: PD-L1 TPS ≥ 50%



- Tira + Tec showed clinically meaningful improvement in ORR and PFS in the ITT population with a greater magnitude of improvement seen in the PD-L1 TPS ≥ 50% subgroup
- Tira + Tec was well-tolerated with a safety profile similar to placebo + Tec
- Ph III in 1L PDL1+ NSCLC (SKYSCRAPER-01) and in 1L ES-SCLC (SKYSCRAPER-02) ongoing
- Signal-seeking in various tumor types ongoing; additional Ph III studies to be initiated in 2020

Johnson et al. Cancer Cell 2014; Rodriguez-Abreu D. et al., ASCO 2020; Follow-up data cut-off: 02 December, 2019; Ab=antibodies; ORR=overall response rate; TPS=tumor proportion score; PFS=progression free survival; NE=non evaluable; ITT=intention-to-treat; * unstratified HR

Immunology franchise: Overall stable sales



Immunology Q2 update

Esbriet (+2%)

- Growth in mild/moderate segments; remains EU market leader

Actemra (+40%)

- Sales positively impacted by COVID-19

Xolair (+1%)

- Remains leader in biologics asthma market; growth in CIU

Rituxan (-34%)

- Decline due to biosimilars and COVID-19 market contraction

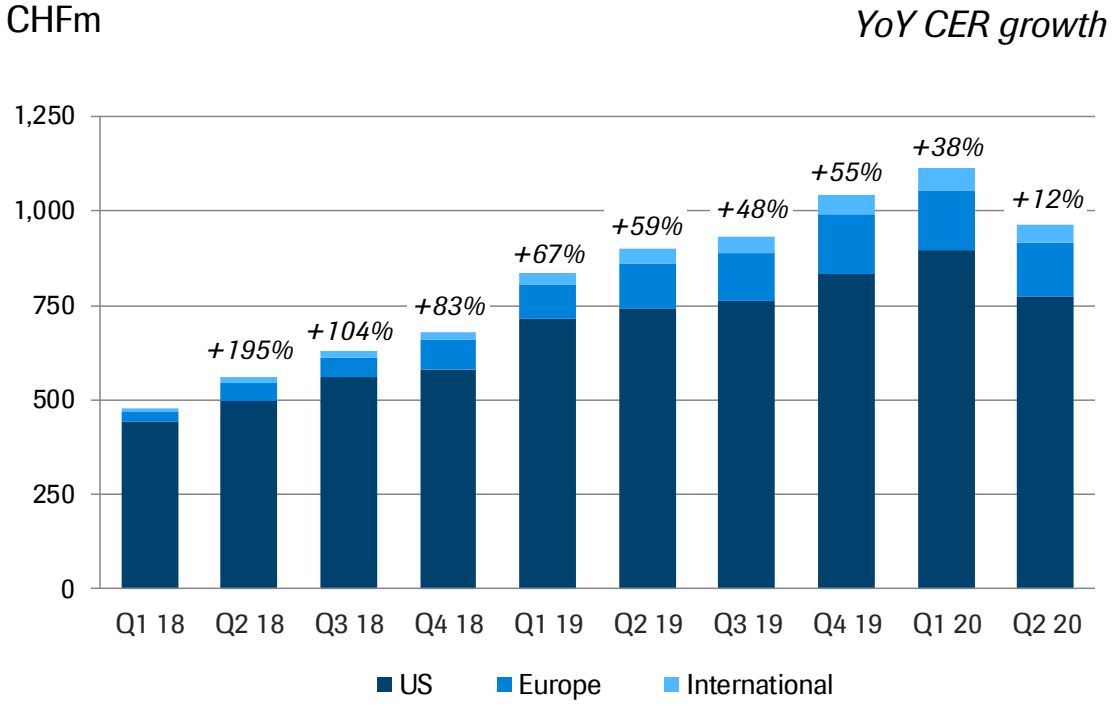
Outlook 2020

- PH III (COVACTA) results of Actemra expected this summer
- Ph III results for etrolizumab in UC this summer
- Ph III (REGENCY) initiation of Gazyva in lupus nephritis
- Ph III initation of pentraxin-2 + SOC in IPF

CER=Constant Exchange Rates; CIU=chronic idiopathic urticaria; UC=ulcerative colitis; SOC=standard of care; IPF=idiopathic pulmonary fibrosis

Neuroscience franchise: Ocrevus in MS

Market leadership in US continues with 21% total patient share[1]



Ocrevus Q2 update

- COVID-19 impact in April/May due to reduced new patient starts and delayed dosing for existing patients
- Strong recovery starting in June
- Shorter infusion launched in the EU

Outlook 2020

- Continued recovery in HY2 as fundamentals remain strong
- Ongoing launches in EU and International
- US approval of shorter infusion

CER=Constant Exchange Rates; [1] Market leadership by branded product, Symphony Health Claims Data 2019; MS=multiple sclerosis

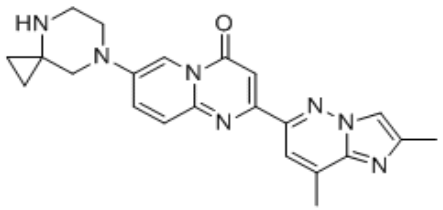
Neuroscience franchise: Risdiplam in type 1/2/3 SMA

Compelling benefit/risk profile in infants, children, and adults

Roche

AAN 2020 Annual Meeting

SMN2 splicing modifier



- Proven efficacy in infants, children, and adults
- Durably increases SMN protein throughout the CNS and in peripheral tissues
- Consistent safety profile in over 450 risdiplam-treated patients in trials
- First and only at-home treatment

FIREFISH part 2 results in type 1 SMA confirm highly competitive profile

The primary endpoint was met (P<0.0001)*

29%

(12/41)

of infants were sitting without support for 5 seconds at Month 12, as measured by the BSID-III

Risdiplam treatment led to a significant improvement in motor function† (P<0.0001)‡

Infants achieved motor milestones, such as sitting and standing§ that would never be seen in untreated infants

93%

(38/41)

of infants were alive and

85% (35/41) of infants were event free‖ at Month 12

95%

(36/38)

of infants alive maintained the ability to swallow after 12 months of treatment

49%

(20/41)

of all infants did not require hospitalization¶ during 12 months of treatment

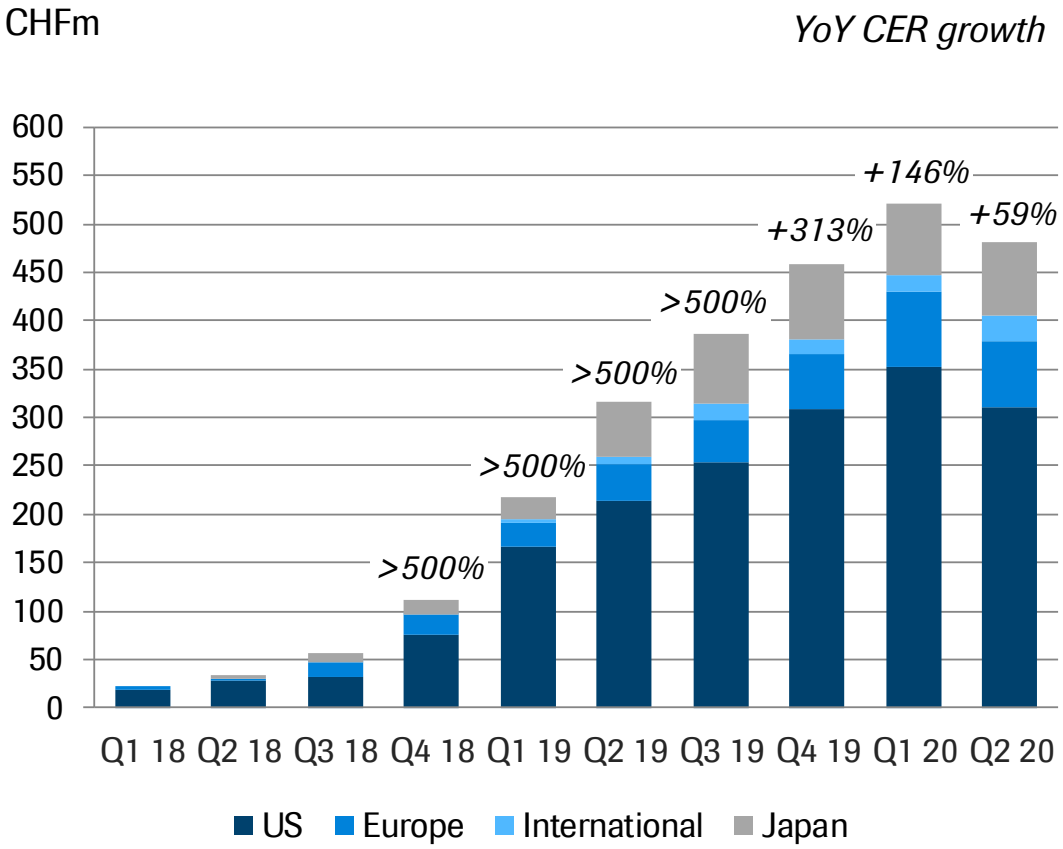
No drug-related safety findings led to withdrawal in FIREFISH Part 2

- Positive Ph III (FIREFISH part 2) in older, symptomatic type 1 infants
- Positive Ph III (SUNFISH part 2) the only placebo controlled study (n=180) in a broad spectrum of type 2/3 patients (age 2-25)
- US priority review with PDUFA date set for August 24; EU filing imminent; EU Accelerated Assessment; filed in China

Servait L.. et al. AAN 2020; *Performance criterion=5%, exact binomial test. †As measured by CHOP-INTEND. ‡Performance criterion=12%, exact binomial test. §As measured by HINE-2; ‖Event-free in FIREFISH is defined as alive with no permanent ventilation (i.e. no tracheostomy or BiPAP ≥16 hours per day continuously for >3 weeks or continuous intubation >3 weeks, in the absence of, or following the resolution of, an acute reversible event). ¶Hospitalizations include hospital admissions ≥1 night; BiPAP, Bilevel Positive Airway Pressure; BSID-III, Bayley Scales of Infant and Toddler Development, Third edition; CHOP-INTEND, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders; HINE-2, Hammersmith Infant Neurological Examination, Module 2.; Risdiplam in collaboration with PTC Therapeutics and the SMA Foundation

Hemophilia A franchise

Hemlibra with 23% total US patient share after 33 months



Hemophilia Q2 update

- US: Gaining market share in non-inhibitors; patients on treatment stay on treatment, COVID-19 impact due to postponed new patient starts
- EU-5: Strong initial non-inhibitor uptake following reimbursement in all major markets
- Spark Therapeutics: SPK-8011 (gene therapy) results at ISTH show durable and stable expression at 2 to 3.3 years with acceptable safety profile

Outlook 2020

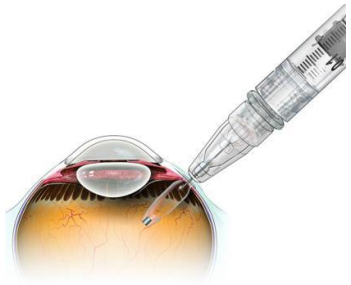
- Further recovery which started in June
- US: Further uptake in non-inhibitors
- EU: On-going launches in major markets

CER=Constant Exchange Rates; ISTH=International Society on Thrombosis and Haemostasis

Ophthalmology franchise: Building a global PDS platform
Positive Ph III results in nAMD to be discussed at ASRS

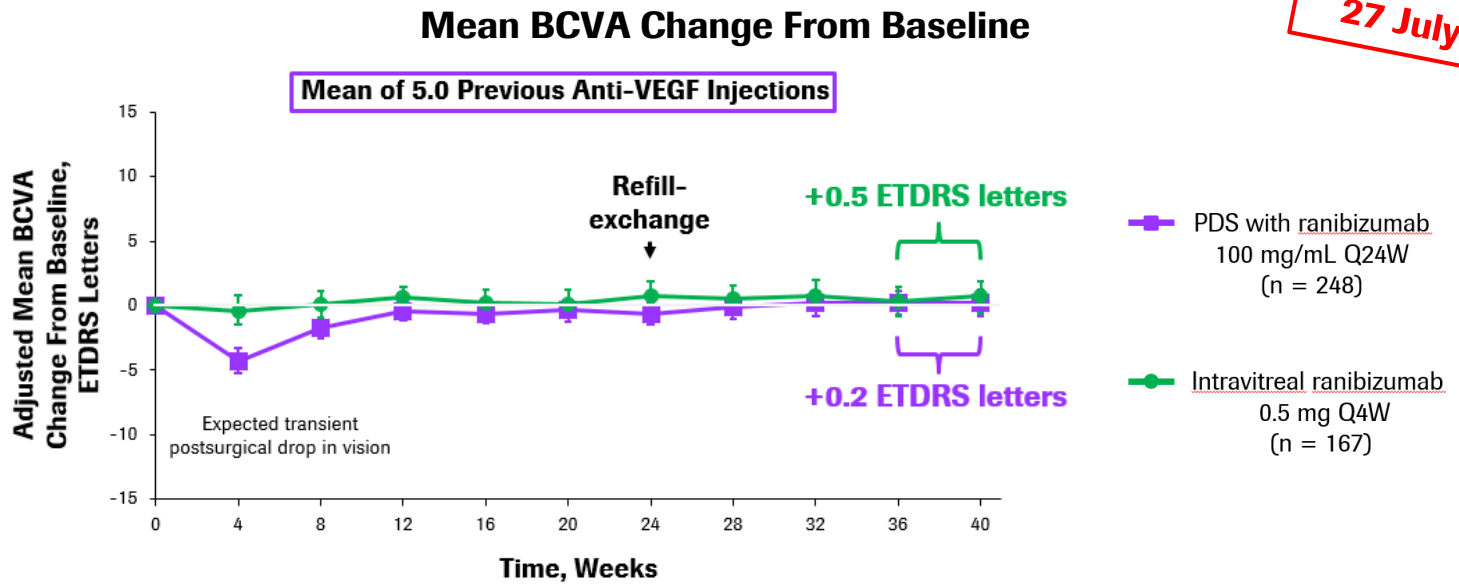
IR event 27 July

Port Delivery System (PDS)



- Refillable intraocular implant using proprietary needle assembly and customized formulation
- Reduced treatment burden and potentially improved RW outcomes
- Continuous delivery platform to be combined with NMEs

Phase III (ARCHWAY) results in nAMD:

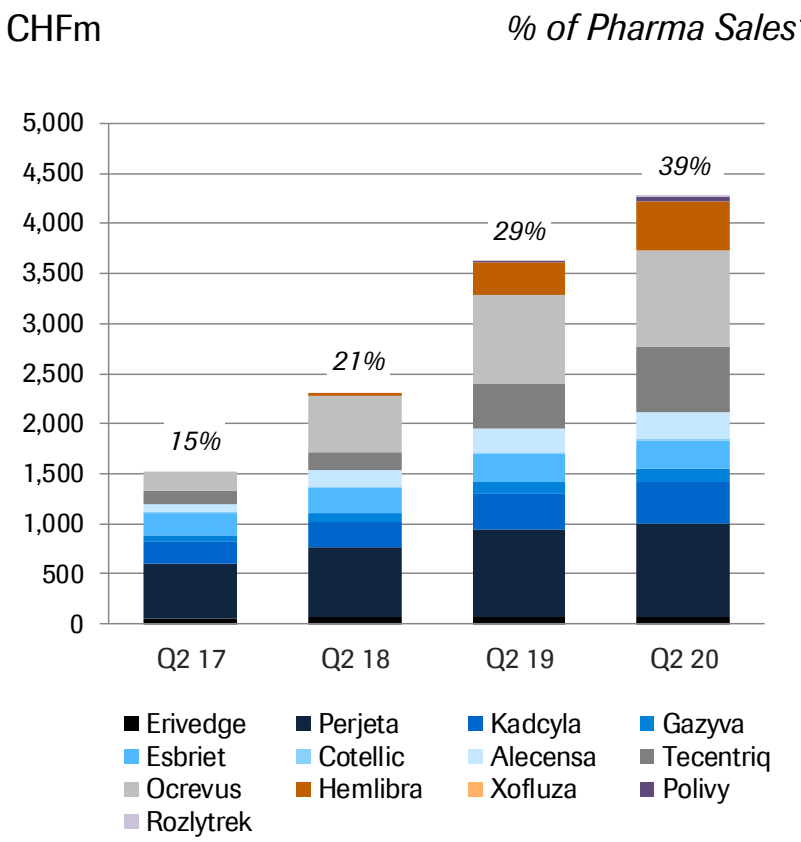


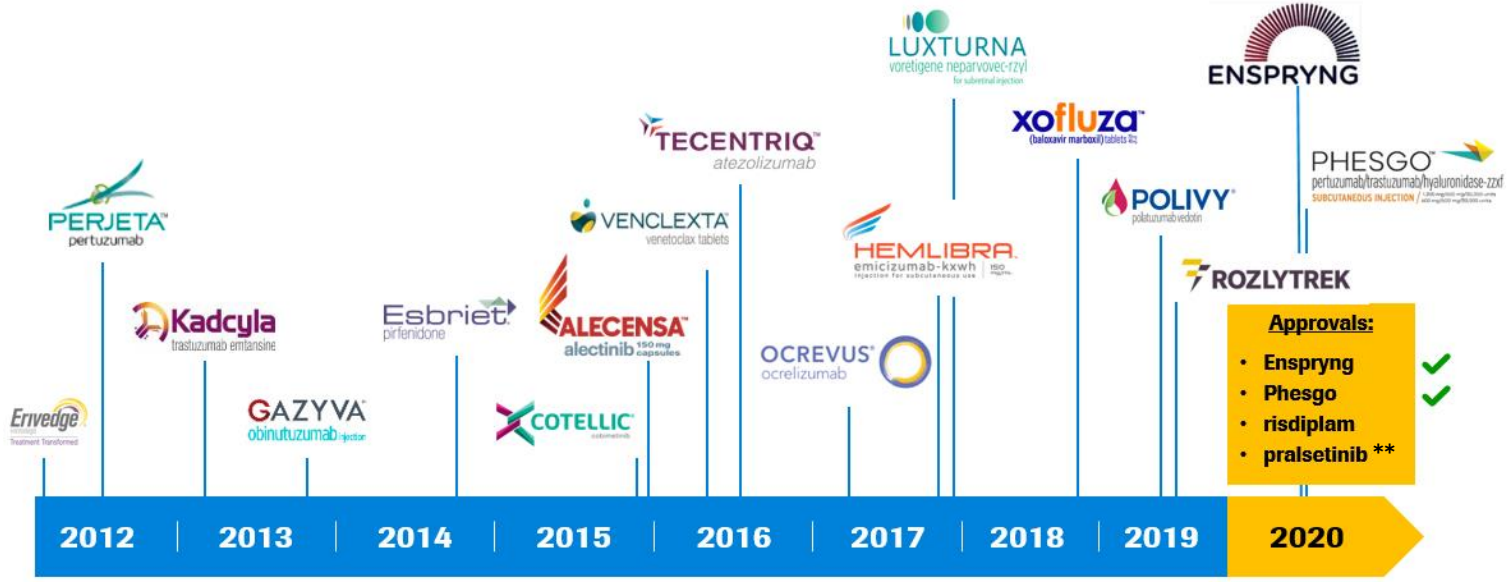
- Positive Ph III (ARCHWAY) results in nAMD using 6m dosing interval released at ASRS
- Ph III (PAGODA) in DME using 6m dosing interval on-going; Ph III (PAVILLION) in DR initiated
- PDS approval in the US expected in 2021

Campochiaro, Peter A. et al., ASRS 2020; nAMD=neovascular age-related macular degeneration; RW=real world; NME=new molecular entity; BCVA= best-corrected visual acuity; Q24W=once every six months dosing; Q4W=once every 4 weeks dosing; DME=diabetic macular edema; DR=diabetic retinopathy

New products account for ~40% of Pharma sales*

4 NME approvals in 2020: ENSPRYNG and PHESGO approved in Q2

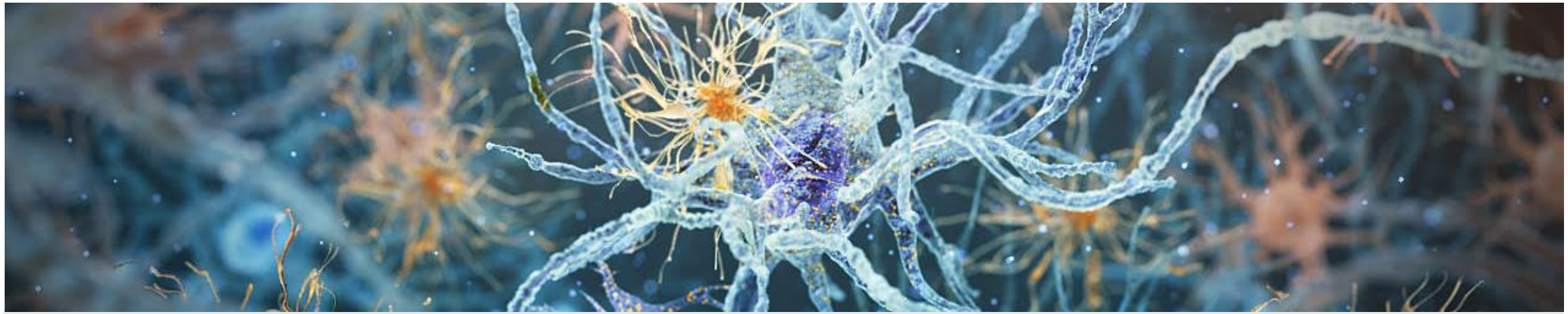




* Venclexta sales are booked by partner AbbVie and therefore not included ** subject to the expiration or termination of the waiting period under the HSR Act

Roche Pharma Day 2020

Strategic business outlook and late stage pipeline update



Virtual Roche Pharma Day 2020

Monday, 14 September 2020
2pm–5pm CEST

Senior management presenting:

- Bill Anderson, CEO Pharma
- Teresa Graham, Head of Global Product Strategy
- Levi Garraway, Chief Medical Officer and Head Global Product Development
- Paulo Fontoura, Global Head Neuroscience and Rare Diseases Clinical Development
- Cristin Hubbard, Head I2O Global Product Strategy
- John Young, Global Head of Infectious Diseases, Roche Pharma Research & Early Development

I2O=immunology, Infectious diseases, Ophthalmology

2020: Key late-stage news flow*

	Compound	Indication	Milestone	
Regulatory	**Rozlytrek**	NTRK pan tumor; ROS1+ NSCLC	EU approval	
	Venclexta + Gazyva	1L unfit CLL	EU approval	✓
	Polivy + Rituxan +chemo	R/R DLBCL	EU approval	✓
	risdiplam	SMA type 1/2/3	US approval; EU filing	
	Enspryng (satralizumab)	NMOSD	US/EU approval	
	Xolair	Nasal polyps	US approval	
	Zelboraf + Cotellic + Tecentriq	1L+ BRAF+ Melanoma	US approval	
	Tecentriq + Avastin	1L HCC	US approval; EU filing	✓
	Tecentriq	1L PDL1+ NSCLC	US/EU approval	✓
	Phesgo (PH FDC SC)	HER2+ breast cancer	US approval; EU filing	✓
Phase III / pivotal readouts	**idasanutlin + chemo**	R/R AML	Ph III MIRROS	✗
	risdiplam	SMA type 1	Ph II/III FIREFISH (part 2)	✓
	Tecentriq + Avastin	1L OC	Ph III IMagyn050	✗
	Tecentriq + chemo	Neoadjuvant TNBC	Ph III IMpassion031	✓
	Venclexta + azacitidine	1L unfit AML	Ph III Viale A	✓
	ipatasertib + chemo	Dx+ HR+ breast cancer	Ph III IPATunity130	
	ipatasertib + chemo	Dx+ 1L TNBC	Ph III IPATunity130	
	ipatasertib + abiraterone	1L mCRPC	Ph III IPATential150	✓
	PDS	nAMD	Ph III Archway	✓
	faricimab	DME	Ph III YOSEMITE/RHINE	
	etrolizumab	Ulcerative Colitis	Ph III HIBISCUS/LAUREL/HICKORY/GARDENIA	
	balovaptan	Autism spectrum disorders	Ph II aV1ation	✗

Virtual IR Event ASRS

Monday, 27 July
4:30pm-5:30pm CEST

Roche Pharma Day

Monday, 14 September
2pm-5pm CEST

* Outcome studies are event-driven: timelines may change

Diagnostics Division

Thomas Schinecker
CEO Roche Diagnostics

HY 2020: Diagnostics Division sales

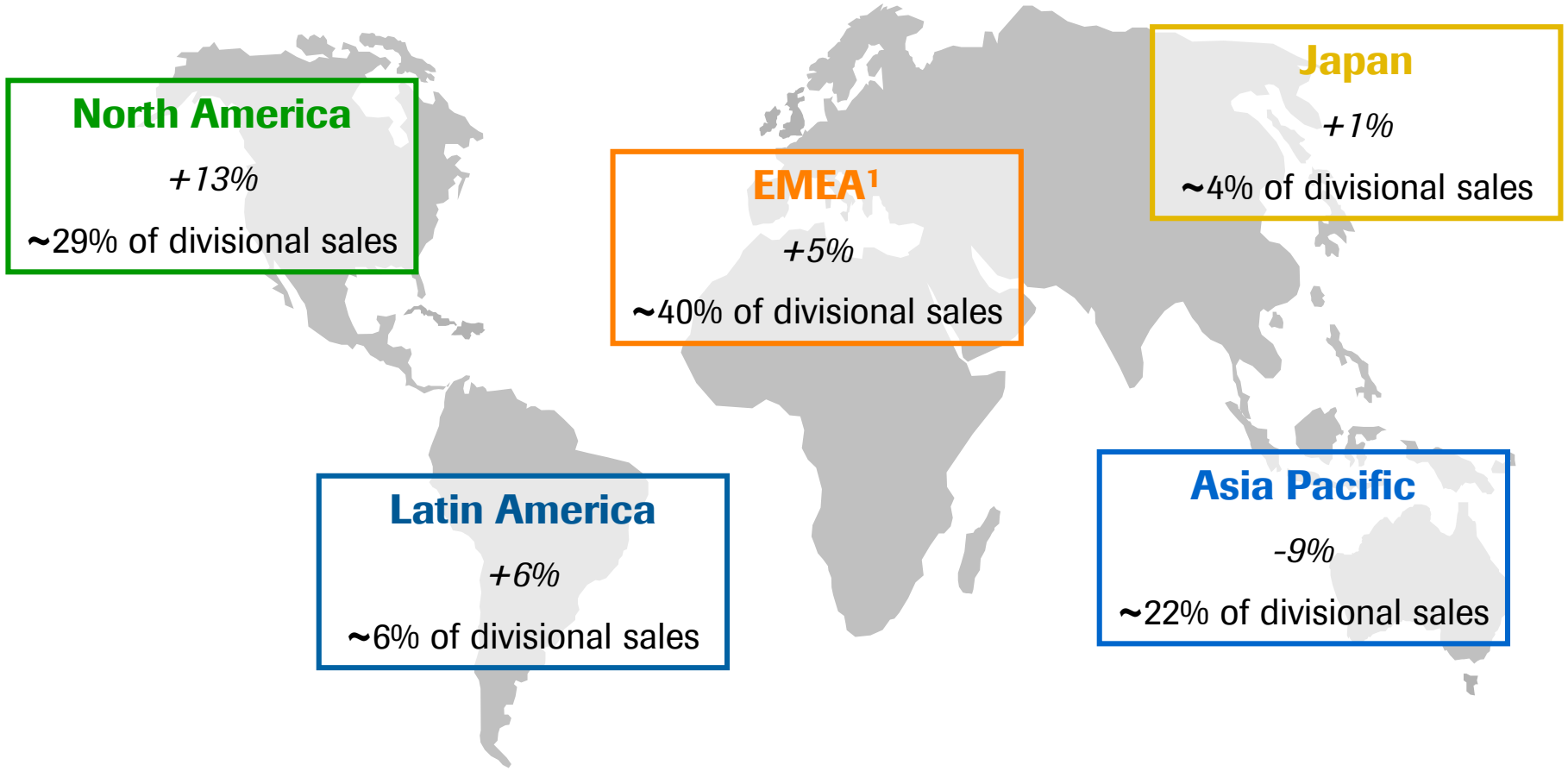
Growth driven by Molecular Diagnostics offsetting decline in routine testing due to COVID-19

	HY 2020 CHFm	HY 2019 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**6,079**	**6,275**	**-3**	**3**
Centralised and Point of Care Solutions	3,181	3,762	-15	-10
Molecular Diagnostics	1,558	1,029	51	61
Diabetes Care	832	958	-13	-6
Tissue Diagnostics	508	526	-3	2

CER=Constant Exchange Rates; Underlying growth of Molecular Diagnostics excluding sequencing business: +69%

HY 2020: Diagnostics Division regional sales

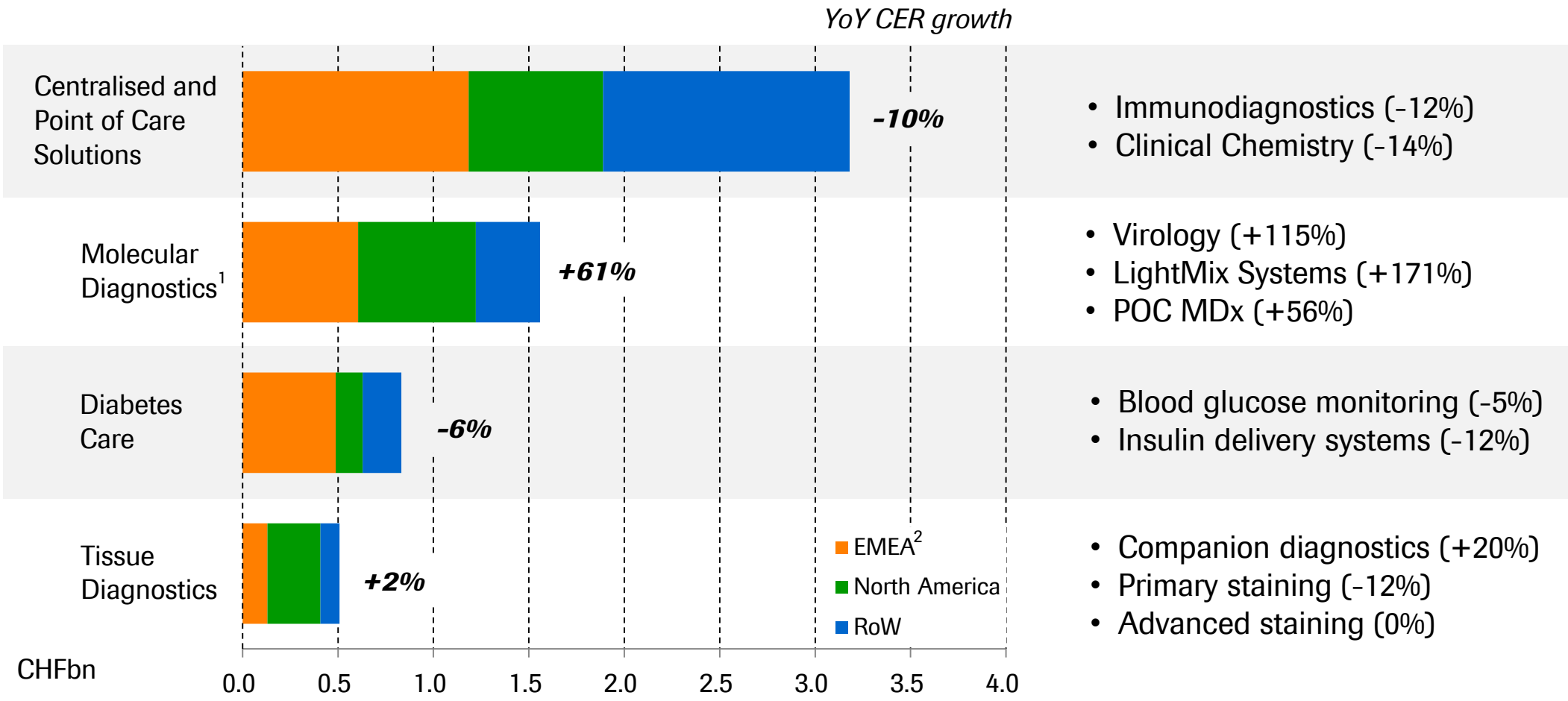
Growth driven by North America and EMEA



[1] Europe, Middle East and Africa; all growth rates at Constant Exchange Rates (CER)

HY 2020: Diagnostics Division highlights

Growth driven by Molecular Diagnostics



- Immunodiagnostics (-12%)
- Clinical Chemistry (-14%)

- Virology (+115%)
- LightMix Systems (+171%)
- POC MDx (+56%)

- Blood glucose monitoring (-5%)
- Insulin delivery systems (-12%)

- Companion diagnostics (+20%)
- Primary staining (-12%)
- Advanced staining (0%)

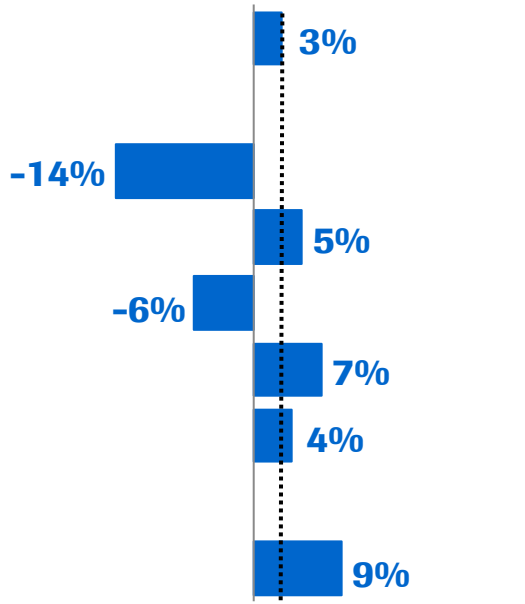
[1] Underlying growth of Molecular Diagnostics excluding sequencing business: +69%; [2] EMEA=Europe, Middle East and Africa CER=Constant Exchange Rates

HY 2020: Diagnostic Division

Core operating profit growing at +9%

	2020 CHFm	abs. CER
Sales	**6,079**	**+213**
Royalties & other op. inc.	27	-5
Cost of sales	-2,904	-138
M & D	-1,249	+80
R & D	-710	-49
G & A	-221	-9
Core operating profit	**1,022**	**+95**
Core OP in % of sales	16.8%	

CER growth vs PY

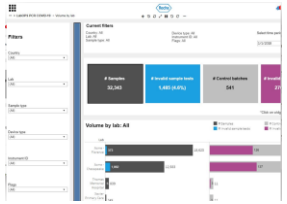


-4% in CHF

CER=Constant Exchange Rates

SARS-CoV-2 diagnostics portfolio

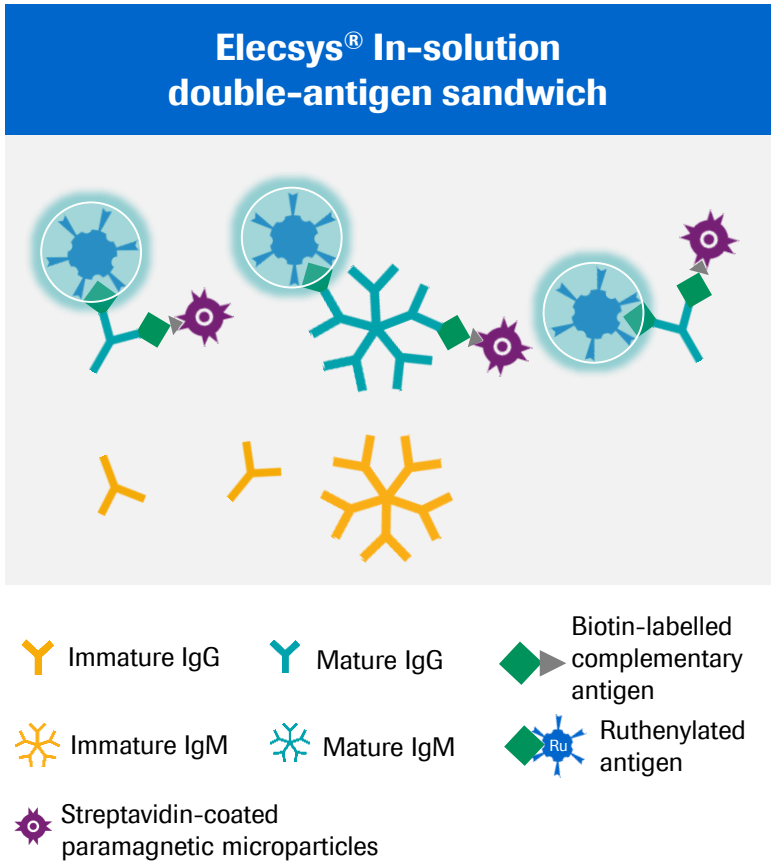
Comprehensive portfolio launched in record time

	Clinical Labs		Point of Care	
Molecular solutions	 • **cobas**® SARS-CoV-2 ✓ • TIB MOLBIOL LightMix® Modular SARS-CoV-2 ✓ • **cobas**® Flu A, Flu B and SARS-CoV-2	In development	 • **cobas**® SARS-CoV-2 & Influenza A/B	In development
Serology solutions	 • Elecsys ® Anti-SARS-CoV-2 ✓ • Elecsys ® IL-6 ✓ • Elecsys ® Anti-SARS-CoV-2 S	In development	 • SARS-CoV-2 Rapid Antibody	In development
Digital solutions	 • Viewics LabOps COVID-19 ✓		 • NAVIFY Symptom Tracker* ✓ • Roche v-TAC algo for blood gas ✓	

✓ Launched; * US only; IL-6: Interleukin 6; v-TAC: venous to arterial conversion

Elecsys® SARS-CoV-2 serology solutions

Broadening the portfolio for SARS-CoV-2 antibody testing



Elecsys® Anti-SARS-CoV-2

- Immunoassay detecting antibodies to nucleocapsid protein (anti-N)
- Excellent performance confirmed in internal as well as external studies[1]
  - Specificity 99.8% (n=10,453 negative samples)[3]
  - Sensitivity 99.5%[2] (n=185 positive samples)[3]
- Preliminary data shows good correlation with neutralizing antibodies
- Available on all cobas e[4] immunoanalyzers (global installed base >40,000 systems)

Elecsys® Anti-SARS-CoV-2 S[5]

- Quantitative immunoassay detecting antibodies to spike protein (anti-S)[5]
- Will be available on all cobas e[4] immunoanalyzers
- Important in the context of vaccines

[1] Ekelund O. et al.; Favresse J, et al.; Perkmann T et al.; Herroelen PH et al;. [2] Sensitivity for samples taken ≥14 days after positive PCR; [3] Roche internal data; [4] cobas e: cobas e 801, cobas e 602, cobas e 601, cobas e 411; [5] under development

Global launch of cobas® prime Pre-analytical System*

Accelerating speed and efficiency in the molecular lab

cobas® prime **cobas® 6800**

Multiple sample types

- First-of-its-kind solution for multiple sample types
- End-to-end automation for testing consolidation
- Reduces manual steps in molecular labs by 86%**
- Reduces manual errors and increases confidence in results

* CE-IVD and in the US Class I Exempt; ** Based on a workflow configuration that includes cobas® prime Pre-analytical System connected via cobas® connection modules to cobas® 6800 System. Results may vary depending on different workflows.

PD-L1 (SP263) and HER2 Dual ISH digital pathology algorithms*

Improving the speed and accuracy of cancer diagnosis

SCANNING

VENTANA DP 200

PATHOLOGIST WORKFLOW

NAVIFY Digital Pathology

IMAGE ANALYSIS

uPath Image Analysis Algorithms

PD-L1

HER2 Dual ISH

HER2 (4B5)**

*NAVIFY Tumor Board***

- The first next generation CE-IVD algorithms utilizing whole slide analysis
- uPath PD-L1 (SP263) image analysis aids in the detection and semi-quantitative measurement of PD-L1 protein
- uPath HER2 Dual ISH image analysis supports the determination of patients' HER2 gene status
- Uses artificial intelligence that was trained by leading pathologists

* CE-IVD; ** In-development

Key launches 2020

	Area	Product	Description	Market[1]
Instruments/ Devices	**Workflow**	cobas® prime	Next generation pre-analytical platform to support cobas® 6800/8800 Systems	CE ✓
	Diabetes Care	Accu-Chek Solo Diabetes Manager	Integration of the Accu-Chek Guide test strip technology into the Accu-Chek Solo Diabetes Manager (remote control)	CE
Tests/ Assays	**Infectious Diseases**	cobas® EBV EBNA IgG cobas® EBV VCA IgG	EBV panel offering 3 different assays (EBV IgM, EBV VCA IgG, and EBV EBNA IgG) for the qualitative detection of antibodies to Epstein-Barr Virus (EBV)	CE
		cobas® EBV IgM		
		cobas® HIV-1&2 Qual	Qualitative detection and confirmation of HIV-1 & HIV-2	US
		cobas® EBV	Monitoring tests for transplant patients to aid in the management of EBV and BKV infections	US
		cobas® BKV		
	Cervical Cancer	cobas® HPV (6800/8800)	The world's leading cobas® HPV assay for use on the fully automated cobas® 6800/8800 Systems	US ✓
		CINtec *PLUS* Cytology	Next generation "Pap" test which leverages p16/Ki-67 dual-stain biomarker technology on cervical cytology samples	US ✓
	Tissue Dx	VENTANA HER2 Dual ISH	Fully automated, brightfield ISH assay to determine eligibility for HER2 targeted therapy	US
		Algorithm - HER2 (4B5)	Whole slide image analysis algorithm for HER2 (4B5)	CE
Software	**Sequencing**	NAVIFY Mutation Profiler	Software as a medical device for annotating, variant classification, clinical interpretation and reporting from comprehensive genomic profile testing	US
	Diabetes Care	RocheDiabetes InsulinStart	A messaging service designed for people with type 2 diabetes to ease the transition from oral antidiabetics to a complimentary insulin therapy	CE ✓
		mySugr app	Enabling control of the Accu-Chek Insight insulin pump from the mySugr app	WW
		RocheDiabetes Care Platform	New releases with improved features focusing on device connectivity, integration of 3rd parties, and healthcare professionals' workflow optimisation	WW ✓

[1] CE=European Conformity; US=FDA approval; WW=Worldwide; EBV=Epstein-Barr virus; BKV=BK virus

Finance

Alan Hippe
Chief Financial Officer

HY 2020 results

Focus on Cash

Outlook

HY 2020: Highlights

Business

- Sales growth of +1%[1] and Core operating profit up +2%[1]
- Core EPS growth +2%[1]

Cash flow

- Operating Free Cash Flow of CHF 5.0bn, -26%[1] lower due to higher net working capital and higher investments in intangible assets
- Net debt slightly up by CHF 0.4bn vs. Jun 30th 2019; higher by CHF 6.3bn vs. Dec 31st 2019 due to dividend payments

Net financial results

- Core net financial result improved by +3%[1] driven by lower interest expenses 30%[1]

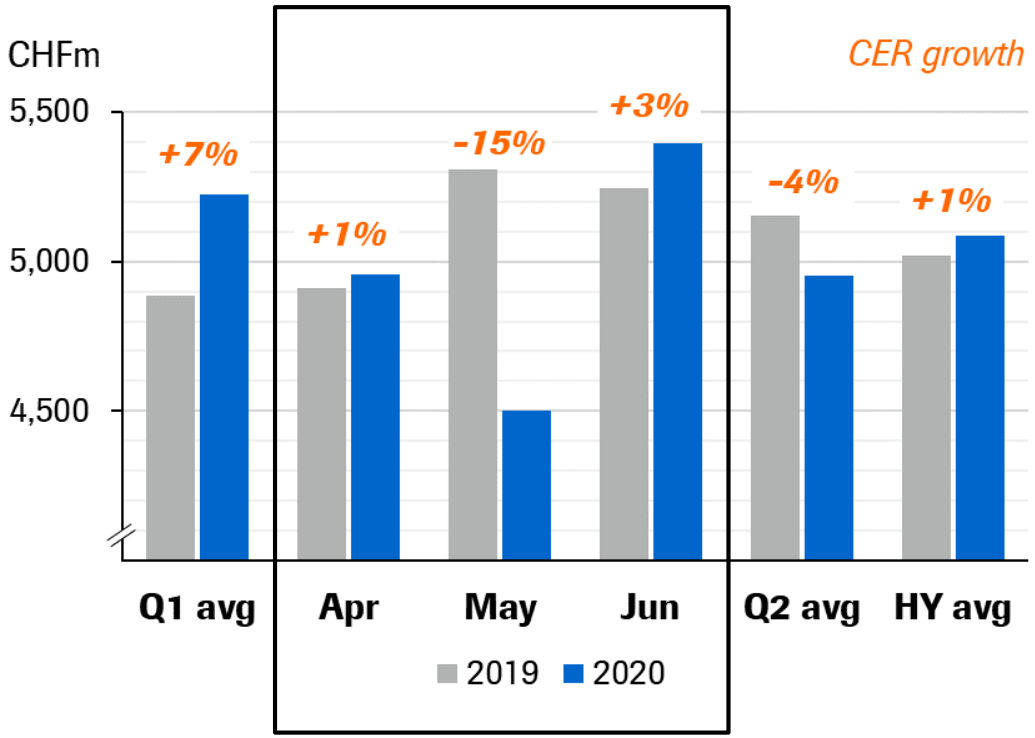
IFRS

- Net income +3%[1] driven by the operating results

[1] At Constant Exchange Rates (CER)

HY 2020: Group sales – May heavily impacted by COVID-19

Recovery started in June



Pharmaceuticals

- Impact in May driven by patients delaying appointments (mainly but not only chronic diseases)
- Recovery in the last weeks of the quarter

Diagnostics

- Impact in April/May driven by decline in routine testing, partially compensated by COVID-19 testing
- Recovery started with easing of restrictions

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

HY 2020: Group performance

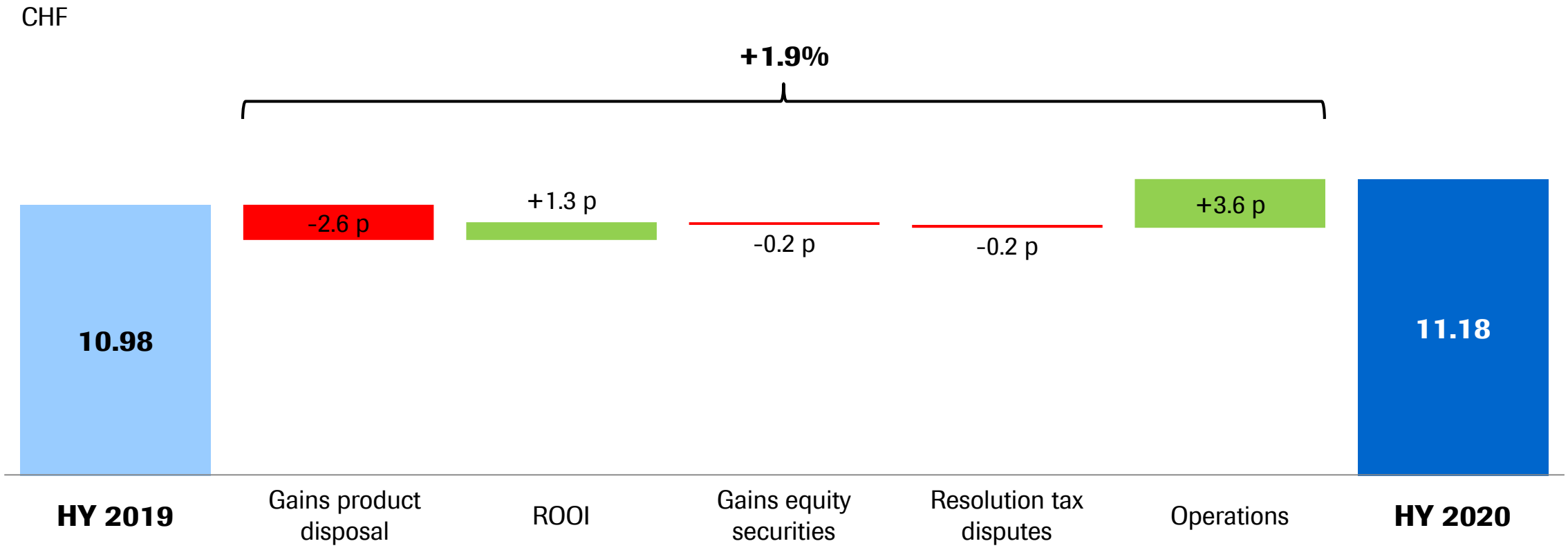
Sales up by +1% and Core EPS up by +2%

	HY 2020 CHFm	HY 2019 CHFm	Change in % CHF	Change in % CER
Sales	**29,281**	**30,469**	**-4**	**1**
Core operating profit	**11,766**	**12,363**	**-5**	**2**
as % of sales	*40.2*	*40.6*		
Core net income	**9,443**	**9,896**	**-5**	**3**
as % of sales	*32.2*	*32.5*		
Core EPS (CHF)	**10.44**	**11.12**	**-6**	**2**
IFRS net income	**8,465**	**8,904**	**-5**	**3**
Operating free cash flow	**5,036**	**7,508**	**-33**	**-26**
as % of sales	*17.2*	*24.6*		
Free cash flow	**3,274**	**5,277**	**-38**	**-29**
as % of sales	*11.2*	*17.3*		

CER=Constant Exchange Rates

HY 2020: Core EPS development

Operations growth is driver for Core EPS growth, more than compensating lower gains on product disposals



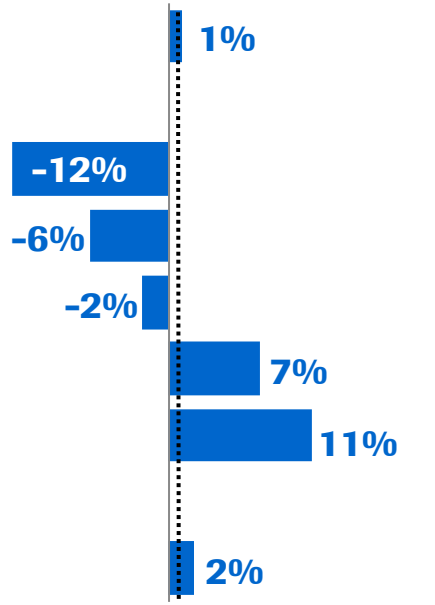
All at CER (Constant Exchange Rates, average FY 2019); ROOI=Royalties and other operating income excl. Gains on product disposals

HY 2020: Group operating performance

Core operating profit growth ahead of sales growth

	2020 CHFm	abs. CER
Sales	**29,281**	**+406**
Royalties & other op. inc.	1,097	-154
Cost of sales	-7,079	+484
M & D	-4,515	+73
R & D	-5,787	-407
G & A	-1,231	-123
Core operating profit	**11,766**	**+280**
Core OP in % of sales	40.2%	

CER growth vs PY

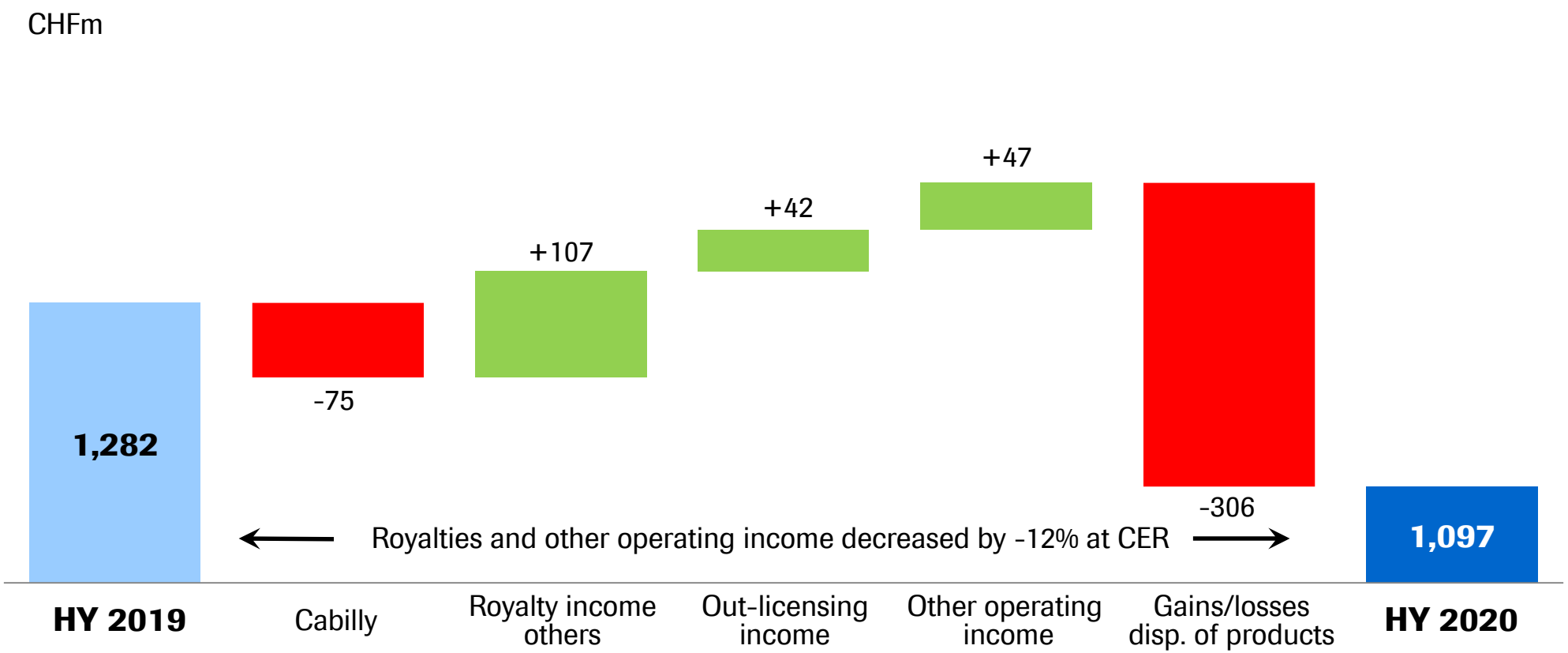


-5% in CHF

CER=Constant Exchange Rates

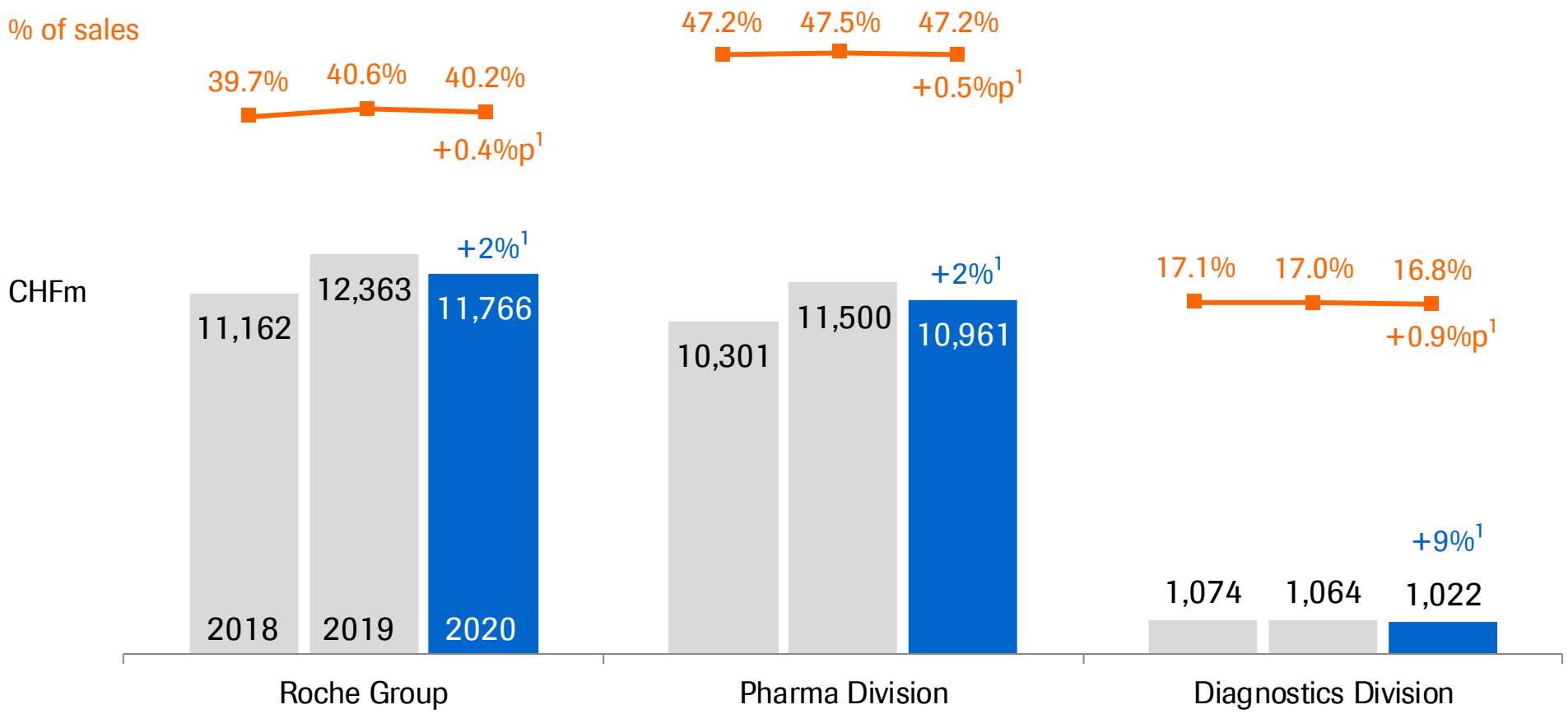
HY 2020: Royalties and other operating income

Decline driven by lower income from product disposals



CER=Constant Exchange Rates

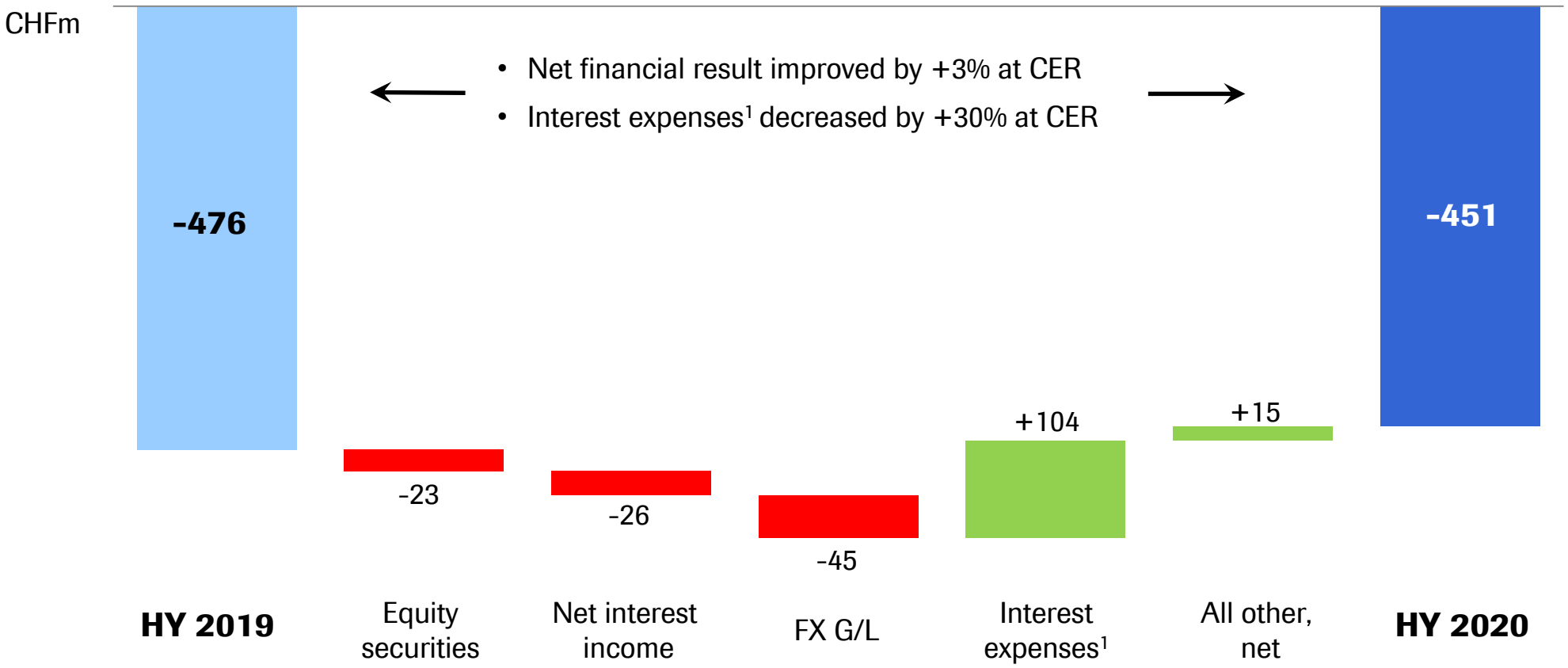
HY 2020: Core OP and margin maintained at high levels



[1] At CER=Constant Exchange Rates

HY 2020: Core net financial result

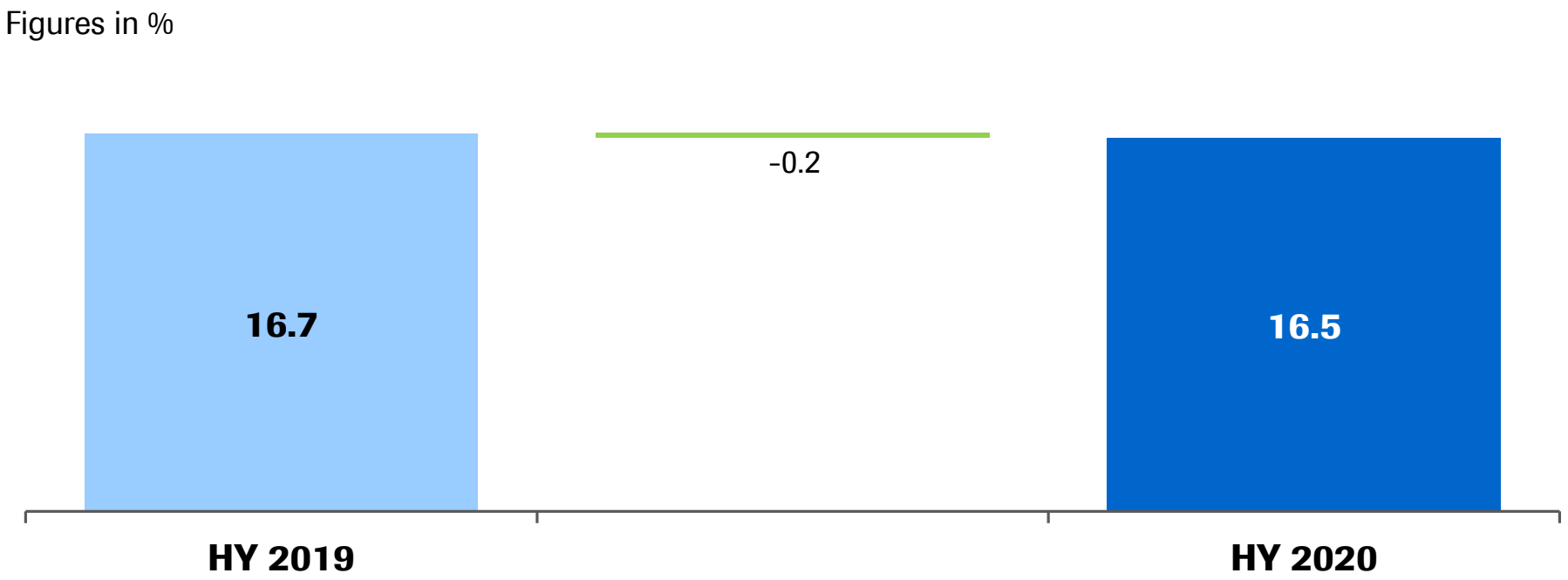
Improvement driven by lower interest expenses



CER=Constant Exchange Rates; [1] incl. amortisation of debt discount and net gains on interest rate derivatives

HY 2020: Group Core tax rate

Stable tax rate with similar impacts from resolution of tax disputes in HY 2020 and HY 2019



HY 2020: Non-core items

Non-core operating expenses lower than in 2019 driven by the Accutane provision release

	2019	2020		Change in %	
	CHFbn	CHFbn	CHFbn	CHF	CER
Core operating profit	**12.4**	**11.8**	**-0.6**	**-5**	**+2**
Global restructuring plans	-0.5	-0.3	+0.2		
Amortisation of intangible assets	-0.7	-0.8	-0.1		
Impairment of intangible assets[1]	-0.3	-0.3	-0.0		
M&A and alliance transactions	0.1	0.0	-0.1		
Legal & Environmental	-0.1	0.3	+0.4		
Total non-core operating items	-1.5	-1.1	+0.4		
IFRS Operating profit	**10.8**	**10.6**	**-0.2**	**-2**	**+6**
Total financial result & taxes	-1.9	-2.2	-0.2		
IFRS net income	**8.9**	**8.5**	**-0.4**	**-5**	**+3**

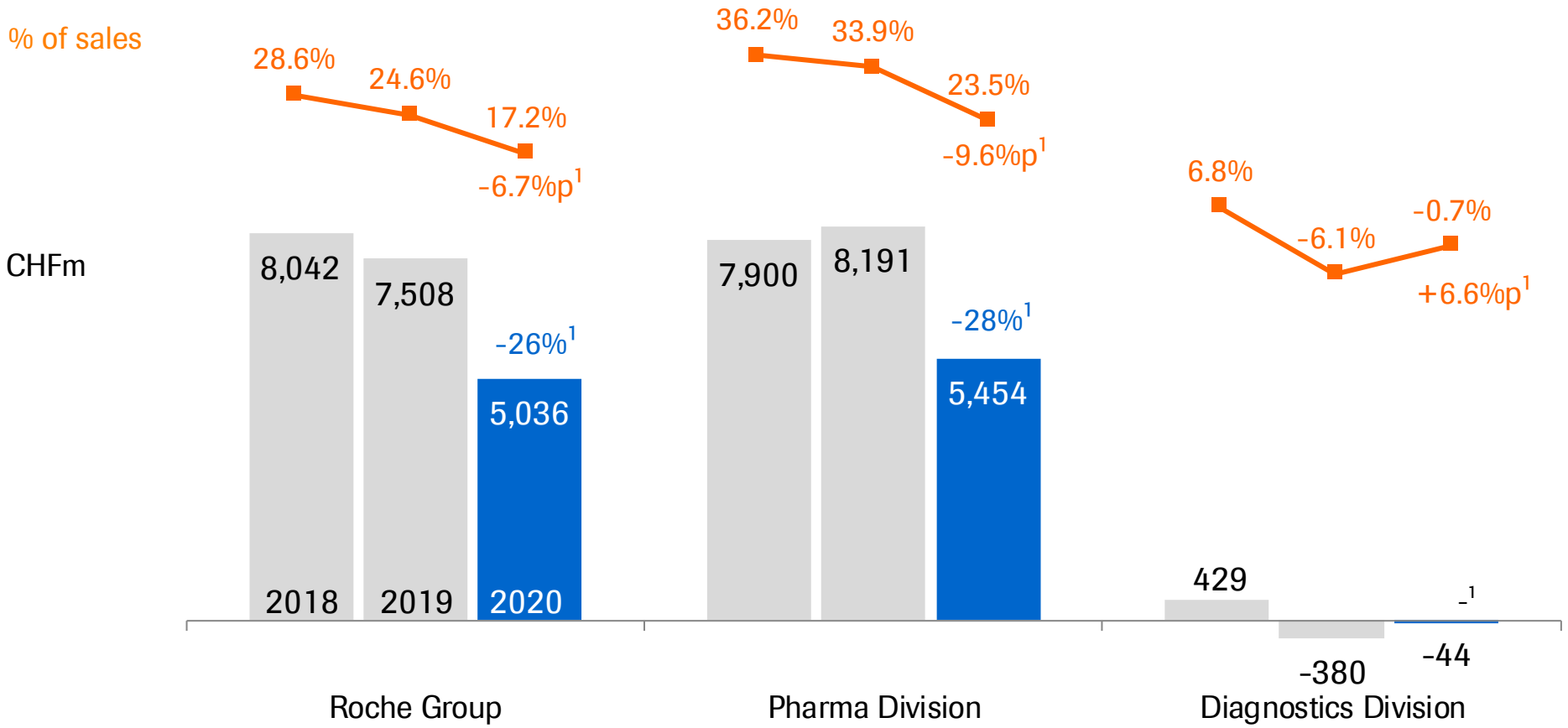
CER=Constant Exchange Rates; [1] incl. goodwill

HY 2020 results

Focus on Cash

Outlook

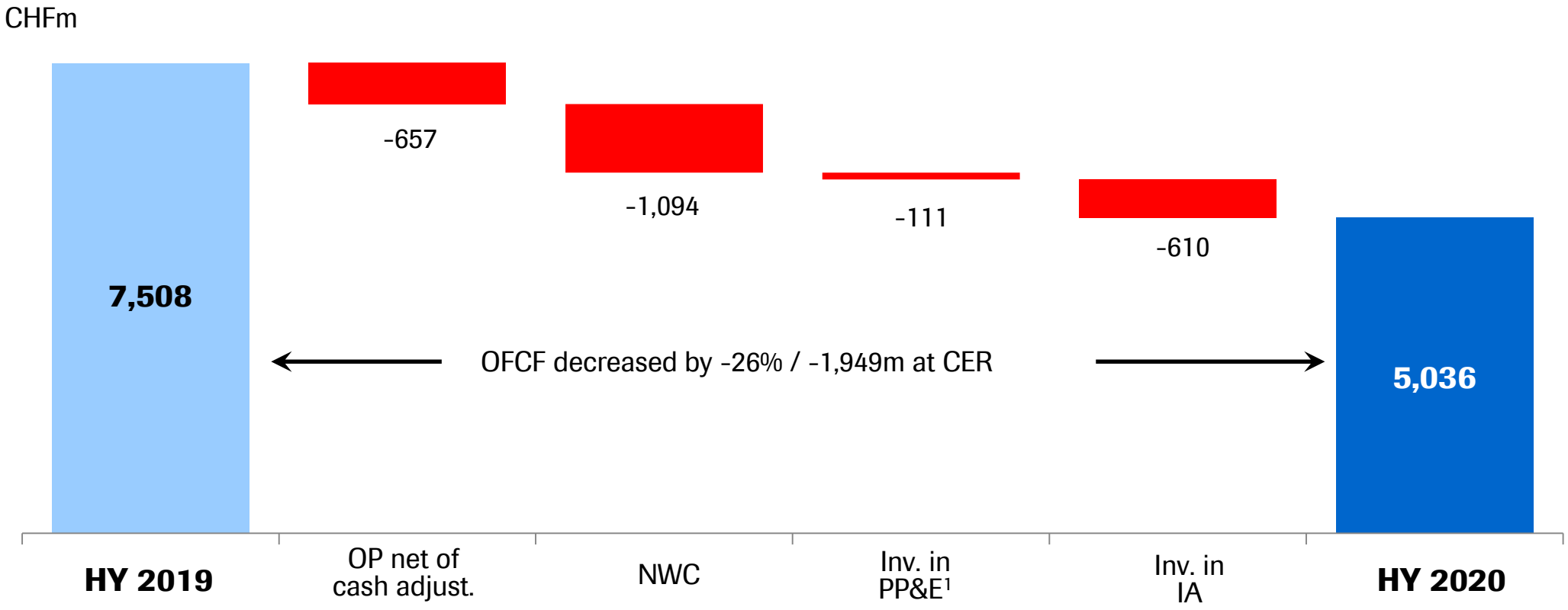
HY 2020: Operating free cash flow and margin



[1] At CER=Constant Exchange Rates

HY 2020: Operating free cash flow

Lower than PY (-26%) driven by higher NWC and higher IA investments

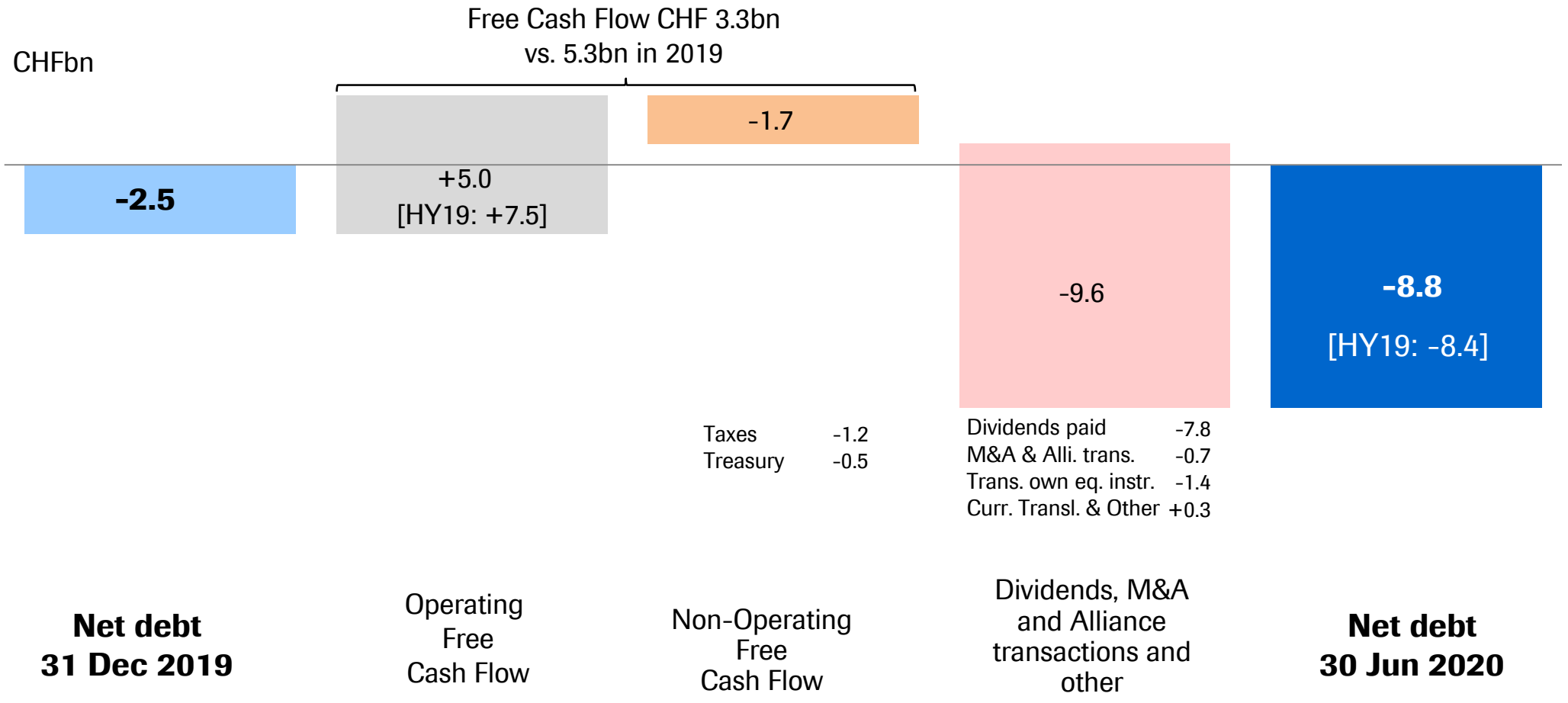


CER=Constant Exchange Rates; OP=operating profit; NWC=net working capital; PP&E=property, plant & equipment; IA=intangible assets, OFCF=Operating Free Cash Flow

[1] Incl. increase in lease liability paid of CHFm -5

HY 2020: Group net debt up vs. YE 2019

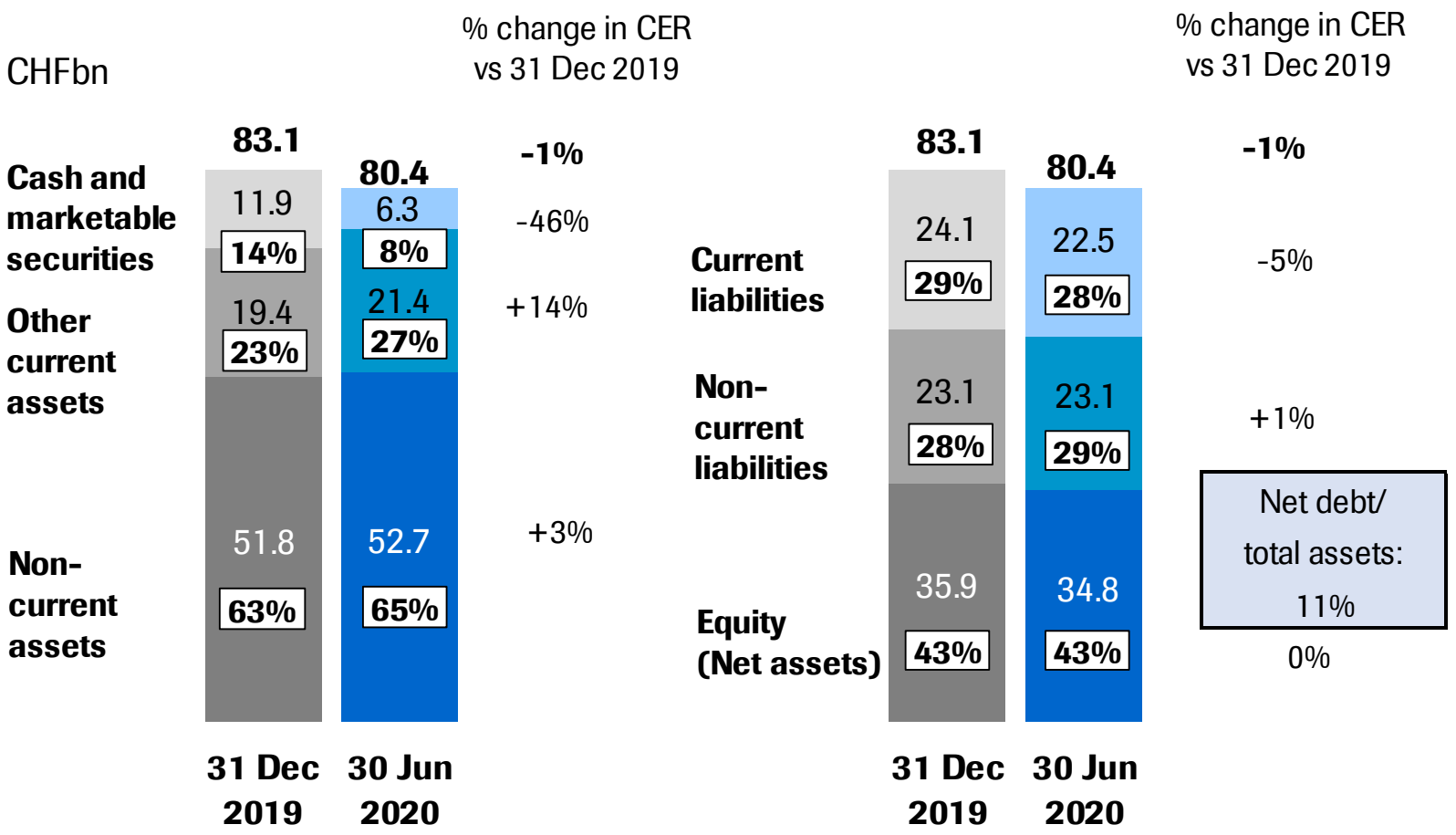
Driven by dividends paid



CER=Constant Exchange Rates (avg full year 2019)

Balance sheet 30 June 2020

Equity ratio at 43% (30 June 2019: 39%; 31 Dec 2019 43%)



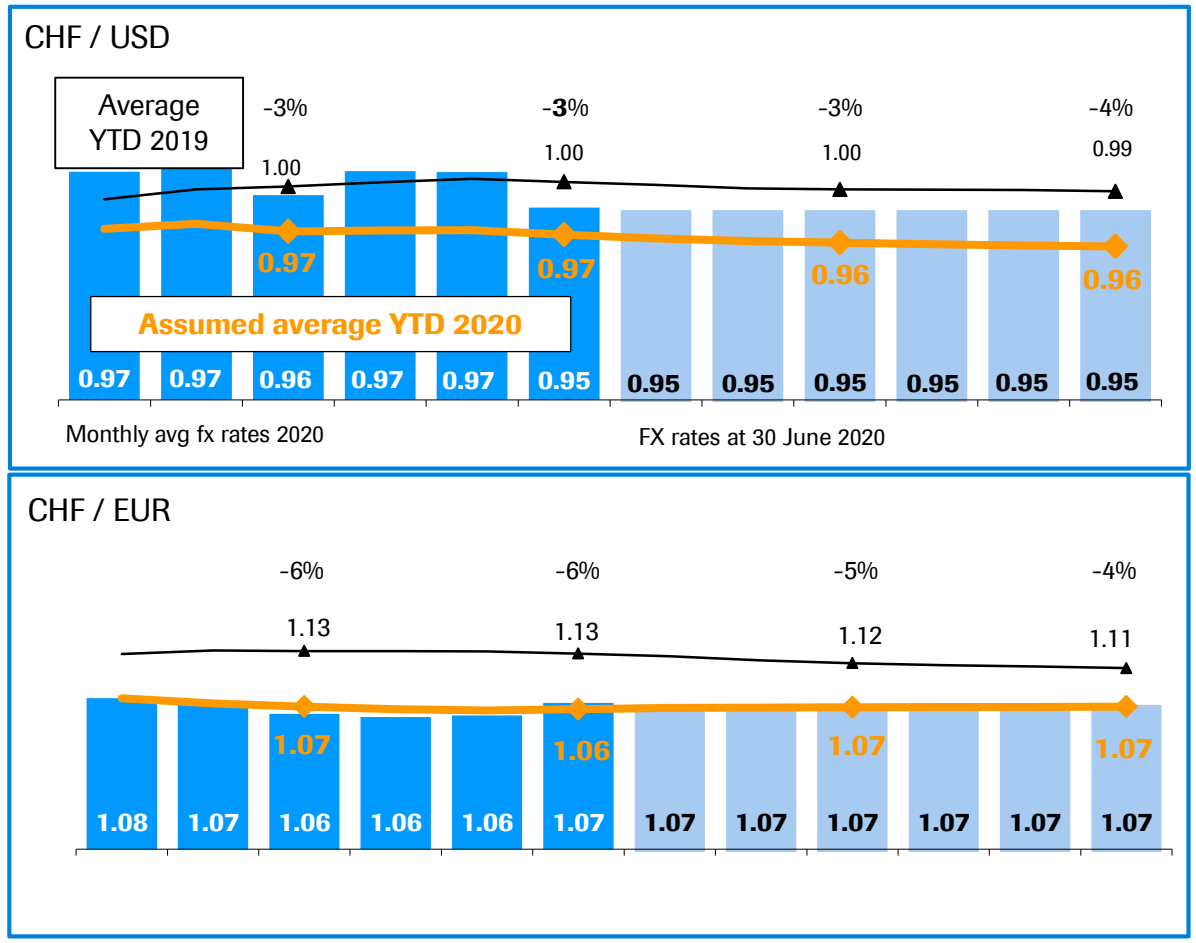
CER=Constant Exchange Rates

HY 2020 results

Focus on Cash

Outlook

High currency impact expected in 2020



Assuming the 30 June 2020 exchange rates remain stable until end of 2020, 2020 impact [1] is expected to be (%p):

	Q1	HY	Sep YTD	FY
Sales	-5	-5	-5	-5
Core operating profit		-7		-7
Core EPS		-8		-8

[1] On group growth rates

2020 outlook confirmed

Further growing top and bottom line

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

[1] At Constant Exchange Rates (CER); based on the current assessment of the COVID-19 impact

Changes to the development pipeline
Q2 2020 update

New to phase I

5 NMEs:
RG6279 PD1-IL2v - solid tumors
RG6247 4D-R110 - choroideremia
RG6296 BCMA x CD16a - r/r MM
RG7637 NME - neurodevelopmental disorders
RG6115 TLR7 agonist (4) - HCC

New to phase II

3 NMEs: (transitioned from phase I)
RG7774 NME - retinal disease
RG7854 TLR7 agonist (3) **+ RG7907** CpAM (2) combination - HBV

3 AIs:
RG6058 tiragolumab+Tecentriq - cervical cancer
RG6149 or RG7880 ST2 MAb or IL22-Fc - COVID-19 pneumonia
IONIS ASO factor B - IgA-nephropathy

New to phase III

1 AI:
RG1569 Actemra+remdesivir - COVID-19 pneumonia

New to registration

2 AIs:
RG7421 Cotellic+Zelboraf+Tecentriq - 1L+ BRAFm melanoma
RG7601 Venclexta+azacitidine - 1L AML

Removed from phase I

1 NME:
RG6217 - HBV

4 AIs:
RG7421 Cotellic+Tecentriq - RCC, bladder, head & neck ca
RG7421 Cotellic+Zelboraf+Tecentriq - melanoma
RG7421 Cotellic+Tecentriq - 2L BRAF WT MM
RG7601 Venclexta+idasanutlin – r/r AML

Removed from phase II

2 NMEs:
RG7314 balovaptan - autism
RG7388 idasanutlin - 1L AML

Removed from phase III

1 AI:
RG3502 Kadcyla+Perjeta - Her2+ EBC

Approvals

1 NME approved in US
RG6264 Phesgo Perjecta+Herceptin FDC SC – HER2+ BC

2 AIs approved in US
RG7446 Tecentriq+Avastin – 1L HCC
RG7446 Tecentriq - 1L non-sq + sq NSCLC Dx+

1 AI approved in EU
RG1594 Ocrevus Short infusion - RMS & PPMS

Status as of July 23, 2020

Roche Group development pipeline

Phase I (43 NMEs + 14 AIs)

RG6026	glofitamab / combos	heme tumors
RG6058	tiragolumab combos	heme & solid tumors
RG6076	CD19-4-1BBL	heme tumors
RG6107	crovalimab	PNH
RG6115	TLR7 agonist (4)	HCC
RG6139	PD1 x LAG3	solid tumors
RG6160	FcRH5/ x CD3	r/r MM
RG6171	SERD (3)	ER+/HER2- mBC
RG6180	iNeST*± T	solid tumors
RG6185	belvarafenib (pan-RAF inh)+Cotellic	solid tumors
RG6194	HER2 x CD3	BC
RG6279	PD1-IL2v	solid tumors
RG6290	MAGE-A4 ImmTAC	solid tumors
RG6292	CD25 MAb	solid tumors
RG6296	BCMA x CD16a	r/r MM
RG6323	IL15/IL15Ra-Fc	solid tumors
RG7440	ipatasertib + Taxane + T	TNBC
	ipatasertib + rucaparib	mCRPC, solid tumors
RG7446	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chemo	HCC, GC, PaC
	T + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + rucaparib	ovarian cancer
	T + CD47 MAb	r/r AML
RG7461	simlukafusp alpha (FAP IL2v FP) / combos	solid tumors
RG7601	Venclexta + AMG176	AML
	Venclexta ± azacitidine	r/r MDS
	Venclexta + gilteritinib	r/r AML
RG7769	PD1 x TIM3	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab/combos	heme tumors
RG7876	selicrelumab combos	solid tumors
CHU	FIXa x FX	hemophilia
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
SQZ	PBMC vaccine	solid tumors
RG6151	-	asthma
RG6244	-	asthma
RG6287	-	IBD
RG7835	IgG–IL2	autoimmune diseases
RG6084	-	HBV
RG6346	HBV siRNA	HBV
RG7861	anti-S. *aureus* TAC	infectious diseases
RG7992	FGFR1 x KLB MAb	metabolic diseases
RG6000	DLK inh	ALS
RG6102	brain shuttle gantenerumab	Alzheimer's
RG6237	-	neuromuscular disorders
RG7637	-	neurodevelopmental disorders
RG7816	GABA Aa5 PAM	autism
RG6179	-	DME
RG6247	4D-R110	choroideremia
RG7921	-	nAMD
CHU	PTH1 recep. ago	hypoparathyroidism
CHU	-	hyperphosphatemia
CHU	-	endometriosis

RG-No - Roche/Genentech
CHU- Chugai managed
IONIS – IONIS managed
SQZ- SQZ Biotechnology managed
NOV- Novimmune managed

*Individualized Neoantigen Specific Immunotherapy
T=Tecentriq

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

CardioMetabolism
Neuroscience
Ophthalmology
Other

Phase II (20 NMEs + 12 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016	hemophilia A with inhibitors to factor VIII
RG6058	tiragolumab + T	NSCLC
	tiragolumab + T	cervical cancer
RG7421	Cotellic + T ± taxane	TNBC
RG7446	Tecentriq	SC NSCLC
RG7596	Polivy	r/r FL
RG7601	Venclexta + azacitidine	1L MDS
	Venclexta + fulvestrant	2L HR+BC
	Venclexta + carfilzomib	r/r MM t(11:14)
RG6149	ST2 MAb	asthma
RG6173	anti-tryptase	asthma
RG6354	rh pentraxin-2 (PRM-151)	myelofibrosis
	rh pentraxin-2 (PRM-151)	idiopathic pulmonary fibrosis
RG7159	Gazyva	lupus nephritis
RG7845	fenebrutinib	RA
RG7880	IL22-Fc	inflammatory diseases
RG6149/RG7880	ST2 MAb or IL22-Fc	COVID-19 pneumonia
NOV	TLR4 MAb	autoimmune diseases
RG7854+RG7907	TLR7 ago(3) + CpAM (2)	HBV
IONIS	ASO factor B	IgA nephropathy
RG6100	semorinemab	Alzheimer's
RG6356	microdystrophin (SRP-9001)	DMD
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7906	ralmitaront	schizophrenia
RG7935	prasinezumab	Parkinson's
RG6147	-	geographic atrophy
RG6367	SPK-7001	choroideremia
RG7774	-	retinal disease
IONIS	ASO factor B	geographic atrophy

Status as of July 23, 2020

Roche Group development pipeline

Phase III (8 NMEs + 30 AIs)

RG6013	Hemlibra	mild to moderate hemophilia A
RG6058	tiragolumab + T + chemo	1L SCLC
	tiragolumab + T	1L PD-L1+ NSCLC
RG6114	mPI3K alpha inh	1L HR+ mBC
RG7440	ipatasertib + abiraterone	1L CRPC
	ipatasertib + chemo	1L TNBC/HR+ BC
	ipatasertib + fulvestrant + palbociclib	1L HR+ mBC
	ipatasertib + Tecentriq + taxane	1L TNBC
RG7596	Polivy	1L DLBCL
RG7446	Tecentriq	NSCLC adj
	Tecentriq	NMIBC, high risk
	Tecentriq	RCC adj
	T + chemo + Avastin	1L ovarian cancer
	T ± chemo	SCCHN adj
	Tecentriq	HER2+ BC neoadj
	T + paclitaxel	1L TNBC
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + nab-paclitaxel	TNBC neoadj
	T + Avastin	HCC adj
	T ± chemo	1L mUC

RG7446/ RG6268	Tecentriq bTMB-high or entrectinib ROS1+	1L NSCLC
RG7601	Venclexta	r/r MM t(11:14)
RG7853	Alecensa	ALK+ NSCLC adj
RG1569	Actemra	COVID-19 pneumonia
RG1569	Actemra + remdesivir	COVID-19 pneumonia
RG3648	Xolair	food allergy
RG7413	etrolizumab	ulcerative colitis
	etrolizumab	Crohn's
RG6152	Xofluza	influenza, hospitalized pts
	Xofluza	influenza, pediatric (0-1 year)
	Xofluza	influenza direct transmission
RG1450	gantenerumab	Alzheimer's
RG6042	tominersen	Huntington's
RG6321	port delivery system with ranibizumab	wAMD
	port delivery system with ranibizumab	DME
RG7716	faricimab	DME
	faricimab	wAMD

Registration (5 NMEs + 11 AIs)

RG6264	Phesgo [1] Perjeta + Herceptin FDC SC	HER2+ BC
RG6268	Rozlytrek (entrectinib) [1]	ROS1+ NSCLC
	Rozlytrek (entrectinib) [1]	NTRK+ tumor-agnostic
RG7446	Tecentriq Dx+ [1]	1L sq + non-sq NSCLC
	Tecentriq+ Avastin [1]	1L HCC
RG7421	Cotellic + Zelboraf + T [2]	1L+ BRAFm melanoma
RG7601	Venclexta + azacitidine	1L AML
RG7853	Alecensa	1LNSCLC Dx+
RG3648	Xolair [2]	nasal polyps
RG6152	Xofluza [1]	influenza
	Xofluza [1]	influenza, high risk
	Xofluza [2]	influenza post exposure prophylaxis
	Xofluza [2]	influenza, pediatric (1-12 yrs)
RG1594	Ocrevus [3]	short infusion RMS & PPMS
RG6168	satralizumab	NMOSD
RG7916	risdiplam [2]	SMA

[1] Approved in US, filed in EU

[2] Filed in US

[3] Filed in US, approved in EU

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

Status as of July 23, 2020

NME submissions and their additional indications

Projects in phase II and III

2020		2021		2022		2023 and beyond			
RG6321	**Port Delivery System with ranibizumab** wAMD				**RG6058**	**tiragolumab + Tecentriq** 1L PD-L1+ cervical ca			**RG6354**	**rh pentraxin-2 PRM-151 IPF**
RG7413	**etrolizumab** ulcerative colitis				**RG6058**	**tiragolumab + Tecentriq** 1L PD-L1+ NSCLC	**RG7907 + RG7854**	**TLR7 ago (3) + CpAM (2)** HBV	**RG6354**	**rh pentraxin-2 PRM-151 myelofibrosis**
RG6152	**Xofluza** ✓ influenza, pediatric (1-12 yrs)	**RG6152**	**Xofluza** direct transmission	**RG6042**	**tominersen** Huntington's	**RG6114**	**mPI3K alpha inh** 1L HR+ BC	**RG7906**	**ralmitaront** schizophrenia	**RG6149**	**ST2 MAb** asthma
RG6152	**Xofluza** ✓ influenza post-exposure prophylaxis	**RG6152**	**Xofluza** influenza, pediatric (0-1 year)	**RG1450**	**gantenerumab** Alzheimer's	**RG6180**	**iNeST*** oncology	**RG6356**	**microdystrophin SRP-9001** DMD	**RG6173**	**Anti-tryptase** asthma
RG7916	**risdiplam** SMA (EU)	**RG6152**	**Xofluza** influenza, hospitalized	**RG7413**	**etrolizumab** Crohn's	**RG7440**	**ipatasertib + fulv + palbociclib** 1L HR+ mBC	**RG6100**	**semorinemab (Tau MAb)** Alzheimer's	**RG7845**	**fenebrutinib** autoimmune diseases
RG7440	**ipatasertib + abiraterone** 1L CRPC	**RG7716**	**faricimab** DME	**RG6321**	**Port Delivery System with ranibizumab** DME	**RG7440**	**ipatasertib + Tecentriq + taxane** 1L TNBC	**RG7935**	**prasinezumab** Parkinson's	**RG7880**	**IL22-Fc** inflammatory diseases
RG7440	**ipatasertib + chemo** 1L TNBC / HR+ BC	**RG7716**	**faricimab** wAMD	**RG6058**	**tiragolumab + Tecentriq** 1L SCLC						

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU

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

CardioMetabolism
Neuroscience
Ophthalmology
Other

*Individualized NeoAntigen Specific Immunotherapy

Status as of July 23, 2020

AI submissions for existing products

Projects in phase II and III

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

2020

RG1569	**Actemra** COVID-19 pneumonia
RG1569	**Actemra + remdesivir** COVID-19 pneumonia
RG7421	**Cotellic + Tecentriq + Zelboraf** ✓ 1L+ BRAFm melanoma
RG7446	**Tecentriq + nab-paclitaxel** TNBC neoadj
RG7446	**Tecentriq + paclitaxel** 1L TNBC
RG7446	**Tecentriq ± chemo** 1L mUC
RG7446	**Tecentriq + chemo + Avastin** 1L ovarian cancer
RG7446	**Tecentriq + Avastin** ✓ 1L HCC
RG7601	**Venclexta +azacitidine** ✓ 1L AML
RG7853	**Alecensa (BFAST)** ✓ 1L NSCLC ALK+

2021

RG3648	**Xolair** Food allergy
RG6268	**Rozlytrek (BFAST)** 1L NSCLC ROS1+
RG7446	**Tecentriq (BFAST)** 1L NSCLC bTMB-high
RG7596	**Polivy** 1L DLBCL

2022

RG6013	**Hemlibra** Mild to moderate hemophilia A (EU)
RG7446	**Tecentriq** NSCLC adj
RG7446	**Tecentriq** RCC adj

2023 and beyond

RG7446	**Tecentriq + Avastin** HCC adj
RG7446	**Tecentriq SC** NSCLC
RG7446	**Tecentriq** HER2+ BC neoadj
RG7446	**Tecentriq + paclitaxel** TNBC adj
RG7446	**Tecentriq** High risk NMIBC
RG7446	**Tecentriq + chemo** SCCHN adj
RG7446	**Tecentriq + capecitabine or carbo/gem** TNBC
RG7596	**Polivy** r/r FL
RG7159	**Gazyva** lupus nephritis
RG7421	**Cotellic + Tecentriq ± taxane** TNBC
RG7601	**Venclexta** r/r MM t(11:14)
RG7601	**Venclexta + carfilzomib** r/r MM t(11:14)
RG7601	**Venclexta + azacitidine** 1L MDS
RG7601	**Venclexta + fulvestrant** 2L HR+BC
RG7853	**Alecensa** ALK+ NSCLC adj

Status as of July 23, 2020

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU

Major pending approvals 2020

US

RG6168	**satralizumab** NMOSD Filed Aug 2019
RG3648	**Xolair** nasal polyps Filed Sept 2019
RG7916	**risdiplam** SMA Filed Nov 2019
RG7853	**Alecensa (BFAST)** 1L NSCLC ALK+ Filed Jan 2020
RG1594	**Ocrevus** Short infusion RMS & PPMS Filed Feb 2020
RG6152	**Xofluza** post exposure prophylaxis Filed March 2020
RG6152	**Xofluza** influenza, pediatric (1-12 yrs) Filed March 2020
RG7421	**Cotellic + Zelboraf+ Tecentriq** 1L+ BRAFm melanoma Filed May 2020
RG7601	**Venclexta+ azacitidine** 1L AML Filed May 2020

EU

RG6268	**Rozlytrek (entrectinib)** ROS1+ NSCLC Filed Jan 2019
RG6268	**Rozlytrek (entrectinib)** NTRK+ tumor-agnostic Filed Jan 2019
RG6168	**satralizumab** NMOSD Filed Aug 2019
RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+ Filed Nov 2019
RG6152	**Xofluza** influenza Filed Nov 2019
RG6152	**Xofluza** influenza, high risk Filed Nov 2019
RG7446	**Tecentriq +Avastin** 1L HCC Filed Jan 2020
RG6264	**Perjeta+Herceptin FDC SC** Her2+BC Filed Jan 2020
RG7601	**Venclexta+ azacitidine** 1L AML Filed May 2020

China

RG99	**CellCept** lupus nephritis Filed Aug 2018
RG405	**Avastin** 1L/2L glioblastoma Filed Jan 2019
RG105	**MabThera** CLL Filed Apr 2019
RG105	**MabThera** FL Filed Apr 2019
RG7159	**Gazyva** 1L FL Filed Sept 2019
RG7159	**Gazyva** r/r FL Filed Sept 2019
RG7446	**Tecentriq +Avastin** 1L HCC Filed Jan 2020
RG6168	**satralizumab** NMOSD Filed April 2020
RG7916	**risdiplam** SMA Filed March 2020
RG6152	**Xofluza** influenza Filed May 2020
RG6152	**Xofluza** influenza, high risk Filed May 2020
RG6013	**Hemlibra** Hemophilia A Filed June 2020

Japan-Chugai

RG3502	**Kadcyla** HER2+ eBC adj Filed Aug 2019
RG7446	**Tecentriq +Avastin** HCC Filed Feb 2020
RG7596	**Polivy** r/r DLBCL Filed June 2020

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

FDC = fixed-dose combination

Status as of July 23, 2020

Major granted approvals 2020

US		EU		China		Japan-Chugai	
RG7601	**Venclexta+Gazyva** 1L CLL Mar 2020	**RG7596**	**Polivy** r/r DLBCL January 2020	**RG3502**	**Kadcyla** HER2+ eBC Jan 2020	**RG6268**	**Rozlytrek (entrectinib)** ROS1+ NSCLC Feb 2020
RG7446	**Tecentriq + Avastin** 1L HCC May 2020	**RG7601**	**Venclexta+Gazyva** 1L CLL Mar 2020	**RG7446**	**Tecentriq + chemo** 1L extensive stage SCLC Feb 2020	**RG7853**	**Alecensa** r/r ALK+ ALCL Feb 2020
RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+ May 2020	**RG1594**	**Ocrevus** Short infusion RMS & PPMS May 2020			**RG105**	**Rituxan** thrombocytopenic purpura Feb 2020
RG6264	**Phesgo (Perjeta+Herceptin FDC) SC** Her2+BC June 2020					**RG6168**	**Enspryng (satralizumab)** NMOSD June 2020

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

Status as of July 23, 2020

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group HY 2020 results

Diagnostics

Foreign exchange rate information

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients with inhibitors to factor VIII	Hemophilia A pediatric patients with inhibitors to factor VIII
Phase/study	**Phase III HAVEN 1**	**Phase III HAVEN 2**
# of patients	N=118	N=88
Design	Patients on episodic treatment prior to study entry: ▪ **ARM A:** Hemlibra prophylaxis ▪ **ARM B:** Episodic treatment (no prophylaxis) Patients on prophylaxis prior to study entry: ▪ **ARM C:** Hemlibra prophylaxis Patients on episodic treatment previously on non-interventional study: ▪ **ARM D:** Hemlibra prophylaxis	Patients on prophylactic or episodic treatment prior to study entry: ▪ **Cohort A:** Hemlibra prophylaxis qw ▪ **Cohort B:** Hemlibra prophylaxis q2w ▪ **Cohort C:** Hemlibra prophylaxis q4w
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 52 weeks
Status	▪ FPI Q4 2015, recruitment completed in arms A and B Q2 2016 ▪ Primary and all secondary endpoints met Q4 2016 ▪ Data published in *NEJM* 2017; 377:809-818	▪ FPI Q3 2016, recruitment completed Q2 2017 ▪ Positive interim data in Q2 2017 ▪ FPI cohorts B/C Q4 2017 ▪ Full primary data at ASH 2018
	▪ Data presented at ISTH 2017, updated data presented at ASH 2017 ▪ Filed in US and EU in Q2 2017; granted accelerated assessment (EMA) and priority review (FDA) ▪ Approved in US Q4 2017 and EU Q1 2018	
CT Identifier	NCT02622321	NCT02795767

In collaboration with Chugai

ASH=American Society of Hematology; ISTH=International Society on Thrombosis and Haemostasis; *NEJM=New England Journal of Medicine*

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients without inhibitors to factor VIII	Hemophilia A patients with and without inhibitors to Factor VIII, 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 1:** Pharmacokinetic (PK) run-in part (N=6) ▪ **Part 2:** Expansion part (N=40)
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 24 weeks
Status	▪ FPI Q3 2016, recruitment completed Q2 2017 ▪ Study met primary and key secondary endpoints Q4 2017 ▪ FDA granted Breakthrough Therapy Designation April 2018 ▪ Data presented at WFH 2018 ▪ Filed in US (priority review) and EU in Q2 2018 ▪ Data published in *NEJM* 2018; 379: 811-822	▪ FPI Q1 2017, recruitment completed Q2 2017 ▪ PK 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

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**: emicizumab prophylaxis qw ▪ **Arm B**: emicizumab 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
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Safety and efficacy
Status	▪ FPI Q2 2018 ▪ Recruitment completed Q1 2019 ▪ Filed in China Q2 2020	▪ FPI Q1 2020
CT Identifier	NCT03315455	NCT04158648

In collaboration with Chugai

Alecensa

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK+ advanced NSCLC	Adjuvant ALK+ NSCLC
Phase/study	**Phase III ALEX**	**Phase III ALINA**
# of patients	N=286	N=255
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 600 mg 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
CT Identifier	NCT02075840	NCT03456076

In collaboration with Chugai

NSCLC=non-small cell lung cancer; ASCO=American Society of Clinical Oncology; *NEJM*=New England Journal of Medicine; ESMO=European Society for Medical Oncology

Cotellic

Selective small molecule inhibitor of MAPK kinase

Indication	First-line metastatic triple negative breast cancer
Phase/study	**Phase II** **COLET**
# of patients	N=160
Design	▪ **ARM A:** Cotellic plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel ▪ **ARM C:** Cotellic plus Tecentriq plus nab-paclitaxel ▪ **ARM D:** Cotellic plus Tecentriq plus paclitaxel
Primary endpoint	▪ Progression-free survival and safety
Status	▪ FPI Q1 2015 ▪ FPI arms C and D: Q4 2016 ▪ Data arms A and B presented at SABCS 2017
CT Identifier	NCT02322814

In collaboration with Exelixis
SABCS=San Antonio Breast Cancer Symposium; CPI=Checkpoint inhibitor

Kadcyla

First ADC for HER2-positive breast cancer

Indication	HER2-positive early breast cancer high-risk patients
Phase/study	**Phase III** **KATHERINE**
# of patients	N=1,484
Design	▪ **ARM A:** Kadcyla 3.6mg/kg q3w ▪ **ARM B:** Herceptin
Primary endpoint	▪ 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
CT Identifier	NCT01772472

In collaboration with ImmunoGen, Inc.
ADC=antibody drug conjugate; SABCS=San Antonio Breast Cancer Symposium; RTOR=Real time oncology review

Perjeta

First-in-class HER2 dimerization inhibitor

Indication	Adjuvant HER2-positive breast cancer	Neoadjuvant/adjuvant HER2-positive breast cancer
Phase/study	**Phase III** **APHINITY**	**Phase II** **BERENICE**
# of patients	N=4,803	N=401
Design	▪ **ARM A:** Perjeta (840mg loading, 420 q3w) + Herceptin for 52 weeks plus chemotherapy (6-8 cycles) ▪ **ARM B:** Placebo + Herceptin (52 weeks) plus chemotherapy (6-8 cycles)	*Neoadjuvant treatment:* ▪ **ARM A:** ddAC q2w x4 followed by wkly paclitaxel for 12 wks, with P+H x 4 cycles ▪ **ARM B:** FEC plus P+H x 4 cycles followed by docetaxel plus P+H x 4 cycles *Adjuvant treatment:* ▪ P+H q3w to complete 1 year of HER2 therapy ▪ Hormonal and radiation therapy as indicated
Primary endpoint	▪ Invasive disease-free survival (IDFS)	▪ Safety
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 ▪ Six year IDFS data presented at SABCS 2019	▪ Recruitment completed Q3 2015 ▪ Data presented at SABCS 2016 ▪ Data published in Ann Oncol. 2018 Mar 1; 29(3): 646-653
CT Identifier	NCT01358877	NCT02132949

ddAC=dose-dense doxorubicin plus cyclophosphamide; FEC=fluorouracil, epirubicin and cyclophosphamide; ASCO=American Society of Clinical Oncology; SABCS=San Antonio Breast Cancer Symposium

Perjeta

First-in-class HER2 dimerization inhibitor

Indication	HER2-positive early breast cancer subcutaneous co-formulation		Neoadjuvant HER2-positive breast cancer
Phase/study	**Phase III FeDeriCa**	**Phase II Phrancesca**	**Phase III IMpassion050**
# of patients	N=500	N=140	N=453
Design	Fixed-dose combination (FDC) of Perjeta (P) and Herceptin (H) for subcutaneous administration in combination with chemotherapy in the neoadjuvant/adjuvant setting ▪ **ARM A:** P IV+H IV+chemotherapy ▪ **ARM B:** FDC of PH SC+chemotherapy	▪ **ARM A:** PH IV followed by FDC SC ▪ **ARM B:** PH FDC SC followed by IV	▪ **ARM A:** ddAC Herceptin/Perjeta + paclitaxel followed by surgery and chemotherapy ▪ **ARM B:** ddAC Herceptin/Perjeta + chemotherapy +Tecentriq followed by surgery and chemotherapy +Tecentriq
Primary endpoint	▪ Trough Serum Concentration (Ctrough) of Pertuzumab During Cycle 7	▪ Percentage who preferred PH FDC SC	▪ Pathologic complete response (pCR)
Status	▪ Recruitment completed Q4 2018 ▪ Study met primary endpoint Q3 2019 ▪ Data presented at SABCS 2019	▪ FPI Q4 2018 ▪ Final analysis completed, 85% patients preferred FDC SC	▪ FPI Q4 2018
	▪ Filed in US Q4 2019 & in EU Jan 2020 ▪ Approved in US Q2 2020		
CT Identifier	NCT03493854	NCT03674112	NCT03726879

SABCS=San Antonio Breast Cancer Symposium

Perjeta/Kadcyla and Tecentriq

Her2 targeted agents in combination with anti-PD-L1

Indication	Metastatic and locally advanced early breast cancer (HER2-positive)
Phase/study	**Phase I**
# of patients	N=76
Design	▪ **Cohort 1A (mBC):** Tecentriq plus Perjeta plus Herceptin ▪ **Cohort 1B (mBC):** Tecentriq plus Kadcyla[1] ▪ **Cohort 1F (mBC):** Tecentriq plus Perjeta plus Herceptin plus docetaxel ▪ **Cohort 2A (eBC):** Tecentriq plus Perjeta plus Herceptin ▪ **Cohort 2B (eBC):** Tecentriq plus Kadcyla[1] ▪ **Cohort 2C (expansion on cohort 1B):** Tecentriq plus Kadcyla[1]
Primary endpoint	▪ Safety
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q2 2018
CT Identifier	NCT02605915

[1] In collaboration with ImmunoGen, Inc.
eBC=early breast cancer; mBC=metastatic breast cancer

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous NSCLC	
Phase/study	**Phase III IMpower150**	**Phase III IMpower132**
# of patients	N=1,202	N=568
Design	▪ **ARM A:** Tecentriq plus paclitaxel plus carboplatin ▪ **ARM B:** Tecentriq plus Avastin plus paclitaxel plus carboplatin ▪ **ARM C:** Avastin plus paclitaxel plus carboplatin	▪ **ARM A:** Tecentriq plus carboplatin or cisplatin plus pemetrexed ▪ **ARM B:** Carboplatin or cisplatin plus pemetrexed
Primary endpoint	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival
Status	▪ Study met co-primary endpoint of PFS in Q4 2017 and OS in Q1 2018 ▪ PFS data presented at ESMO IO 2017 and OS at ASCO 2018 ▪ Filed in US Q1 2018 (priority review) and EU (Q1 2018) ▪ Data published in *NEJM* 2018; 378:2288-2301 ▪ Approved in US Q4 2018 and EU Q1 2019	▪ FPI Q2 2016 ▪ Recruitment completed Q2 2017 ▪ Study met co-primary endpoint of PFS in Q2 2018 ▪ Data presented at WCLC 2018
CT Identifier	NCT02366143	NCT02657434

NSCLC=non-small cell lung cancer; ESMO=European Society for Medical Oncology; ASCO=American Society of Clinical Oncology; *NEJM*=New England Journal of Medicine; WCLC=World Conference on Lung Cancer

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous and squamous NSCLC PD-L1-selected patients	1L extensive-stage SCLC
Phase/study	**Phase III** **IMpower110**	**Phase III** **IMpower133**
# of patients	N=570	N=400
Design	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** *NSq*: carboplatin or cisplatin plus pemetrexed *Sq:* carboplatin or cisplatin plus gemcitabine	▪ **ARM A:** Tecentriq plus carboplatin plus etoposide ▪ **ARM B:** Placebo plus carboplatin plus etoposide
Primary endpoint	▪ Overall survival	▪ Progression-free survival and overall survival
Status	▪ IMpower111 consolidated into IMpower110 Q3 2016 ▪ Recruitment completed Q1 2018 ▪ Study met primary endpoint in PD-L1 high (IC3/TC3) Q3 2019 ▪ Data presented at ESMO and ESMO-IO 2019 ▪ Filed in EU and US (priority review) Q4 2019 ▪ Approved in US Q2 2020	▪ FPI Q2 2016 ▪ Orphan drug designation granted by FDA Q3 2016 ▪ Study met endpoints of OS and PFS in Q2 2018 ▪ Primary data presented at WCLC 2018 ▪ Data published in *NEJM* 2018; 379:2220-2229 ▪ Filed with the US and EU Q3 2018 ▪ Approved in US Q1 2019 and EU Q3 2019
CT Identifier	NCT02409342	NCT02763579

NSCLC=non-small cell lung cancer; NSq=non-squamous; Sq=squamous; SCLC=small cell lung cancer; ESMO=European Society for Medical Oncology; *NEJM*=New England Journal of Medicine; WCLC=World Conference on Lung Cancer

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	Adjuvant NSCLC	Neoadjuvant NSCLC
Phase/study	**Phase III** **IMpower010**	**Phase III** **IMpower030**
# of patients	N=1,127	N=450
Design	Following adjuvant cisplatin-based chemotherapy ▪ **ARM A:** Tecentriq ▪ **ARM B:** Best supportive care	▪ **ARM A:** Tecentriq + platinum-based chemotherapy ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Disease-free survival	▪ Major pathological response and event free survival
Status	▪ FPI Q3 2015 ▪ Trial amended from PD-L1+ selected patients to all-comers ▪ FPI for all-comer population Q4 2016 ▪ Recruitment completed Q3 2018	▪ FPI Q2 2018
CT Identifier	NCT02486718	NCT03456063

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L NSCLC	Stage IV non-small cell lung cancer
Phase/study	**Phase II/III** **B-FAST**	**Phase Ib/II** **IMscin001**
# of patients	N=660	N=260
Design	▪ **Cohort A:** ALK+ (Alecensa) ▪ **Cohort B:** RET+ (Alecensa) ▪ **Cohort C:** bTMB-high (Tecentriq) ▪ **Cohort D:** ROS1+ (Rozlytrek) ▪ **Cohort E:** BRAF+ (vemurafenib plus cobimetinib plus Tecentriq)	▪ Part 1: dose finding, atezo SC followed by atezo IV ▪ Part 2: non inferiority of atezo SC + Avastin + chemo vs atezo IV + Avastin+ chemo
Primary endpoint	▪ Cohort A/B: Objective response rate ▪ Cohort C: Progression-free survival	▪ Observed concentration of atezolizumab in serum at cycle 1
Status	▪ FPI Q3 2017 ▪ Recruitment completed for cohort A Q3 2018 and cohort C Q3 2019 ▪ Study met primary endpoint in cohort A (ALK+) Q3 2019; presented at ESMO 2019 ▪ ALK+ Alecensa (cohort A) filed in US Q1 2020	▪ FPI Q4 2018
CT Identifier	NCT03178552	NCT03735121

[1]Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a subsidiary of Astellas US, LLC;
NSCLC=non-small cell lung cancer; ESMO=European Society for Medical Oncology

Tecentriq

Anti-PD-L1 cancer immunotherapy – SCCHN

Indication	Adjuvant squamous cell carcinoma of the head and neck
Phase/study	**Phase III** **IMvoke010**
# of patients	N=400
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

Anti-PD-L1 cancer immunotherapy – UC

Indication	1L metastatic urothelial carcinoma	High-risk non-muscle-invasive bladder cancer
Phase/study	**Phase III IMvigor130**	**Phase III ALBAN**
# of patients	N=1,200	**N=614**
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+ BCG induction and maintenance
Primary endpoint	▪ Progression-free survival, overall survival and safety	▪ 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	▪ FPI Q4 2018
CT Identifier	NCT02807636	NCT03799835

UC=urothelial carcinoma; BCG=Bacille Calmette-Guérin

Tecentriq

Anti-PD-L1 cancer immunotherapy – renal cell cancer

Indication	Adjuvant renal cell carcinoma	Advanced renal cell carcinoma after immune checkpoint inhibitor treatment
Phase/study	**Phase III** **IMmotion010**	**Phase III** **Contact-03**[1]
# of patients	N=664	N=500
Design	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Observation	▪ **ARM A:** Tecentriq plus cabozantinib ▪ **ARM B:** cabozantinib
Primary endpoint	▪ Disease-free survival	▪ Progression-free survival and overall survival
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q1 2019	▪ FPI expected Q3
CT Identifier	NCT03024996	NCT04338269

[1]In collaboration with Exelixis

Tecentriq

Anti-PD-L1 cancer immunotherapy – CRC and HCC

Indication	2/3L metastatic colorectal cancer	1L hepatocellular carcinoma	Adjuvant hepatocellular carcinoma
Phase/study	**Phase I**	**Phase III IMbrave150**	**Phase III IMbrave050**
# of patients	N=84	N=501	N=662
Design	Open-label, single-arm, two-stage study with Cotellic plus Tecentriq plus Avastin ▪ **Stage 1:** Safety run-in ▪ **Stage 2:** Dose-expansion with two cohorts: – Expansion – Biopsy	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Sorafenib	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Active surveillance
Primary endpoint	▪ Safety	▪ Overall survival and progression free survival	▪ Recurrence-Free Survival (RFS)
Status	▪ FPI Q3 2016 ▪ Recruitment completed Q3 2018 ▪ Data presented at ESMO 2019	▪ FPI Q1 2018 ▪ Recruitment completed Q1 2019 ▪ Data presented at ESMO Asia 2019 ▪ US filing completed under RTOR Q1 2020; filed in EU Q1 2020 ▪ Data published in NEJM 2020;382:1894-1905 ▪ Approved in US Q2 2020	▪ FPI Q4 2019
CT Identifier	NCT02876224	NCT03434379	NCT04102098

Cotellic in collaboration with Exelixis

ESMO=European Society for Medical Oncology; *NEJM*=New England Journal of Medicine; RTOR=Real time oncology review

Tecentriq

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Previously untreated metastatic triple negative breast cancer		
Phase/study	**Phase III IMpassion130**	**Phase III IMpassion131**	**Phase III IMpassion132**
# of patients	N=900	N=540	N=572
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel	▪ **ARM A:** Tecentriq plus paclitaxel ▪ **ARM B:** Placebo plus 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)	▪ Progression-free survival	▪ Overall survival
Status	▪ Recruitment completed Q2 2017 ▪ Study met co-primary endpoint of PFS in both PDL1+ and ITT populations Jul 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 ▪ Approved in EU Q3 2019	▪ FPI Q3 2017 ▪ Recruitment completed Q3 2019	▪ FPI Q1 2018
CT Identifier	NCT02425891	NCT03125902	NCT03371017

ESMO=European Society for Medical Oncology; ASCO=American Society of Clinical Oncology; *NEJM*=New England Journal of Medicine

Tecentriq

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Neoadjuvant triple negative breast cancer	Adjuvant triple negative breast cancer
Phase/study	**Phase III** **IMpassion031**	**Phase III** **IMpassion030**
# of patients	N=324	N=2,300
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel	▪ **ARM A:** Tecentriq + paclitaxel followed by AC followed by Tecentriq + AC, followed by Tecentriq maintenance ▪ **ARM B:** Placebo + paclitaxel followed by AC followed by placebo
Primary endpoint	▪ Percentage of participants with pathologic complete response (pCR)	▪ Invasive Disease Free Survival
Status	▪ FPI Q3 2017 ▪ Recruitment completed Q2 2018 ▪ Q1 2019 IDMC recommendation to expand study to recruit 120 additional patients (all comers and PDL1-positive). Recruitment completed for additional patients Q3 2019 ▪ Study met primary endpoint Q2 2020	▪ FPI Q3 2018
CT Identifier	NCT03197935	NCT03498716

IDMC=Independent data monitoring committee

Tecentriq

Anti-PD-L1 cancer immunotherapy – ovarian cancer

Indication	Front-line ovarian cancer	Advanced gynecological cancers and triple negative breast cancer
Phase/study	**Phase III IMaGYN050**	**Phase Ib**
# of patients	N=1,300	N=48
Design	▪ **ARM A:** Tecentriq plus carboplatin plus paclitaxel plus Avastin ▪ **ARM B:** Carboplatin plus paclitaxel plus Avastin	▪ **Part 1:** Dose finding Tecentriq plus rucaparib (CO-338)[1] ▪ **Part 2:** Expansion Tecentriq plus rucaparib (CO-338)[1]
Primary endpoint	▪ Progression-free survival and overall survival (co-primary endpoint)	▪ Safety
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q1 2019 ▪ Primary endpoint not met Q2 2020	▪ FPI Q2 2017
CT Identifier	NCT03038100	NCT03101280

[1]Rucaparib in collaboration with Clovis

Tecentriq

Anti-PD-L1 cancer immunotherapy – melanoma

Indication	First-line BRAFv600 mutation-positive metastatic or unresectable locally advanced melanoma
Phase/study	**Phase III** **IMspire150 TRILOGY**
# of patients	N=500
Design	Double-blind, randomized, placebo-controlled study ▪ **ARM A:** Tecentriq plus Cotellic plus Zelboraf[1] ▪ **ARM B:** Placebo plus Cotellic plus Zelboraf[1]
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2018 ▪ Primary endpoint met Q4 2019 ▪ Data presented at AACR 2020 ▪ Data published in Lancet;395(10240):1835-1844 ▪ Filed in US Q2 2020 under Project Orbis[2]
CT Identifier	NCT02908672

In collaboration with Exelixis; [1]Zelboraf in collaboration with Plexxikon, a member of Daiichi Sankyo Group; [2] Project Orbis=FDA framework for concurrent submission and review of oncology products among international partners; AACR=American Association for Cancer Research

Tecentriq

Anti-PD-L1 cancer immunotherapy – hematology

Indication	Relapsed or refractory AML
Phase/study	**Phase I**
# of patients	N=21
Design	▪ Tecentriq plus anti-CD47
Primary endpoint	▪ Safety and efficacy
Status	▪ FPI Q4 2019
CT Identifier	NCT03922477

AML=acute myeloid leukemia

Venclexta

Novel small molecule Bcl-2 selective inhibitor – CLL

Indication	Untreated CLL patients with coexisting medical conditions	Relapsed or refractory CLL	Untreated fit CLL patients
Phase/study	**Phase III CLL14**	**Phase III MURANO**	**Phase III CristaLLo**
# of patients	N=432	N=391	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 + cyclophosphamide + Rituxan or bendamustine + 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 and ASH 2019 ▪ 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 and ASH 2019 ▪ 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

CLL=chronic lymphocytic leukemia; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology; RTOR=Real time oncology review; *NEJM*=New England Journal of Medicine; MRD=Minimal Residual Disease

Venclexta

Novel small molecule Bcl-2 selective inhibitor – MM

Indication	Relapsed or refractory multiple myeloma		
Phase/study	**Phase I**	**Phase Ib/II**	**Phase III CANOVA**
# of patients	N=166	N=120	N=244
Design	▪ **Dose escalation cohort:** Venclexta dose escalation ▪ **Safety expansion cohort (t11:14):** Venclexta expansion ▪ **Combination:** Venclexta plus dexamethasone	▪ Venclexta plus carfilzomib plus dexamethasone in t(11;14) positive r/r MM	▪ Venclexta plus dexamethazone vs pomalidomide plus dexamethasone in t(11;14) positive r/r MM
Primary endpoint	▪ Safety and maximum tolerated dose	▪ Safety, objective response rate, PK, PD	▪ Progression-free survival
Status	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016 and ASH 2016	▪ FPI Q1 2017	▪ FPI Q4 2018
CT Identifier	NCT01794520	NCT02899052	NCT03539744

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute;
MM=multiple myeloma; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Treatment-naïve AML not eligible for standard induction therapy	
Phase/study	**Phase III Viale-A**	**Phase III Viale-C**
# of patients	N=443	N=175
Design	▪ **ARM A:** Venclexta plus azacitidine ▪ **ARM B:** Azacitidine	▪ **ARM A:** Venclexta plus low-dose cytarabine ▪ **ARM B:** Low-dose cytarabine
Primary endpoint	▪ Overall survival and percentage of participants with complete remission	▪ Overall survival
Status	▪ FPI Q1 2017 ▪ Study met dual primary endpoints Q1 2020 ▪ Data presented at EHA 2020	▪ FPI Q2 2017 ▪ Study did not meet primary endpoint Q1 2020 ▪ Primary and additional 6 month overall survival data presented at ASCO 2020
	▪ Filed in US and EU Q2 2020	
CT Identifier	NCT02993523	NCT03069352

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
AML=acute myeloid leukemia

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Treatment-naïve AML not eligible for standard induction therapy	
Phase/study	**Phase Ib**	**Phase Ib/II**
# of patients	N=212	N=92
Design	▪ Venclexta (dose escalation) plus decitabine ▪ Venclexta (dose escalation) plus azacitidine ▪ Venclexta (dose escalation) plus decitabine plus posaconazole	▪ Venclexta (dose escalation) plus low-dose cytarabine
Primary endpoint	▪ Safety	▪ Safety, PK, PD and efficacy
Status	▪ FPI Q4 2014 ▪ Initial data presented at ASH 2015, updated data presented at ASCO 2016 and ASCO 2018 ▪ Breakthrough Therapy Designation granted by FDA Q1 2016 ▪ Data published in Blood. 2019 Jan 3;133(1):7-17	▪ FPI Q1 2015 ▪ Initial data presented at ASCO 2016, updated data presented at ASH 2016 and ASH 2017 ▪ Breakthrough Therapy Designation granted by FDA Q3 2017
	▪ Filed in US Q3 2018 ▪ US accelerated approval Q4 2018	
CT Identifier	NCT02203773	NCT02287233

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute;
AML=acute myeloid leukemia; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Relapsed or refractory AML	Relapsed or refractory hematological malignancies
Phase/study	**Phase I**	**Phase I**
# of patients	N=52	N=86
Design	▪ Venclexta in combination with gilteritinib	▪ Venclexta plus AMG176 dose escalation ▪ Dose expansion phase to confirm safety and preliminary RPTD
Primary endpoint	▪ Dose and composite complete remission (CRc) Rate	▪ Maximum tolerated dose and safety
Status	▪ FPI Q4 2018 ▪ Initial data presented at ASH 2019	▪ FPI Q2 2019 ▪ Study on clinical hold
CT Identifier	NCT03625505	NCT03797261

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute;
AML=acute myeloid leukemia; ASH=American Society of Hematology; RPTD =recommended phase II dose

Venclexta

Novel small molecule Bcl-2 selective inhibitor – MDS

Indication	Relapsed or refractory myelodysplastic syndromes	Treatment-naive myelodysplastic syndromes
Phase/study	**Phase Ib**	**Phase II**
# of patients	N=68	N=129
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	▪ **ARM A:** Venclexta 400 mg plus azacitidine ▪ **ARM B:** Venclexta 800 mg plus azacitidine ▪ **ARM C:** Azacitidine
Primary endpoint	▪ Safety, efficacy, PK and PD	▪ Overall response rate
Status	▪ FPI Q1 2017	▪ FPI Q1 2017 ▪ Data presented at ASH 2019
CT Identifier	NCT02966782	NCT02942290

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
MDS=myelodysplastic syndromes; ASH=American Society of Hematology

Venclexta

Novel small molecule Bcl-2 selective inhibitor – breast cancer

Indication	≥2L HR+ breast cancer
Phase/study	**Phase II** **VERONICA**
# of patients	N=100
Design	▪ **ARM A:** Venclexta plus fulvestrant ▪ **ARM B:** Fulvestrant
Primary endpoint	▪ Clinical benefit lasting equal or more than 24 weeks
Status	▪ FPI Q3 2018
CT Identifier	NCT03584009

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

Polivy (polatuzumab vedotin)

ADC targeting CD79b to treat B cell malignancies

Indication	Relapsed or refractory FL and DLBCL	1L DLBCL
Phase/study	**Phase Ib/II**	**Phase III POLARIX**
# of patients	N=329	N=875
Design	▪ **PIb:** Dose escalation ▪ **PhII:** Polatuzumab vedotin plus BR vs. BR ▪ **PhII expansion:** Polatuzumab vedotin plus Gazyva (non-randomized)	▪ **ARM A:** Polatuzumab vedotin plus R-CHP ▪ **ARM B:** R-CHOP
Primary endpoint	▪ Safety and response by PET/CT	▪ Progression-free survival
Status	▪ FPI Q4 2014 ▪ PRIME Designation (Q2 2017) and Breakthrough Therapy Designation (Q3 2017) granted for r/r DLBCL ▪ Pivotal randomized Ph2 in r/r DLBCL presented at ASH 2017 ▪ Filed in US and EU Q4 2018; US priority review granted Q1 2019 ▪ Approved in US Q2 2019 and in EU Jan 2020 ▪ Published in J Clin Oncol. 2020 Jan 10;38(2):155-165	▪ FPI Q4 2017 ▪ Recruitment completed Q2 2019
CT Identifier	NCT02257567	NCT03274492

In collaboration with Seattle Genetics

ADC=antibody–drug conjugate; DLBCL=diffuse large B cell lymphoma; FL=follicular lymphoma; r/r=relapsed or refractory; ASH=American Society of Hematology; BR=bendamustine and Rituxan; R-CHP=Rituxan, cyclophosphamide, hydroxydoxorubicin, prednisone; R-CHOP=Rituxan, cyclophosphamide, doxorubicin, vincristine, and prednisone

Polivy (polatuzumab vedotin)

ADC targeting CD79b to treat B cell malignancies

Indication	Relapsed or refractory FL or DLBCL	
Phase/study	**Phase I/II**	**Phase I/II**
# of patients	N=134	N=128
Design	▪ **Dose escalation cohort:** Polatuzumab vedotin plus Gazyva plus Venclexta[1] ▪ **Expansion cohort DLBCL:** Polatuzumab vedotin plus Rituxan plus Venclexta[1] ▪ **Expansion cohort FL:** Polatuzumab vedotin plus Gazyva plus Venclexta[1]	▪ **Dose escalation cohort:** Polatuzumab vedotin plus Gazyva plus lenalidomide ▪ **Expansion cohort DLBCL:** Polatuzumab vedotin plus Rituxan plus lenalidomide ▪ **Expansion cohort FL:** Polatuzumab vedotin plus Gazyva plus lenalidomide
Primary endpoint	▪ Percentage of participants with CR	▪ Percentage of participants with CR
Status	▪ FPI Q1 2016	▪ FPI Q1 2016 ▪ Interim data in FL presented at ASCO, EHA and ICML 2019 ▪ Primary data presented at ASH 2019
CT Identifier	NCT02611323	NCT02600897

In collaboration with Seattle Genetics; [1]Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
ADC=antibody–drug conjugate; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; CR=complete response; ASH=American Society of Hematology; EHA=European Hematology Association; ICML=International Conference on Malignant Lymphoma

Rozlytrek (entrectinib)

CNS-active and selective inhibitor of NTRK/ROS1

Indication	Locally Advanced or Metastatic tumors with ROS1 gene rearrangement	Locally Advanced or Metastatic tumors with NTRK1/2/3 gene rearrangement	Pediatric tumors with NTRK 1/2/3, ROS-1 or ALK rearrangement
Phase/study	**Phase II STARTRK2**	**Phase II STARTRK2**	**Phase I/Ib STARTRK - NG**
# of patients	N~300 total	N~300 total	N~80
Design	Single arm with Baskets based on tumor type and genomic alteration status	Single arm with Baskets based on tumor type and genomic alteration status	Single arm with Baskets based on tumor type and genomic alteration status
Primary endpoint	▪ Objective response rate	▪ Objective response rate	▪ Maximum tolerated dose (MTD) and recommended phase II dose (RP2D)
Status	▪ FPI Q1 2016 ▪ Data presented at WCLC 2018	▪ FPI Q1 2016 ▪ Data presented at ESMO 2018	▪ FPI Q2 2016 ▪ Initial data presented at ASCO 2019
	▪ Breakthrough Therapy Designation granted by FDA (Q2 2017), PRIME designation granted by EMA (Q1 2018) and Sakigake Designation granted by MHLW (Q4 2017) for NTRK fusion-positive, locally advanced or metastatic solid tumors ▪ Filed in US Q4 2018 and EU Q1 2019 ▪ Approved in US Q3 2019		
CT Identifier	NCT02568267	NCT02568267	NCT02650401

WCLC=World Conference on Lung Cancer; ESMO=European Society for Medical Oncology; ASCO=American Society of Clinical Oncology; NTRK=neurotrophic receptor tyrosine kinase; PRIME= priority medicines

Ocrevus (ocrelizumab, RG1594)

Humanized mAb 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:** Ocrelizumab 2x300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	120-week treatment period: ▪ **ARM A:** Ocrelizumab 2x300 mg 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 Expanded Disability Status Scale (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		▪ 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

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 mAb selectively targeting CD20+ B cells

Indication	**Relapsing and primary progressive multiple sclerosis (RMS & PPMS)**
Phase/study	**Phase IIIb** **ENSEMBLE PLUS**
# of patients	N ~ 700
Design	▪ Substudy of ongoing phase IIIb, open-label, single-arm ENSEMBLE study ▪ Shorter two-hour infusion time
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)
Status	▪ Filed in US and EU Q1 2020 ▪ Approved in EU Q2 2020 ▪ Data published Neurol, Neuroimmunol and Neuroinflamm Sept 2020; 7(5), e807, publication available since June 2020
CT Identifier	NCT03085810

Gazyva (obinutuzumab)

Immunology development program

Indication	Lupus nephritis	
Phase/study	**Phase II** **NOBILITY**	**Phase III** **REGENCY**
# of patients	N=120	N=252
Design	▪ **ARM A:** Obinutuzumab 1000mg IV plus mycophenolate mofetil / mycophenolic acid ▪ **ARM B:** Placebo IV plus mycophenolate mofetil / mycophenolic acid	▪ **ARM A:** Obinutuzumab 1000 mg IV (six doses through Week 52) plus mycophenolate mofetil ▪ **ARM B:** Obinutuzumab 1000 mg IV (five doses through Week 52) plus mycophenolate mofetil ▪ **ARM C:** Placebo IV plus mycophenolate mofetil
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of participants who achieve complete renal response (CRR)
Status	▪ Recruitment completed Q4 2017 ▪ Primary endpoint met Q2 2019 ▪ Breakthrough therapy designation granted by the FDA Q3 2019 ▪ Data presented at ASN and ACR 2019	▪ FPI expected Q3 2020
CT Identifier	NCT02550652	NCT04221477

In collaboration with Biogen
ASN=American Society of Nephrology; ACR=American College of Rheumatology

Actemra/RoActemra (RG-1569)

Interleukin 6 receptor inhibitor

Indication	Adult hospitalised with severe COVID-19 pneumonia	
Phase/study	**Phase III COVACTA[1]**	**Phase III REMDACTA[2]**
# of patients	N=450	N=450
Design	▪ **Arm A:** tocilizumab plus standard of care ▪ **Arm B:** placebo plus standard of care	▪ **Arm A:** remdesivir plus tocilizumab ▪ **Arm B:** remdesivir plus placebo
Primary endpoint	▪ Clinical status assessed using 7-Category Ordinal Scale (Day 28)	▪ Clinical status assessed using 7-Category Ordinal Scale (Day 28)
Status	▪ FPI Q1 2020 ▪ LPI Q2 2020	▪ FPI Q2 2020
CT Identifier	NCT04320615	NCT04409262

[1]In collaboration with BARDA; [2]In collaboration with Gilead Sciences, Inc.
BARDA=Biomedical Advanced Research and Development Authority

Actemra/RoActemra (RG-1569)

Interleukin 6 receptor inhibitor

Indication	Adult hospitalised with severe COVID-19 pneumonia	
Phase/study	**Phase II MARIPOSA**	**Phase III EMPACTA**
# of patients	N=100	N=379
Design	▪ **Arm A:** 8 mg/kg tocilizumab plus standard of care ▪ **Arm B:** 4mg/kg tocilizumab 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:** tocilizumab 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 ▪ LPI Q2 2020	▪ FPI Q2 2020
CT Identifier	NCT04363736	NCT04372186

Xolair

Humanized mAb that selectively binds to IgE

Indication	Chronic rhinosinusitis with nasal polyps		Food allergy
Phase/study	**Phase III POLYP 1**	**Phase III POLYP 2**	**Phase III OUtMATCH[1]**
# of patients	N=138	N=127	N=225
Design	Adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had an inadequate response to SOC: ▪ **ARM A:** Xolair every 2 wks or every 4 wks ▪ **ARM B:** Placebo	Adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had an inadequate response to SOC: ▪ **ARM A:** Xolair every 2 wks or every 4 wks ▪ **ARM B:** Placebo	▪ Xolair by subcutaneous injection either every 2 weeks or every 4 weeks for 16 to 20 weeks
Primary endpoint	▪ Change from baseline in average daily nasal congestion score (NCS) at week 24 ▪ Change from baseline in nasal polyp score (NPS) to week 24	▪ Change from baseline in average daily nasal congestion score (NCS) at week 24 ▪ Change from baseline in nasal polyp score (NPS) to week 24	▪ Number of participants who successfully consume ≥600 mg of peanut protein without dose-limiting symptoms
Status	▪ FPI Q4 2017 ▪ Recruitment completed Q3 2018 ▪ Co-primary endpoints met Q2 2019	▪ FPI Q4 2017 ▪ Recruitment completed Q3 2018 ▪ Co-primary endpoints met Q2 2019	▪ FPI July 2019
	Filed in US Q4 2019		
CT Identifier	NCT03280550	NCT03280537	NCT03881696

In collaboration with Novartis; [1] Sponsor of the study is the National Institute of Allergy and Infectious Diseases (NIAID)

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza	
Phase/study	**Phase III CAPSTONE-1**	**Phase III CAPSTONE-2**
# of patients	N=1,436	N=2,184
Design	▪ Randomized, double-blind study of a single dose of Xofluza compared with placebo or Tamiflu 75 mg twice daily for 5 days in otherwise healthy patients with influenza	▪ Randomized, double-blind study of a single dose of Xofluza compared with placebo or Tamiflu 75 mg twice daily for 5 days in patients with influenza at high risk of influenza complications
Primary endpoint	▪ Time to alleviation of symptoms	▪ Time to improvement of influenza symptoms
Status	▪ FPI Q4 2016, recruitment completed Q1 2017 ▪ Primary endpoint met Q3 2017 ▪ Filed in US Q2 2018 (priority review), approval Q4 2018 ▪ Data published in *NEJM* 2018; 379:913-923 ▪ Filed in EU Q4 2019	▪ FPI Q1 2017, recruitment completed Q1 2018 ▪ Primary endpoint met Q3 2018 ▪ Data presented at IDweek 2018 ▪ Filed in US Q1 2019, approval Q4 2019 ▪ Filed in EU Q4 2019 ▪ Data published in Lancet Infectious Diseases 2020 Jun 8;S1473-3099(20)30004-9
CT Identifier	NCT02954354	NCT02949011

In collaboration with Shionogi & Co., Ltd.
NEJM=New England Journal of Medicine

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza		
Phase/study	**Phase III** **FLAGSTONE (hospitalised patients)**	**Phase III** **miniSTONE 1 (0-1 year old)**	**Phase III** **miniSTONE 2 (1-12 years old)**
# of patients	N=366	N=30	N=176
Design	▪ Xofluza + neuraminidase inhibitor vs placebo + neuraminidase inhibitor in hospitalized patients with influenza	▪ Xofluza on Day 1 (based on body weight and age) in healthy pediatric patients from birth to <1 year with influenza-like symptoms	▪ Xofluza vs Tamiflu in healthy pediatric patients 1 to <12 years of age with influenza-like symptoms
Primary endpoint	▪ Time to clinical improvement	▪ Safety	▪ Safety
Status	▪ FPI Jan 2019 ▪ Recruitment completed Q1 2020	▪ FPI Q1 2019	▪ FPI Q4 2018 ▪ Recruitment completed 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
CT Identifier	NCT03684044	NCT03653364	NCT03629184

In collaboration with Shionogi & Co., Ltd.

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza	
Phase/study	**Phase III** **BLOCKSTONE**	**Phase IIIb** **CENTERSTONE**
# of patients	N= 752	N= 3,160
Design	▪ Post exposure prophylaxis to prevent disease onset in household contacts. Used after known exposure to infected person. ▪ Patients treated with Xofluza vs placebo	▪ Reduction of direct transmission of influenza from otherwise healthy patients to household contacts ▪ Patients treated with Xofluza vs placebo
Primary endpoint	▪ Percentage of household contacts who developed clinical influenza	▪ Percentage of household contacts who are PCR-positive for influenza by day 5 post randomization of index patients
Status	▪ Study met primary endpoint Q2 2019 ▪ Data presented at OPTIONS X 2019 ▪ Filed in US Q1 2020 ▪ Data published in *NEJM* 2020 Jul 8. doi:10.1056/NEJMoa1915341	▪ FPI Q4 2019
CT Identifier	JapicCTI-184180	NCT03969212

In collaboration with Shionogi & Co., Ltd.
PCR=Polymerase chain reaction; NEJM=New England Journal of Medicine

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group HY 2020 results

Diagnostics

Foreign exchange rate information

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L castration-resistant prostate cancer	Advanced prostate cancer and solid tumors
Phase/study	**Phase III** **IPATential150**	**Phase Ib**
# of patients	N=1,100	N=54
Design	▪ **ARM A:** Ipatasertib plus abiraterone ▪ **ARM B:** Placebo plus abiraterone	▪ Ipatasertib plus rucaparib **Stage 1**: Dose escalation in advanced breast, ovarian and prostate cancer ▪ **Stage 2:** Dose expansion in prostate cancer
Primary endpoint	▪ Radiographic progression-free survival (rPFS) in patients with PTEN loss tumors and overall population	▪ Safety and efficacy
Status	▪ FPI Q2 2017 ▪ Recruitment completed Jan 2019 ▪ Study met co-primary endpoint in rPFS in patients with PTEN loss tumors	▪ FPI Q2 2019
CT Identifier	NCT03072238	NCT03840200

In collaboration with Array BioPharma

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L TNBC and HR+ breast cancer	1L TNBC	TNBC
Phase/study	**Phase III** **IPATunity130**	**Phase II** **LOTUS**	**Phase Ib**
# of patients	N=450	N=120	N=202
Design	**Cohort A:** Dx+ 1L TNBC (N=249): ▪ **ARM A:** Ipatasertib+paclitaxel ▪ **ARM B:** Placebo+paclitaxel **Cohort B:** Dx+ HR+ mBC (N=201): ▪ **ARM A:** Ipatasertib+paclitaxel ▪ **ARM B:** Placebo+paclitaxel	▪ ARM A: Ipatasertib+paclitaxel ▪ ARM B: Placebo+paclitaxel	▪ ARM A: Ipatasertib+Tecentriq +paclitaxel ▪ ARM B: Ipatasertib+Tecentriq+nab-paclitaxel
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Safety and efficacy
Status	▪ FPI Q1 2018 ▪ Recruitment cohort B completed Q1 2019 and cohort A Q1 2020	▪ Recruitment completed Q1 2016 ▪ Data presented at ASCO 2017 and ASCO 2018 ▪ Data published in Lancet Oncology 2017 Aug 8. pii: S1470-2045(17)30450-3	▪ FPI Q1 2018 ▪ Data presented at AACR 2019
CT Identifier	NCT03337724	NCT02162719	NCT03800836

In collaboration with Array BioPharma

TNBC=triple-negative breast cancer; ASCO=American Society of Clinical Oncology; AACR=American Association for Cancer Research

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L HR+ mBC	1L TNBC
Phase/study	**Phase Ib/III** **IPATunity150**	**Phase III** **IPATunity170**
# of patients	N=370	N=1,155
Design	▪ **ARM A:** Ipatasertib plus fulvestrant and palbociclib ▪ **ARM B:** Placebo plus fulvestrant and palbociclib	Ipatasertib plus Tecentriq plus paclitaxel: ▪ **ARM A:** PD-L1 negative ▪ **ARM B:** PD-L1 positive
Primary endpoint	▪ Progression free survival in ITT and in patients with PIK3CA/AKT1/PTEN altered tumors	▪ Progression free survival and overall survival
Status	▪ FPI Q4 2019 in Phase Ib part	▪ FPI Q4 2019
CT Identifier	NCT04060862	NCT04177108

In collaboration with Array BioPharma

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	1L NSCLC PD-L1 TPS>50%	1L ES-SCLC	Metastatic and/or recurrent PD-L1+ cervical cancer
Phase/study	**Phase III SKYSCRAPER-01**	**Phase III SKYSCRAPER-02**	**Phase II SKYSCRAPER-04**
# of patients	N=500	N=424	N=160
Design	▪ **Arm A:** Tiragolumab +Tecentriq ▪ **Arm B:** Placebo +Tecentriq	▪ **Arm A:** Tiragolumab + Tecentriq +carboplatin +etoposide ▪ **Arm B:** Placebo +Tecentriq +carboplatin +etoposide	▪ **Arm A:** Tiragolumab + Tecentriq ▪ **Arm B:** Tecentriq
Primary endpoint	▪ Overall survival and progression free survival	▪ Overall survival and progression free survival	▪ Objective Response Rate (ORR)
Status	▪ FPI Q1 2020	▪ FPI Q1 2020	▪ FPI Q2 2020
CT Identifier	NCT04294810	NCT04256421	NCT04300647

NSCLC=Non-small cell lung cancer; r/r=Relapsed refractory; NHL=Non-Hodgkin's lymphoma

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	Solid tumors	NSCLC	R/R Multiple Myeloma (MM) or R/R B-cell NHL
Phase/study	**Phase I**	**Phase II CITYSCAPE**	**Phase I**
# of patients	N=400	N=135	N=52
Design	▪ **Phase Ia:** Dose escalation and expansion of tiragolumab ▪ **Phase Ib:** Dose escalation and expansion Tecentriq plus tiragolumab ▪ **Phase Ib:** Chemo combinations with tiragolumab (cis, carbo, pem, pac, etoposide)	▪ **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	▪ FPI Q2 2019
CT Identifier	NCT02794571	NCT03563716	NCT04045028

NSCLC=Non-small cell lung cancer; r/r=Relapsed refractory; NHL=Non-Hodgkin's lymphoma; ASCO=American Society of Clinical Oncology; AACR=American Association for Cancer Research

Glofitamab (CD20-TCB, RG6026)

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

Indication	Relapsed or refractory Non-Hodgkin's lymphoma		Non-Hodgkin's lymphoma
Phase/study	**Phase I**	**Phase Ib**	**Phase Ib**
# of patients	N=700	N=140	Part I: 15-60 Part II: ~66-104
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 + Gazyva (i.e. continuous treatment with Gazyva)	Dose escalation and expansion ▪ **Arm A:** glofitamab + Tecentriq ▪ **Arm B:** glofitamab + Polivy	▪ **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
Primary endpoint	▪ Safety	▪ Safety	▪ Safety
Status	▪ FPI Q1 2017 ▪ Data presented at ASH 2018, ICML 2019, ASH 2019	▪ FPI Q2 2018 ▪ Data presented at ASH 2019	▪ FPI Q1 2018
CT Identifier	NCT03075696	NCT03533283	NCT03467373

DLBCL=diffuse large B cell lymphoma; FL=Follicular lymphoma; ASH=American Society of Hematology; ICML=International Conference on Malignant Lymphoma; CHOP=cyclophosphamide, doxorubicin, vincristine and prednisone; R=Rituxan/MabThera; G=Gazyva

Glofitamab (CD20-TCB, RG6026)

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

Indication	Relapsed/refractory DLBCL and High-Grade Large B-Cell Lymphoma	Relapsed/refractory DLBCL
Phase/study	**Phase Ib**	**Phase III**
# of patients	N=20	N=270
Design	▪ Glofitamab plus gemcitabine and oxaliplatin, followed by up to 4 cycles of glofitamab monotherapy ▪ A single dose of obinutuzumab will be administered 7 days prior to the first dose of glofitamab	▪ **Arm A:** glofitamab plus gemcitabine and oxaliplatin, followed by up to 4 cycles of glofitamab monotherapy ▪ **Arm B:** Rituxan in combination with gemcitabine and oxaliplatin A single dose of obinutuzumab will be administered 7 days prior to the first dose of glofitamab
Primary endpoint	▪ Safety	▪ Overall survival
Status	▪ FPI Q2 2020	▪ FPI expected H2 2020
CT Identifier	NCT04313608	NCT04408638

PI3K alpha inhibitor (RG6114, GDC-0077)

A potent, orally available, and selective PI3Kα inhibitor

Indication	PIK3CA-mutant HR+ mBC	PIK3CA mutant solid tumors and metastatic ER+ HER2-neg breast cancer
Phase/study	**Phase III INAVO120**	**Phase I**
# of patients	N=400	N=156
Design	▪ **Arm A:** GDC-0077 plus palbociclib plus fulvestrant ▪ **Arm B:** Placebo plus palbociclib plus fulvestrant	Monotherapy and in combination with SoC (letrozole; letrozole plus palbociclib; fulvestrant) ▪ **Stage 1:** Dose escalation ▪ **Stage 2:** Expansion
Primary endpoint	▪ Progression-free survival	▪ Safety, tolerability and PK
Status	▪ FPI Q1 2020	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017 ▪ Data presented at SABCS 2019
CT Identifier	NCT04191499	NCT03006172

AACR=American Association for Cancer Research; SABCS=San Antonio Breast Cancer Symposium

Crenezumab (RG7412)

Humanized mAb targeting all forms of Aβ

Indication	Alzheimer's Prevention Initiative (API) Colombia
Phase/study	**Phase II** Cognition study
# of patients	N=252
Design	▪ **ARM A:** PSEN1 E280A mutation carriers recieve crenezumab SC ▪ **ARM B:** PSEN1 E280A mutation carriers receive placebo ▪ **ARM C:** non-mutation carriers receive placebo
Primary endpoint	▪ Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score
Status	▪ FPI Q4 2013 ▪ Recruitment completed Q1 2017
CT Identifier	NCT01998841

In collaboration with AC Immune
Aβ=amyloid-beta

Gantenerumab (RG1450)

Fully human mAb binding aggregated forms of Aβ

Indication	Prodromal to mild Alzheimer's disease	
Phase/study	**Phase III GRADUATE 1**	**Phase III GRADUATE 2**
# of patients	N=1,016	N=1,016
Design	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo
Primary endpoint	▪ Change in CDR-SOB at 27 months	▪ Change in CDR-SOB at 27 months
Status	▪ FPI Q2 2018 ▪ Recruitment completed Q2 2020	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2020
CT Identifier	NCT03443973	NCT03444870

In collaboration with MorphoSys AG

Aβ=amyloid-beta; CDR-SOB=Clinical Dementia Rating Scale Sum of Boxes

Gantenerumab (RG1450)

Fully human mAb binding aggregated forms of Aβ

Indication	Prodromal Alzheimer's disease	Mild Alzheimer's disease
Phase/study	**Phase II/III** **SCarlet RoAD**	**Phase III** **Marguerite RoAD**
# of patients	N=799	N=389
Design	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab (225 mg) ▪ **ARM B:** Gantenerumab (105 mg) ▪ **ARM C:** Placebo	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab ▪ **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)
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 ▪ OLE data presented at CTAD 2017, AD/PD and AAN 2018 and 2019	▪ FPI Q1 2014 ▪ Recruitment stopped Q4 2015 ▪ FPI Q1 2016 for open label extension ▪ OLE data (MRI) presented at CTAD 2017, AD/PD, AAIC 2018 and AAN 2018 and 2019
CT Identifier	NCT01224106	NCT02051608

In collaboration with MorphoSys AG

Aβ=amyloid-beta; CDR-SOB=Clinical Dementia Rating Scale Sum of Boxes; PET= positron emission tomography; ADAS-cog=Alzheimer's Disease Assessment Scale cognitive subscale; AAIC=Alzheimer's Association International Conference; CTAD=Clinical Trials on Alzheimer's Disease; AD/PD=Alzheimer's & Parkinson's Diseases Congress; AAN=American Academy of Neurology; MRI=Magnetic resonance imaging

Risdiplam (RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy		
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 spinal muscular atrophy: ▪ **Part 1 (dose-finding):** At least 4 weeks ▪ **Part 2 (confirmatory):** 24 months	Randomized, double-blind, placebo-controlled study in adult and pediatric patients with type 2 or type 3 spinal muscular atrophy: ▪ **Part 1 (dose-finding):** At least 12 weeks ▪ **Part 2 (confirmatory):** 24 months	▪ Open-label single arm study adult and pediatric patients (0.5-60 years) 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 and PK/PD
Status	▪ Recruitment completed for part 2 Q4 2018 ▪ 12 month data from Part 1 presented at AAN, CureSMA and EAN 2019; 16 month data presented at WMS 2019 ▪ Study met primary endpoint in part 2 Jan 2020 ▪ Part 2 data presented at AAN 2020	▪ Recruitment completed for part 2 Q3 2018 ▪ 12 month data from Part 1 presented at AAN, CureSMA and EAN 2019; 16 month data presented at WMS 2019 ▪ Study met primary endpoint in part 2 Q4 2019 ▪ Part 2 Data presented at SMA Europe 2020	▪ FPI Q1 2017 ▪ Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, WMS 2019 and CureSMA2020 ▪ Recruitment completed Q1 2020
	Orphan drug designation granted by FDA Q1 2017 and EU Q1 2019, PRIME designation in Q4 2018, filed in US Q4 2019		
CT Identifier	NCT02913482	NCT02908685	NCT03032172

In collaboration with PTC Therapeutics and SMA Foundation

AAN=American Academy of Neurology; WMS=World Muscle Society; EAN=European Academy of Neurology; PRIME=priority medicines

Risdiplam (RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy
Phase/study	**Phase II** **RAINBOWFISH**
# of patients	N=25
Design	Open-label, single-arm, multicenter study in infants aged from birth to 6 weeks who have been genetically diagnosed with SMA but are not yet presenting with symptoms
Primary endpoint	▪ Proportion who are sitting without support after 12 months of treatment
Status	▪ FPI Q3 2019
CT Identifier	NCT03779334

In collaboration with PTC Therapeutics and SMA Foundation

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 RG6042 administered intrathecally to adult patients with early manifest Huntington's Disease	▪ Patients from phase I are enrolled into OLE
Primary endpoint	▪ Safety, tolerability, PK and PD	▪ Longer term safety, tolerability, 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

cUHDRS = composite Unified Huntington's Disease Rating Scale; TFC = total function capacity; AAN=American Academy of Neurology; *NEJM=New England Journal of Medicine*

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=1050
Design	▪ **ARM A:** RG6042 120mg bimonthly ▪ **ARM B:** RG6042 120mg every four months ▪ **ARM C:** Placebo bimonthly	Open-Label Extension study in patients participating in prior Roche and Genentech sponsored studies ▪ **Arm A:** RG6042 120mg bimonthly ▪ **Arm B:** RG6042 120mg every four months
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	▪ FPI April 2019
CT Identifier	NCT03761849	NCT03842969

In collaboration with Ionis Pharmaceuticals
cUHDRS = composite Unified Huntington's Disease Rating Scale; TFC = total function capacity

Satralizumab (RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Neuromyelitis optica spectrum disorder (NMOSD)	
Phase/study	**Phase III Sakura Star**	**Phase III Sakura Sky**
# of patients	N=90	N=70 (adults); N=6 (adolescents)
Design	Satralizumab as monotherapy: ▪ **Group A:** Satralizumab 120mg SC monthly ▪ **Group B:** Placebo SC monthly	Add-on therapy of satralizumab: ▪ **Group A:** Satralizumab 120mg SC monthly ▪ **Group B:** Placebo SC Both arms on top of baseline therapies: azathioprine, mycophenolate mofetil or oral corticosteroids
Primary endpoint	▪Efficacy (time to first relapse) and safety, PD, PK	▪ Efficacy (time to first relapse) and safety, PD, PK
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 Q4 2018 ▪ Filed in EU Q3 2019; US acceptance of filing Q4 2019	
CT Identifier	NCT02073279	NCT02028884

*Trials managed by Chugai (Roche opted-in)

ECTRIMS=European Committee for Treatment and Research in Multiple Sclerosis; AAN=American Academy of Neurology; *NEJM=New England Journal of Medicine*

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

Indication	Ulcerative colitis patients who are TNF-naïve		
Phase/study	**Phase III** **HIBISCUS I** Induction study	**Phase III** **HIBISCUS II** Induction study	**Phase III** **GARDENIA** Sustained remission study
# of patients	N=358	N=358	N=390
Design	▪ **ARM A:** Etrolizumab 105mg SC q4w plus adalimumab placebo SC ▪ **ARM B:** Etrolizumab placebo SC plus adalimumab SC ▪ **ARM C:** Etrolizumab placebo SC plus adalimumab placebo SC	▪ **ARM A:** Etrolizumab 105mg SC q4w plus adalimumab placebo SC ▪ **ARM B:** Etrolizumab placebo SC plus adalimumab SC ▪ **ARM C:** Etrolizumab placebo SC plus adalimumab placebo SC	Time on treatment 54 weeks: ▪ **ARM A:** Etrolizumab 105mg SC q4w plus placebo IV ▪ **ARM B:** Placebo SC q4w plus infliximab IV
Primary endpoint	▪ Induction of remission compared with placebo as determined by the Mayo Clinic Score (MCS) at week 10	▪ Induction of remission compared with placebo as determined by the Mayo Clinic Score (MCS) at week 10	▪ Proportion of patients in sustained clinical remission as determined by Mayo Clinic Score (MCS) at weeks 10, 30 and 54
Status	▪ FPI Q4 2014 ▪ Recruitment completed Q4 2019	▪ FPI Q4 2014 ▪ Recruitment completed Q4 2019	▪ FPI Q4 2014 ▪ Recruitment completed Q2 2019
CT Identifier	NCT02163759	NCT02171429	NCT02136069

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

Indication	Ulcerative colitis patients who are TNF-naïve and refractory or intolerant to immunosuppressant and/or corticosteroid treatment	Ulcerative colitis patients who are refractory or intolerant of TNF inhibitors	Moderate to severe ulcerative colitis patients
Phase/study	**Phase III** **LAUREL** Maintenance study	**Phase III** **HICKORY** Induction and maintenance study	**Phase III** **COTTONWOOD** Open label extension study
# of patients	N=359	N=609	N=2,100
Design	Induction phase: ▪ **ARM A:** Open label etrolizumab 105mg SC q4w Maintenance study: ▪ **ARM B:** Etrolizumab 105mg SC q4w ▪ **ARM C:** Placebo	Cohort 1 (open-label): ▪ **ARM A:** Etrolizumab induction + placebo maintenance ▪ **ARM B:** Etrolizumab induction + maintenance Cohort 2 (blinded): ▪ **ARM A:** Etrolizumab induction + maintenance ▪ **ARM B:** Placebo induction + maintenance	▪ Patients who were previously enrolled in etrolizumab phase II and phase III studies and meet recruitment criteria will receive etrolizumab 105 SC q4w
Primary endpoint	▪ Maintenance of remission (at week 62) among randomized patients in remission at Week 10 as determined by the Mayo Clinic Score (MCS)	▪ Clinical Remission (Mayo Clinic Score, MCS) at Week 14 ▪ Remission maintenance (by MCS, at Week 66) among patients with remission at Week 14	▪ Long-term efficacy as determined by partial Mayo Clinic Score (pMCS), incidence of adverse events
Status	▪ FPI Q3 2014 ▪ Recruitment completed Q1 2019	▪ FPI Q2 2014 ▪ First data presented at ECCO 2017 ▪ Open label induction and endoscopy data presented at UEGW 2017 ▪ Recruitment completed Q1 2019	▪ FPI Q3 2014
CT Identifier	NCT02165215	NCT02100696	NCT02118584

ECCO=European Crohn's and Colitis Organisation; UEGW=United European Gastroenterology Week

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

Indication	Moderately to severely active Crohn's disease	Moderately to severely active Crohn's disease
Phase/study	**Phase III** **BERGAMOT** Induction and maintenance study	**Phase III** **JUNIPER** Open label extension study for BERGAMOT
# of patients	N=1,150	N=900
Design	▪ **ARM A:** Etrolizumab SC 210 mg (induction only) ▪ **ARM B:** Etrolizumab SC 105 mg and maintenance ▪ **ARM C:** Placebo	▪ Etrolizumab SC 105mg q4w
Primary endpoint	▪ Induction and maintenance of clinical remission	▪ Safety
Status	▪ FPI Q1 2015 ▪ Cohort 1 data presented at UEGW 2017	▪ FPI Q2 2015
CT Identifier	NCT02394028	NCT02403323

UEGW=United European Gastroenterology Week

Crovalimab (RG6107; SKY59)

A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH)
Phase/study	**Phase I/II** **COMPOSER**
# of patients	N=44
Design	Healthy volunteers and treatment naïve and pretreated patients with PNH: ▪ **Part 1:** single ascending dose study in healthy subjects ▪ **Part 2:** intra-patient single ascending dose study in PNH patients ▪ **Part 3:** Multiple-dose study in PNH patients ▪ **Part 4:** Dose confirmation in PNH patients
Primary endpoint	▪ Safety, PK, PD
Status	▪ Part 1: FPI Q4 2016 ▪ Part 2/3: FPI Q2 2017 ▪ Part 4: FPI Q2 2019 ▪ Nonclinical data published in Scientific Reports 2017 Apr; 7(1):1080 ▪ Data presented for Part 2 and 3 at ASH 2018 and 2019
CT Identifier	NCT03157635

In collaboration with Chugai
ASH=American Society of Hematology

RG6354 (PRM-151)

Recombinant human innate immunity protein pentraxin-2

Indication	Idiopathic pulmonary fibrosis (IPF)	Myelofibrosis
Phase/study	**Phase II**	**Phase II**
# of patients	N=117	N=98
Design	▪ Randomized, double-blind, placebo-controlled trial: 4-week screening period, 24-week randomized treatment period, 4-week follow-up visit (week 28) ▪ RG6354 at days 1, 3 and 5 then every 4 weeks vs placebo	▪ Multiple dose study of RG6354
Primary endpoint	▪ Least-squares mean change in forced vital capacity (FVC) percentage of predicted value from baseline to week 28	▪ Bone marrow response rate
Status	▪ Study met its primary endpoint ▪ Data published in JAMA 2018;319(22):2299-2307	▪ Ongoing
CT Identifier	NCT02550873	NCT01981850

JAMA=Journal of the American Medical Association

Faricimab (RG7716)

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

Indication	Neovascular age related macular degeneration (nAMD)		Center-involving diabetic macular edema (CI-DME)
Phase/study	**Phase II AVENUE**	**Phase II STAIRWAY**	**Phase II BOULEVARD**
# of patients	N=271	N=75	N=210
Design	▪ **ARM A:** SoC (Lucentis), q4w ▪ **ARM B:** 1.5 mg faricimab, q4w ▪ **ARM C:** 6mg faricimab, q4w ▪ **ARM D:** 6mg faricimab, q4w / q8w ▪ **ARM E:** SoC q4w x 3 doses, switch group to 6 mg faricimab q4w	▪ **ARM A:** SoC (Lucentis), q4w ▪ **ARM B:** 6mg faricimab, q>8w (short interval duration) ▪ **ARM C:** 6mg faricimab, q>8w (long interval duration)	▪ **ARM A:** SoC (Lucentis), 0.3 mg q4w ▪ **ARM B:** 1.5mg faricimab, q4w ▪ **ARM C:** 6mg faricimab, q4w
Primary endpoint	▪ Change from baseline BCVA after 32 weeks	▪ Change from baseline BCVA at Week 40	▪ Mean change from baseline BCVA at week 24
Status	▪ FPI Q3 2015 ▪ Recruitment completed Q1 2017 ▪ Data presented at Retina Society 2018	▪ FPI Q1 2017 ▪ Recruitment completed Q1 2017 ▪ Data presented at Retina Society 2018 (24 week data) and AAO 2018 (full data)	▪ FPI Q2 2016 ▪ Recruitment completed Q1 2017 ▪ Data presented at Angiogenesis 2018 and Retina Society 2018 ▪ Data published in Ophthalmology. 2019 Aug;126(8):1155-1170
CT Identifier	NCT02484690	NCT03038880	NCT02699450

BCVA=best corrected visual acuity; SoC=standard of care; AAO=American Academy of Ophthalmology

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=900	N=900
Design	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab (RG7716) q8w/PTI ▪ **ARM C:** Aflibercept, q8w	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab (RG7716) q8w/PTI ▪ **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	▪ FPI Oct 2018 ▪ Recruitment completed Q3 2019
CT Identifier	NCT03622580	NCT03622593

PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity

Faricimab (RG7716)

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

Indication	Neovascular age related macular degeneration (nAMD)	
Phase/study	**Phase III TENAYA**	**Phase III LUCERNE**
# of patients	N=640	N=640
Design	▪ **ARM A:** Faricimab 6.0mg Q16 flex after 4 initiating doses (IDs) ▪ **ARM B:** Aflibercept 2.0mg Q8 after 3 IDs	▪ **ARM A:** Faricimab 6.0mg Q16 flex after 4 initiating doses (IDs) ▪ **ARM B:** Aflibercept 2.0mg Q8 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	▪ FPI Q1 2019 ▪ Recruitment completed Q4 2019
CT Identifier	NCT03823287	NCT03823300

BCVA=best corrected visual acuity

Port Delivery System with ranibizumab

First eye implant to achieve sustained delivery of a biologic medicine

Indication	wAMD		DME
Phase/study	**Phase III Archway**	**Phase II+III extension Portal**	**Phase III Pagoda**
# of patients	N=418	N=500	N=545
Design	▪ **ARM A:** PDS with ranibizumab every 24 weeks ▪ **ARM B:** Intravitreal ranibizumab every 4 weeks	▪ Patients from LADDER or Archway will receive refills of 100 mg/mL ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)	▪ **ARM A:** PDS with ranibizumab every 24 weeks ▪ **ARM B:** Intravitreal ranibizumab every 4 weeks
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 at the average of week 48 and week 52
Status	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2019 ▪ Study met primary endpoint Q2 2020	▪ FPI Q3 2018	▪ FPI Q3 2019
CT Identifier	NCT03677934	NCT03683251	NCT04108156

BCVA=best corrected visual acuity; wAMD=wet age-related macular degeneration

Roche pRED

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group HY 2020 results

Diagnostics

Foreign exchange rate information

Oncology development programs

Antibody fusion proteins

Molecule	simlukafusp alfa (FAP-IL2v FP, RG7461)	
Indication	**Solid tumors**	**Solid tumors**
Phase/study	**Phase I**	**Phase Ib**
# of patients	N=60	N=360
Design	▪ **Part A:** Dose escalation study (monotherapy) ▪ **Part B:** Dose escalation and extension in combination with trastuzumab (HER2+ breast cancer) ▪ **Part C:** Dose escalation and extension in combination with cetuximab (head & neck cancer)	Open-label multicenter basket study of FAP-IL2v plus Tecentriq in CPI-naïve and/or CPI–experienced NSCLC, HNSCC, cervical cancer and esophageal cancer
Primary endpoint	▪ Safety, PK/PD and efficacy (Part B/C only)	▪ Safety, PD and efficacy
Status	▪ FPI Q4 2015 ▪ FPI Part B/C Q4 2017	▪ FPI Q1 2018
CT Identifier	NCT02627274	NCT03386721

FP= Fusion protein; HNSCC=head and neck squamous cell carcinoma; NSCLC=non-small cell lung cancer; CPI=checkpoint inhibitor

Oncology development programs

Antibody fusion proteins

Molecule	simlukafusp alfa (FAP-IL2v FP, RG7461)	
Indication	**1L Renal call carcinoma**	**1L/2L+ melanoma**
Phase/study	**Phase Ib**	**Phase I**
# of patients	N=110	N=150
Design	**Part I:** Dose escalation ▪ **ARM A:** FAP-IL2v plus Tecentriq ▪ **ARM B:** FAP-IL2v plus Tecentriq plus Avastin **Part II:** Dose expansion ▪ **ARM A:** FAP-IL2v plus Tecentriq ▪ **ARM B:** FAP-IL2v plus Tecentriq plus Avastin	▪ **Part 1:** FAP-IL2v plus pembrolizumab safety run in ▪ **Part 2:** FAP-IL2v plus pembrolizumab expansion cohort
Primary endpoint	▪ Safety, PD and efficacy	▪ Safety
Status	▪ FPI Q1 2017	▪ FPI Q2 2019
CT Identifier	NCT03063762	NCT03875079

FP= Fusion protein

Oncology development programs

Antibody fusion proteins

Molecule	FAP-4-1BBL FP (RG7827)	CD19-4-1BBL (RG6076)
Indication	Solid tumors	Relapsed or refractory B cell non-Hodgkin's lymphoma
Phase/study	Phase I	Phase I
# of patients	N=200	N=207
Design	▪ **Part 1:** Single agent dose escalation ▪ **Part 2:** Combo dose escalation with Tecentriq ▪ **Part 3:** Combo expansion with Tecentriq	▪ **Part 1**: Dose-escalation in combination with Gazyva ▪ **Part 2**: Dose-escalation in combination with CD20-TCB
Primary endpoint	▪ Safety, efficacy, PK and PD	▪ Safety, PK/PD and efficacy
Status	▪ FPI Q2 2018	▪ FPI Q3 2019
CT Identifier		NCT04077723

FP=antibody fusion protein

Oncology development programs

Antibody fusion proteins

Molecule	**PD1-IL2v** (RG6279)
Indication	**Solid tumors**
Phase/study	**Phase I**
# of patients	N=440
Design	▪ **Part 1:** Dose-escalation (iv and sc) of RG6279 as a single agent ▪ **Part 2:** Dose-escalation of RG6279 in combination with atezolizumab ▪ **Part 3:** Extension of RG6279 as a single agent and/or in combination with atezolizumab
Primary endpoint	▪ Safety, PK/PD, efficacy
Status	▪ FPI Q2 2020
CT Identifier	NCT04303858

Oncology development programs

Bispecific antibody

Molecule	cibisatamab (CEA x CD3, RG7802)		
Indication	**CEA-positive solid tumors**		**3L+ MSS mCRC**
Phase/study	**Phase Ia**	**Phase Ib**	**Phase Ib**
# of patients	N=149	N=228	N=46
Design	▪ **Part I:** Dose escalation ▪ **Part II:** Dosing strategy ▪ **Part III:** Assessment of schedule ▪ **Part IV:** Dose and schedule expansion	▪ **Part I:** RG7802 dose escalation + Tecentriq ▪ **Part II:** Expansion at defined dose and schedule	▪ RG7802 + Tecentriq after pre-treatment with Gazyva in patients with high CEACAM5 expression
Primary endpoint	▪ Safety, Efficacy, PK and PD	▪ Safety, Efficacy, PK and PD	▪ Safety, Efficacy, PK, PD
Status	▪ FPI Q4 2014 ▪ Data presented at ASCO 2017	▪ FPI Q1 2016 ▪ Data presented at ASCO 2017	▪ FPI Q1 2019
CT Identifier	NCT02324257	NCT02650713	NCT03866239

ASCO=American Society of Clinical Oncology; MSS=microsatellite stable; CEA=carcinoembryonic antigen; mCRC=metastatic colorectal cancer

Oncology development programs

Bispecific antibodies

Molecule	PD1-TIM3 (RG7769)	PD1-LAG3 (RG6139)
Indication	Advanced and metastatic solid tumors	Advanced and metastatic solid tumors
Phase/study	Phase Ia/b	Phase I
# of patients	N=280	N=320
Design	▪ **Part A1**: Dose escalation (Q2W) ▪ **Part A2**: Dose escalation (Q3W) ▪ **Part B1**: Dose expansion metastatic melanoma ▪ **Part B2**: Dose expansion NSCLC 2L+ ▪ **Part B3**: Dose expansion NSCLC 1L (PD-L1 high cohort)	Open-label, multicenter, multiple-ascending dose (MAD) study ▪ **Part A**: Dose escalation (Q2W or Q3W) ▪ **Part B**: Tumor specific dose expansion
Primary endpoint	▪ Safety, PK/PD and efficacy	▪ Safety, PK/PD and efficacy
Status	▪ FPI Q4 2018	▪ FPI Q4 2019
CT Identifier	NCT03708328	NCT04140500

NSCLC=non-small cell lung cancer

Oncology development programs

Monoclonal antibodies

Molecule	**selicrelumab** (CD40 MAb, RG7876)	**Anti-CD25** (RG6292)
Indication	**Solid tumors**	**Advanced and metastatic solid tumors**
Phase/study	**Phase Ib**	**Phase I**
# of patients	N=170	N=110
Design	▪ **Part I:** Selicrelumab dose escalation in combination with vanucizumab ▪ **Part II:** Selicrelumab dose expansion in combination with Avastin in PROC, HNSCC and CPI exp. NSCLC	▪ **Part A**: Dose escalation Q3W ▪ **Part B**: Tumor specific expansion cohorts
Primary endpoint	▪ Safety, PD and efficacy	▪ Safety, PK/PD and efficacy
Status	▪ FPI Q1 2016 ▪ Part II FPI Q2 2018 ▪ Selicrelumab+vanucizumab no longer recruiting	▪ FPI Q4 2019
CT Identifier	NCT02665416	NCT04158583

HNSCC=head and neck squamous cell carcinoma; NSCLC=non-small cell lung cancer; CPI=checkpoint inhibitor; MAb=monoclonal antibody, PROC= Palliative Radiation Oncology Consult

Oncology development programs

Small molecules

Molecule	TLR7 agonist (4) (RG6115)
Indication	Hepatocellular carcinoma
Phase/study	Phase I
# of patients	N=100
Design	▪ Open label, multi-center, single arm, multiple-ascending dose escalation and expansion study
Primary endpoint	▪ Safety
Status	▪ FPI July 2020
CT Identifier	NCT04338685

Neuroscience development programs

Molecule	**Brain Shuttle gantenerumab** (RG6102)
Indication	**Alzheimer's disease**
Phase/study	**Phase I**
# of patients	N~60
Design	▪ Single and multiple ascending dose study with healthy volunteer and patient cohorts
Primary endpoint	▪ Safety, tolerability, PK
Status	▪ FPI Q3 2019
CT Identifier	NCT04023994

Neuroscience development programs

Molecule	ralmitaront (partial TAAR1 agonist, RG7906)	
Indication	**Schizophrenia**	
Phase/study	**Phase II**	**Phase II**
# of patients	N=36	N=345
Design	▪ Randomized, double-blind, placebo-controlled, crossover study for two weeks in patients	▪ **Part A:** Monotherapy, one dose, qd, 12 weeks (N=125) ▪ **Part B:** Add-on therapy, two dose levels, qd, 12 weeks (N=220)
Primary endpoint	▪ Effects on dopamine synthesis capacity	▪ Effects on negative symptoms (Brief Negative Symptoms Scale, BNSS)
Status	▪ FPI Q4 2018 ▪ LPI Q3 2019	▪ FPI Q4 2019
CT Identifier		NCT03669640

Neuroscience development programs

Parkinson's disease and autism

Molecule	**prasinezumab** (anti-αSynuclein, RG7935, PRX002)	**GABA-Aa5 PAM** (RG7816)	
Indication	**Parkinson's disease**	**Autism**	
Phase/study	**Phase II PASADENA**	**Phase I**	**Phase I**
# of patients	N=316	N=105	N=15
Design	▪ Randomized, double-blind, placebo-controlled study to evaluate the efficacy of prasinezumab in participants with early PD (52 weeks (Part 1) plus a 52-week blinded extension (Part 2))	▪ Randomized, double-blind, adaptive single-ascending-dose SAD/MAD/FE study in healthy volunteers	▪ PET study to assess occupancy of brain alpha5-containing GABAA receptors of RG7816 using [11C] Ro15-4513 following single oral doses in healthy participants
Primary endpoint	▪ Change from baseline in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) total score (sum of Parts I, II, and III) at week 52	▪ Safety and tolerability	▪ Percentage of brain alpha5-containing GABA-A receptors occupied by RG7816, plasma concentrations of RG7816
Status	▪ Study did not meet its primary objective, but showed signals of efficacy ▪ Roche is evaluating data to determine next steps ▪ The 52-week blinded extension (Part 2) is ongoing	▪ FPI Q4 2017	▪ FPI Q2 2018
CT Identifier	NCT03100149		NCT03507569
Collaborator	Prothena		

PD=Parkinson's disease; SAD=single ascending dose; MAD=multiple ascending dose; FE=food effect; PET=positron emission tomography

Neuroscience development programs

Molecule	**NME** RG7637
Indication	**Neurodevelopmental disorders**
Phase/study	**Phase I**
# of patients	N=80
Design	▪ Randomized, double-blind, single- and multiple-ascending dose, placebo-controlled study to investigate safety, tolerability, pharmacokinetics, pharmacodynamics and food effect
Primary endpoint	▪ Percentage of participants with adverse events
Status	▪ FPI July 2020
CT Identifier	

Infectious diseases development programs

Chronic hepatitis B

Molecule	TLR7 agonist (3) (RG7854)	CpAM (RG7907)
Indication	Chronic hepatitis B	Chronic hepatitis B
Phase/study	Phase I	Phase I/II
# of patients	N=150	N=190
Design	▪ Healthy volunteer and chronic hepatitis B patient study	▪ **Part 1:** Healthy volunteers ▪ **Part 2:** Chronic hepatitis B patients, 4 week dosing ▪ **Part 3:** Chronic hepatitis B patients, 48 week on top of SoC
Primary endpoint	▪ Safety, tolerability	▪ Safety, tolerability
Status	▪ FPI Q4 2016 ▪ Data presented at APASL 2019	▪ FPI Q4 2016 ▪ Data presented at EASL 2018 and 2019
CT Identifier	NCT02956850	NCT02952924

APASL=Asian Pacific Association for the Study of the Liver; EASL=European Association for the Study of the Liver

Infectious diseases development programs

Chronic hepatitis B

Molecule	TLR7 agonist (3) + CpAM (RG7854 + RG7907)	NME (RG6084)
Indication	Chronic hepatitis B	Chronic hepatitis B
Phase/study	Phase II Piranga	Phase I
# of patients	N=65	N=27
Design	▪ Efficacy and safety of TLR7 (3) in combination with CpAM in HBV patients previously treated with nucleosides	▪ MAD study in chronic hepatitis B patients
Primary endpoint	▪ Safety and efficacy	▪ Safety
Status	▪ FPI July 2020	▪ FPI Q1 2019
CT Identifier	NCT04225715	

Immunology development programs

Molecule	IgG-IL2 FP (RG7835)
Indication	Ulcerative Colitis
Phase/study	**Phase 1b**
# of patients	N=50
Design	▪ Multicenter, randomized, double-blind, placebo controlled study to investigate the subcutaneously administered RG7835 in participants with active ulcerative colitis
Primary endpoint	▪ Safety, tolerability, PK/PD, efficacy
Status	▪ FPI Q2 2019
CT Identifier	NCT03943550

Ophthalmology development programs

Molecule	NME (RG6179)	NME (RG7774)
Indication	DME	Retinal disease
Phase/study	Phase I	Phase II CANBERRA
# of patients	N~50	N=180
Design	▪ **Part 1:** Open label, multiple ascending dose study evaluating safety, tolerability and pharmacokinetics (PK) of intravitreal monotherapy ▪ **Part 2:** Safety, tolerability and pharmacodynamics of RG6179 in combination with anti-VEGF (ranibizumab) treatment	▪ Randomized, double-blind, placebo controlled study in patients with severe and moderately severe Non Proliferative Diabetic Retinopathy
Primary endpoint	▪ Safety, tolerability, PK	▪ Safety, PK, PD, efficacy
Status	▪ FPI July 2019	▪ FPI Q2 2020
CT Identifier		NCT04265261
Collaborator	Sesen Bio	

DME=diabetic macular edema

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group HY 2020 results

Diagnostics

Foreign exchange rate information

Oncology development programs

Bispecific antibodies

Molecule	mosunetuzumab (CD20 x CD3, RG7828)			
Indication	**3L+ DLBCL & 3L+ FL & ibrutinib R/R MCL**	**1L DLBCL**	**R/R DLBCL & FL**	**1L DLBCL & 2L DLBCL following 1L induction**
Phase/study	**Phase I**	**Phase Ib/II**	**Phase Ib**	**Phase I**
# of patients	N=665	N=160	N=276	N=40
Design	▪ Dose escalation study of mosunetuzumab as single agent and in combination with Tecentriq ▪ Expansion cohorts for r/r FL, r/r DLBCL and ibrutinib r/r MCL	▪ Mosunetuzumab plus CHOP ▪ Mosunetuzumab plus CHP plus polatuzumab vedotin	▪ Mosunetuzumab plus polatuzumab vedotin	▪ **Cohort A:** Mosunetuzumab monotherapy (after a response to prior systemic chemotherapy) ▪ **Cohort B:** Mosunetuzumab monotherapy (1L treatment in elderly/frail)
Primary endpoint	▪ Safety, tolerability, dose/schedule, PK, and response rates	▪ Safety/tolerability and response	▪ Safety/tolerability and response	▪ Safety/tolerability and response
Status	▪ FPI Q3 2015 ▪ First data in r/r NHL presented at ASH 2018 and 2019 ▪ BTD granted by FDA Q2 2020	▪ FPI Q1 2019	▪ FPI Q3 2018	▪ FPI Q2 2019 – Cohort B ▪ FPI Q3 2019 – Cohort A
CT Identifier	NCT02500407	NCT03677141	NCT03671018	NCT03677154

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; r/r=relapsed/refractory; NHL=non-Hodgkin's lymphoma; CHOP=cyclophosphamide, doxorubicin, vincristine, and prednisone; CHP=cyclophosphamide, doxorubicin, and prednisone); ASH=American Society of Hematology

Oncology development programs

Bispecific antibodies

Molecule	FcRH5 X CD3 (RG6160)	HER2 x CD3 (RG6194)	BCMA x CD16a (RG6296)
Indication	**Relapsed/refractory multiple myeloma**	**Metastatic HER2-expressing cancers**	**Relapsed/refractory multiple myeloma**
Phase/study	**Phase I**	**Phase I**	**Phase I**
# of patients	N=80	N=449	N=80
Design	▪ Dose escalation and expansion of single agent	▪ Dose escalation and expansion of single agent	▪ Dose escalation and expansion of single agent
Primary endpoint	▪ Safety and tolerability	▪ Safety and tolerability	▪ Safety and tolerability
Status	▪ FPI Q3 2017	▪ FPI Q2 2018	▪ FPI Q3 2020
CT Identifier	NCT03275103	NCT03448042	NCT04434469
Collaborator			Affimed

Oncology development programs

Small molecules and fusion proteins

Molecule	SERD (3) (RG6171, GDC-9545)			IL15/IL15Ra-Fc (RG6323)
Indication	**Metastatic ER+ HER2-neg breast cancer**	**ER+ HER2-neg Stage I-III operable breast cancer**	**Neoadjuvant ER+ BC**	**Solid Tumors**
Phase/study	**Phase I**	**Phase I**	**Phase II**	**Phase I/II**
# of patients	N=220	N=75	N=215	N=250
Design	▪ Dose escalation and expansion at recommended phase II dose (RP2D) ▪ Single agent and in combination with palbociclib and/or luteinizing hormone–releasing hormone (LHRH) agonist	▪ Open-label, pre-operative administration ▪ Dose escalation	▪ **ARM A:** Single agent followed by combo with palbociclib ▪ **ARM B:** anastrazole followed by anastrazole plus palbociclib	▪ Dose escalation and expansion of single agent and in combination with Tecentriq
Primary endpoint	▪ Safety	▪ Safety, tolerability and PK/PD	▪ Safety, tolerability and PK/PD	▪ Safety and tolerability
Status	▪ FPI Q4 2017 ▪ Data presented at SABCS 2019	▪ FPI Q3 2019	▪ FPI expected Q3 2020	▪ FPI Q1 2020
CT Identifier	NCT03332797	NCT03916744	NCT04436744	NCT04250155
Collaborator				Xencor

SABCS=San Antonio Breast Cancer Symposium

Oncology development programs

Individualized Neoantigen-Specific Therapy

Molecule	**Individualized Neoantigen-Specific Therapy (iNeST)** (RG6180)	
Indication	**Locally advanced or metastatic solid tumors**	**1L Advanced Melanoma**
Phase/study	**Phase Ia/Ib**	**Phase II IMcode001**
# of patients	N=770	N=132
Design	Open-label, multicenter, global study: ▪ **Phase Ia:** Dose escalation of RG6180 as single agent ▪ **Phase Ib:** Dose escalation, exploration and expansion trial of RG6180 in combination with Tecentriq	▪ **ARM A:** Pembrolizumab ▪ **ARM B:** iNeST in combination with pembrolizumab
Primary endpoint	▪ Safety, tolerability, PK and immune response	▪ Progression free survival and objective response rate
Status	▪ FPI Q4 2017 ▪ Data presented at AACR 2020	▪ FPI Q1 2019
CT Identifier	NCT03289962	NCT03815058
Collaborator	BioNTech	

AACR=American Association for Cancer Research

Neuroscience development programs

gRED Genentech Research & Early Development

Molecule	DLK inhibitor (RG6000, GDC-0134)	Semorinemab (RG6100)	
Indication	**Amyotrophic lateral sclerosis**	**Prodromal to mild Alzheimer's disease**	**Moderate Alzheimer's disease**
Phase/study	**Phase I**	**Phase II TAURIEL**	**Phase II LAURIET**
# of patients	N=82	N=457	N=260
Design	▪ Randomized, double-blind, placebo-controlled, multicenter, single and multiple ascending dose study	▪ Randomized, double-blind, placebo-controlled, multi-center efficacy and safety study	▪ Randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety study
Primary endpoint	▪ Safety, tolerability, and PK of single and multiple doses	▪ Safety, CDR-SOB score from baseline to week 72	▪ Safety, ADAS-Cog11 and ADCS-ADL from baseline to week 49
Status	▪ FPI Q2 2016	▪ FPI Q4 2017	▪ FPI Q1 2019
CT Identifier	NCT02655614	NCT03289143	NCT03828747
Collaborator		AC Immune	

CDR-SOB=Clinical Dementia Rating Scale Sum of Boxes; ADAS-Cog=Alzheimer's Disease Assessment Scale-cognitive subscale; ADCS-ADL=Alzheimer's Disease Cooperative Study ADL Scale

Immunology development programs

Molecule	IL-22Fc (RG7880)		NME (RG6287, GDC-8264)
Indication	**Inflammatory diseases**	**Inflammatory bowel disease**	**Inflammatory bowel disease**
Phase/study	**Phase Ib**	**Phase II**	**Phase I**
# of patients	N=90	N=270	N=114
Design	▪ Multiple ascending dose study with healthy volunteer and patient cohorts	IL-22Fc compared with vedolizumab and with placebo in the treatment of participants with moderate to severe UC: ▪ **Part A:** Induction of clinical remission ▪ **Part B:** Durability of clinical remission	▪ Single and multiple ascending dose study with food effect in healthy volunteers
Primary endpoint	▪ Safety and tolerability	▪ Percentage of participants with clinical remission at week 8	▪ Safety, tolerability, PK and PD for target engagement
Status	▪ FPI Q2 2016	▪ FPI Q4 2018	▪ FPI Jan 2020
CT Identifier	NCT02749630	NCT03558152	

UC=Ulcerative Colitis

Immunology development programs

Molecule	NME (RG6151, GDC-0214)	NME (RG6244, GDC-4379)
Indication	**Asthma**	
Phase/study	**Phase I**	**Phase I**
# of patients	N=84	N=84
Design	▪ Single and multiple ascending dose study with healthy volunteer and patient cohorts	▪ Single and multiple ascending dose study with healthy volunteer and patient cohorts
Primary endpoint	▪ Safety, tolerability and biomarker for target engagement (FeNO reduction)	▪ Safety, tolerability and biomarker for target engagement (FeNO reduction)
Status	▪ FPI Q4 2017 ▪ Recruitment completed Q1 2018	▪ FPI Q2 2019
CT Identifier	ACTRN12617001227381p	ACTRN12619000227190p

FeNO=Fractional exhaled nitric oxide

Immunology development programs

Molecule	**ST2 MAb** (RG6149, AMG 282, MSTT1041A) or **IL-22Fc** (RG7880)
Indication	**Adult hospitalised with severe COVID-19 pneumonia**
Phase/study	**Phase II** **COVASTIL**
# of patients	N=300
Design	▪ **Arm A:** anti-ST2 plus standard of care ▪ **Arm B:** anti-ST2 matched placebo ▪ **Arm C:** IL-22Fc plus standard of care ▪ **Arm D:** IL-22Fc matched placebo
Primary endpoint	▪ Clinical Status, Assessed Using a 7-Category Ordinal Scale (Day 28)
Status	▪ FPI Q2 2020
CT Identifier	NCT04386616
Collaborator	Amgen (for ST2 Mab)

Immunology development programs

gRED Genentech Research & Early Development

Molecule	Anti-tryptase (RG6173, MTPS9579A)		ST2 MAb (RG6149, AMG 282, MSTT1041A)
Indication	**Asthma**		
Phase/study	**Phase I**	**Phase IIa**	**Phase IIb ZENYATTA**
# of patients	N=70	N=160	N=515
Design	▪ Single and multiple ascending dose study of MTPS9579A in healthy adult subjects	▪ MTPS9579A compared to placebo in patients with uncontrolled moderate to severe asthma	Add-on therapy for the treatment of high-need, uncontrolled asthma in adults (50-week subcutaneous treatment period): ▪ **ARM A:** RG6149 (70 mg) ▪ **ARM B:** RG6149 (210mg) ▪ **ARM C:** RG6149 (490mg) ▪ **ARM D:** Placebo
Primary endpoint	▪ Safety, tolerability and PK	▪ Time to first CompEx event	▪ Percentage of participants with asthma exacerbations
Status	▪ FPI Q1 2018	▪ FPI Q4 2019	▪ FPI Q3 2016 ▪ Recruitment completed Apr 2018
CT Identifier		NCT04092582	NCT02918019
Collaborator			Amgen

Time to first CompEx event =a composite endpoint defined as time from randomization to first asthma exacerbation or diary worsening during the 48-week double-blind treatment period

Immunology development programs

Molecule	fenebrutinib (BTKi, RG7845, GDC-0853)	
Indication	**Rheumatoid arthritis**	
Phase/study	**Phase II ANDES**	**Phase II Open label extension**
# of patients	N=578	N=578
Design	Randomized, double-blind, parallel group study in rheumatoid arthritis patients: ▪ **Cohort 1:** Fenebrutinib vs adalimumab in patients with inadequate response to previous MTX ▪ **Cohort 2:** Fenebrutinib vs placebo in patients with inadequate response to previous TNF	Patients enter the study after completing 12 weeks of treatment in the ANDES Randomized study: ▪ 200mg BID of fenebrutinib for 52 weeks
Primary endpoint	▪ ACR 50 at week12 and safety	▪ ACR 50 at week12 and safety
Status	▪ FPI Q3 2016 ▪ Recruitment completed Q1 2018; ▪ Data presented at EULAR and ACR in 2019	▪ FPI Q4 2016 ▪ Recruitment completed Q2 2018
CT Identifier	NCT02833350	NCT02983227

MTX=methotrexate; EULAR=European League Against Rheumatism; ACR=American College of Rheumatology

Infectious diseases development programs

Molecule	**Anti-*S. aureus* TAC** (RG7861)
Indication	**Serious infections caused by *Staphylococcus aureus***
Phase/study	**Phase Ib**
# of patients	N=25
Design	▪ Establish safety and PK in patients (*S. aureus* bacteremia)
Primary endpoint	▪ Safety and PK
Status	▪ FPI Q3 2017 ▪ Recruitment completed Q3 2019
CT Identifier	NCT03162250
Collaborator	Seattle Genetics, Symphogen

TAC=THIOMAB™ antibiotic conjugate

Ophthalmology development programs

Molecule	**NME** (RG6147)
Indication	**Geographic atrophy**
Phase/study	**Phase II** **GALLEGO**
# of patients	N=285
Design	▪ Multicenter, Randomized, Single-Masked, Sham-Controlled Study to assess RG6147 in patients With GA secondary to AMD ▪ RG6147 Q4W ▪ RG6147 Q8W ▪ Sham IVT injections Q4W or Q8W
Primary endpoint	▪ Safety, Tolerability, and Efficacy
Status	▪ FPI Q2 2019
CT Identifier	NCT03972709

GA=Geographic atrophy; AMD=Age-related macular degeneration

Metabolic diseases development programs

Molecule	FGFR1 X KLB (RG7992)		
Indication	**Metabolic diseases**		**NASH**
Phase/study	**Phase Ia**	**Phase Ib**	**Phase II**
# of patients	N=79	N=140	N=260
Design	Healthy volunteer study ▪ Randomized, blinded, placebo-controlled, single ascending dose of RG7992	Obese type 2 diabetes ▪ Randomized, blinded, placebo-controlled, multiple ascending dose of RG7992	Non-Alcoholic Steatohepatitis (NASH) ▪ Randomized, blinded, placebo-controlled study of RG7992
Primary endpoint	▪ Safety and tolerability	▪ Safety, tolerability and PK	▪ Efficacy (NASH resolution on overall histopathological reading without worsening of fibrosis at week 52), safety and PK
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q1 2017	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2019	▪ FPI expected in H2 2020
CT Identifier	NCT02593331	NCT03060538	NCT04171765

FGFR1=Fibroblast growth factor receptor 1; KLB=β-Klotho

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group HY 2020 results

Diagnostics

Foreign exchange rate 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 ▪ Updated data presented at ISTH 2020	▪ Safety; peak and steady state FVIII activity levels at week 52
Status	▪ Ongoing	▪ Ongoing	▪ Ongoing
CT Identifier	NCT03432520	NCT03003533	NCT03734588

Choroideremia

Unique gene therapy platform

Molecule	**SPK-7001 (RG6367)**
Indication	**Choroideremia**
Phase/study	**Phase I/II**
# of patients	N=15
Design	▪ Safety study in subjects with CHM (choroideremia) gene mutations
Primary endpoint	▪ Safety and tolerability
Status	▪ FPI Q1 2015 ▪ Recruitment completed Q2 2017
CT Identifier	NCT02341807

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group HY 2020 results

Diagnostics

Foreign exchange rate information

HY 2020: Geographical sales split by Divisions and Group*

CHFm	HY 2019	HY 2020	% change CER
Pharmaceuticals Division	**24,194**	**23,202**	**+1**
United States	13,370	12,464	**-4**
Europe	4,221	4,190	**+5**
Japan	1,988	1,908	**-2**
International	4,615	4,640	**+11**
Diagnostics Division	**6,275**	**6,079**	**+3**
United States	1,443	1,583	**+14**
Europe	2,000	1,936	**+3**
Japan	226	226	**+1**
International	2,606	2,334	**-2**
Group	**30,469**	**29,281**	**+1**
United States	14,813	14,047	**-2**
Europe	6,221	6,126	**+5**
Japan	2,214	2,134	**-2**
International	7,221	6,974	**+6**

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

Pharma Division sales HY 2020

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Avastin	2,835	-18	1,057	-33	796	-8	363	-13	619	-1
MabThera	2,440	-23	1,693	-23	202	-34	33	-42	512	-17
Herceptin	2,200	-28	848	-42	361	-33	77	-37	914	-5
Ocrevus	2,076	25	1,671	19	297	49	-	-	108	75
Perjeta	1,941	17	770	1	567	11	149	27	455	65
Actemra / RoActemra	1,461	36	692	56	382	14	181	-2	206	77
Tecentriq	1,297	74	744	52	282	123	148	102	123	111
Hemlibra	1,003	94	664	80	146	143	151	87	42	418
Xolair	958	2	958	2	-	-	-	-	-	-
Kadcyla	837	39	404	51	257	34	41	3	135	35
Lucentis	728	-19	728	-19	-	-	-	-	-	-
TNKase / Activase	691	4	664	4	-	-	-	-	27	14
Esbriet	566	11	402	11	134	12	-	-	30	12
Alecensa	540	34	168	17	125	39	115	11	132	102
Pulmozyme	352	0	244	0	68	6	-	-	40	-6
CellCept	314	3	32	-23	80	-2	40	-3	162	14
Gazyva	310	35	144	35	101	34	36	77	29	11
Mircera	251	-7	-	-	31	-4	75	-23	145	3
Madopar	194	13	-	-	53	1	-	-	141	19
Tamiflu	186	-12	-1	-	45	18	29	-59	113	47

CER=Constant Exchange Rates (avg full year 2019)

Pharma Division sales HY 2020

New products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Erivedge	147	23	100	23	31	15	-	-	16	46
Perjeta	1,941	17	770	1	567	11	149	27	455	65
Kadcyla	837	39	404	51	257	34	41	3	135	35
Gazyva	310	35	144	35	101	34	36	77	29	11
Esbriet	566	11	402	11	134	12	-	-	30	12
Cotellic	26	-5	6	-4	12	-27	-	-	8	51
Alecensa	540	34	168	17	125	39	115	11	132	102
Tecentriq	1,297	74	744	52	282	123	148	102	123	111
Ocrevus	2,076	25	1,671	19	297	49	-	-	108	75
Hemlibra	1,003	94	664	80	146	143	151	87	42	418
Xofluza	28	357	26	345	-	-	-	-	2	*
Polivy	83	*	56	*	26	*	-	-	1	-
Rozlytrek	8	-	7	-	-	-	1	-	-	-
Total	**8,862**	**37**	**5,162**	**29**	**1,978**	**40**	**641**	**47**	**1,081**	**69**

CER=Constant Exchange Rates (avg full year 2019); * over 500%

Pharma Division sales HY 2020

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Avastin	2,835	-18	1,057	-33	796	-8	363	-13	619	-1
MabThera	2,440	-23	1,693	-23	202	-34	33	-42	512	-17
Herceptin	2,200	-28	848	-42	361	-33	77	-37	914	-5
Ocrevus	2,076	25	1,671	19	297	49	-	-	108	75
Perjeta	1,941	17	770	1	567	11	149	27	455	65
Actemra / RoActemra	1,461	36	692	56	382	14	181	-2	206	77
Tecentriq	1,297	74	744	52	282	123	148	102	123	111
Hemlibra	1,003	94	664	80	146	143	151	87	42	418
Xolair	958	2	958	2	-	-	-	-	-	-
Kadcyla	837	39	404	51	257	34	41	3	135	35
Lucentis	728	-19	728	-19	-	-	-	-	-	-
TNKase / Activase	691	4	664	4	-	-	-	-	27	14
Esbriet	566	11	402	11	134	12	-	-	30	12
Alecensa	540	34	168	17	125	39	115	11	132	102
Pulmozyme	352	0	244	0	68	6	-	-	40	-6
CellCept	314	3	32	-23	80	-2	40	-3	162	14
Gazyva	310	35	144	35	101	34	36	77	29	11
Mircera	251	-7	-	-	31	-4	75	-23	145	3
Madopar	194	13	-	-	53	1	-	-	141	19
Tamiflu	186	-12	-1	-	45	18	29	-59	113	47
Pharma Division	**23,202**	**1**	**12,464**	**-4**	**4,190**	**5**	**1,908**	**-2**	**4,640**	**11**

CER=Constant Exchange Rates (avg full year 2019); * over 500%

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q1/19	Q2/19	Q3/19	Q4/19	Q1/20	Q2/20
Avastin	9	6	8	-6	-13	-24
MabThera	-3	-5	-1	-6	-15	-32
Herceptin	-6	-12	-7	-24	-24	-33
Ocrevus	67	59	48	55	38	12
Perjeta	41	29	33	16	22	12
Actemra / RoActemra	6	10	9	5	30	40
Tecentriq	135	146	154	136	99	54
Hemlibra	*	*	*	313	146	59
Xolair	1	2	3	0	3	1
Kadcyla	24	42	54	57	55	26
Lucentis	11	9	7	7	-13	-25
TNKase / Activase	7	-3	5	0	11	-3
Esbriet	10	13	6	9	22	2
Alecensa	61	41	50	11	43	27
Pulmozyme	6	0	7	-5	10	-10
CellCept	4	-4	3	-3	7	-2
Gazyva	35	38	45	51	49	23
Mircera	16	10	11	5	-8	-7
Madopar	16	-1	22	9	5	23
Tamiflu	-40	110	369	104	-13	-10

CER=Constant Exchange Rates; * over 500% [1] Q1-Q4/19 vs Q1-Q4/18; Q1-Q2/20 vs. Q1-Q2/19;

CER sales growth (%)
Quarterly development

	2019 vs. 2018				2020 vs. 2019	
	Q1	Q2	Q3	Q4	Q1	Q2
Pharmaceuticals Division	**10**	**11**	**15**	**8**	**7**	**-6**
United States	14	13	14	11	3	-10
Europe	-6	-2	5	6	14	-3
Japan	7	12	14	3	3	-7
International	17	16	27	2	16	5
Diagnostics Division	**1**	**4**	**6**	**1**	**5**	**2**
Roche Group	**8**	**9**	**13**	**6**	**7**	**-4**

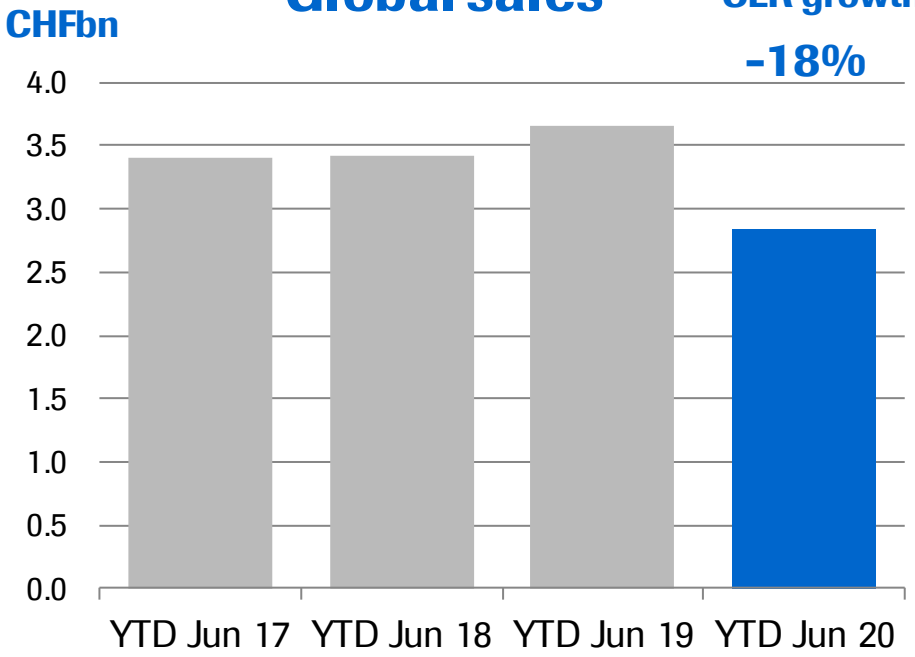
CER=Constant Exchange Rates

Avastin

Global sales

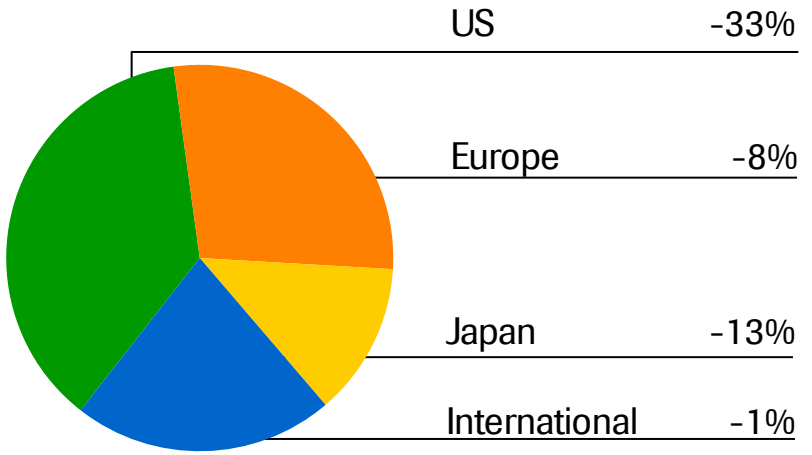
CER growth

-18%



Regional sales

CER growth



HY 2020 sales of CHF 2,835m

- US: Decline due to biosimilars and new competition in OC
- EU: Decline due to rebates upfront of biosimilars; new competition in OC
- Japan: Decline due to biosimilars and new competition in OC

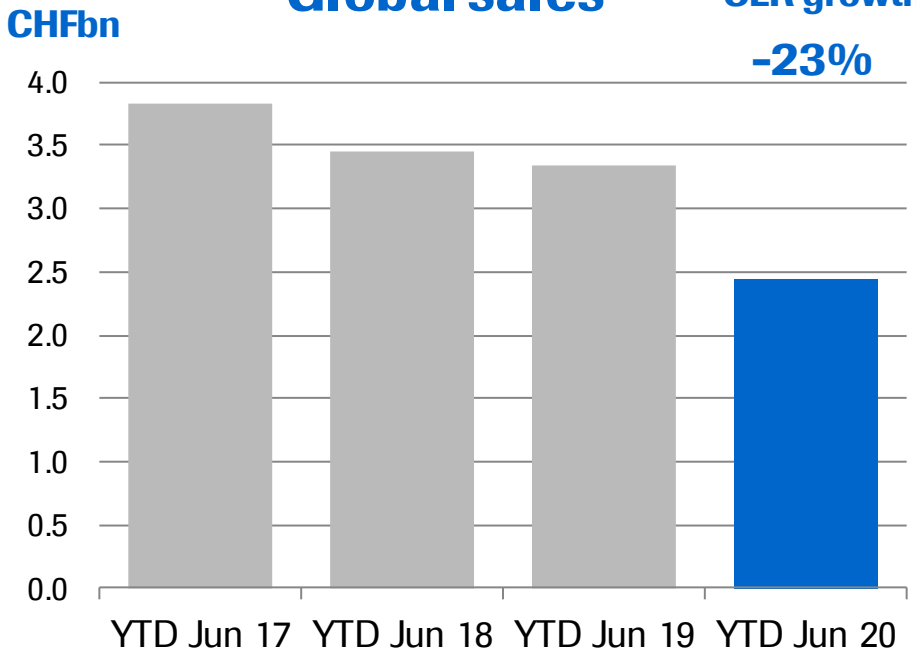
CER=Constant Exchange Rates

MabThera/Rituxan

Global sales

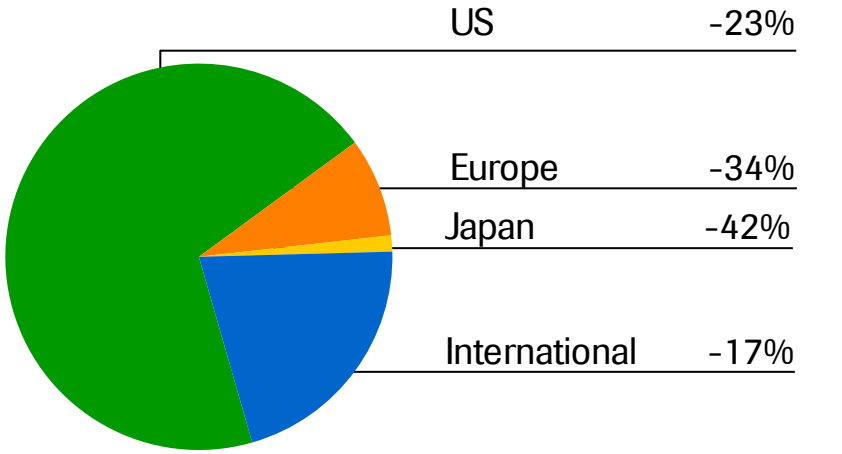
CER growth

-23%



Regional sales

CER growth



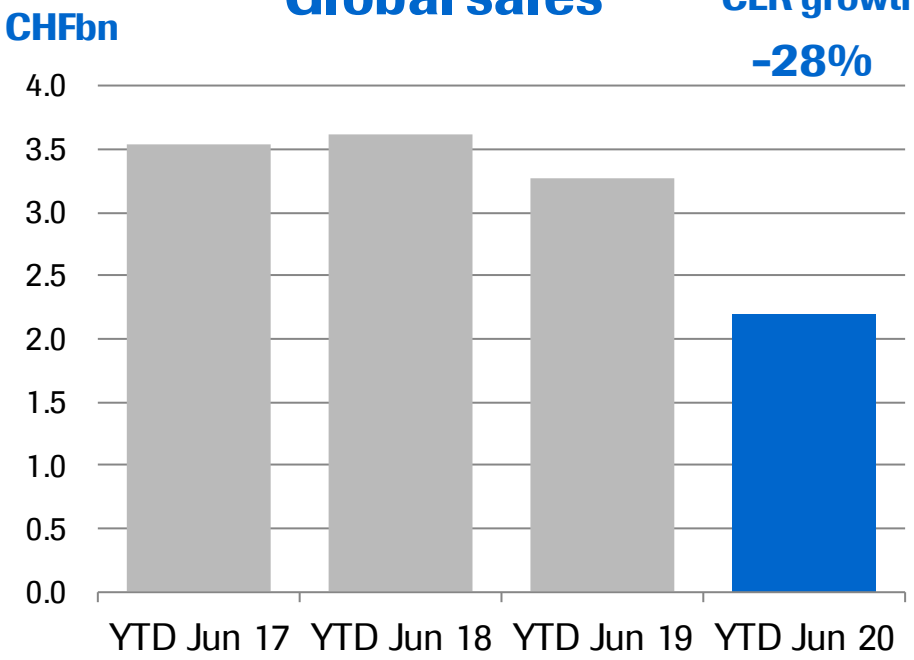
HY 2020 sales of CHF 2,440m

- US: Decline due to biosimlars and COVID-19 market contraction in Q2
- EU: Biosimilar erosion rate softening; COVID-19 market contraction in Q2
- Japan: Decline due to biosimilars and COVID-19 market contraction in Q2
- International: Biosimilar erosion, price decline in China, recovery from COVID-19 impact in China in Q2

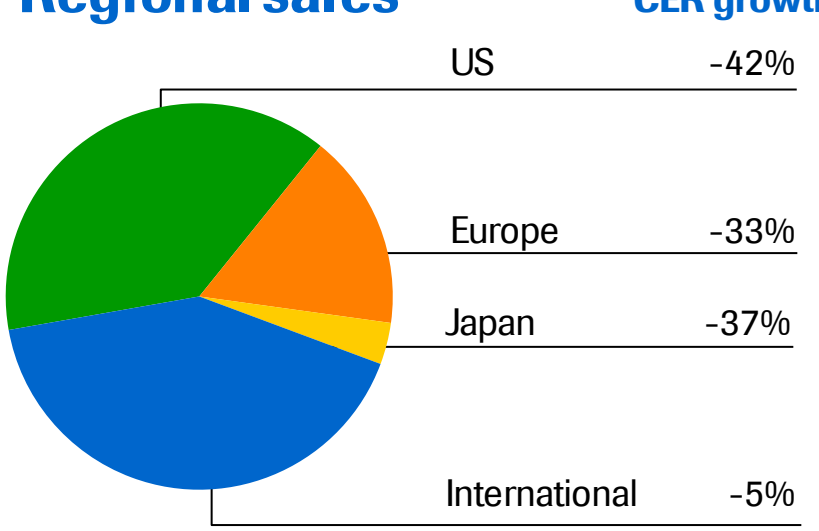
CER=Constant Exchange Rates

Herceptin

Global sales



Regional sales

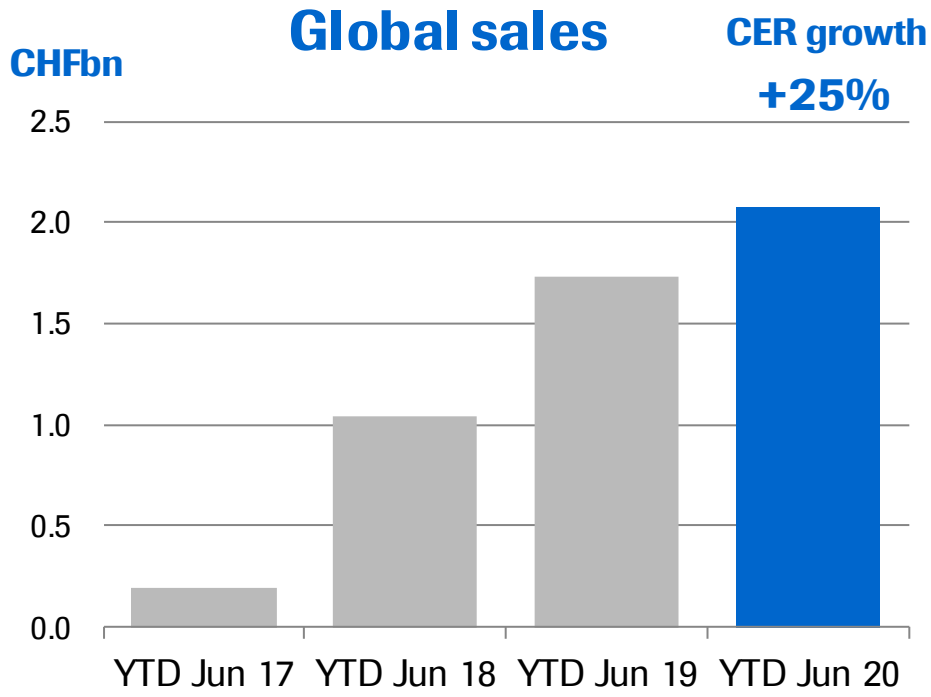


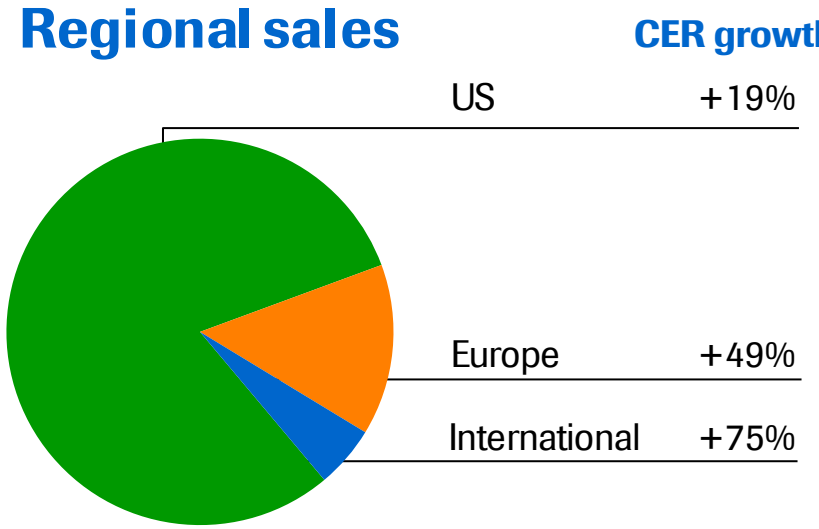
HY 2020 sales of CHF 2,200m

- US: Biosimilar erosion and switching of eligible adjuvant patients to Kadcyla; minor COVID-19 impact
- EU: Decline due to biosimilars and switching
- Japan: Decline due to biosimilars
- International: Price decline in China

CER=Constant Exchange Rates

Ocrevus





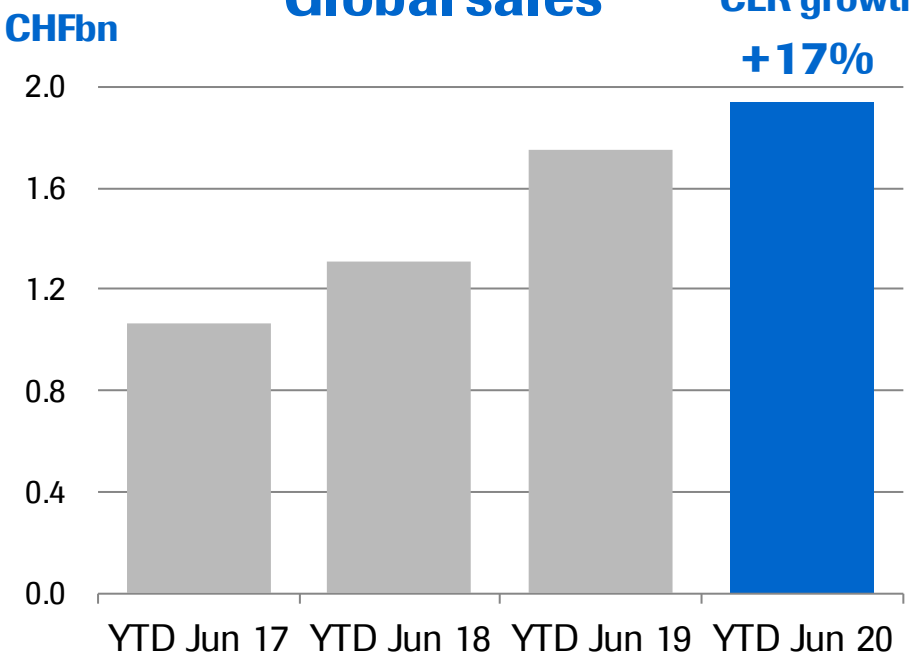
HY 2020 sales of CHF 2,076m

- US: Moving into earlier lines displacing orals; gaining market shares in all MS indications; COVID-19 impact seen in April/May, recovery started in June
- EU: Uptake dynamics in EU5 countries overall similar to the US; COVID-19 impact in Q2

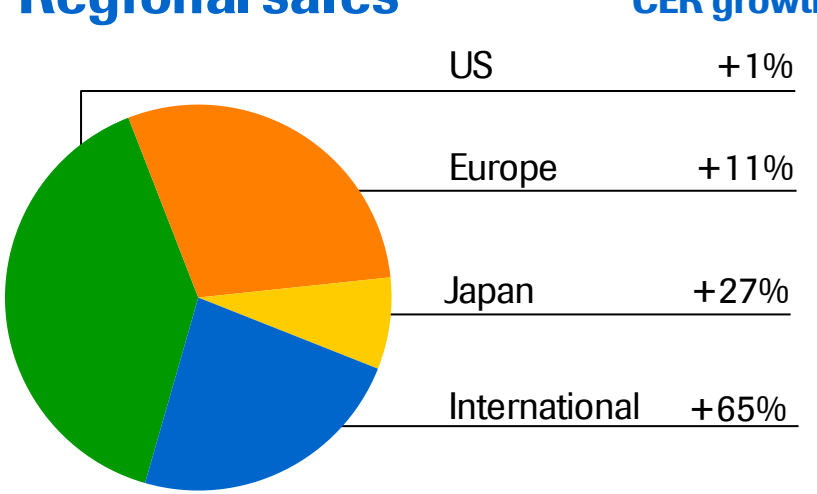
CER=Constant Exchange Rates

Perjeta

Global sales



Regional sales



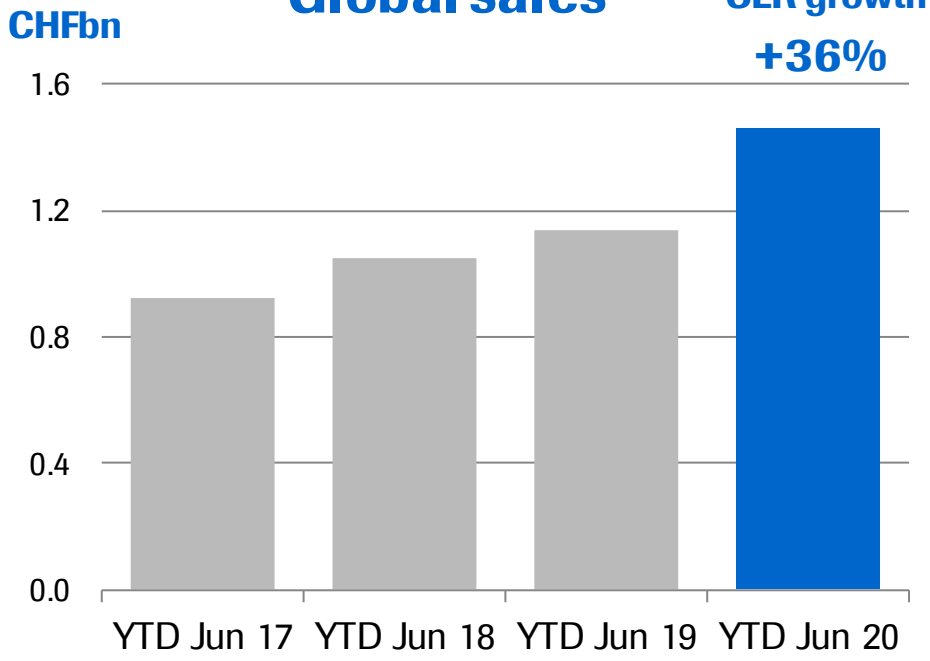
HY 2020 sales of CHF 1,941m

- US: Increased DoT in eBC compensates for patients with residual disease being switched to Kadcyla
- EU: Growth driven by eBC adjuvant setting; COVID-19 impact in Q2
- International: Accelerated growth in all regions, especially in China after NRDL was achieved
- Japan: Growth driven by eBC and mBC

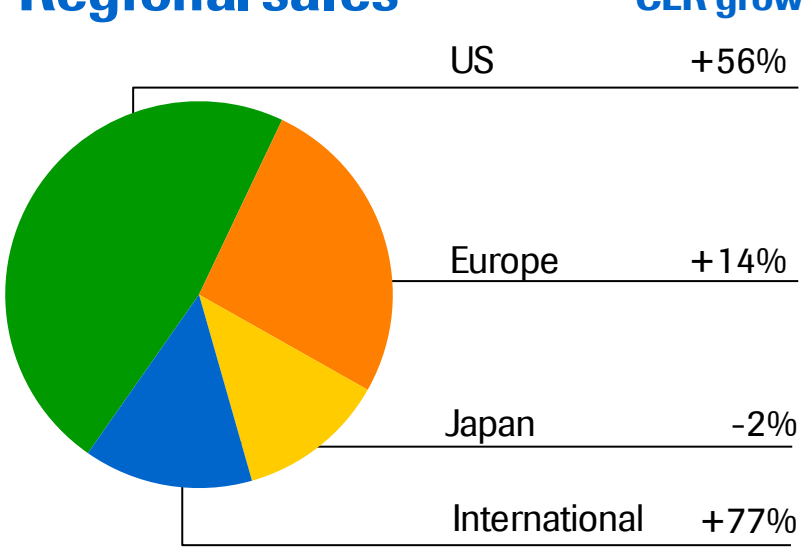
CER=Constant Exchange Rates

Actemra/RoActemra

Global sales



Regional sales



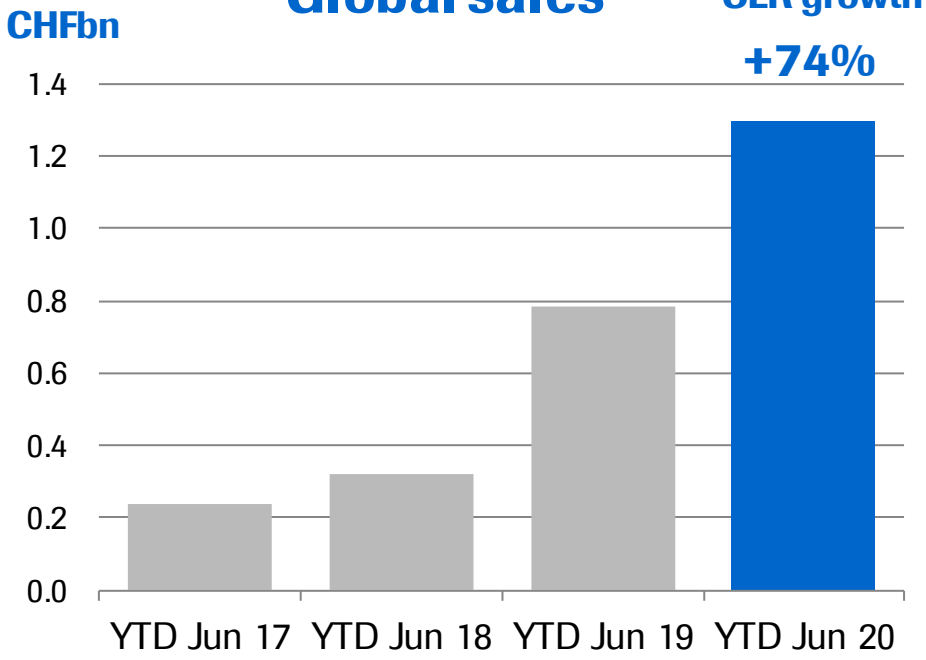
HY 2020 sales of CHF 1,461m

- US: Increased demand for SC formulation (home administration) and due to COVID-19
- EU: Market leadership in 1L RA monotherapy maintained; Growth driven by new RA, GCA and due to COVID-19
- International: Strong growth driven by all regions and due to COVID-19

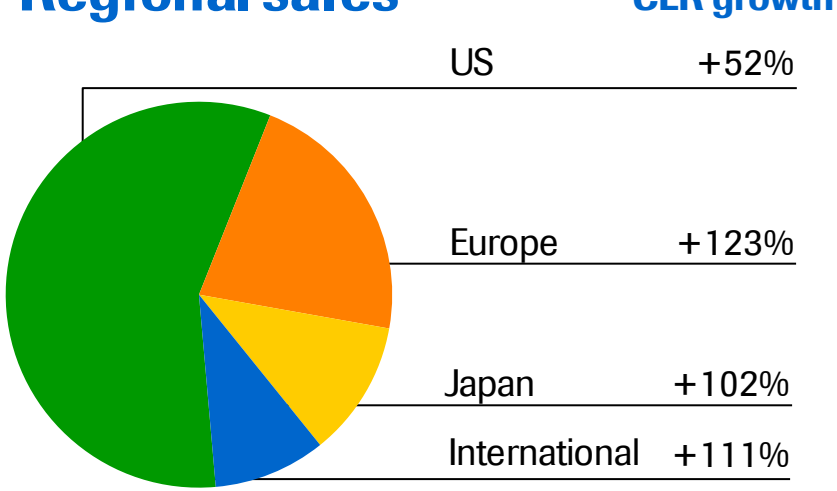
CER=Constant Exchange Rates

Tecentriq

Global sales



Regional sales



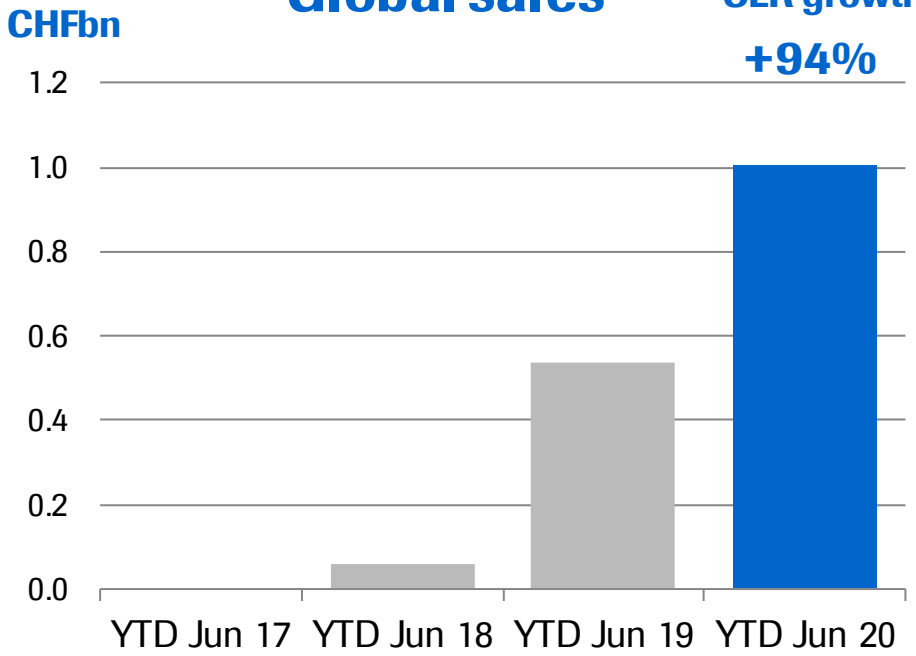
HY 2020 sales of CHF 1,297m

- US: Growth driven by first-in-class launches in 1L SCLC, 1L TNBC and 1L HCC
- EU: Growth driven by first-in-class launches in 1L SCLC and 1L TNBC and by share gains in 2L NSCLC
- Japan: Growth driven by first-in-class launches in 1L SCLC and 1L TNBC

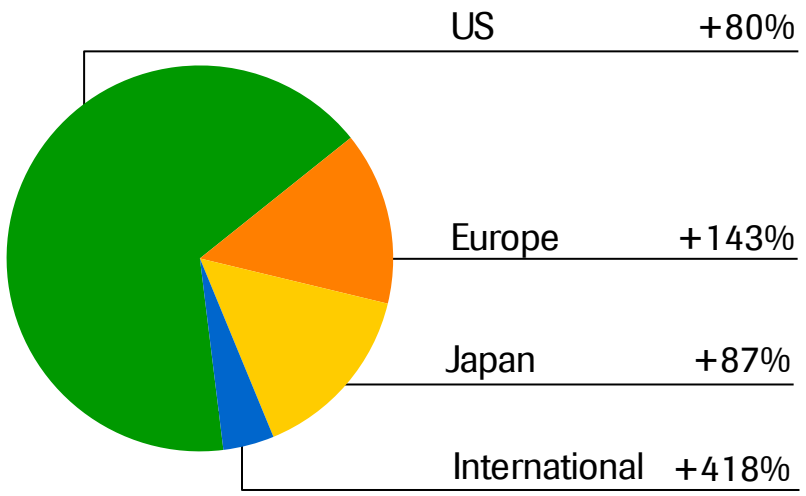
CER=Constant Exchange Rates

Hemlibra

Global sales



Regional sales

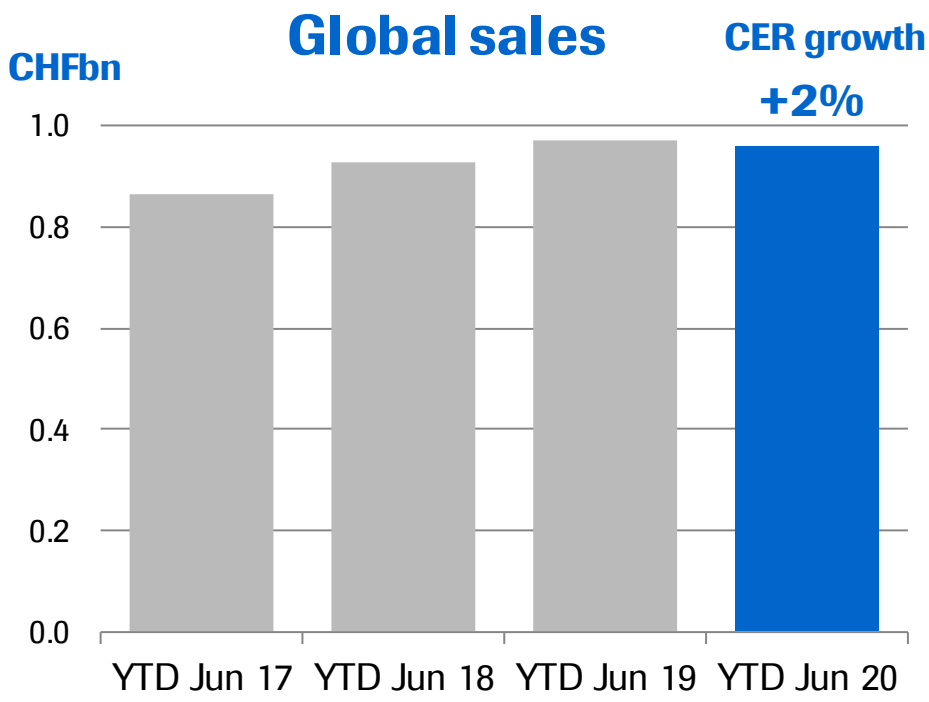


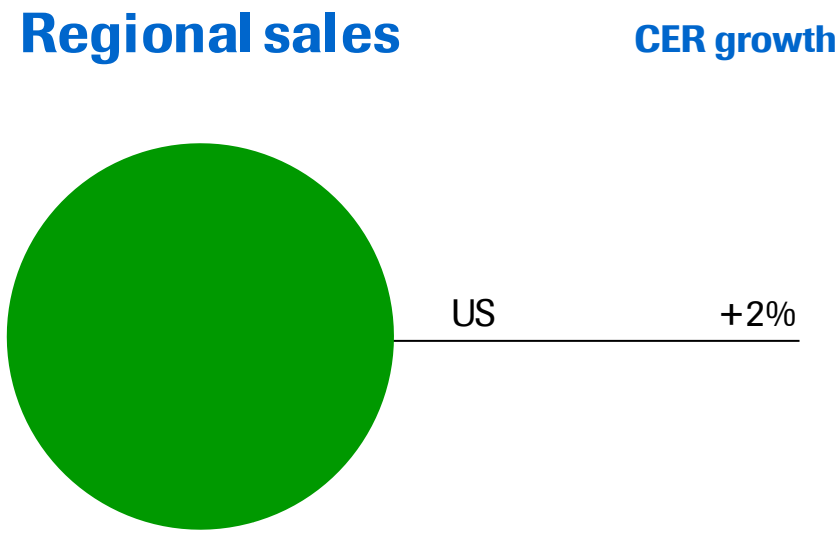
HY 2020 sales of CHF 1,003m

- US: Continued share gains in non-inhibitors; COVID-19 impact in Q2 with early signs of recovery
- EU: Growth driven by strong non-inhibitor launches in EU5
- Japan: Very strong uptake in non-inhibitors

CER=Constant Exchange Rates

Xolair





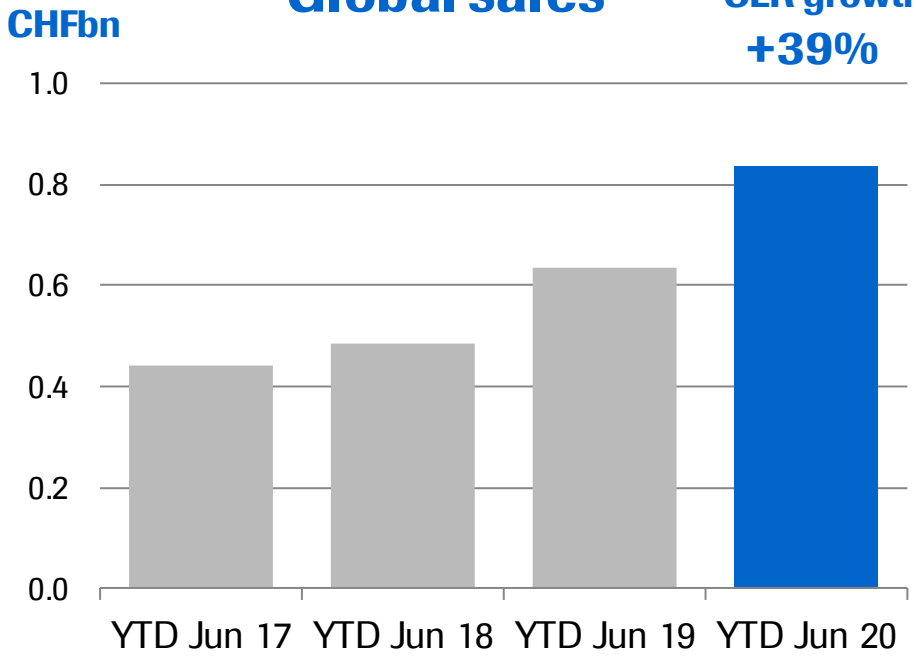
HY 2020 sales of CHF 958m

- Xolair remains market leader in a growing biologics asthma market; patients are eager to stay on their treatments in face of COVID-19
- Growth due to chronic idiopathic urticaria (CIU)

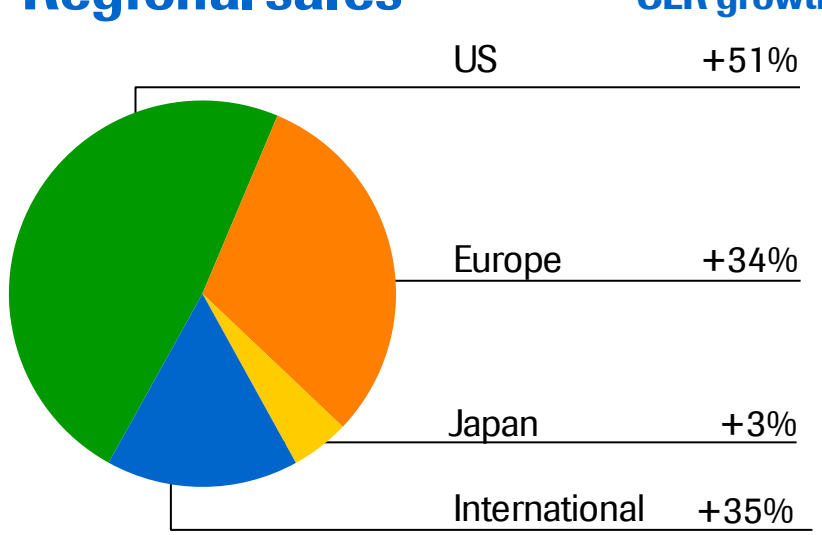
CER=Constant Exchange Rates

Kadcyla

Global sales



Regional sales



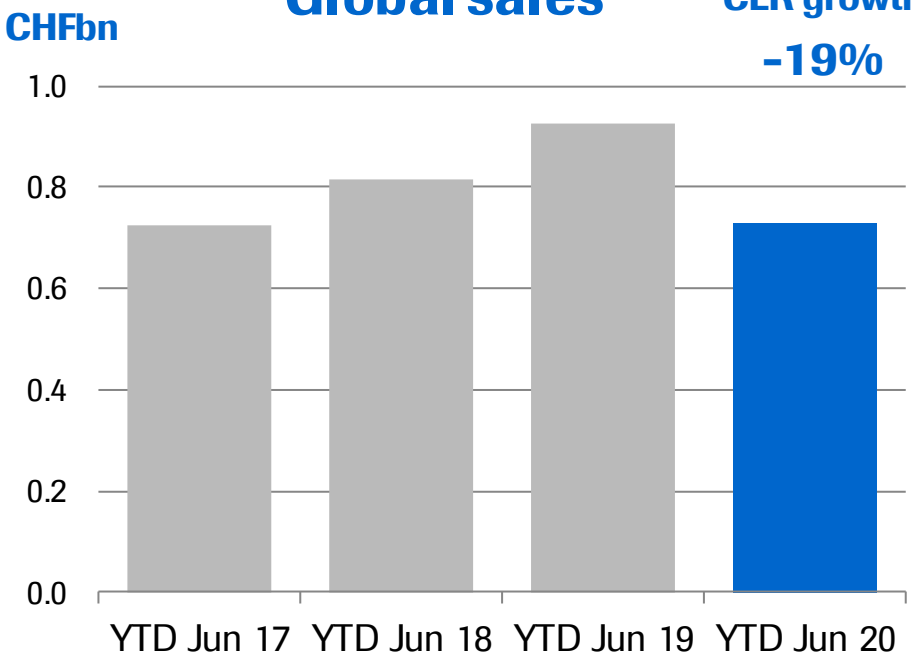
HY 2020 sales of CHF 837m

- US: Strong uptake in adjuvant eBC in patients with residual disease after neoadjuvant treatment; COVID-19 impact in Q2
- EU: Strong uptake in adjuvant eBC in early launch countries; COVID-19 impact in Q2
- International: Growth driven by all regions (especially China) in 2L mBC and due to first launches in adjuvant eBC

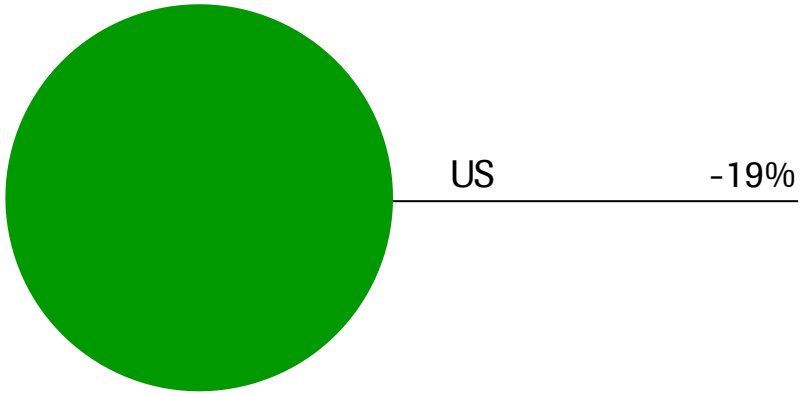
CER=Constant Exchange Rates

Lucentis

Global sales



Regional sales



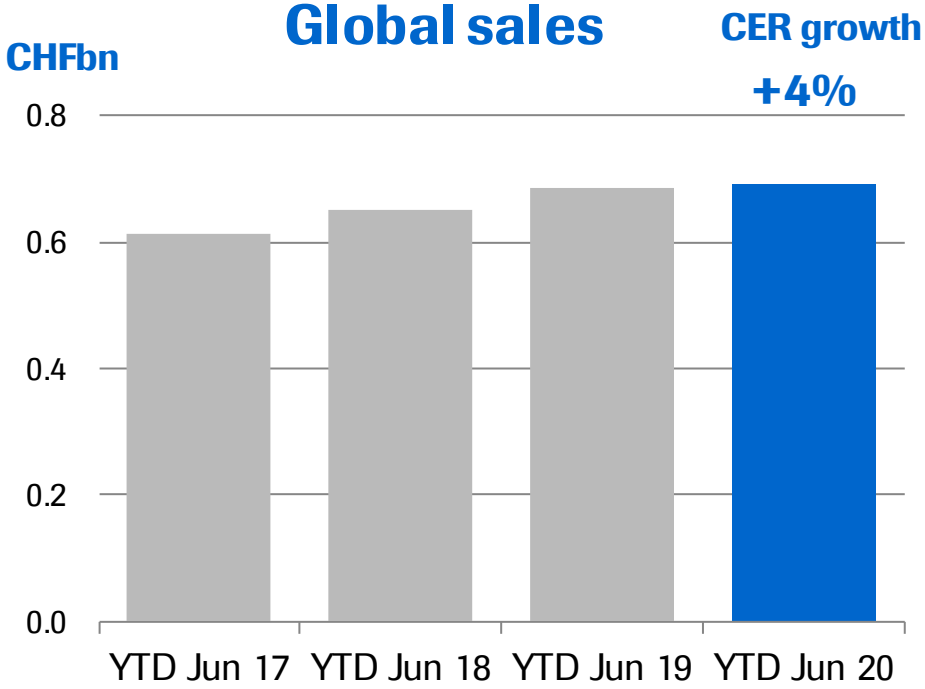
HY 2020 sales of CHF 728m

- Decline due to pronounced COVID-19 impact; partial recovery from lows in April
- Overall market shares stable

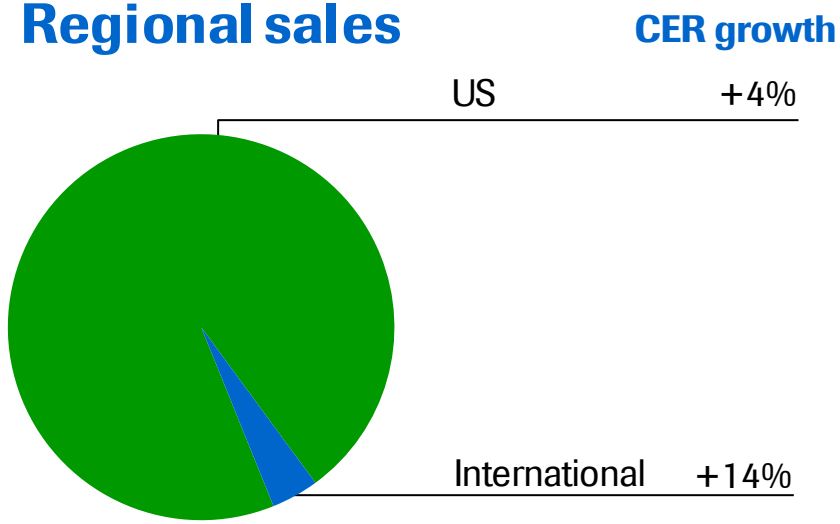
CER=Constant Exchange Rates

TNKase/Activase

Global sales



Regional sales



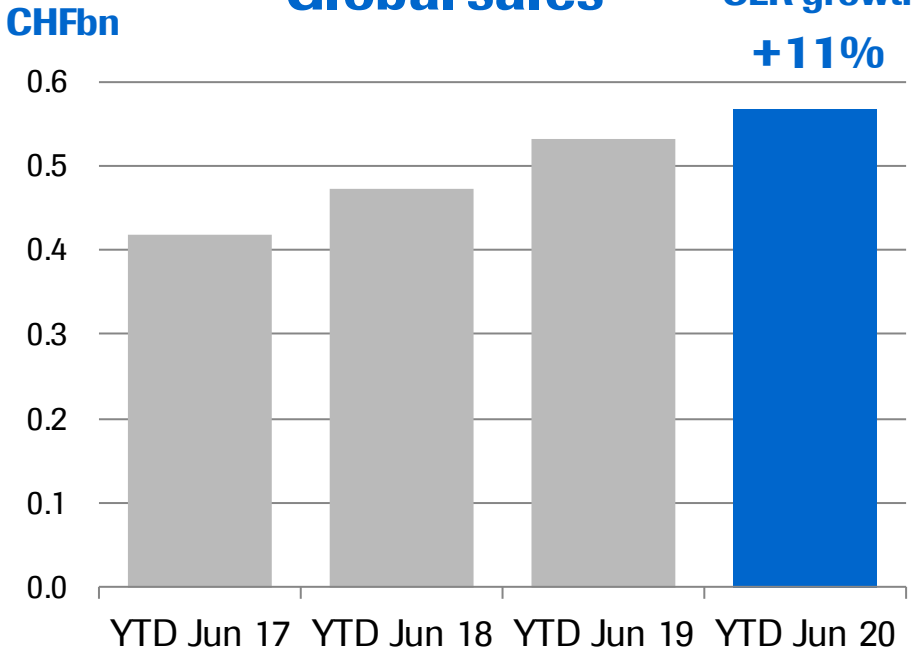
HY 2020 sales of CHF 691m

US: Growth driven by demand

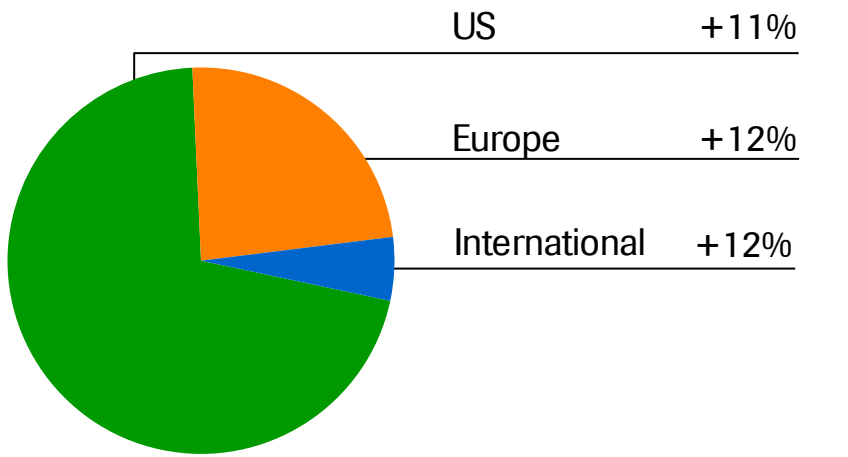
CER=Constant Exchange Rates

Esbriet

Global sales



Regional sales



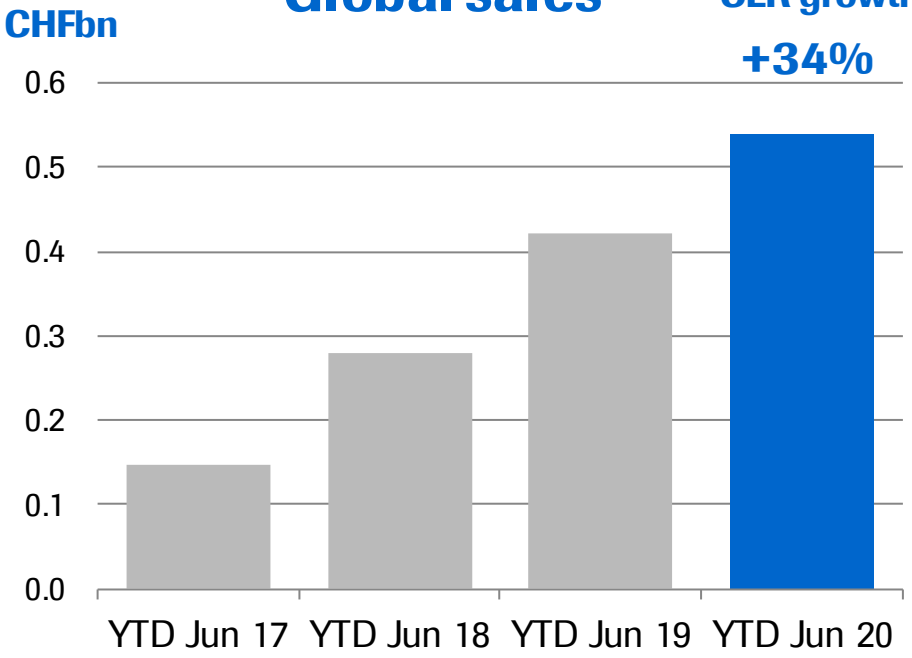
HY 2020 sales of CHF 566m

- US: Growth driven by continued penetration in moderate and mild patients; improved patient compliance; patients are eager to stay on their treatments in face of COVID-19
- EU: Growth driven by continued penetration in moderate and mild patients

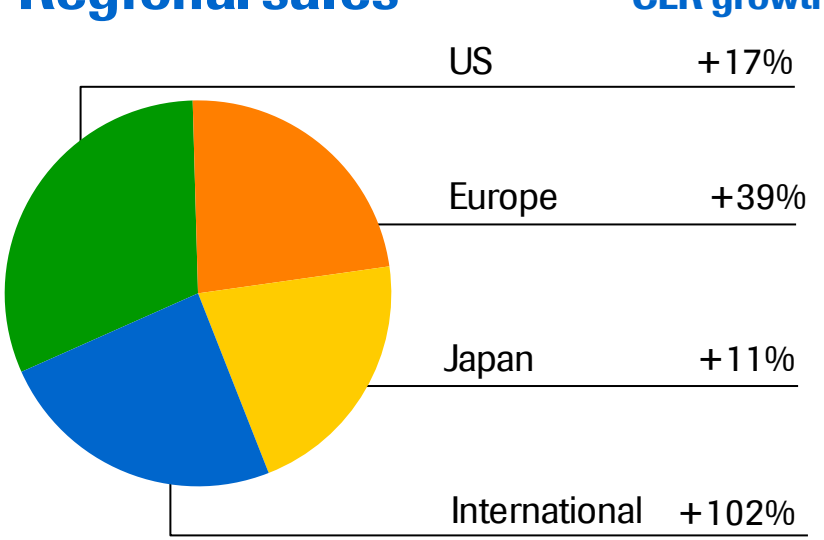
CER=Constant Exchange Rates

Alecensa

Global sales



Regional sales

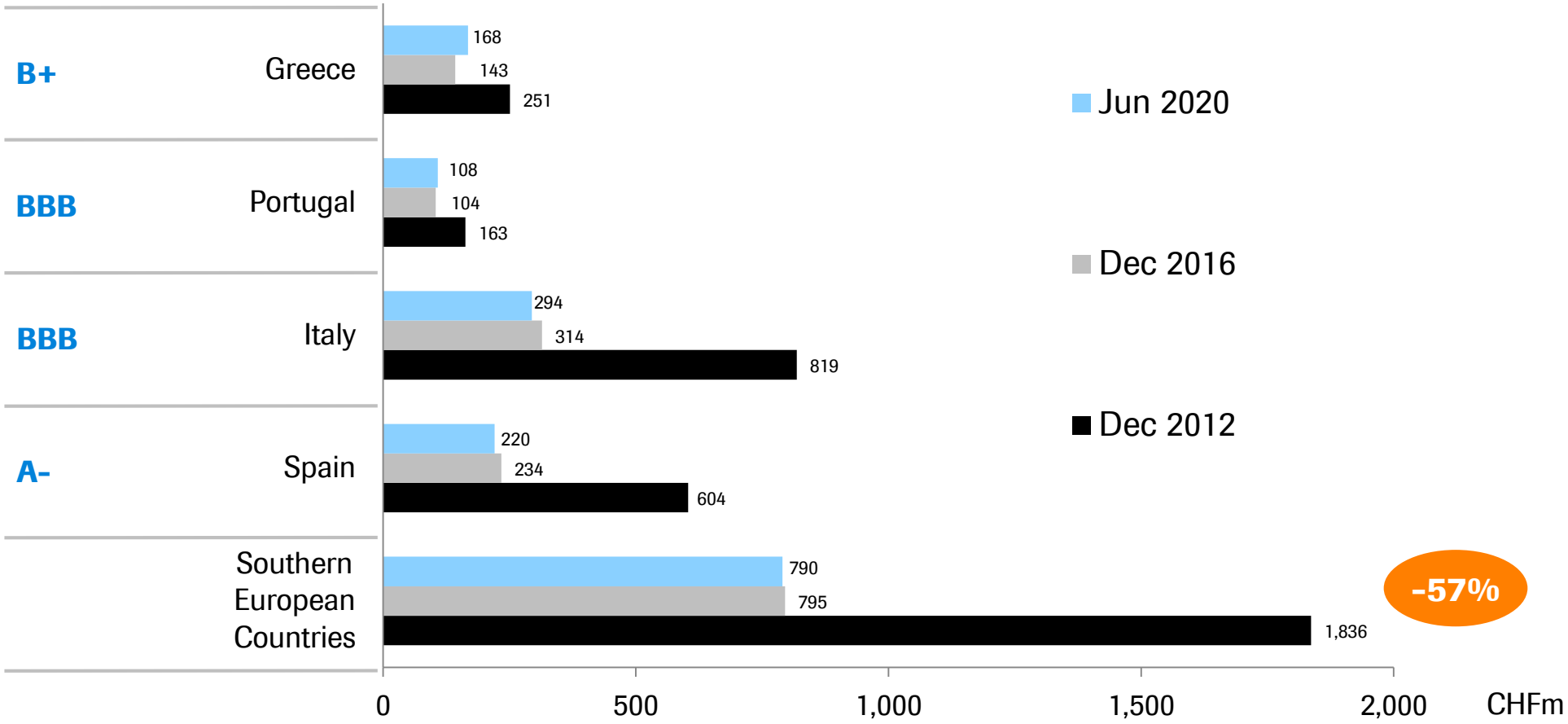


HY 2020 sales of CHF 540m

- US: Growth driven by 1L new patient share reaching >70%
- EU: Growth driven by 1L launches
- Japan: Growth due to 1L new patient share reaching >70%
- International: Growth driven by launch in China following NRDL listing

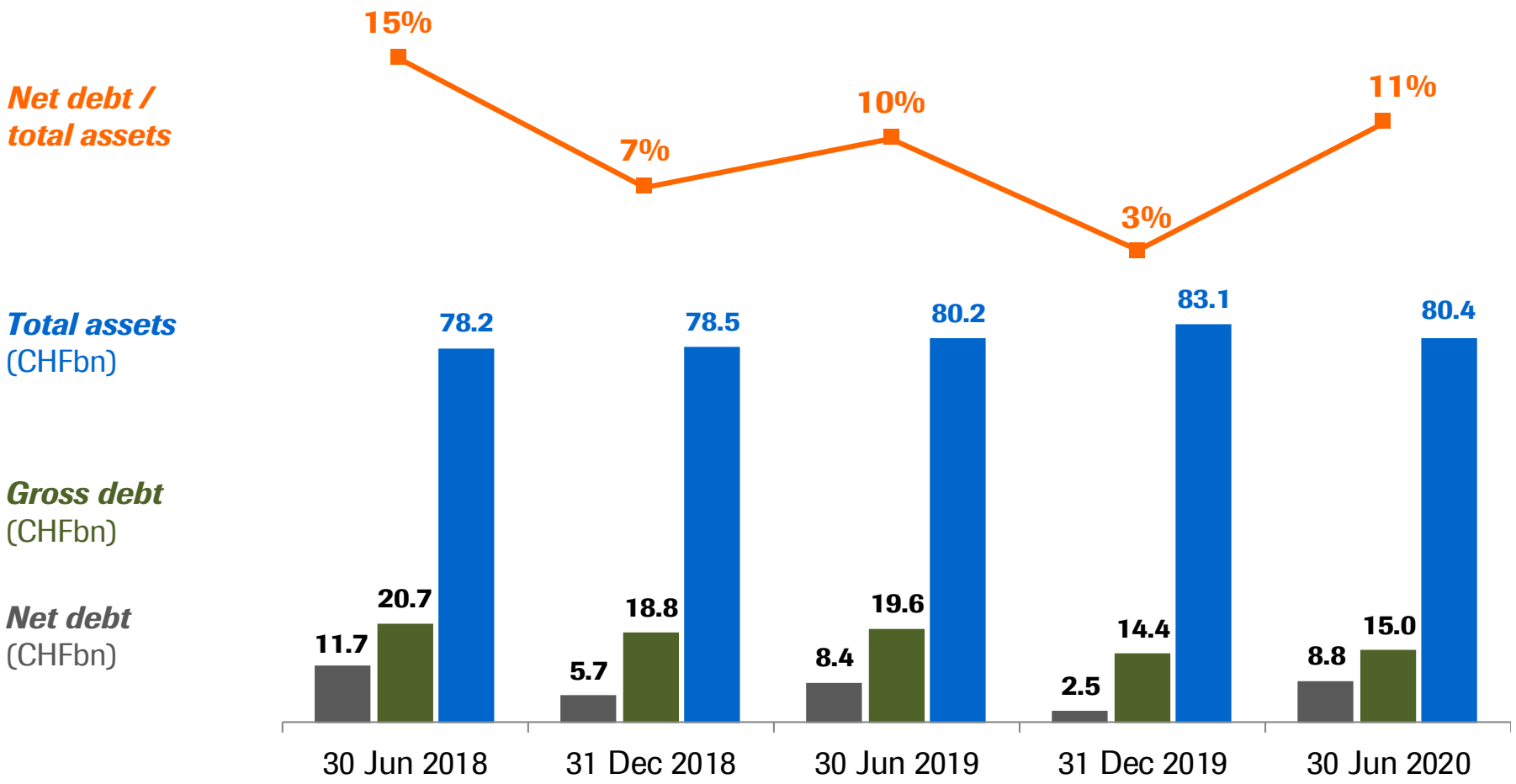
CER=Constant Exchange Rates

HY 2020: Accounts receivable in Southern Europe decreased by –57% since Dec 2012



Sovereign country ratings from Standard & Poor's, as of 6 July 2020

Balance sheet: Net debt, gross debt, and total assets



Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group HY 2020 results

Diagnostics

Foreign exchange rate information

HY 2020: Diagnostics Division CER growth

By Region and Business Area (vs. 2019)

	Global		EMEA[1]		North America		RoW	
	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth
Centralised and Point of Care Solutions	3,181	-10	1,185	-6	704	-5	1,292	-15
Molecular Diagnostics	1,558	61	605	65	617	62	336	52
Diabetes Care	832	-6	488	-10	141	8	203	-2
Tissue Diagnostics	508	2	130	0	278	-1	100	12
Diagnostics Division	**6,079**	**3**	**2,408**	**5**	**1,740**	**13**	**1,931**	**-5**

CER=Constant Exchange Rates; [1] Europe, Middle East and Africa

Diagnostics Division quarterly sales and CER growth[1]

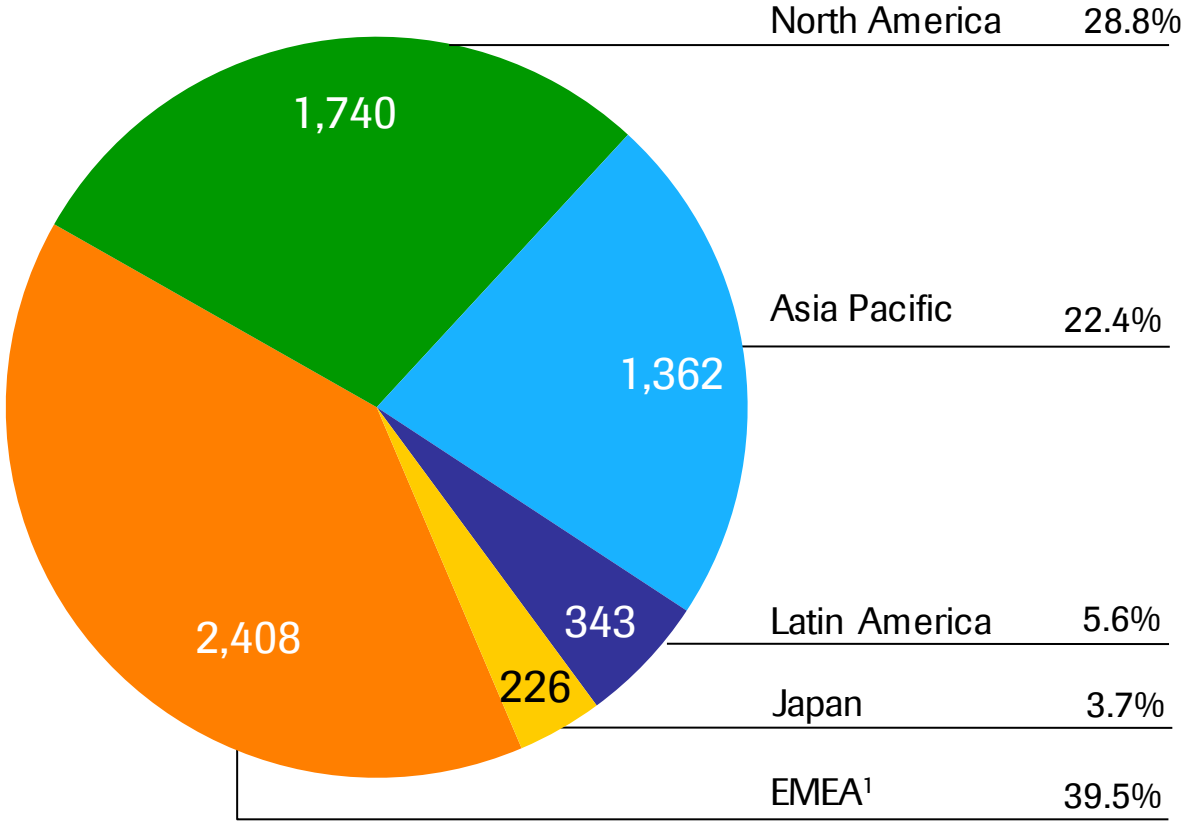
	Q1 19		Q2 19		Q3 19		Q4 19		Q1 20		Q2 20	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Centralised and Point of Care Solutions	1,681	-1	2,081	5	2,004	9	2,053	-2	1,572	-1	1,609	-17
Molecular Diagnostics	502	7	527	6	518	8	562	4	614	29	944	91
Diabetes Care	465	1	493	0	437	-8	523	9	425	-2	407	-9
Tissue Diagnostics	251	-1	275	-4	273	6	305	-1	270	12	238	-8
Diagnostics Division	**2,899**	**1**	**3,376**	**4**	**3,232**	**6**	**3,443**	**1**	**2,881**	**5**	**3,198**	**2**

CER=Constant Exchange Rates; [1] Versus same period of prior year

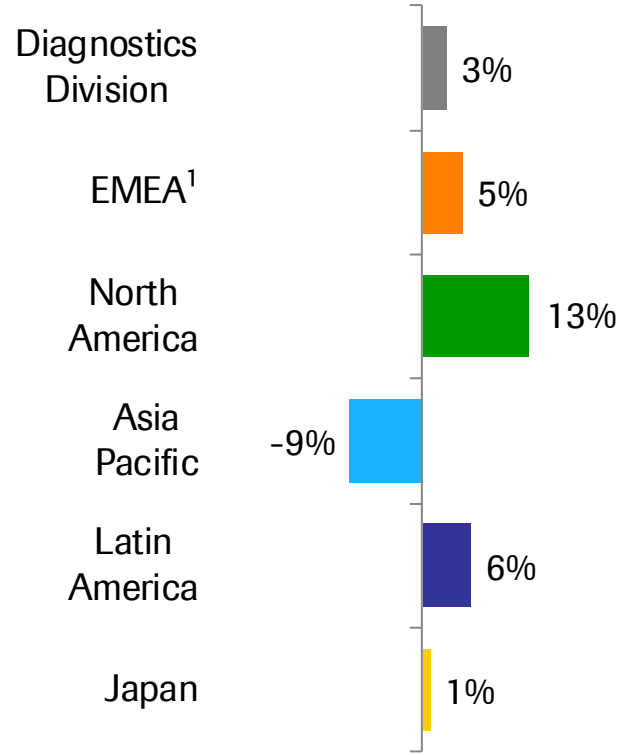
HY 2020: Diagnostics Division sales

Growth driven by North America and EMEA, partly offset by Asia Pacific

CHF 6,079m



CER sales growth

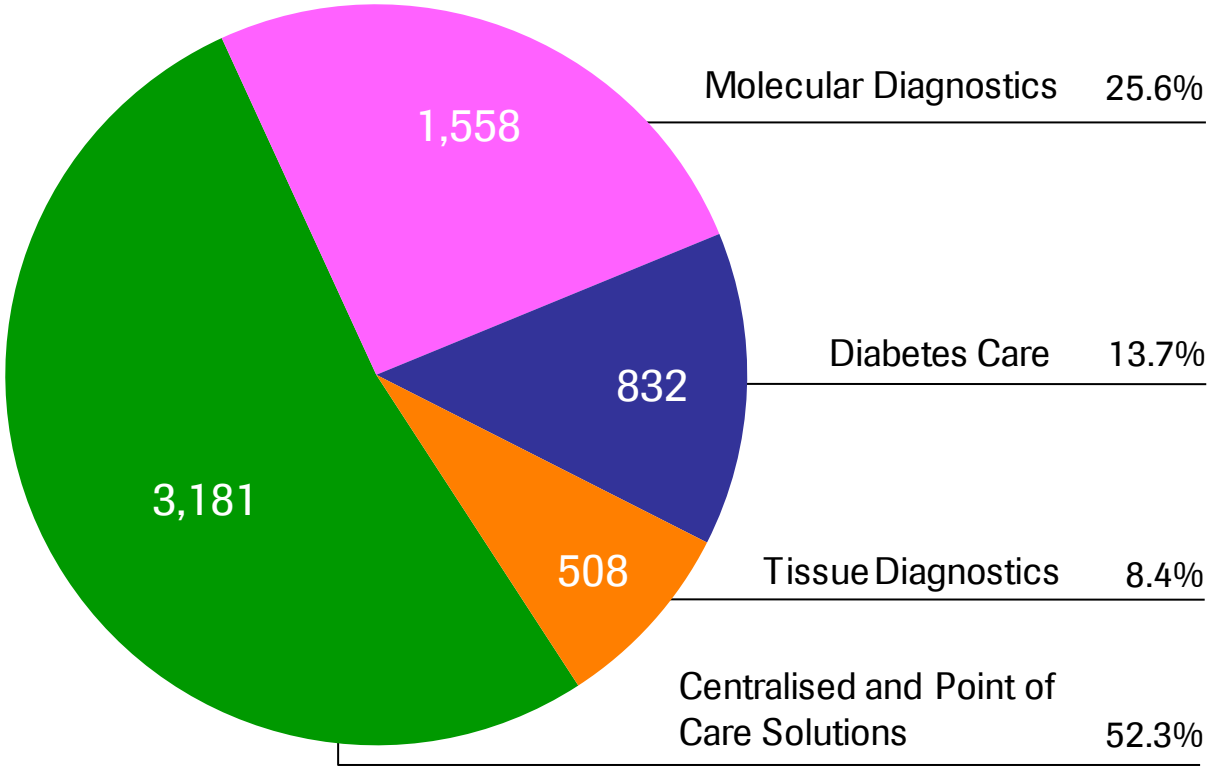


CER=Constant Exchange Rates; ¹ Europe, Middle East and Africa

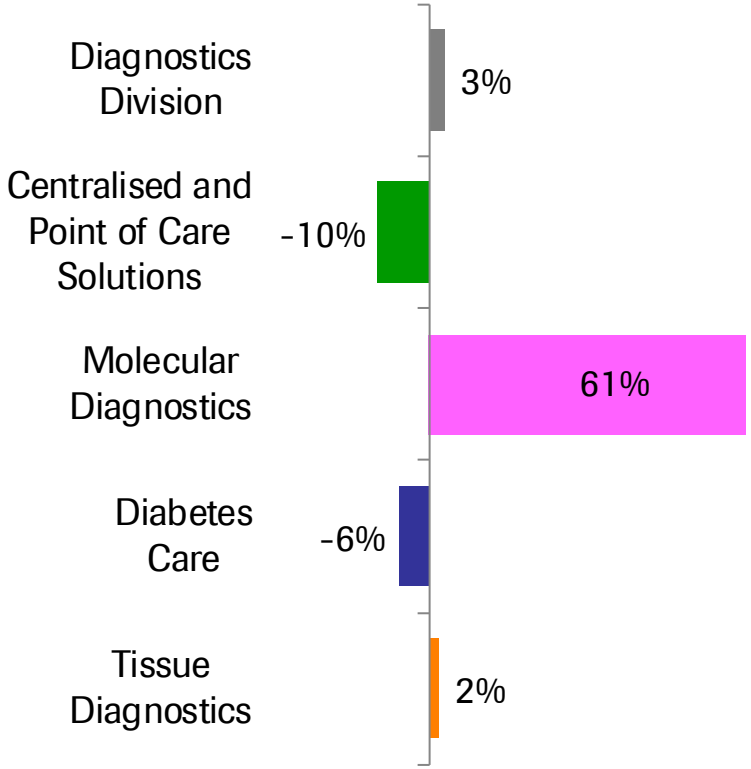
HY 2020: Diagnostics Division sales

Growth driven by Molecular Diagnostics, partially offset by Centralised and Point of Care Solutions

CHF 6,079m

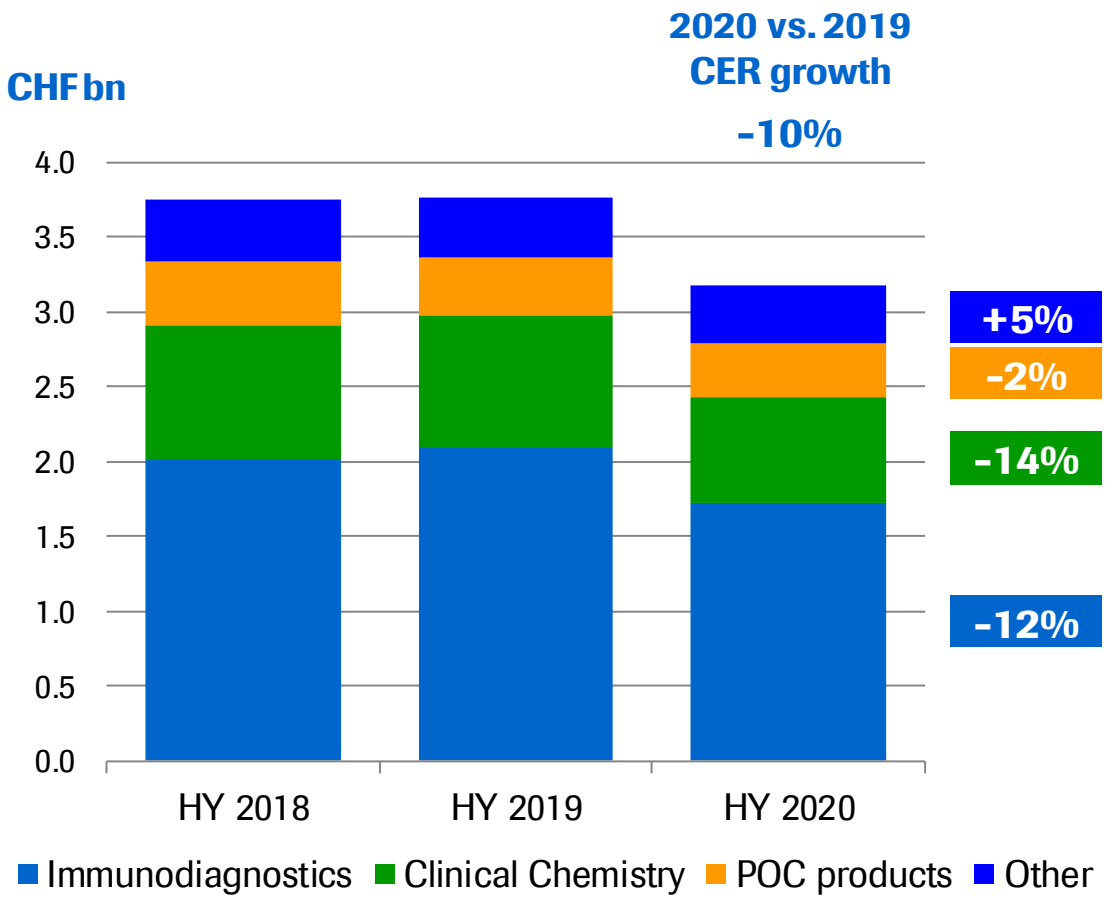


CER sales growth



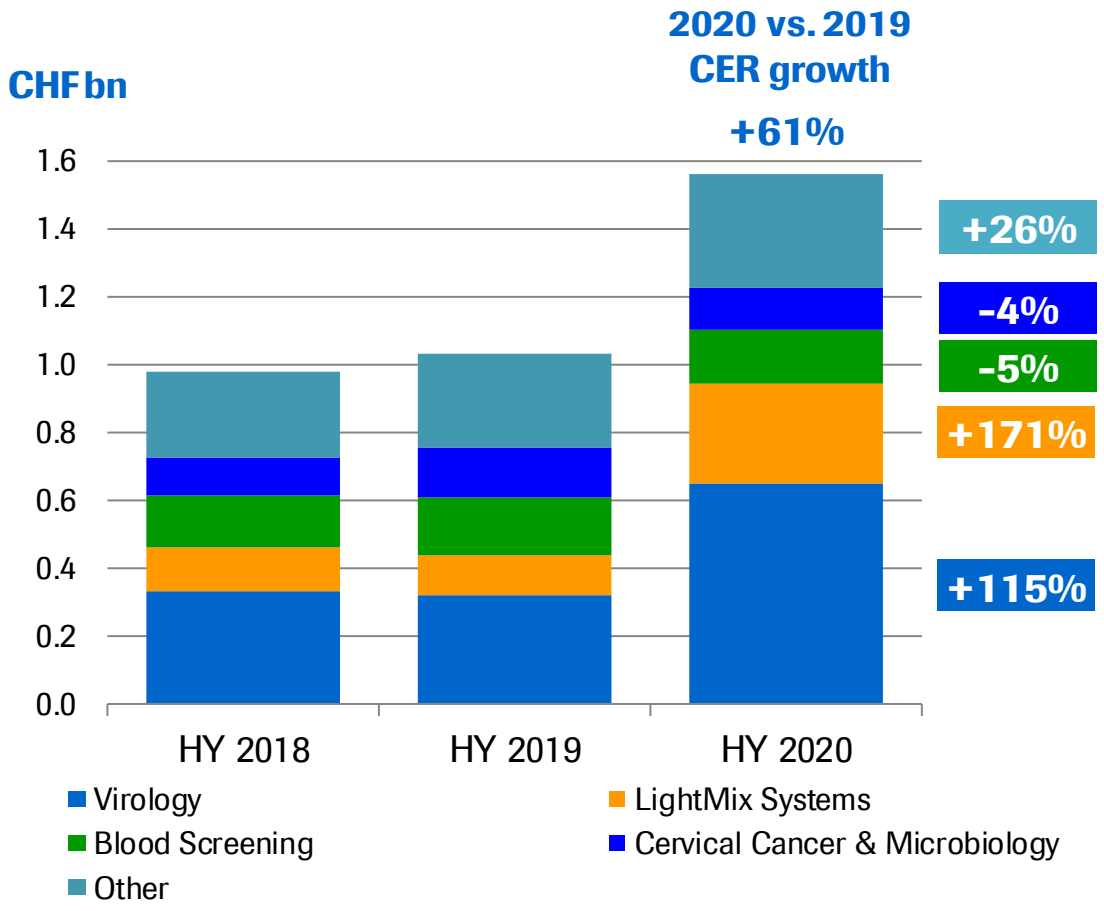
CER=Constant Exchange Rates

Centralised and Point of Care Solutions



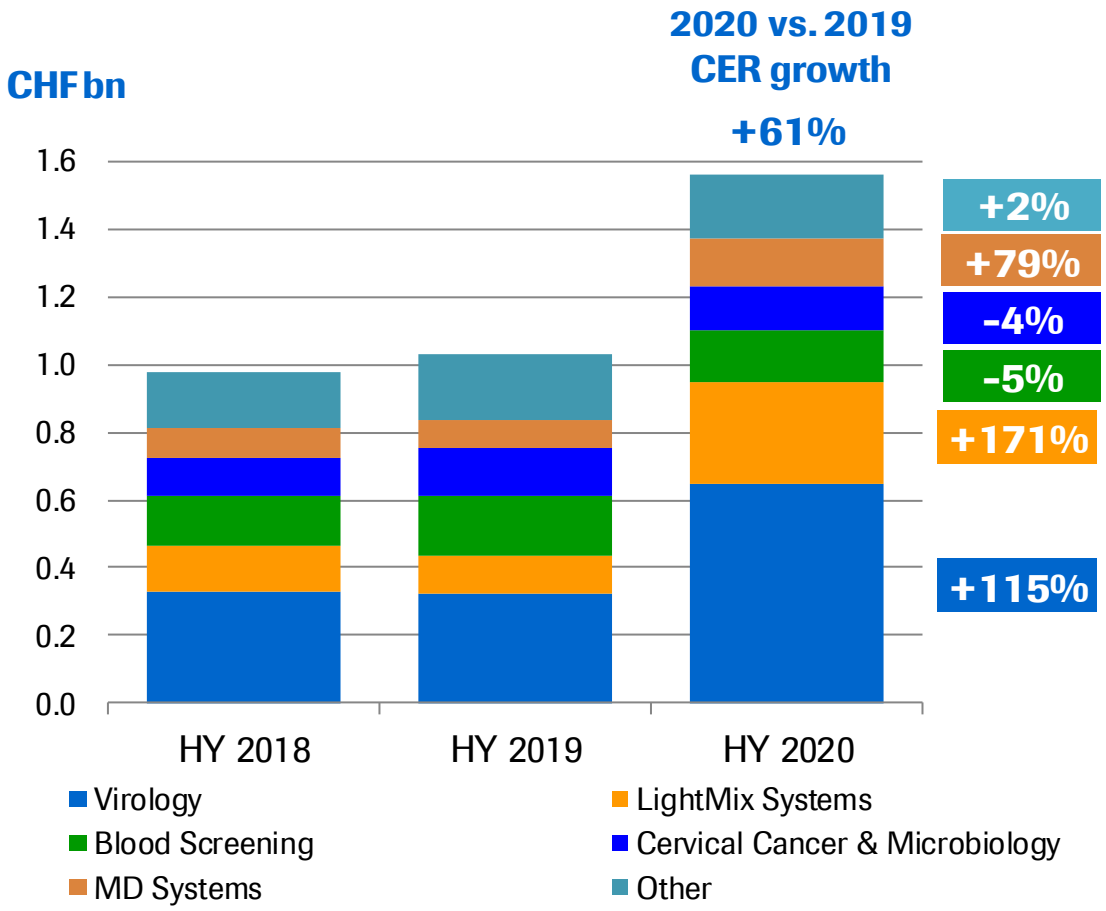
CER=Constant Exchange Rates

Molecular Diagnostics



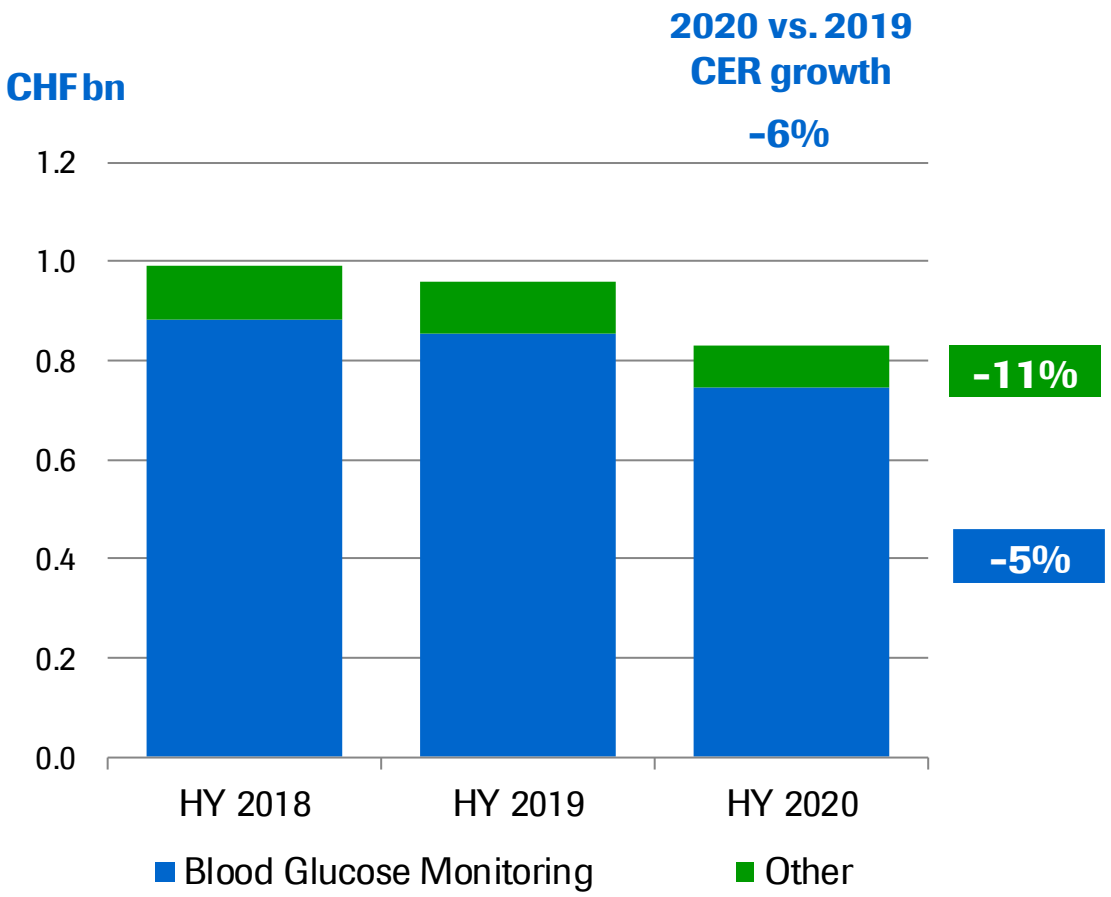
CER=Constant Exchange Rates

Molecular Diagnostics



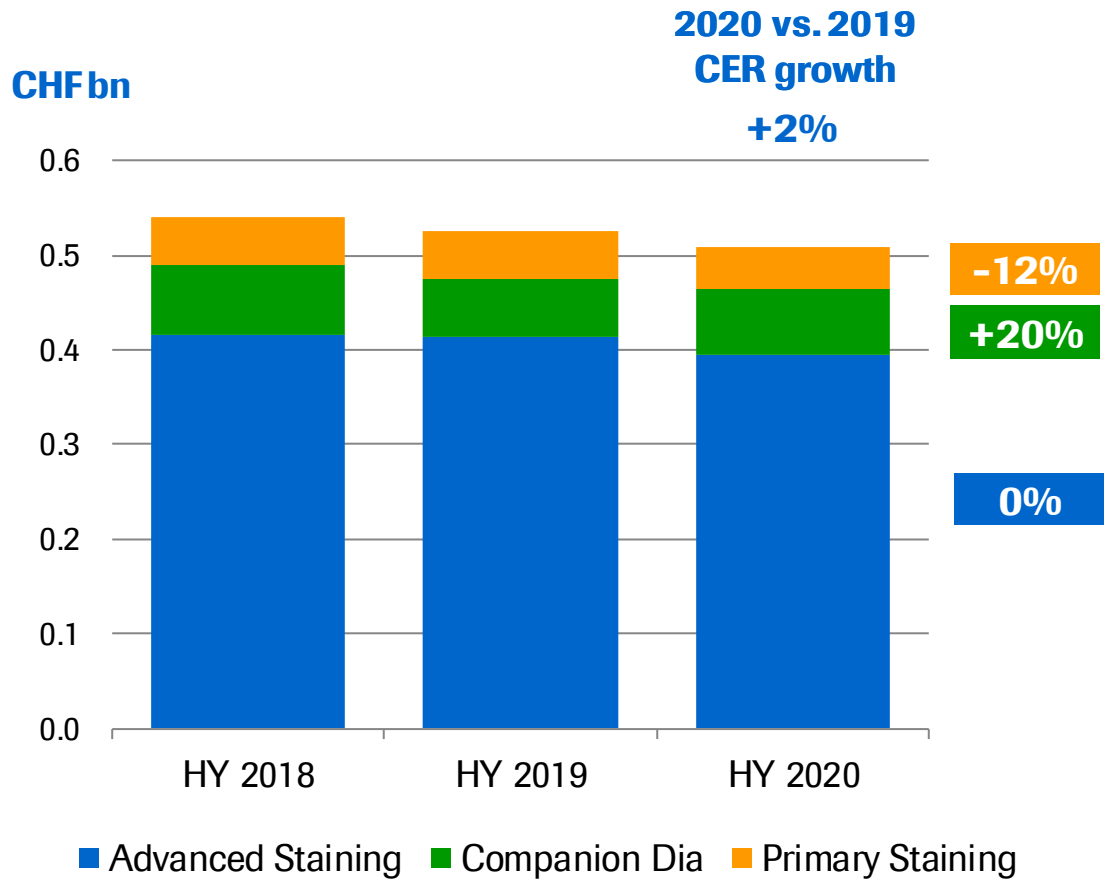
CER=Constant Exchange Rates

Diabetes Care



CER=Constant Exchange Rates

Tissue Diagnostics



CER=Constant Exchange Rates

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Roche Group HY 2020 results

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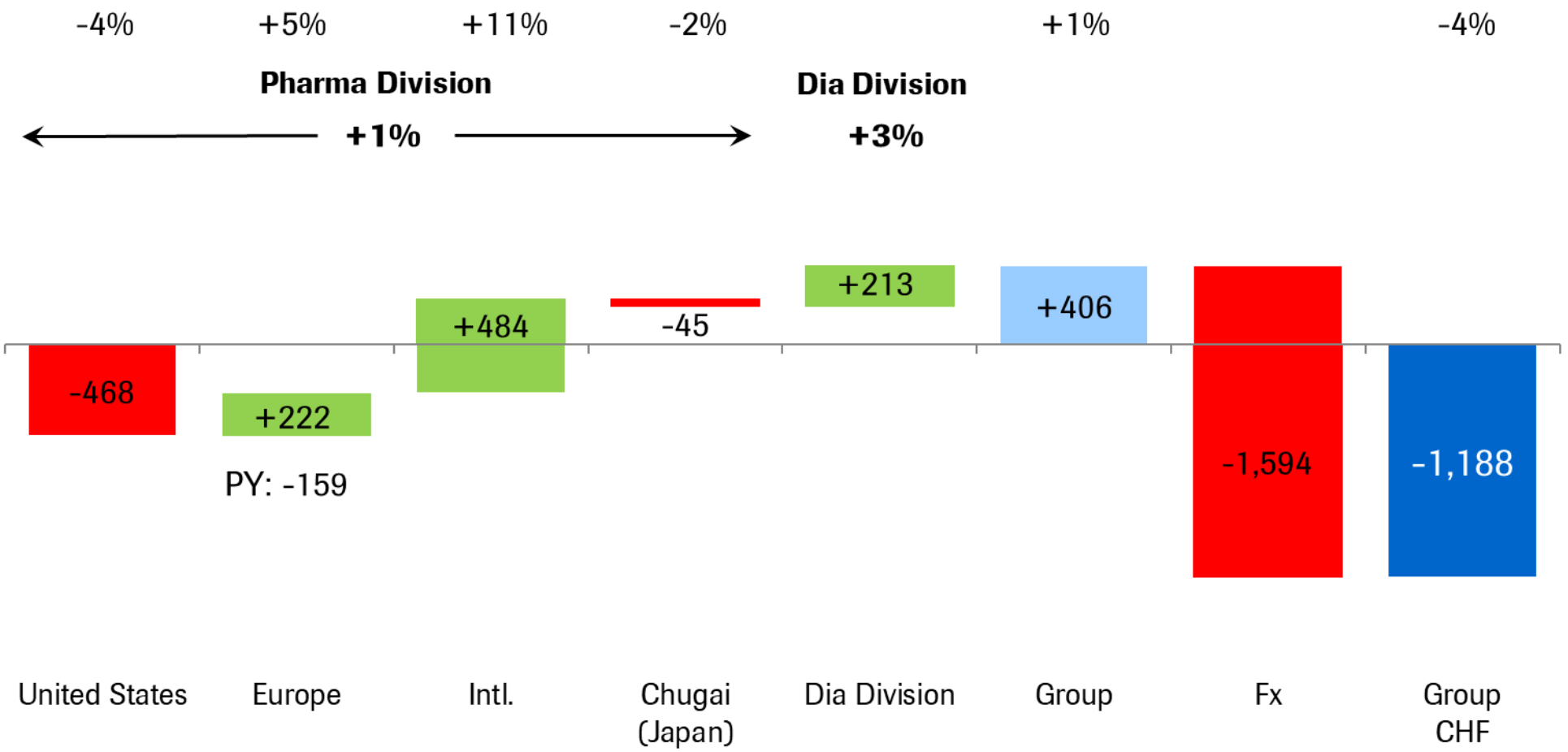
Foreign exchange rate information

Group sales HY 2020

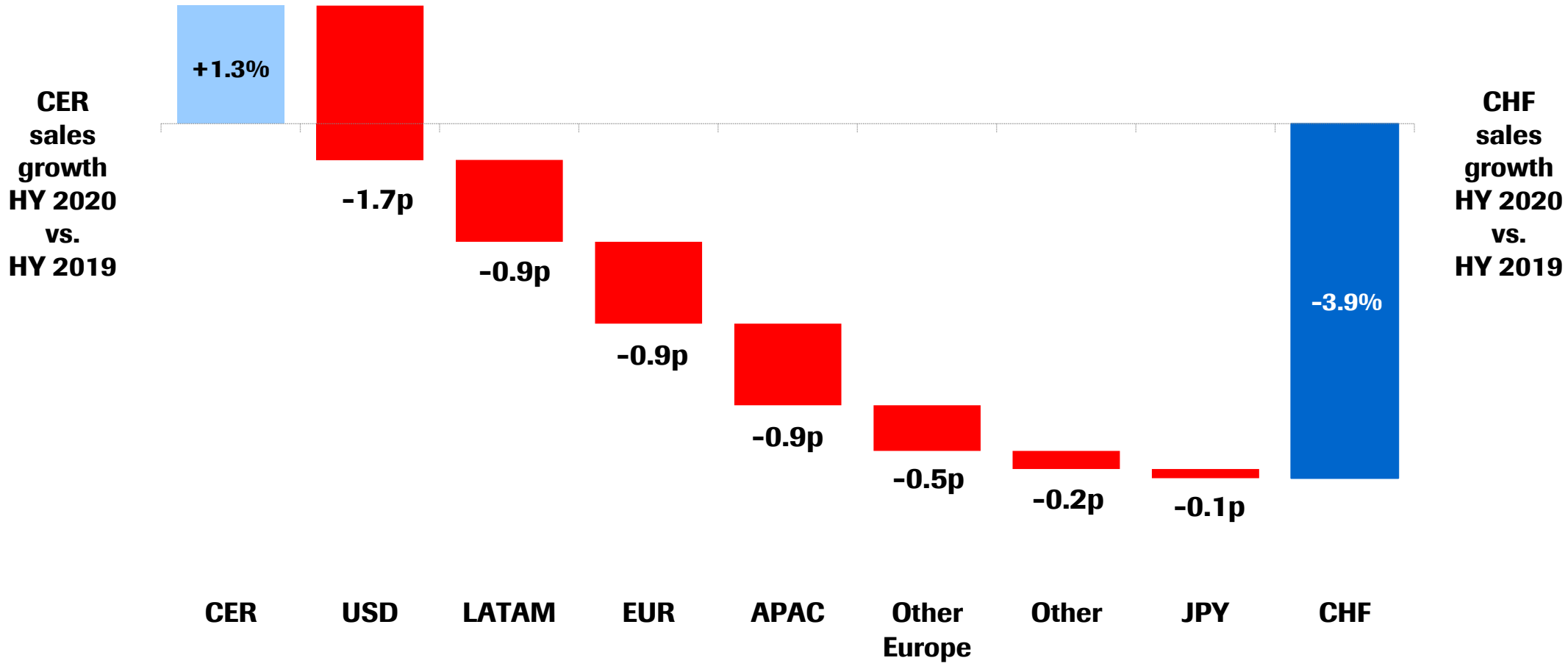
CER sales increase of +1% driven by International, Diagnostics and Europe, partially offset by US; Fx impact of -5%p



[1] avg full year 2019 to avg YTD June 2020 fx

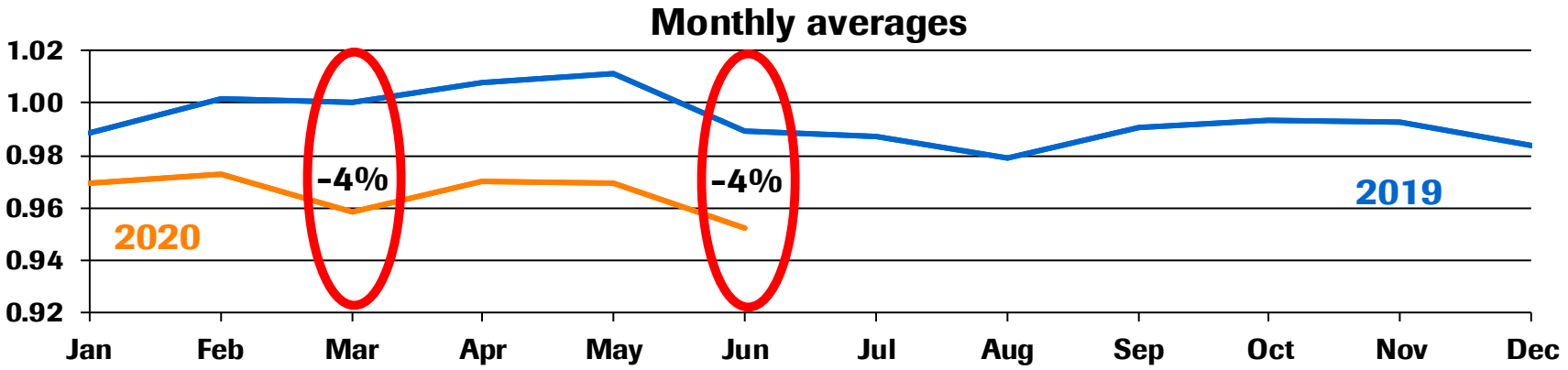
Exchange rate impact on sales growth

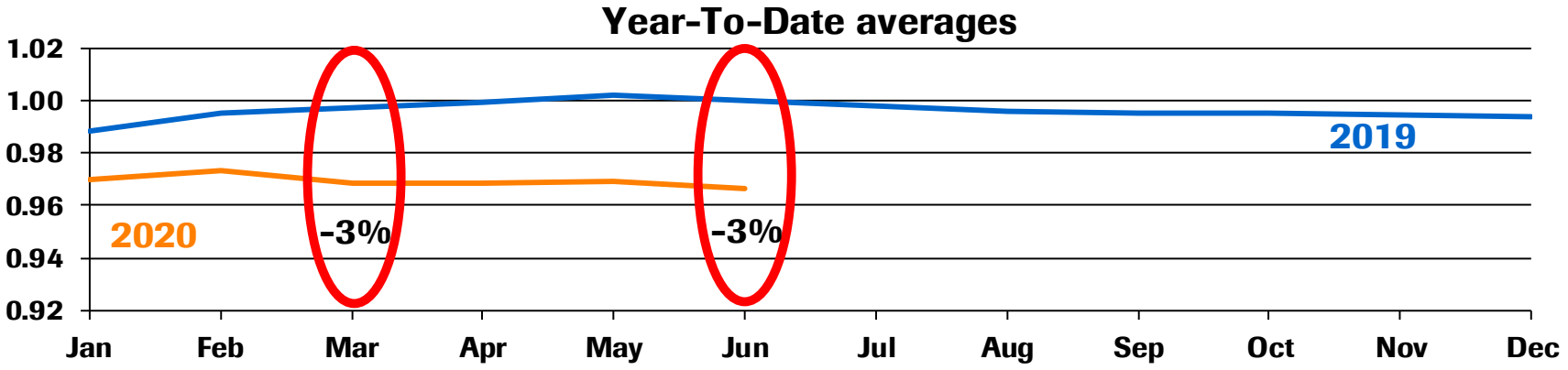
Negative impact due to all currencies



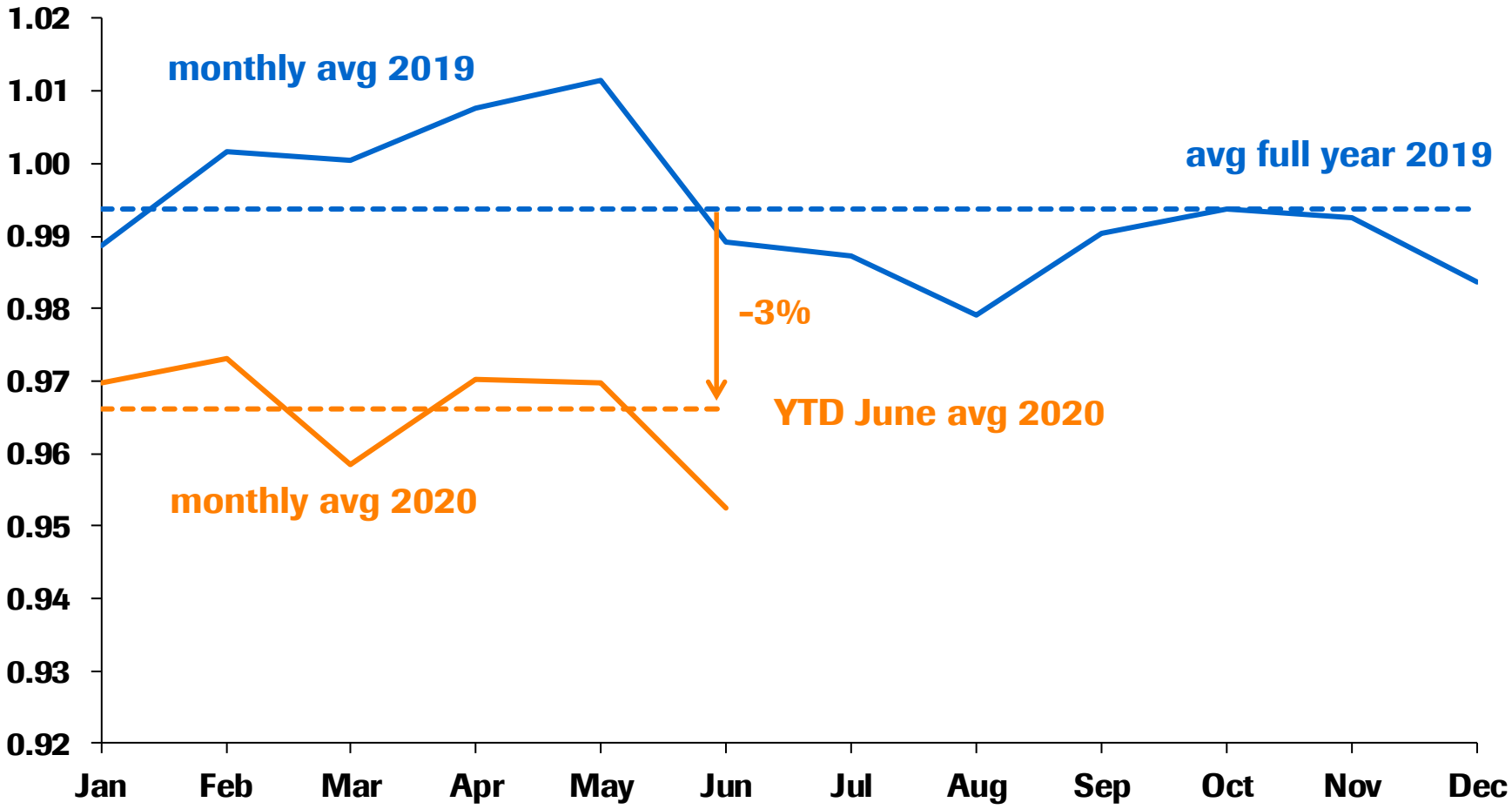
CER = Constant Exchange Rates (avg full year 2019)

CHF / USD

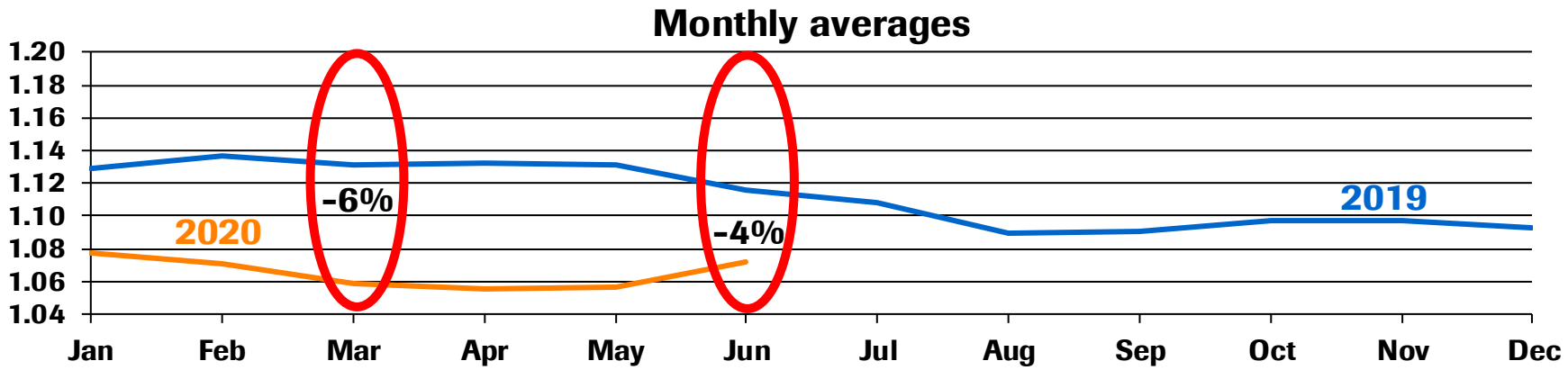

Monthly averages
1.02
1.00
0.98
0.96
0.94
0.92
-4%
-4%
2020
2019
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

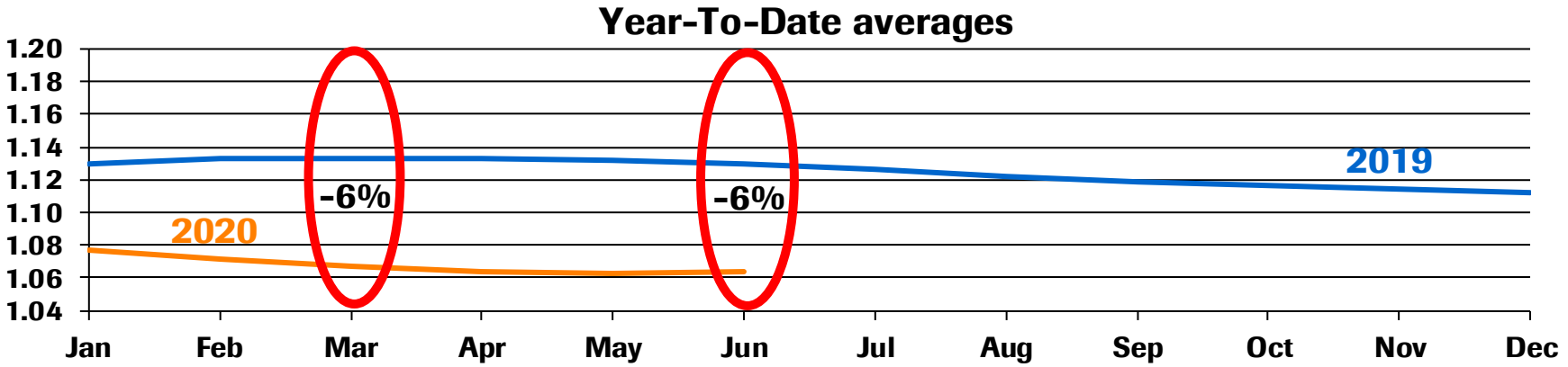

Year-To-Date averages
1.02
1.00
0.98
0.96
0.94
0.92
2020
-3%
-3%
2019
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / USD

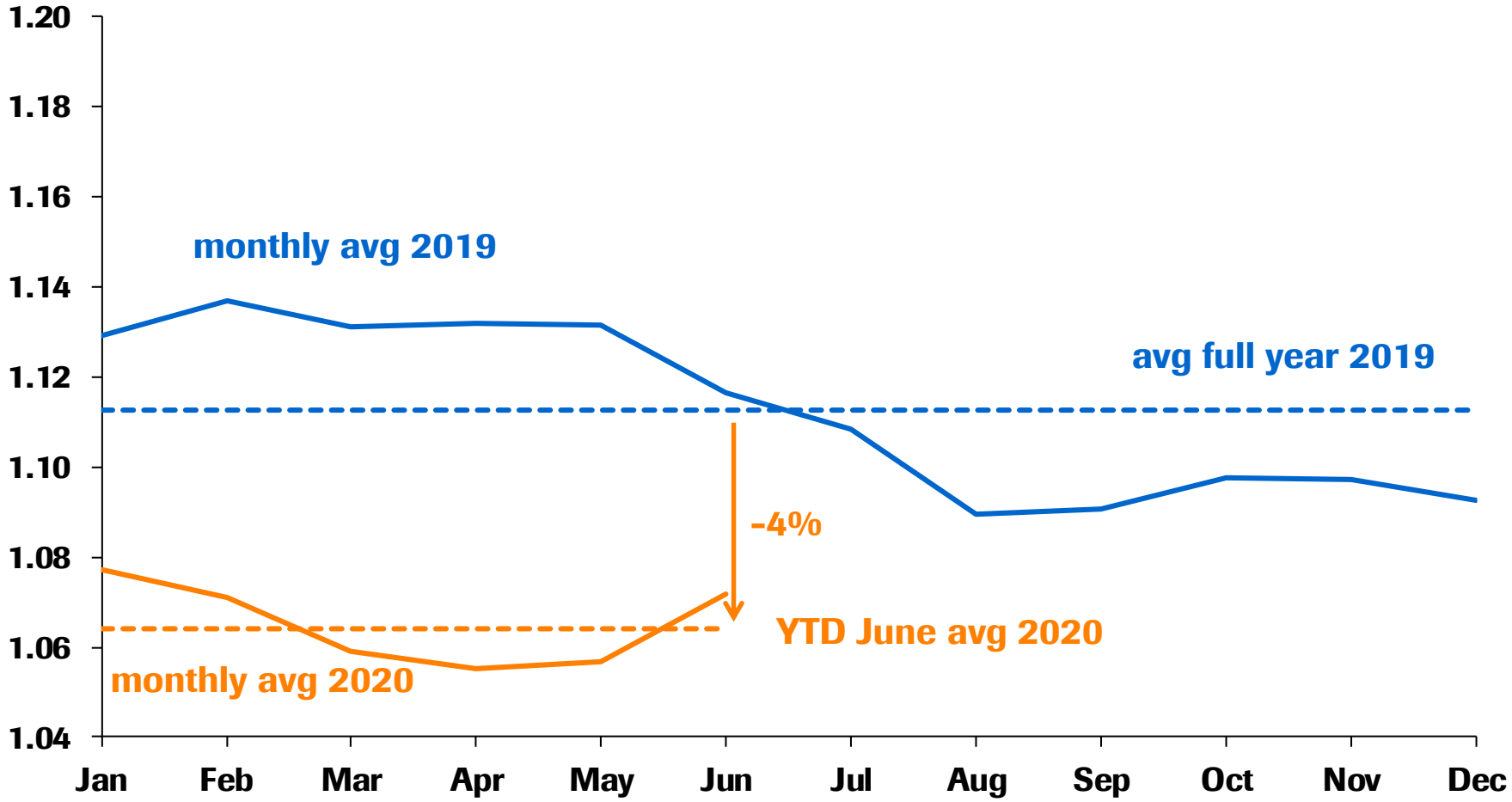

1.02
1.01
1.00
0.99
0.98
0.97
0.96
0.95
0.94
0.93
0.92
monthly avg 2019
avg full year 2019
-3%
YTD June avg 2020
monthly avg 2020
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / EUR


Monthly averages
1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2020
2019
-6%
-4%

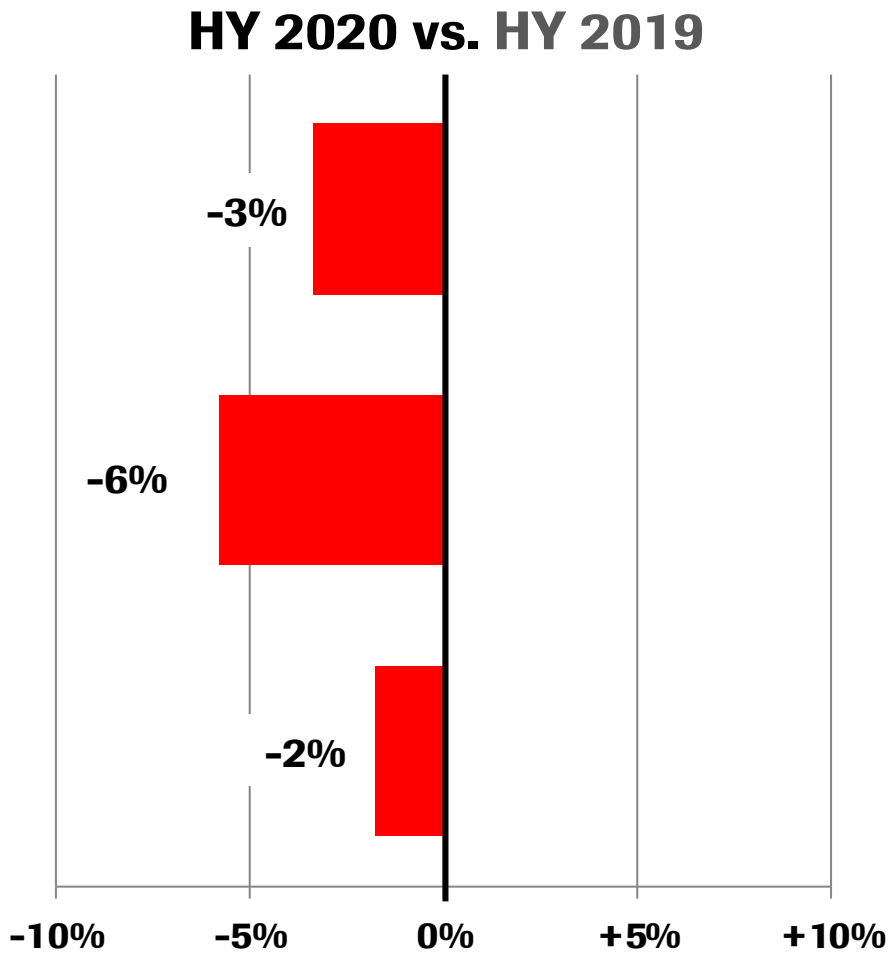

Year-To-Date averages
1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2020
2019
-6%
-6%

CHF / EUR


1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
monthly avg 2019
avg full year 2019
-4%
YTD June avg 2020
monthly avg 2020
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

Average CHF exchange rates

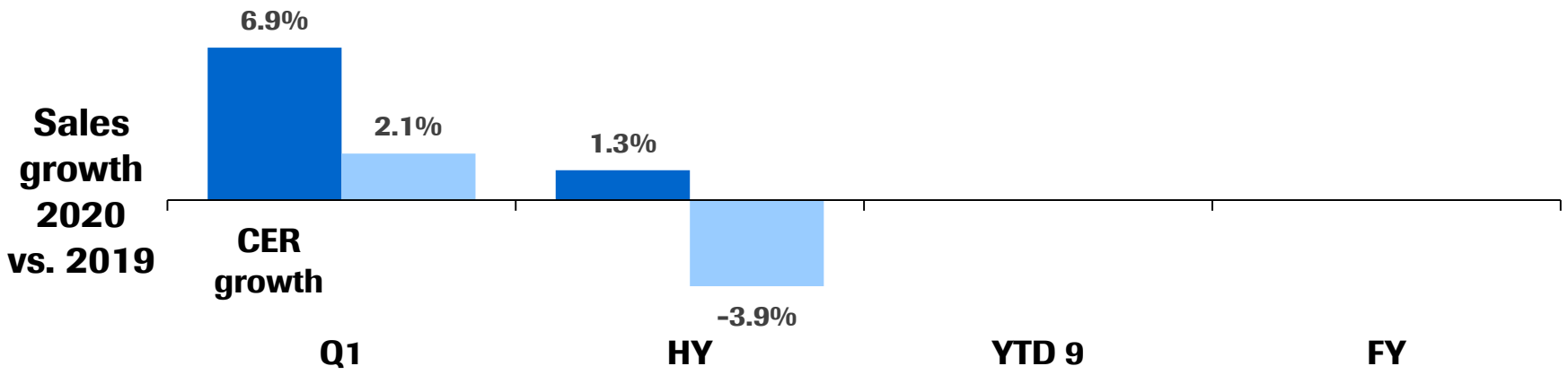
	HY 2020	HY 2019
USD	0.97	1.00
EUR	1.06	1.13
JPY	0.89	0.91



Exchange rate impact on sales growth

In HY 2020 negative impact of all currencies

Development of average exchange rates versus prior year period		
CHF / USD	-2.9%	-3.4%
CHF / EUR	-5.8%	-5.8%
CHF / JPY	-1.9%	-1.8%
Difference in CHF / CER growth	-4.8%p	-5.3%p

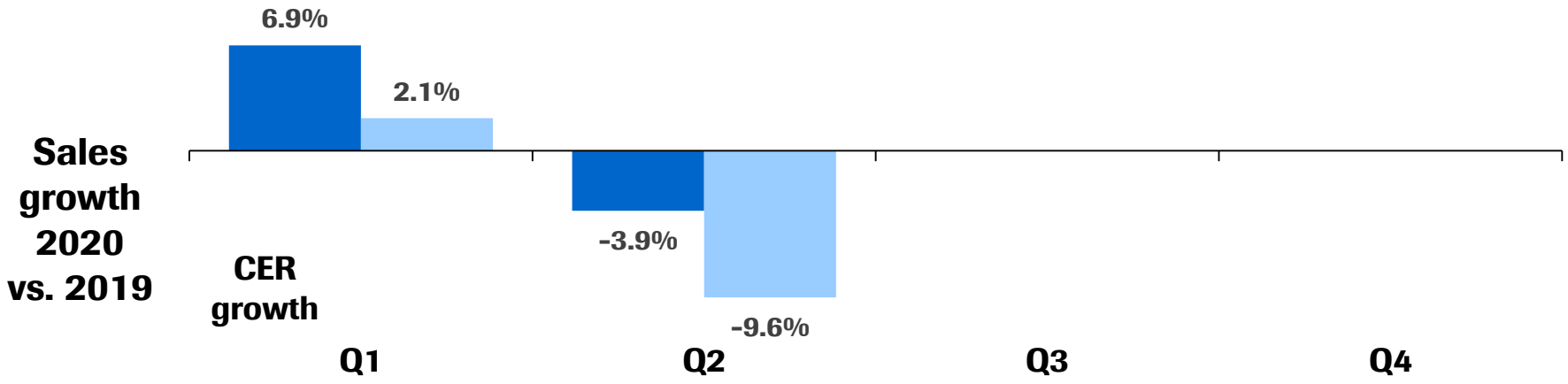


CER=Constant Exchange Rates (avg full year 2019)

Exchange rate impact on sales growth

In Q2 2020 negative impact of EUR, USD and JPY

Development of average exchange rates versus prior year period		
CHF / USD	-2.9%	-3.9%
CHF / EUR	-5.8%	-5.8%
CHF / JPY	-1.9%	-1.3%
Difference in CHF / CER growth	-4.8%p	-5.7%



CER=Constant Exchange Rates (avg full year 2019)

Doing now what patients need next