
Roche

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

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

Any statements regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche’s earnings or earnings per share for this year or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

For marketed products discussed in this presentation, please see full prescribing information on our website www.roche.com

Roche

HY 2019 results

Basel, 25 July 2019

Group

Severin Schwan
Chief Executive Officer

HY 2019 performance

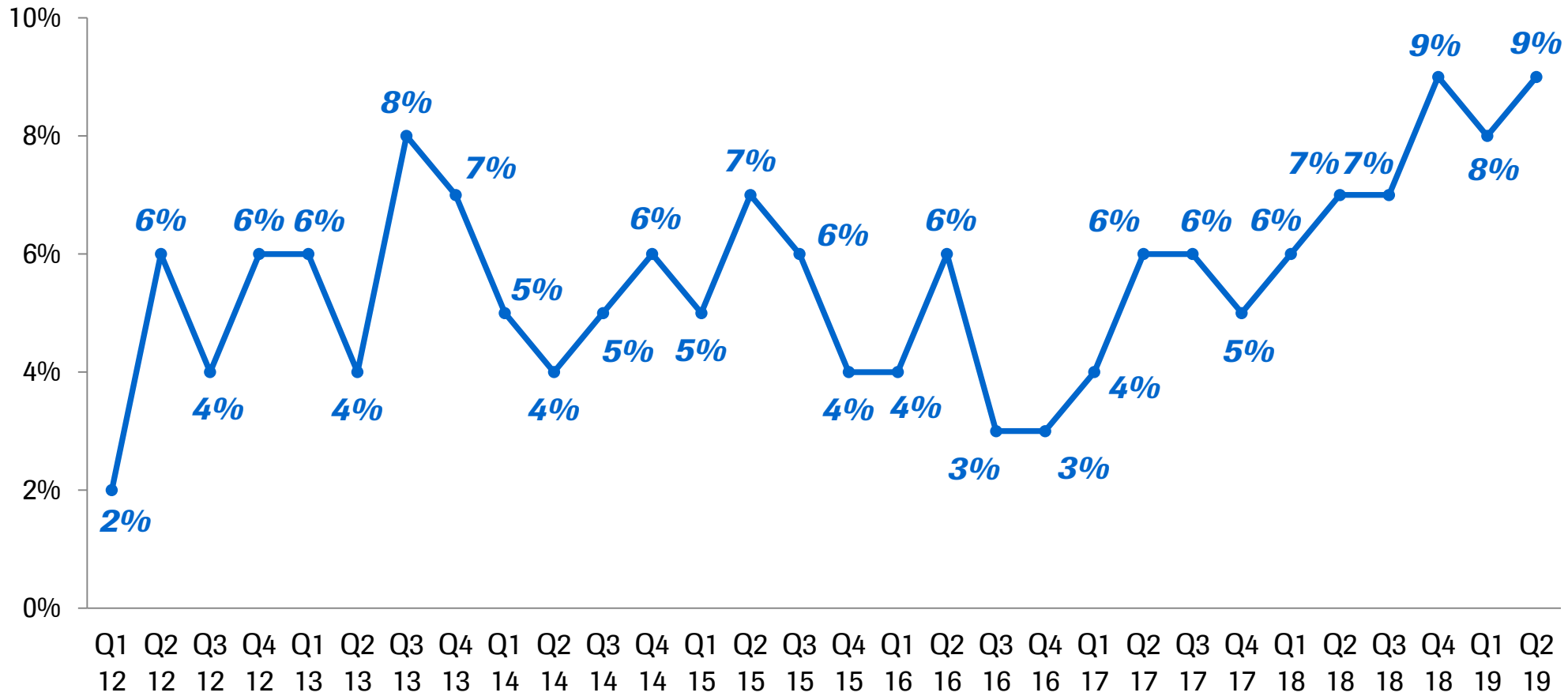
Outlook

HY 2019: Strong sales growth

	HY 2019 CHFbn	HY 2018 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	**24.2**	21.8	**11**	**10**
Diagnostics Division	**6.3**	6.3	**0**	**2**
Roche Group	**30.5**	28.1	**8**	**9**

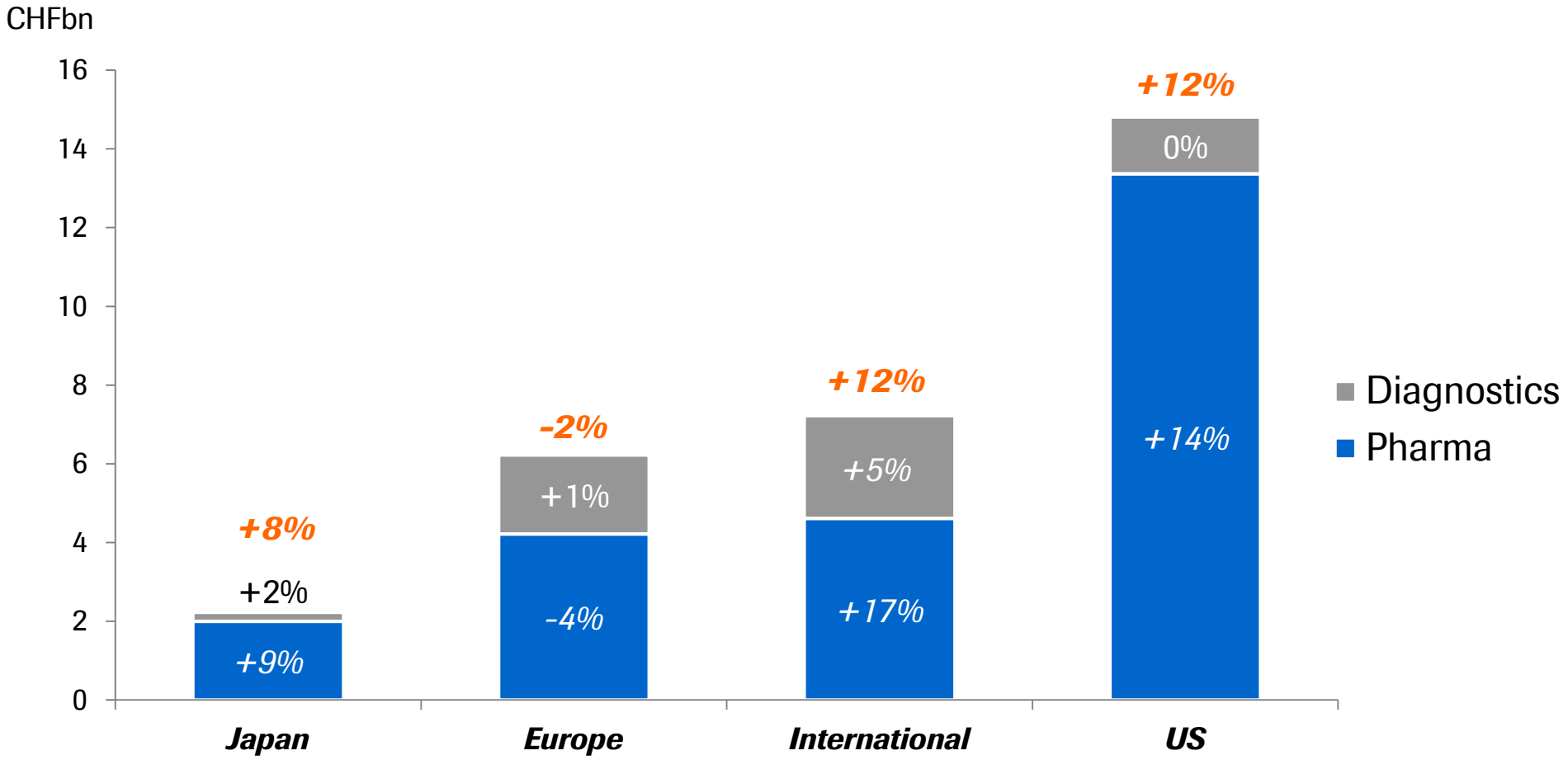
CER=Constant Exchange Rates

Q2 2019: Group sales growth for the eighth consecutive year



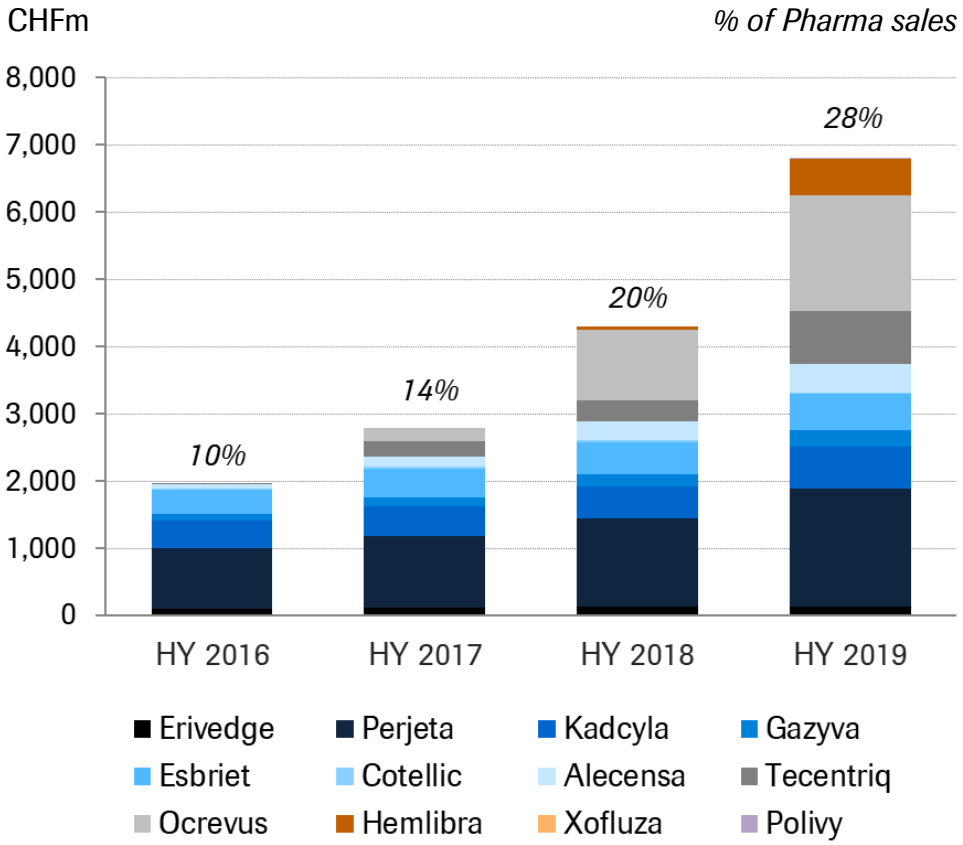
All growth rates at Constant Exchange Rates (CER)

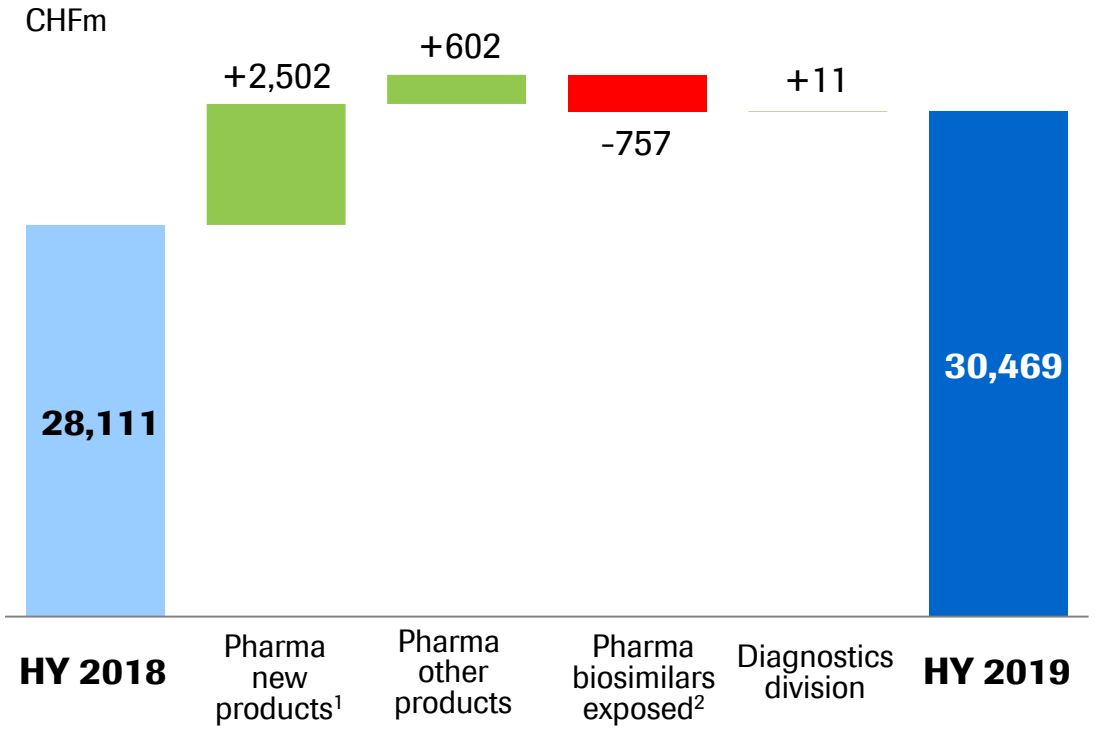
HY 2019: Strong sales growth in US, International and Japan



All growth rates at Constant Exchange Rates (CER)

New products with strong momentum



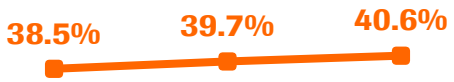


All absolute values are presented in CHFm reported; [1] Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, and Polivy; [2] MabThera and Herceptin in Europe and Japan

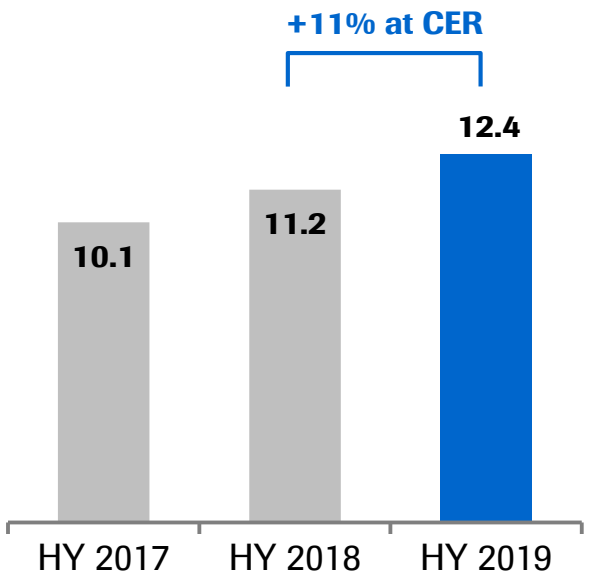
HY 2019: Strong profitability growth

Core operating profit

% of sales

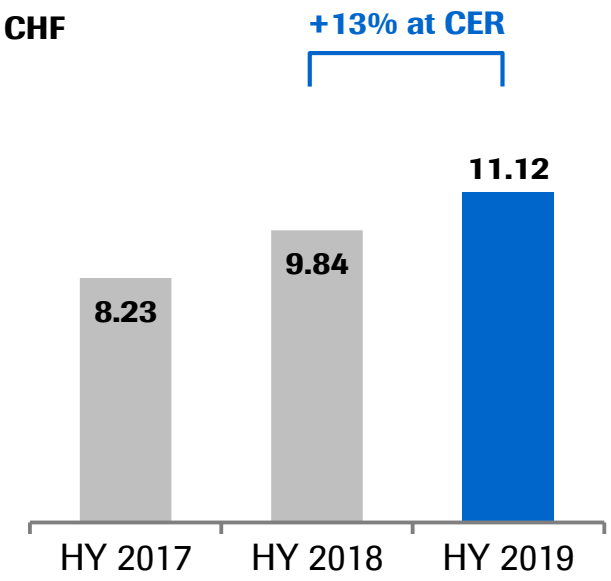


CHFbn

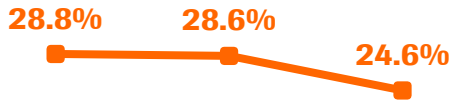


Core EPS

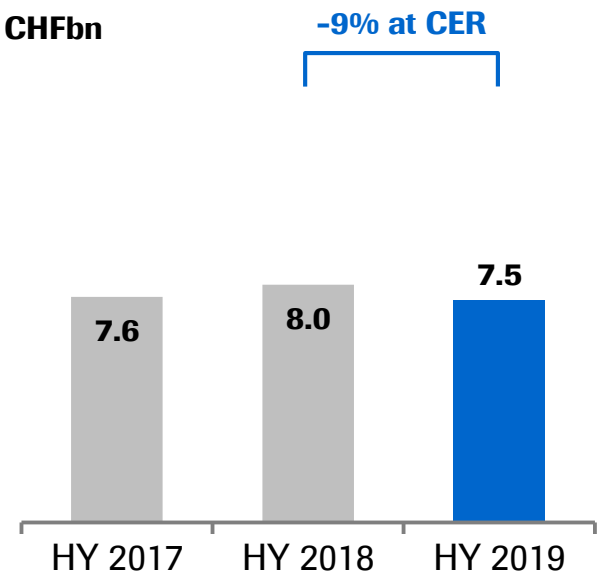
CHF



Operating free cash flow



CHFbn



CER=Constant Exchange Rates

Roche significantly advancing patient care

BTD's and BDD's reflecting the quality of our research

26 *Breakthrough Therapy Designations (BTD)*

Year	Molecule	Indication
2019	**Venclexta + Gazyva**	1L unfit CLL
	Kadcyla	Adjuvant HER2+ BC
2018	**satralizumab**	NMOSD
	Xolair	Food allergies
	Tecentriq + Avastin	HCC
	Hemlibra	Hemophilia A non-inhibitors
	entrectinib	NTRK+ solid tumors
	balovaptan	Autism spectrum disorders
2017	**polatuzumab vedotin + BR**	R/R DLBCL
	Venclexta + LDAC	1L unfit AML
	Zelboraf	BRAF-mutated ECD
	Rituxan	Pemphigus vulgaris
2016	**Actemra**	Giant cell arteritis
	Alecensa	1L ALK+ NSCLC
	Ocrevus	PPMS
	Venclexta + HMA	1L unfit AML
	Venclexta + Rituxan	R/R CLL
2015	**Actemra**	Systemic sclerosis
	Tecentriq	NSCLC
	Venclexta	R/R CLL 17p del
	Hemlibra	Hemophilia A inhibitors
2014	**Esbriet**	IPF
	Lucentis	Diabetic retinopathy
	Tecentriq	Bladder
2013	**Alecensa**	2L ALK+ NSCLC
	Gazyva	1L CLL

7 *Breakthrough Device Designations (BDD)*

Year	Device	Intended use
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

Replace and extend the business: Excellent start into the year

Replace/extend existing businesses		Entering new franchises
MabThera/Rituxan	Gazyva, Venclexta, Polivy, mosunetuzumab, CD20 x CD3	**MS:** Ocrevus
Herceptin	Perjeta, Kadcyla, Herceptin + Perjeta FDC-SC	**Hemophilia A:** Hemlibra
Avastin	Tecentriq, Alecensa, Rozlytrek	
Lucentis	faricimab Port delivery system (PDS)	**CNS:** NMOSD, SMA, Huntington's, Autism, Alzheimer's
Tamiflu	Xofluza	

Achievements HY 2019

Entering new franchises

Ocrevus:	Treat early and with full dose to max benefit, good safety sustained (Data at AAN)
satralizumab:	Ph III mono & combo data – filing on-going
risdiplam:	1 year data in types 1/2/3 SMA
Gazyva:	Ph II positive headline in lupus nephritis
Hemlibra:	EU approval in Hemophilia A (non-inhibitors)

Replace/extend existing businesses

Gazyva+Ven:	US approval in 1L CLL
Polivy:	US approval in R/R DLBCL
Kadcyla:	US approval in adj. HER2+ BC
Tecentriq:	EU approval in 1L NSCLC with Avastin
	US approval in 1L SCLC & 1L TNBC
Herceptin:	US approval Hylecta (SC formulation)
Rozlytrek:	JP approval in NTRK+ solid tumors
Xofluza:	US filing acceptance in high risk patients positive Ph IIIs in prevention and children

FDC=fixed dose combination; NMOSD=neuromyelitis optica spectrum disorder; SMA=spinal muscular atrophy; AAN=American Academy of Neurology; CLL=chronic lymphocytic leukemia; R/R DLBCL=relapsed/refractory diffuse large B-cell lymphoma; BC=breast cancer; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; TNBC=triple-negative breast cancer

Outlook

Roche: Strong news flow over next 18 months

Diversifying the late stage pipeline and setting new SOC

Product	Status
risdiplam in SMA	Phase II/III types 1/2/3
HTT-ASO in Huntington's	Phase II/III
satralizumab in NMOSD	Phase III (broad label)
Gazyva in lupus nephritis	Phase II
etrolizumab in UC and Crohn's	Phase III (induction and maintenance)
PDS in nAMD	Phase III
faricimab in DME/nAMD	Phase III

Product	Status
Tecentriq in 1L HCC	Phase III
Tecentriq in FL ovarian cancer	Phase III
Tecentriq in adj bladder cancer	Phase III
Tecentriq in neoadj TNBC	Phase III
Tecentriq in (neo)adj NSCLC	Phase III
Tecentriq in 1L melanoma	Phase III (Dx+)
Perjeta + Herceptin FDC-SC	Phase III
ipatasertib 1/2L TNBC	Phase III (Dx+)
ipatasertib 1L+ HR+	Phase III (Dx+)
ipatasertib in 1L mCRPC	Phase III (all comers and Dx+)
idasanutlin in R/R AML	Phase III
Polivy in 1L DLBCL	Phase III

Neuroscience
Immunology
Ophthalmology
Oncology

SOC=standard of care; SMA=spinal muscular atrophy; NMOSD=neuromyelitis optica spectrum disorder; UC=ulcerative colitis; PDS=port delivery system; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; HCC=hepatocellular carcinoma; FL=first line; TNBC=triple-negative breast cancer; NSCLC=non-small cell lung cancer; FDC=fixed dose combination; HR=hormone receptor; mCRPC=metastatic castration resistant prostate cancer; R/R AML=relapsed/refractory acute myeloid leukemia; DLBCL=diffuse large B-cell lymphoma

2019 outlook further raised

Sales growth to "mid- to high-single digit" from "mid-single digit"

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

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Bill Anderson
CEO Roche Pharmaceuticals

HY 2019: Pharmaceuticals Division sales

Strong growth in US, International and Japan

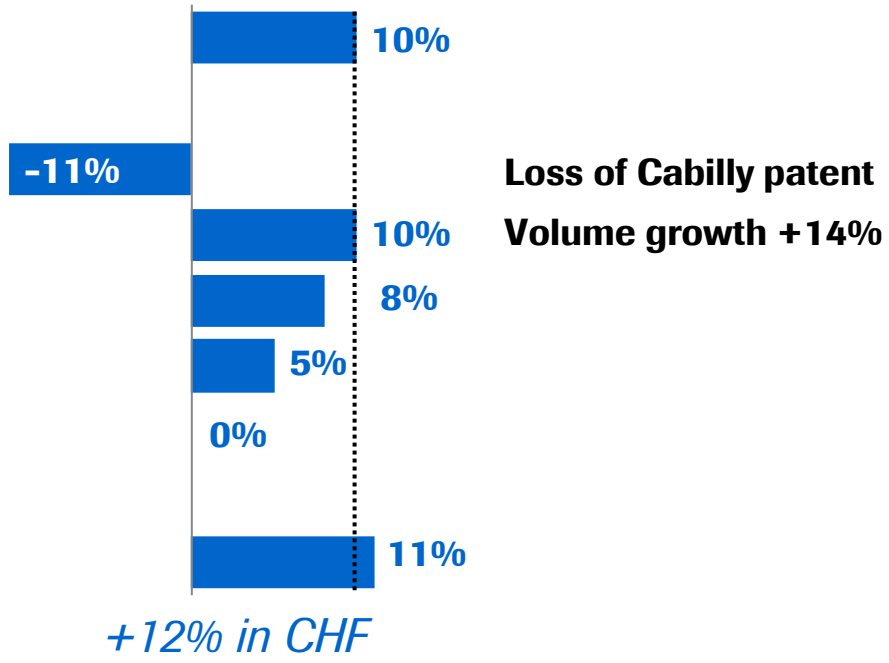
	HY 2019 CHFm	HY 2018 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**24,194**	**21,847**	**11**	**10**
United States	13,370	11,378	18	14
Europe	4,221	4,528	-7	-4
Japan	1,988	1,781	12	9
International	4,615	4,160	11	17

CER=Constant Exchange Rates

HY 2019: Pharma Division

Strong Core operating profit grows ahead of sales

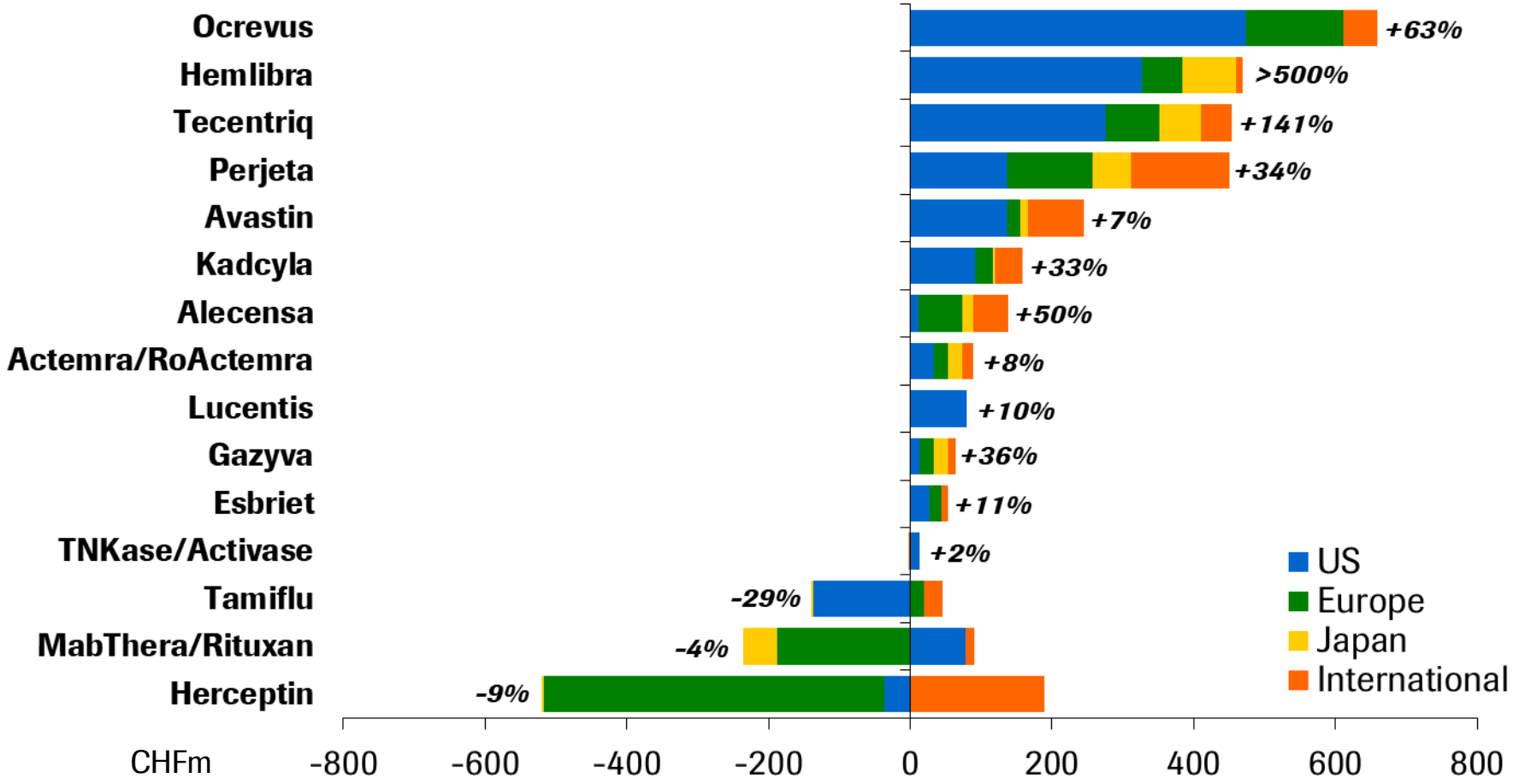
	HY 2019 CHFm	HY 2019 % sales
Sales	**24,194**	**100.0**
Royalties & other op. inc.	1,249	5.2
Cost of sales	-4,939	-20.6
M & D	-3,395	-14.0
R & D	-4,873	-20.1
G & A	-736	-3.0
Core operating profit	**11,500**	**47.5**



CER=Constant Exchange Rates

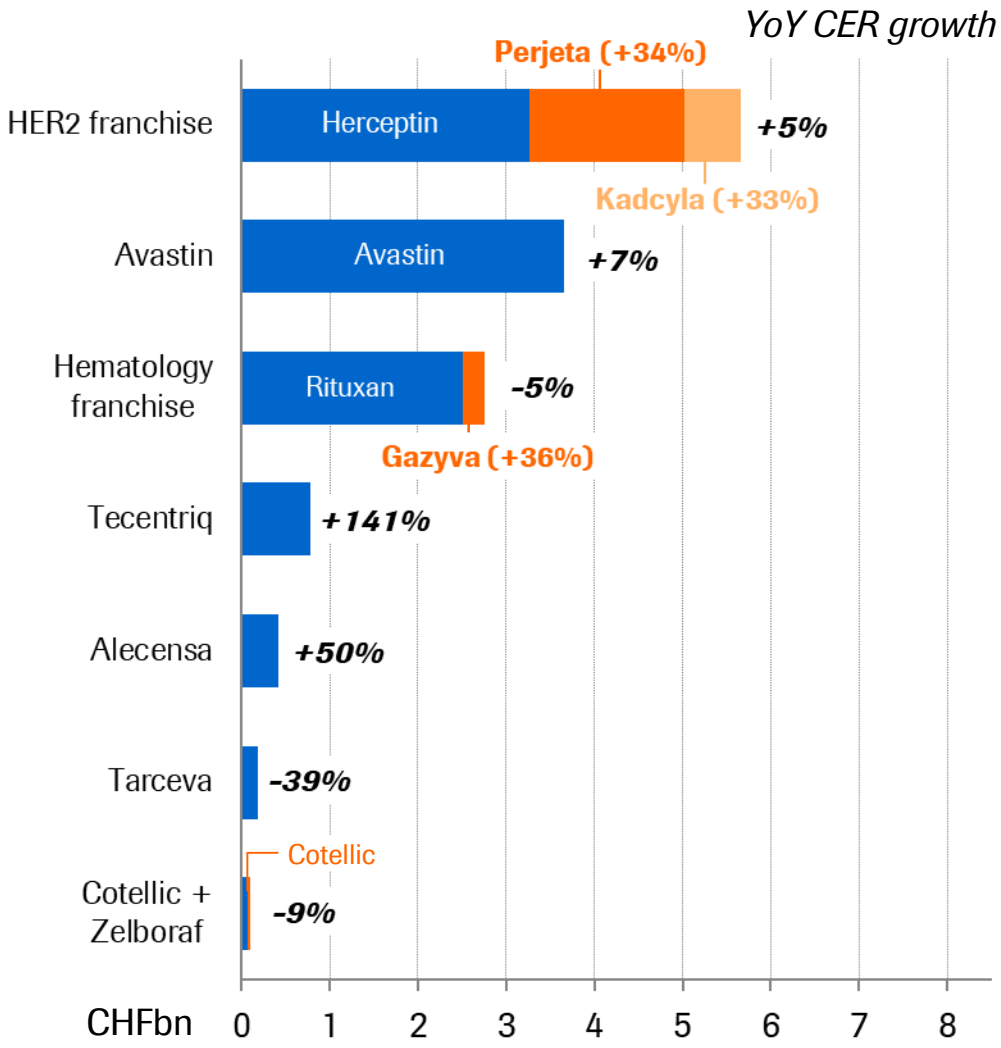
HY 2019: Portfolio rejuvenation on-going

Strong growth from new products



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

HY 2019: Oncology sales +6% driven by recent approvals



Oncology Q2 update

HER2 franchise

- Perjeta: Growth driven by eBC
- Kadcyla: Strong uptake in adj BC and growth in 2L mBC

Avastin franchise

- Stable growth in CRC and OC; strong uptake in China

Hematology franchise

- Venclexta:* Strong growth in 1L AML & 1L and R/R CLL
- Gazyva: Growth driven by approved indications

Tecentriq

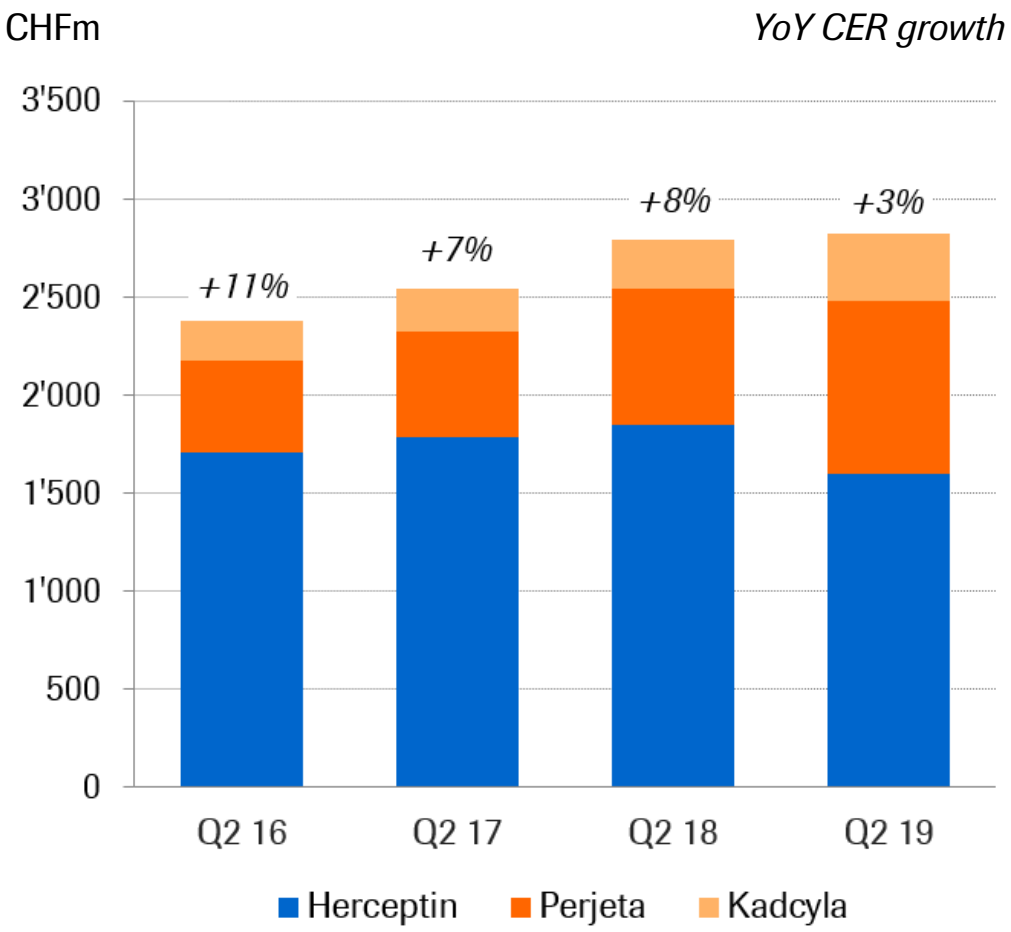
- Growth driven by first-in-class launches in 1L SCLC & 1L TNBC

Alecensa

- Further market share gains in 1L ALK+ NSCLC

CER=Constant Exchange Rates; HY 2019 Oncology sales: CHF 13.9bn; CER growth +6%; * Venclexta sales booked by AbbVie and therefor not included; eBC=early breast cancer; mBC=metastatic breast cancer; CRC=colorectal cancer; OC=ovarian cancer; AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; SCLC=small cell lung cancer; TNBC=triple-negative breast cancer; NSCLC=non-small cell lung cancer

HER2 franchise: Growth due to Perjeta and Kadcyla



HER2 franchise Q2 update

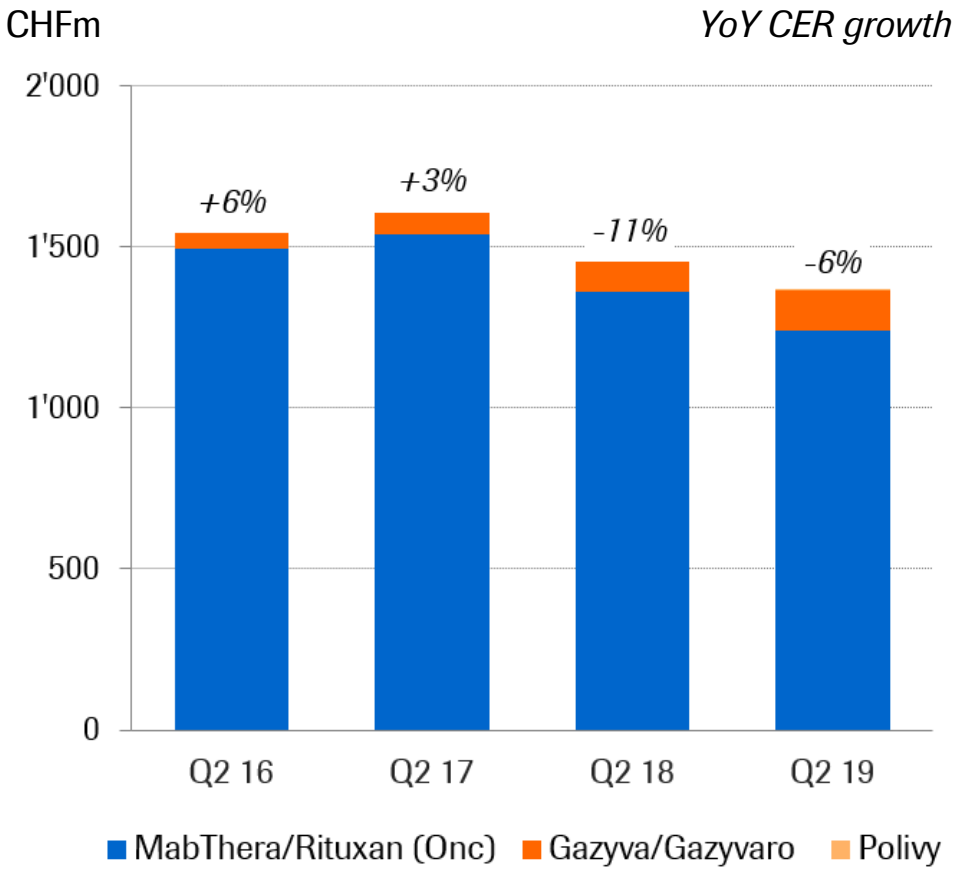
- Perjeta US (+9%): Growth driven by eBC (APHINITY); QoQ switching of eligible new patients to Kadcyla as planned
- Perjeta EU (+28%): Strong eBC uptake
- Kadcyla US (+62%): Growth in adjuvant setting for patients with residual disease (KATHERINE)

Outlook 2019

- US/EU: Continued Perjeta and Kadcyla uptake in eBC
- US: Market entry of Herceptin biosimilars
- APHINITY 2nd OS interim analysis (5 years) and longer term iDFS results to be presented
- Ph III (FEDERICA) for Herceptin + Perjeta FDC-SC

CER=Constant Exchange Rates; eBC=early breast cancer; OS=overall survival; iDFS=invasive disease free survival; FDC=fixed dose combination

Hematology franchise: Increasing contribution from Gazyva, Venclexta, Polivy



Hematology franchise Q2 update

CD20 franchise

- MabThera (onc) EU (-33%): Erosion rate slows
- Gazyva (+38%): Growth driven by 1L FL

Venclexta*

- US: Strong growth driven by 1L and R/R CLL and 1L unfit AML
- US: Early approval for Venclexta + Gazyva in 1L CLL

Polivy

- US: First sales following early approval in R/R DLBCL

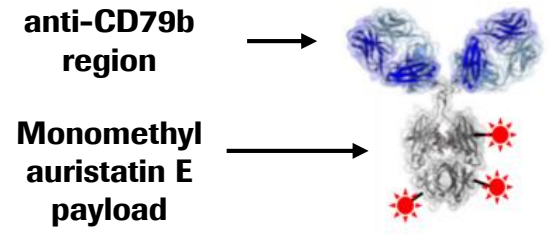
Outlook 2019

- US: Market entry of Rituxan biosimilars expected in November
- EU: Polivy approval in R/R DLBCL

CER=Constant Exchange Rates; FL=follicular lymphoma; CLL=chronic lymphoid leukemia; AML=acute myeloid leukemia; DLBCL=diffuse large B-cell lymphoma; * Venclexta sales are booked by AbbVie.

Hematology franchise:
First approval for Polivy in R/R DLBCL

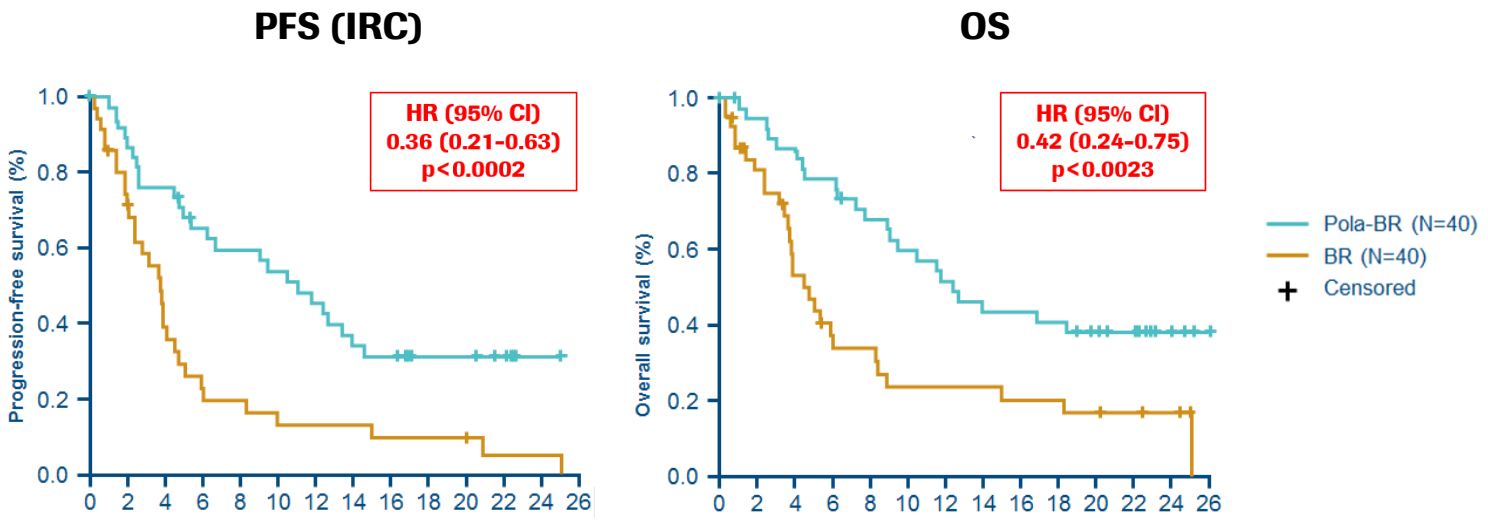
Polivy (polatuzumab vedotin)



- ADC targeting toxic payload to cells expressing CD79b
- Immediately accessible and economic off-the-shelf solution

First and only pivotal randomized Ph II study with survival benefit [1]

FDA BTD
EMA PRIME



- Rapid uptake in R/R DLBCL following early US approval; EU approval expected in 2H
- Safely administered in combination with BR; potentially used as a bridge to consolidative therapies
- Ph III trials in 1L DLBCL (POLARIX) ongoing

Sehn L. H. *et al.*, ASH 2018; ADC=antibody drug conjugate; DLBCL=diffuse large B-cell lymphoma; PFS=progression free survival; OS=overall survival; HR=hazard ratio; BR=bendamustine+Rituxan;
[1] In R/R DLBCL patients not candidates for transplant; Polivy in collaboration with Seattle Genetics

Hematology franchise:
Fast approval for Venclexta + Gazyva in 1L CLL achieved

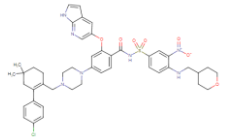
Roche

2019 ASCO ANNUAL MEETING

FDA BTD

Venclexta program

Bcl-2 inhibitor



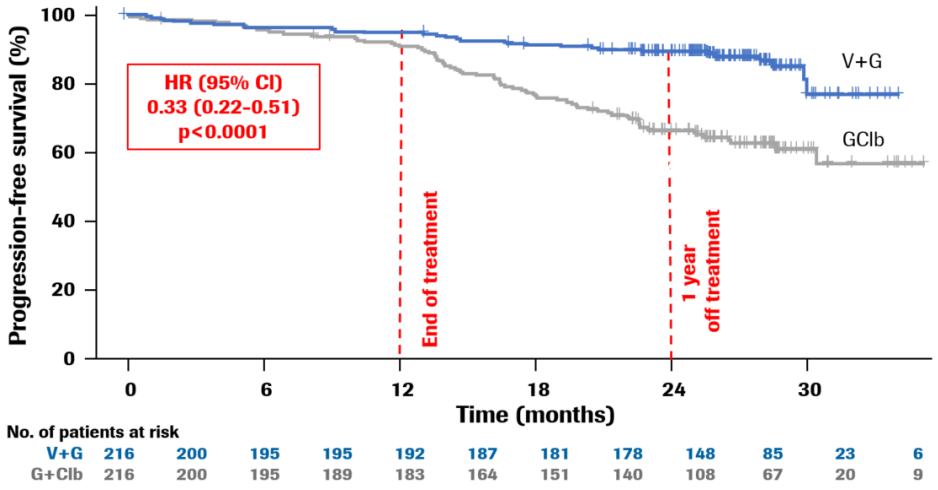
	Combination	Indication	Ph1	Ph2	Ph3
NHL	*V+R/G+CHOP*	1L DLBCL (aNHL)			
	V+R	DLBCL			
	V+pola+G/R	R/R DLBCL/FL			
CLL	*V+G*	1L CLL			✓
	V+R	R/R CLL			✓
	V	R/R CLL 17p			✓
	V	R/R CLL after ibru/idel			
	V+G	1L and R/R CLL			
MM	*V+dex*	t(11;14) R/R MM			
	V+bor+dex	R/R MM			
	V+Cotellic+/-T	R/R MM			
AML	*V+aza*	1L AML			✓
	V+LDAC	1L AML			✓
	V+idasanutlin	R/R AML unfit			
	V+gilteritinib	R/R AML			
MDS	*V+aza*	1L MDS			
	V+/-aza	R/R MDS			

Ph III (CLL14) results:

Minimal residual disease

	V+G	G+Clb
MRD-negative, %, bone marrow (95%CI)	57 (50-64)	17 (12-23)
p-value	<0.0001	
MRD-negative, %, peripheral blood (95%CI)	76 (69-81)	35 (29-42)
p-value	<0.0001	

IRC assessed PFS

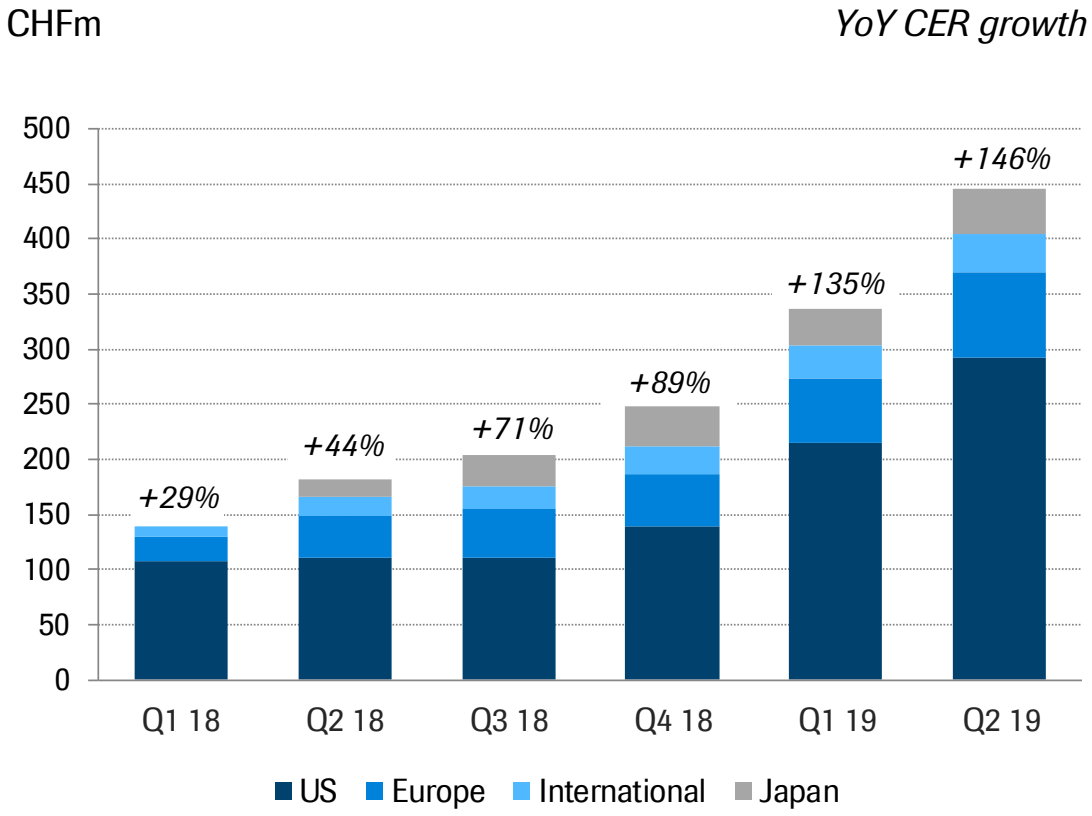


- PFS HR of 0.33 versus Gazyva + chlorambucil; mPFS not yet reached
- First fixed 12-month treatment, chemotherapy-free option
- Approval following 10 weeks after submission via the RTOR pilot program

Fischer K. *et al*., ASCO 2019; PFS=progression free survival; HR=hazard ratio; V=Venclexta; G=Gazyva; clb=chlorambucil; R=Rituxan; dex=dexamethasone; bor=bortezomib; T=Tecentriq; aza=azacitidine; LDAC=low dose cytarabine; RTOR=real-time oncology review; Venclexta in collaboration with AbbVie; Gazyva in collaboration with Biogen; Cotellic in collaboration with Exelixis

Tecentriq Q2 update

Global growth driven by lung and breast franchises



Lung franchise (NSCLC, SCLC)

- US: Growth driven by 1L NSCLC and first-in-class 1L SCLC
- EU: Increasing shares in 2L NSCLC; 1L NSCLC launches
- Japan: Strong launch in 1L NSCLC

GU franchise (bladder cancer)

- US/EU: Stable shares in approved indications

Breast franchise (TNBC)

- US: Growth driven by first-in-class launch in PDL1+ 1L TNBC

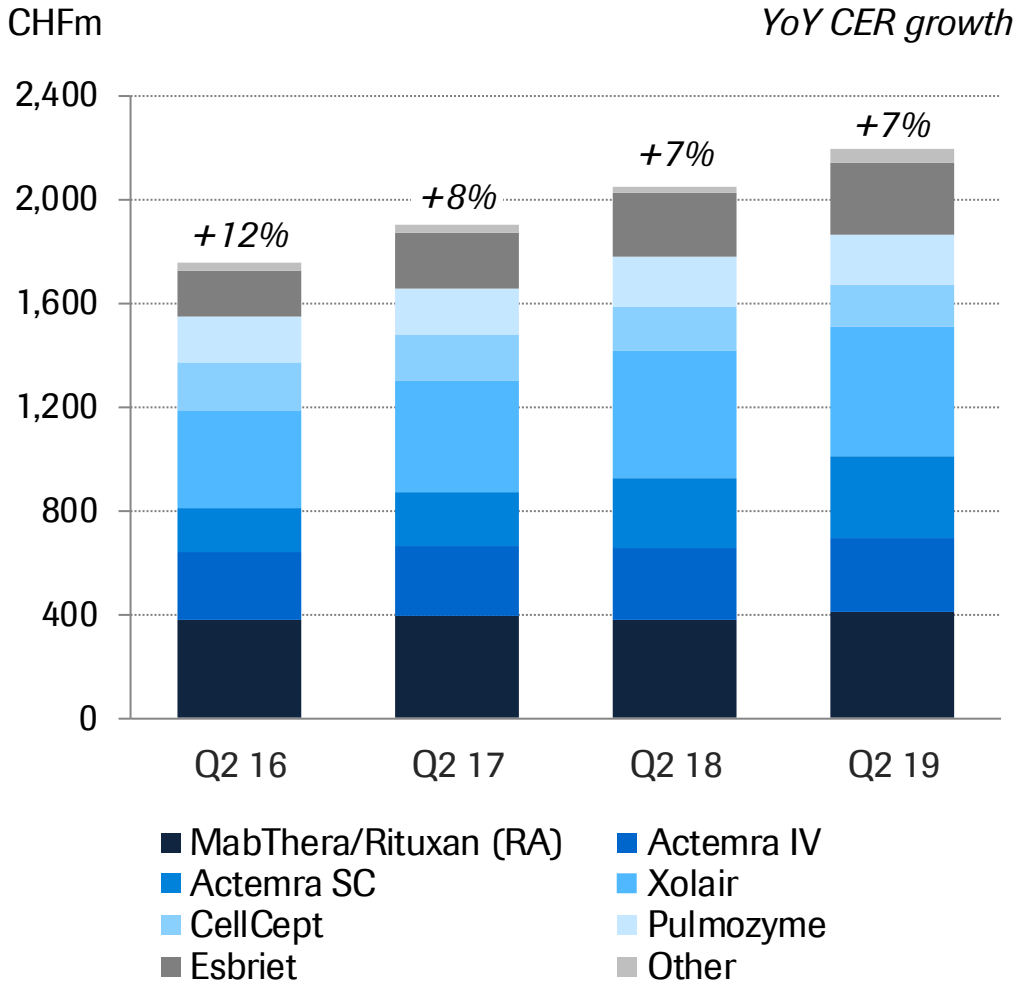
Outlook 2019

- EU approval in 1L SCLC and 1L TNBC
- 5 Ph III read-outs including HCC and BRAF+ melanoma

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

Immunology franchise

Annualized sales approaching CHF 9bn



Immunology Q2 update

Esbriet (+13%)

- Growth in mild to moderate segments

Actemra (+10%)

- EU: Remains leader in overall and 1L monotherapy RA
- Growth driven by RA new patient starts and GCA launches

Xolair (+2%)

- Growth driven by CIU
- Positive Ph III (POLYP I/II) results in nasal polyps

CER=Constant Exchange Rates; RA=rheumatoid arthritis; GCA=giant cell arteritis; CIU=chronic idiopathic urticaria

Immunology franchise

Gazyva in immunology: Positive Ph II results in lupus nephritis

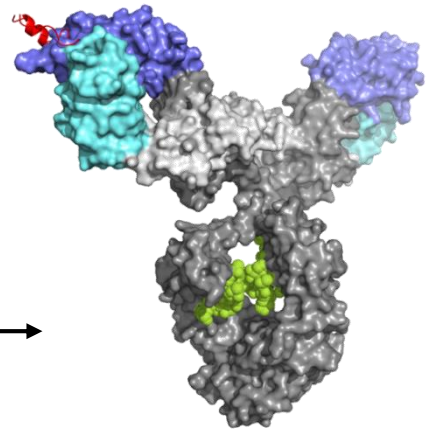
Gazyva (glycoengineered anti-CD20 Mab)

Type II anti-CD20 region:

- Increased direct cell death
- Decreased CDC
- Reduced CD20 internalization

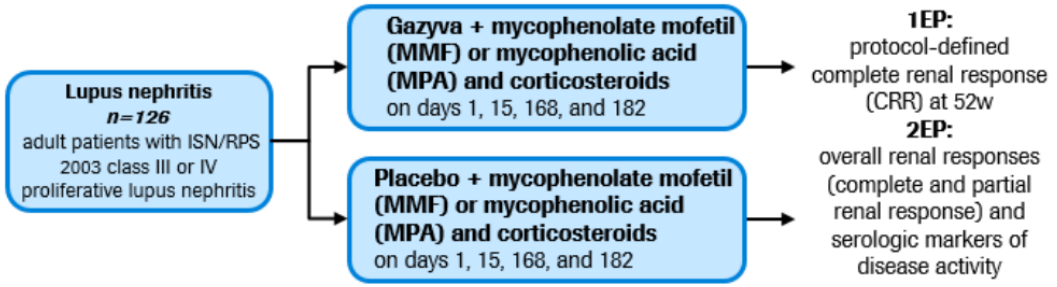
Glycoengineered Fc region:

- Higher FcγR affinity
- Enhanced ADCC/ADCP



- Gazyva's MOA shows greater potency than Rituxan in depleting peripheral and tissue-based B cell populations
- Recent studies suggest that tissue-based B cells play a role in lupus nephritis and that their complete depletion is needed

Ph II (NOBILITY) results:



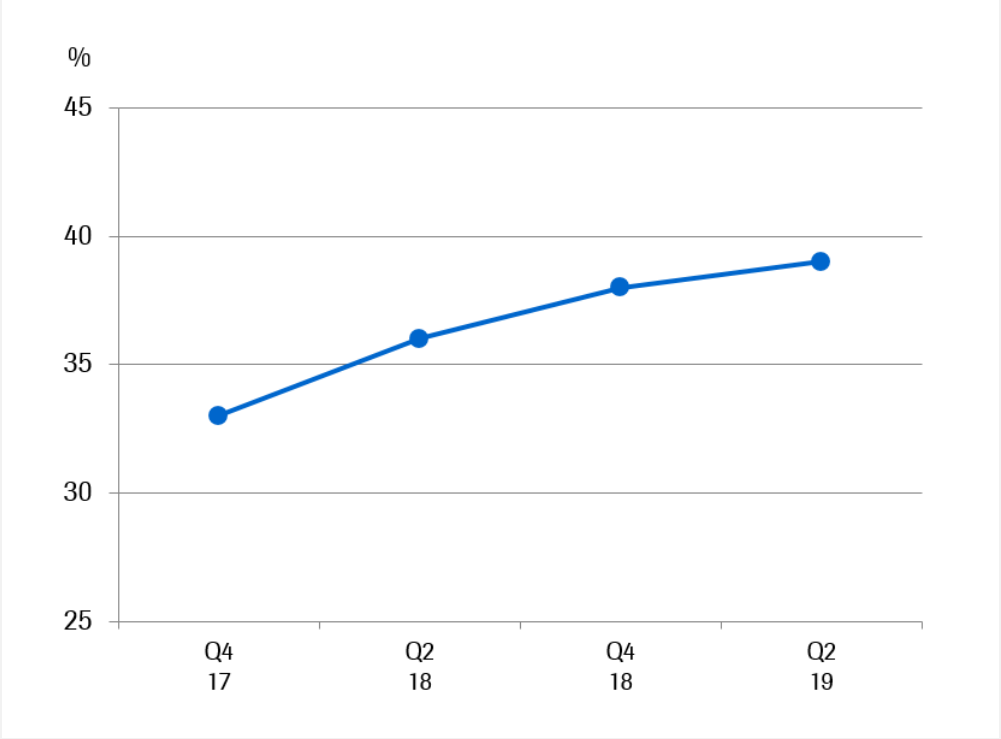
- Ph II (NOBILITY) met both primary and key secondary endpoints
- High unmet medical need; no treatment approved
- Data to be presented; Ph III program to be initiated

CDC=complement-dependent cytotoxicity; ADCC=antibody-dependent cell-mediated cytotoxicity; ADCP=antibody-dependant cellular phagocytosis; MOA=mechanism of action; Moessner et al., Blood, 2010; Niederfellner et al., Blood, 2011; Dalle et al., MCT, 2011; Jak et al., Blood, 2011; Alduaij et al., Blood, 2011; Lim et al., Blood, 2011; Honeychurch et al., Blood, 2012; Pievani et al., Blood, 2011; Bologna et al., JI, 2011; Braza et al., Haematologica, 2011; Patz et al., BJH, 2011

Neuroscience franchise

Close to 4 out of 10 MS patients in the US start a new therapy on Ocrevus

New to brand patient share (US) [1]



OCREVUS® ocrelizumab

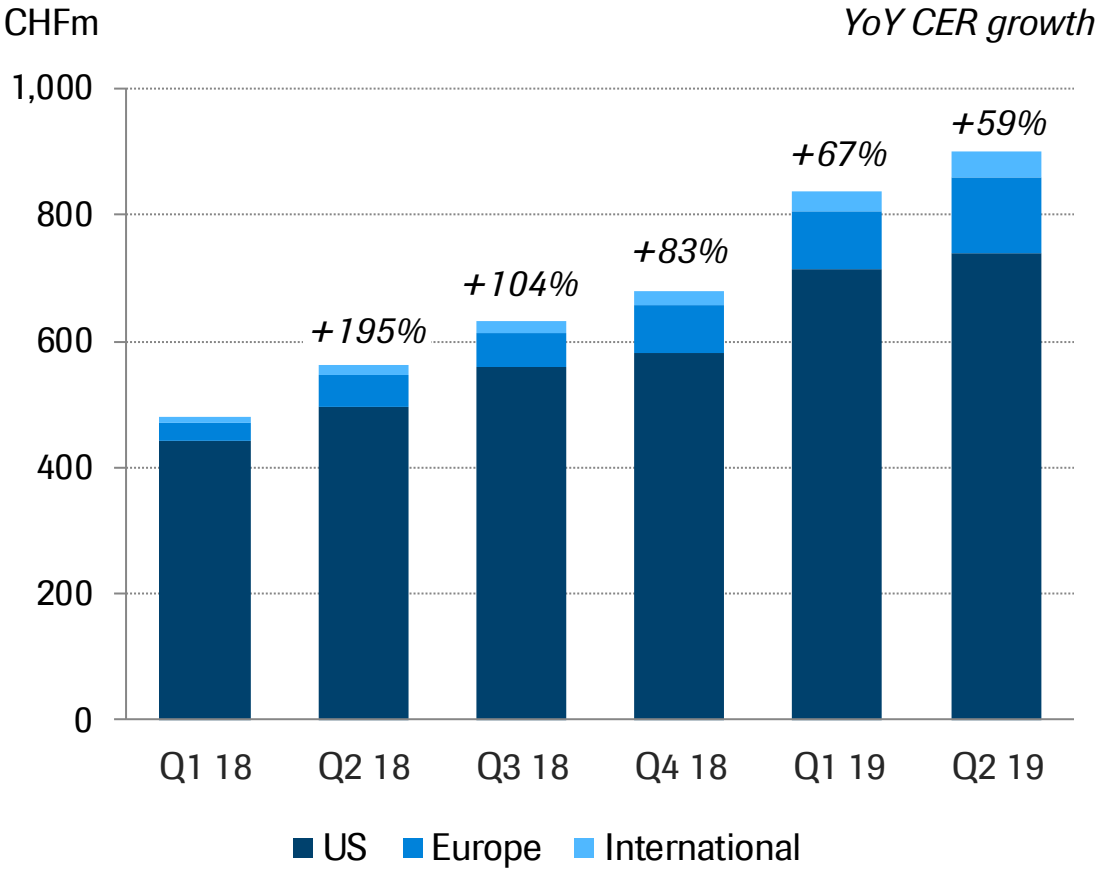
Key milestones achieved

- No.1 prescribed DMT in the US for MS patients starting a new therapy[1]
- >100,000 patients have been treated globally
- >5,000 US neurologists have prescribed Ocrevus
- Safety profile remains in-line with benefit/risk from pivotal studies
- 5.5 years of long term safety data

Source: [1] Symphony Health Claims Data; includes both naïve and switch patients; DMT=disease modifying therapy

Neuroscience franchise

Ocrevus reaches 17% total US market share [1]



Ocrevus Q2 update

- US driven by continued growth in earlier lines and strong demand from returning patients
- Strong launches in EU and International
- Updated US label includes active SPMS and CIS

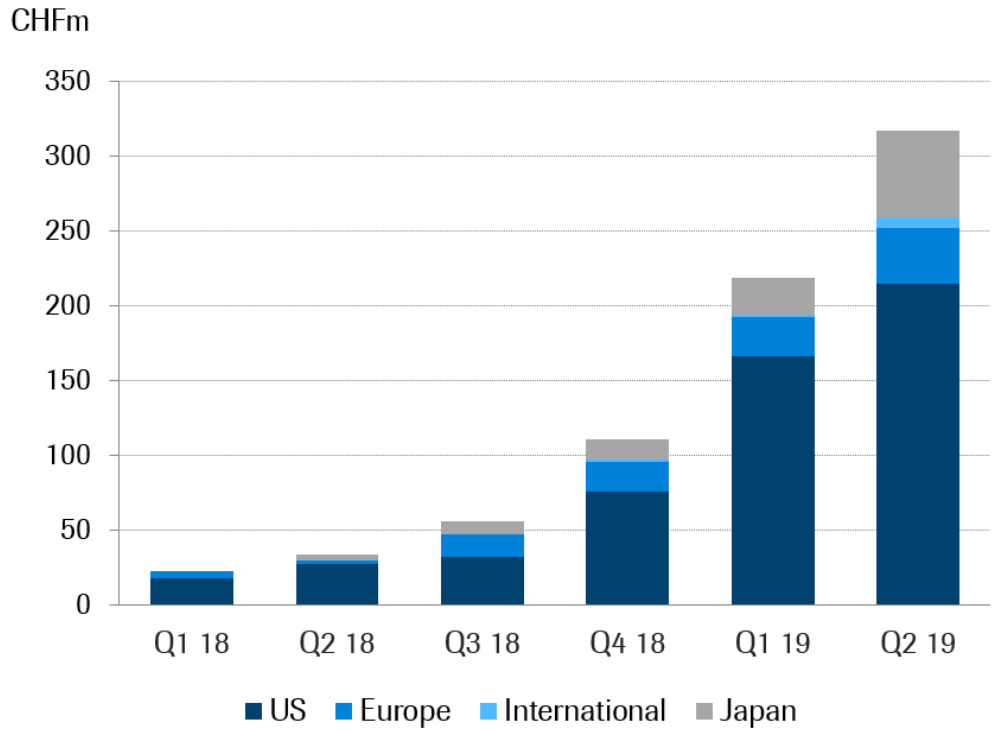
Outlook 2019

- Moving into earlier lines displacing orals
- Ongoing launches in EU and International
- 13 on-going and new Ph III/IV studies

Source: [1] Symphony Health Claims Data 2019; CER=Constant Exchange Rates; SPMS=secondary progressive multiple sclerosis; CIS=clinically isolated syndrome

Hemophilia A franchise

Hemlibra with 14% total US market share after 20 months



Hemlibra Q2 update

- US: Strong uptake in non-inhibitors driven by large centers and patient requests
- Japan: Strong uptake in non-inhibitors and inhibitors
- Overall >3,500 patients treated globally
- ISTH: Pooled HAVEN data analysis shows 87.3% of patients without treated joint bleeds at weeks 25-48

Outlook 2019

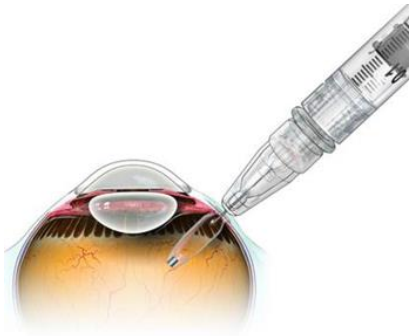
- US/EU: Uptake in non-inhibitors and inhibitors

CER=Constant Exchange Rates

Ophthalmology franchise

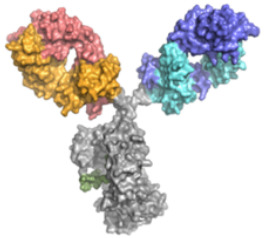
Pivotal studies enrolling rapidly; worldwide rights to PDS secured

Port delivery system (PDS) with ranibizumab



- Ph III (ARCHWAY) in nAMD at fixed Q6M dosing fully recruited, data expected in 2020
- Ex-US rights to PDS with ranibizumab acquired from Novartis
- New indications, new MOAs in PDS planned to leverage platform technology

Faricimab (anti-VEGF/Ang-2 biMab)



anti–Ang-2
- Enhanced vessel stabilisation through Ang-2 inhibition

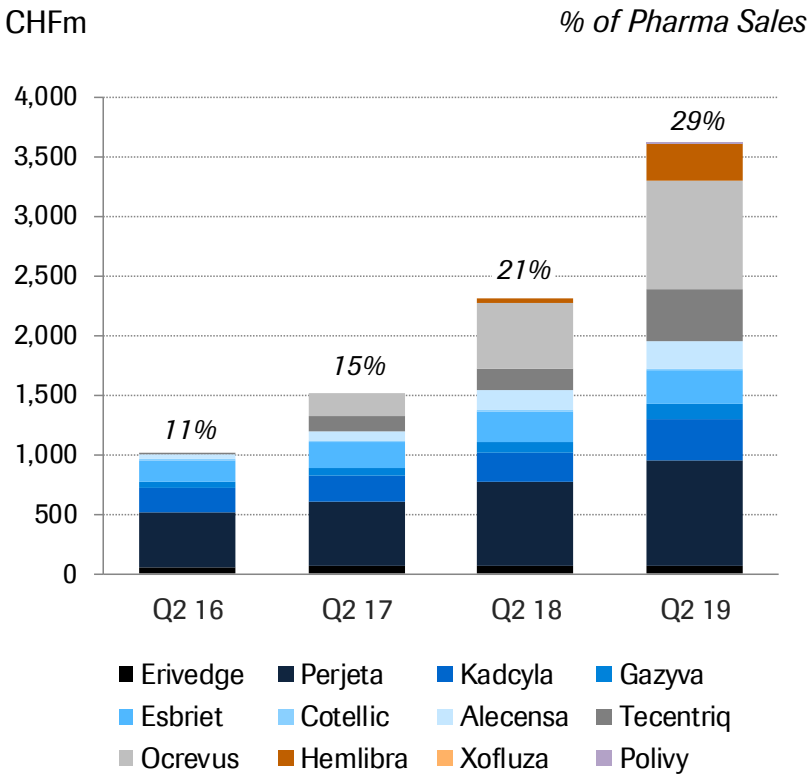
anti–VEGF-A
- Proven efficacy through VEGF-A inhibition

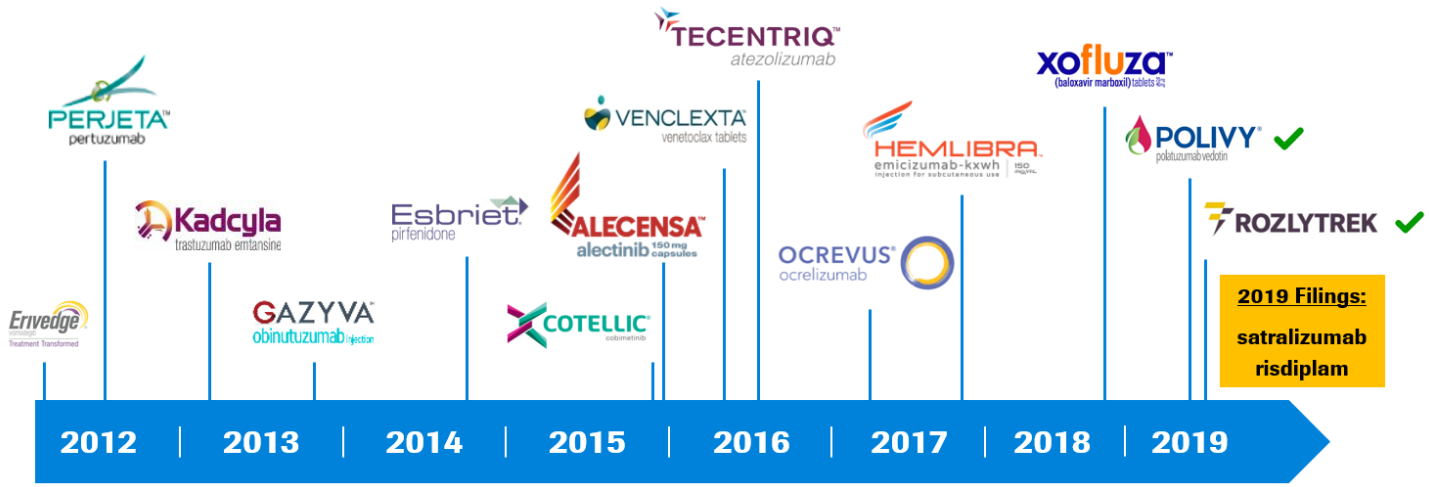
- First bi-specific antibody in ophthalmology
- Robust Ph II data in DME and nAMD
- Rapid enrollment in the global Ph III studies in DME (YOSEMITE, RHINE) and nAMD (TENAYA, LUCERNE)

nAMD=neovascular age-related macular degeneration; Q6M=once every six months dosing; DME=diabetic macular edema; MOA=mechanism of action

New products exceed annualized sales of CHF 14bn*

First approval for Polivy and Rozlytrek achieved





* Venclexta sales are booked by partner AbbVie and therefore not included.

Strong short term news flow

Diversifying the late stage pipeline and setting new standards of care

Product	Filing date	Population
risdiplam in SMA	2019 in type 1/2/3	**~18k** (rare disease)
satralizumab in NMOSD	2019	**~21k** (rare disease)
HTT-ASO in Huntington's	Ph II & III ongoing; filing latest 2022	**~83k** (rare disease)
Gazyva in lupus nephritis	initiating Ph III	**~190k**
etrolizumab in UC and Crohn's Disease	filing in UC in 2020	**UC ~700k** **CD ~640k** (moderate to severe)
PDS in nAMD	fully recruited; filing in 2020	**nAMD ~4,090k** **DME ~4,400k**
faricimab in DME/nAMD	recruitment ahead of plan; filing in 2021/22	

Neuroscience
Ophthalmology
Immunology
Oncology

Product	Filing date	Population
Tecentriq in 1L HCC	2019	**~300k**[1]
Tecentriq in neoadj TNBC	2020	**~19k**
Tecentriq in adj bladder cancer	2020	**~50k**
Tecentriq in 1L melanoma	2020	**~11k** (Dx+)
Tecentriq in FL ovarian cancer	2020	**~41k**
idasanutlin in R/R AML	2020	**~22k**
Perjeta + Herceptin FDC-SC	2020	**~75k**
ipatasertib 1/2L TNBC	2020	**~11k** (Dx+)
ipatasertib 1L+ HR+ (chemo treated only)	2020	**~83k** (Dx+) **~15k** (Dx+/chemo only)
ipatasertib in 1L mCRPC	2020	**~200k** (AC) **100k** (Dx+)
Polivy in 1L DLBCL	2020/21	**~52k**
Tecentriq in (neo)adj NSCLC	2021/22	**~75k**

Source: Roche/Genentech, incidence/prevalence in the major markets (US, FR, DE, IT, ES, GB); [1] including China; SOC=standard of care; SMA=spinal muscular atrophy; NMOSD=neuromyelitis optica spectrum disorder; UC=ulcerative colitis; CD=Crohn's disease; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; HCC=hepatocellular carcinoma; TNBC=triple-negative breast cancer; FL=front line; R/R AML=relapsed/refractory acute myeloid leukemia; FDC=fixed dose combination; HR=hormone receptor; mCRPC=metastatic castration resistant prostate cancer; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer; AC=all comers

Roche Pharma Day 2019

Strategic business outlook and late stage pipeline update

Roche Pharma Day 2019

London

Monday, 16 September 2019, 9:00am–2:45pm BST

Meeting information:
09:00am Registration
09:30am Event starts
2:45pm Event ends
followed by a buffet reception

Venue:
Hilton London Tower Bridge
5 More London Place
Tooley Street, London
SE1 2BY

Senior management present:

- Bill Anderson, CEO Pharma
- Sandra Horning, Chief Medical Officer and Head Global Product Development
- Teresa Graham, Head of Global Product Strategy
- Paulo Fontoura, Global Head Neuroscience and Rare Diseases Clinical Development
- Elena Bernedo-Arzac, Head Oncology Global Product Strategy
- Cristin Hubbard, Head I2O Global Product Strategy
- Zafar Hakim, I2O Global Product Strategy
- Atul Dandekar, Global Head of Ophthalmology, I2O Global Product Strategy
- Sascha Fauser, Global Head of Ophthalmology pRED
- Bryn Roberts, Global Head of Operations pRED

I2O=immunology, Infectious diseases, Ophthalmology

2019: Key late-stage news flow*

	Compound	Indication	Milestone	
Regulatory	**Rozlytrek**	1L ROS1+ NSCLC	US approval; EU filing	
	Rozlytrek	NTRK+ pan tumor	US approval; EU filing	
	Polivy	R/R DLBCL	US/EU approval	✓
	Tecentriq + chemo	1L PDL1+ TNBC	US/EU approval	✓
	Tecentriq + chemo	1L SCLC	US/EU approval	✓
	Xofluza	High risk influenza	US approval	
	Kadcyla	Adjuvant HER2+ BC	US approval; EU filing	✓
	Hemlibra	Non-inhibitors	EU approval	✓
	Tecentriq + Avastin + chemo	1L NSCLC	EU approval	✓
	Venclexta + chemo	1L unfit AML	EU filing	
	Venclexta + Gazyva	1L unfit CLL	US/EU filing	✓
	satralizumab	NMOSD	US/EU filing	
	risdiplam	SMA type 1/2/3	US/EU filing	
Phase III / pivotal readouts	**Tecentriq + Cotellic**	BRAFwt Melanoma	IMspire170	✗
	Tecentriq + Zelboraf + Cotellic	1L BRAF+ Melanoma	Ph III IMspire150 (TRILOGY)	
	Tecentriq	Adjuvant high-risk MIBC	Ph III IMvigor010	
	Tecentriq + chemo	Neoadjuvant TNBC	Ph III IMpassion031	**IA passed**
	Tecentriq + Avastin	1L HCC	Ph Ib/IMbrave150	
	Venclexta + Gazyva	1L unfit CLL	Ph III CLL14	✓
	idasanutlin + chemo	R/R AML	Ph III MIRROS	
	Venclexta + chemo	R/R MM	Ph III BELLINI	**
	risdiplam	SMA type 2/3	Ph II/III SUNFISH	

Additional 2019 news flow:

- **MabThera/Rituxan**: EU approval of pemphigus vulgaris
- **Herceptin Hylecta**: US approval SC formulation
- **Venclexta + Gazyva**: US approval in 1L unfit CLL; EU filed
- **Rozlytrek**: Japan early approval for NTRK+ solid tumors
- **Gazyva**: Positive Ph II results in lupus nephritis
- **Xolair**: Positive Ph III results in nasal polyps

*Outcome studies are event-driven: timelines may change; ** Study met its primary endpoint of PFS: 22.4m vs. 11.5m with a HR of 0.63; Higher proportion of deaths in Venclexta arm; IA=interim analysis

Diagnostics Division

Michael Heuer
CEO Roche Diagnostics

HY 2019: Diagnostics Division sales

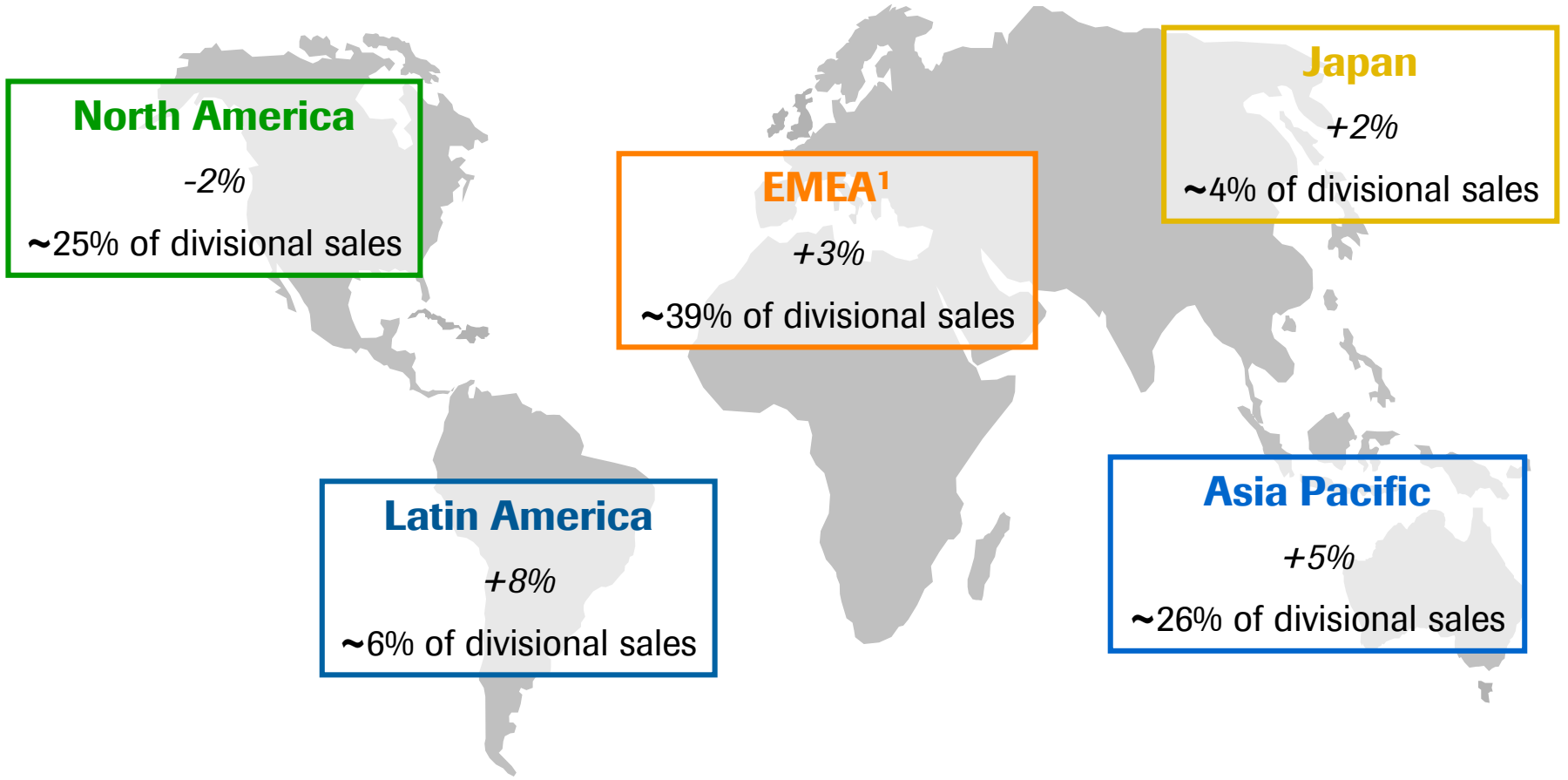
Growth driven by Centralised and Point of Care Solutions and Molecular Diagnostics

	HY 2019 CHFm	HY 2018 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**6,275**	**6,264**	**0**	**2**
Centralised and Point of Care Solutions	3,762	3,755	0	3
Molecular Diagnostics	1,029	979	5	6
Diabetes Care	958	991	-3	1
Tissue Diagnostics	526	539	-2	-3

CER=Constant Exchange Rates; underlying growth of Molecular Diagnostics excluding sequencing business: +5%

HY 2019: Diagnostics Division regional sales

Growth driven by Asia Pacific and EMEA

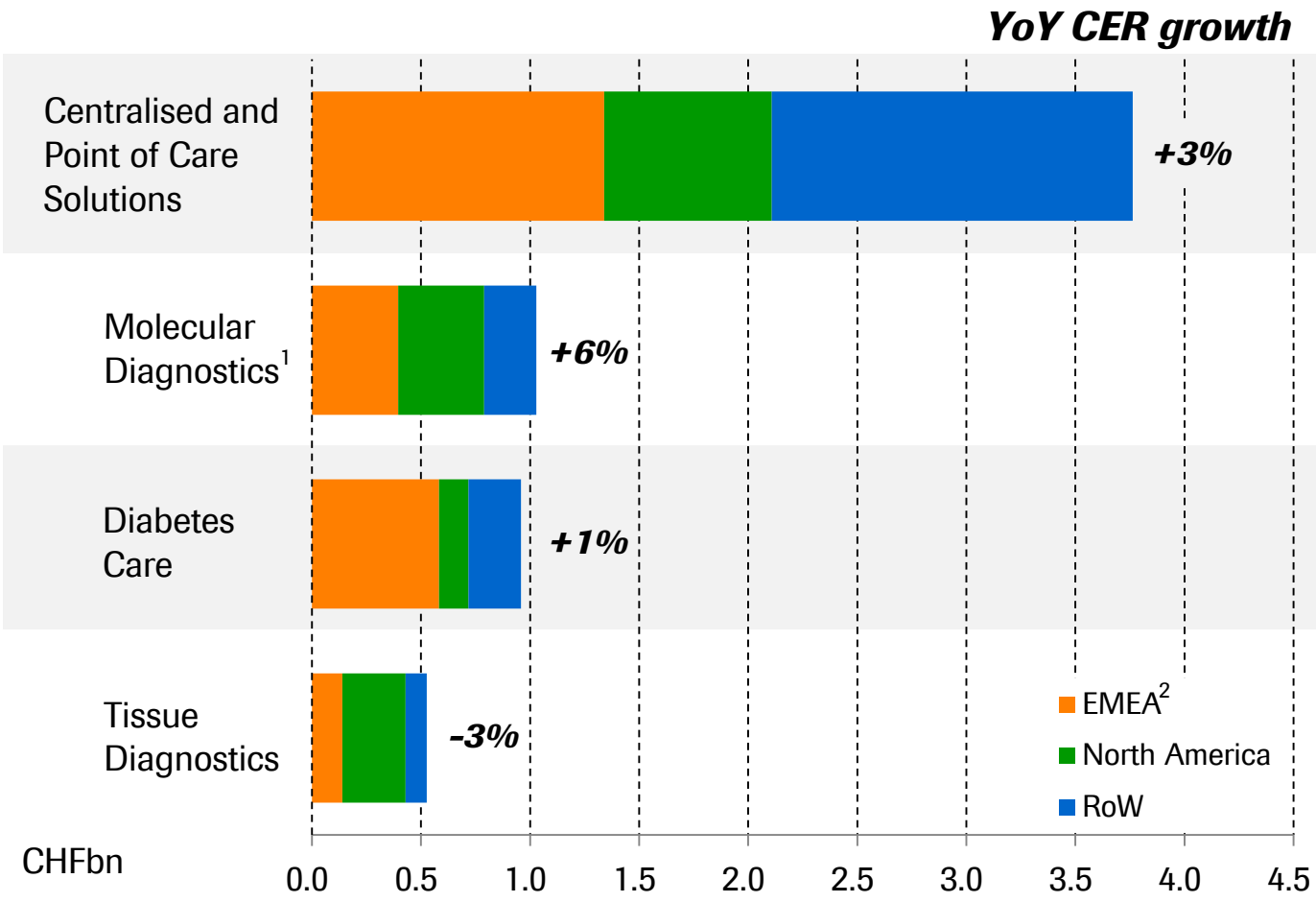


+6% growth in E7 countries[2]

[1] Europe, Middle East and Africa; [2] Brazil, China, India, Mexico, Russia, South Korea and Turkey; all growth rates at Constant Exchange Rates (CER)

HY 2019: Diagnostics Division highlights

Growth driven by Immunodiagnostics



- Immunodiagnostics (+7%)
- Sales affected by reduction of distributor inventories in China and decline in coagulation monitoring

- Blood screening (+16%); Microbiology (+26%); POC MDx (+21%); Virology (0%)

- Blood glucose monitoring (+1%); Insulin delivery systems (-6%)

- Primary staining (+2%); Advanced staining (0%)
- BenchMark and Discovery Ultra shipment delays

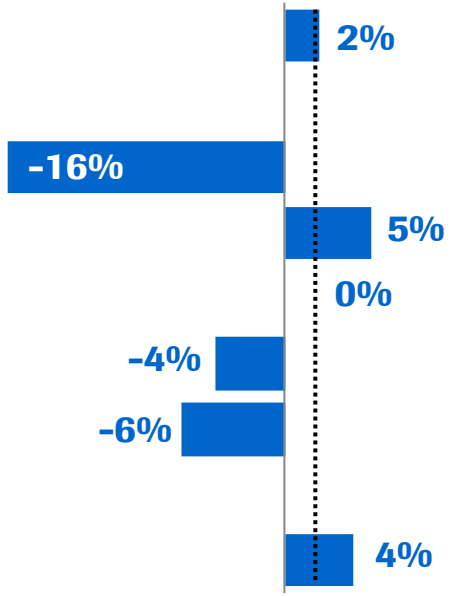
[1] Underlying growth of Molecular Diagnostics excluding sequencing business: +5%; [2] EMEA=Europe, Middle East and Africa; CER=Constant Exchange Rates

HY 2019: Diagnostics Division

Core operating profit growing at +4%

	HY 2019 CHFm	HY 2019 % sales
Sales	**6,275**	**100.0**
Royalties & other op. inc.	33	0.5
Cost of sales	-2,929	-46.6
M & D	-1,405	-22.4
R & D	-688	-11.0
G & A	-222	-3.5
Core operating profit	**1,064**	**17.0**

2019 vs. 2018
CER growth



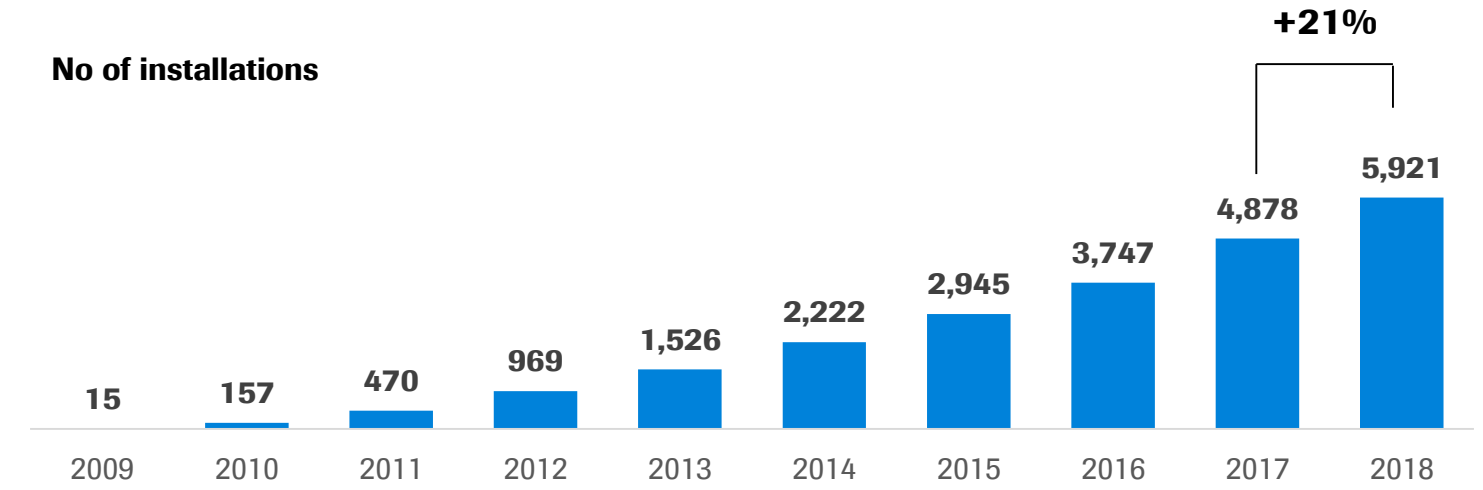
-1% in CHF

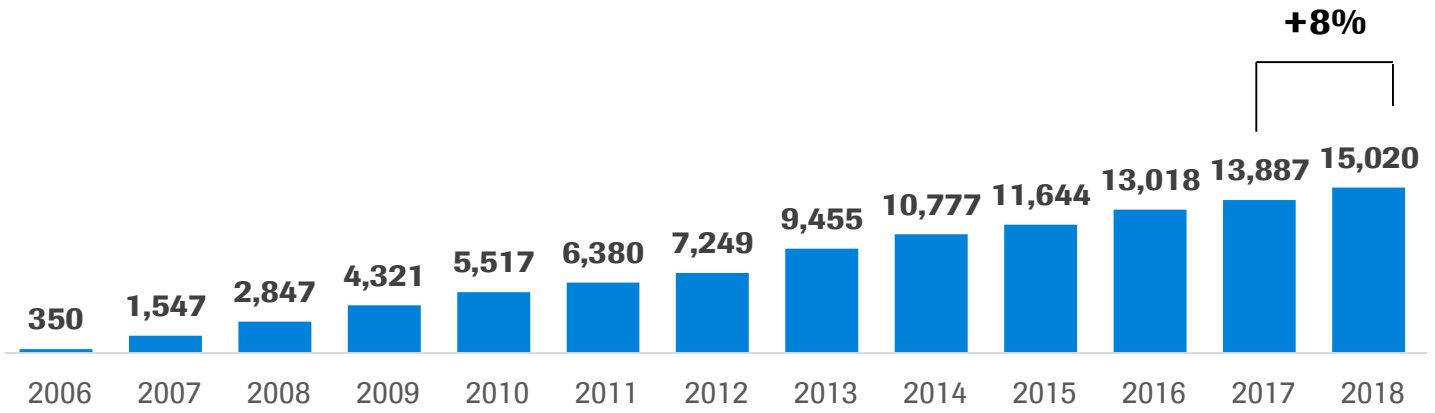
CER=Constant Exchange Rates

Increasing our installed base to ensure future growth

cobas 8000 modular analyzer series

cobas 6000 modular analyzer series





FDA clearance of cobas® TV/MG

Menu expansion of high volume STI testing on cobas 6800/8800

Installed instrument base: >700*

*June 2019

- Better diagnosis and screening of STIs and improved patient care
- Ability to test four STIs from a single patient sample
- Highest throughput testing solution on the market today for combination CT/NG and TV/MG testing

STI=sexually transmitted infections; CT=chlamydia trachomatis; NG=neisseria gonorrhoea; TV=trichomonas vaginalis; MG=mycoplasma genitalium

cobas® 6800/8800 systems driving growth in molecular

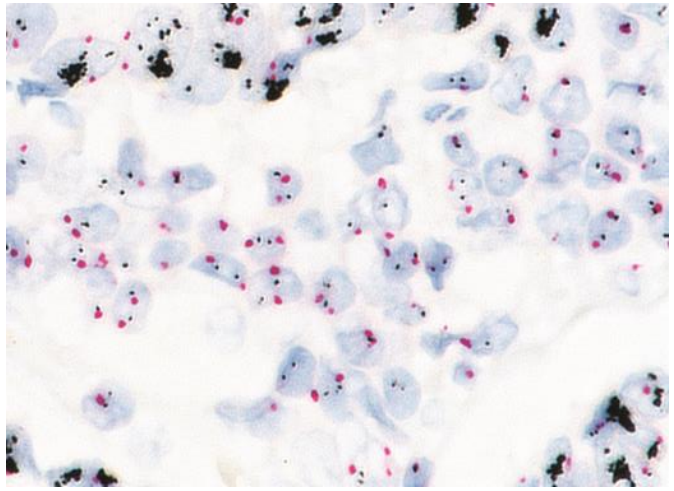
Continued menu expansion of our high medical value assays

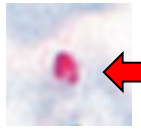
Donor Screening	Infectious Disease	Sexual Health	Transplant	Respiratory	Antimicrobial Stewardship
MPX ✓	HIV-1 ✓	HPV ✓	CMV ✓	MTB ✓	MTB-RIF/INH ✓
WNV ✓	HBV ✓	CT/NG ✓	EBV **Launch 2019** (CE-IVD in 2019, US-IVD in 2020)	MAI ✓	
DPX ✓	HCV ✓	TV/MG ✓ (CE-IVD, **US-IVD in 2019**)	BKV **Launch 2019** (CE-IVD in 2019, US-IVD in 2020)	MPLX Respiratory (CE-IVD in 2020, US-IVD in 2021)	
HEV ✓ (Not available in the US)	HIV-1/2 Qual ✓ (CE-IVD, **US-IVD in 2020**)	HPV Self Sampling (CE-IVD in 2020)			
CHIKV/DENV ✓ (Not available in the US)					
Zika ✓ (US-IVD, **CE-IVD in 2019**)					
Babesia **Launch 2019** (US-IND, US-IVD & CE-IVD in 2019)					

MPX=multiplex detection of HIV-1, HIV-2, HCV and HBV; WNV=West Nile virus; DPX=duplex detection of parvovirus B19 and HAV; HEV=Hepatitis E virus; CHIKVV=chikungunya virus; DENV=Dengue virus; CMV=Cytomegalovirus; MTB=Mycobacterium tuberculosis; MAI=Mycobacterium avium-intracellulare infection; RIF=rifampicin; INH=isoniazid (detection of RIF/INH resistance in MTB positive samples); TV=trichomonas vaginalis; MG=mycoplasma genitalium; Babesia=detection of babesiosis caused by tick-born parasites; EBV=Epstein-Barr virus post-transplant monitoring; BKV=BK virus post-transplant monitoring; ADV=Adenovirus post-transplant monitoring; HSV-1/2/VZV=multiplex detection of Herpes simplex virus 1 and 2 and Varicella-zoster virus; MPLX=detect and discriminate multiple (up to 14) pathogens associated with a clinical syndrome

VENTANA HER2 dual ISH DNA probe cocktail

Brightfield microscopy as an alternative to FISH testing





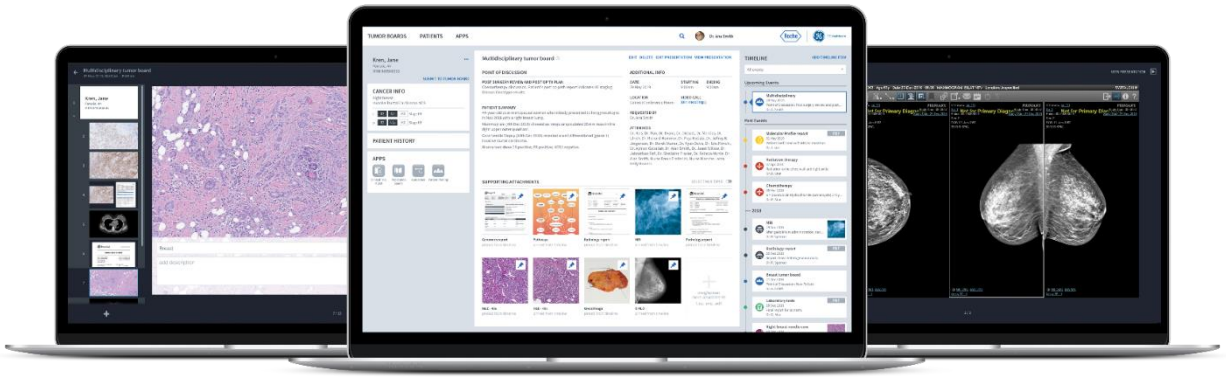
HER2+ receptor

- Increased performance, with oligo probes and new detection kits; highly concordant with FISH
- Brightfield assay that allows for interpretation within the context of tissue morphology
- CE IVD assay, indicated for patients for whom Herceptin treatment is considered

FISH=Fluorescence in situ hybridization

NAVIFY Tumor Board 2.0 in collaboration with GE Healthcare

Clinical decision support with medical imaging capabilities



NAVIFY Tumor Board 2.0:

- Integration of GE Healthcare's medical image viewer* into NAVIFY Tumor Board 2.0
- Enables radiologists to upload patient records to same dashboard as patient files from other disciplines

*Not yet commercially available in all countries; NAVIFY is a trademark of Roche. All other product names and trademarks are the property of their respective owners.

Key launches 2019

	Area	Product	Description	Market[1]
Instruments/ Devices	Workflow	cobas prime	Pre-analytical platform to support cobas 6800/8800	CE/US
Tests/ Assays	Coagulation	Protein C Chrom	Quantitative determination of protein C in citrated plasma on cobas t 511 / t 711 analyzers	CE
	Microbiology	cobas TV/MG	High volume solution for TV/MG testing; dual-target test with ability to test with CT/NG from the same specimen during the same run	US ✓
		cobas vivoDx MRSA	Live cell assay for prevention and control of MRSA infections	CE ✓
	Tissue Dx	VENTANA HER2 Dual ISH	Fully automated, brightfield ISH assay to determine eligibility for HER2 targeted therapy	CE ✓
Software	Central Laboratory	cobas Infinity Central Lab 3.0	One global laboratory middleware solution realizing a very high degree of integration in the laboratory	WW ✓
	Tissue Dx	Algorithm - Breast Panel	Whole slide analysis image analysis algorithm (HER2, ER, PR, Ki-67)	CE
		Algorithm - PD-L1 Lung	Whole slide analysis image analysis algorithm (SP263)	CE
	Sequencing	NAVIFY Mutation Profiler	Software as a medical device for annotating, variant classification, clinical interpretation and reporting from comprehensive genomic profile testing	CE ✓ US[2]
		NAVIFY Therapy Matcher	Informing on treatment options based on local drug labels, medical guidelines and clinical trial outcomes	CE ✓ US[2]
	Decision Support	NAVIFY Tumor Board V2	Integrating a GEHC DICOM imaging viewer into the Tumor Board to support the radiologist	WW ✓
		NAVIFY Oncology Workflow V1	Integration of patient's longitudinal history, diagnosis, and treatment planning by leveraging relevant guidelines	WW
	Diabetes Care	Accu-Chek Sugar View 2.0 (non-ISO)	For non-insulin dependent T2 PwDs, allowing for meter-free blood glucose monitoring using Accu-Chek Active test strips and a smartphone camera	CE

[1] CE: European Conformity, US: FDA approval, WW: Worldwide; GEHC DICOM: GE Healthcare Digital Imaging and Communications in Medicine; T2: Type II Diabetes; PwDs: People with Diabetes
[2] NAVIFY Mutation Profiler and Therapy Matcher received CE mark; US approval expected by end of 2019.

Finance

Alan Hippe
Chief Financial Officer

HY 2019 results

Focus on Cash

Outlook

HY 2019: Highlights

Business

- Sales growth of +9%[1] and Core operating profit up +11%[1]
- Core EPS growth +13%[1]

Cash flow

- Operating Free Cash Flow of CHF 7.5bn, -9%[1] lower due to higher net working capital and higher investments in intangible assets
- Net debt lower by CHF 3.3bn vs. Jun 30th 2018; higher by CHF 2.7bn vs. Dec 31st 2018 due to dividend payments

Net financial results

- Net financial result decreased by -55%[1] driven by lower income from Equity securities

IFRS

- Net income +19%[1] driven by business growth and lower income tax expenses

[1] At Constant Exchange Rates (CER)

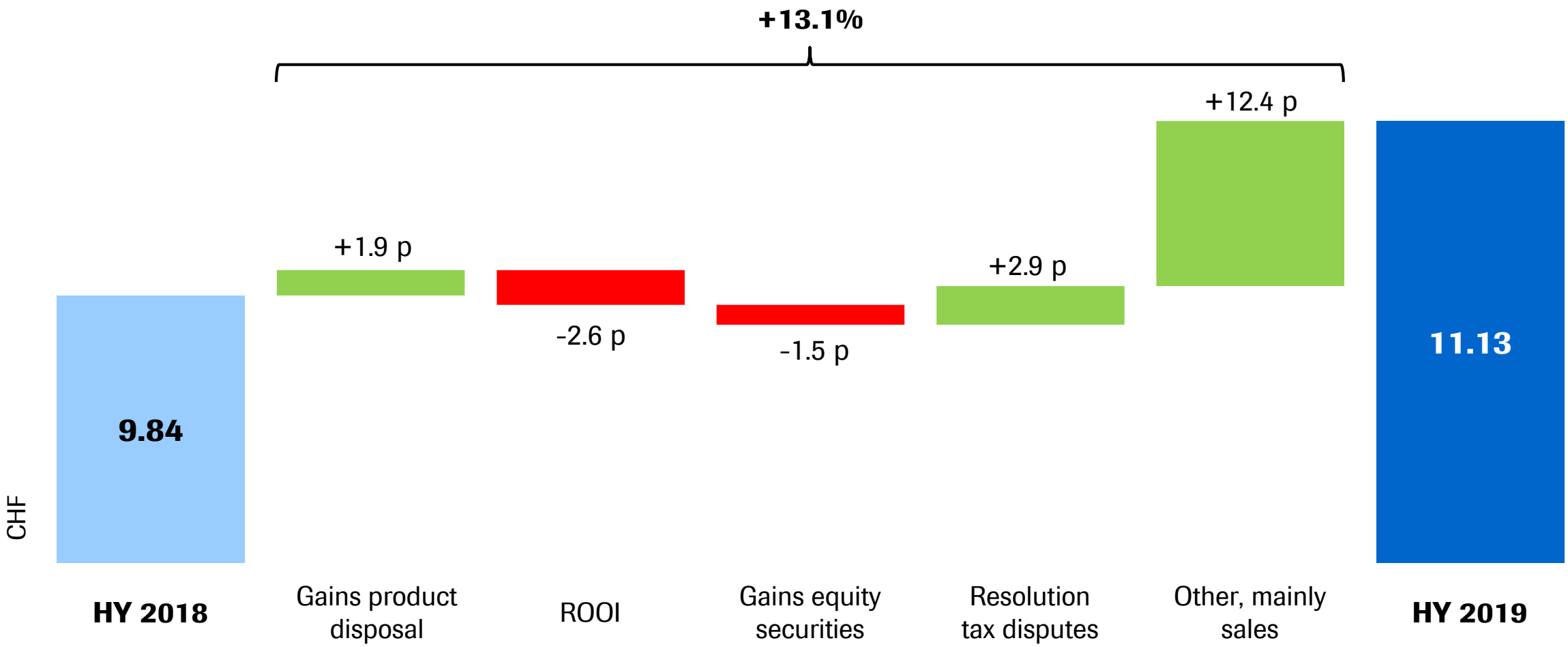
HY 2019: Group performance

Core Operating profit up +11%; Core EPS growth of +13%

	HY 2019 CHFm	HY 2018 CHFm	Change in % CHF	Change in % CER
Sales	**30,469**	**28,111**	**8**	**9**
Core operating profit	**12,363**	**11,162**	**11**	**11**
as % of sales	*40.6*	*39.7*		
Core net income	**9,896**	**8,679**	**14**	**14**
as % of sales	*32.5*	*30.9*		
Core EPS (CHF)	**11.12**	**9.84**	**13**	**13**
IFRS net income	**8,904**	**7,516**	**18**	**19**
Operating free cash flow	**7,508**	**8,042**	**-7**	**-9**
as % of sales	*24.6*	*28.6*		
Free cash flow	**5,277**	**5,966**	**-12**	**-13**
as % of sales	*17.3*	*21.2*		

CER=Constant Exchange Rates

HY 2019: Core EPS development

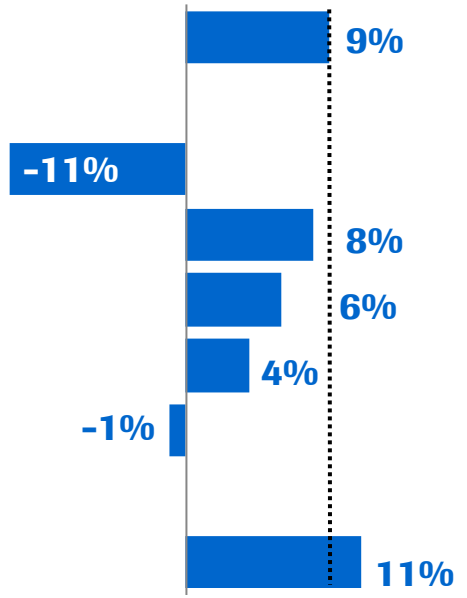


All at CER (Constant Exchange Rates, average FY 2018); [1] ROOI = Royalties and other operating income excl. Gains on product disposals

HY 2019: Group operating performance

Core operating profit growth ahead of sales growth

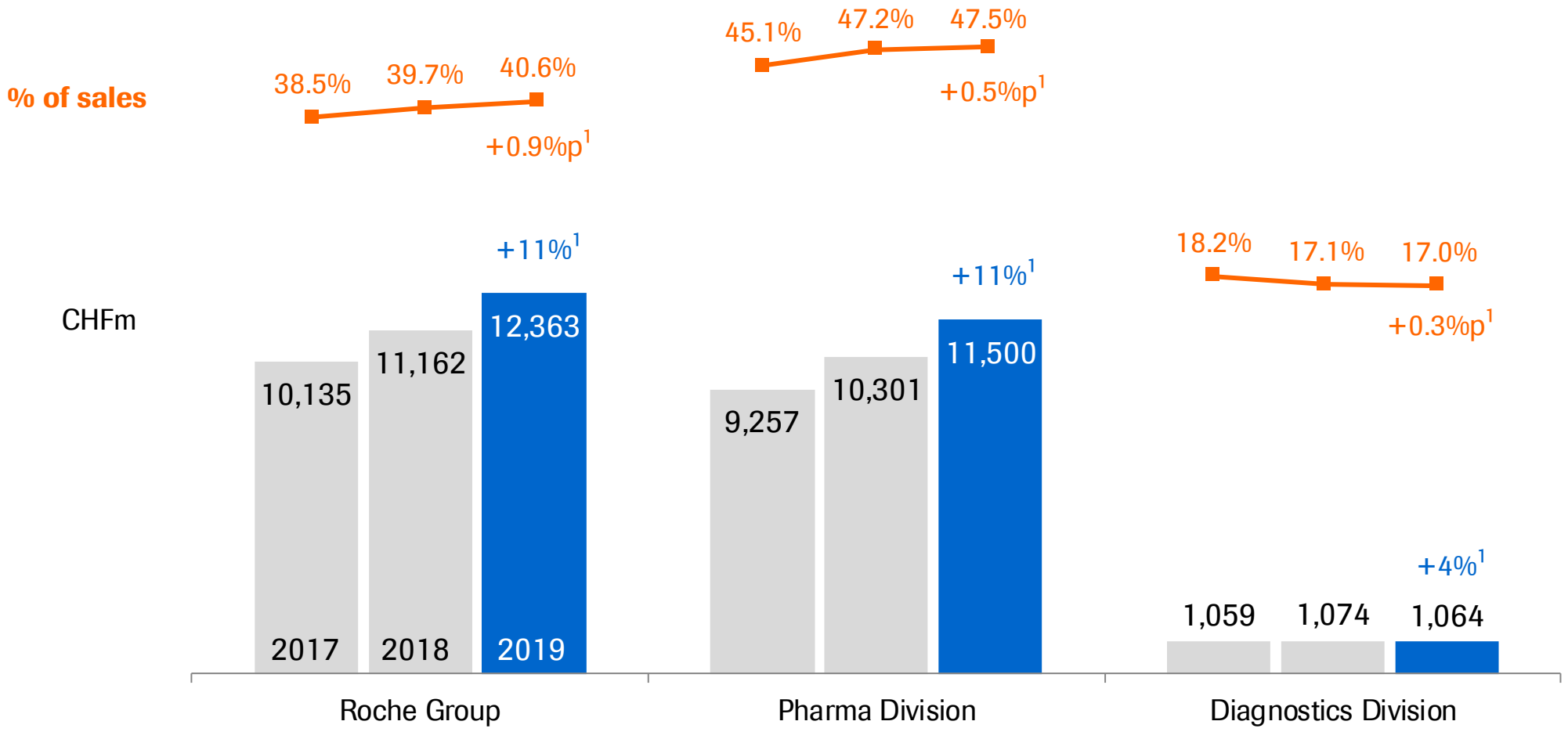
	HY 2019	
	CHFm	abs. CER
Sales	**30,469**	**2,385**
Royalties & other op. inc.	1,282	-159
Cost of sales	-7,868	-591
M & D	-4,800	-250
R & D	-5,561	-200
G & A	-1,159	17
Core operating profit	**12,363**	**1,202**



+11% in CHF

CER=Constant Exchange Rates

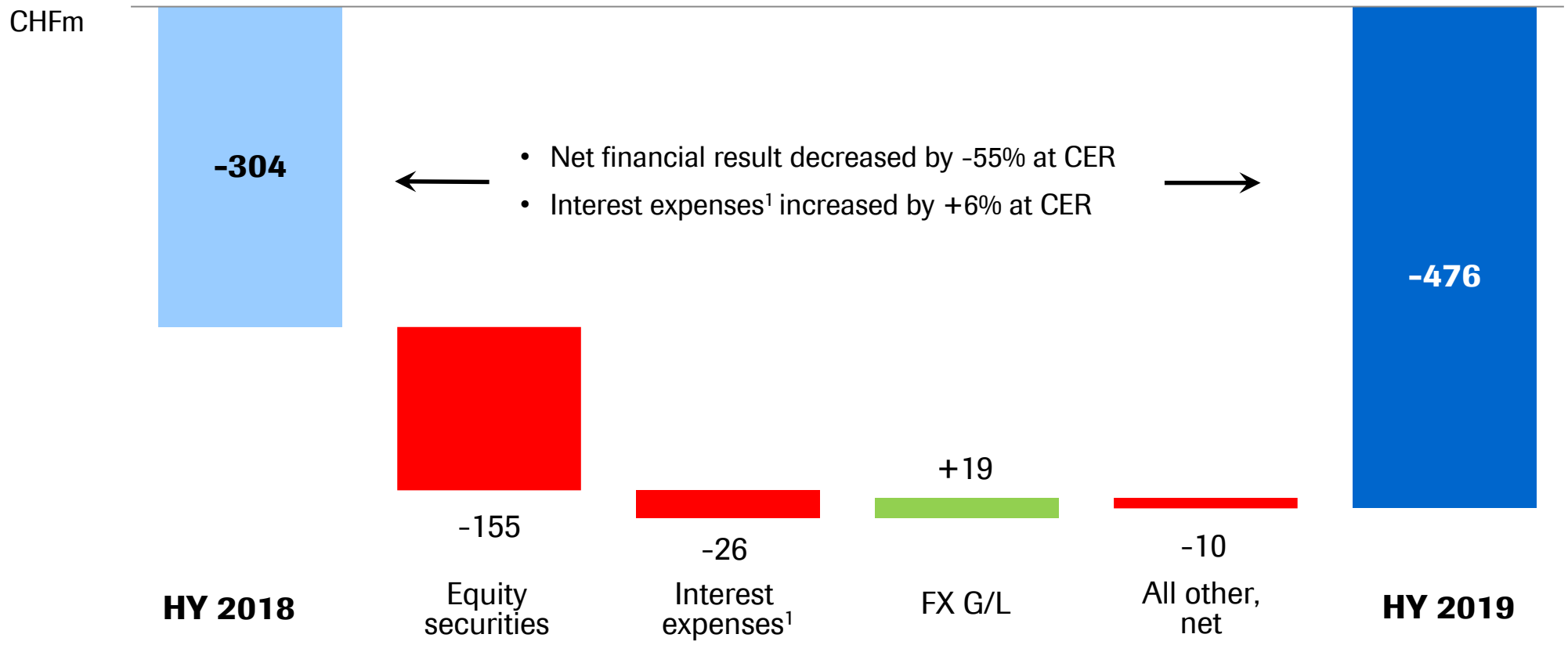
HY 2019: Core operating profit and margin further improved



[1] At Constant Exchange Rates (CER)

HY 2019: Core net financial result

Decline due to lower income from Equity securities

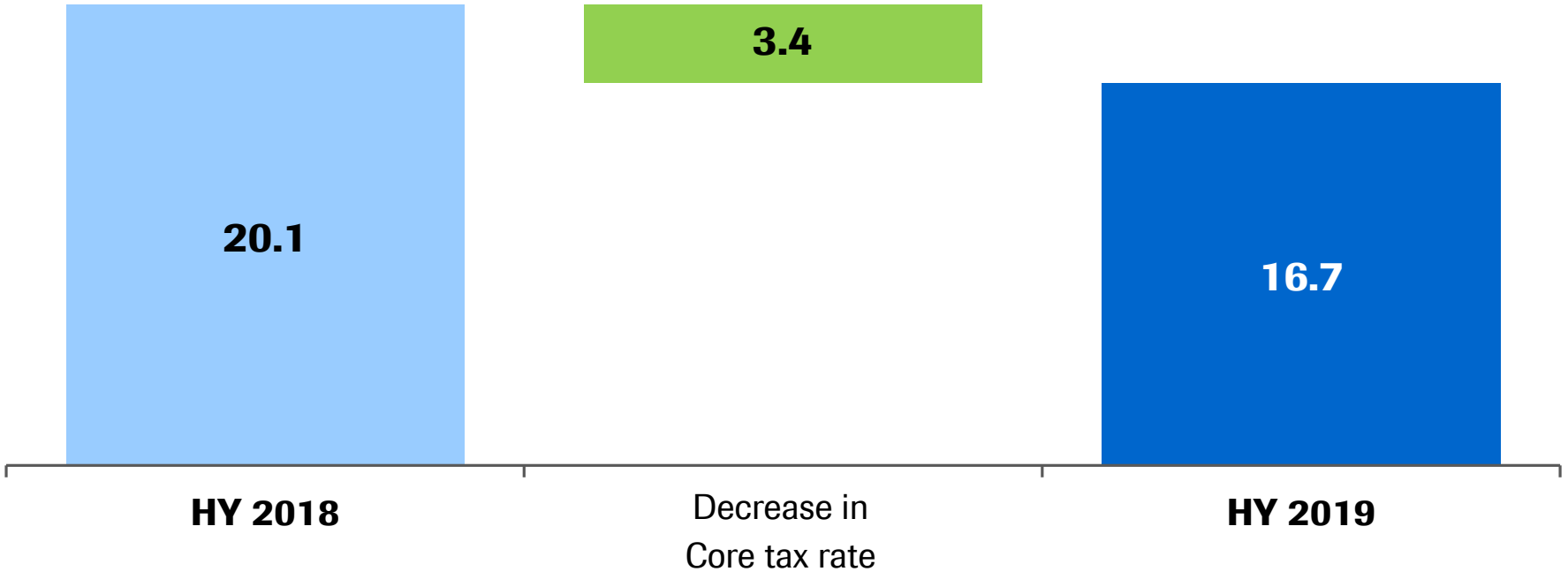


CER=Constant Exchange Rates; [1] incl. amortisation of debt discount and net gains on interest rate derivatives

HY 2019: Group Core tax rate

Decrease mainly due to the impacts from the resolution of tax disputes

Figures in %



HY 2019: Non-core items

Slight increase of total non-core operating items due to amortisation and impairment of IA and Global restructuring plans

	2018	2019		Change in %	
	CHFm	CHFm	CHFm	CHF	CER
Core operating profit	**11,162**	**12,363**	**1,201**	**+11**	**+11**
Global restructuring plans	-427	-477	-50		
Amortisation of intangible assets	-628	-737	-109		
Impairment of intangible assets[1]	-273	-324	-51		
M&A and alliance transactions	46	84	38		
Legal & Environmental	-68	-68	0		
Total non-core operating items	-1,350	-1,522	-172		
IFRS Operating profit	**9,812**	**10,841**	**1,029**	**+10**	**+11**
Total financial result & taxes	-2,296	-1,937	359		
IFRS net income	**7,516**	**8,904**	**1,388**	**+18**	**+19**

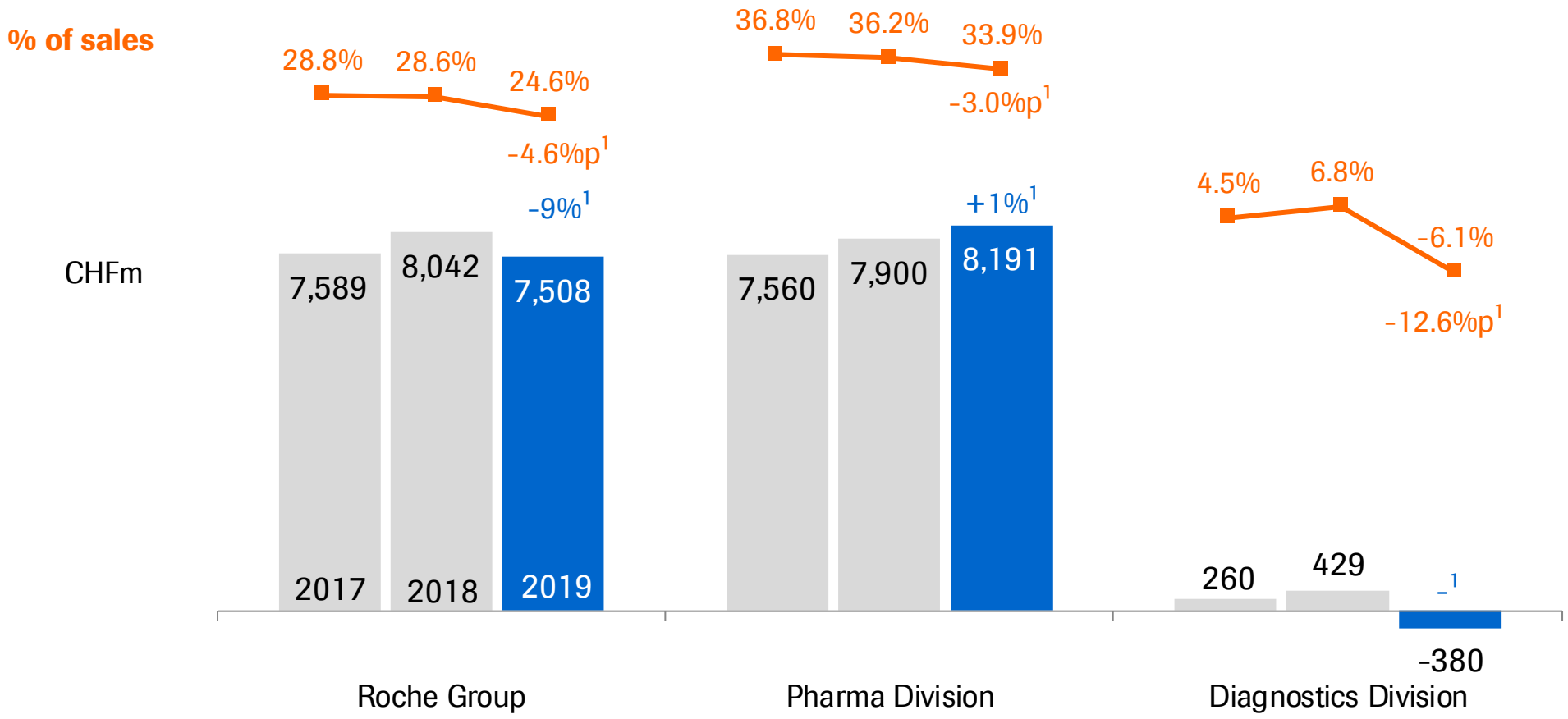
CER = Constant Exchange Rates; IA=intangible assets; [1] incl. goodwill

HY 2019 results

Focus on Cash

Outlook

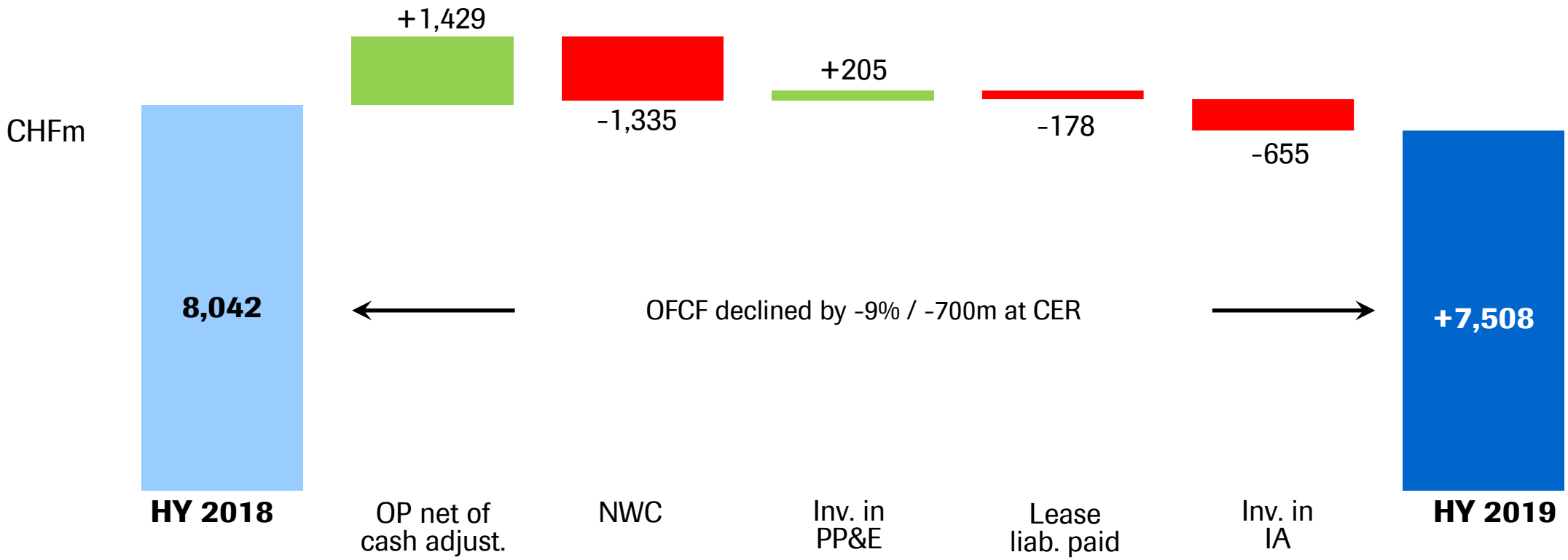
HY 2019: Operating free cash flow and margin



[1] At Constant Exchange Rates (CER)

HY 2019: Operating Free Cash Flow

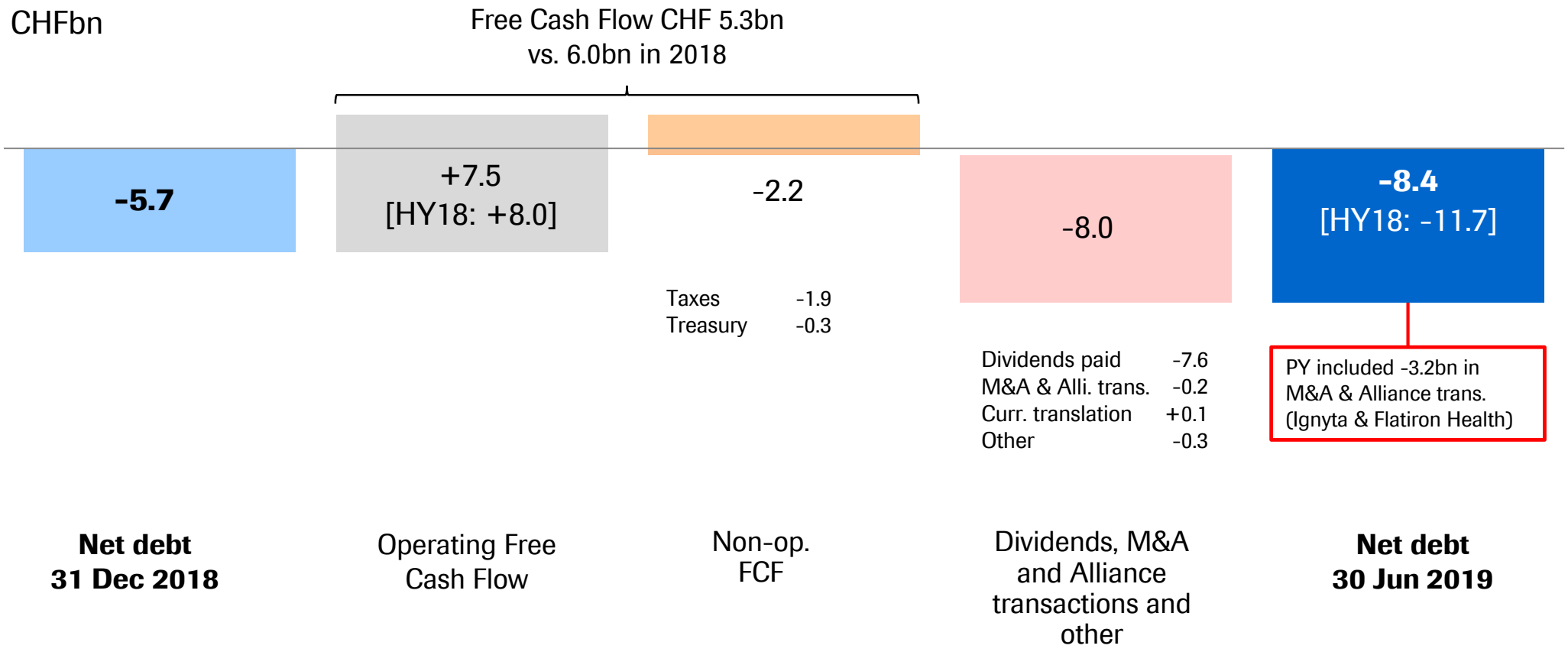
Lower than PY (-9%) driven by higher NWC and higher IA investments



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

HY 2019: Group net debt slightly up

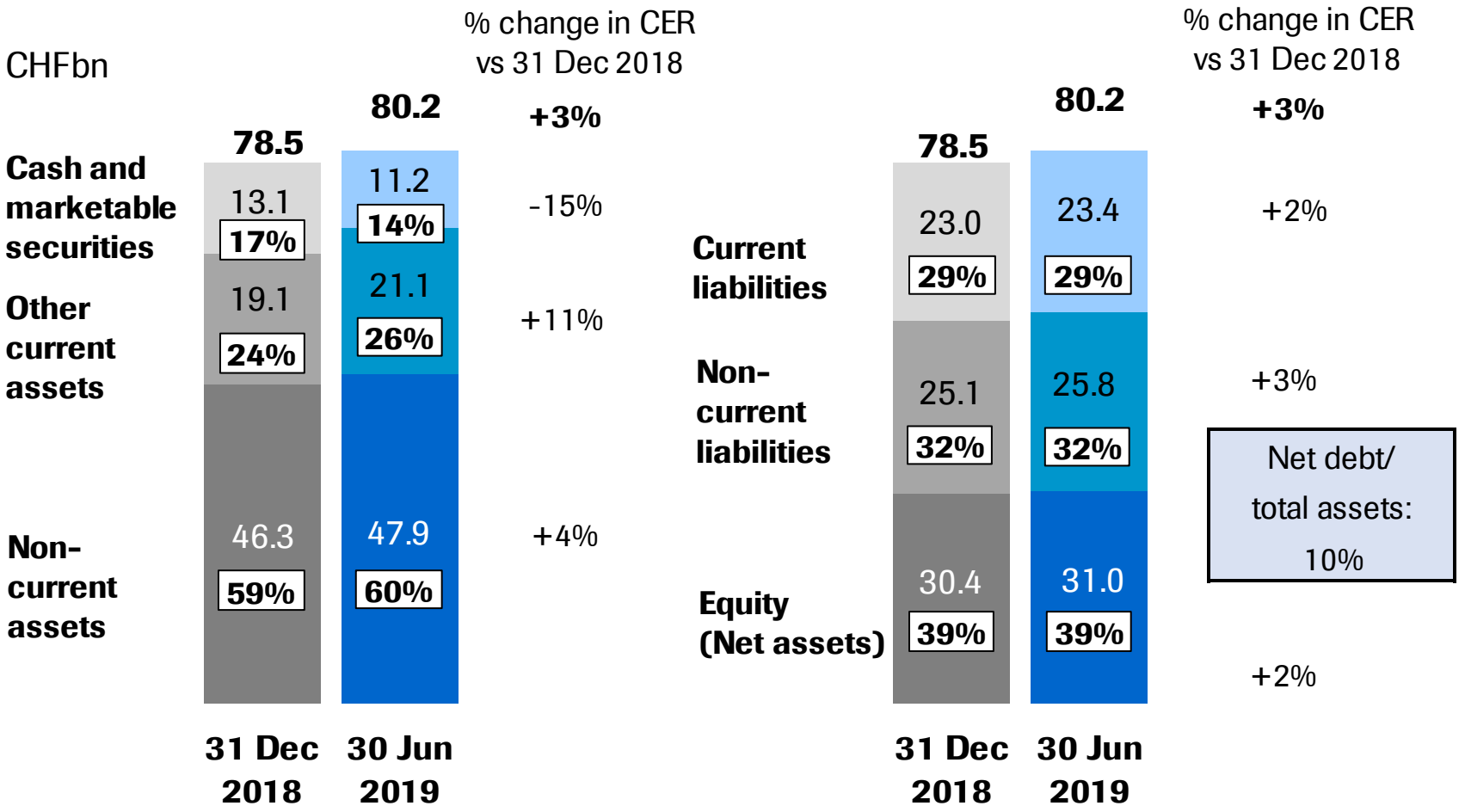
Driven by dividends paid



CER=Constant Exchange Rates

Balance sheet 30 June 2019

Equity ratio at 39% (30 Jun 2018: 39%; 31 Dec 2018: 39%)



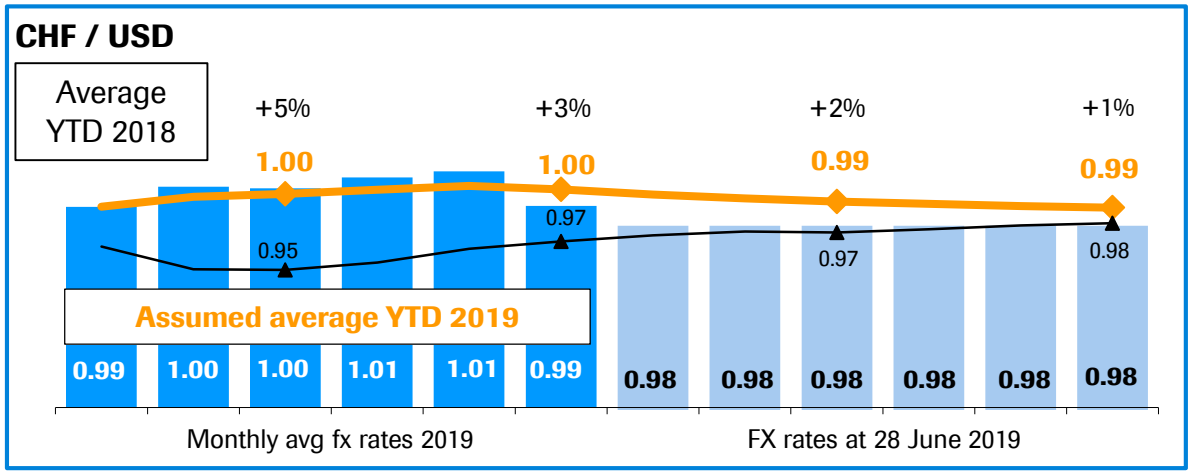
CER=Constant Excha

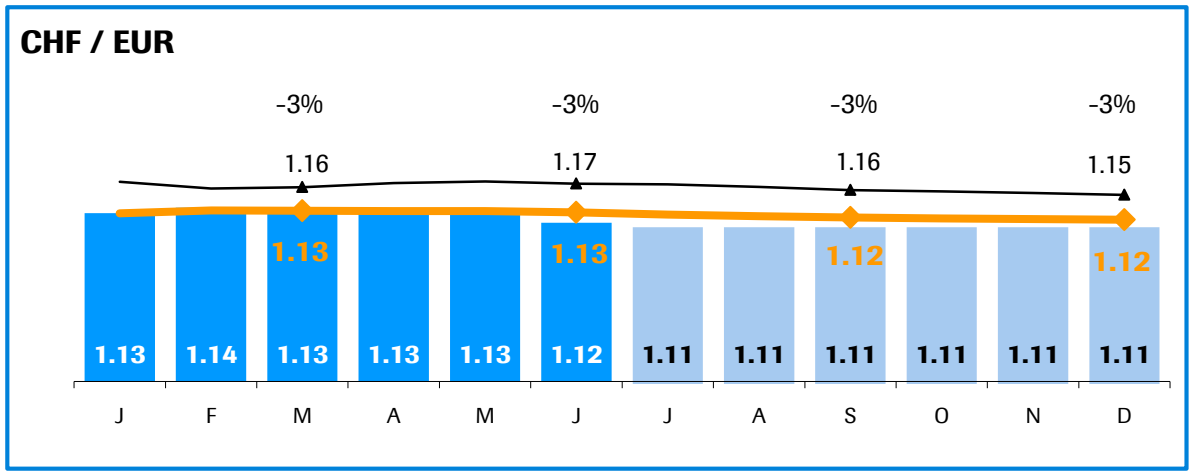
HY 2019 results

Focus on Cash

Outlook

Low currency impact expected in 2019





Assuming the 28 June 2019 exchange rates remain stable until end of 2019, 2019 impact[1] is expected to be (%p):

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

[1] On group growth rates

2019 outlook further raised

Sales growth to "mid- to high-single digit" from "mid-single digit"

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

[1] At Constant Exchange Rates (CER)

Changes to the development pipeline
Q2 2019 update

New to phase I

3 NMEs:
RG7921 – wAMD
RG6244 – asthma
RG6179 – DME

2 AIs:
RG7440 ipatasertib + rucaparib – mCRPC, solid tumors
RG7601 Venclexta + AMG176 – AML

New to phase II

1 NME :
IONIS ASO factor B – geographic atrophy

1NME transitioned from Ph1:
RG6147 – geographic atrophy

New to phase III

New to registration

Removed from phase I

1 NME:
RG6174 – inflammatory diseases

1 AI:
RG7446 Tecentriq + radium 223 – mCRPC

Removed from phase II

Removed from phase III

2 AIs:
RG7421 Cotellic + Tecentriq – 1L BRAF WT melanoma
RG7446 Tecentriq + enzalutamide – mCRPC

Removed from registration

Status as of July 25, 2019

Roche Group development pipeline

Phase I (41 NMEs + 20 AIs)

RG6026	CD20 x CD3 / combos	heme tumors
RG6107	crovalimab (C5 inh MAb)	PNH
RG6109	-	AML
RG6114	mPI3K alpha inh	HR+ BC
RG6123	-	solid tumors
RG6146	BET inh combos	solid & heme tumors
RG6148	-	HER2 expressing BC
RG6160	-	multiple myeloma
RG6171	SERD (3)	ER+ (HER2-) mBC
RG6180	iNeST*± T	solid tumors
RG6185	pan-RAF inh + Cotellic	solid tumors
RG6194	HER2 x CD3	BC
RG7159	anti-CD20 combos	heme tumors
RG7421	Cotellic + Zelboraf + T	melanoma
	Cotellic + T	2L BRAF WT mM
	Cotellic + T	RCC, bladder, head & neck ca
RG7440	ipatasertib + Taxane + T	TNBC
	ipatasertib + rucaparib	mCRPC, solid tumors
RG7446	Tecentriq (T)	solid tumors
	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chemo	HCC, GC, PaC
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + rucaparib	ovarian ca
RG7461	FAP IL2v FP combos	solid tumors
RG7601	Venclexta + idasanutlin	AML
	Venclexta + AMG176	AML
	Venclexta ± azacitidine	r/r MDS
	Venclexta + gilteritinib	r/r AML
	Venclexta + Cotellic + T	MM

RG7769	PD1-TIM3 biMAb	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab / combos	heme tumors
RG7876	selicrelumab + Avastin	solid tumors
CHU	Raf/MEK dual inh	solid tumors
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
RG6151	-	asthma
RG6173	-	asthma
RG6244	-	asthma
RG7835	-	autoimmune diseases
RG7880	IL-22Fc	inflammatory diseases
RG6004	HBV LNA	HBV
RG6084	-	HBV
RG6217	-	HBV
RG7854	TLR7 agonist (3)	HBV
RG7861	anti-*S. aureus* TAC	infectious diseases
RG7907	HBV CpAM (2) (Capsid)	HBV
RG7992	FGFR1/KLB MAb	metabolic diseases
RG6000	-	ALS
RG6237	-	neuromuscular disorders
RG7816	GABA Aa5 PAM	autism
RG6179	-	DME
RG7774	-	retinal disease
RG7921	-	wAMD
CHU	PTH1 recep. ago	hypoparathyroidism
CHU	-	hyperphosphatemia
CHU	-	endometriosis

Phase II (15 NMEs + 10 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6058	tiragolumab ± T	NSCLC
RG7388	idasanutlin	polycythemia vera
	idasanutlin	AML fit 1L
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7440	ipatasertib	TNBC neoadj
RG7446	Tecentriq	SC NSCLC
RG7596	Polivy (polatuzumab vedotin)	r/r FL
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + azacitidine	1L MDS
	Venclexta + fulvestrant	2L HR+BC
RG6149	ST2 MAb	asthma
RG7159	Gazyva	lupus
RG7625	petesicatib	autoimmune diseases
RG7845	fenebrutinib	RA, lupus, CSU
CHU	nemolizumab#	pruritus in dialysis patients
NOV	TLR4 MAb	autoimmune diseases
RG1662	basmisanil	CIAS
RG6100	Tau MAb	Alzheimer's
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7916	risdiplam§	SMA
RG7906	-	psychiatric disorders
RG7935	prasinezumab	Parkinson's
RG6147	-	geographic atrophy
IONIS	ASO factor B	geographic atrophy

NMEs
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

RG-No - Roche/Genentech
CHU- Chugai managed
NOV- Novimmune managed
*Individualized NeoAntigen Specific Immunotherapy
§ Ph2 pivotal
T=Tecentriq
# out-licensed to Galderma and Maruho AD

Status as of July 25, 2019

Roche Group development pipeline

Phase III (11 NMEs + 32 AIs)

RG3502	Kadcyla + Perjeta	HER2+ eBC
RG6264	Perjeta + Herceptin FDC SC	HER2+ BC
RG7388	idasanutlin + chemo	AML
RG7440	ipatasertib + abiraterone	1L CRPC
	ipatasertib + chemo	1L TNBC/HR+ BC
RG7421	Cotellic + Zelboraf + T	1L BRAFm melanoma
RG7596	Polivy (polatuzumab vedotin)	1L DLBCL
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq	NMIBC, high risk
	Tecentriq Dx+	1L sq + non-sq NSCLC
	Tecentriq	RCC adj
	T + chemo + Avastin	1L ovarian cancer
	T + pemetrexed	1L non-sq NSCLC
	T + nab-paclitaxel	1L sq NSCLC
	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	1L HCC
	T + Avastin	1L RCC
	T ± chemo	1L mUC

RG7446/RG7853/RG6268	Tecentriq or Alecensa or entrectinib	1LNSCLC Dx+
RG7601	Venclexta + bortezomib	MM
	Venclexta	r/r MM t(11:14)
	Venclexta + HMA	1L AML
RG7853	Alecensa	NSCLC adj
RG3648	Xolair	nasal polyps
RG7413	etrolizumab	ulcerative colitis
	etrolizumab	Crohn's
RG6152	Xofluza	influenza, hospitalized pts
	Xofluza	influenza, pediatric
	Xofluza	influenza post exposure prophylaxis
RG1450	gantenerumab	Alzheimer's
RG6042	HTT ASO	Huntington's
RG6168	satralizumab	NMOSD
RG6206	anti-myostatin adnectin	DMD
RG7314	balovaptan	autism
RG6321	port delivery system with ranibizumab	wAMD
RG7716	faricimab	DME
	faricimab	wAMD

Registration (3 NMEs + 7 AIs)

RG3502	Kadcyla[1]	HER2+ eBC
RG6268	Rozlytrek (entrectinib)	NSCLC ROS1+
	Rozlytrek (entrectinib)	NTRK1 tumor agnostic
RG7446	T + nab-paclitaxel	1L non-sq NSCLC
	T + nab-paclitaxel [1]	1L TNBC
	T + chemo [1]	1L extensive stage SCLC
RG7596	Polivy (polatuzumab vedotin)[1]	r/r DLBCL
RG7601	Venclexta + Gazyva [1]	1L CLL
RG6152	Xofluza [1]	influenza
	Xofluza [2]	influenza, high risk

[1] Approved in US

[2] Filed in US

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

Status as of July 25, 2019

NME submissions and their additional indications

Projects currently in phase II and III

2019

RG7916	**risdiplam** SMA
RG6168	**satralizumab** NMOSD
RG6152	**Xofluza (EU)** influenza
RG6152	**Xofluza (EU)** influenza, high risk
RG6152	**Xofluza** influenza post-exposure prophylaxis
RG6268	**Rozlytrek (entrectinib) (EU) ✓** NSCLC ROS1+
RG6268	**Rozlytrek (entrectinib) (EU) ✓** NTRK1 tumor agnostic

2020

RG7413	**etrolizumab** ulcerative colitis
RG6152	**Xofluza** influenza, pediatric
RG6206	**anti-myostatin adnectin** DMD
RG6264	**Perjeta + Herceptin FDC SC** HER2+ BC
RG7388	**idasanutlin + chemo** AML
RG7440	**ipatasertib + abiraterone** 1L CRPC
RG7440	**ipatasertib +chemo** 1L TNBC / HR+ BC

2021

RG6321	**Port Delivery System with ranibizumab** wAMD
RG7596	**Polivy (polatuzumab vedotin)** 1L DLBCL

2022 and beyond

RG6058	**tiragolumab + Tecentriq** NSCLC
RG6180	**iNeST*** oncology
RG7388	**idasanutlin** AML fit 1L
RG7388	**idasanutlin** polycythemia vera
RG7440	**ipatasertib** TNBC neoadj
RG7596	**Polivy (polatuzumab vedotin)** r/r FL
RG6152	**Xofluza** influenza, hospitalized pts
RG6042	**HTT ASO** Huntington's
RG1450	**gantenerumab** Alzheimer's
RG1662	**basmisanil** CIAS
RG6100	**Tau MAb** Alzheimer's
RG7314	**balovaptan** autism
RG7935	**prasinezumab** Parkinson's
RG7716	**faricimab** DME
RG7716	**faricimab** wAMD
RG6149	**ST2 Mab** asthma
RG7413	**etrolizumab** Crohn's
RG7625	**petesicatib** autoimmune diseases
RG7845	**fenebrutinib** autoimmune diseases

✓ 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

FDC =fixed-dose combination
*Individualized NeoAntigen Specific Immunotherapy

Status as of July 25, 2019

AI submissions for existing products

Projects currently in phase II and III

2019		2020		2021		2022 and beyond			
RG3648	**Xolair** nasal polyps	RG3502	**Kadcyla + Perjeta** HER2+ eBC	RG7601	**Venclexta + HMA** 1L AML	RG7446	**Tecentriq SC** NSCLC	RG7159	**Gazyva** lupus nephritis
RG3502	**Kadcyla✓** HER2+ eBC	RG7421	**Cotellic + Tecentriq + Zelboraf** 1L BRAFmut melanoma	RG7446/ RG7853/ RG6268	**Tecentriq or Alecensa or entrectinib** 1L NSCLC Dx+	RG7446	**Tecentriq** NSCLC adj	RG7421	**Cotellic + Tecentriq ± taxane** TNBC
RG7446	**Tecentriq + Avastin** 1L HCC	RG7446	**Tecentriq + nab-paclitaxel** TNBC neoadj			RG7446	**Tecentriq** HER2+ BC neoadj	RG7601	**Venclexta** r/r MM t(11:14)
RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+	RG7446	**Tecentriq + pemetrexed** 1L non-sq NSCLC			RG7446	**Tecentriq + paclitaxel** TNBC adj	RG7601	**Venclexta + Rituxan** DLBCL
RG7446	**Tecentriq + nab-paclitaxel** 1L sq NSCLC	RG7446	**Tecentriq + Avastin** 1L RCC			RG7446	**Tecentriq** High risk NMIBC	RG7601	**Venclexta + azacitidine** 1L MDS
RG7601	**Venclexta + Gazyva ✓** 1L CLL	RG7446	**Tecentriq + paclitaxel** 1L TNBC			RG7446	**Tecentriq** RCC adj	RG7601	**Venclexta + fulvestrant** 2L HR+BC
		RG7446	**Tecentriq** MIBC adj			RG7446	**Tecentriq + chemo** SCCHN adj	RG7853	**Alecensa** NSCLC adj
		RG7446	**Tecentriq ± chemo** 1L mUC			RG7446	**Tecentriq + capecitabine or carbo/gem** TNBC		
		RG7446	**Tecentriq + chemo + Avastin** 1L ovarian cancer						

✓ 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

Status as of July 25, 2019

Cancer immunotherapy pipeline overview

Phase I (11 NMEs + 21 AIs)

RG6026	CD20 x CD3 / combos	heme tumors
RG6123	-	solid tumors
RG6160	-	multiple myeloma
RG6180	iNeST* ± T	solid tumors
RG6194	HER2 x CD3	BC
RG7421	Cotellic + Zelboraf + T	melanoma
	Cotellic + T	2L BRAF WT mM
	Cotellic + T	RCC, bladder, head & neck ca
RG7440	ipatasertib + Taxane + T	TNBC
RG7446	Tecentriq (T)	solid tumors
	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chem	HCC, GC, PaC
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + rucaparib	ovarian ca
RG7461	FAP IL2v FP combos	solid tumors
RG7601	Venclexta + Cotellic + T	MM
RG7769	PD1-TIM3 biMAb	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab / combos	heme tumors
RG7876	selicrelumab + Avastin	solid tumors
CHU	glypican-3 x CD3	solid tumors
AMGN**	Tecentriq + talimogene laherp	TNBC, CRC
BLRX**	Tecentriq + BL-8040	AML, solid tumors
CRVS**	Tecentriq + CPI-444	solid tumors
EXEL**	Tecentriq + cabozantinib	solid tumors
HALO**	Tecentriq + PEGPH20	CCC, GBC
INO**	Tecentriq + INO5401+INO9012	bladder ca
KITE**	Tecentriq + KTE-C19	r/r DLBCL

MORPHEUS Platform – Phase Ib/II (7 AIs)

RG7446	T-based Morpheus	pancreatic cancer
	T-based Morpheus	gastric cancer
	T-based Morpheus	HR+ BC
	T-based Morpheus	NSCLC
	T-based Morpheus	2L TNBC
	T-based Morpheus	CRC
	T-based Morpheus	mUC

Phase II (2 NMEs + 5 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6058	tiragolumab ± T	NSCLC
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7446	Tecentriq SC	NSCLC
Gradalis**	Tecentriq + Vigil	ovarian ca
GTHX**	Tecentriq + trilaciclib	SCLC
IMDZ**	Tecentriq + NY-ESO-1	soft tissue sarcoma

Phase III (20 AIs)

RG7421	Cotellic+Zelboraf+T	1L BRAFm melanoma
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq	high risk NMIBC
	Tecentriq	NMIBC
	Tecentriq Dx+	1L sq + non-sq SCLC
	Tecentriq	RCC adj
	T + chemo+ Avastin	1L ovarian cancer
	T + pemetrexed	1L non-sq NSCLC
	T + nab-paclitaxel	1L sq NSCLC
	T ± chemo	SCCHN adj
	Tecentriq	HER2-pos. BC neoadj
	T + nab-paclitaxel 1L	TNBC
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + nab-paclitaxel	TNBC neoadj
	T + Avastin	RCC
	T + Avastin	1L HCC
	T ± chemo	1L mUC
RG7446/RG7853/ RG6268	Tecentriq or Alecensa or entrectinib	1L NSCLC Dx+

Registration (3 AIs)

RG7446	T + nab-paclitaxel	1L non-sq NSCLC
	T + chemo	1L extensive stage SCLC
	T + nab-paclitaxel	1L TNBC

** External collaborations: AMGN – Amgen oncolytic virus; BLRX - BioLine Rx CXCR4 antag; CRVS – Corvus ADORA2A antag; EXEL – Exelexis' TKI; Gradalis – EATC therapy; GTHX – G1 Therapeutics CDK4/6; HALO – Halozyme PEGPH20; IMDZ – Immune Design CMB305; INO - Inovio T cell activating immunotherapy (INO-5401), IL-12 activator (INO-9012); JNJ – Janssen CD38 MAb; KITE – Kite KTE-C19

New Molecular Entity (NME)
Additional Indication (AI)
Oncology

RG-No Roche/Genentech
*Individualized NeoAntigen Specific Immunotherapy
T=Tecentriq

Status as of July 25, 2019

Major pending approvals 2019

US

RG7446	**Tecentriq + nab-paclitaxel** 1L non sq NSCLC Filed Nov 2018
RG6268	**Rozlytrek (entrectinib)** NSCLC ROS1+ Filed Dec 2018
RG6268	**Rozlytrek (entrectinib)** NTRK+ solid tumors Filed Dec 2018
RG6152	**Xofluza** Influenza, high risk pts Filed Dec. 2018

EU

RG7596	**Polivy (polatuzumab vedotin)** r/r DLBCL Filed Dec 2018
RG7446	**Tecentriq + nab-paclitaxel** 1L non sq NSCLC Filed Oct 2018
RG7446	**Tecentriq + nab-paclitaxel** 1L TNBC* Filed Sep.2018
RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Filed Sep. 2018
RG6268	**Rozlytrek (entrectinib)** NSCLC ROS1+ Filed Jan 2019
RG6268	**Rozlytrek (entrectinib)** NTRK1 tumor agnostic Filed Jan 2019
RG3502	**Kadcyla** HER2+EBC Filed Feb 2019
RG7601	**Venclexta+Gazyva** 1L CLL Filed Jul 2019

*CHMP positive opinion

China

RG99	**CellCept** lupus nephritis Filed Aug 2018
RG6264	**Perjeta** HER2+ eBC neoadj Filed Aug 2018
RG105	**MabThera** CLL Filed Apr 2019
RG6264	**Perjeta + Herceptin** 1L HER2+ mBC Filed Dec 2018
RG405	**Avastin** 1L/2L gliobastoma Filed Jan 2019
RG3502	**Kadcyla** HER2+ eBC Filed Feb 2019
RG7159	**Gazyva** 1L FL Filed Feb 2019
RG7159	**Gazyva** r/r FL Filed Feb 2019
RG105	**MabThera** FL Filed Apr 2019

Japan-Chugai

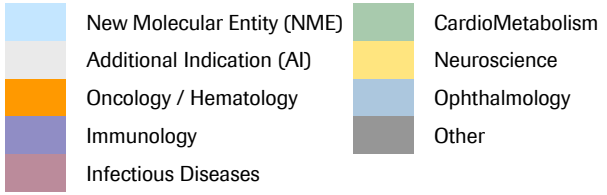
RG7446	**Tecentriq + nab-paclitaxel** 1L TNBC Filed Dec 2018
RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Filed Dec 2018
RG6268	**Rozlytrek (entrectinib)** NSCLC ROS1+ Filed Mar 2019
RG7853	**Alecensa** r/r ALK+ ALCL Filed Jun 2019

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

Status as of July 25, 2019

Major granted approvals 2019

US		EU		China		Japan-Chugai	
RG597	**Herceptin SC Hylecta** Feb 2019	**RG105**	**MabThera** pemphigus vulgaris Mar 2019	**RG1569**	**Herceptin** BC neoadj Jan 2019	**RG105**	**Rituxan** CD20 + CLL Mar 2019
RG7446	**Tecentriq + nab-paclitaxel** 1L TNBC Mar 2019	**RG6013**	**Hemlibra** hemophilia A FVIII non-inh Mar 2019			**RG6268**	**Rozlytrek (entrectinib)** NTRK+ solid tumors June 2019
RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Mar 2019	**RG6013**	**Hemlibra** Q4W hemophilia A Mar 2019			**RG1569**	**Actemra** CRS Mar 2019
RG7601	**Venclexta + Gazyva** 1L CLL May 2019	**RG7446**	**Tecentriq + chemo + Avastin** 1L non-sq NSCLC Mar 2019			**RG1569**	**Actemra** Adult Onset Still's disease Mar 2019
RG3502	**Kadcyla** HER2+ eBC May 2019						
RG7596	**Polivy (polatuzumab vedotin)** r/r DLBCL June 2019						



Status as of July 25, 2019

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group HY 2019 results

Diagnostics

Foreign exchange rate information

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A		
Phase/study	**Phase I** Study in Japan	**Phase I/II** Study in Japan	**Non-interventional study**
# of patients	N=82	N=18	N=221
Design	▪ Enrolled 64 healthy volunteers and 18 patients	▪ Extension study in patients from phase I	Non-interventional study evaluating bleeding incidence, health-related quality of life and safety in patients with hemophilia A and inhibitors to factor VIII under SoC treatment ▪ **Cohort A:** Adults and adolescents with FVIII Inhibitors ▪ **Cohort B:** Children with FVIII Inhibitors ▪ **Cohort C:** Adults and adolescents without FVIII Inhibitors
Primary endpoint	▪ Exploratory safety and efficacy	▪ Exploratory safety and efficacy	▪ Number of bleeds over time, sites of bleed, type of bleed
Status	▪ Recruitment completed Q2 2014 ▪ Data presented at ASH 2014	▪ Recruitment completed Q4 2014 ▪ Data presented at ISTH 2015 ▪ Extension data presented at WFH 2016	▪ Inhibitor cohort closed Q4 2015, except China ▪ FPI in non-inhibitor and pediatric subjects in Q1 2016 ▪ Cohort A presented at ASH 2016 and EAHAD 2017; Cohort B presented at ASH 2017 and WFH 2018; Cohort C presented at EAHAD and WFH 2018 ▪ Study completed
	▪ Breakthrough Therapy Designation granted by FDA Q3 2015		
CT Identifier	JapicCTI-121934	JapicCTI-132195	NCT02476942

In collaboration with Chugai

SoC=Standard of care; FVIII=Factor VIII; ASH=American Society of Hematology; ISTH=International Society on Thrombosis and Haemostasis; WFH=World Federation of Hemophilia; EAHAD=European Association for Haemophilia and Allied Disorders

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 Aug 31;377(9):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
	▪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*

Alecensa

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK-positive advanced NSCLC	ALK-positive advanced NSCLC in ALK inhibitor-naïve patients who are chemotherapy-naïve or have received one previous line of chemotherapy	Adjuvant ALK+ NSCLC
Phase/study	**Phase III** **ALEX**	**Phase III** **J-ALEX/Japic CTI-132316** Japanese study	**Phase III** **ALINA**
# of patients	N=286	N=207	N=255
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 300mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 600 mg BID ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Disease-free survival
Status	▪ Recruitment completed Q3 2015 ▪ Primary endpoint met Q1 2017 ▪ Data presented at ASCO 2017, ESMO 2017, ASCO 2018 and ESMO 2018 ▪ Data published in *NEJM* 2017 June; 377:829-838 ▪ CNS data presented at ESMO 2017	▪ Primary data analysis positive ▪ Data presented at ASCO 2016 and 2017 ▪ Breakthrough Therapy Designation granted by FDA Q3 2016 ▪ Data published in *Lancet* 2017 Jul; 390(10089):29–39	▪ FPI Q3 2018
	▪ Approved in US Q4 2017 (priority review) and in EU Q4 2017		
CT Identifier	NCT02075840	JapicCTI-132316	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	Recurrent or advanced solid tumors
Phase/study	**Phase II** **COLET**	**Phase Ib** **COTEST**
# of patients	N=160	N=250
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	Cotellic plus Tecentriq in head and neck, bladder and renal cancer (cohorts for each cancer type in CPI naive and CPI experienced patients)
Primary endpoint	▪ Progression-free survival and safety	▪ Objective response rate
Status	▪ FPI Q1 2015 ▪ FPI arms C and D: Q4 2016 ▪ Data from arm A and B presented at SABCS 2017	▪ FPI Q4 2017
CT Identifier	NCT02322814	NCT03264066

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

Gazyva/Gazyvaro

Oncology development program

Indication	Front-line indolent non-Hodgkin's lymphoma
Phase/study	**Phase III** **GALLIUM** Induction and maintenance study
# of patients	N=1,401
Design	▪ **ARM A:** Gazyva 1000mg IV + chemo followed by Gazyva maintenance ▪ **ARM B:** MabThera/Rituxan + chemo followed by MabThera/Rituxan maintenance *Chemotherapy:* ▪ For follicular lymphoma (FL): CHOP, CVP or bendamustine ▪ For non-FL: physician's choice
Primary endpoint	▪ Progression-free survival in FL patients (N=1,202)
Status	▪ Trial stopped at interim for efficacy (May 2016) ▪ Data presented at ASH 2016 ▪ Approved in EU Q3 2017 ▪ Approved by the FDA Q4 2017 after priority review ▪ Data published in *NEJM* 2017 Oct 5;377(14):1331-1344
CT Identifier	NCT01332968

In collaboration with Biogen

ASH=American Society of Hematology; CHOP=cyclophosphamide, doxorubicin, vincristine and prednisone; CVP=cyclophosphamide, vincristine and prednisolone; ; *NEJM*=New England Journal of Medicine

Kadcyla

First ADC for HER2-positive breast cancer

Indication	HER2-positive early breast cancer high-risk patients	Operable HER2-positive early breast cancer
Phase/study	**Phase III KATHERINE**	**Phase III KAITLIN**
# of patients	N=1,484	N=1,850
Design	▪ **ARM A:** Kadcyla 3.6mg/kg Q3W ▪ **ARM B:** Herceptin	Following surgery and antracycline-based therapy: ▪ **ARM A:** Herceptin 6mg/kg Q3W plus Perjeta 420 mg/kg Q3W plus chemo ▪ **ARM B:** Kadcyla 3.6mg/kg Q3W plus Perjeta 420mg/kg Q3W plus chemo
Primary endpoint	▪ Invasive disease-free survival	▪ Invasive disease-free survival
Status	▪ Recruitment completed Q4 2015 ▪ Stopped at pre-planned interim data analysis for efficacy Q4 2018 ▪ Data presented at SABCS 2018 ▪ BTD granted by FDA in Q1 2019 ▪ US filling completed under RTOR Q1 2019 ▪ Filled in EU Q1 2019 ▪ Approved in US Q2 2019	▪ Recruitment completed Q2 2015 ▪ Data expected in 2020
CT Identifier	NCT01772472	NCT01966471

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	HER2-positive early breast cancer subcutaneous co-formulation
Phase/study	**Phase III APHINITY**	**Phase II BERENICE**	**Phase III FeDeriCa**
# of patients	N=4,803	N=401	N=500
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 x4 cycles ▪ **ARM B:** FEC plus P+H x4 followed by docetaxel plus P+H x4 *Adjuvant treatment:* ▪ P+H q3w to complete 1 year of HER2 therapy ▪ Hormonal and radiation therapy as indicated	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
Primary endpoint	▪ Invasive disease-free survival	▪ Safety	▪ Trough Serum Concentration (Ctrough) of Pertuzumab During Cycle 7
Status	▪ Primary endpoint met Q1 2017 ▪ Data presented at ASCO 2017 ▪ Filed in US and EU Q3 2017 ▪ Approved in US Q4 2017 (priority review) and EU Q2 2018	▪ Recruitment completed Q3 2015 ▪ Data presented at SABCS 2016 ▪ Data published Ann Oncol. 2018 Mar 1; 29(3): 646-653	▪ FPI Q2 2018 ▪ Recruitment completed Q4 2018
CT Identifier	NCT01358877	NCT02132949	NCT03493854

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous NSCLC		
Phase/study	**Phase III IMpower150**	**Phase III IMpower130**	**Phase III IMpower132**
# of patients	N=1,202	N=650	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 nab-paclitaxel plus carboplatin ▪ **ARM B:** Nab-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	▪ 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 Jun 14;378(24):2288-2301 ▪ Approved in US Q4 2018 and EU Q1 2019	▪ FPI Q1 2015 ▪ Recruitment completed Q1 2017 ▪ Study met co-primary endpoint of OS and PFS in Q2 2018 ▪ Filed in US and EU Q4 2018 ▪ Data published in Lancet Oncol. 2019 Jul;20(7):924-937	▪ 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	NCT02367781	NCT02657434

NSCLC=non-small cell lung cancer; NSq=non-squamous; ESMO=European Society for Medical Oncology; AACR=American Association for Cancer Research; ; *NEJM*=New England Journal of Medicine; WCLC=world Lung Cancer Congress

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous and squamous NSCLC PD-L1-selected patients	1L squamous NSCLC	1L extensive-stage SCLC
Phase/study	**Phase III IMpower110**	**Phase III IMpower131**	**Phase III IMpower133**
# of patients	N=570	N=1,025	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 paclitaxel plus carboplatin ▪ **ARM B:** Tecentriq plus nab-paclitaxel plus carboplatin ▪ **ARM C:** Nab-paclitaxel plus carboplatin	▪ **ARM A:** Tecentriq plus carboplatin plus etoposide ▪ **ARM B:** Placebo plus carboplatin plus etoposide
Primary endpoint	▪ Overall survival	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival
Status	▪ FPI Q3 2015 ▪ IMpower111 consolidated into IMpower110 Q3 2016 ▪ Recruitment completed Q1 2018	▪ FPI Q2 2015 ▪ Recruitment completed Q1 2017 ▪ Study met co-primary endpoint of PFS in Q1 2018 ▪ Primary PFS data presented at ASCO 2018 ▪ Interim OS data presented at ESMO 2018	▪ 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 at NEJM 2018 Sep 25 2018 2018; 379:2220-2229 ▪ Filed with the US and EU Q3 2018 ▪ Approved in US Q1 2019
CT Identifier	NCT02409342	NCT02367794	NCT02763579

NSCLC=non-small cell lung cancer; NSq=non-squamous; Sq=squamous; SCLC=small cell lung cancer; ASCO=American Society of Clinical Oncology; *NEJM*=New England Journal of Medicine; WCLC=World Lung Cancer Congress

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=302
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 non-squamous NSCLC	NSCLC	Stage IV non-small cell lung cancer
Phase/study	**Phase II/III B-FAST**	**Phase I**	**Phase Ib/II IMnscin**
# of patients	N=580	N=53	N=245
Design	▪ **Cohort A:** ALK + (Alecensa) ▪ **Cohort B:** ROS1 + (entrectinib) ▪ **Cohort C:** bTMB-high (Tecentriq)	▪ Tecentriq plus Tarceva[1] or Alecensa	▪ 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	▪ Safety	▪ Observed concentration of atezolizumab in serum at cycle 1
Status	▪ FPI Q3 2017 ▪ Recruitment completed for cohort A Q3 2018	▪ FPI Q1 2014 ▪ FPI in Alecensa arm Q3 2015 ▪ Recruitment completed in Tarceva arm Q3 2015 ▪ Data from Tarceva presented at WCLC and ESMO Asia 2016	▪ FPI Q4 2018
CT Identifier	NCT03178552	NCT02013219	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; ECC=European Cancer Congress; WCLC=World Conference on Lung Cancer

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
CT Identifier	NCT03452137

SCCHN=squamous cell carcinoma of the head and neck

Tecentriq

Anti-PD-L1 cancer immunotherapy – UC

Indication	Locally advanced or metastatic urothelial bladder cancer	
Phase/study	**Phase III** **IMvigor211**	**Phase II** **IMvigor210**
# of patients	N=932	N=439
Design	Patients who progressed on at least one platinum-containing regimen will receive: ▪ **ARM A:** Tecentriq 1200mg q3w ▪ **ARM B:** Chemotherapy (vinflunine, paclitaxel or docetaxel)	▪ **Cohort 1:** Treatment-naive and cisplatin-ineligible patients ▪ **Cohort 2:** Patients with disease progression following or during platinum-containing treatment
Primary endpoint	▪ Overall survival	▪ Objective response rate
Status	▪ Recruitment completed Q1 2016 ▪ Data presented at EACR-AACR-SIC Special Conference 2017 ▪ Data published in *Lancet* in Dec 2017; 391(10122):p748–757	▪ Cohort 2: US accelerated approval Q2 2016; filed in EU Q2 2016 ▪ Cohort 2 data published in *Lancet* May 2016; 387(10031):p1909–1920 ▪ Updated data (Cohorts 1 and 2) presented at ESMO 2016 ▪ Cohort 1: Approved in US Q2 2017 (priority review)
	▪ Approved in EU Q3 2017	
CT Identifier	NCT02302807	NCT02951767 (Cohort 1), NCT02108652 (Cohort 2)

UC=urothelial carcinoma; ESMO=European Society for Medical Oncology; EACR-AACR-SIC=European Association for Cancer Research - American Association for Cancer Research - Italian Cancer Society

Tecentriq

Anti-PD-L1 cancer immunotherapy – UC

Indication	Adjuvant high-risk muscle-invasive urothelial cancer	1L metastatic urothelial carcinoma
Phase/study	**Phase III IMvigor010**	**Phase III IMvigor130**
# of patients	N=800	N=1,200
Design	After cystectomy: ▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Observation	▪ **ARM A:** Tecentriq plus gemcitabine and carboplatin or cisplatin ▪ **ARM B:** Tecentriq monotherapy ▪ **ARM C:** Placebo plus gemcitabine and carboplatin or cisplatin
Primary endpoint	▪ Disease-free survival	▪ Progression-free survival, overall survival and safety
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q3 2018	▪ FPI Q3 2016 ▪ FPI for arm B (amended study) Q1 2017 ▪ Recruitment completed Q3 2018
CT Identifier	NCT02450331	NCT02807636

UC=urothelial carcinoma

Tecentriq

Anti-PD-L1 cancer immunotherapy – UC

Indication	High-risk non-muscle-invasive bladder cancer
Phase/study	**Phase III ALBAN**
# of patients	N=614
Design	▪ **ARM A:** BCG induction and maintenance ▪ **ARM B:** Tecentriq+ BCG induction and maintenance
Primary endpoint	▪ Recurrence-free survival
Status	▪ FPI Q4 2018
CT Identifier	NCT03799835

UC=urothelial carcinoma; BCG=Bacille Calmette-Guérin

Tecentriq

Anti-PD-L1 cancer immunotherapy – renal cell cancer

Indication	Adjuvant renal cell carcinoma	Untreated advanced renal cell carcinoma	
Phase/study	**Phase III IMmotion010**	**Phase III IMmotion151**	**Phase II IMmotion150**
# of patients	N=664	N=900	N=305
Design	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Observation	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Sunitinib	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Tecentriq; following PD: Tecentriq plus Avastin ▪ **ARM C:** Sunitinib; following PD: Tecentriq plus Avastin
Primary endpoint	▪ Disease-free survival	▪ Progression-free survival and overall survival (co-primary endpoint)	▪ Progression-free survival
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q1 2019	▪ FPI Q2 2015 ▪ Recruitment completed Q4 2016 ▪ Study met co-primary endpoint (PFS in PD-L1+ patients) in Q4 2017 ▪ Data presented at ASCO GU 2018 ▪ Published in the Lancet. 2019 May 9. pii: S0140-6736(19)30723-8	▪ Recruitment completed Q1 2015 ▪ Presented at ASCO GU and AACR 2017 ▪ Updated data presented at ASCO 2017
CT Identifier	NCT03024996	NCT02420821	NCT01984242

ASCO GU=American Society of Clinical Oncology Genitourinary Cancers; AACR=American Association for Cancer Research; PD=progressive disease

Tecentriq

Anti-PD-L1 cancer immunotherapy – prostate cancer

Indication	Metastatic castration-resistant prostate cancer
Phase/study	**Phase III** **IMbassador250**
# of patients	N=730
Design	▪ **ARM A:** Tecentriq plus enzalutamide ▪ **ARM B:** Enzalutamide
Primary endpoint	▪ Overall survival
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2018 ▪ Study stopped due to futility Q2 2019
CT Identifier	NCT03016312

Tecentriq

Anti-PD-L1 cancer immunotherapy – CRC and HCC

Indication	2/3L metastatic colorectal cancer	1L hepatocellular carcinoma
Phase/study	**Phase I**	**Phase III** **IMbrave150**
# of patients	N=84	N=480
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
Primary endpoint	▪ Safety	▪ Overall survival and progression free survival
Status	▪ FPI Q3 2016 ▪ Recruitment completed Q3 2018	▪ FPI Q1 2018 ▪ Recruitment completed Q1 2019
CT Identifier	NCT02876224	NCT03434379

Cotellic in collaboration with Exelixis

Tecentriq

Anti-PD-L1 cancer immunotherapy – solid tumors

Indication	Solid tumors	Locally advanced or metastatic solid tumors
Phase/study	**Phase I**	**Phase I**
# of patients	N=430	N=661
Design	▪ **ARM A:** HCC: Tecentriq + Avastin ▪ **ARM B:** HER2-neg. GC: Tecentriq+Avastin+oxaliplatin+leucovorin+5-FU ▪ **ARM C:** PaC: Tecentriq + nab-paclitaxel + gemcitabine ▪ **ARM D:** HCC: Tecentriq + vanucizumab or Tecentriq + Avastin ▪ **ARM E:** Squamous cell mEC: Tecentriq + 5FU-Cis and Tecentriq + FOLFOX; adenocarcinoma mEC: Tecentriq + FOLFOX ▪ **ARM F:** HCC: Tecentriq vs Tecentriq + Avastin (randomized)	▪ Dose escalation study
Primary endpoint	▪ Safety	▪ Safety and PK
Status	▪ FPI Q2 2016 ▪ FPI arm E Q1 2017 ▪ FPI arm F Q2 2018 ▪ Breakthrough Therapy Designation granted by FDA for HCC Jul 2018	▪ FPI Q2 2011 ▪ Initial efficacy data presented at ASCO 2013, data from bladder cohort presented at ASCO and ESMO 2014; TNBC cohort presented at AACR 2015; updated lung and bladder data presented at ASCO 2015; GBM data presented at SNO 2015; SCCHN data presented at ESMO 2017
CT Identifier	NCT02715531	NCT01375842

HCC=hepatocellular carcinoma; GC=gastric cancer; PaC=pancreatic cancer; mEC=metastatic esophageal cancer; CRC=colorectal cancer; TNBC=triple-negative breast cancer; GBM=glioblastoma multiforme; SCCHN=squamous cell carcinoma of the head and neck; AACR=American Association for Cancer Research; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; SNO=Society for Neuro-Oncology;

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=350
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	▪ FPI Q3 2015 ▪ 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 ▪ US accelerated approval Q1 2019 ▪ CHMP positive opinion Q2 2019	▪ FPI Q3 2017	▪ FPI Q1 2018
CT Identifier	NCT02425891	NCT03125902	NCT03371017

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=204	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)	▪ FPI Q3 2018
CT Identifier	NCT03197935	NCT03498716

[1] In collaboration with ImmunoGen, Inc.
eBC=early breast cancer; mBC=metastatic breast cancer; IDMC=Independent data monitoring committee

Tecentriq

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Metastatic and locally advanced early breast cancer (HER2-positive)	Neoadjuvant HER2-positive breast cancer
Phase/study	**Phase I**	**Phase III** **IMpassion050**
# of patients	N=76	N=224
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]	▪ **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	▪ Safety	▪ pCR
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q2 2018	▪ FPI Q4 2018
CT Identifier	NCT02605915	NCT03726879

[1] In collaboration with ImmunoGen, Inc.
eBC=early breast cancer; mBC=metastatic breast cancer; ddAC=doxorubicin 60 mg/m2 and cyclophosphamide 600 mg/m2 IV

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	▪ 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	First-line BRAF-WT metastatic or unresectable locally advanced melanoma	Previously untreated metastatic melanoma BRAF mutation-positive	BRAF-WT metastatic or unresectable locally advanced melanoma after immunotherapy
Phase/study	**Phase III IMspire150 TRILOGY**	**Phase III IMspire170**	**Phase I**	**Phase Ib**
# of patients	N=500	N=500	N=67	N=152
Design	Double-blind, randomized, placebo-controlled study ▪ **ARM A:** Tecentriq plus Cotellic plus Zelboraf[1] ▪ **ARM B:** Placebo plus Cotellic plus Zelboraf[1]	▪ **ARM A:** Cotellic plus Tecentriq ▪ **ARM B:** Pembrolizumab	▪ Dose-finding study of Cotellic plus Tecentriq plus Zelboraf[1] and Tecentriq plus Zelboraf[1] combinations	▪ Preliminary efficacy of Cotellic plus Tecentriq in patients who have progressed on prior aPD-1 therapy
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival and overall survival	▪ Safety and PK	▪ Objective response rate and disease control rate
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2018	▪ FPI Q4 2017 ▪ Recruitment completed Q4 2018 ▪ Study did not meet primary endpoint Q2 2019	▪ FPI Q4 2012 ▪ Data presented at ESMO 2016	▪ FPI Q2 2017 ▪ Recruitment completed Q4 2018
CT Identifier	NCT02908672	NCT03273153	NCT01656642	NCT03178851

In collaboration with Exelixis; [1]Zelboraf In collaboration with Plexxikon, a member of Daiichi Sankyo Group
ESMO=European Society for Medical Oncology

Tecentriq

Anti-PD-L1 cancer immunotherapy – hematology

Indication	1L FL and 1L DLBCL	Relapsed or refractory FL
Phase/study	**Phase I**	**Phase I**
# of patients	N=92	N=38
Design	▪ Tecentriq plus Gazyva plus bendamustine ▪ Tecentriq plus Rituxan plus CHOP	▪ Tecentriq plus Gazyva plus lenalidomide
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy
Status	▪ FPI Q4 2015	▪ FPI Q4 2015 ▪ Data presented at ASH 2018
CT Identifier	NCT02596971	NCT02631577

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma

Venclexta

Novel small molecule Bcl-2 selective inhibitor – CLL

Indication	Untreated CLL patients with coexisting medical conditions	Relapsed or refractory CLL
Phase/study	**Phase III CLL14**	**Phase III MURANO**
# of patients	N=432	N=391
Design	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Chlorambucil plus Gazyva	▪ **ARM A:** Venclexta plus Rituxan ▪ **ARM B:** Rituxan plus bendamustine
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival
Status	▪ Recruitment completed Q3 2016 ▪ 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 ▪ Approved US Q2 2019 ▪ Data presented at ASCO 2019 ▪ Data published in NEJM 2019; 380:2225-2236	▪ Recruitment completed Q3 2015 ▪ 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 ▪ Approved in US Q2 2018 (priority review) ▪ EU approval Q4 2018
CT Identifier	NCT02242942	NCT02005471

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – CLL

Indication	Relapsed or refractory CLL	Relapsed or refractory or previously untreated CLL
Phase/study	**Phase II**	**Phase Ib**
# of patients	N=120	N=90
Design	▪ Venclexta after ibrutinib therapy ▪ Venclexta after idelalisib therapy	▪ Venclexta in combination with Gazyva
Primary endpoint	▪ Overall response rate	▪ Safety and maximum tolerated dose
Status	▪ FPI Q3 2014 ▪ Data presented at ASH 2015 ▪ Updated data presented at ASCO 2016 ▪ Interim data published in *Lancet Oncology* 2018 Jan;19(1):65-75	▪ FPI Q1 2014 ▪ Data presented at ASH 2015 and ASH 2017 ▪ Data published in Blood 2019 April; 01-896290
CT Identifier	NCT02141282	NCT01685892

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – NHL

Indication	B cell NHL and front-line DLBCL
Phase/study	**Phase I/II** **CAVALLI**
# of patients	N=248
Design	Phase I (dose finding, patients with B cell NHL): ▪ **ARM A:** Venclexta plus R-CHOP ▪ **ARM B:** Venclexta plus G-CHOP Phase II (expansion, patients with 1L DLBCL): ▪ Venclexta plus R-CHOP
Primary endpoint	▪ Safety and efficacy
Status	▪ FPI Q2 2014 ▪ Data presented at ASCO 2016 and ASH 2016 and 2018 ▪ Data published in Blood-2018-11-880526
CT Identifier	NCT02055820

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

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; NHL=non-Hodgkin's lymphoma; CHOP=cyclophosphamide, doxorubicin, vincristine and prednisone; R=Rituxan/MabThera; G=Gazyva; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Venclexta

Novel small molecule Bcl-2 selective inhibitor – MM

Indication	Relapsed or refractory multiple myeloma	
Phase/study	**Phase III BELLINI**	**Phase III CANOVA**
# of patients	N=291	N=244
Design	▪ **ARM A:** Venclexta plus bortezomib plus dexamethasone ▪ **ARM B:** Placebo plus bortezomib plus dexamethasone	▪ Venclexta + dexamethazone vs pomalidomide + dexamethasone in t(11;14) positive r/r MM
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival
Status	▪ FPI Q3 2016 ▪ Recruitment completed Q4 2017 ▪ Study met its primary endpoint of PFS, however due to a safety imbalance in the experimental arm the study was placed on partial clinical hold ▪ Data presented at EHA 2019	▪ FPI Q4 2018
CT Identifier	NCT02755597	NCT03539744

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute; [1]Cotellic in collaboration with Exelixis
MM=multiple myeloma; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology

Venclexta

Novel small molecule Bcl-2 selective inhibitor – MM

Indication	Relapsed or refractory multiple myeloma	
Phase/study	**Phase I**	**Phase Ib**
# of patients	N=166	N=65
Design	▪ **Dose escalation cohort:** Venclexta dose escalation ▪ **Safety expansion cohort (t11:14):** Venclexta expansion ▪ **Combination:** Venclexta plus dexamethasone	▪ **ARM A:** Cotellic[1] ▪ **ARM B:** Cotellic[1] plus Venclexta ▪ **ARM C:** Cotellic[1] plus Venclexta plus Tecentriq
Primary endpoint	▪ Safety and maximum tolerated dose	▪ Safety and objective response rate
Status	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016 and ASH 2016 ▪ Study on partial clinical hold	▪ FPI Q4 2017 ▪ Study on partial clinical hold
CT Identifier	NCT01794520	NCT03312530

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute; [1]Cotellic in collaboration with Exelixis
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		Relapsed or refractory hematological malignancies
Phase/study	**Phase III Viale-A**	**Phase III Viale-C**	**Phase I**
# of patients	N=400	N=175	N=85
Design	▪ **ARM A:** Venclexta plus azacitidine ▪ **ARM B:** Azacitidine	▪ **ARM A:** Venclexta plus low-dose cytarabine ▪ **ARM B:** Low-dose cytarabine	▪ Venclexta plus AMG176 dose escalation ▪ Dose expansion phase to confirm safety and preliminary RPTD
Primary endpoint	▪ Overall survival and percentage of participants with complete remission	▪ Overall survival	▪ Maximum tolerated dose and safety
Status	▪ FPI Q1 2017	▪ FPI Q2 2017	▪ FPI Q2 2019
CT Identifier	NCT02993523	NCT03069352	NCT03797261

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
AML=acute myeloid leukemia RPTD =recommended phase II dose

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	▪ 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 Jul 2018 ▪ US accelerated approval Q4 2018	
CT Identifier	NCT02203773	NCT02287233

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute; [1]Cotellic in collaboration with Exelixis
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 AML not eligible for cytotoxic therapy
Phase/study	**Phase I**	**Phase Ib/II**
# of patients	N=52	N=140
Design	▪ Venclexta in combination with gilteritinib	Phase I (dose escalation): ▪ **ARM A:** Cotellic[1] plus Venclexta ▪ **ARM B:** Idasanutlin plus Venclexta Phase II (expansion): ▪ **ARM B:** Idasanutlin plus Venclexta
Primary endpoint	▪ Dose and composite complete remission (CRc) Rate	▪ Safety and efficacy
Status	▪ FPI Q4 2018	▪ FPI Q1 2016 ▪ Data presented at ASH 2017 ▪ Arm A closed Q2 2019
CT Identifier	NCT03625505	NCT02670044

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute; [1]Cotellic in collaboration with Exelixis
AML=acute myeloid leukemia; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

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=44
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
CT Identifier	NCT02966782	NCT02942290

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
MDS=myelodysplastic syndromes

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=224	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 ▪ Data presented at ASH 2016, ICML and EHA 2017 ▪ 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 ▪ Additional data presented at ASCO and EHA 2018 ▪ Filed in US and EU Q4 2018; US priority review granted Q1 2019 ▪ Approved in US Q2 2019	▪ 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; ICML=international Conference on Malignant Lymphoma; EHA=European Hematology Association; 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=116	N=116
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
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

Ocrevus

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 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	120-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 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 Jan 19;376(3):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 Jan 19;376(3):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

MabThera/Rituxan

Immunology development program

Indication	Moderate to severely active pemphigus vulgaris		Relapsing ANCA-associated vasculitis
Phase/study	**Phase III PEMPHIX**	**Phase III Ritux 3**	**Phase III MAINRITSAN**
# of patients	N=132	N=90	N=117
Design	▪ **ARM A:** Rituxan ▪ **ARM B:** Mycophenolate mofetil	▪ **ARM A:** Rituxan ▪ **ARM B:** General corticotherapy	▪ **ARM A:** Rituxan ▪ **ARM B:** Azathioprine
Primary endpoint	▪ Proportion of patients who achieve sustained complete remission	▪ Number of patients with pemphigus controlled 24 months after the start of Rituxan treatment and with both cutaneous and mucosal lesions healing after 6 months of Rituxan treatment	▪ Number of major relapses at the end of the maintenance treatment (18 months + 10 months follow-up)
Status	▪ FPI Q2 2015 ▪ Breakthrough Therapy Designation granted by FDA in Q1 2017 ▪ Recruitment completed Q4 2017 ▪ Study met primary endpoint Q2 2019	▪ FPI Q3 2009 ▪ Data published in *Lancet* 2017 May 20;389(10083):2031–2040	▪ FPI Q4 2008 ▪ Data published in *NEJM* 2014;371(19):1771–80 ▪ US and EU approval Q4 2018
	▪ Approved in US Q2 2018 and in EU Q1 2019 based on Roche-supported randomized controlled IST Ritux 3		
CT Identifier	NCT02383589	NCT00784589	NCT00748644

IST=Investigator sponsored trial; ANCA=Antineutrophil cytoplasmic antibodies

Gazyva (obinutuzumab)

Immunology development program

Indication	Lupus nephritis
Phase/study	**Phase II** **NOBILITY**
# of patients	N=120
Design	▪ **ARM A:** Obinutuzumab 1000mg IV plus mycophenolate mofetil / mycophenolic acid ▪ **ARM B:** Placebo IV plus mycophenolate mofetil / mycophenolic acid
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q4 2017 ▪ Primary endpoint met Q2 2019
CT Identifier	NCT02550652

In collaboration with Biogen

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**
# of patients	N=138	N=127	N=225
Design	Placebo-controlled study of Xolair in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had an inadequate response to standard-of-care treatments: ▪ **ARM A:** Xolair every 2 weeks or every 4 weeks ▪ **ARM B:** Placebo	Placebo-controlled study of Xolair in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had an inadequate response to standard-of-care treatments: ▪ **ARM A:** Xolair every 2 weeks or every 4 weeks ▪ **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 ▪ Study met co-primary end points Q2 2019	▪ FPI Q4 2017 ▪ Recruitment completed Q3 2018 ▪ Study met co-primary end points Q2 2019	▪ FPI expected Q3 2019
CT Identifier	NCT03280550	NCT03280537	NCT03881696

In collaboration with Novartis

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 (time to alleviation of symptoms versus placebo) ▪ Filed in US Q2 2018 (priority review), US approval Q4 2018 ▪ Data published in NEJM 2018; 379:913-923	▪ FPI Q1 2017, recruitment completed Q1 2018 ▪ Primary endpoint met Q3 2018 (time to improvement of influenza symptoms versus placebo) ▪ Data presented at IDweek 2018 ▪ Filed in US Q1 2019
CT Identifier	NCT02954354	NCT02949011

NEJM=New England Journal of Medicine
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** **FLAGSTONE (hospitalised patients)**	**Phase III** **miniSTONE 1 (0-1 year old)**	**Phase III** **miniSTONE 2 (1-12 years old)**
# of patients	N=240	N=30	N=120
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	▪ FPI Q1 2019	▪ FPI Q4 2018 ▪ Recruitment completed Q1 2019 ▪ Primary endpoint met Q2 2019
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 IIIb** **CENTERSTONE**
# of patients	N= 3,160
Design	Reduction of direct transmission of influenza from otherwise healthy patients to household contacts
Primary endpoint	Percentage of household contacts who are PCR-positive for influenza by day 5 post randomization of index patients
Status	▪ FPI expected Q3 2019
CT Identifier	NCT03969212

In collaboration with Shionogi & Co., Ltd.
PCR=Polymerase chain reaction

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group HY 2019 results

Diagnostics

Foreign exchange rate information

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 December 2018 and EU January 2019		
CT Identifier	NCT02568267	NCT02568267	NCT02650401

WCLC=World Congress on Lung Cancer; ESMO=European Society for Medical Oncology; NTRK=neurotrophic receptor tyrosine kinase; PRIME= priority medicines

Idasanutlin (RG7388)

Small molecule MDM2 antagonist

Indication	Relapsed/refractory AML	Polycythemia vera	1L AML
Phase/study	**Phase III MIRROS**	**Phase II**	**Phase Ib/II**
# of patients	N=440	N=20	N=80
Design	▪ **ARM A:** Idasanutlin plus cytarabine ▪ **ARM B:** Placebo plus cytarabine	Single-arm study of idasanutlin monotherapy in participants with hydroxyurea (HU)-resistant/intolerant Polycythemia vera (PV)	Idasanutlin plus cytarabine and daunorubicin
Primary endpoint	▪ Overall survival	▪ Composite response at week 32 for participants with splenomegaly at baseline ▪ Hematocrit (Hct) control without phlebotomy at week 32 for participants without splenomegaly at baseline	▪ Safety, PK/PD, efficacy
Status	▪ FPI Q4 2015	▪ FPI Q1 2018	▪ FPI Q1 2019
CT Identifier	NCT02545283	NCT03287245	NCT03850535

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L castration-resistant prostate cancer	2L castration-resistant prostate cancer	Advanced prostate cancer and solid tumors
Phase/study	**Phase III** **IPATential150**	**Phase II** **A.MARTIN**	**Phase Ib**
# of patients	N=1,100	N=262	N=54
Design	▪ **ARM A:** Ipatasertib plus abiraterone ▪ **ARM B:** Placebo plus abiraterone	▪ **ARM A:** Ipatasertib 400 mg plus abiraterone ▪ **ARM B:** Ipatasertib 200 mg plus abiraterone ▪ **ARM C:** 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	▪ Progression-free survival	▪ Progression-free survival	▪ Safety and efficacy
Status	▪ FPI Q2 2017 ▪ Recruitment completed Jan 2018	▪ Recruitment completed Q4 2014 ▪ ITT data presented at ASCO 2016 ▪ Biomarker data at ESMO 2016	▪ FPI Q2 2019
CT Identifier	NCT03072238	NCT01485861	NCT03840200

In collaboration with Array BioPharma

ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; mFOLFOX6=modified FOLFOX (folinic acid, fluorouracil, oxaliplatin)

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	**1L metastatic gastric or gastroesophageal junction adenocarcinoma**
Phase/study	**Phase II** **JAGUAR**
# of patients	N=153
Design	▪ **ARM A:** Ipatasertib plus mFOLFOX6 ▪ **ARM B:** Placebo plus mFOLFOX6
Primary endpoint	▪ Progression-free survival
Status	▪ Recruitment completed Q4 2014 ▪ Data showed no benefit in treated vs control group Q2 2016 ▪ Data published in Eur J Cancer. 2019 Feb;108:17-24
CT Identifier	NCT01896531

In collaboration with Array BioPharma

ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; mFOLFOX6=modified FOLFOX (folinic acid, fluorouracil, oxaliplatin)

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L TNBC and HR+ breast cancer	1L TNBC	Neoadjuvant TNBC	TNBC
Phase/study	**Phase III IPATunity130**	**Phase II LOTUS**	**Phase II FAIRLANE**	**Phase Ib**
# of patients	N=450	N=120	N=150	N=114
Design	Cohort 1: Dx+ 1L TNBC (N=249) ▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel Cohort 2: Dx+ HR+ mBC (N=201) ▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel	▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel	▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel	▪ **ARM A:** Ipatasertib plus Tecentriq plus paclitaxel ▪ **ARM B:** Ipatasertib plus Tecentriq plus nab-paclitaxel
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Pathologic complete response (pCR)	▪ Safety and efficacy
Status	▪ FPI Q1 2018	▪ 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 2015 ▪ Recruitment completed Q2 2017 ▪ Data presented at AACR 2018 ▪ Data published in Ann Oncol. 2019 May 30. pii: mdz177	▪ FPI Q1 2018 ▪ Data presented at AACR 2019
CT Identifier	NCT03337724	NCT02162719	NCT02301988	NCT03800836

In collaboration with Array BioPharma

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

Balovaptan (RG7314)

Small molecule antagonist of the V1A vasopressin receptor

Indication	Autism Spectrum Disorder		
Phase/study	**Phase II VANILLA**	**Phase II aV1ation**	**Phase III V1aduct**
# of patients	N=223	N=340	N=350
Design	▪ Multi-center, randomized, double-blind, placebo-controlled proof-of-concept study in adult males with ASD	▪ Multi-center, randomized, double-blind, placebo-controlled proof-of-concept study in pediatrics (5-17 yrs) with ASD	Study in Adults (≥18 ys) with ASD with a 2-year open-label extension: ▪ **ARM A:** Balovaptan 10mg/day ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ Change from baseline at week 24 on the Vineland Adaptive Behavior Scales (Vineland-II) two-domain composite (2DC) score
Status	▪ FPI Q3 2013 ▪ Data presented at IMFAR 2017 ▪ Breakthrough Therapy Designation granted by FDA Q1 2018 ▪ Published in Science Translational Medicine 2019 May 8;11(491). pii: eaat7838	▪ FPI Q4 2016	▪ FPI Q3 2018
CT Identifier	NCT01793441	NCT02901431	NCT03504917

ASD=Autism spectrum disorder; IMFAR=International Meeting For Autism Research

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:** 100 carriers receive crenezumab SC ▪ **ARM B:** 100 carriers receive placebo ▪ **ARM C:** 100 non-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; 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

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=760	N=760
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 2 years	▪ Change in CDR-SOB at 2 years
Status	▪ FPI Q2 2018	▪ FPI Q3 2018
CT Identifier	NCT03443973	NCT03444870

In collaboration with MorphoSys AG

Aβ=amyloid-beta; CDR-SB=Clinical Dementia Rating, 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-SB at 2 years ▪ Sub-study: change in brain amyloid by PET at 2 years	▪ Change in ADAS-Cog and CDR-SB 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-SB=Clinical Dementia Rating, Sum of Boxes; 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

RG6206

Myostatin-inhibiting adnectin fusion protein

Indication	Duchenne muscular dystrophy	
Phase/study	**Phase I/II THUNDERJET**	**Phase II/III SPITFIRE**
# of patients	N=43	N=159
Design	▪ Randomized, double-blind, placebo-controlled, multiple ascending dose study in ambulatory boys with Duchenne muscular dystrophy	Randomized, double blind, placebo-controlled study in ambulatory boys age 6-11 years with Duchenne muscular dystrophy ▪ **ARM A:** RG6206 low dose ▪ **ARM B:** RG6206 high dose ▪ **ARM C:** Placebo
Primary endpoint	▪ Safety	▪ Change from baseline in NSAA total score after 48 weeks
Status	▪ FPI Q4 2015 ▪ 24 week data presented at BPNA and AAN 2018 ▪ 72 week data presented at AAN 2019	▪ FPI Q3 2017 ▪ Recruitment completed July 2019
CT Identifier	NCT02515669	NCT03039686

BPNA=British Paediatric Neurology Asscoiation; AAN=American Academy of Neurology

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=180
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	▪ FPI Q4 2016, FPI Part 2 Q1 2018 ▪ Recruitment completed for part 2 Q4 2018 ▪ One year data from Part 1 presented at AAN, CureSMA and EAN 2019	▪ FPI Q4 2016, FPI Part 2 Q4 2017 ▪ Recruitment completed for part 2 Q3 2018 ▪ One year data from Part 1 presented at AAN, CureSMA and EAN 2019	▪ FPI Q1 2017 ▪ Data presented at WMS 2017, AAN 2018, WMS 2018 and CureSMA 2019
	Orphan drug designation granted by FDA Q1 2017 and EU Jan 2019, PRIME designation in Q4 2018		
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 expected Q3 2019
CT Identifier	NCT03779334

In collaboration with PTC Therapeutics and SMA Foundation
AAN=American Academy of Neurology; WMS=World Muscle Society

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 1 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
CT Identifier	NCT02519036	NCT03342053

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

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=660	N=950
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	▪ FPI April 2019
CT Identifier	NCT03761849	NCT03842969

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

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 120mcg FSC monthly; ▪ Group B: Placebo SC monthly	Add-on therapy of satralizumab; ▪ Group A: Satralizumab 120mcg 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	▪ FPI Q3 2017 ▪ Primary endpoint met Q3 2018 ▪ Data presented at ECTRIMS 2018 and AAN 2019
	▪ BTD granted Q4 2018	
CT Identifier	NCT02073279	NCT02028884

*Trials managed by Chugai (Roche opted-in)

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=350	N=350	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 inflixumab 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	▪ FPI Q4 2014	▪ 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=350	N=609	N=2,625
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**	**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=49
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
CT Identifier	NCT03157635

In collaboration with Chugai

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 Mar 21. pii: S0161-6420(18)33358-X
CT Identifier	NCT02484690	NCT03038880	NCT02699450

BCVA=best corrected visual acuity; SoC=standard of care

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/PRN ▪ **ARM C:** Aflibercept, q8w	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab (RG7716) q8w/PRN ▪ **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	▪ FPI Oct 2018
CT Identifier	NCT03622580	NCT03622593

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	▪ FPI Q1 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		
Phase/study	**Phase II LADDER**	**Phase III Archway**	**Phase II+III extension Portal**
# of patients	N=220	N=360	N=500
Design	▪ Four-arm study: Lucentis monthly intravitreal control vs three ranibizumab formulations delivered via implant	▪ **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)
Primary endpoint	▪ Time to first refill	▪ Change in BCVA from baseline at the average of week 36 and week 40	▪ Safety
Status	▪ FPI Q3 2015 ▪ Recruitment completed Q3 2017 ▪ Positive primary data presented at ASRS 2018 ▪ Data Published in Ophthalmology. 2019 Apr 1. pii: S0161-6420(18)33328-1	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2019	▪ FPI Q3 2018
CT Identifier	NCT02510794	NCT03677934	NCT03683251

In collaboration with Forsight and Novartis
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)

Roche Group HY 2019 results

Diagnostics

Foreign exchange rate information

Oncology development programs

Small molecules

Molecule	BET inhibitor (RG6146, TEN-010)		
Indication	**Multiple myeloma**	**Relapsed/refractory DLBCL**	**Advanced ovarian cancer and triple negative breast cancer**
Phase/study	**Phase Ib**	**Phase Ib**	**Phase Ib**
# of patients	N=86	N=94	N=30-90
Design	Dose escalation and cohort expansion study: ▪ **Part 1:** RG6146 monotherapy ▪ **Part 2:** RG6146 in combination with daratumumab	▪ Dose escalation and cohort expansion study of the doublet or triplet combination with RG6146 plus Venclexta[1] ± Rituxan	▪ Dose escalation and expansion study of RG6146 plus Tecentriq
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ Safety and efficacy
Status	▪ FPI Part 1 Q2 2017	▪ FPI Q3 2017	▪ FPI Q4 2017
CT Identifier	NCT03068351	NCT03255096	NCT03292172

[1]Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
MM=multiple myeloma; DLBCL=diffuse large B cell lymphoma

Oncology development programs

Monoclonal antibodies

Molecule	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

Oncology development programs

Monoclonal antibodies

Molecule	FAP-IL2v FP (RG7461)	
Indication	**1L Renal call carcinoma**	**1L/2L Melanoma**
Phase/study	**Phase Ib**	**Phase Ib**
# of patients	N=110	N=40
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	NCT03386721

Oncology development programs

Monoclonal antibodies

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≈286	N=410	N=46
Design	▪ **Part I:** Dose escalation of RG7802 ▪ **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; CEACAM5=carcinoembryonic antigen related cell adhesion molecule 5

Oncology development programs

Monoclonal antibodies

Molecule	CD20 x CD3 (RG6026)		
Indication	**Relapsed or refractory B cell non-Hodgkin's lymphoma**		**Non-Hodgkin's lymphoma**
Phase/study	**Phase I**	**Phase Ib**	**Phase Ib**
# of patients	N=260	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:** RG6026 + Gazyva (i.e. continuous treatment with Gazyva	▪ Dose escalation and expansion of RG6026 plus Tecentriq	▪ **Part I:** Dose-finding for the combination of RG6026 plus G/R CHOP in r/r indolent NHL ▪ **Part II:** Dose expansion RG6026 plus G/R-CHOP or R-CHOP in 1L DLBCL
Primary endpoint	▪ Safety	▪ Safety	▪ Safety
Status	▪ FPI Q1 2017 ▪ Data presented at ASH 2018 and ICML 2019	▪ FPI Q2 2018	▪ FPI Q1 2018
CT Identifier	NCT03075696	NCT03533283	NCT03467373

DLBCL=diffuse large B cell lymphoma; FL=Follicular lymphoma

Oncology development programs

Monoclonal antibodies

Molecule	**selicrelumab** (CD40 MAb, RG7876)
Indication	**Solid tumors**
Phase/study	**Phase Ib**
# of patients	N=170
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
Primary endpoint	▪ Safety, PD and efficacy
Status	▪ FPI Q1 2016 ▪ Part II FPI Q2 2018 ▪ Selicrelumab + vanucizumab arm is no longer recruiting patients
CT Identifier	NCT02665416

CRC=colorectal cancer; 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

Monoclonal antibodies

Molecule	NME (RG6123)	FAP-4-1BBL FP (RG7827)	PD1-TIM3 (RG7769)
Indication	**Solid tumors**	**Solid tumors**	**advanced and metastatic solid tumors**
Phase/study	**Phase I**	**Phase I**	**Phase Ia/b**
# of patients	N=125	N=200	N=280
Design	▪ Dose escalation of single agent RG6123	▪ **Part 1:** Single agent dose escalation ▪ **Part 2:** Combo dose escalation with Tecentriq ▪ **Part 3:** Combo expansion with Tecentriq	▪ **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)
Primary endpoint	▪ Safety, efficacy, PK and PD	▪ Safety, efficacy, PK and PD	▪ Safety, PD and efficacy
Status	▪ FPI Jul 2018	▪ FPI Q2 2018	▪ FPI Q4 2018
CT Identifier	NCT03539484		NCT03708328

ASCO=American Society of Clinical Oncology; ECC=European Cancer Congress; ESMO=European Society for Medical Oncology; FP=antibody fusion protein

Neuroscience development programs

Molecule	**basmisanil** (GABRA5 NAM, RG1662)
Indication	**Cognitive impairment associated with schizophrenia**
Phase/study	**Phase II**
# of patients	N=180
Design	For 24 weeks patients will receive: ▪ **ARM A:** RG1662 80mg twice daily ▪ **ARM B:** RG1662 240mg twice daily ▪ **ARM C:** Placebo
Primary endpoint	▪ Efficacy (cognitive function), PK, safety and tolerability
Status	▪ FPI Q4 2016 ▪ Recruitment completed Q2 2019
CT Identifier	NCT02953639

NAM= negative allosteric modulator

Neuroscience development programs

Molecule	NME (RG7906)	
Indication	**Schizophrenia**	
Phase/study	**Phase II**	**Phase II**
# of patients	N=36	N=500
Design	▪ Randomized, double-blind, placebo-controlled, crossover study for two weeks in patients.	▪ **Part 1:** Monotherapy, one dose, qd, 12 weeks (N=125) ▪ **Part B:** Add-on therapy, two dose levels, qd, 12 weeks (N=375)
Primary endpoint	▪ Effects on dopamine synthesis capacity	▪ Effects on negative symptoms (Brief Negative Symptoms Scale, BNSS)
Status	▪ FPI Q4 2018	▪ FPI Q4 2018
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 plus a 52-week blinded extension)	▪ 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	▪ FPI Q2 2017 ▪ Recruitment completed Q4 2018 ▪ Ph1 data published online in *JAMA Neurol.* 2018 Jun 18	▪ 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

Infectious diseases development programs

Chronic hepatitis B

Molecule	TLR7 agonist (3) (RG7854)	HBV LNA (RG6004)
Indication	Chronic hepatitis B	Chronic hepatitis B
Phase/study	Phase I	Phase I
# of patients	N=140	N=160
Design	▪ Healthy volunteer and chronic hepatitis B patient study	▪ Healthy volunteer and chronic hepatitis B patient study
Primary endpoint	▪ Safety, PK and PD	▪ Safety, PK and PD
Status	▪ FPI Q4 2016 ▪ Data presented at APASL 2019	▪ FPI Q1 2017
CT Identifier	NCT02956850	NCT03038113

LNA=locked nucleic acid

Infectious diseases development programs

Chronic hepatitis B

Molecule	CpAM (RG7907)	NME (RG6217)	NME (RG6084)
Indication	**Chronic hepatitis B**	**Chronic hepatitis B**	**Chronic hepatitis B**
Phase/study	**Phase I**	**Phase I**	**Phase I**
# of patients	N=128	N=75	N=27
Design	▪ **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	▪ Healthy volunteer and chronic hepatitis B patient study	▪ Chronic hepatitis B patient study
Primary endpoint	▪ Safety, PK and PD and efficacy	▪ Safety	▪ Safety
Status	▪ FPI Q4 2016 ▪ Data presented at EASL 2018 and 2019	▪ FPI Q4 2018	▪ FPI Q1 2019
CT Identifier	NCT02952924	NCT03762681	

LNA=locked nucleic acid

Immunology development programs

Molecule	petesicatib (CAT-S inh, RG7625)	IgG-IL2 FP (RG7835)	
Indication	**Psoriasis**	**Autoimmune diseases**	**Ulcerative Colitis**
Phase/study	**Phase II**	**Phase I**	**Phase 1b**
# of patients	N=30	N=56	N=50
Design	▪ An open label phase 2a trial assessing the clinical efficacy and safety of RO5459072 in moderate to severe psoriasis	▪ A randomized, adaptive, investigator/subject blind, single ascending dose, placebo-controlled study of subcutaneously administered RG7835 in healthy volunteers	▪ A multicenter, randomized, double-blind, placebo controlled study to investigate the subcutaneously administered RG7835 in participants with active ulcerative colitis
Primary endpoint	▪ Proportion of patients achieving a PASI75 response after twelve weeks	▪ Safety, PK and PD	▪ Safety, tolerability, PK/PD, efficacy
Status	▪ FPI Q4 2018	▪ FPI Q3 2017 ▪ Recruitment completed Q3 2018	▪ FPI Q2 2019
CT Identifier		NCT03221179	NCT03943550

PASI75=A 75% reduction in the Psoriasis Area and Severity Index

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group HY 2019 results

Diagnostics

Foreign exchange rate information

Oncology development programs

Monoclonal 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	▪ FPI Q1 2019	▪ FPI Q3 2018	▪ FPI Q2 2019
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)

Oncology development programs

Monoclonal antibodies

Molecule	tiragolumab (anti-TIGIT, RG6058, MTIG7192A)	
Indication	**Solid tumors**	**NSCLC**
Phase/study	**Phase I**	**Phase II CITYSCAPE**
# of patients	N=300	N=135
Design	▪ **Phase Ia:** Dose escalation and expansion of tiragolumab ▪ **Phase Ib:** Dose escalation and expansion Tecentriq plus tiragolumab	▪ **Arm A:** Tecentriq plus tiragolumab ▪ **Arm B:** Tecentriq monotherapy
Primary endpoint	▪ Safety, tolerability, PK variability and preliminary efficacy	▪ Overall response rate and progression-free survival
Status	▪ FPI Q2 2016	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2019
CT Identifier	NCT02794571	NCT03563716

NSCLC=Non-small cell lung cancer

Oncology development programs

Monoclonal antibodies

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

Oncology development programs

Antibody–drug conjugates

Molecule	NME (RG6109)	HER2-TDC (RG6148)
Indication	**AML**	**HER2+ breast cancer**
Phase/study	**Phase I**	**Phase I**
# of patients	N=110	N=55
Design	Dose escalation and expansion study: ▪ **ARM A:** RG6109 monotherapy in r/r AML ▪ **ARM B:** RG6109 + azacitidine in 1L AML patients not eligible for intensive induction chemotherapy	▪ Dose escalation and expansion study
Primary endpoint	▪ Safety and PK	▪ Safety and PK
Status	▪ FPI Q4 2017	▪ FPI Q2 2018
CT Identifier	NCT03298516	NCT03451162

AML=acute myeloid leukemia; r/r=relapsed/refractory

Oncology development programs

Small molecules

Molecule	SERD (3) (RG6171, GDC-9545)	PI3K inhibitor (RG6114, GDC-0077)
Indication	**Metastatic ER+ HER2- breast cancer**	**PIK3CA mutant solid tumors and metastatic ER+ HER2- breast cancer**
Phase/study	**Phase I**	**Phase I**
# of patients	N=130	N=156
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	Monotherapy and in combination with SoC (letrozole; letrozole plus palbociclib; fulvestrant) ▪ **Stage 1:** Dose escalation ▪ **Stage 2:** Expansion
Primary endpoint	▪ Safety	▪ Safety, tolerability and PK
Status	▪ FPI Q4 2017	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017
CT Identifier	NCT03332797	NCT03006172

AACR=American Association for Cancer Research; SoC=standard of care

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	▪ FPI Q1 2019
CT Identifier	NCT03289962	NCT03815058
Collaborator	BioNTech	

Neuroscience development programs

gRED Genentech Research & Early Development

Molecule	DLK inhibitor (RG6000, GDC-0134)	Anti-Tau (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=360	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-SB 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-SB=Clinical Dementia Rating, 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)		
Indication	**Inflammatory diseases**	**Diabetic foot ulcer**	**Inflammatory bowel disease**
Phase/study	**Phase Ib**	**Phase Ib**	**Phase II**
# of patients	N=90	N=72	N=270
Design	▪ Multiple ascending dose study with healthy volunteer and patient cohorts	▪ Multiple ascending dose study in patients with neuropathic diabetic foot ulcers that do not respond adequately to standard wound care	IL-22 Fc 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
Primary endpoint	▪ Safety and tolerability	▪ Safety and tolerability	▪ Percentage of participants with clinical remission at week 8
Status	▪ FPI Q2 2016	▪ FPI Q4 2016 ▪ Recruitment completed Q2 2018	▪ FPI Q4 2018
CT Identifier	NCT02749630	NCT02833389	NCT03558152

UC=Ulcerative Colitis

Immunology development programs

gRED Genentech Research & Early Development

Molecule	NME (RG6151, GDC-0214)	NME (RG6244, GDC-4379)	NME (RG6173, MTPS9579A)	ST2 MAb (RG6149, AMG 282, MSTT1041A)
Indication	**Asthma**			
Phase/study	**Phase I**	**Phase I**	**Phase I**	**Phase IIb ZENYATTA**
# of patients	N=84	N=84	N=70	N=515
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	▪ Single and multiple ascending dose study of MTPS9579A in healthy adult subjects	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 biomarker for target engagement (FeNO reduction)	▪ Safety, tolerability and biomarker for target engagement (FeNO reduction)	▪ Safety, tolerability and PK	▪ Percentage of participants with asthma exacerbations
Status	▪ FPI Q4 2017 ▪ Recruitment completed Q1 2018	▪ FPI Q2 2019	▪ FPI Q1 2018	▪ FPI Q3 2016 ▪ Recruitment completed Apr 2018
CT Identifier	ACTRN12617001227381p	ACTRN12619000227190p		NCT02918019
Collaborator				Amgen

FeNO=Fractional exhaled nitric oxide

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	▪ FPI Q4 2016 ▪ Recruitment completed Q2 2018
CT Identifier	NCT02833350	NCT02983227

MTX=methotrexate

Immunology development programs

gRED Genentech Research & Early Development

Molecule	**fenebrutinib** (BTKi, RG7845, GDC-0853)	
Indication	**Moderate to severe active systemic lupus erythematosus**	
Phase/study	**Phase II ATHOS**	**Phase II Open-label extension**
# of patients	N=240	N=240
Design	Randomized, double-blind, placebo-controlled study in active systemic lupus erythematosus patients ▪ **ARM A:** Fenebrutinib (high dose) ▪ **ARM B:** Fenebrutinib (low dose) ▪ **ARM C:** Placebo	▪ Open-Label extension study of patients previously enrolled in study GA30044 to evaluate the long-term safety and efficacy of fenebrutinib
Primary endpoint	▪ Systemic Lupus Erythematosus Responder Index (SRI)-4 response at week 48	▪ Safety
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2018	▪ FPI Q1 2018
CT Identifier	NCT02908100	NCT03407482

Immunology development programs

Molecule	**fenebrutinib** (BTKi, RG7845, GDC-0853)	
Indication	**Chronic spontaneous urticaria**	
Phase/study	**Phase II** **SHASTA**	**Phase II** **Open-label extension**
# of patients	Cohort 1: N=41 Cohort 2: N=120	TBD
Design	Randomized, double-blind, placebo-controlled study in patients with CSU refractory to H1 anti-histamines *Cohort 1:* ▪ **ARM A:** Fenebrutinib ▪ **ARM B:** Placebo *Cohort 2:* ▪ **ARM A:** Fenebrutinib high dose ▪ **ARM B:** Fenebrutinib mid dose ▪ **ARM C:** Fenebrutinib low dose ▪ **ARM D:** Placebo	▪ A study to evaluate the long-term Safety and efficacy of fenebrutinib in participants previously enrolled in a fenebrutinib chronic spontaneous urticaria (CSU) study
Primary endpoint	▪ Change from baseline in the Urticaria Activity Score over 7 days (UAS7) at day 57	▪ Safety
Status	▪ FPI Q2 2017	▪ FPI Q4 2018
CT Identifier	NCT03137069	NCT03693625

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
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/KLB MAb (RG7992)	
Indication	**Metabolic diseases**	
Phase/study	**Phase Ia**	**Phase Ib**
# of patients	N=79	N=140
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
Primary endpoint	▪ Safety and tolerability	▪ Safety, tolerability and PK
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q1 2017	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2019
CT Identifier	NCT02593331	NCT03060538

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)

Roche Group HY 2019 results

Diagnostics

Foreign exchange rate information

Geographical sales split by divisions and Group*

CHFm	HY 2018	HY 2019	% change CER
Pharmaceuticals Division	**21,847**	**24,194**	**+10**
United States	11,378	13,370	**+14**
Europe	4,528	4,221	**-4**
Japan	1,781	1,988	**+9**
International	4,160	4,615	**+17**
Diagnostics Division	**6,264**	**6,275**	**+2**
United States	1,400	1,443	**0**
Europe	2,057	2,000	**+1**
Japan	216	226	**+2**
International	2,591	2,606	**+5**
Group	**28,111**	**30,469**	**+9**
United States	12,778	14,813	**+12**
Europe	6,585	6,221	**-2**
Japan	1,997	2,214	**+8**
International	6,751	7,221	**+12**

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

Pharma Division sales HY 2019

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Avastin	3,659	7	1,630	9	920	2	424	3	685	13
MabThera	3,339	-4	2,281	4	323	-36	58	-46	677	2
Herceptin	3,264	-9	1,509	-2	568	-45	123	-2	1,064	21
Perjeta	1,755	34	788	22	541	28	120	87	306	77
Ocrevus	1,735	63	1,456	50	211	179	-	-	68	204
Actemra / RoActemra	1,135	8	460	8	355	6	188	12	132	13
Xolair	972	1	972	1	-	-	-	-	-	-
Lucentis	928	10	928	10	-	-	-	-	-	-
Tecentriq	782	141	508	124	134	129	75	386	65	173
TNKase / Activase	686	2	661	2	-	-	-	-	25	-2
Kadcyla	636	33	278	51	204	14	40	11	114	48
Hemlibra	535	*	381	*	63	*	82	*	9	-
Esbriet	532	11	374	8	128	16	-	-	30	44
Alecensa	421	50	149	9	96	167	105	19	71	220
Pulmozyme	371	3	253	3	68	6	-	40	50	2
CellCept	325	-1	43	-23	87	0	42	7	153	6
Mircera	282	13	-	-	34	-9	100	3	148	28
Gazyva	241	36	110	14	80	31	21	-	30	59
Tamiflu	227	-29	31	-82	41	92	72	-6	83	46
Xeloda	216	1	15	-18	8	-7	43	-23	150	14

* over 500%; CER=Constant Exchange Rates (avg full year 2018)

Pharma Division sales HY 2019

New products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Erivedge	127	1	84	7	29	-20	-	-	14	22
Perjeta	1,755	34	788	22	541	28	120	87	306	77
Kadcyla	636	33	278	51	204	14	40	11	114	48
Gazyva	241	36	110	14	80	31	21	-	30	59
Esbriet	532	11	374	8	128	16	-	-	30	44
Cotellic	30	-4	6	-33	17	-3	-	-	7	46
Alecensa	421	50	149	9	96	167	105	19	71	220
Tecentriq	782	141	508	124	134	129	75	386	65	173
Ocrevus	1,735	63	1,456	50	211	179	-	-	68	204
Hemlibra	535	*	381	*	63	*	82	*	9	-
Xofluza	6	-	6	-	-	-	-	-	-	-
Polivy	2	-	2	-	-	-	-	-	-	-
Total	**6,802**	**57**	**4,142**	**51**	**1,503**	**50**	**443**	**113**	**714**	**90**

* over 500%; CER=Constant Exchange Rates (avg full year 2018)

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q1/18	Q2/18	Q3/18	Q4/18	Q1/19	Q2/19
Avastin	-2	1	6	5	9	6
MabThera	-8	-11	-7	-6	-3	-5
Herceptin	2	2	1	-3	-6	-12
Perjeta	18	28	27	35	41	29
Ocrevus	-	195	104	83	67	59
Actemra / RoActemra	13	13	9	14	6	10
Xolair	7	14	9	12	1	2
Lucentis	6	27	2	47	11	9
Tecentriq	29	44	71	89	135	146
TNKase / Activase	8	10	1	4	7	-3
Kadcyla	6	11	8	7	24	42
Hemlibra	-	-	-	*	*	*
Esbriet	13	15	21	26	10	13
Alecensa	81	98	62	69	61	41
Pulmozyme	0	6	1	3	6	0
CellCept	-8	-4	4	-9	4	-4
Mircera	5	4	16	-4	16	10
Gazyva	27	38	51	44	35	38
Tamiflu	11	-75	-63	-67	-40	110
Xeloda	-2	-11	-2	-8	5	-2

* over 500%; [1] Q1-Q4/18 vs Q1-Q4/17; Q1-Q2/19 vs. Q1-Q2/18; CER=Constant Exchange Rates (avg full year 2018);

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Avastin	5	3	12	7	-1	1	1	3	2	2	2	4	21	15	16	10
MabThera	5	7	9	-1	-49	-46	-38	-35	-40	-54	-50	-42	18	12	-4	8
Herceptin	11	0	3	-8	-21	-34	-44	-47	-19	-17	-9	6	13	32	26	17
Perjeta	34	38	36	9	15	25	27	28	12	35	74	99	42	46	83	73
Ocrevus	82	59	54	46	*	*	232	149	-	-	-	-	*	459	261	173
Actemra / RoActemra	8	17	5	11	11	8	4	8	16	13	13	11	-4	24	10	15
Xolair	9	12	1	2	-	-	-	-	-	-	-	-	-	-	-	-
Lucentis	2	47	11	9	-	-	-	-	-	-	-	-	-	-	-	-
Tecentriq	-4	21	91	158	*	286	158	112	-	-	-	169	*	458	262	127
TNKase / Activase	1	4	7	-4	-	-	-	-	-	-	-	-	-1	3	-10	6
Kadcyla	6	1	39	62	7	9	9	18	8	3	12	11	13	14	32	62
Hemlibra	-	*	*	*	-	*	450	*	-	-	-	*	-	-	-	-
Esbriet	21	33	7	9	15	14	14	18	-	-	-	-	40	-5	37	49
Alecensa	56	44	14	5	137	217	182	154	26	20	24	16	289	343	278	177
Pulmozyme	2	4	6	-1	8	8	8	3	32	26	43	38	-11	-8	4	0
CellCept	16	-24	-20	-25	-1	0	2	-2	0	-4	8	7	4	-11	13	-1
Mircera	-	-	-	-	-7	-8	-11	-7	-4	-4	3	4	44	-3	35	21
Gazyva	24	25	22	8	79	52	31	31	-	-	-	-	58	24	31	101
Tamiflu	-86	-100	-86	*	-33	-77	38	*	-77	-73	-6	153	-4	11	55	30
Xeloda	50	183	10	-41	-52	-27	-13	0	5	1	-14	-30	-3	-17	13	15

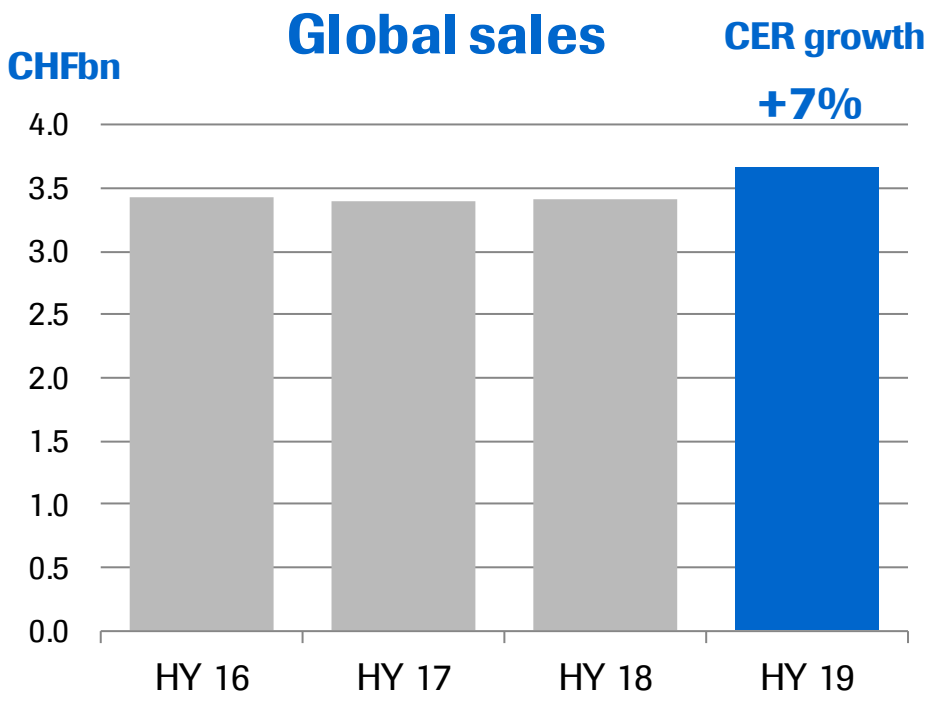
* over 500%; [1] Q3-Q4/18 vs Q3-Q4/17; Q1-Q2/19 vs. Q1-Q2/18; CER=Constant Exchange Rates (avg full year 2018);

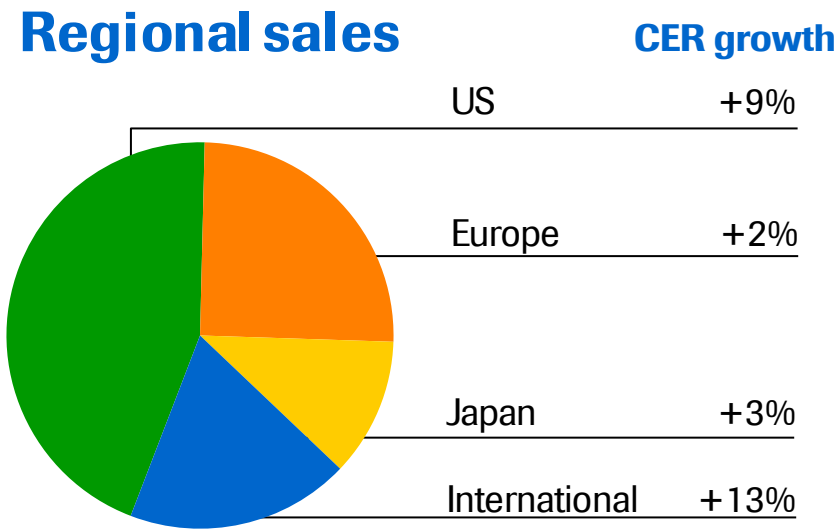
CER sales growth (%)
Quarterly development

	2018 vs. 2017				2019 vs. 2018	
	Q1	Q2	Q3	Q4	Q1	Q2
Pharmaceuticals Division	**7**	**7**	**7**	**8**	**10**	**11**
United States	15	15	12	14	14	13
Europe	-7	-8	-7	-6	-6	-2
Japan	0	0	0	-5	7	12
International	5	6	14	14	17	16
Diagnostics Division	**5**	**7**	**6**	**10**	**1**	**4**
Roche Group	**6**	**7**	**7**	**9**	**8**	**9**

CER=Constant Exchange Rates

Avastin





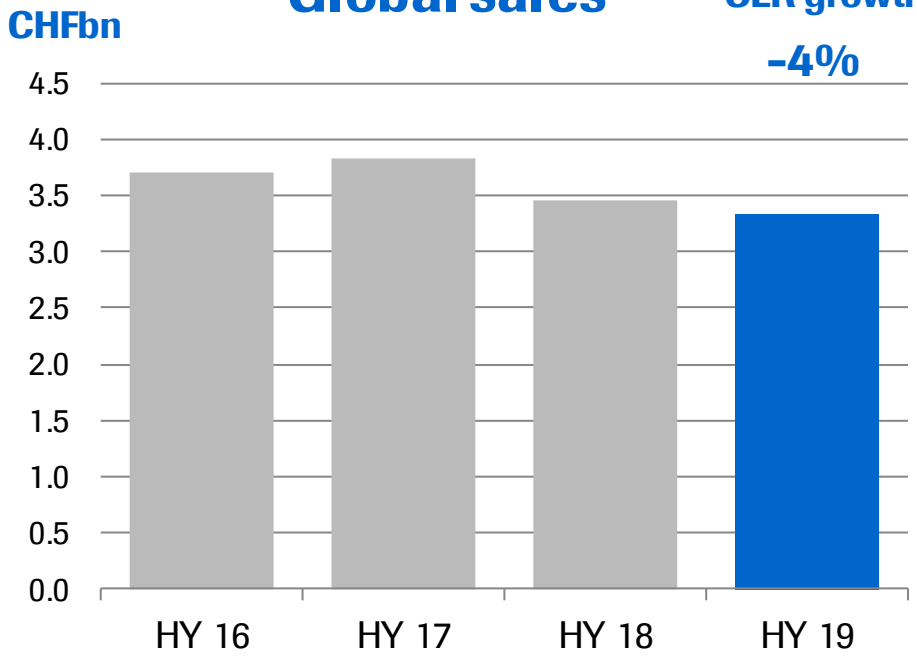
HY 2019 sales of CHF 3,659m

- US: Demand growth driven by 1L CRC, 1L OC and 1L NSCLC
- EU: Growth driven by 1L CRC
- International: Growth driven by China in 1L CRC and 1L NSCLC and by longer duration of treatment

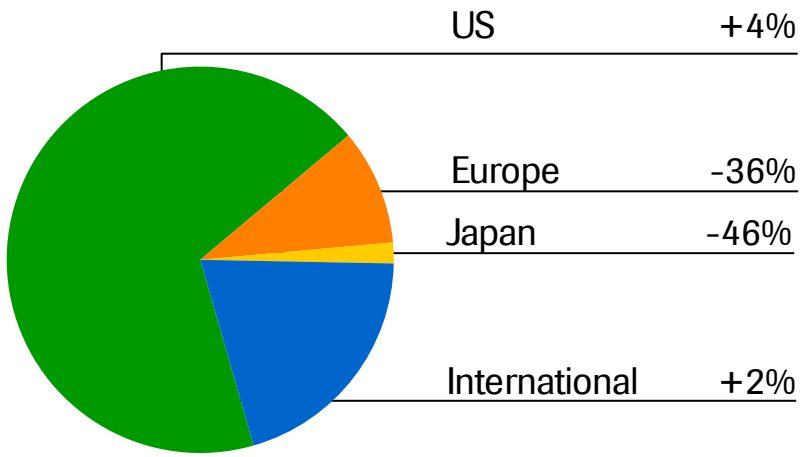
CER=Constant Exchange Rates; CRC=colorectal cancer; OC=ovarian cancer; NSCLC=non-small cell lung cancer

MabThera/Rituxan

Global sales



Regional sales

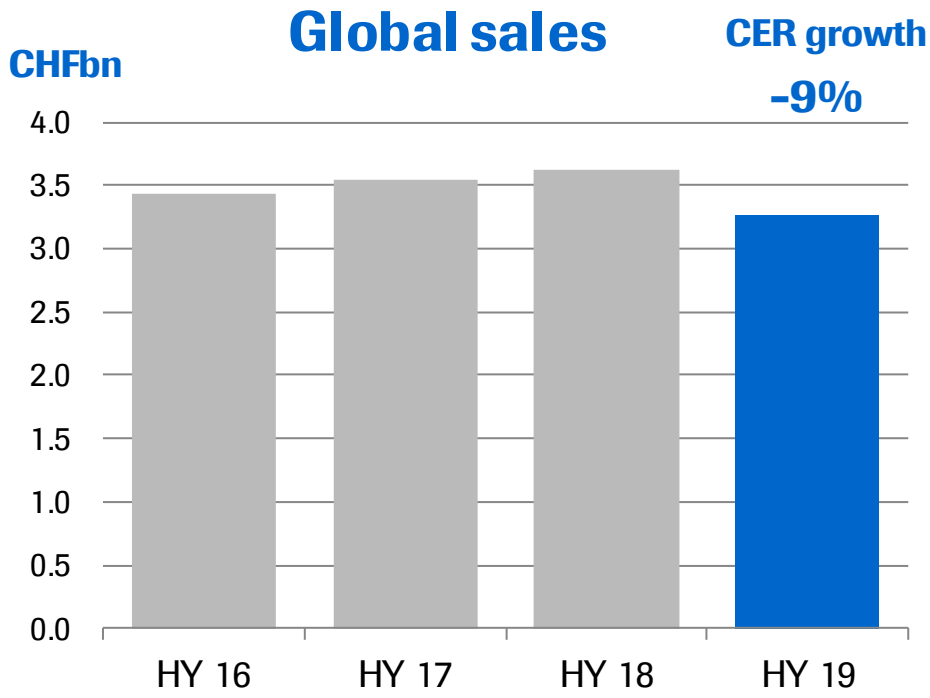


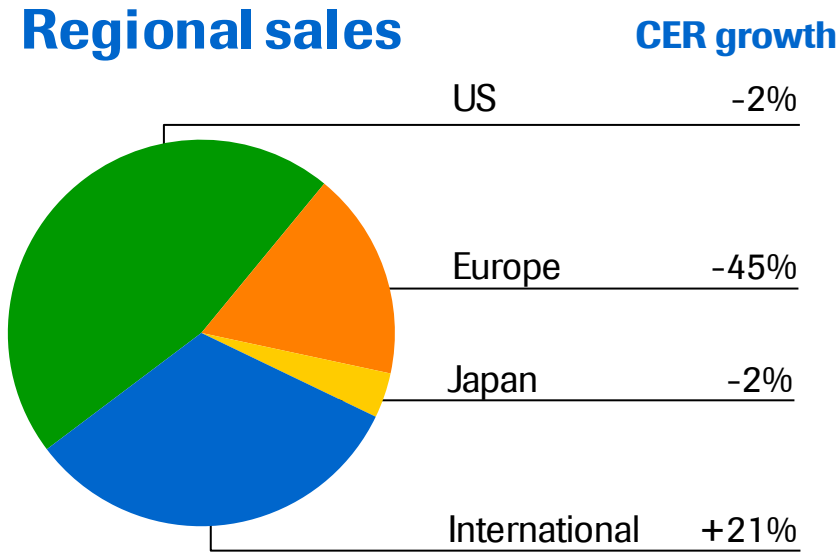
HY 2019 sales of CHF 3,339m

- US: Growth driven by approved oncology/immunology indications; first biosimilar launch expected in November
- EU: Biosimilar erosion rate softening
- Japan: Decline due to biosimilars
- International: Overall growth driven by China

CER=Constant Exchange Rates

Herceptin



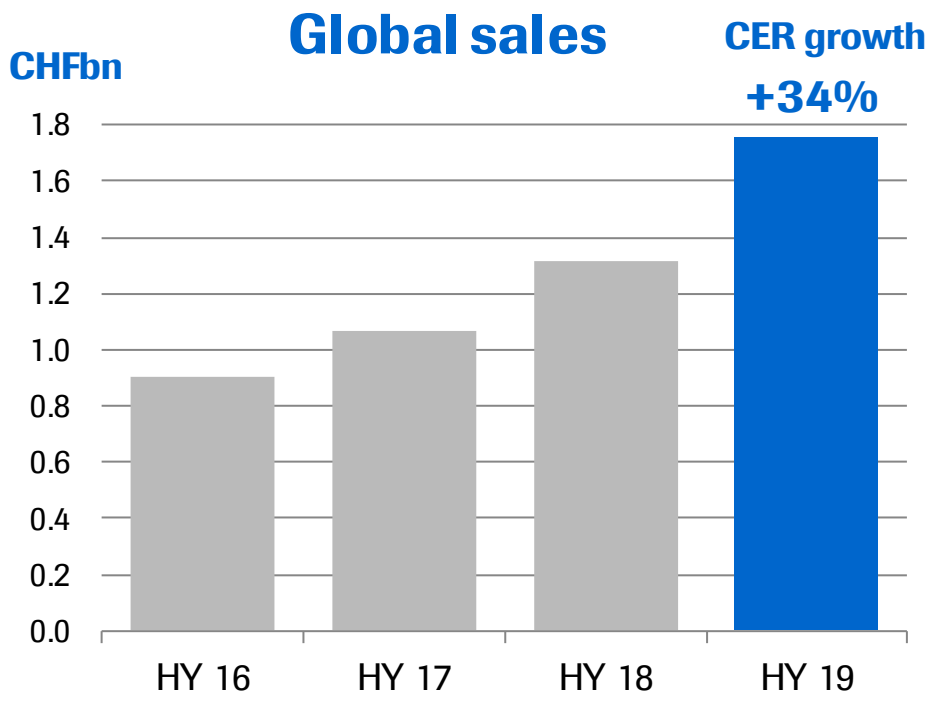


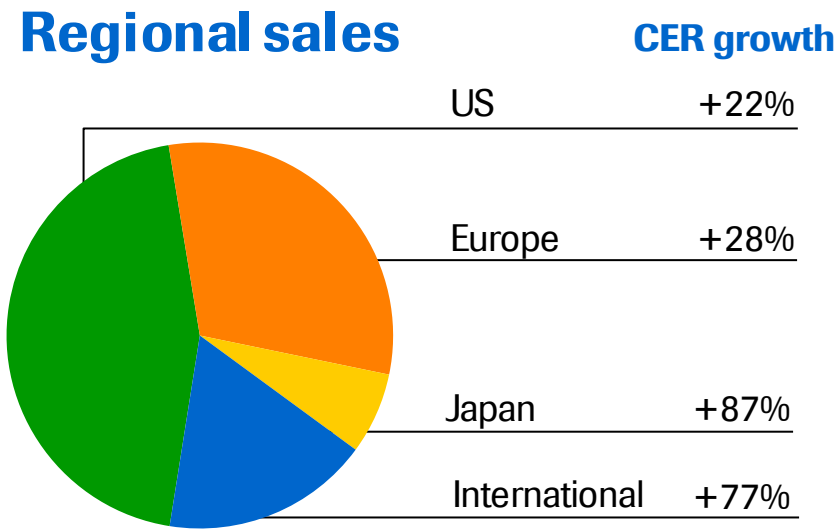
HY 2019 sales of CHF 3,264m

- US: Switching of eligible adjuvant patients to Kadcyla (KATHERINE)
- EU: Decline due to biosimilars
- Japan: Limited decline due to biosimilars with restricted label
- International: Growth driven by volume demand in China

CER=Constant Exchange Rates

Perjeta



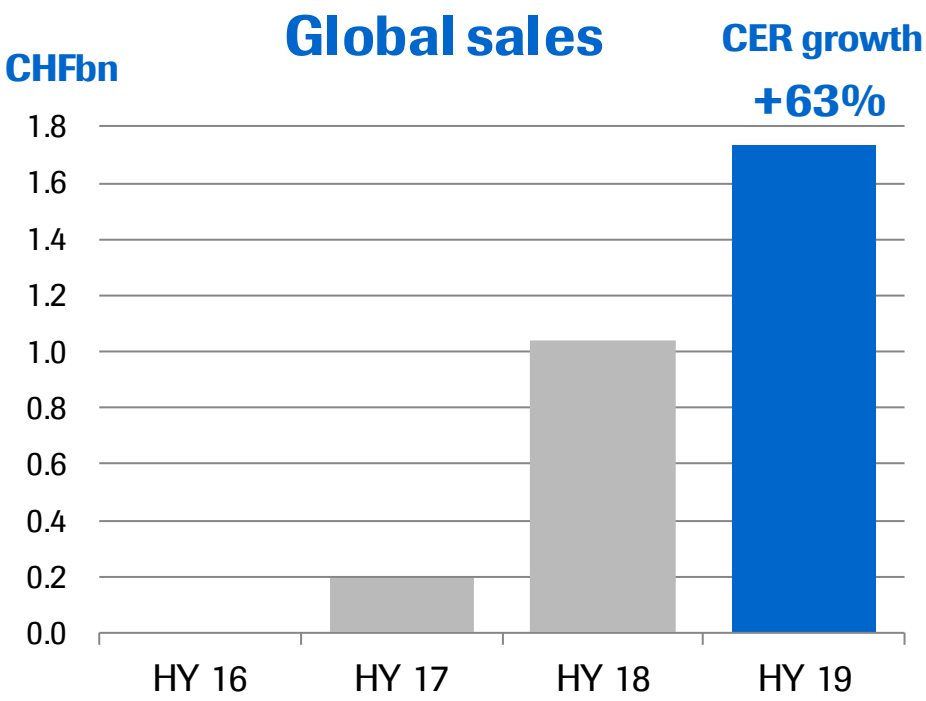


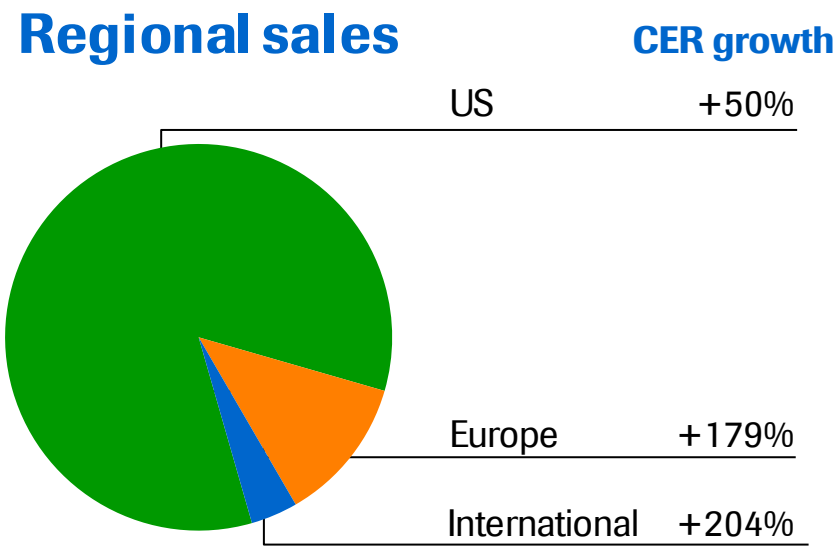
HY 2019 sales of CHF 1,755m

- US: Growth driven by eBC adjuvant; Q2 growth slow down due to switching to Kadcyla as planned
- EU: Growth in the eBC adjuvant setting following APHINITY approval in Q2 18
- International: Accelerated growth in all regions driven by eBC adjuvant setting and by China
- Japan: Growth driven by eBC adjuvant setting following APHINITY approval in Q4 18

CER=Constant Exchange Rates; eBC=early breast cancer

Ocrevus





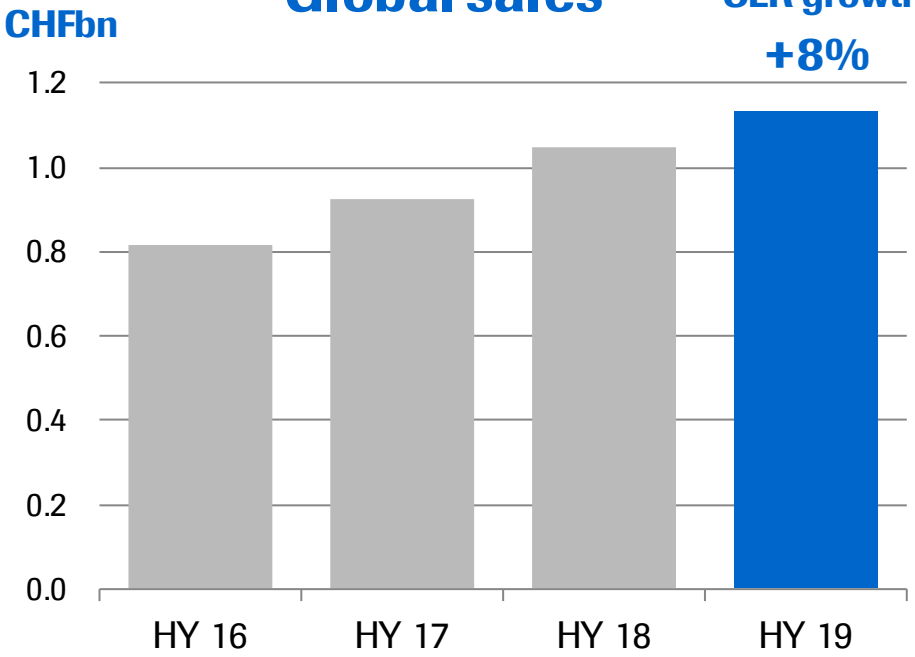
HY 2019 sales of CHF 1,735m

- US: Moving into earlier lines displacing orals; gaining market shares in all MS indications
- EU: Uptake dynamics in EU5 countries overall similar to the US

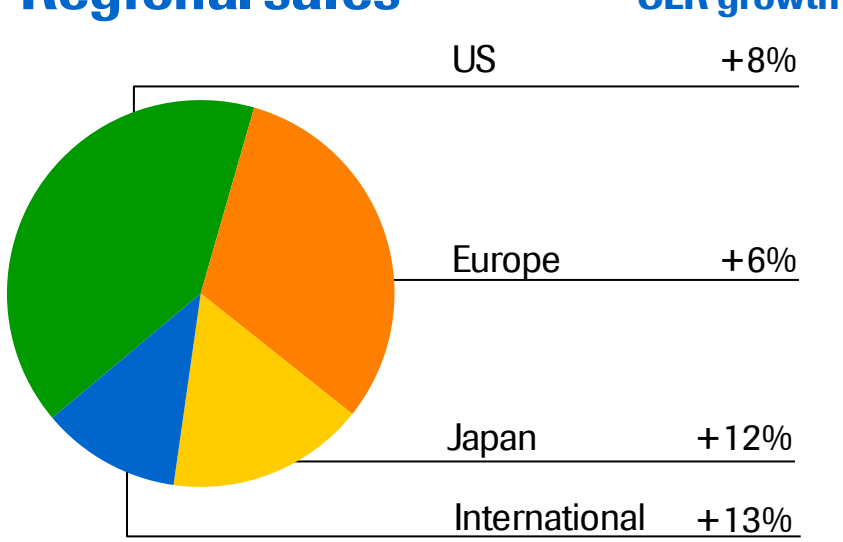
CER=Constant Exchange Rates

Actemra/RoActemra

Global sales



Regional sales

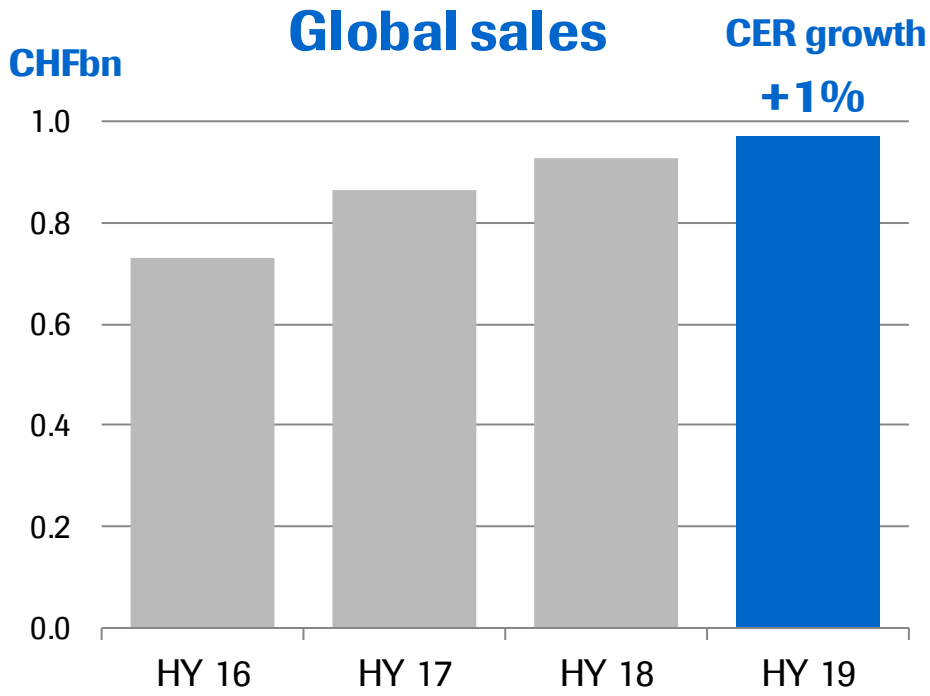


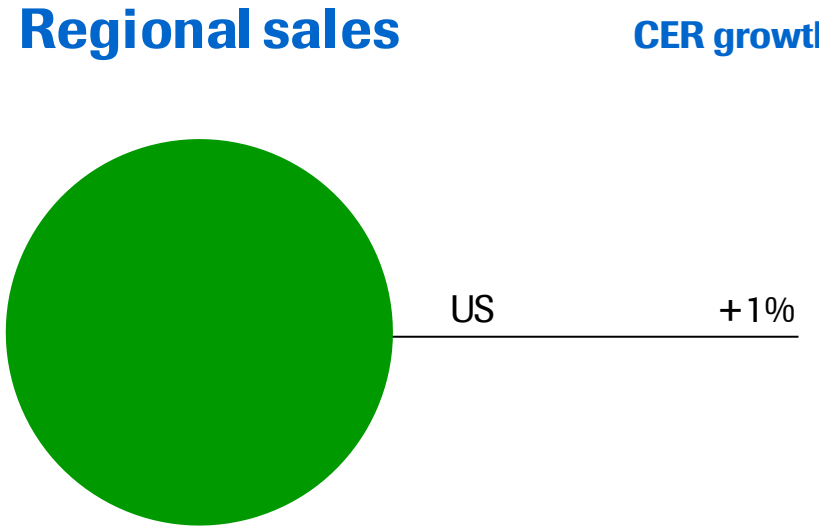
HY 2019 sales of CHF 1,135m

- US: Growth driven by Giant Cell Arteritis (GCA) and continued SC and autoinjector uptake
- EU: Market leadership in 1L RA monotherapy maintained; Growth driven by new RA starts and GCA
- International: Growth driven by all regions

CER=Constant Exchange Rates; RA=Rheumatoid Arthritis

Xolair



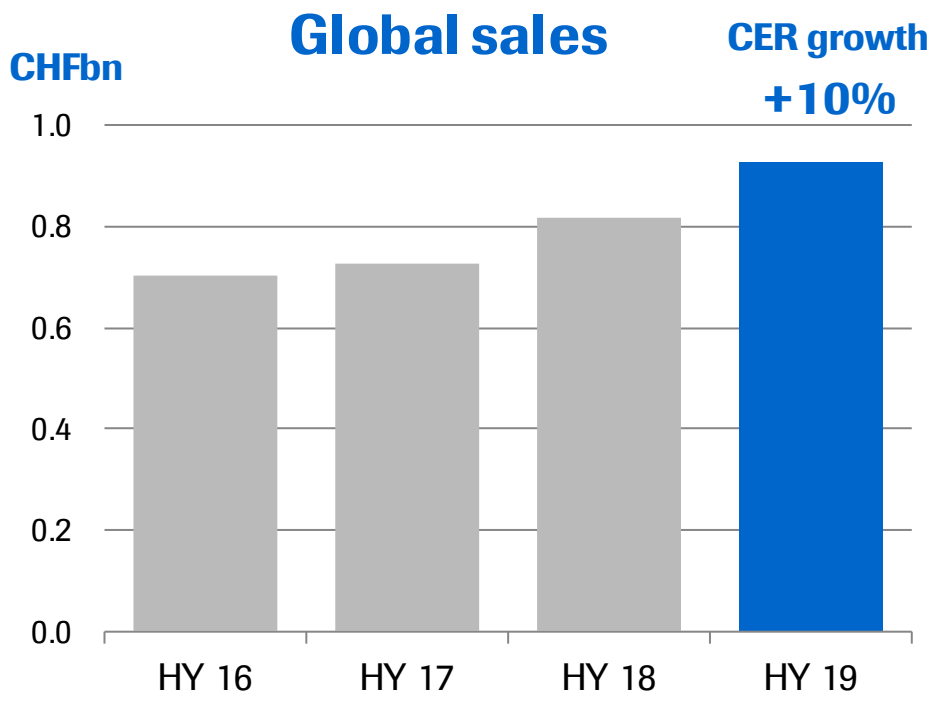


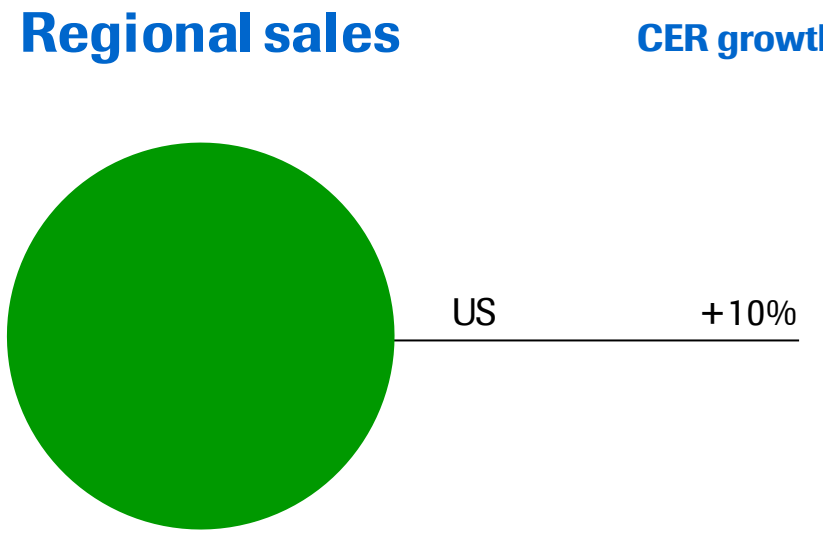
HY 2019 sales of CHF 972m

- Xolair remains market leader in a growing biologics asthma market
- Growth due to chronic idiopathic urticaria (CIU)

CER=Constant Exchange Rates

Lucentis



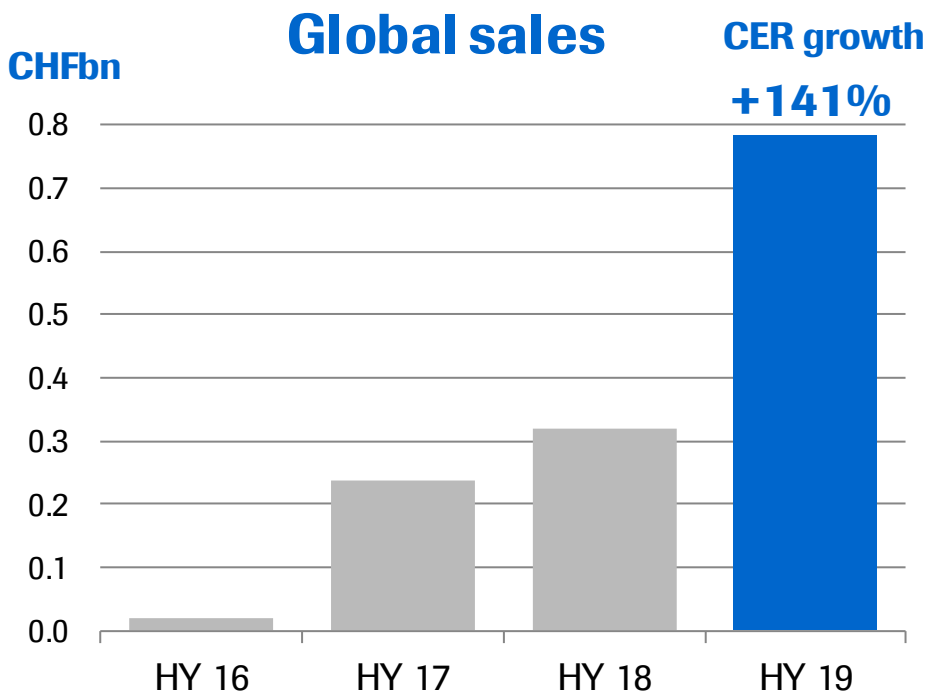


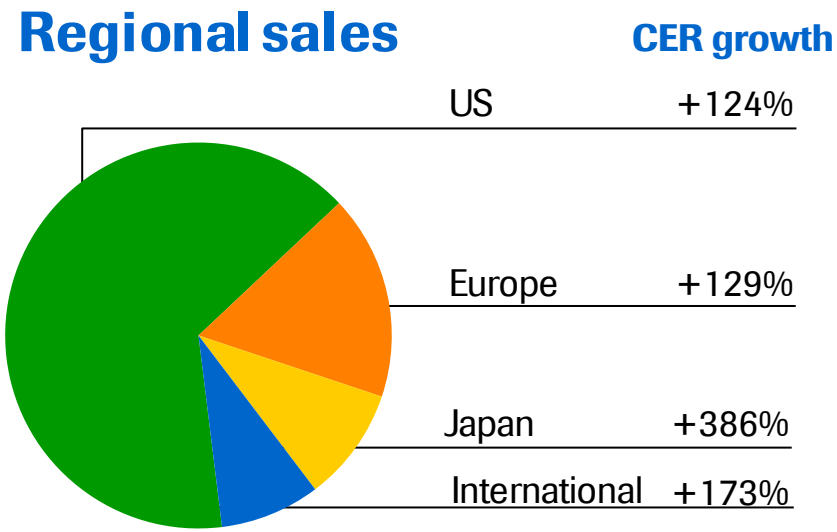
HY 2019 sales of CHF 928m

- Strong growth due to prefilled syringe and macular edema after retinal vein oclusion
- Increasing market shares in all approved indications

CER=Constant Exchange Rates

Tecentriq





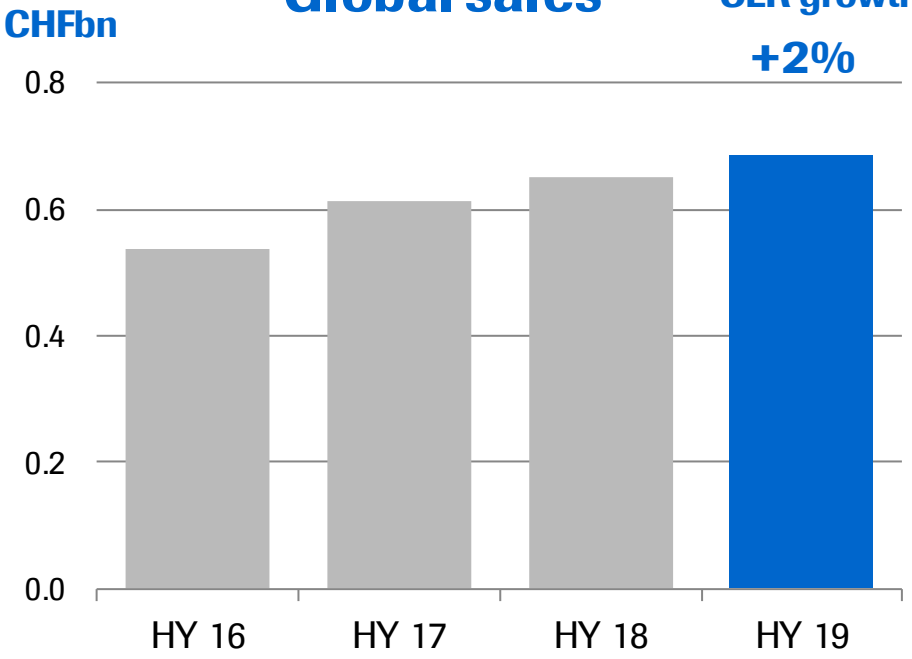
HY 2019 sales of CHF 782m

- US: Growth driven by 1L NSCLC and first-in-class launches in 1L SCLC and 1L TNBC
- EU: Growth driven by continued market share gains in 2L NSCLC and 1L NSCLC launches
- Japan: Strong launch in 1L NSCLC

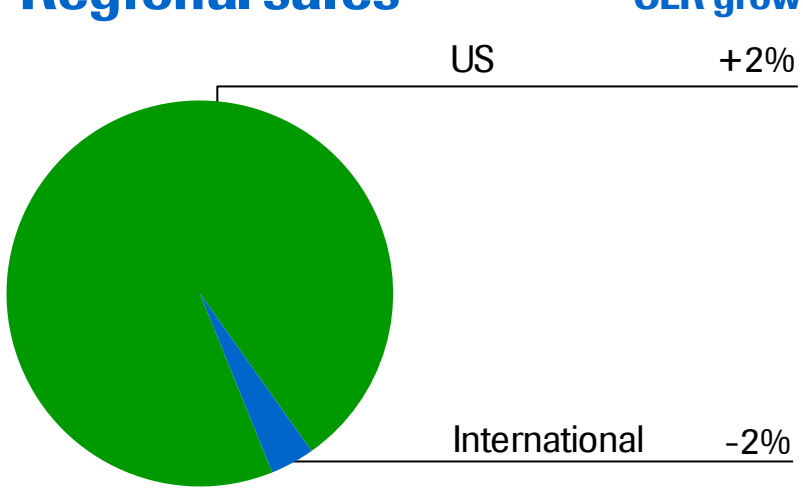
CER=Constant Exchange Rates; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; TNBC=triple-negative breast cancer

TNKase / Activase

Global sales



Regional sales

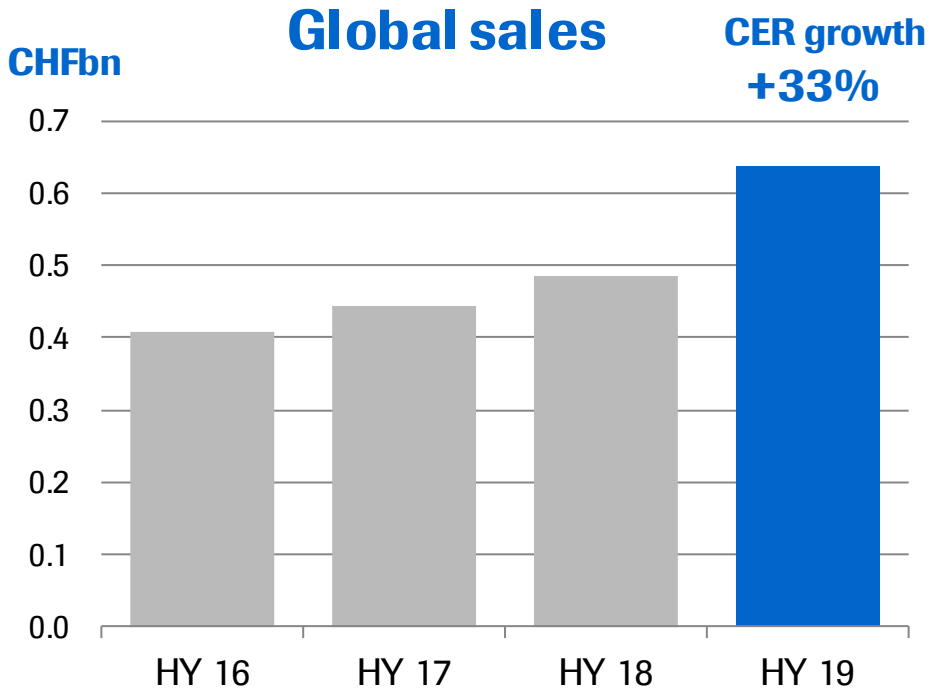


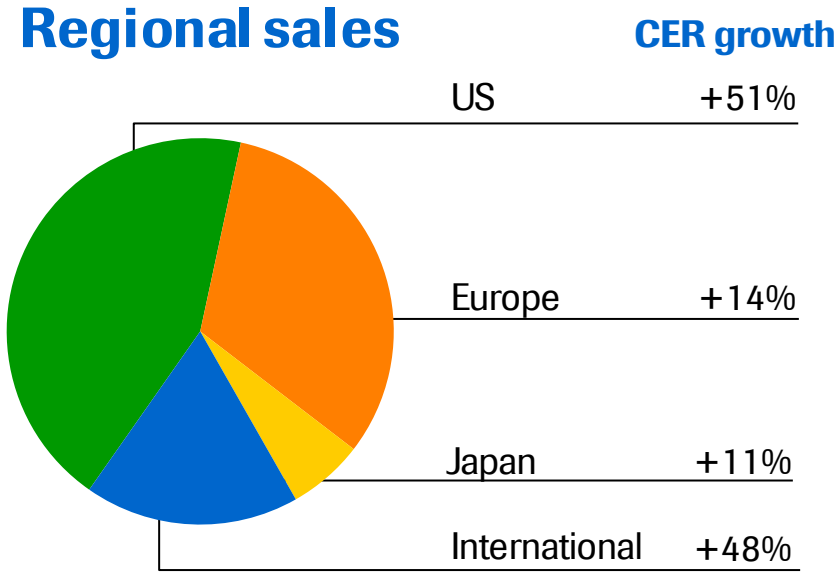
HY 2019 sales of CHF 686m

- US: Growth driven by demand

CER=Constant Exchange Rates

Kadcyla



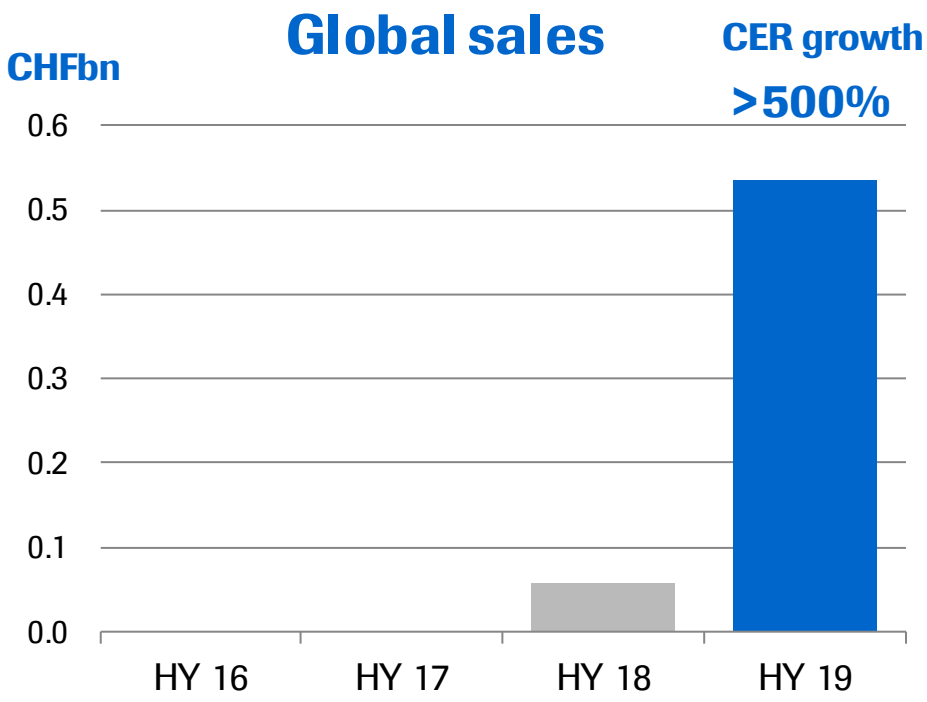


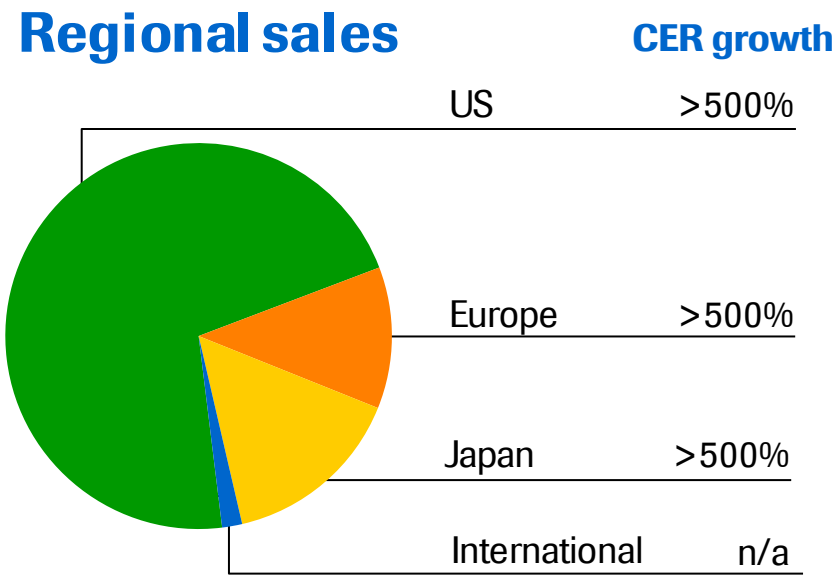
HY 2019 sales of CHF 636m

- US: Strong uptake in adjuvant eBC in patients with residual disease after neoadjuvant treatment (KATHERINE)
- EU: Increasing patient shares in 2L mBC
- International: Growth driven by all regions as 2L mBC roll-out progresses

CER=Constant Exchange Rates; eBC=early breast cancer; mBC=metastatic breast cancer

Hemlibra



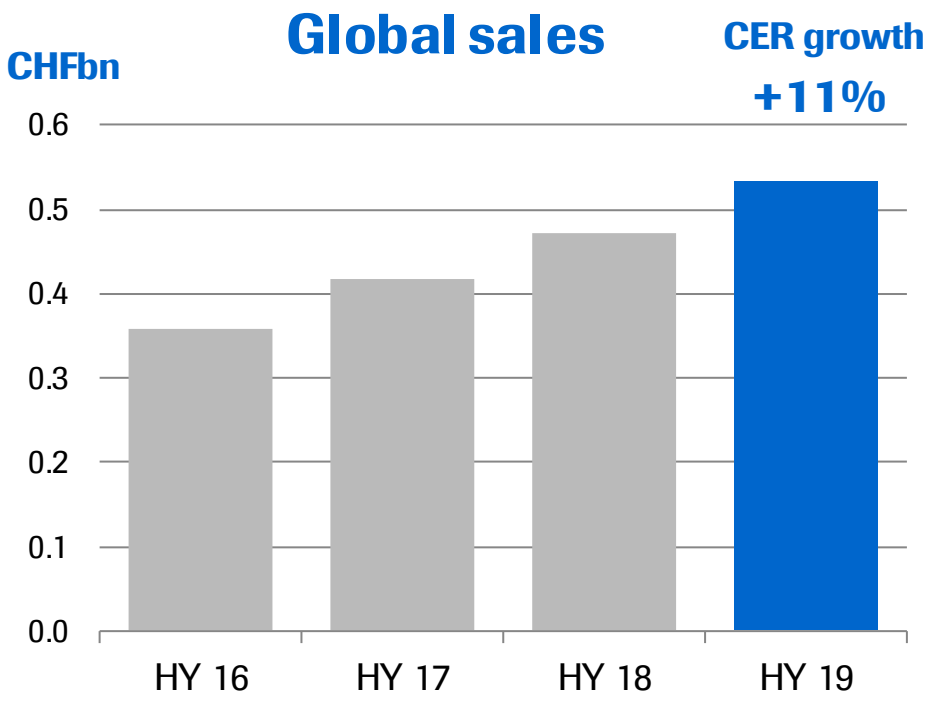


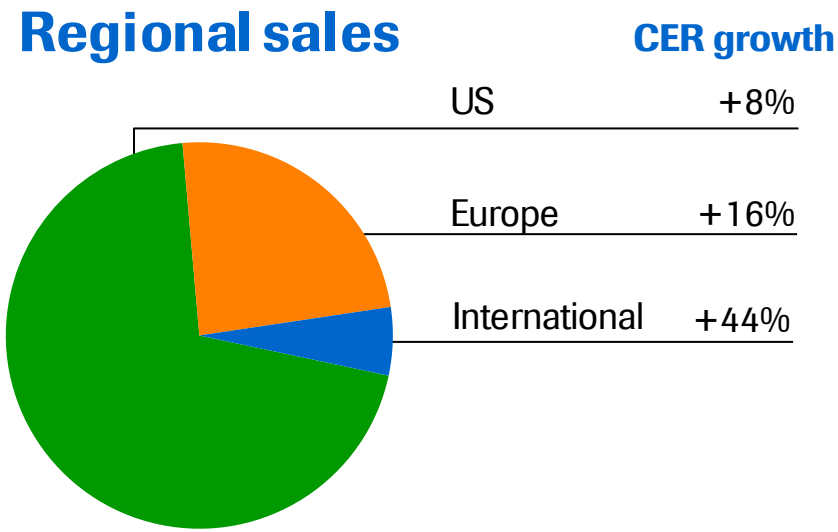
HY 2019 sales of CHF 535m

- US: Strong uptake in non-inhibitors and continued market share gains in inhibitors
- EU: Growth mainly driven by non-inhibitors; first non-inhibitor launch initiated
- Japan: Very strong uptake in non-inhibitors

CER=Constant Exchange Rates

Esbriet





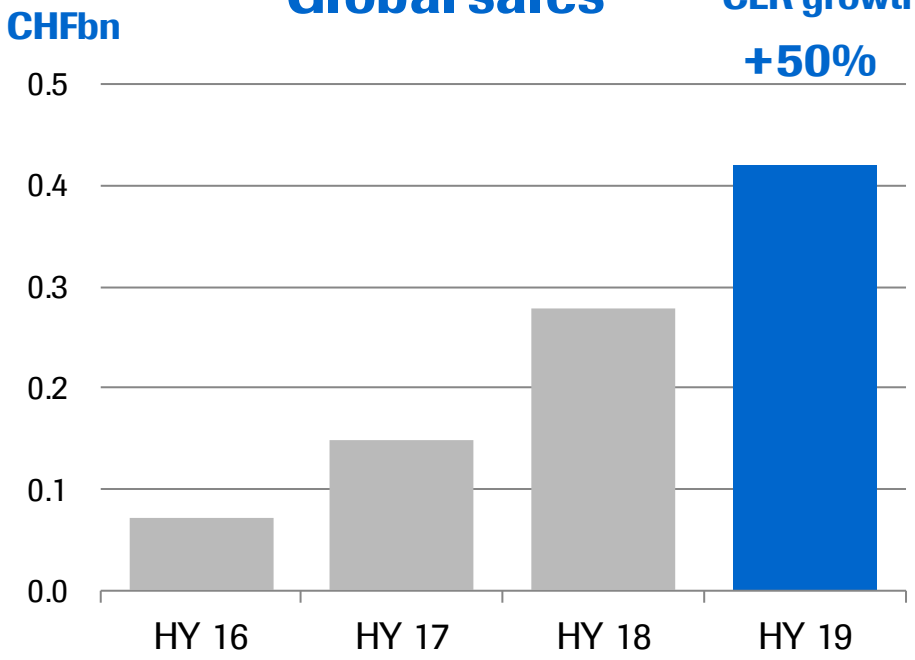
HY 2019 sales of CHF 532m

- US: Growth driven by continued penetration in moderate and mild patients; improved patient compliance
- EU: Growth driven by continued penetration in moderate and mild patients

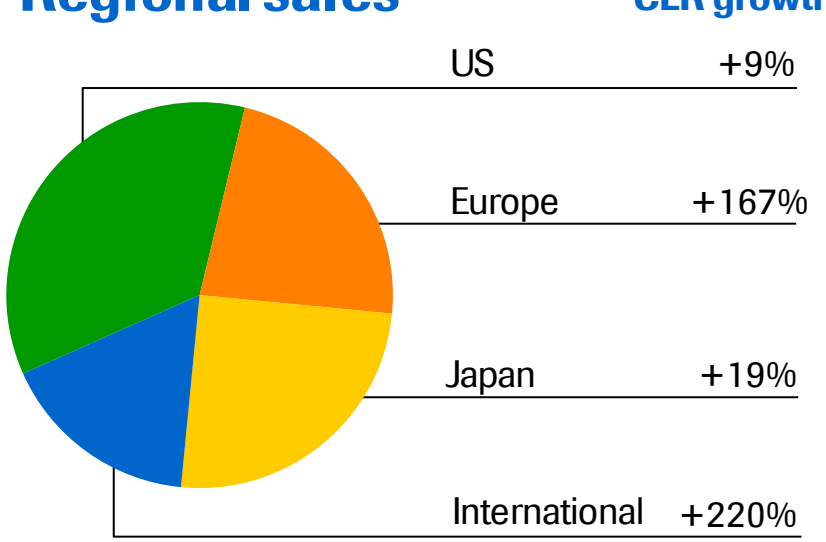
CER=Constant Exchange Rates

Alecensa

Global sales



Regional sales

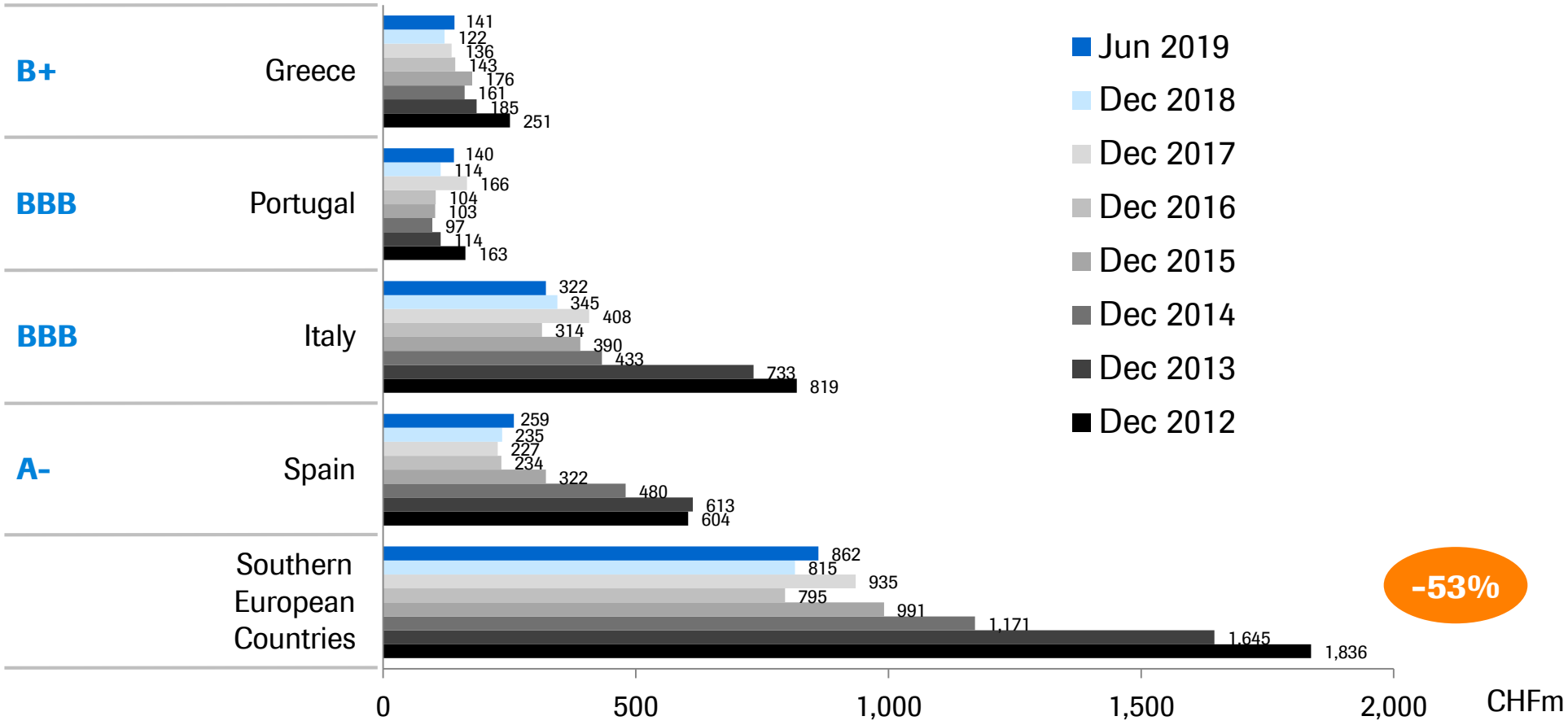


HY 2019 sales of CHF 421m

- 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

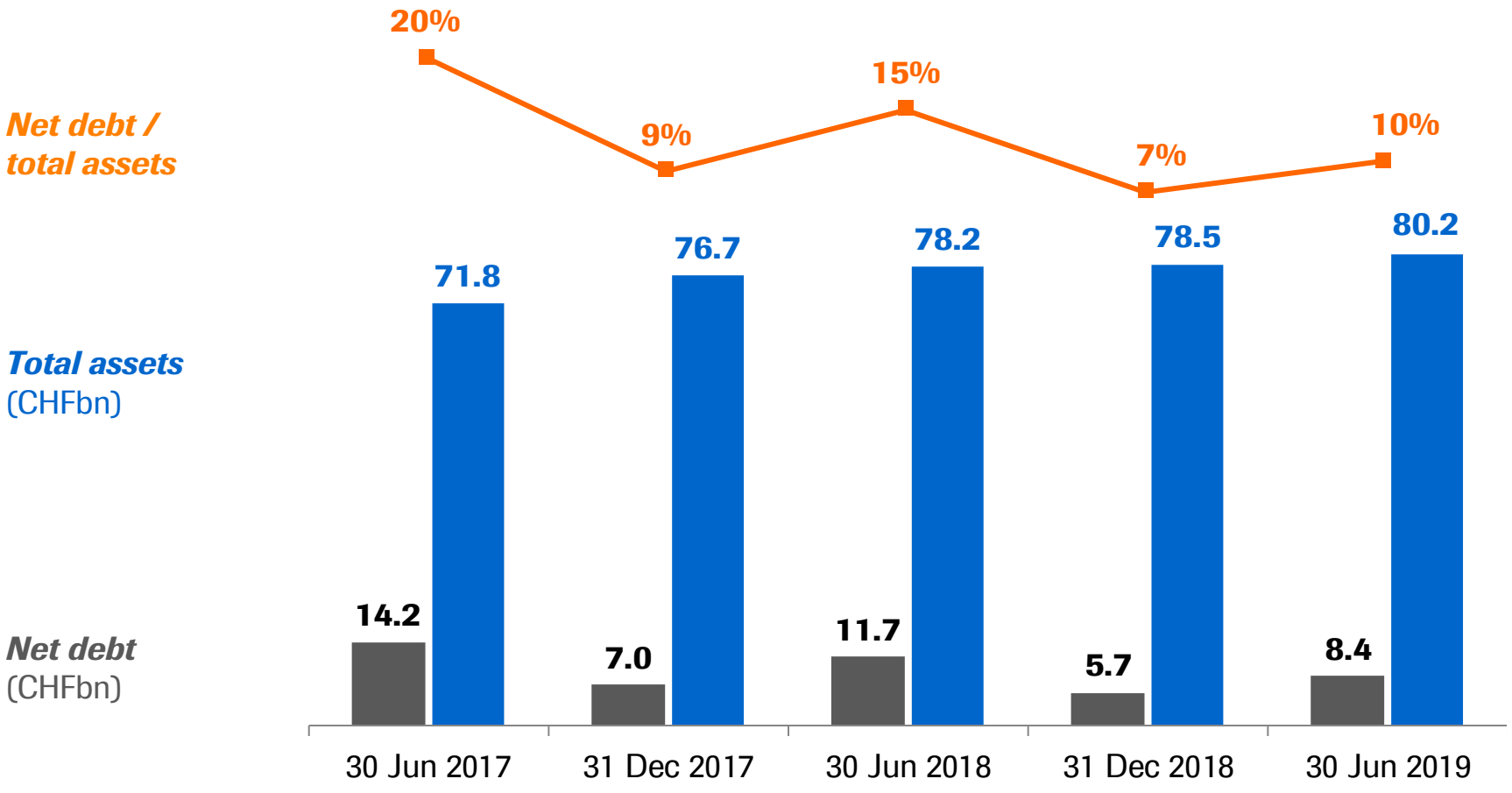
CER=Constant Exchange Rates

HY 2019: Accounts receivable in Southern Europe decreased by –53% since Dec 2012

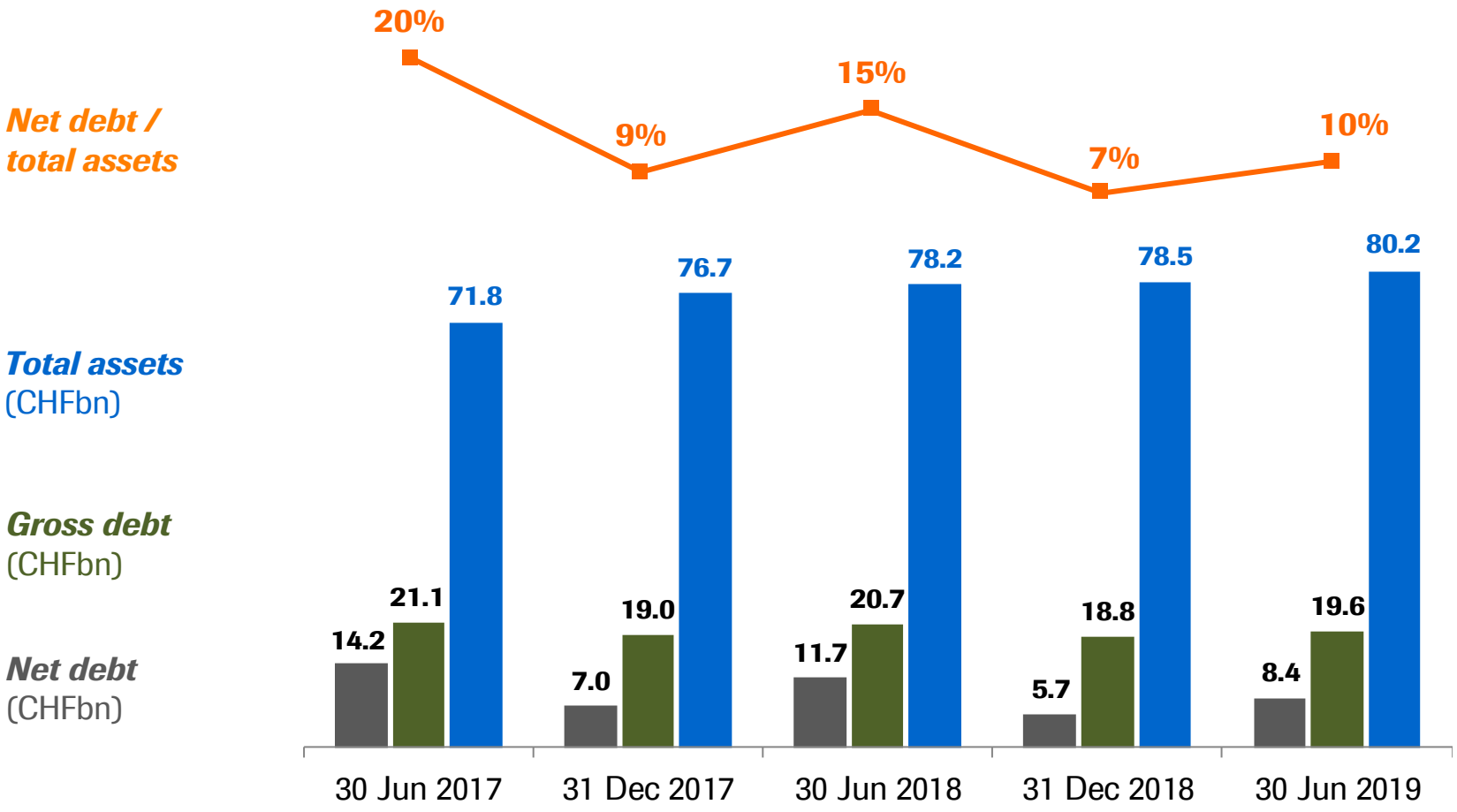


Sovereign country ratings from Standard & Poor's, as of 3 July 2019

Balance sheet: Net debt to total assets



Balance sheet: Gross debt, Net 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)

Roche Group HY 2019 results

Diagnostics

Foreign exchange rate information

HY 2019: Diagnostics Division CER growth

By Region and Business Area (vs. 2018)

	Global		North America		EMEA[1]		RoW	
	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth
Centralised and Point of Care Solutions	3,762	3	768	-2	1,340	3	1,654	4
Molecular Diagnostics	1,029	6	394	2	395	10	240	9
Diabetes Care	958	1	136	5	582	-2	240	4
Tissue Diagnostics	526	-3	291	-9	139	2	96	13
Diagnostics Division	**6,275**	**2**	**1,589**	**-2**	**2,456**	**3**	**2,230**	**5**

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

Diagnostics Division quarterly sales and CER growth[1]

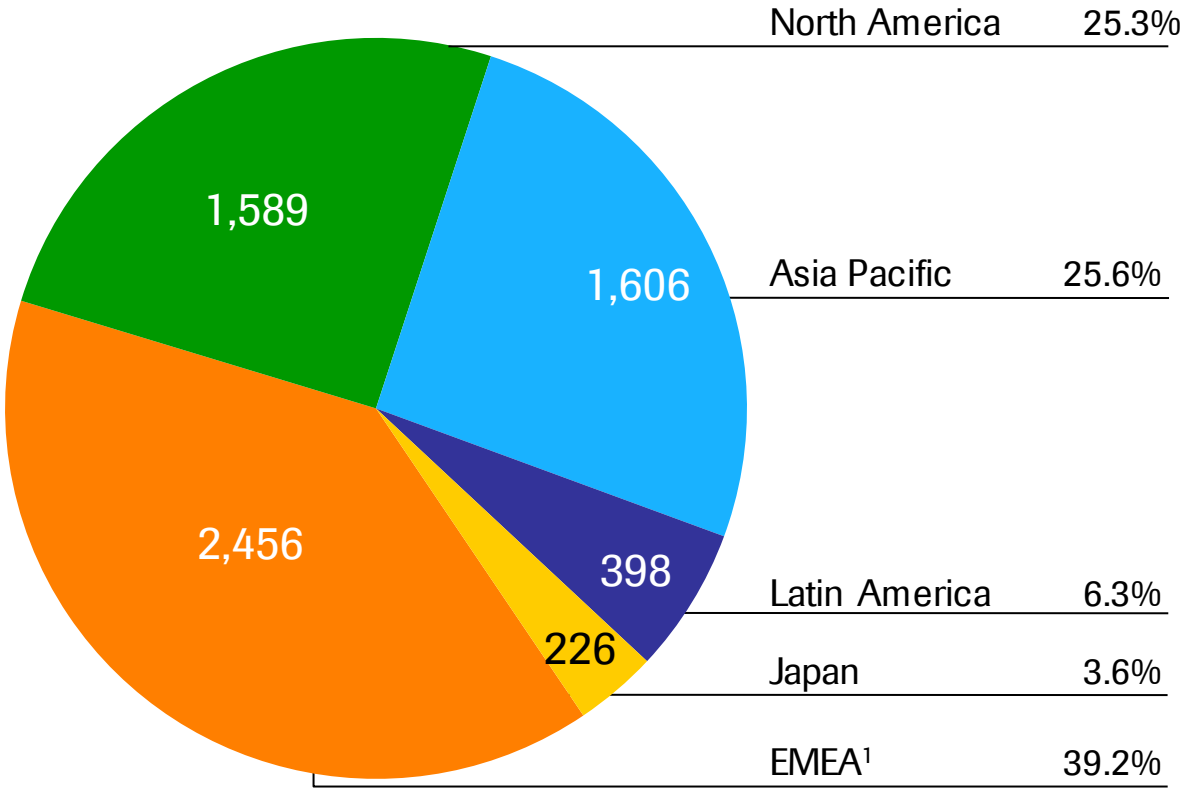
	Q1 18		Q2 18		Q3 18		Q4 18		Q1 19		Q2 19	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Centralised and Point of Care Solutions	1,716	4	2,039	9	1,870	8	2,143	12	1,681	-1	2,081	5
Molecular Diagnostics	468	6	511	4	489	5	551	6	502	7	527	6
Diabetes Care	478	5	513	-3	493	1	496	5	465	1	493	0
Tissue Diagnostics	249	7	290	15	262	4	311	13	251	-1	275	-4
Diagnostics Division	**2,911**	**5**	**3,353**	**7**	**3,114**	**6**	**3,501**	**10**	**2,899**	**1**	**3,376**	**4**

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

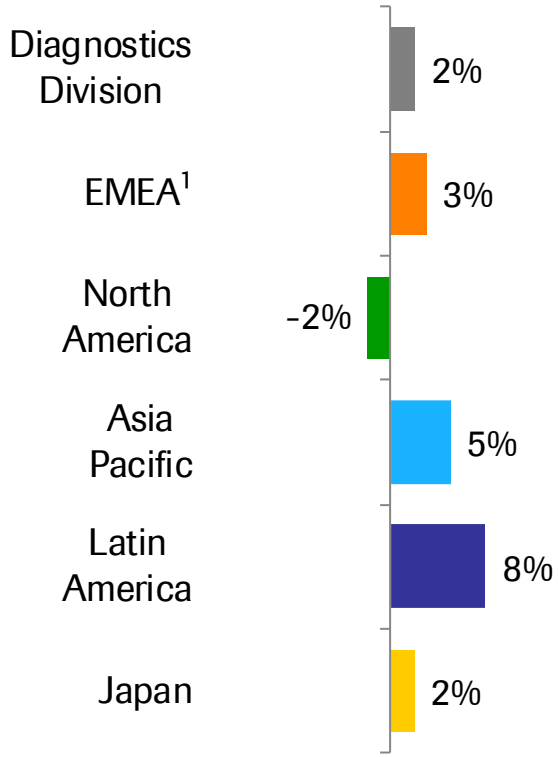
HY 2019: Diagnostics Division sales

Growth driven by Asia Pacific and EMEA

CHF 6,275m



CER sales growth

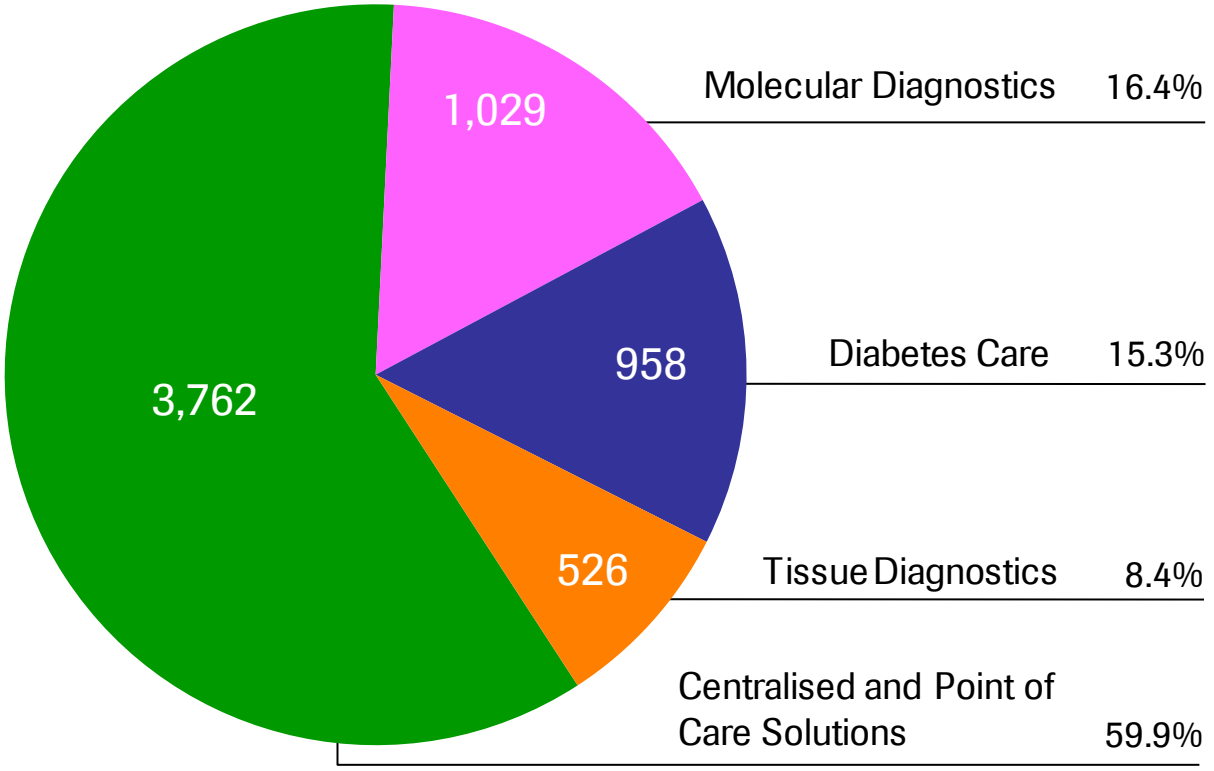


CER=Constant Exchange Rates; [1] Europe, Middle East and Africa

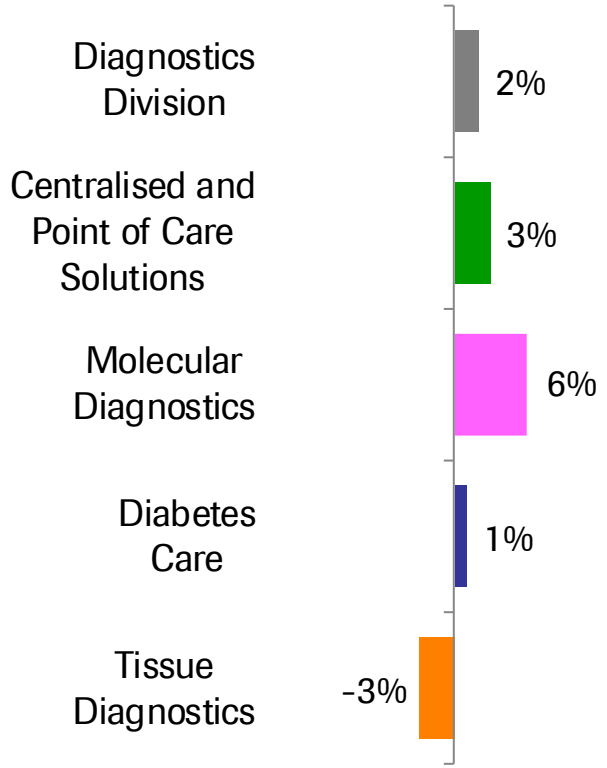
HY 2019: Diagnostics Division sales

Growth due to Centralised and Point of Care Solutions and Molecular Diagnostics

CHF 6,275m

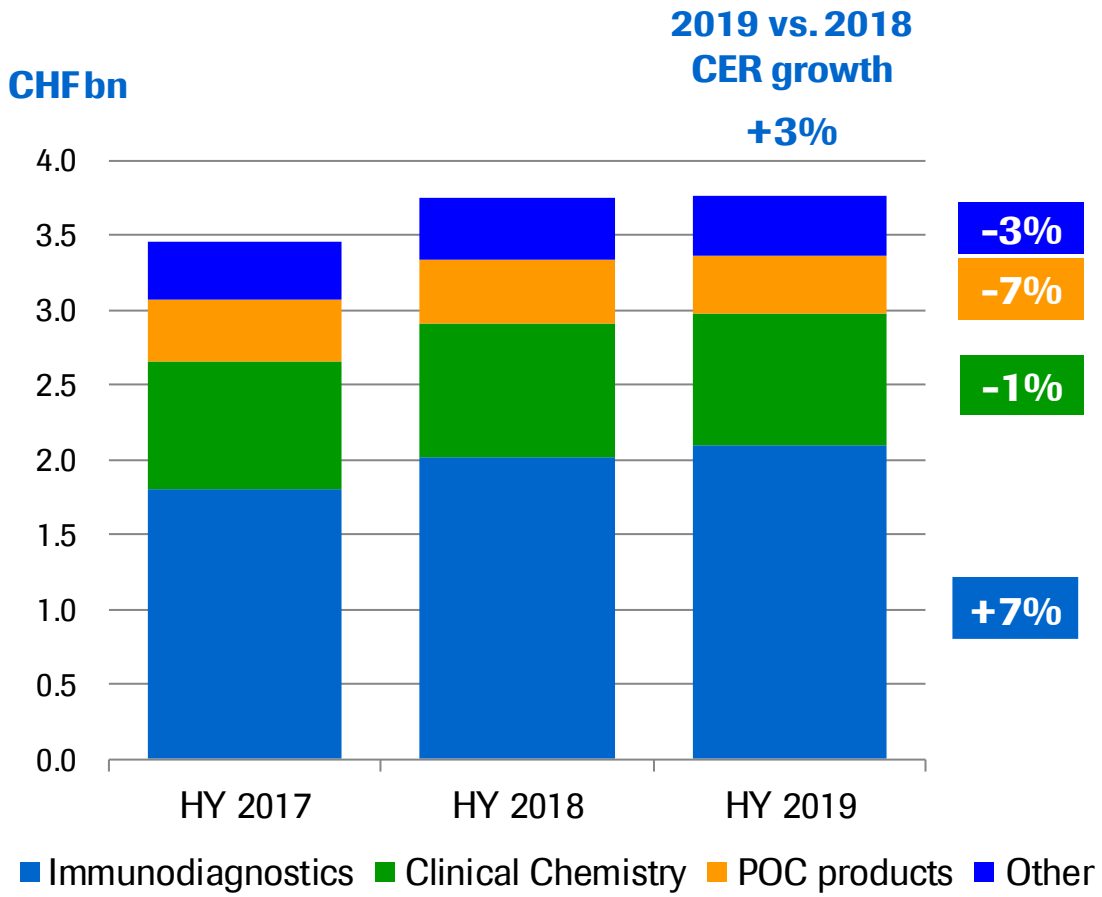


CER sales growth



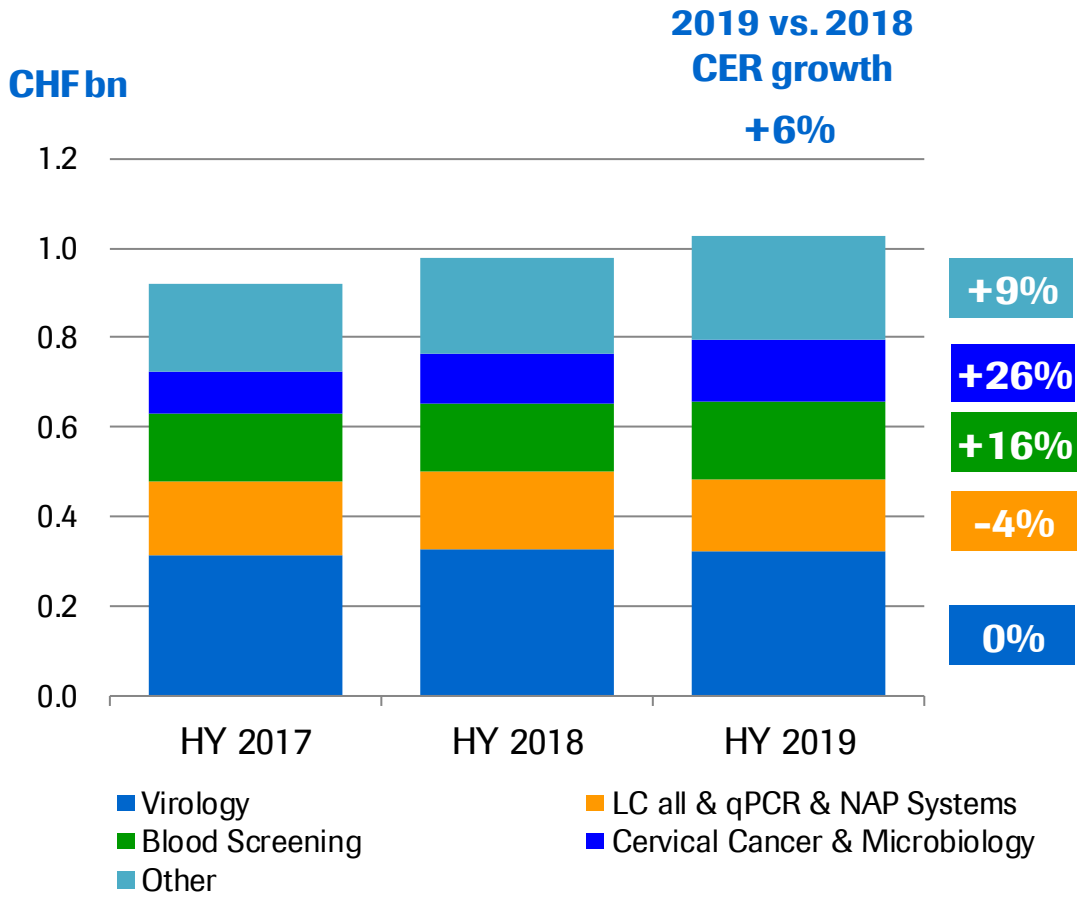
CER=Constant Exchange Rates

Centralised and Point of Care Solutions



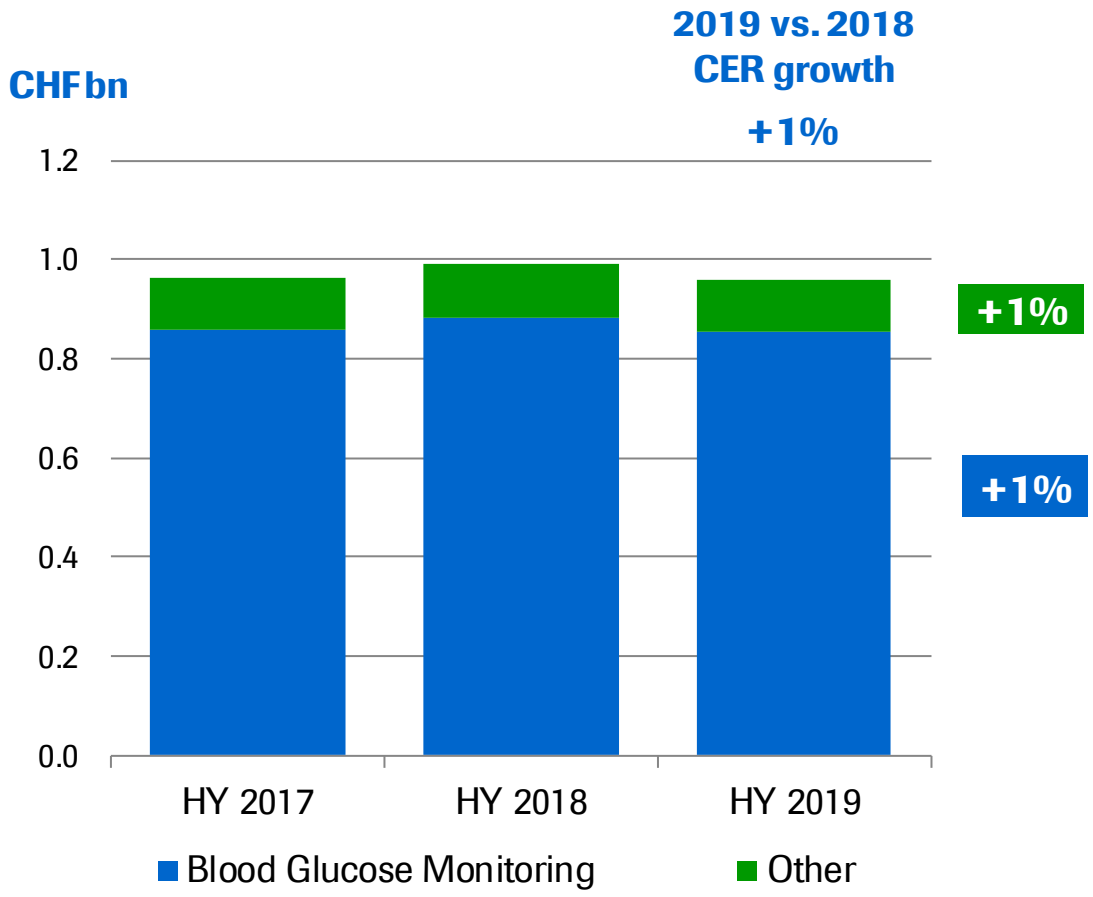
CER=Constant Exchange Rates

Molecular Diagnostics



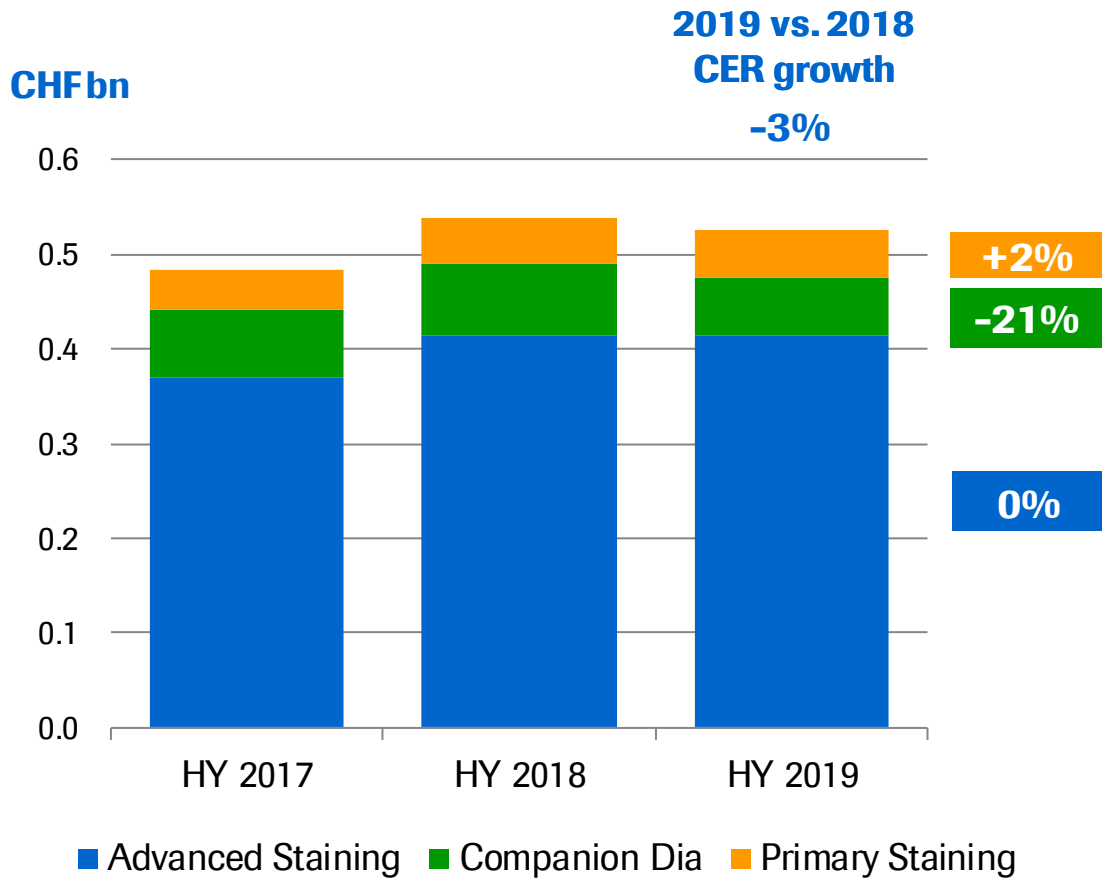
CER=Constant Exchange Rates

Diabetes Care



CER=Constant Exchange Rates

Tissue Diagnostics



CER=Constant Exchange Rates

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

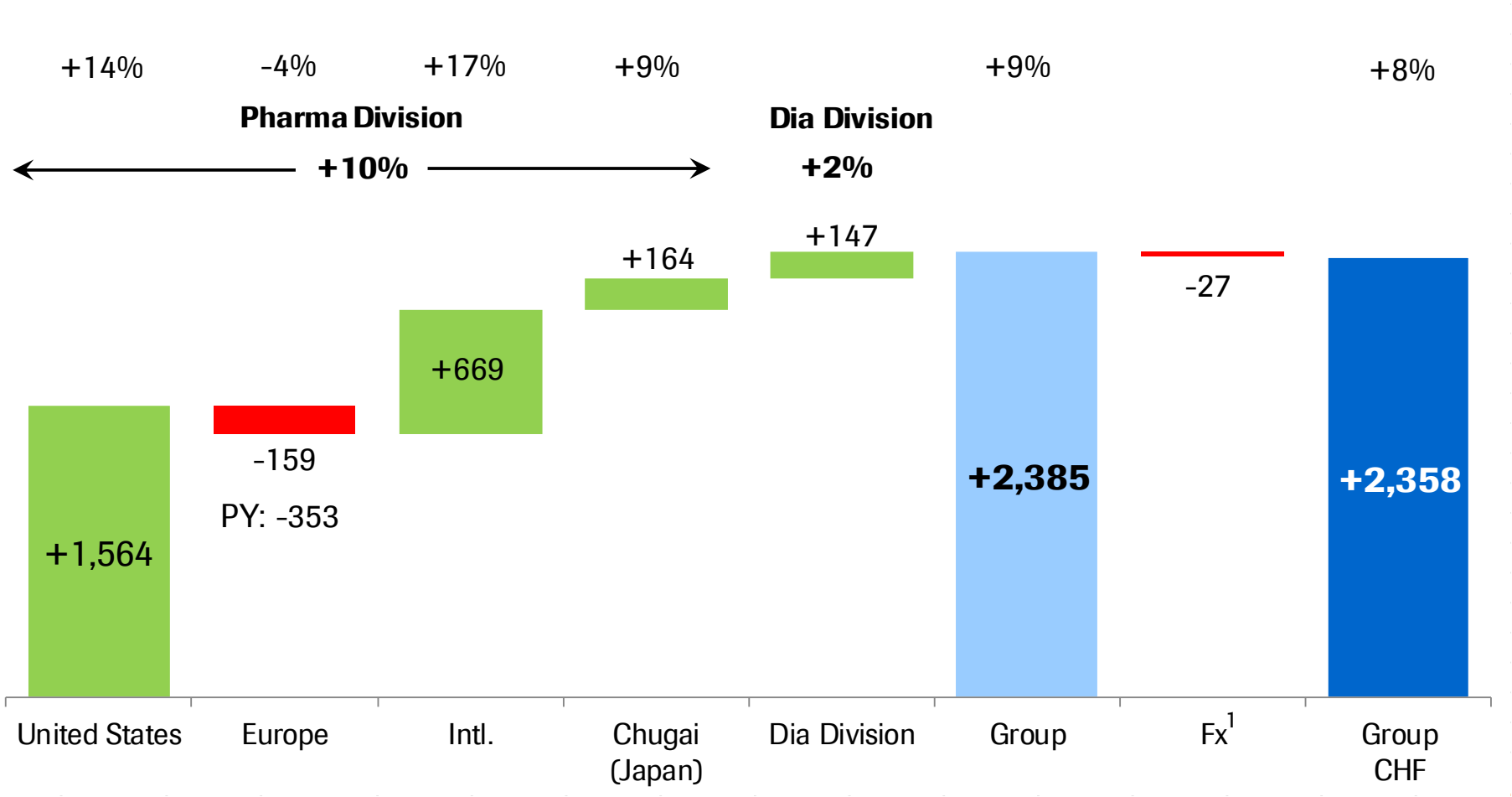
Roche Group HY 2019 results

Diagnostics

Foreign exchange rate information

Group sales HY 2019

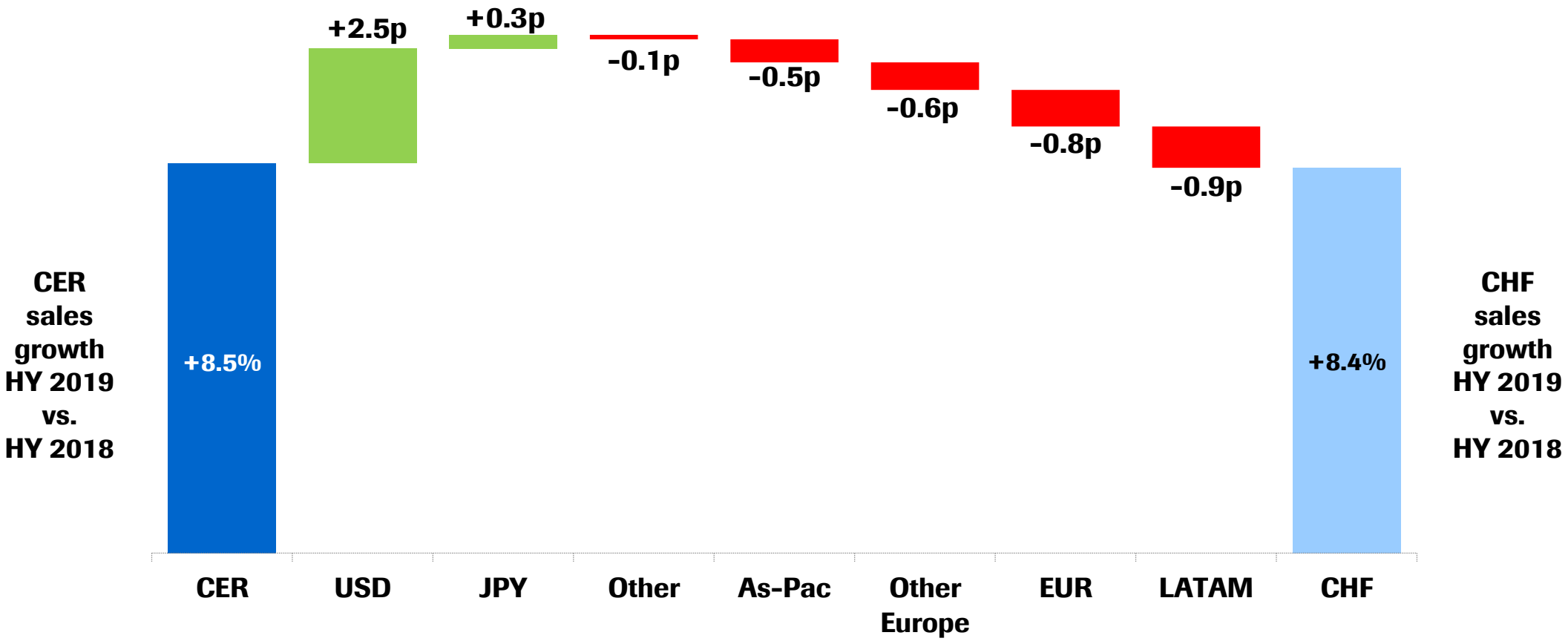
CER sales increase of +9% driven by US and International partially offset by Europe



Absolute values in CHFm at Constant Exchange Rates (avg full year 2018); [1] avg full year 2018 to avg HY 2019 fx

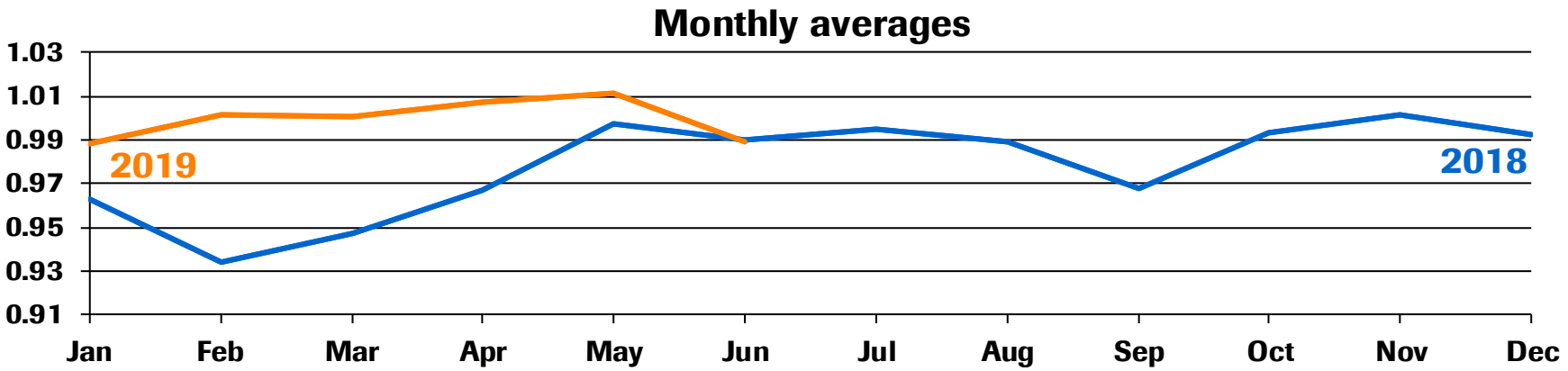
Exchange rate impact on sales growth

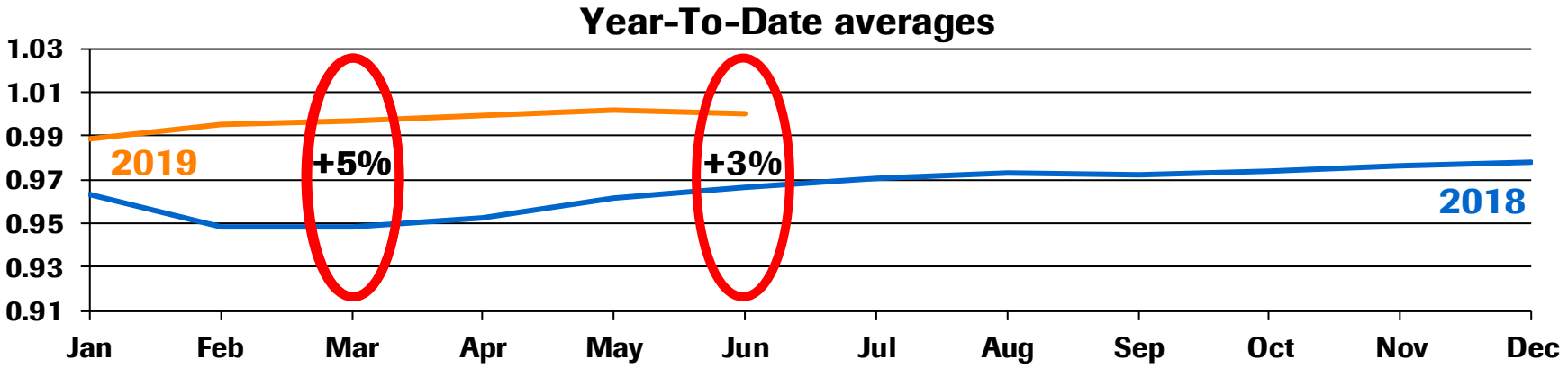
Positive impact from USD partially offset by LATAM currencies and EUR



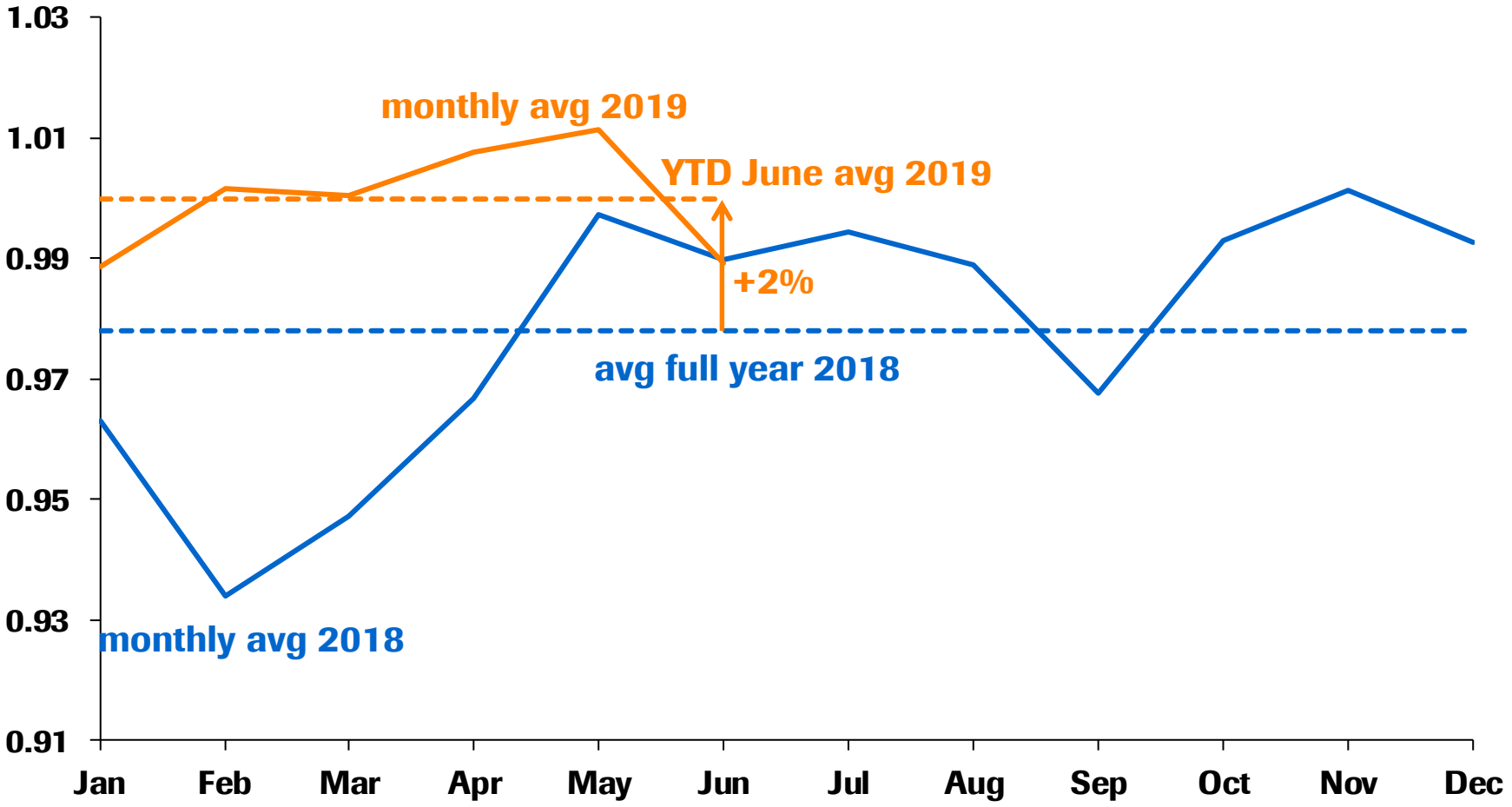
CER=Constant Exchange Rates (avg full year 2018)

CHF / USD

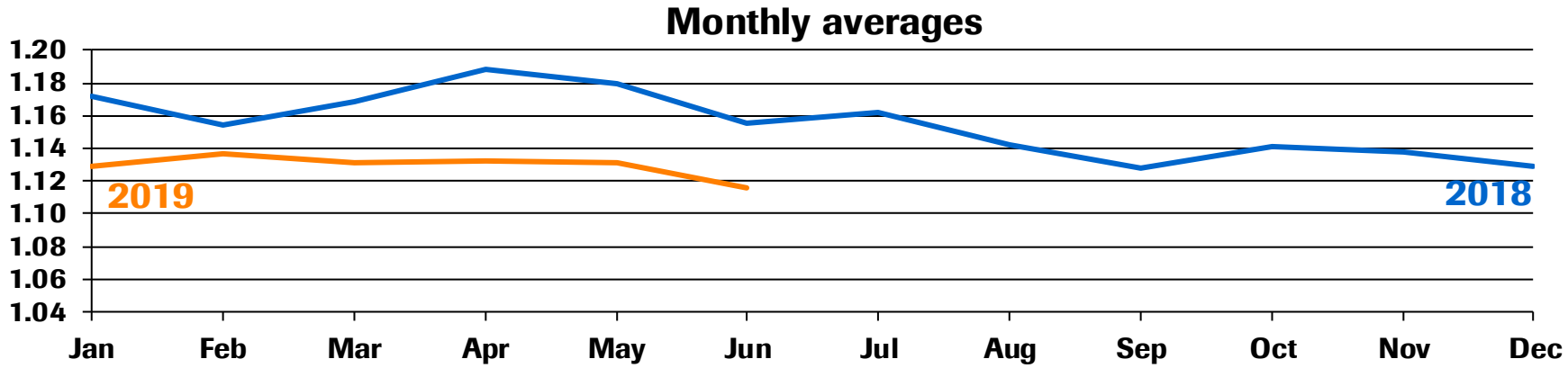

Monthly averages
1.03
1.01
0.99
0.97
0.95
0.93
0.91
2019
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

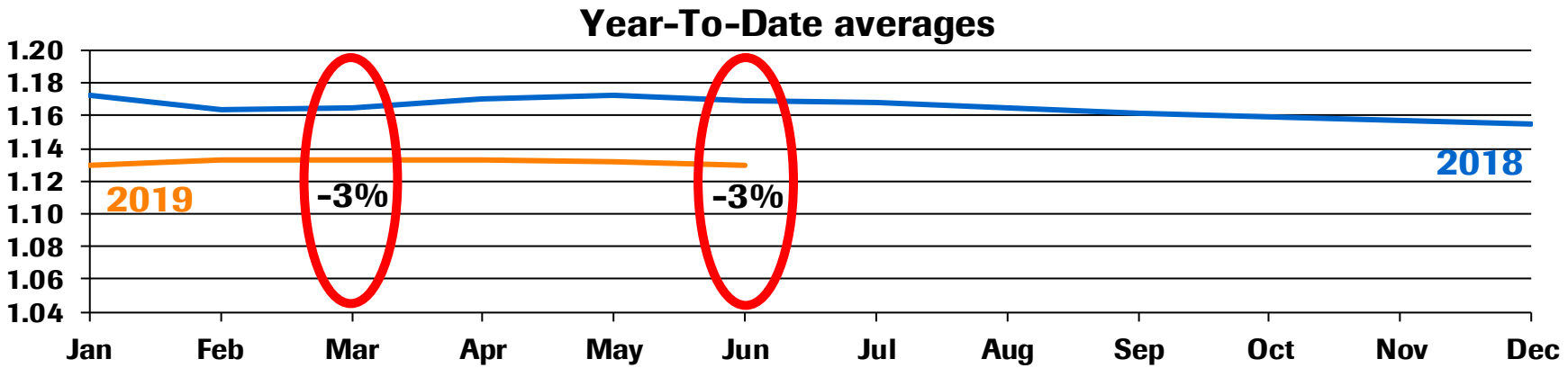

Year-To-Date averages
1.03
1.01
0.99
0.97
0.95
0.93
0.91
2019
+5%
+3%
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / USD

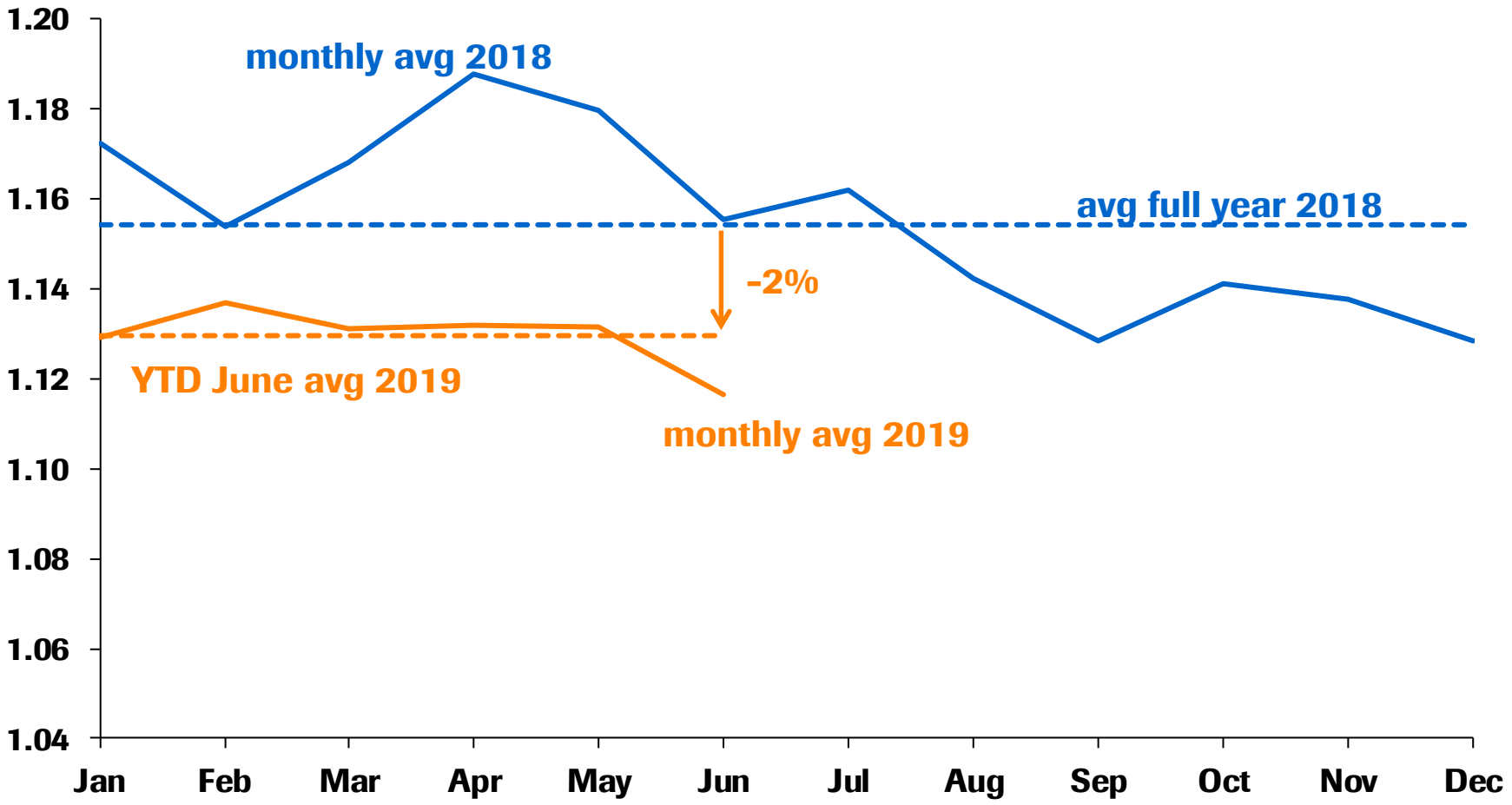

1.03
1.01
0.99
0.97
0.95
0.93
0.91
monthly avg 2019
YTD June avg 2019
+2%
avg full year 2018
monthly avg 2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / EUR


Monthly averages
1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
2019
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

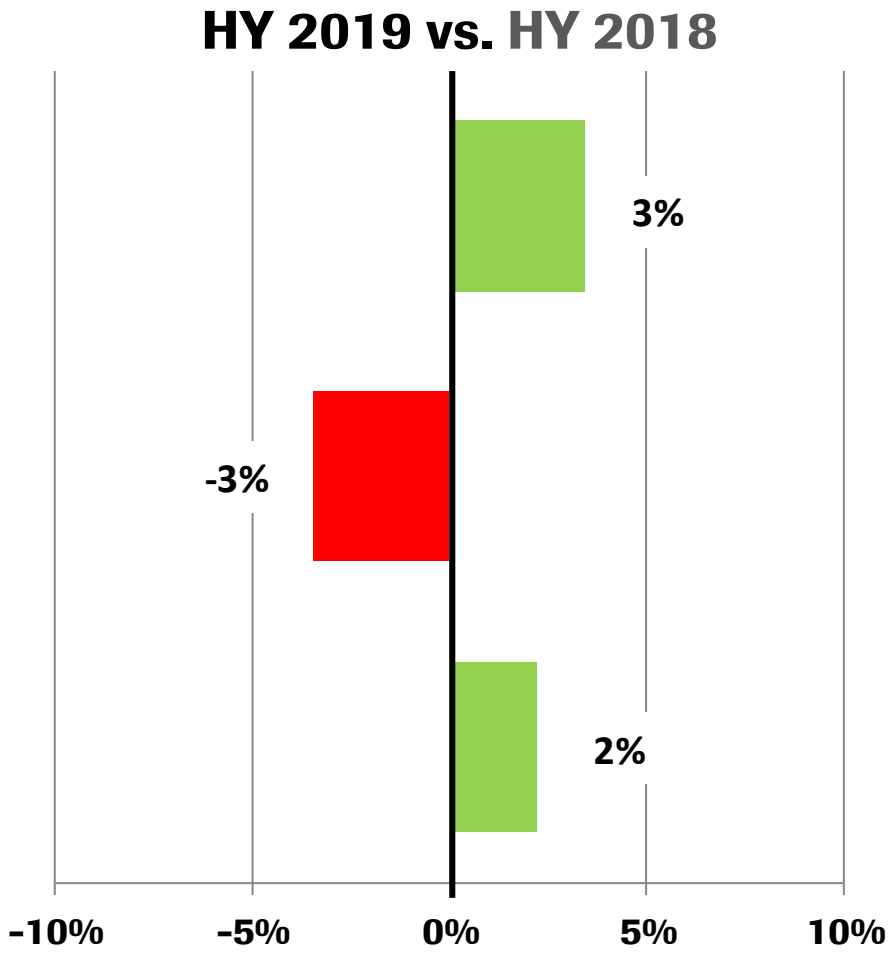

Year-To-Date averages
1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
2019
-3%
-3%
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / EUR


1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
monthly avg 2018
avg full year 2018
-2%
YTD June avg 2019
monthly avg 2019
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

Average CHF exchange rates

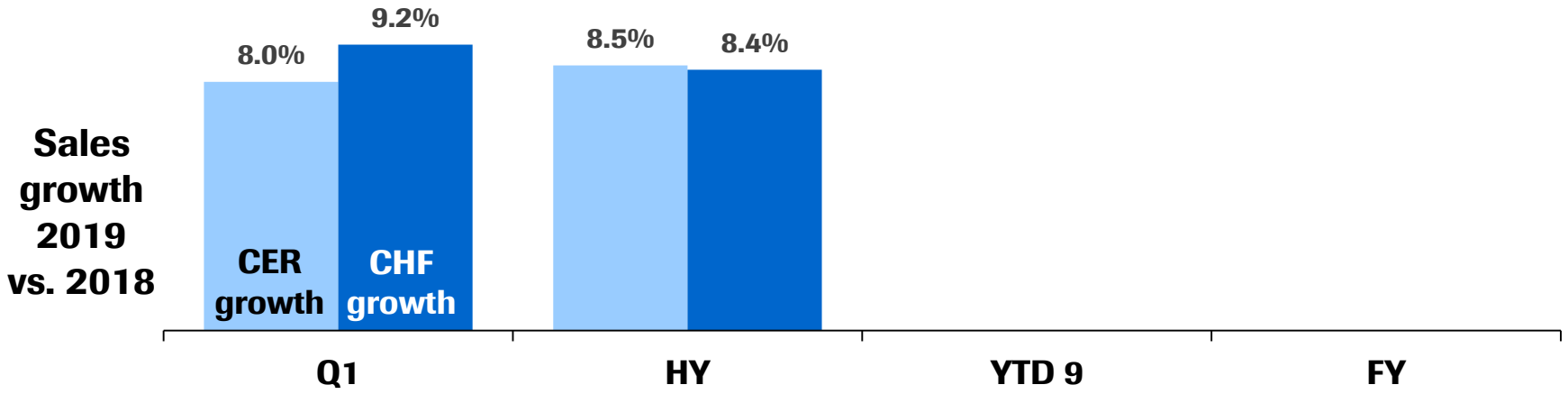
	HY 2019	HY 2018
USD	1.00	0.97
EUR	1.13	1.17
JPY	0.91	0.89



Exchange rate impact on sales growth

In HY 2019 negative impact of EUR and positive impact of USD & JPY

Development of average exchange rates versus prior year period		
CHF / USD	+5.1%	+3.5%
CHF / EUR	-2.8%	-3.4%
CHF / JPY	+3.4%	+2.2%
Difference in CHF / CER growth	+1.2%p	-0.1%p

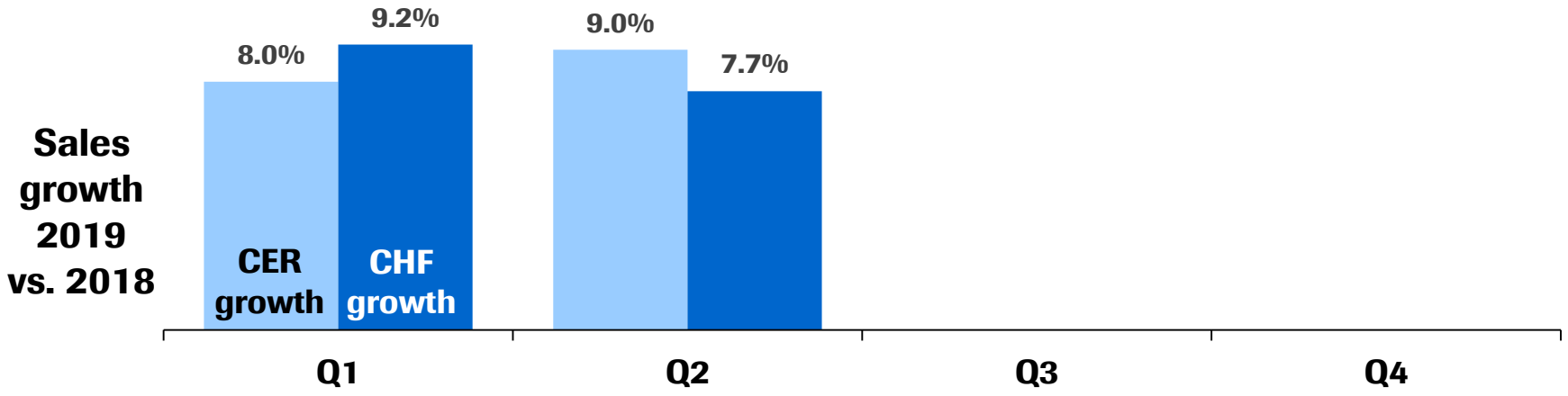


CER=Constant Exchange Rates

Exchange rate impact on sales growth

In Q2 2019 negative impact of EUR and positive impact of USD & JPY

Development of average exchange rates versus prior year period		
CHF / USD	+5.1%	+1.8%
CHF / EUR	-2.8%	-4.1%
CHF / JPY	+3.4%	+1.0%
Difference in CHF / CER growth	+1.2%p	-1.3%



CER=Constant Exchange Rates

Doing now what patients need next