
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

FY 2019 results

London, 30 January 2020

Group

Severin Schwan
Chief Executive Officer

2019 performance

Outlook

2019: Targets fully achieved

Targets for 2019		*FY 2019*	
Group sales growth[1]	High-single digit (raised during the year)	**+9%**	✔
Core EPS growth[1]	Broadly in line with sales growth	**+13%**	✔
Dividend outlook	Further increase dividend in Swiss francs[2]	**CHF 9.00**	✔

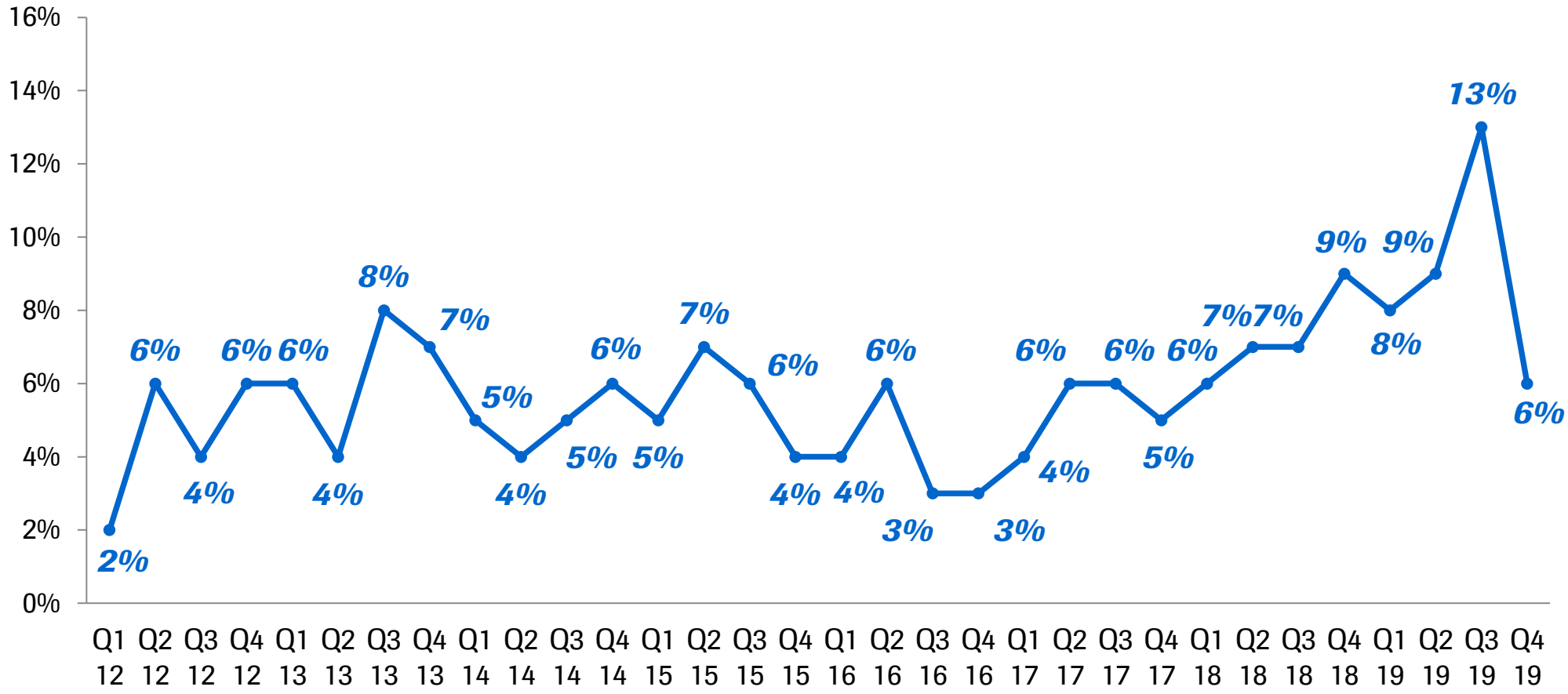
[1] At constant exchange rates (CER); [2] 2019 dividend as proposed by the Board of Directors

2019: Strong sales growth

	2019	2018	Change in %	
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	**48.5**	44.0	**10**	**11**
Diagnostics Division	**12.9**	12.9	**1**	**3**
Roche Group	**61.5**	56.8	**8**	**9**

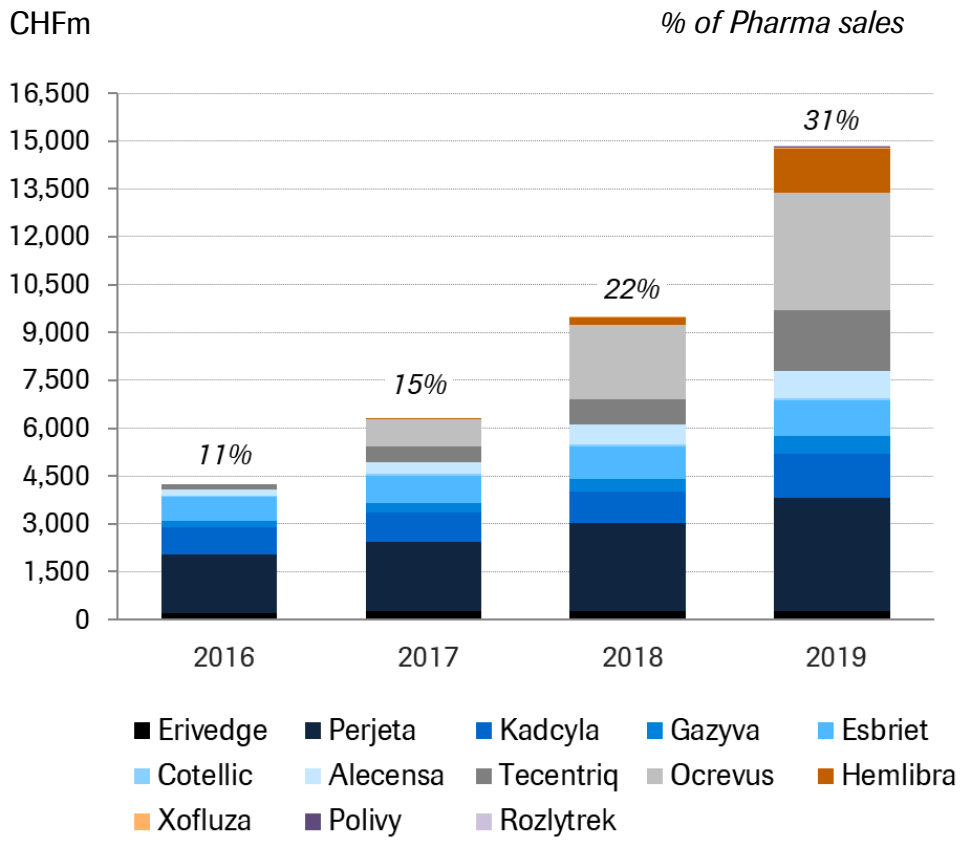
CER=Constant Exchange Rates

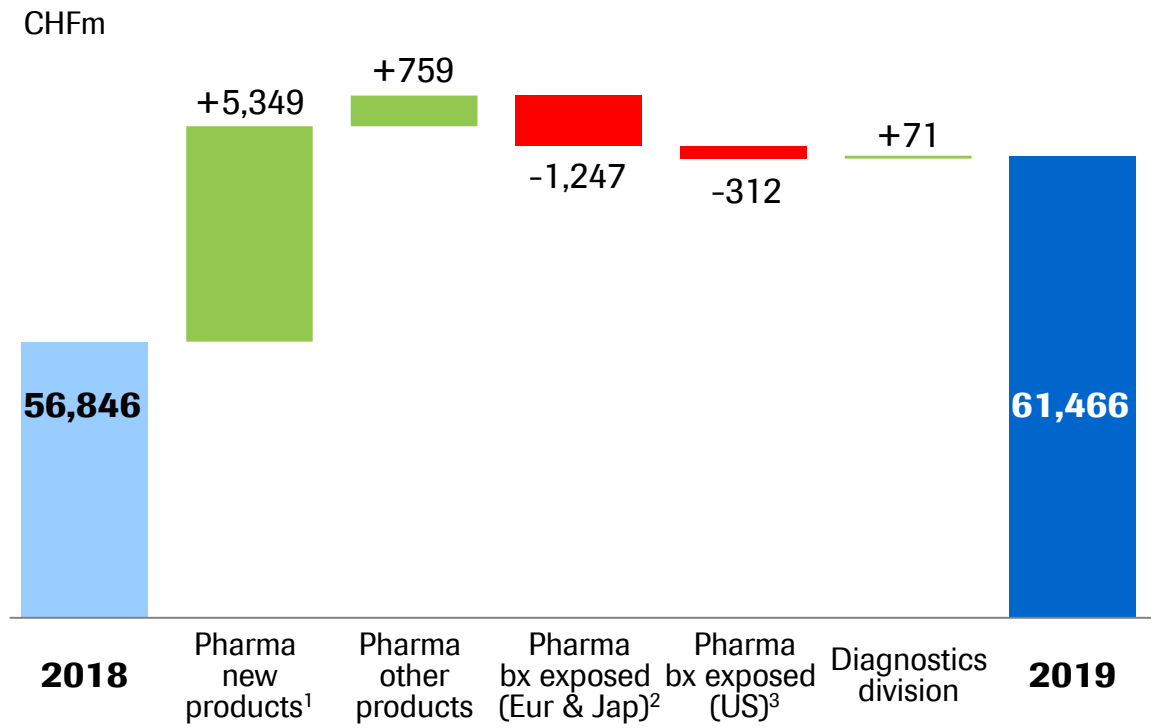
Q4 2019: Group sales growth for the eighth consecutive year



At constant exchange rates (CER)

New products with strong momentum

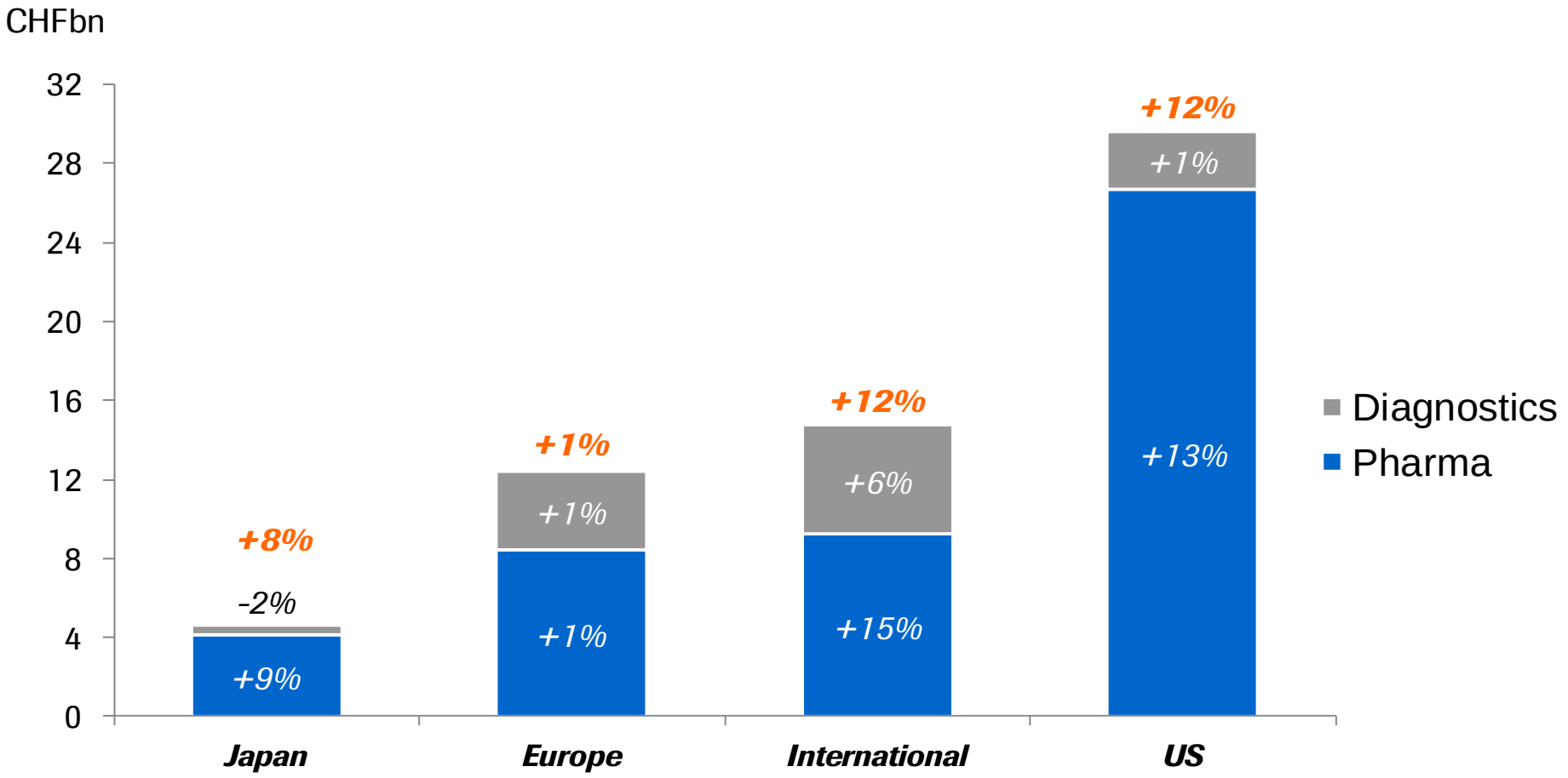




All absolute values are presented in CHFm reported; [1] Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, and Rozlytrek; [2] MabThera and Herceptin in Europe and Japan; [3] Avastin and Herceptin in US Jul-Dec & MabThera/Rituxan in US Nov-Dec

2019: Strong sales growth in US, International and Japan

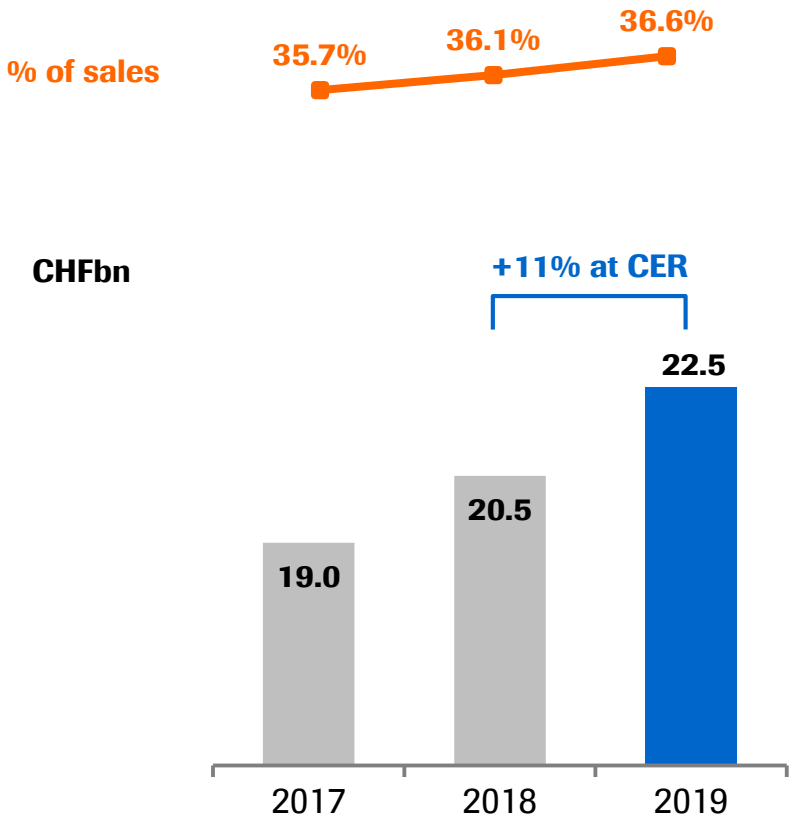
Europe back to growth



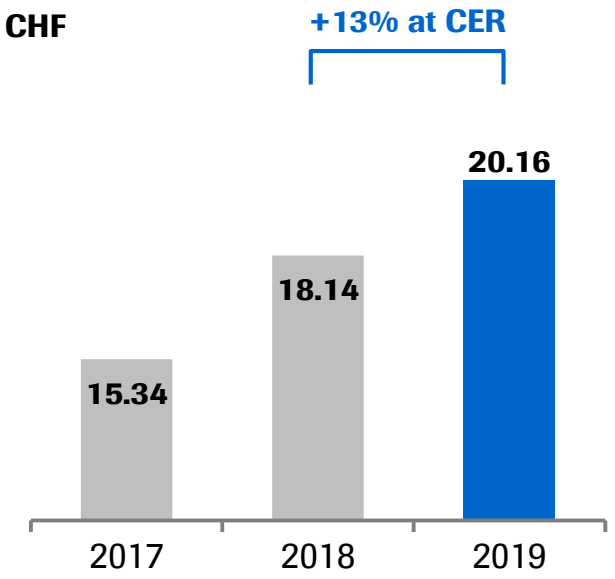
At constant exchange rates (CER)

2019: Strong growth of profitability and cash generation

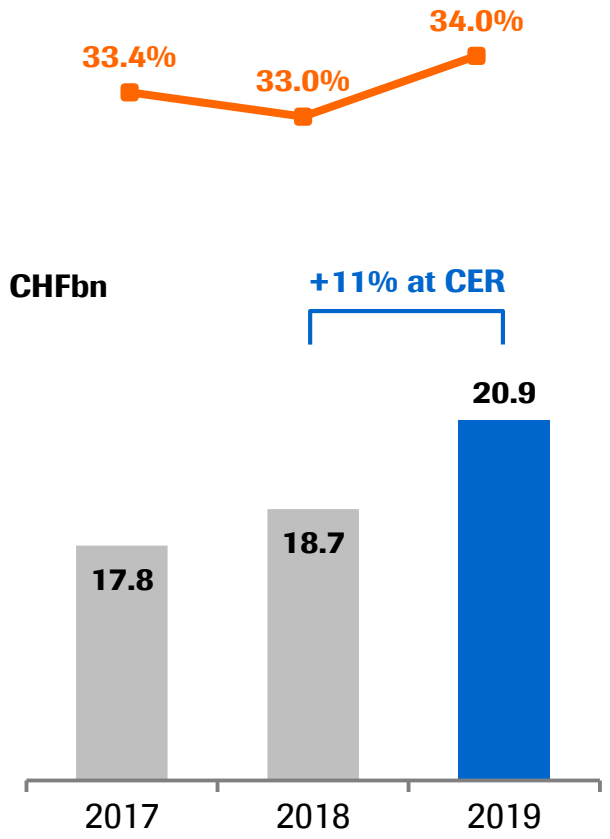
Core operating profit



Core EPS



Operating free cash flow



CER=Constant Exchange Rates

Roche significantly advancing patient care

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

31 *Breakthrough Therapy Designations (BTD)*

Year	Molecule	Indication
2019	**Cotellic**	Histiocytic neoplasms
	Gazyva	Lupus nephritis
	Venclexta + Gazyva	1L unfit CLL
	Kadcyla	Adjuvant HER2+ BC
2018	**SPK-8011**	Hemophilia A
	satralizumab	NMOSD
	Xolair	Food allergies
	Tecentriq + Avastin	1L HCC
	Hemlibra	Hemophilia A non-inhibitors
	Rozlytrek	NTRK+ solid tumors
	balovaptan	Autism spectrum disorders
2017	**Polivy + BR**	R/R DLBCL
	Venclexta + LDAC	1L unfit AML
	Zelboraf	BRAF-mutated ECD
	Rituxan	Pemphigus vulgaris
2016	**SPK-9001**	Hemophilia B
	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	**Luxturna**	RPE65 mutation-associated retinal dystrophy
	Esbriet	IPF
	Lucentis	Diabetic retinopathy
	Tecentriq	Bladder
2013	**Alecensa**	2L ALK+ NSCLC
	Gazyva	1L CLL

3 *Real Time Oncology Reviews (RTOR)*

Year	Device	Intended use
2020	**Tecentriq + Avastin**	1L HCC
2019	**Venclexta + Gazyva**	1L unfit CLL
	Kadcyla	Adjuvant HER2+ BC

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

2019: A year of achievements – unprecedented pipeline progress

Key positive pivotal data

Tecentriq + Avastin	*1L HCC (IMbrave150)*
Tecentriq + chemo	*1L mUC (IMvigor130)*
Tecentriq + Zelboraf + Cotellic	*1L BRAF+ Melanoma (IMspire150)*
Tecentriq (monotherapy)	*1L PDL1+ NSCLC (IMpower 110)*
Herceptin + Perjeta FDC	*HER2+ eBC (FeDeriCa)*
Gazyva + Venclexta	*1L unfit CLL (CLL14)*
risdiplam	*SMA type 2/3 (SUNFISH)*

Advancing 4 molecules into pivotal

Gazyva	*Lupus Nephritis*
GDC-0077 (PI3Ki)	*1L HR+ mBC*
GDC-9545 (SERDi)	*1L HR+ mBC*
tiragolumab (anti-TIGIT)	*1L SCLC*

Key regulatory filings

satralizumab	*NMOSD*
risdiplam	*SMA type 1/2/3*
Gazyva + Venclexta	*1L unfit CLL*
Xofluza	*High-risk influenza*

Key approvals

Rozlytrek	*ROS1+ NSCLC*
Rozlytrek	*NTRK+ pan tumor*
Polivy	*R/R DLBCL*
Tecentriq + chemo	*1L PD-L1+ TNBC*
Tecentriq + chemo	*1L SCLC*
Kadcyla	*Adj. HER2+ BC*
Gazyva + Venclexta	*1L unfit CLL*

Key Diagnostics news flow

Instruments/ Devices	*Launch of cobas pro integrated solutions in the US driving future serum work area growth*
Tests/ Assays	*Significant menu expansion across multiple platforms*
Software	*Launch of NAVIFY Tumor Board V2 and NAVIFY Apps for clinical decision support*

Oncology Neuroscience Infectious Disease

Recent deals and partnerships

Adding new technologies and driving personalized healthcare

Adding new technologies

- Acquisition of Spark Therapeutics
- Pioneer of gene therapy, founded in 2013, as a spin off of the Children's Hospital of Philadelphia
- Know-how and capabilities across full value chain, including R&D and manufacturing

Adding new medicines

- Entered into definitive merger agreement to acquire Promedior
- Ph II trial demonstrated that PRM-151 is the first molecule, when used in combination with current IPF therapies, to show significant clinical benefit over current therapies alone

Adding new diagnostic tests

- Partnership with Illumina
- Broadens patient access to genomic testing and expanding the reach of Foundation Medicine
- Strengthening Roche's sequencing strategy to accelerate clinical research, streamline workflows, and expand assay menus

2019 performance

Outlook

Strong short term news flow

Diversifying the late stage pipeline and setting new standards of care

Product	Timing	
risdiplam in SMA	Filed for Type 1/2/3	✓
satralizumab in NMOSD	Filed	✓
HTT-ASO in Huntington's	Ph II & III ongoing; filing latest 2022	
Gazyva in lupus nephritis	initiating Ph III	
etrolizumab in UC and Crohn's Disease	filing in UC in 2020	
PDS in nAMD	fully recruited; filing in 2020	
faricimab in DME/nAMD	recruitment ahead of plan; filing in 2021	

Neuroscience
Ophthalmology
Immunology
Oncology

Product	Filing date	
Tecentriq in 1L HCC	Filed	✓
Tecentriq in neoadj TNBC	2020	
Tecentriq in adj bladder cancer	2020	✗
Tecentriq in 1L melanoma	2020	
Tecentriq in FL ovarian cancer	2020	
idasanutlin in R/R AML	2020	
Perjeta + Herceptin FDC-SC	Filed	✓
ipatasertib 1/2L TNBC	2020	
ipatasertib 1L+ HR+ (chemo treated only)	2020	
ipatasertib in 1L mCRPC	2020	
Polivy in 1L DLBCL	2020/21	
Tecentriq in (neo)adj NSCLC	2021/22	

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; TNBC=triple-negative breast cancer; FL=front line; R/R AML=relapsed/refractory acute myeloid leukemia; FDC-SC=fixed dose combination subcutaneous; HR=hormone receptor; mCRPC=metastatic castration resistant prostate cancer; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer

2020 outlook
Further growing top and bottom line

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

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Bill Anderson
CEO Roche Pharmaceuticals

2019: Pharmaceuticals Division sales

Strong growth in US, International and Japan

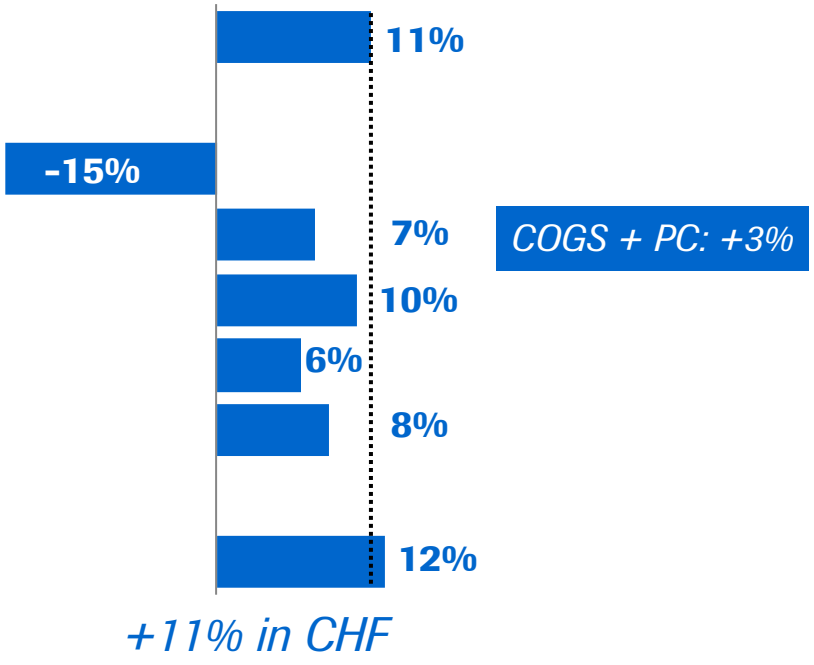
	2019 CHFm	2018 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**48,516**	**43,967**	**10**	**11**
United States	26,711	23,233	15	13
Europe	8,453	8,693	-3	1
Japan	4,143	3,701	12	9
International	9,209	8,340	10	15

CER=Constant Exchange Rates

2019: Pharma core operating profit growth ahead of sales growth

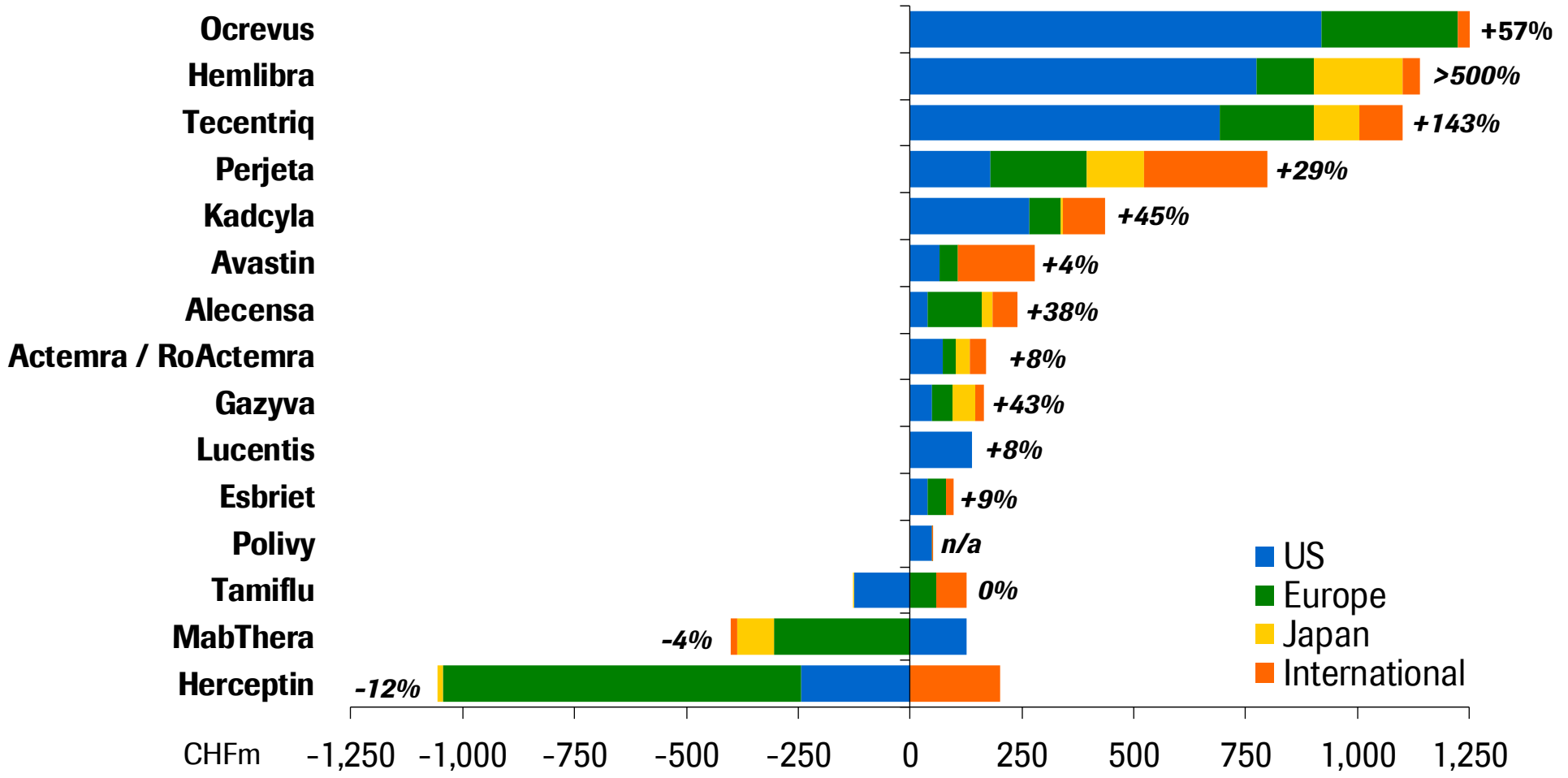
Operational efficiencies compensating for Cabilly patent loss

	2019 CHFm	2019 % sales
Sales	**48,516**	**100**
Royalties & other op. inc.	2,198	4.5
Cost of sales	-10,180	-20.9
M & D	-7,604	-15.7
R & D	-10,228	-21.1
G & A	-1,687	-3.5
Core operating profit	**21,015**	**43.3**



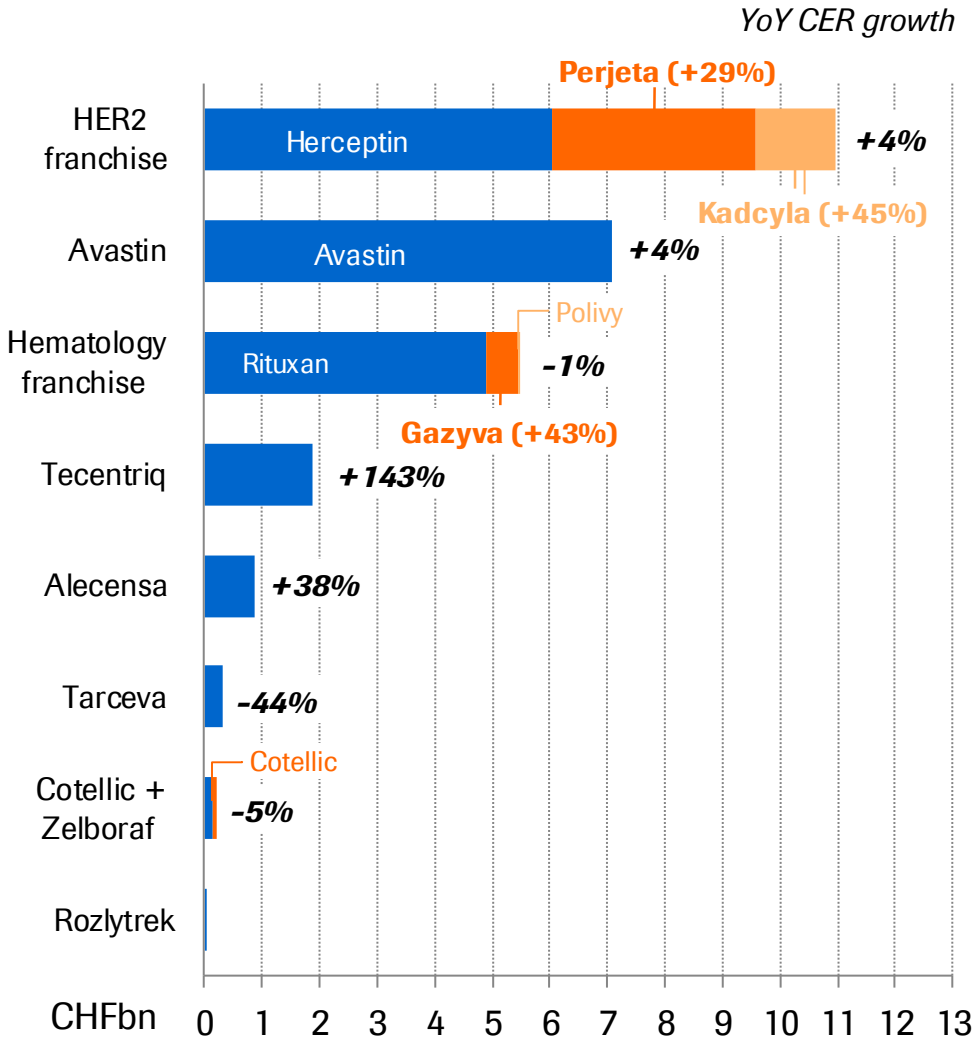
CER=Constant Exchange Rates; COGS=costs of goods sold; PC=period costs

2019: Strong growth driven by new medicines



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

2019: Oncology +6% growth driven by recent approvals



HER2 franchise

- Kadcyla and Perjeta with strong global uptake in adj BC

Avastin franchise

- First biosimilar erosion in US and Japan

Hematology franchise

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

Tecentriq

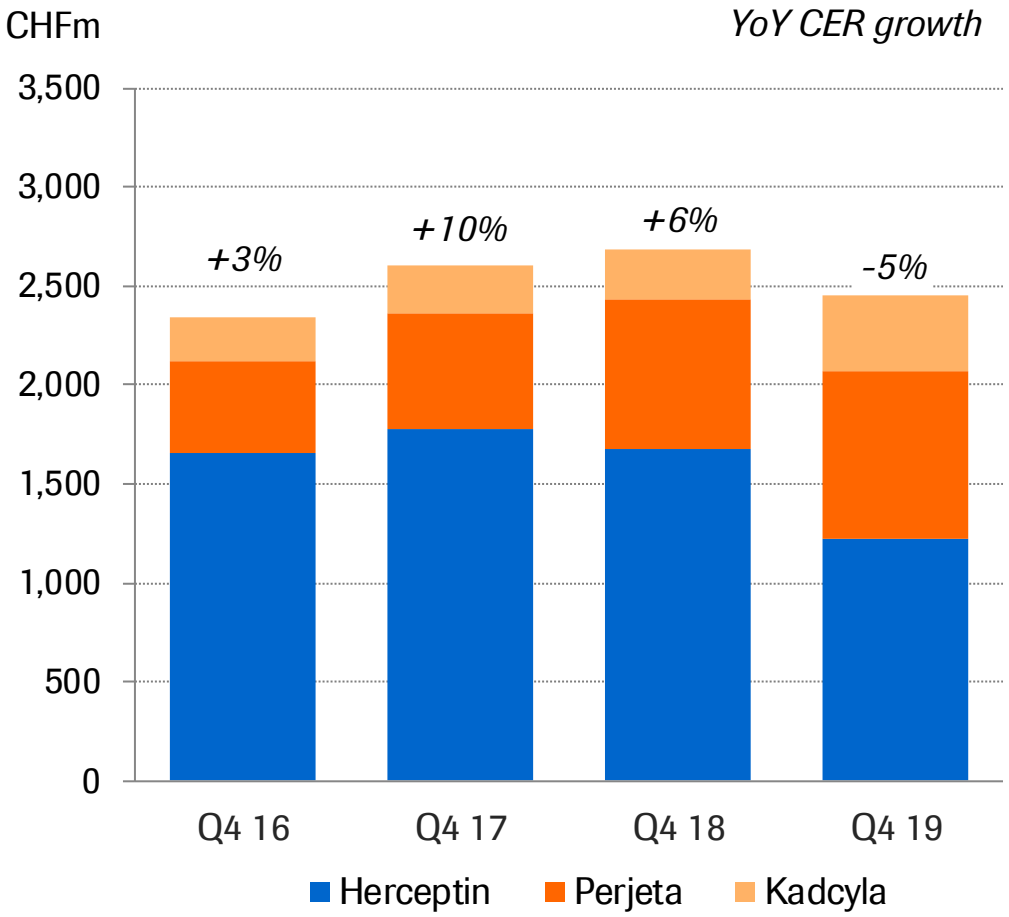
- Growth driven by first-in-class launches in 1L SCLC & 1L TNBC

Alecensa

- Market leader in 1L ALK+ NSCLC; NDRL listing in China

CER=Constant Exchange Rates; 2019 Oncology sales: CHF 27.6bn; CER growth +6%; * Venclexta sales booked by AbbVie and therefore not included; BC=breast cancer; AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; R/R DLBCL=relapsed/refractory diffuse large B cell lymphoma; SCLC=small cell lung cancer; TNBC=triple negative breast cancer; NSCLC=non-small cell lung cancer; NDRL=national drug reimbursement list

HER2 franchise: Perjeta + Kadcyla sales exceeding Herceptin sales



HER2 franchise Q4 update

- Perjeta (+16%): Global growth driven by eBC (APHINITY)
- Kadcyla (+57%): Growth in adjuvant setting for patients with residual disease (KATHERINE); switching as planned
- Herceptin (-24%): Decline due to switching to Kadcyla and biosimilar erosion in the US

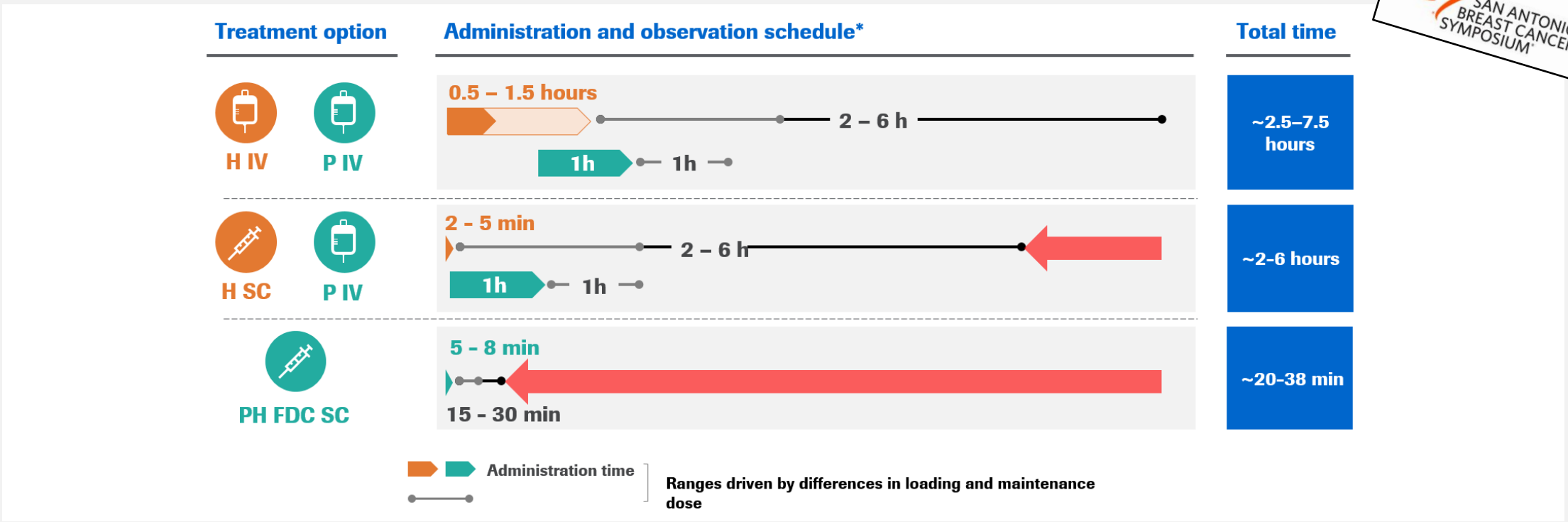
Outlook 2020

- Continued global Perjeta and Kadcyla uptake in eBC including China
- Accelerated Herceptin erosion in the US
- US approval for PH FDC-SC (FeDeriCa)

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

HER2 franchise: PH FDC-SC formulation to cut administration time

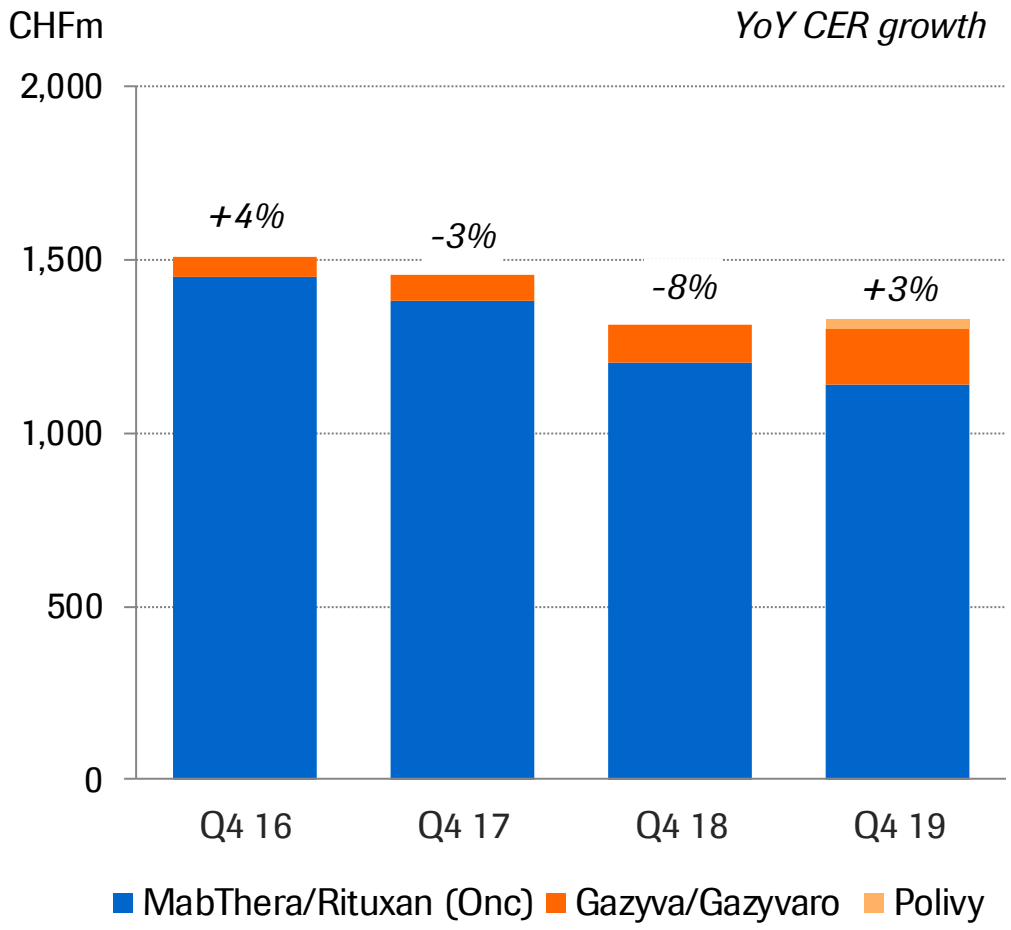
Positive conference feedback on Ph III results



- Positive Ph III (FeDeriCa) results show PH FDC-SC achieves equivalent serum concentrations as IV at cycle 7 in neoadjuvant HER2+ eBC
- P+H FDC-SC administration results in significantly reduced healthcare costs and resource use
- US/EU filed; US launch expected in 2020

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

Hematology franchise: Growth from Venclexta, Gazyva and Polivy



Hematology franchise Q4 update

CD20 franchise

- MabThera/Rituxan (-6%): First biosimilar in the US
- Gazyva (+51%): Growth driven by 1L CLL and 1L FL

Venclexta*

- US: Strong growth driven by 1L unfit AML and 1L CLL

Polivy

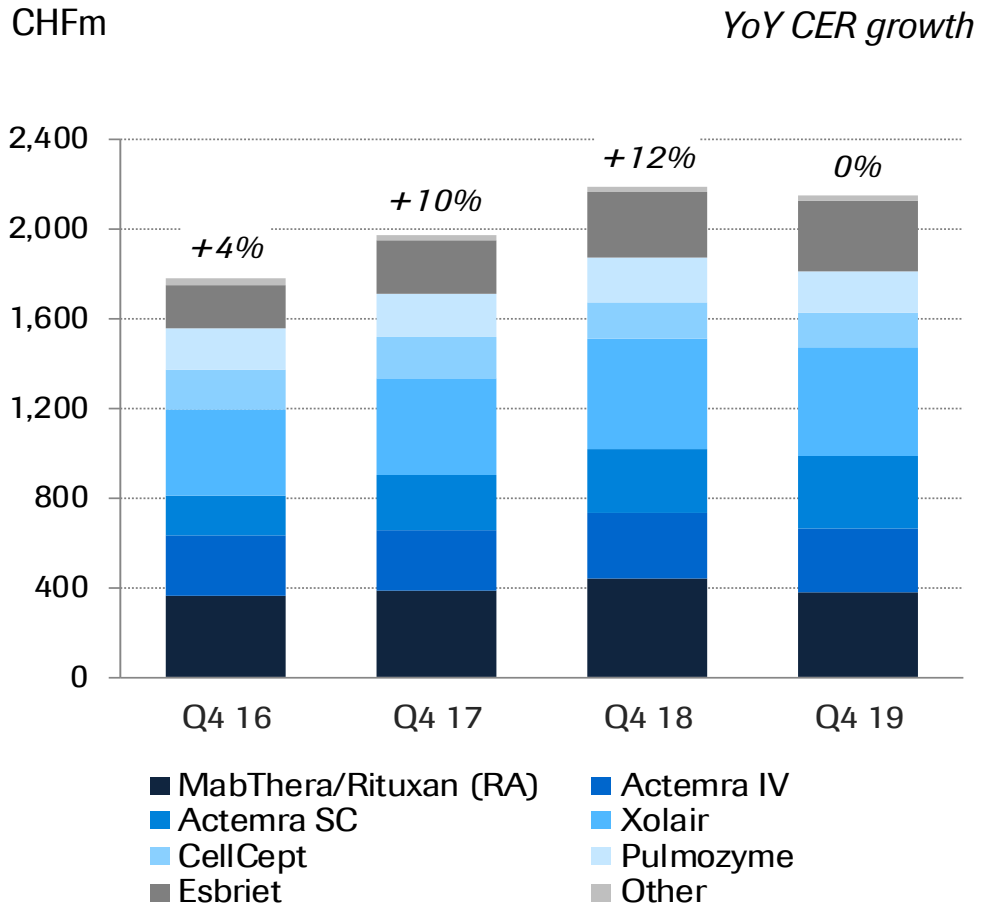
- US: Strong uptake in 3L+ DLBCL and as CAR-T bridging therapy

Outlook 2020

- Strong growth of new products and Rituxan erosion
- Ph III interim results for Venclexta in 1L unfit AML (Viale-A)
- Ph III results for idasanutlin in R/R AML (MIRROS)
- Updates on the CD20 x CD3 program and Polivy combinations

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

Immunology franchise
New pipeline opportunities emerging



Immunology Q4 update

Esbriet (+9%)

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

Actemra (+5%)

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

Xolair (+0%)

- Remains leader in biologics asthma market; Growth in CIU
- Nasal polyps filing accepted; Potential launch in 2020

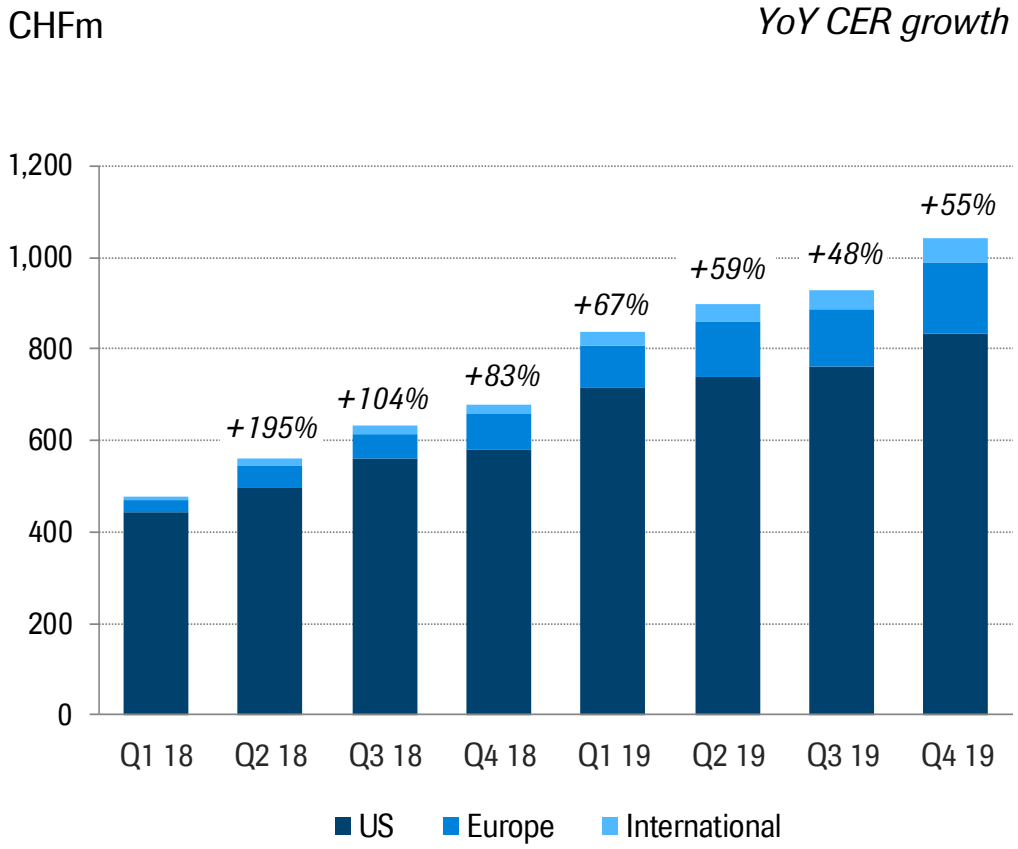
Outlook 2020

- Ph III results for etrolizumab program in UC
- Ph III initiation of Gazyva in lupus nephritis

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

Neuroscience franchise: Ocrevus in MS

Market leadership in US expanded with 20% total patient share[1]



Ocrevus Q4 update

- US driven by continued growth in earlier lines and strong demand from returning patients
- ~40% new and switching patient share
- Strong launches in EU and International

Outlook 2020

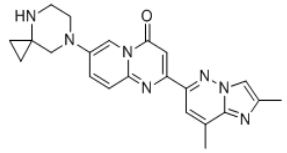
- Moving into earlier lines displacing orals
- Ongoing launches in EU and International

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

Neuroscience franchise: Upcoming NME launches in 2020

Defining new standards of care in SMA and NMOSD

Risdiplam in SMA type 1/2/3

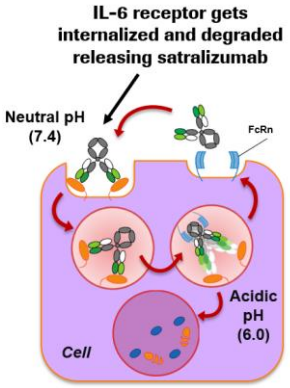


- Oral, systemically available SMN2 splicing modifier
- Durably increases SMN protein both in the CNS and in periphery
- Excellent efficacy

- Positive Ph III (FIREFISH part 2) results in type 1 patients with excellent efficacy/safety profile;
  Data submitted to AAN in April 2020
- US launch for types 1/2/3 expected in 2020;
  Priority review granted, PDUFA date set for May 24

Satralizumab in NMOSD

FDA BTD

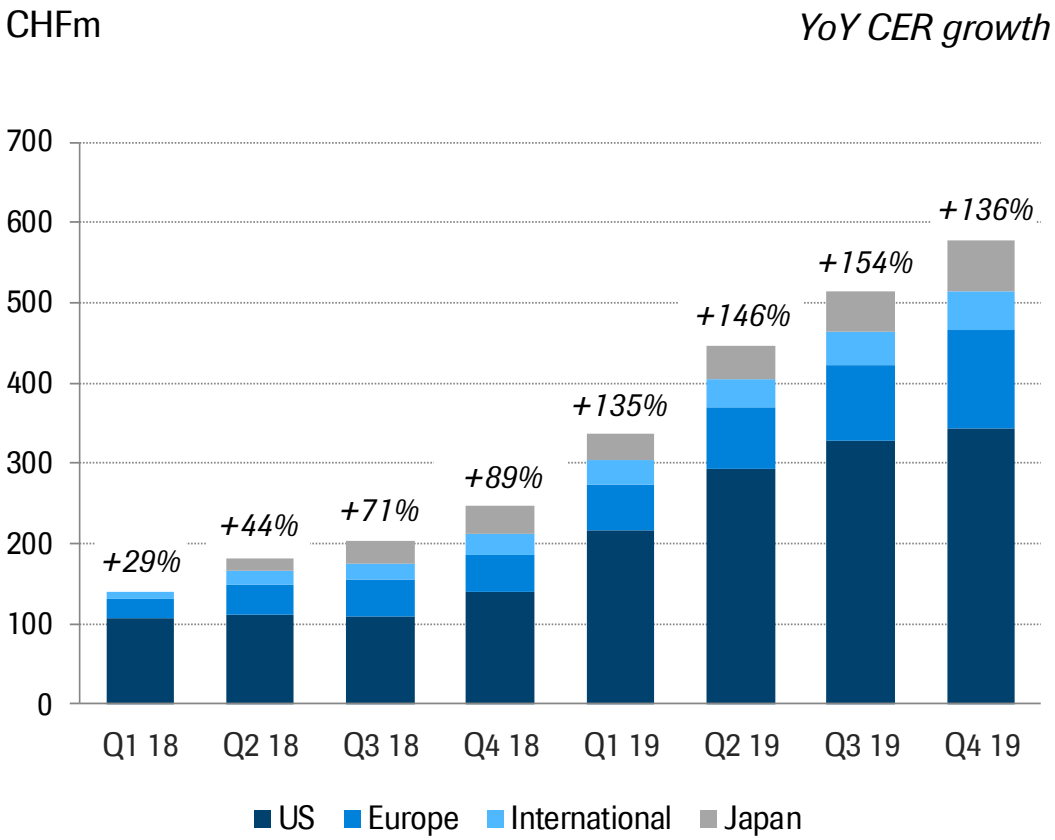


- Recycling mAb with high-affinity to soluble and membrane-bound IL-6R
- Convenient SC Q4W dosing at home
- Well tolerated as monotherapy and in combination with immunosuppressants

- Robust efficacy, sustained for 144 weeks and with reduced risk of relapse across a broad patient population
- Clinically relevant population reflecting real world patients
- US/EU launch expected in 2020

Risdiplam in collaboration with PTC Therapeutics and the SMA Foundation; NME=new molecular entity; SMA=spinal muscular atrophy; NMOSD=neuromyelitis optica spectrum disorder

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



Tecentriq Q4 update

Lung franchise (NSCLC, SCLC)

- US: Growth driven by first-in-class 1L SCLC and 1L NSCLC
- EU: 1L NSCLC & SCLC launches; NPS in 2L NSCLC >30%
- Japan: Strong launch in 1L NSCLC and 1L SCLC

GU franchise (bladder cancer)

- US/EU: Stable shares in approved indications

Breast franchise (TNBC)

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

Outlook 2020

- US/EU/China first-in-class filing/approval in 1L HCC
- First-in-class filing/approval in 1L BRAF+ melanoma
- Ph III results in 1L OC
- First Ph III results of the adjuvant program

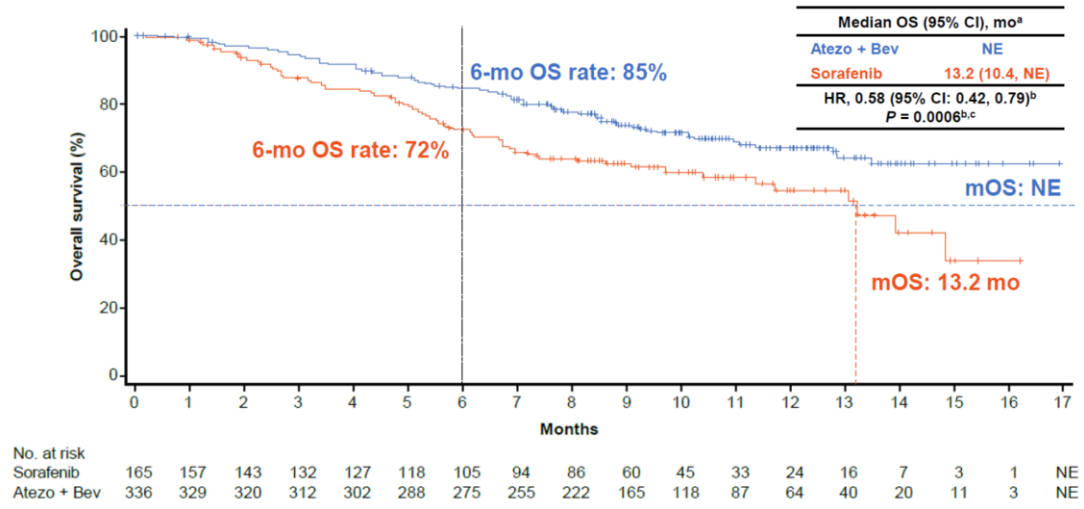
CER=Constant Exchange Rates; SCLC=small cell lung cancer; NSCLC=non small cell lung cancer; NPS=new patient shares; TNBC=triple negative breast cancer; HCC=hepatocellular carcinoma; OC=ovarian cancer

Tecentriq + Avastin in 1L HCC

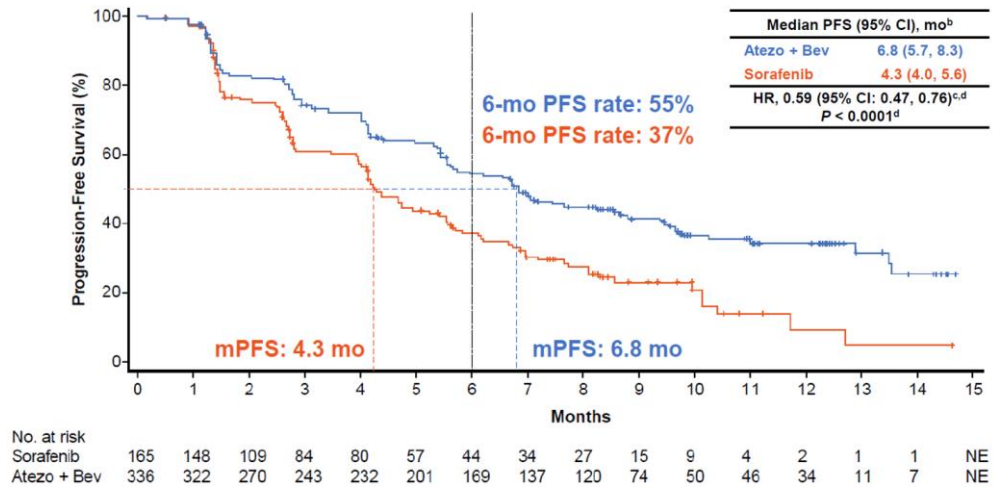
New SOC in HCC; Real-time oncology review granted

Ph III (IMbrave150) results:

Overall Survival (OS)



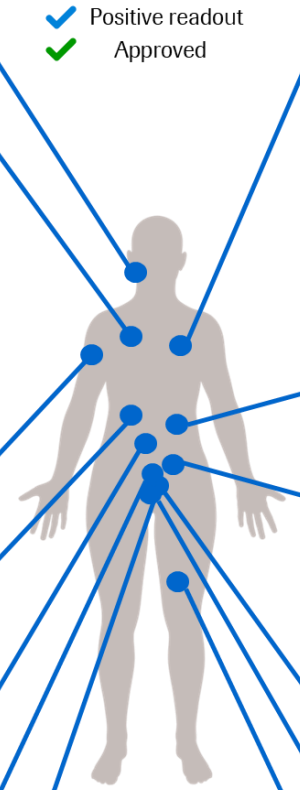
Progression Free Survival (PFS)



- Ph III demonstrated statistically significant improvement of Tecentriq + Avastin vs sorafenib with an OS HR of 0.58 (p=0.0006) and an IRF-assessed PFS HR of 0.59 (p<0.0001); mOS not reached
- US: BTD and RTOR (Real-Time Oncology Review) granted; US launch expected in mid 2020
- EU/China: Filing in 2020

HCC=hepatocellular carcinoma; SOC=standard of care; BTD=break through designation

Ph III Oncology pipeline at record high with >45 trials ongoing…



✓ Positive readout
✓ Approved

Head and neck

Adj SCCHN	Tecentriq+/-chemo	**IMvoke010**

Lung: NSCLC, SCLC

1L non-sq NSCLC	Tecentriq+carbo/pac+/-Avastin	**IMpower150** ✓
1L non-sq NSCLC	Tecentriq+carbo+nab-pac	**IMpower130** ✓
1L sq NSCLC	Tecentriq+carbo+pac/nab-pac	**IMpower131** ✓
1L non-sq NSCLC	Tecentriq+cis/carbo+pem	**IMpower132** ✓
1L Dx+ NSCLC	Tecentriq	**IMpower110** ✓
Adj NSCLC	Tecentriq	**IMpower010**
Neoadj NSCLC	Tecentriq+chemo	**IMpower030**
2L CPI exp NSCLC	Tecentriq+carbozantinib	**CONTACT-01**
1L SCLC	Tecentriq+carbo+etoposide	**IMpower133** ✓
Adj ALK+ NSCLC	Alecensa	**ALINA**
SCLC	Tecentriq+tiragolumab+carbo+etoposide	**SKYSCRAPER-02**

Melanoma

1L BRAFmut	Tecentriq+Cotellic+Zelboraf	**IMspire150** ✓

Renal

1L	Tecentriq+Avastin	**IMmotion151**
2L	Tecentriq+carbozantinib	**CONTACT-03**
Adj	Tecentriq	**IMmotion010**

Colorectal

1L MSI-H	Tecentriq+/-Avastin+chemo	**COMMIT**
Adj MSI-H	Tecentriq+/-chemo	**ATOMIC**

Bladder

1/2L	Tecentriq	**IMvigor210** ✓
1L	Tecentriq+/-gem/plat	**IMvigor130** ✓
NMIBC	Tecentriq+BCG	**ALBAN**
Adj MIBC	Tecentriq	**IMvigor010** ✗

Prostate

1L CRPC	ipatasertib+abiraterone	**IPATential150**

Breast: TNBC; ER+/HER2-; HER2+

1L TNBC	Tecentriq+nab-pac	**IMpassion130** ✓
1L TNBC	Tecentriq+pac	**IMpassion131**
1L TNBC	Tecentriq+gem/carbo or cap	**IMpassion132**
Neoadj TNBC	Tecentriq+nab-pac+AC	**IMpassion031**
Adj TNBC	Tecentriq+pac+AC/EC	**IMpassion030**
Neoadj/adj	Tecentriq+carbo+pac+AC/EC	**GeparDouze**
1L Dx+ TNBC	ipatasertib+paclitaxel	**IPATunity130 C1**
1L TNBC	Tecentriq+ipatasertib+paclitaxel	**IPATunity170**
1L Dx+ HR+/HER2-	ipatasertib+paclitaxel	**IPATunity130 C2**
1L HR+/HER2-	ipatasertib+fulvestrant+palbociclib	**IPATunity150**
1L Dx+ HR+/HER2-	PI3Ki+endocrine therapy+CDKi	**INAVO120**
1L HR+/HER2-	SERD+CDKi	**tba**
Neoadj HER2+	Tecentriq+ddAC+pac+H+P	**IMpassion050**

Hepatocellular

1L	Tecentriq+Avastin	**IMbrave150** ✓
Adj	Tecentriq+Avastin	**IMbrave050**

Ovarian

1L	Avastin/carbo/pac+Tecentriq	**IMaGYN050**
PS recureent OC	Tecentriq+carbo+pac/gem/PLD -> Niraparib+Tecentriq	**ANITA**
PS recurrent OC	Tecentriq+Avastin+carbo+PLD/gem/pac	**ATALANTE**
2/3L PR	Tecentriq+Avastin+PLD/pac	**AGO-OVAR2.29**
2/3L PR	Tecentriq+PLD ± Avastin	**NRG-GY009**

Endometrial

1L	Tecentriq+carbo/pac	**AtTEnd**

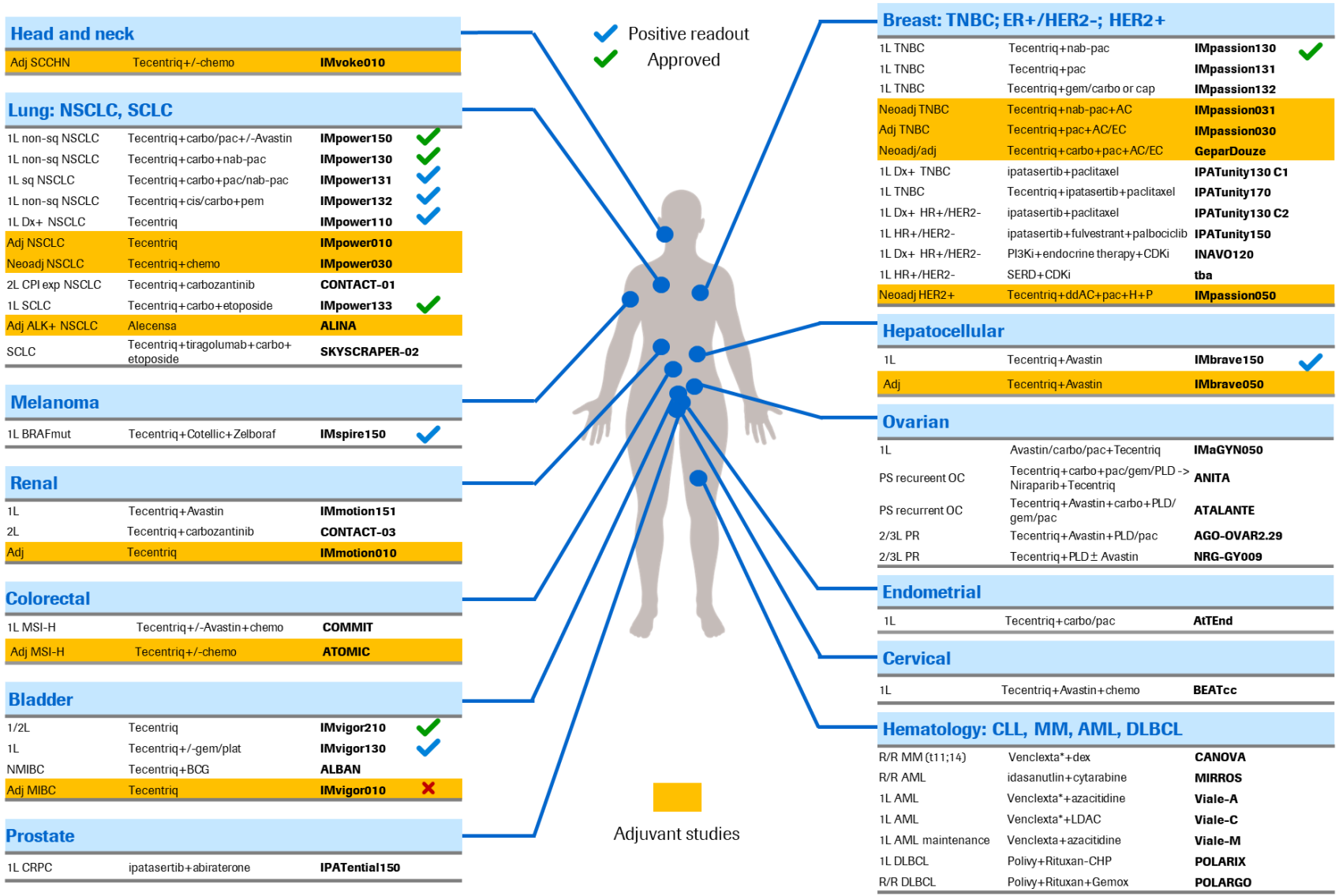
Cervical

1L	Tecentriq+Avastin+chemo	**BEATcc**

Hematology: CLL, MM, AML, DLBCL

R/R MM (t11;14)	Venclexta*+dex	**CANOVA**
R/R AML	idasanutlin+cytarabine	**MIRROS**
1L AML	Venclexta*+azacitidine	**Viale-A**
1L AML	Venclexta*+LDAC	**Viale-C**
1L AML maintenance	Venclexta+azacitidine	**Viale-M**
1L DLBCL	Polivy+Rituxan-CHP	**POLARIX**
R/R DLBCL	Polivy+Rituxan+Gemox	**POLARGO**

… including significant investments in the adjuvant setting and …



Head and neck

Adj SCCHN	Tecentriq+/-chemo	**IMvoke010**

Lung: NSCLC, SCLC

1L non-sq NSCLC	Tecentriq+carbo/pac+/-Avastin	**IMpower150** ✓
1L non-sq NSCLC	Tecentriq+carbo+nab-pac	**IMpower130** ✓
1L sq NSCLC	Tecentriq+carbo+pac/nab-pac	**IMpower131** ✓
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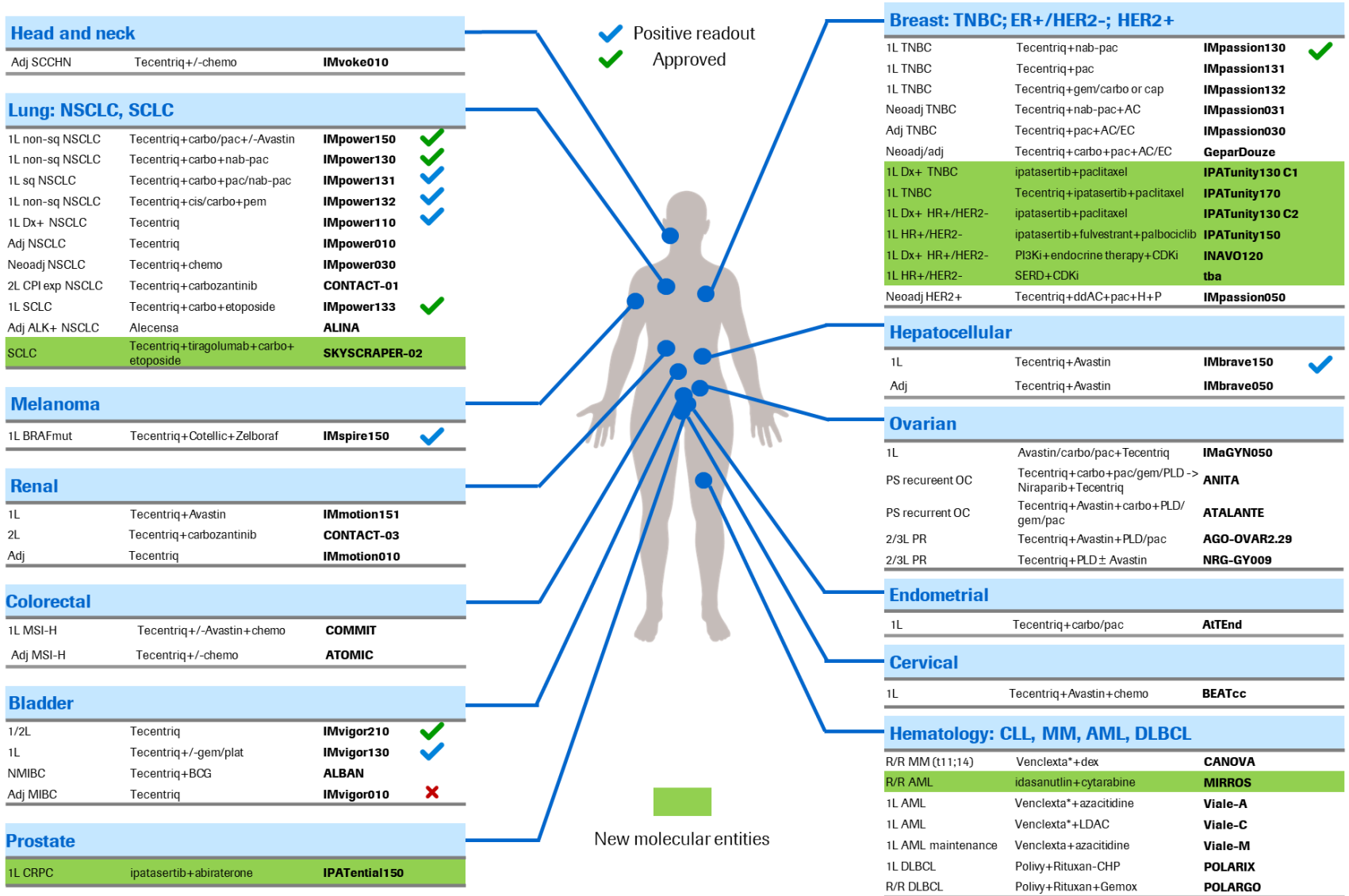
R/R DLBCL	Polivy+Rituxan+Gemox	**POLARGO**

… 5 NMEs (ipatasertib, idasanutlin, SERDi, PI3Ki, tiragolumab)



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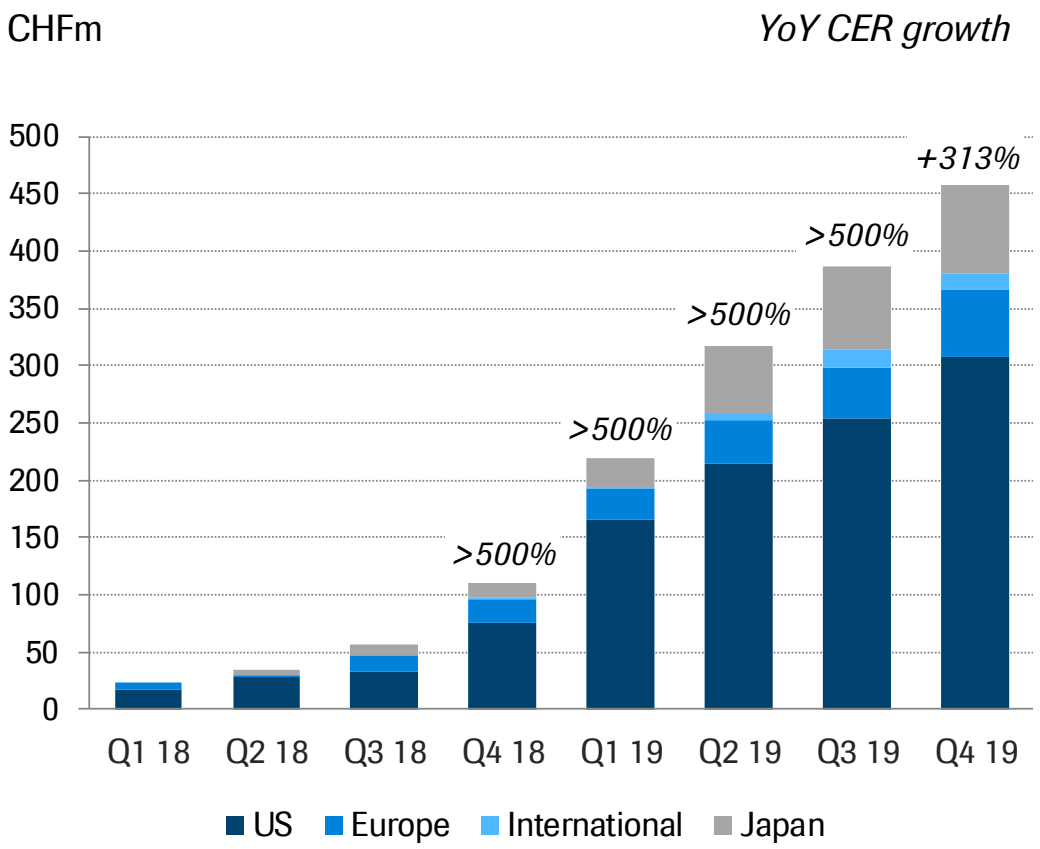
R/R DLBCL	Polivy+Rituxan+Gemox	**POLARGO**

Hemophilia A franchise

Hemlibra with 21% total US patient share after 27 months



Hemlibra Q4 update

- US: Gaining market share in non-inhibitors driven by large centers and patient requests
- EU: Strong non-inhibitor uptake in initial launch countries
- Japan: Strong uptake in non-inhibitors and inhibitors
- Overall >6,000 patients treated globally

Outlook 2020

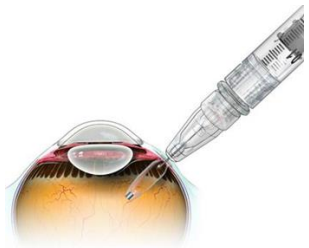
- US: Further uptake in non-inhibitors
- EU: Upcoming non-inhibitor launches in major markets

CER=Constant Exchange Rates

Ophthalmology franchise: Upcoming NME results in 2020

Opportunity to build a global business

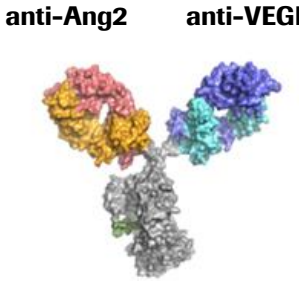
Port Delivery System in nAMD, DME and DR



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

- Ph II: ~80% of AMD patients with ≥6 months time to first refill; Median time to refill at 15 months
- Ph III (PAGODA) in DME using 6m dosing interval started in H2 19
- Ph III (PAVILLION) in DR to start in early 2020
- Ph III (ARCHWAY) results in nAMD using 6m dosing interval expected mid 2020

Faricimab in nAMD, DME and RVO



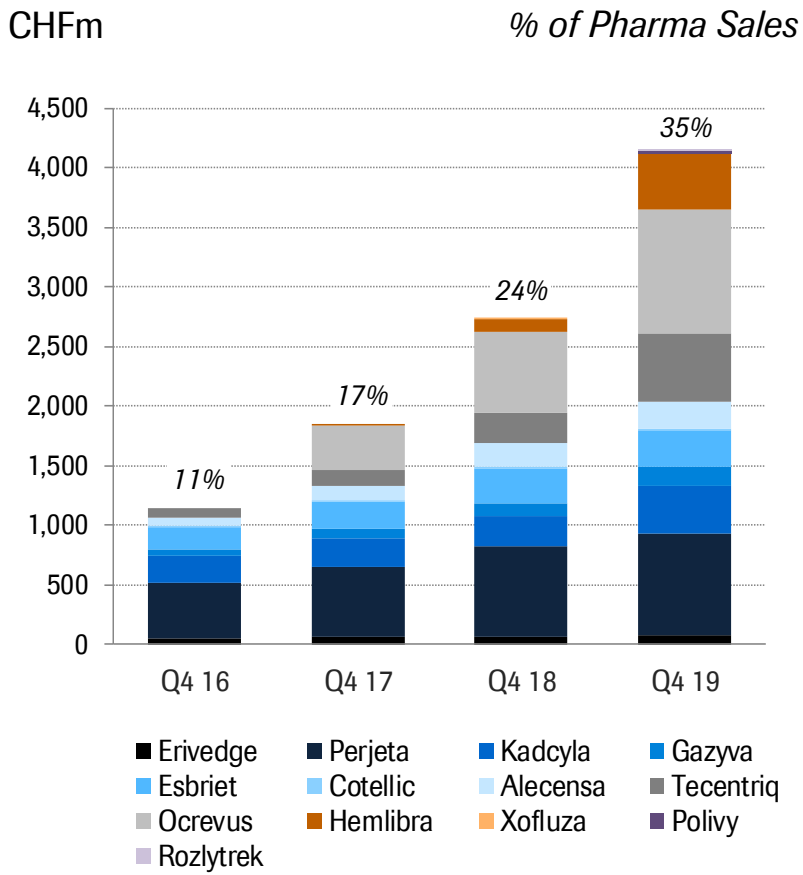
- First bispecific binding simultaneously to VEGF and Ang2 for intravitreal use
- Potentially improved vascular stability and reduced retinal inflammation

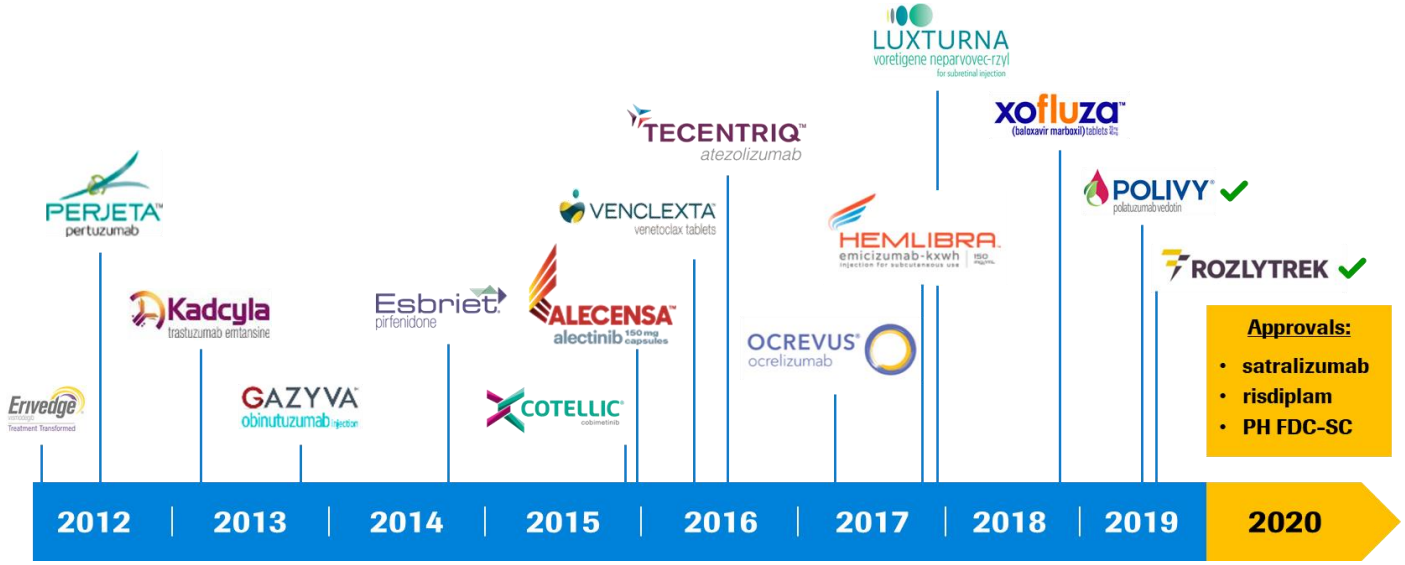
- Ph II (DME): BCVA gains of +13.9 letters, superior by +3.6 letters vs Lucentis at 6m, secondary endpoints including DRSS support superior efficacy
- Ph III (LUCERNE, TENAYA) in nAMD completed enrollment ahead of plan
- Ph III (YOSEMITE, RHINE) results in DME expected in late 2020

NME=new molecular entities; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; DR=diabetic retinopathy; RVO=retinal vein occlusion; RW=real world; Ang2=angiopoetin2; BCVA=best-corrected visual acuity; DRSS=Diabetic Retinopathy Severity Score

New products exceed annualized sales of CHF 16bn*

Up to 3 additional NME approvals expected in 2020





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

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 + Rituxan + chemo	R/R DLBCL	US approval; EU filing	✓
	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/EU approval	✓
	Hemlibra	Non-inhibitors	EU approval	✓
	Tecentriq + Avastin + chemo	1L NSCLC	EU approval	✓
	Venclexta + chemo	1L unfit AML	EU filing	2020+
	Venclexta + Gazyva	1L unfit CLL	US approval; EU filing	✓
	satralizumab	NMOSD	US/EU filing	✓
	risdiplam	SMA type 1/2/3	US filing	✓
Phase III / pivotal readouts	**Tecentriq + Cotellic**	1L BRAFwt Melanoma	Ph III IMspire170	✗
	Tecentriq + Zelboraf + Cotellic	1L BRAF+ Melanoma	Ph III IMspire150 (TRILOGY)	✓
	Tecentriq	Adjuvant PDL1+ mUBC	Ph III Imvigor010	✗
	Tecentriq + chemo	Neoadjuvant TNBC	Ph III IMpassion031	IA passed
	Tecentriq + Avastin	1L HCC	Ph III IMbrave150	✓
	Venclexta + Gazyva	1L unfit CLL	Ph III CLL14	✓
	idasanutlin + chemo	R/R AML	Ph III MIRROS	2020
	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
- **Rozlytrek**: Japan early approval for NTRK+ solid tumors
- **Gazyva**: Positive Ph II results in lupus nephritis
- **Xolair**: US filing in nasal polyps
- **Tecentriq**: US/EU filing in 1L PDL1+ NSCLC
- **satralizumab:** Positive Ph III (SAkuraStar) in NMOSD
- **PH FDC SC**: US filing in HER2+ eBC
- **Rituxan:** US approval in GPA and MPA for pediatrics
- **Tecentriq+chemo**: Positive Ph III (Imvigor130) in 1L mUC

*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

2020: Key late-stage news flow*

	Compound	Indication	Milestone	
Regulatory	**Rozlytrek**	NTRK pan tumor; ROS1+ NSCLC	EU approval	
	Venclexta + Gazyva	1L unfit CLL	EU approval	
	Polivy + Rituxan +chemo	R/R DLBCL	EU approval	✔
	risdiplam	SMA type 1/2/3	US approval; EU filing	
	satralizumab	NMOSD	US/EU approval	
	Xolair	Nasal polyps	US approval	
	Zelboraf + Cotellic + Tecentriq	1L BRAF+ Melanoma	US approval	
	Tecentriq + Avastin	1L HCC	US approval; EU filing	
	Tecentriq	1L PDL1+ NSCLC	US/EU approval	
	PH FDC SC	HER2+ breast cancer	US approval; EU filing	
Phase III / pivotal readouts	**idasanutlin + chemo**	R/R AML	Ph III MIRROS	
	risdiplam	SMA type 1	Ph II/III FIREFISH (part 2)	✔
	Tecentriq + Avastin	1L OC	Ph III IMagyn050	
	Tecentriq + chemo	Neoadjuvant TNBC	Ph III IMpassion031	
	Venclexta + azacitidine	1L unfit AML	Ph III Viale A	
	ipatasertib + chemo	Dx+ HR+ breast cancer	Ph III IPATunity130	
	ipatasertib + chemo	Dx+ 1L TNBC	Ph III IPATunity130	
	ipatasertib + abiraterone	1L mCRPC	Ph III IPATential150	
	PDS	nAMD	Ph III Archway	
	faricimab	DME	Ph III YOSEMITE/RHINE	
	etrolizumab	Ulcerative Colitis	Ph III HIBISCUS/LAUREL/HICKORY/GARDENIA	
	balovaptan	Autism spectrum disorders	Ph III V1aduct	

Virtual Event *SMA Europe*	*Virtual Event* *gRED*	*Virtual Event* *AAN*	*Virtual Event* *Digitalisation*	*Roche Pharma Day*
Thursday, 6 February 15:00 to 16:00 CEST	**Tuesday, 18 February 15:30 to 17:00 CEST**	**Monday, 4 May 15:00 to 16:30 CEST**	**Thursday, 7 May 15:00 to 16:30 CEST**	**Monday, 14 September live event**

* Outcome studies are event-driven: timelines may change

Diagnostics Division

Thomas Schinecker
CEO Roche Diagnostics

2019: Diagnostics Division sales

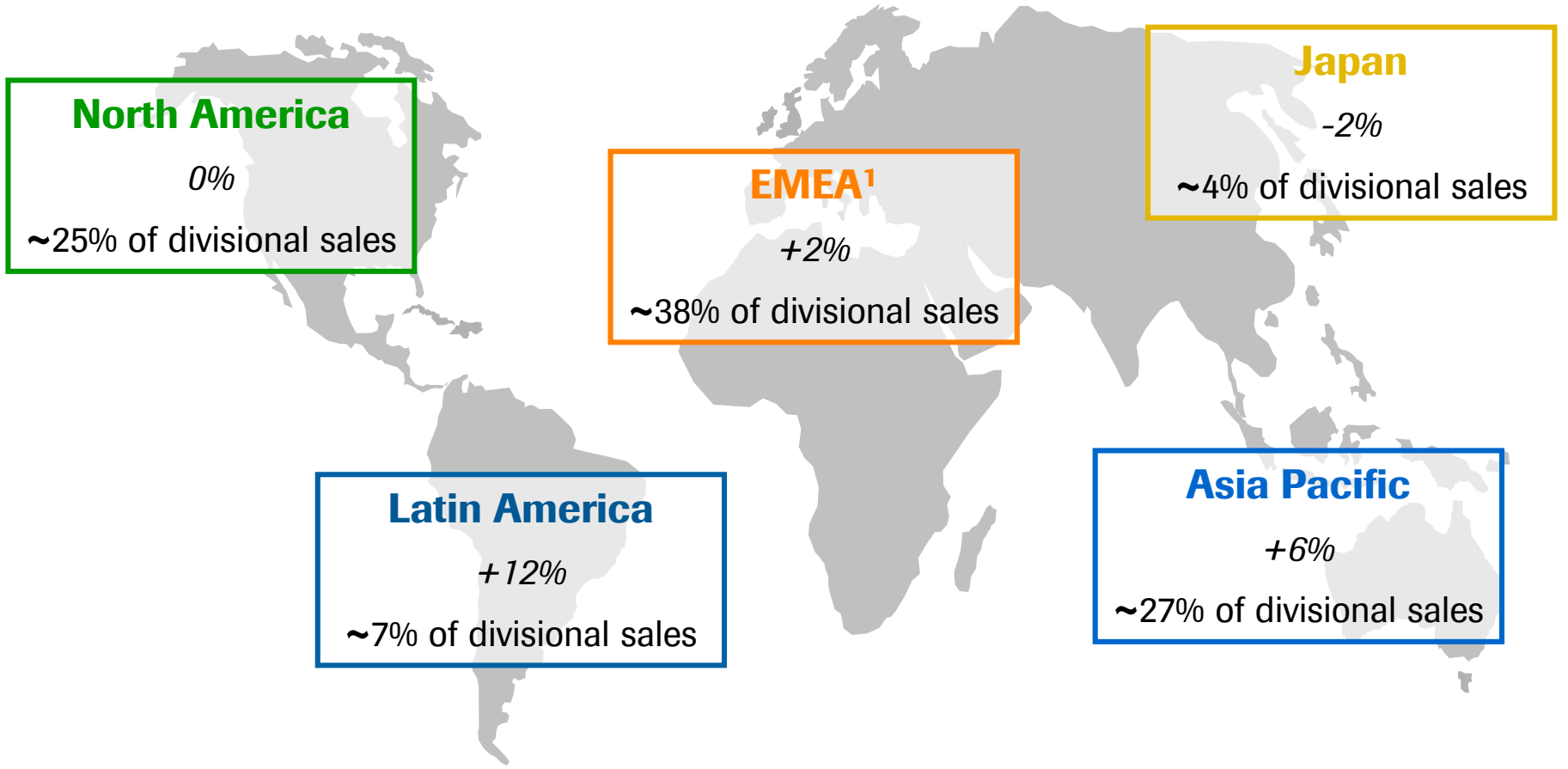
Growth driven by Centralised and Point of Care Solutions and Molecular Diagnostics

	2019 CHFm	2018 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**12,950**	**12,879**	**1**	**3**
Centralised and Point of Care Solutions	7,819	7,768	1	3
Molecular Diagnostics	2,109	2,019	4	6
Diabetes Care	1,918	1,980	-3	1
Tissue Diagnostics	1,104	1,112	-1	0

CER=Constant Exchange Rates; underlying growth of Molecular Diagnostics excluding sequencing business: +6%

2019: Diagnostics Division regional sales

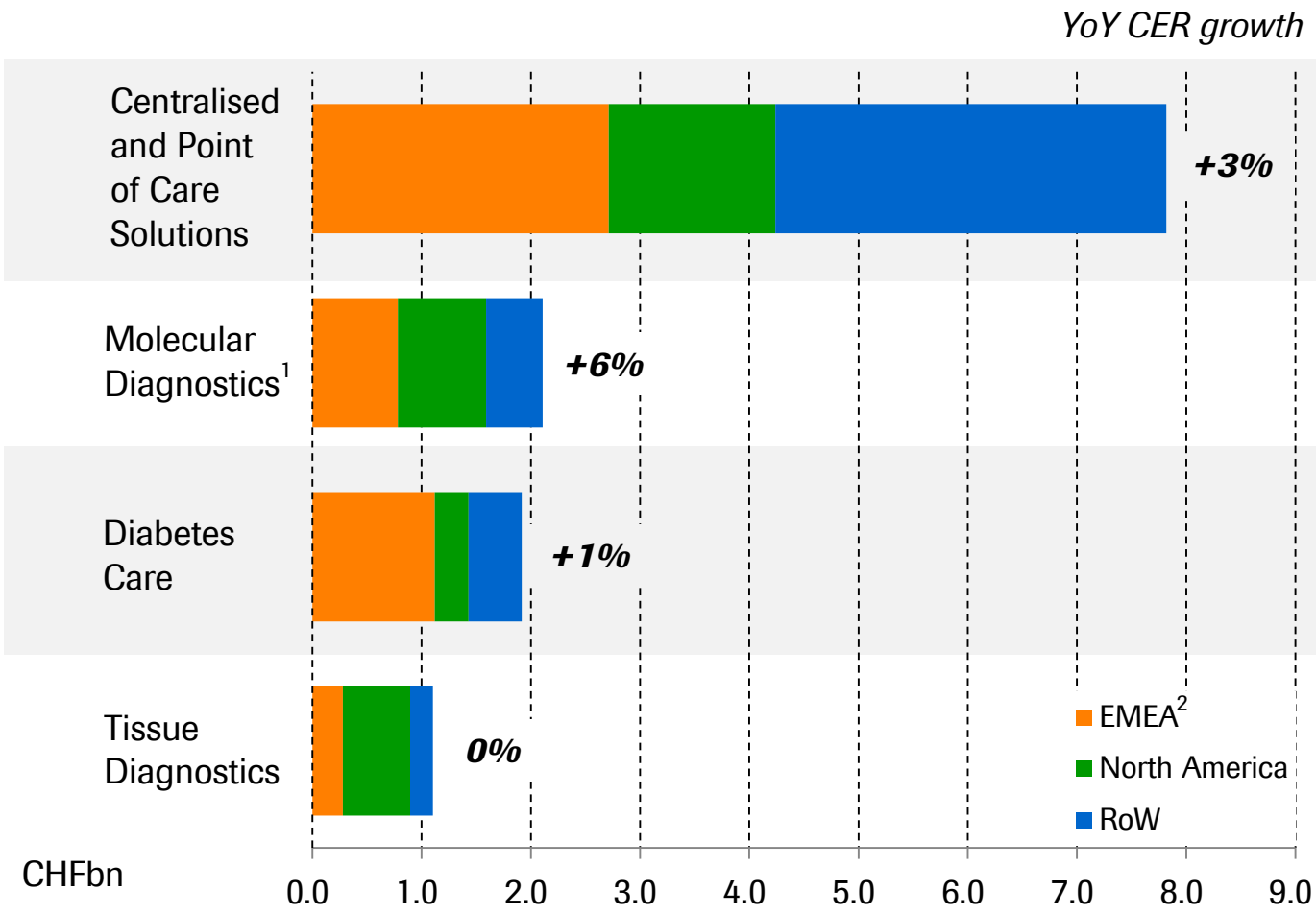
Growth driven by Asia Pacific and Latin America



+7% 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)

2019: Diagnostics Division highlights
Growth driven by immunodiagnostics



- Immunodiagnostics (+6%; reagents +8%)
- Decline in coagulation monitoring

- Blood screening (+7%); Point of Care molecular diagnostics (+35%)

- Glucose monitoring[3] (+1%); Insulin delivery systems (-1%)

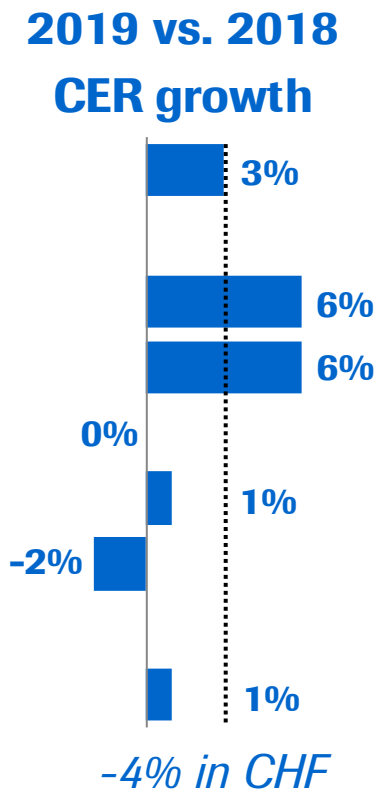
- Primary staining (+3%)
- Advanced staining (+1%; reagents +5%)
- BenchMark and Discovery Ultra shipment delays

[1] Underlying growth of Molecular Diagnostics excluding sequencing business: +6%; [2] EMEA=Europe, Middle East and Africa; [3] Glucose monitoring=Blood glucose monitoring and continuous glucose monitoring; CER=Constant Exchange Rates

2019: Diagnostics Division

Core operating profit growing at +1%

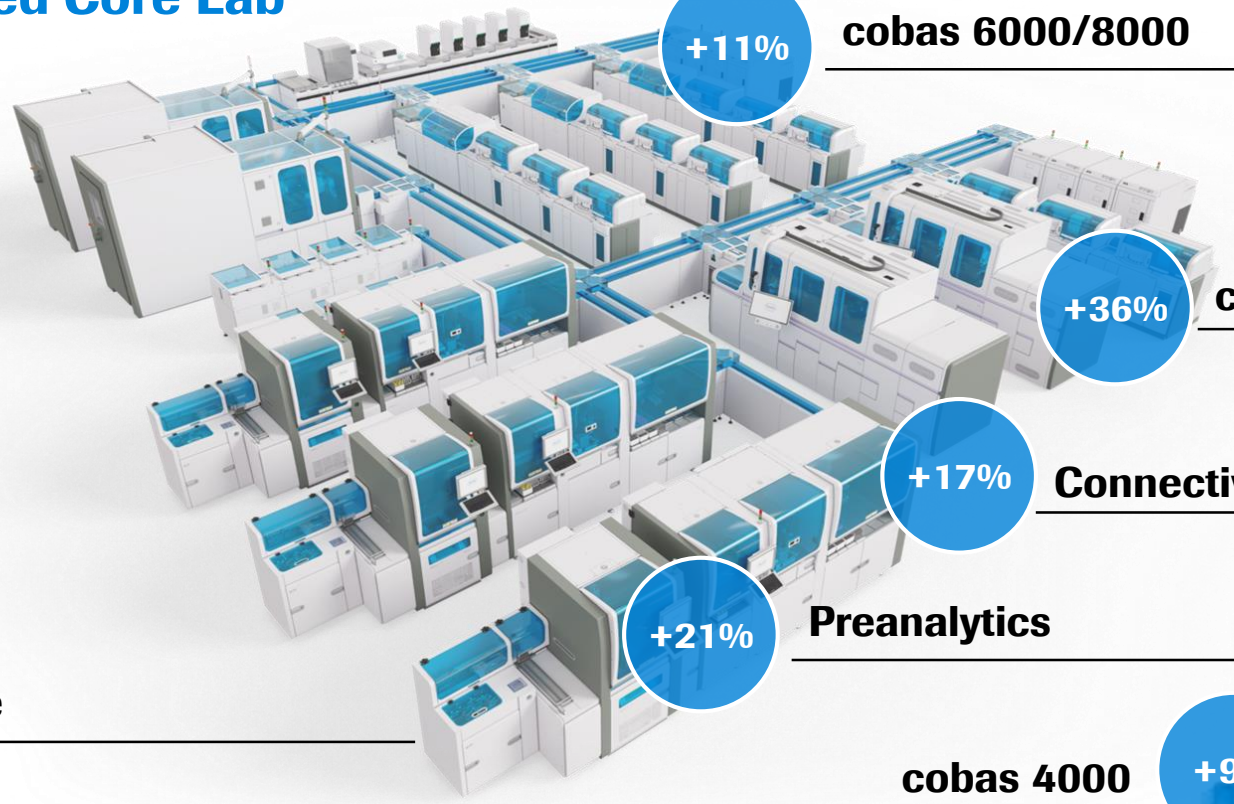
	2019 CHFm	2019 % sales
Sales	**12,950**	**100**
Royalties & other op. inc.	87	0.7
Cost of sales	-6,183	-47.8
M & D	-2,909	-22.5
R & D	-1,468	-11.3
G & A	-511	-3.9
Core operating profit	**1,966**	**15.2**



CER=Constant Exchange Rates

Growing installed base worldwide driving reagents consumption

Integrated Core Lab



+11% cobas 6000/8000

+36% cobas 6800/8800

+17% Connectivity

+21% Preanalytics

+21% Middleware

cobas 4000 +9%

2019 Growth

Growth rates being from the period of January 1, 2019 to December 31, 2019

Further expanding the industry-leading reagent menu

Investing in innovative biomarkers, algorithms & claim extensions

Disease area	Infectious Diseases	Oncology	Women's Health	Cardiology	Critical Care	Others
Diseases/ Indications	• Antimicrobial resistance • Syndromic panels • Sexually transmitted infections • Hepatitis • Arbovirus • Transplant	• Prostate • Breast • Liver • Cervical • PD-L1 • Multiplex tissue imaging	• Polycystic ovarian syndrome • Endometriosis • Non-invasive prenatal testing	• Atrial fibrillation ischemic stroke • Heart failure • Coronary artery disease	• Sepsis • Traumatic brain injury • Acute kidney injury & chronic kidney disease	• Alzheimer's • Parkinson's • Hypertension • Skeletal muscle disease

Elecsys® HIV Duo launch in China

Completing the infectious diseases menu

cobas e801

Elecsys® HIV Duo tests for HIV antigens & antibodies in one test:

- Reducing complexity of testing compared to most other 4th generation HIV screening tests
- Discriminating acute infection from chronic infection
- Not offered by local players in China

Strong growth of Blood Screening driven by tender wins and portfolio expansion

2019 tender wins

- Austria ★ *Red Cross Vienna*
- Belgium ★ *Croix -Rouge Namur*
- Colombia ★ *Fundacion Hematologica*
- Germany ★ *Red Cross Springe & Munich*
- Greece ★ *National Blood Center (EKEA)*
- Hungary *Red Cross*
- Serbia *Blood Transfusion Inst. of Serbia*
- Thailand *Red Cross*
- Turkey ★ *Red Crescent*
- Ukraine *Biopharma*

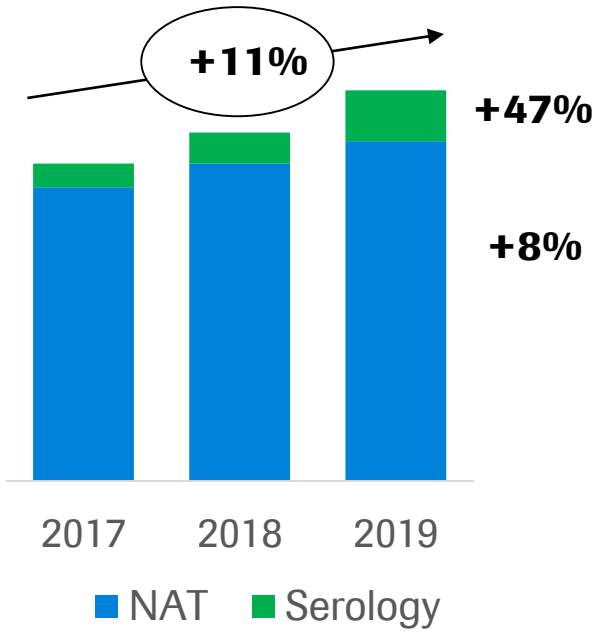
★ Win from competition

2019 portfolio launches

- cobas Zika (CE)
- cobas pro LCP1 (CE)
- cobas Babesia (CE and US)
- Cadaveric claim extension

Blood screening sales growth

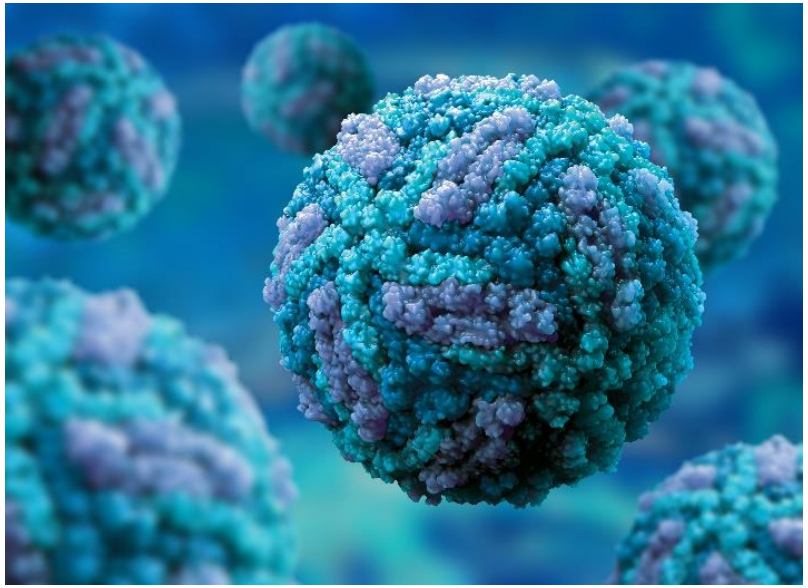
Sales in CHF CER, growth rates shown are CAGRs



CER=Constant Exchange Rates; NAT=nucleic acid testing

cobas® Zika CE-IVD test launches on cobas® 6800/8800 Systems

Expands emergency preparedness in blood screening



Zika virus illustration

- Important milestone in effort to protect blood supply from Zika virus globally
- Helps preserve blood safety in regions with local outbreaks and from donors exposed while traveling to affected areas
- Expands emergency preparedness solution for customers and minimizes risk of transmission through infected blood and plasma donations

COVID-19[1] response
Launch of LightCycler® Modular SARS-CoV-2 assays

MagNA Pure 24

LightCycler 480 Instrument

- TIB MOLBIOL LightMix® Modular assays for screening and confirmation
  - E-gene[2] assay used to detect SARS and SARS-CoV-2
  - RdRP assay specific for the detection of SARS-CoV-2
  - N-gene[3] assay detects presence of SARS-CoV-2 as well as other SARS-related viruses
- Research use only
- Roche is actively monitoring the situation and committed to support

[1] Coronavirus disease - viral pneumonia that can be severe in immunocompromised/elderly individuals; [2] E-gene encodes the Envelope protein; [3] N-gene encodes the Nucleocapsid; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; SARS=severe acute respiratory syndrome; RdRP=RNA-dependent RNA polymerase

CE mark for Accu-Chek® SugarView app*

Broadens access to diabetes management solutions

- First app that determines blood glucose ranges by using the Accu-Chek Active test strip in combination with a smartphone camera
- Bypasses the additional need for a blood glucose meter
- Designed to help non-insulin-dependent people with type 2 diabetes or pre-diabetes live healthier lives
- Provides decision and treatment support in-between doctors' visits
- Critical in low- and middle-income countries that often have limited access to care and scarce healthcare resources

* currently available for Android

Key launches 2019

	Area	Product	Description	Market[1]
Instruments/ Devices	**Workflow**	cobas prime	Pre-analytical platform to support cobas 6800/8800 Systems	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 detection assay utilizing Smarticles technology to aid in the 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 in 2020

Key launches 2020

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

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

Finance

Alan Hippe
Chief Financial Officer

2019 results

Focus on Cash

Outlook

2019: Highlights

Business

- Sales growth of +9%[1] despite biosimilars impact of CHF -1.5bn[1]
- Core operating profit up +11%[1] and Core EPS growth of +13%[1]
- Dividend[2] in Swiss francs further increased

Cash flow

- Significant cash generation (Operating Free Cash Flow of CHF 20.9bn, +11%[1])
- Net debt lower by CHF 3.1bn vs. YE 2018 as Free Cash Flow of CHF 16.8bn more than offsets dividends paid (CHF -7.7bn) and cash outflow for M&A (CHF -4.8bn)
- Gross debt reduced from CHF 18.8bn to CHF 14.4bn

Net financial result

- Core net financial expenses increased by +52%[1] driven by early bond redemption and lower income from equity securities

IFRS

- Net income +32%[1] driven by the operating results and lower impairments of intangible assets & goodwill

[1] At Constant Exchange Rates (CER); [2] based on 2019 dividend as proposed by the Board of Directors

2019: Group performance

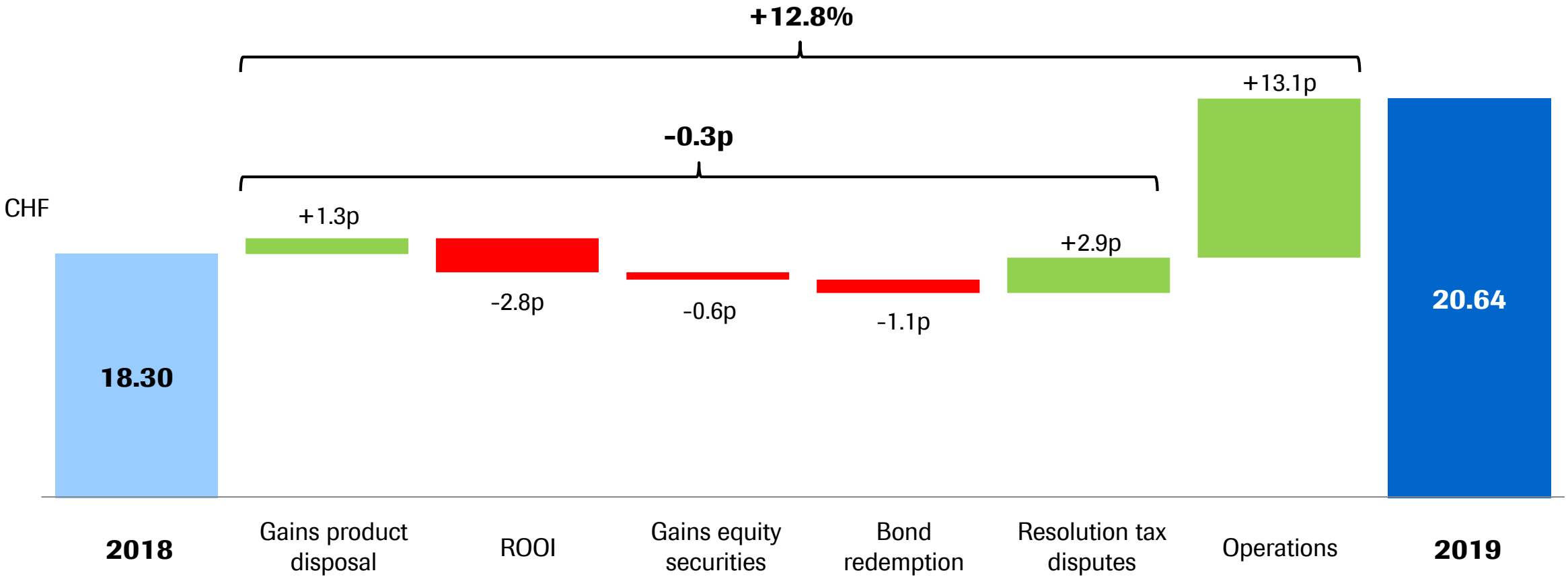
Core Operating profit up +11% & Core EPS growth of +13%

	2019 CHFm	2018 CHFm	Change in % CHF	Change in % CER
Sales	**61,466**	**56,846**	**8**	**9**
Core operating profit	**22,479**	**20,505**	**10**	**11**
as % of sales	*36.6*	*36.1*		
Core net income	**18,062**	**15,981**	**13**	**14**
as % of sales	*29.4*	*28.1*		
Core EPS (CHF)	**20.16**	**18.14**	**11**	**13**
IFRS net income	**14,108**	**10,865**	**30**	**32**
Operating free cash flow	**20,921**	**18,741**	**12**	**11**
as % of sales	*34.0*	*33.0*		
Free cash flow	**16,764**	**14,811**	**13**	**12**
as % of sales	*27.3*	*26.1*		

CER=Constant Exchange Rates

2019: Core EPS development

Operations growth is main driver for Core EPS growth, significantly outpacing lower royalty income

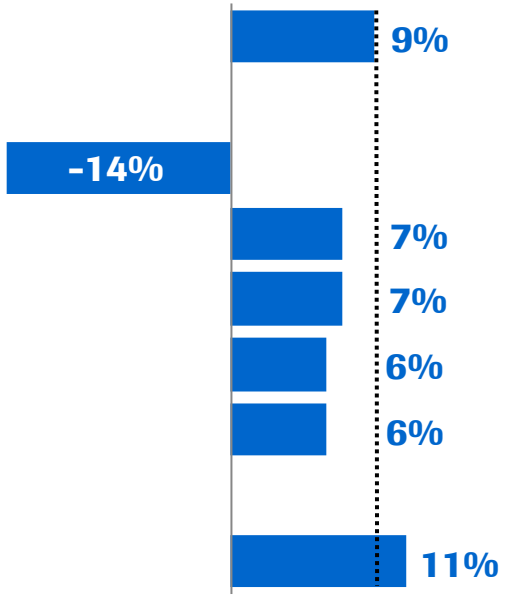


All at constant exchange rates (CER); ROOI=Royalties and other operating income excl. gains on product disposals

2019: Group operating performance

Core operating profit growth ahead of sales growth

	2019 CHFm	2019 abs. CER
Sales	**61,466**	**5,083**
Royalties & other op. inc.	2,285	-375
Cost of sales	-16,363	-1,050
M & D	-10,513	-674
R & D	-11,696	-633
G & A	-2,700	-151
Core operating profit	**22,479**	**2,201**

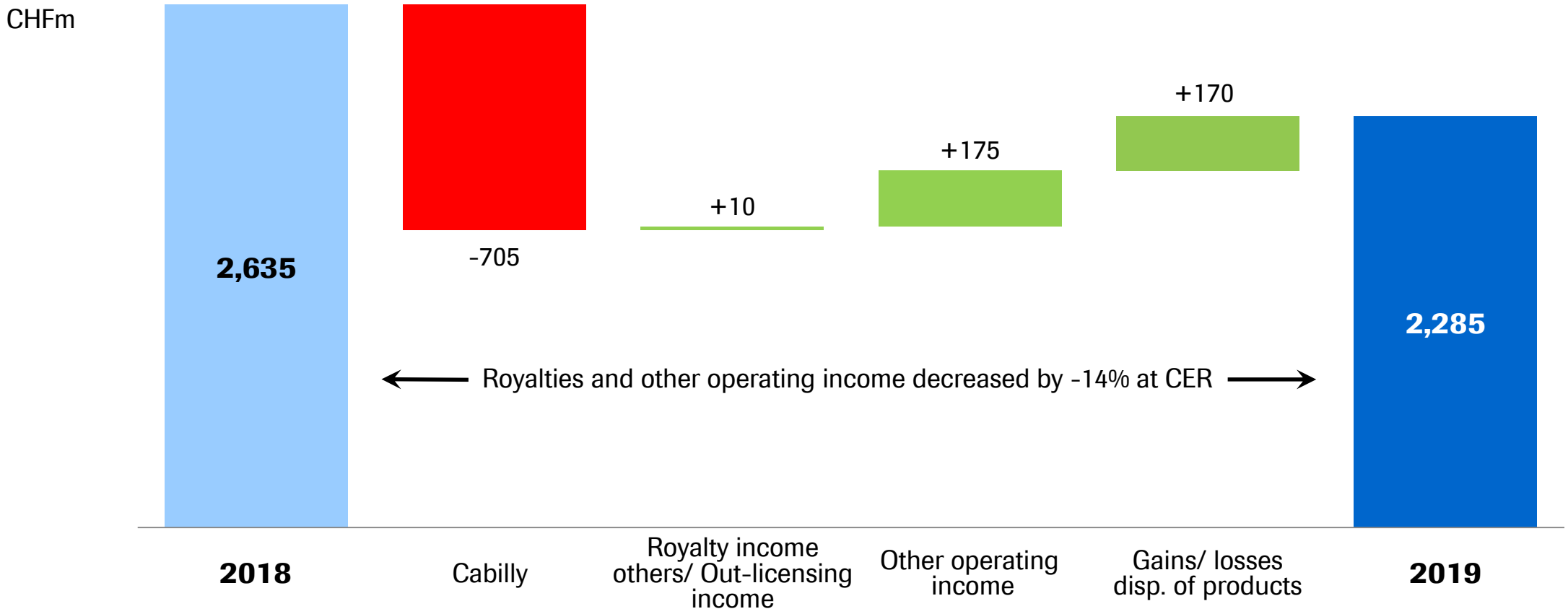


+10% in CHF

CER=Constant Exchange Rates

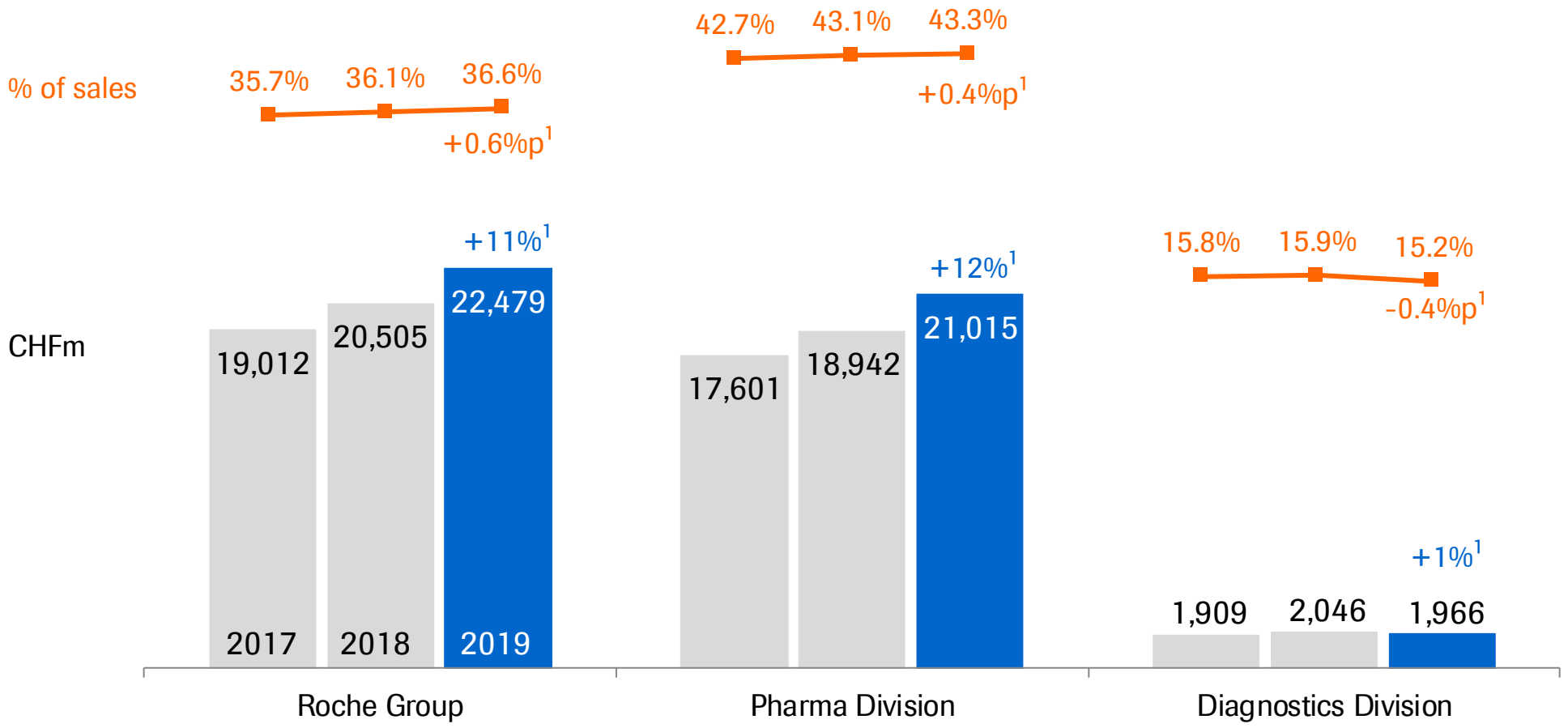
2019: Royalties and other operating income

Decline driven by expiry of Cabilly patent, partially offset by higher other operating income and higher income from product disposal



CER=Constant Exchange Rates

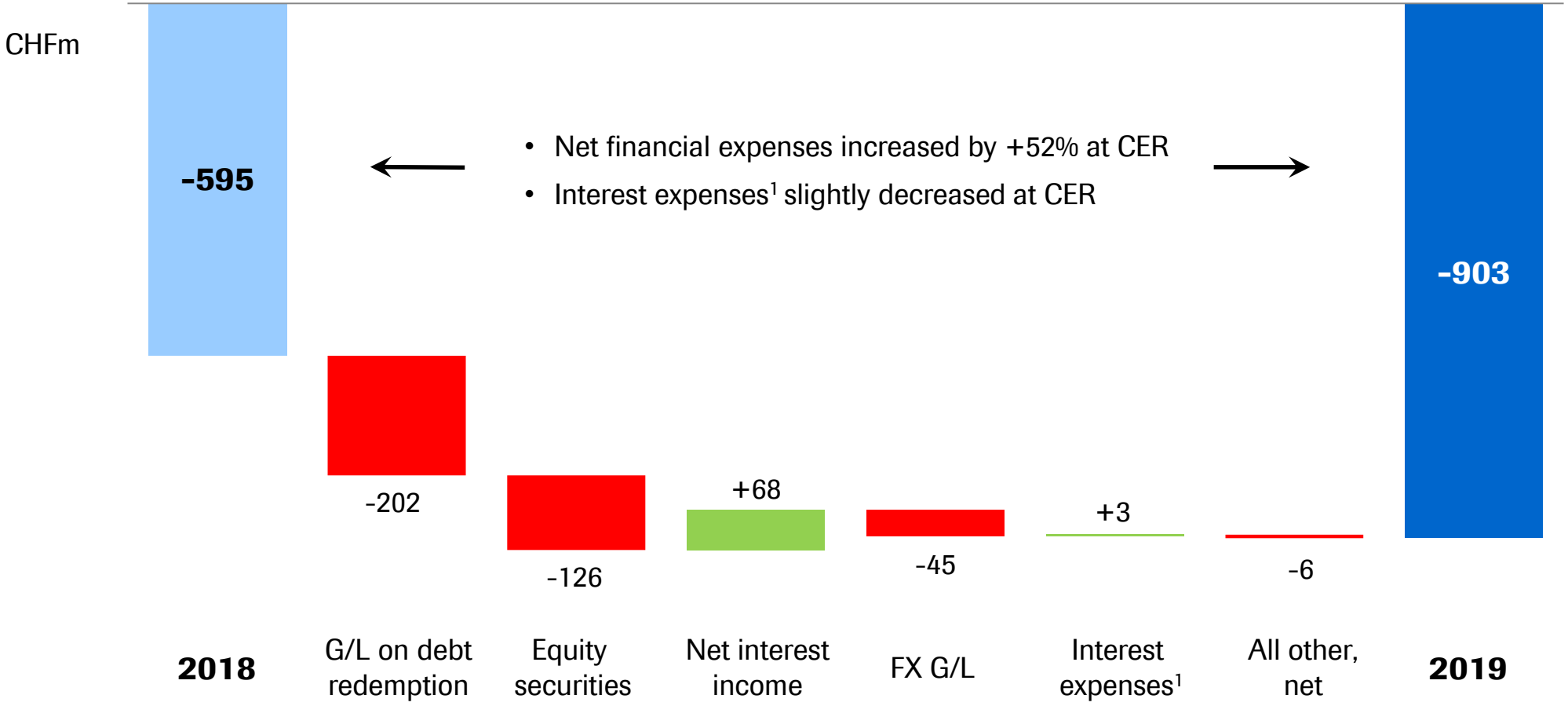
2019: Core operating profit and margin further improved



[1] At CER=Constant Exchange Rates

2019: Core net financial result

Net financial expenses up vs. prior year due to early bond redemption and lower income from equity securities



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

2019: Debt repayments and bond redemptions

Scheduled debt repayments

- On the due date of 30 September 2019 of USD 2.0 billion of bonds
- On 13 December 2019 of USD 0.6 billion of bonds repaid at the option of the issuer at par 3 months before the scheduled due date of 13 March 2020

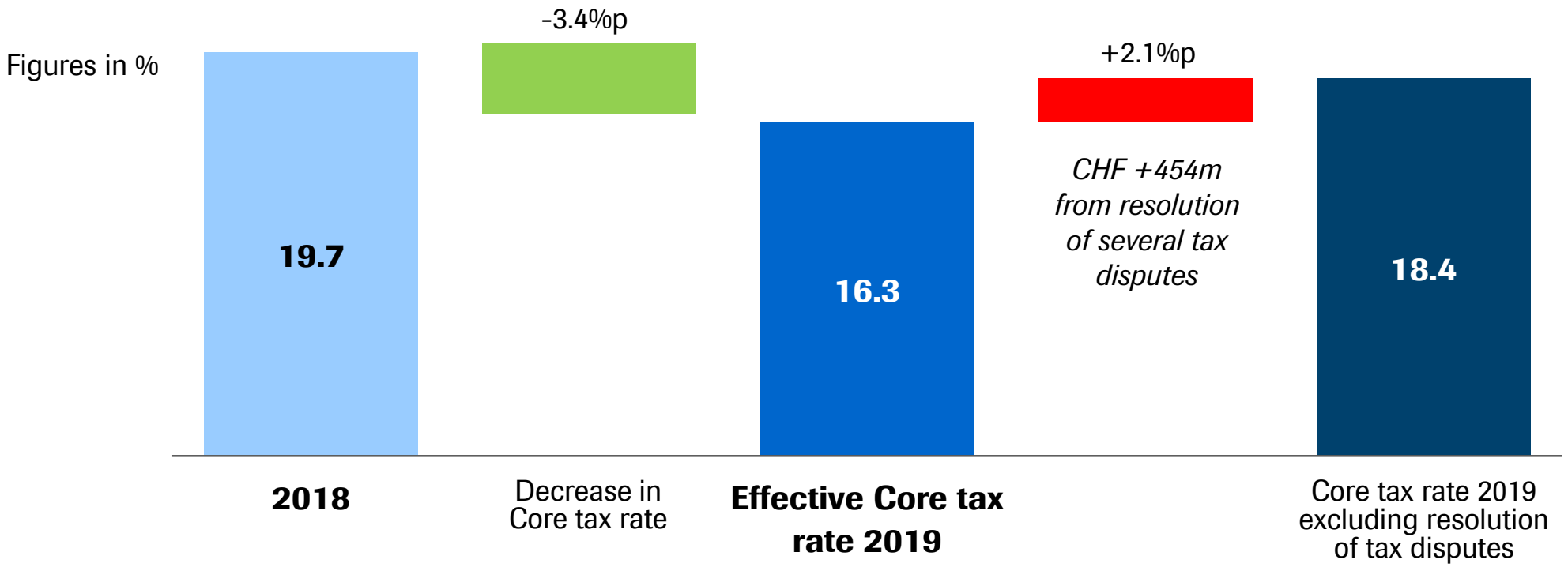
Early debt redemptions

- Completed tender offer on 5 December 2019 to redeem the following instruments:
  - USD 656 million 2.875% fixed rate notes due 29 September 2021
  - USD 360 million 3.25% fixed rate notes due 17 September 2023
  - USD 1,061 million 3.35% fixed rate notes due 30 September 2024
  - USD 494 million 3.0% fixed rate notes due 10 November 2025
  - USD 37 million 5.25% fixed rate notes due 15 July 2035
  - USD 73 million 7.0% fixed rate notes due 1 March 2039
- Total payment of USD 2,874 million and a reported loss on redemption of CHF 202 million

→ **Reduction in gross debt to CHF 14.4 billion from CHF 18.8 billion at YE 2018**

2019: Group Core tax rate

Decrease mainly due to resolution of tax disputes



2019: Non-core and IFRS income

Total non-core operating items decreasing due to lower IA impairments; partially offset by higher L&E and higher GRPs

	2018 CHFm	2019 CHFm	CHFm	Change in % CHF	Change in % CER
Core operating profit	**20,505**	**22,479**	**1,974**	**+10**	**+11**
Global restructuring plans	-907	-1,206	-299		
Amortisation of intangible assets	-1,294	-1,532	-238		
Impairment of intangible assets[1]	-3,336	-1,756	1,580		
M&A and alliance transactions	-35	43	78		
Legal & Environmental[2]	-164	-480	-316		
Total non-core operating items	-5,736	-4,931	805		
IFRS Operating profit	**14,769**	**17,548**	**2,779**	**+19**	**+21**
Total financial result & taxes	-3,904	-3,440	464		
IFRS net income	**10,865**	**14,108**	**3,243**	**+30**	**+32**

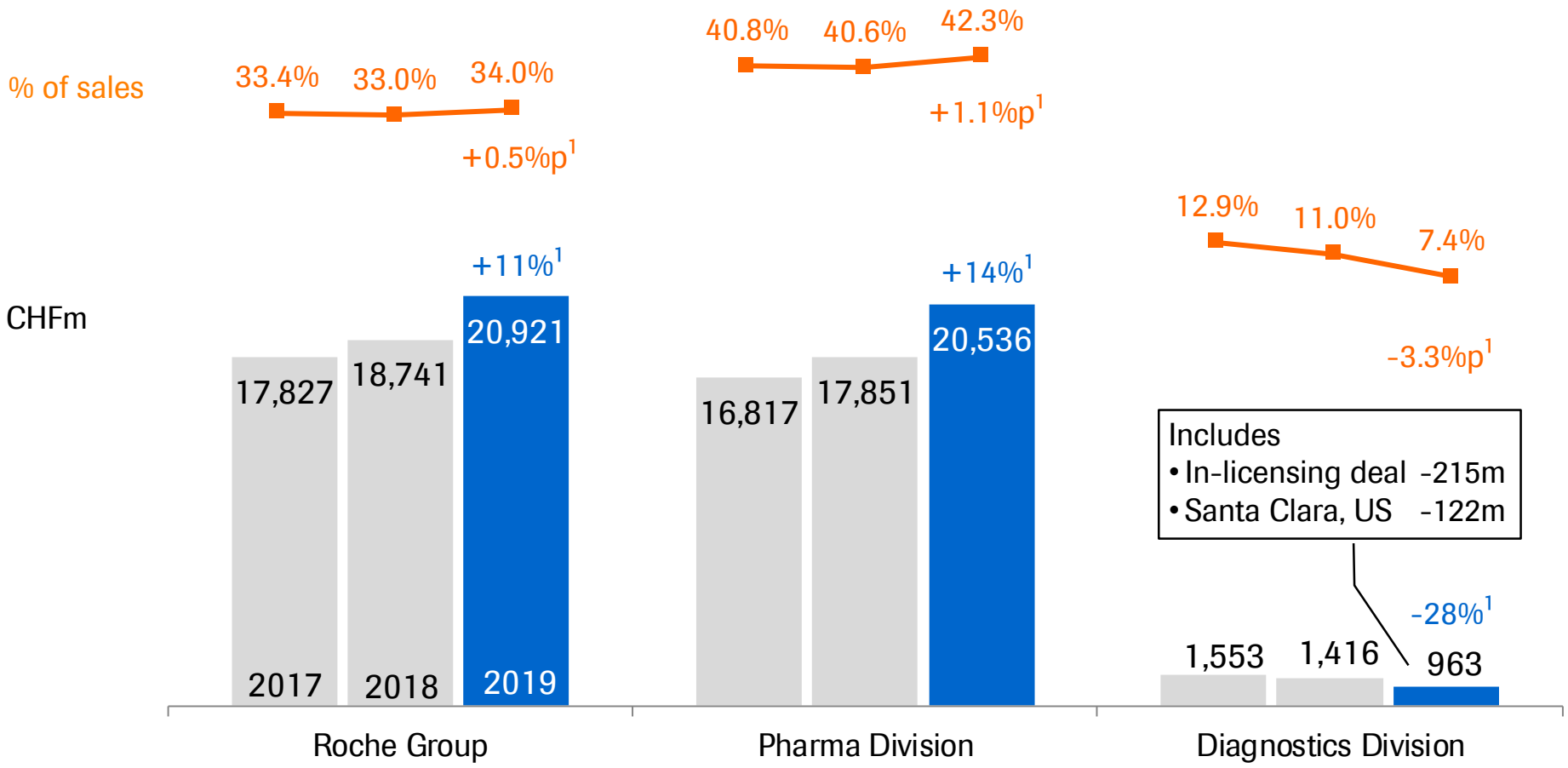
CER=Constant Exchange Rates; IA=intangible assets; L&E=legal & environmental; GRPs=global restructuring plans; [1] incl. goodwill; [2] incl. pension plan settlements

2019 results

Focus on Cash

Outlook

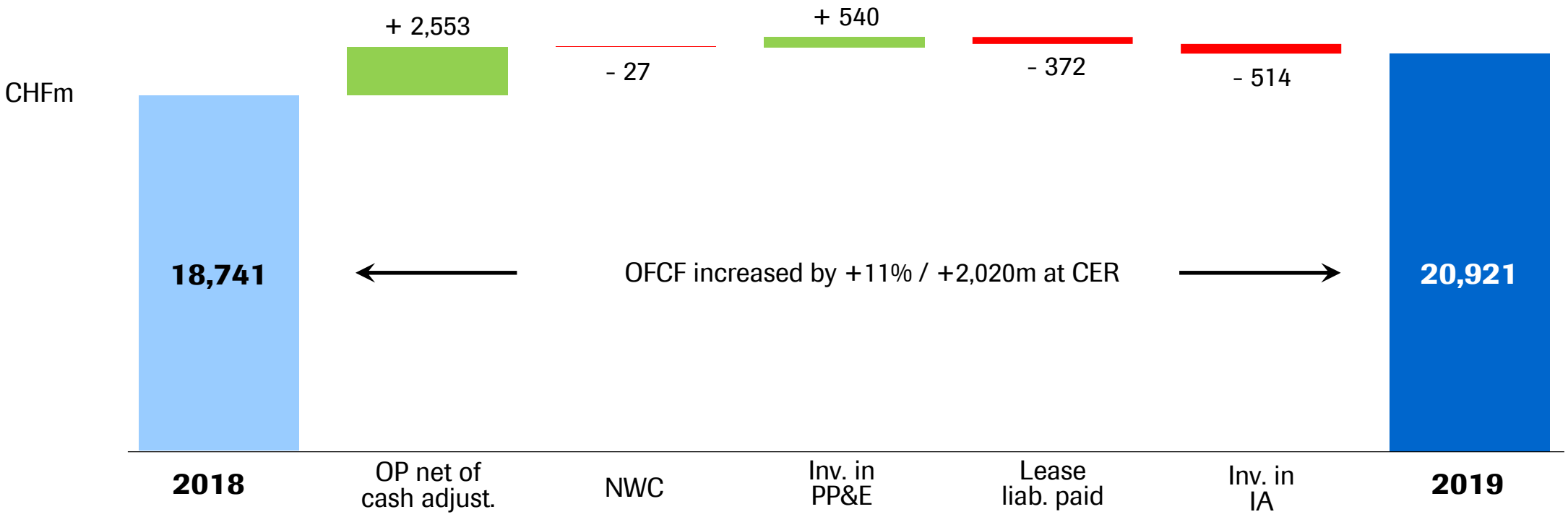
2019: Operating free cash flow and margin



[1] At CER=Constant Exchange Rates

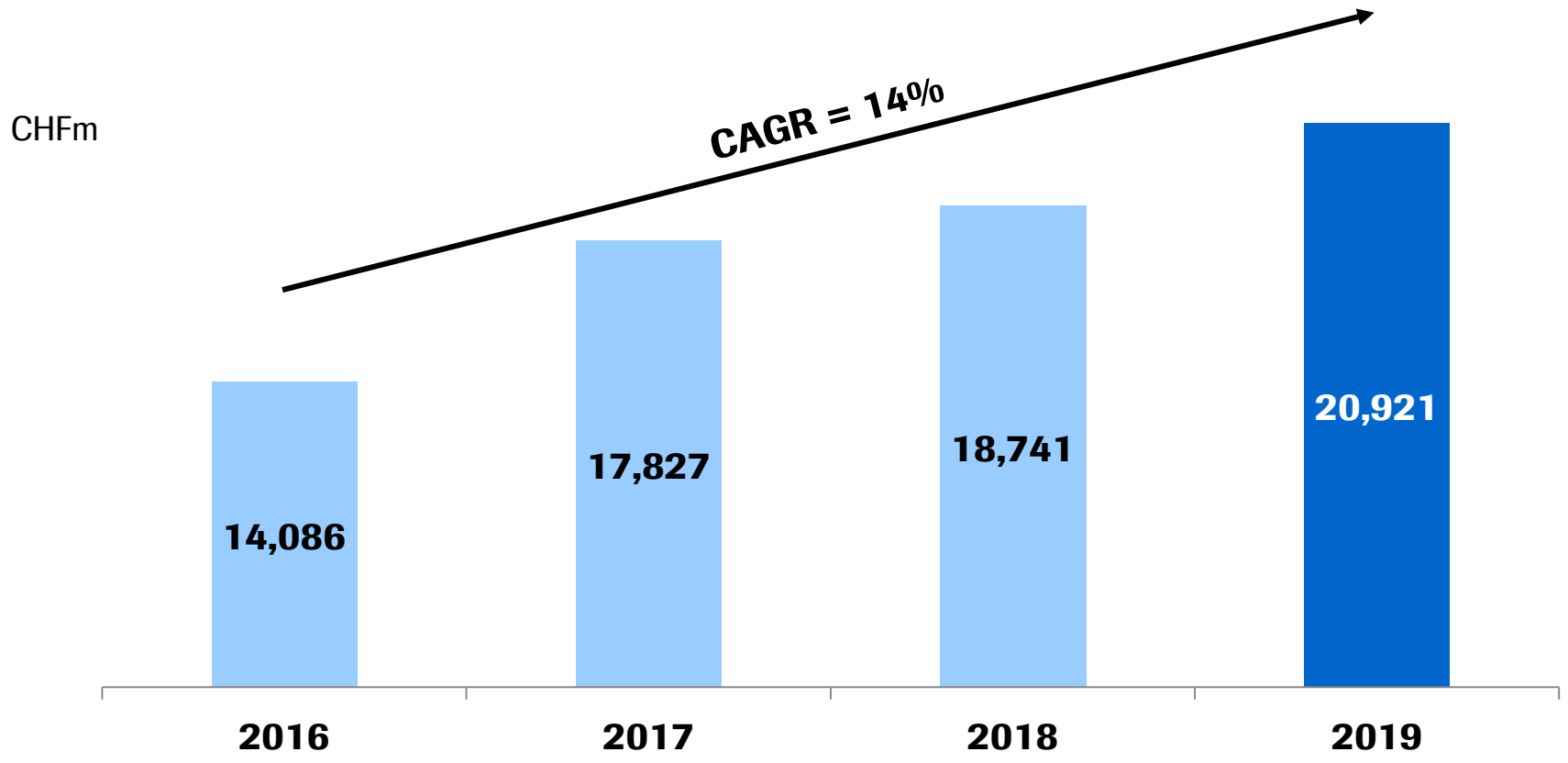
2019: Operating Free Cash Flow

Higher than PY (+11%) driven by strong operating performance

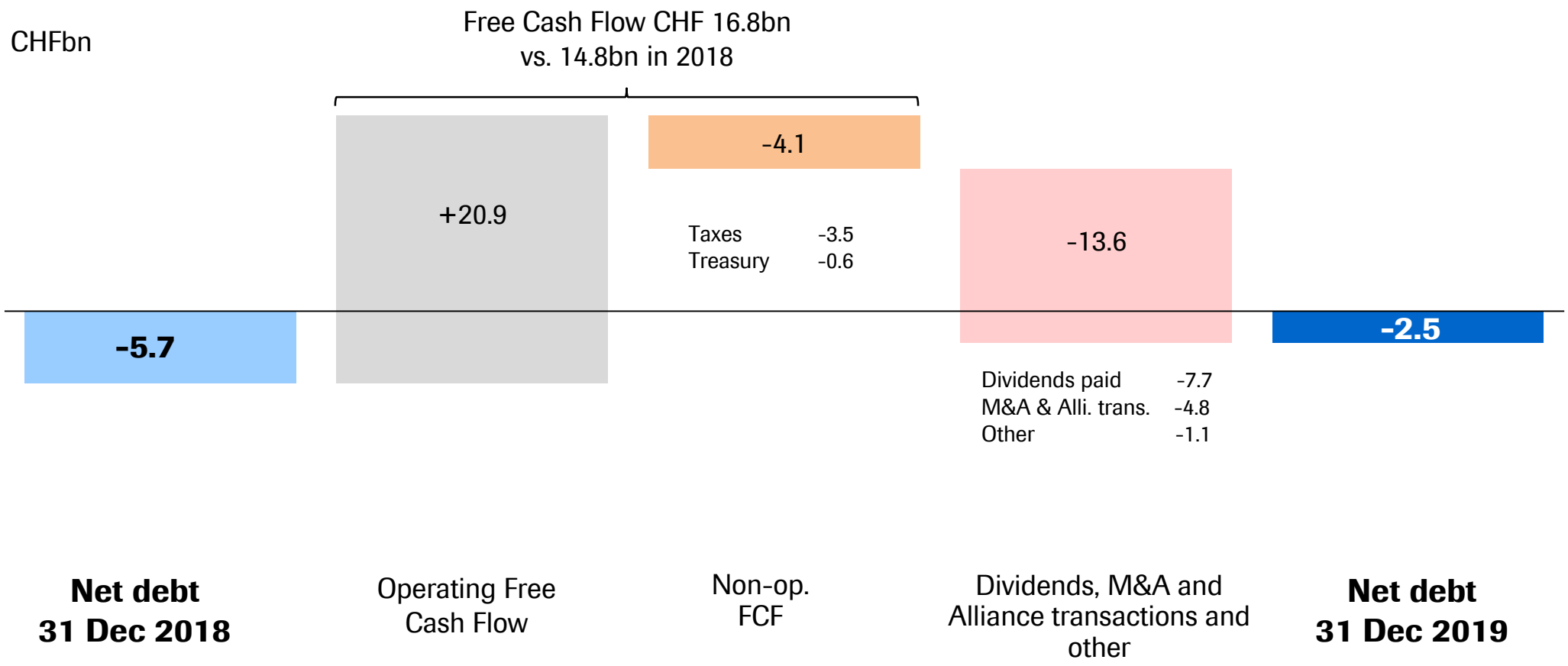


CER=Constant Exchange Rates; OP=operating profit; NWC=net working capital; PP&E=property, plant & equipment; IA=intangible assets

Operating free cash flow: Continuous improvement



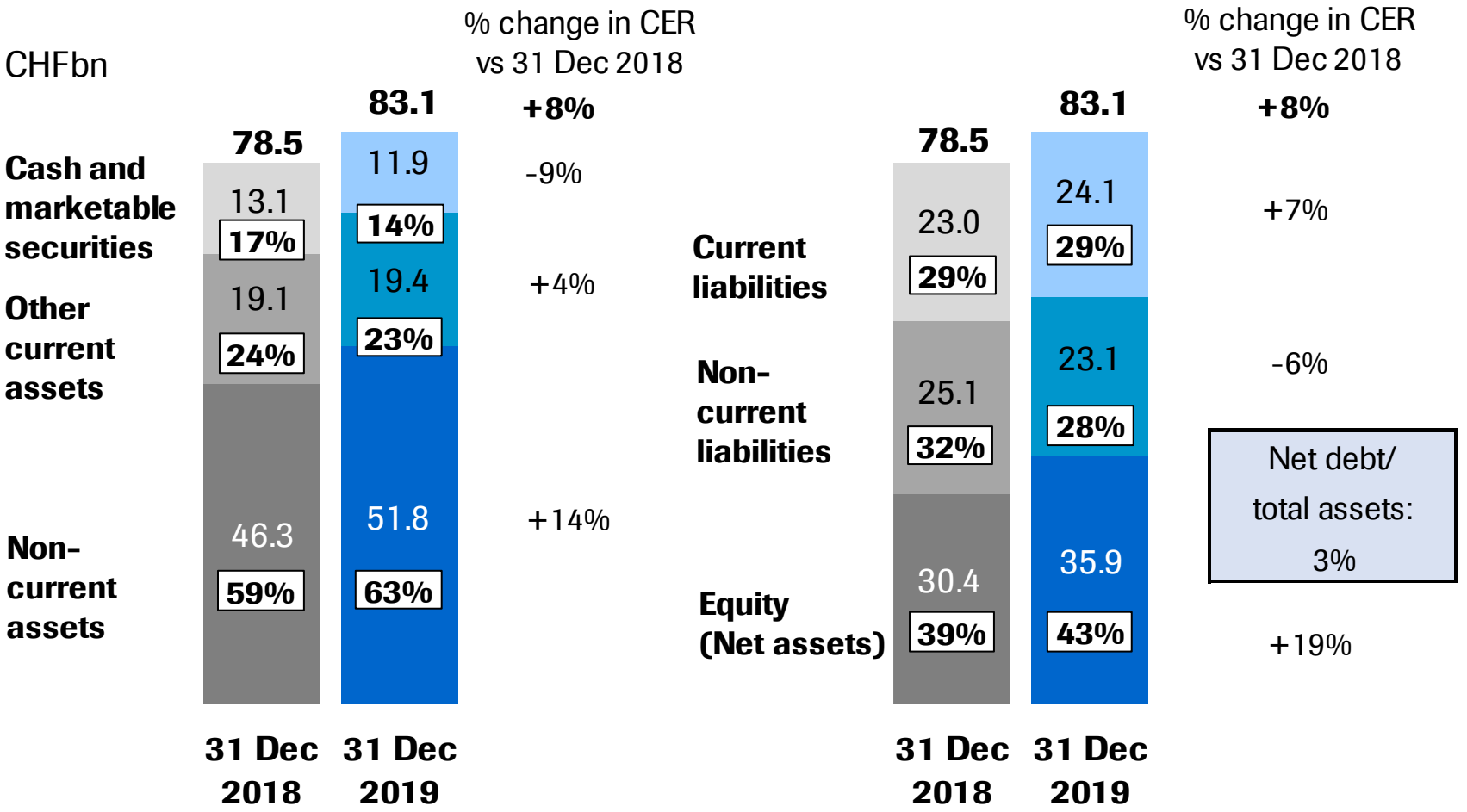
2019: Group net debt lower vs. YE 2018 driven by strong cash generation



CER=Constant Exchange Rates

Balance sheet 31 December 2019

Equity ratio at 43% (31 Dec 2018: 39%)



CER=Constant Exchange Rates

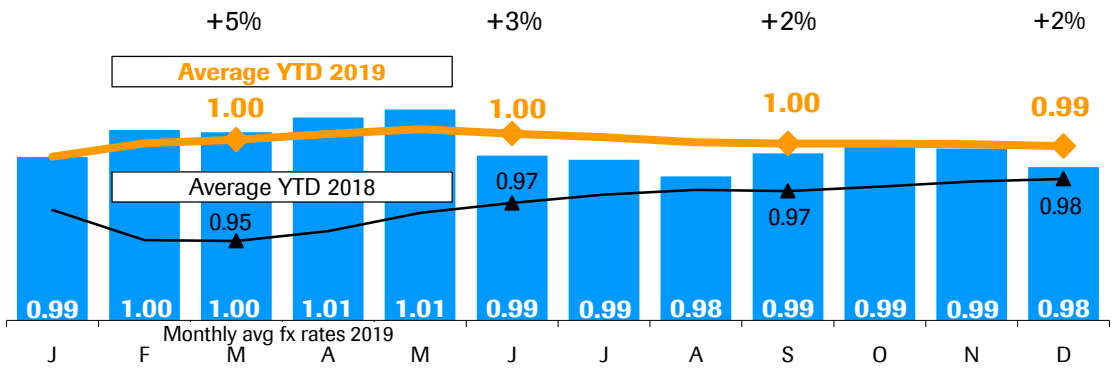
2019 results

Focus on Cash

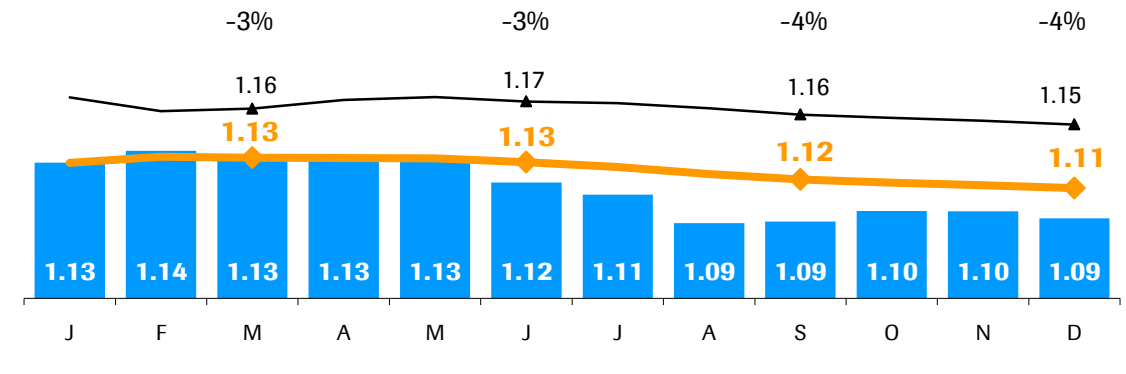
Outlook

Low currency impact in 2019

CHF / USD



CHF / EUR



[1] On group growth rates

In 2019 impact[1] is (%p):

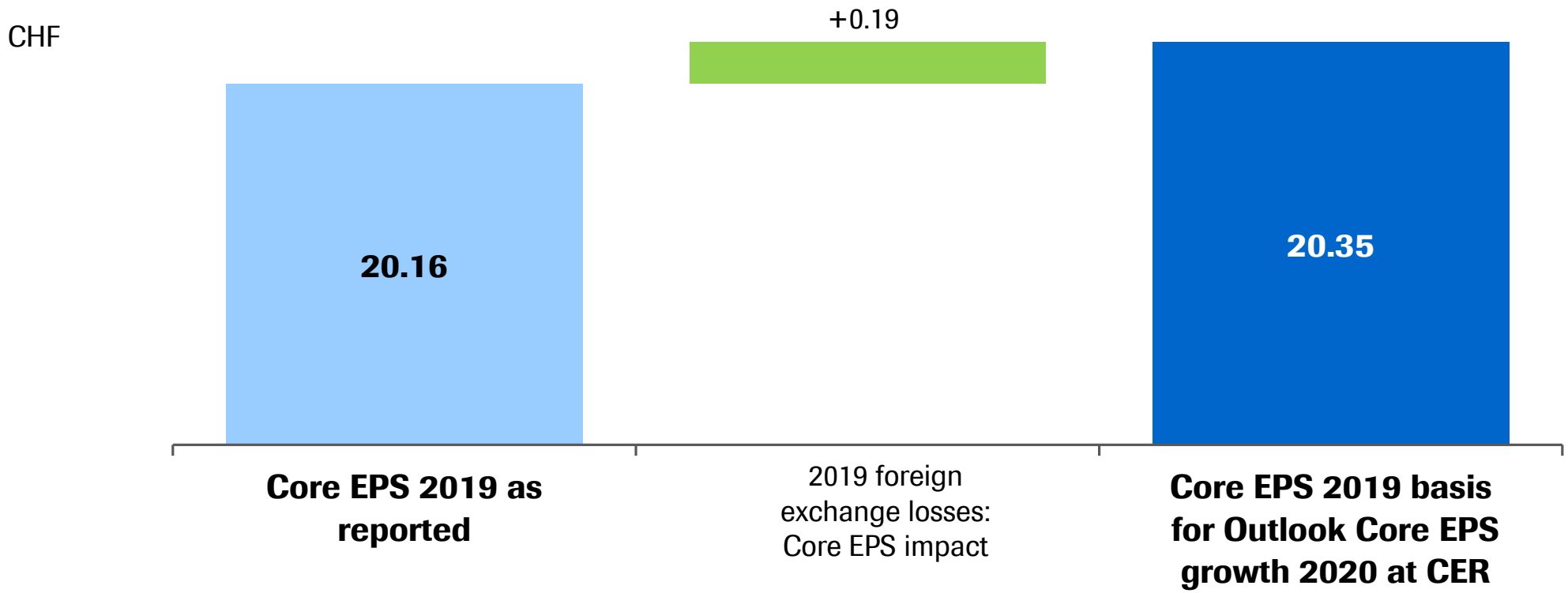
	Q1	HY	Sep YTD	FY
Sales	**1**	**0**	**-1**	**-1**
Core operating profit		**0**		**-1**
Core EPS		**0**		**-2**

***2020** currency impact[1] expected (based on **31 Dec 2019** FX rates):*

- Around -3%p FX impact on Sales, Core OP & Core EPS

2019: Core EPS

Core EPS 2019 of CHF 20.35 is basis for Core EPS outlook 2020 at CER



CER=Constant Exchange Rates

2020 outlook
Further growing top and bottom line

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

[1] At Constant Exchange Rates (CER)


Roche

Changes to the development pipeline
Q4 2019 update

New to phase I

5 NMEs:
RG6292 CD25 MAb - solid tumors
RG6139 PD1 x LAG3 - bispecific MAb solid tumors
RG6346 HBV siRNA - HBV
RG6287 - IBD
RG6290 MAGE-A4 ImmTAC - solid tumors
1 NME added by Chugai
FIXa x FX bispecific MAb - hemophilia A
1 AI:
RG7446 Tecentriq + CD47 MAb - r/r AML

New to phase II

5 NMEs:
RG7880 IL22-Fc - inflammatory diseases
RG6173 – asthma
RG6357 SPK-8011 - hemophilia A
RG6358 SPK-8016 - hemophilia A with inhibitors to factor VIII
RG6367 SPK-7001 - choroideremia
1 AI:
RG7601 Venclexta + carfilzomib - r/r MM t(11:14)

New to phase III

4 AIs
RG7446 Tecentriq + Avastin - HCC adj
RG7440 ipatasertib + fulvestrant + palbociclib - 1L HR+ mBC
RG7440 ipatasertib + Tecentriq + taxane - 1L TNBC
RG6321 port delivery system with ranibizumab - DME

New to registration

2 NMEs:
RG7916 risdiplam - SMA
RG6264 Perjeta + Herceptin FDC SC - HER2+ BC
3 AIs:
RG3648 Xolair – nasal polyps
RG7446 Tecentriq + Avastin - HCC
RG7446 Tecentriq – Dx-pos. 1L sq + non-sq NSCLC

Removed from phase I

1 NME:
RG6004 HBV LNA - HBV
1 NME removed by Chugai (out licensed to Verastem Oncology)
RAF/MEK dual inh - solid tumors
1 AI:
RG7601 Venclexta +Cotellic + Tecentriq - multiple myeloma

Removed from phase II

1 AI:
RG7440 ipatasertib -TNBC neoadj

Removed from phase III

1 NME:
RG6206 anti-myostatin adnectin - Duchenne muscular dystrophy
1 AI:
RG7446 Tecentriq + pemetrexed - 1L non-sq NSCLC

Approvals

1 NME approved in EU
RG7596 Polivy - r/r DLBCL
1 AI approved in US
RG7446 Tecentriq + nab paclitaxel -1L non-sq NSCLC
1 AI approved in EU
RG3502 Kadcyla - Her2-pos eBC

Status as of January 30, 2020

Roche Group development pipeline

Phase I (41 NMEs + 19 AIs)

RG6026	CD20 x CD3 / combos	heme tumors
RG6076	CD19-4-1BBL	heme tumors
RG6107	crovalimab	PNH
RG6114	mPI3K alpha inh	HR+ BC
RG6139	PD1 x LAG3	solid tumors
RG6160	FcRH5/ x CD3	r/r MM
RG6171	SERD (3)	ER+/HER2- mBC
RG6180	iNeST*± T	solid tumors
RG6185	belvarafenib (pan-RAF inh) + Cotellic	solid tumors
RG6194	HER2 x CD3	BC
RG6290	MAGE-A4 ImmTAC	solid tumors
RG6292	CD25 MAb	solid tumors
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 + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + rucaparib	ovarian ca
	T + CD47 MAb	r/r AML
RG7461	FAP IL2v FP combos	solid tumors
RG7601	Venclexta + idasanutlin	AML
	Venclexta + AMG176	AML
	Venclexta ± azacitidine	r/r MDS
	Venclexta + gilteritinib	r/r AML
RG7769	PD1 x TIM3	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab / combos	heme tumors
RG7876	selicrelumab combos	solid tumors
CHU	FIXa x FX	hemophilia
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
RG6151	-	asthma
RG6244	-	asthma
RG6287	-	IBD
RG7835	IgG–IL2	autoimmune diseases
RG6084	-	HBV
RG6217	-	HBV
RG6346	HBV siRNA	HBV
RG7854	TLR7 agonist (3)	HBV
RG7861	anti-S. *aureus* TAC	infectious diseases
RG7907	HBV CpAM (2) (Capsid)	HBV
RG7992	FGFR1 x KLB MAb	metabolic diseases
RG6000	DLK inh	ALS
RG6102	brain shuttle gantenerumab	Alzheimer's
RG6237	-	neuromuscular disorders
RG7816	GABA Aa5 PAM	autism
RG6179	-	DME
RG7774	-	retinal disease
RG7921	-	wAMD
CHU	PTH1 recep. ago	hypoparathyroidism
CHU	-	hyperphosphatemia
CHU	-	endometriosis

RG-No - Roche/Genentech

CHU- Chugai managed

IONIS – IONIS managed

NOV- Novimmune managed

*Individualized Neoantigen Specific Immunotherapy

T=Tecentriq

Phase II (18 NMEs + 10 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6058	tiragolumab ± T	NSCLC
RG7388	idasanutlin	polycythemia vera
	idasanutlin	1L AML
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7446	Tecentriq	SC NSCLC
RG7596	Polivy	r/r FL
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + azacitidin	1L MDS
	Venclexta + fulvestrant	2L HR+BC
	Venclexta + carfilzomib	r/r MM t(11:14)
RG6149	ST2 MAb	asthma
RG6173	-	asthma
RG7159	Gazyva	lupus
RG7845	fenebrutinib	RA, lupus, CSU
RG7880	IL22-Fc	inflammatory diseases
CHU	nemolizumab#	pruritus in dialysis patients
NOV	TLR4 MAb	autoimmune diseases
RG1662	basmisanil	CIAS
RG6100	semorinemab (Tau MAb)	Alzheimer's
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7906	-	psychiatric disorders
RG7935	prasinezumab	Parkinson's
RG6147	-	geographic atrophy
IONIS	ASO factor B	geographic atrophy
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016	hemophilia A with inhibitors to factor VIII
RG6367	SPK-7001	choroideremia

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

out-licensed to Galderma (AD, PN) and Maruho (AD)

Status as of January 30, 2020

Roche Group development pipeline

Phase III (8 NMEs + 31 AIs)

RG3502	Kadcyla + Perjeta	HER2+ eBC
RG7388	idasanutlin + chemo	r/r AML
RG7440	ipatasertib + abiraterone	1L CRPC
	ipatasertib + chemo	1L TNBC/HR+ BC
	ipatasertib + fulvestrant + palbociclib	1L HR+ mBC
	ipatasertib + Tecentriq + taxane	1L TNBC
RG7421	Cotellic + Zelboraf + T	1L BRAFm melanoma
RG7596	Polivy	1L DLBCL
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq	MIBC, high risk
	Tecentriq	RCC adj
	T + chemo + Avastin	1L ovarian cancer
	T ± chemo	SCCHN adj
	Tecentriq	HER2+ BC neoadj
	T + paclitaxel	1L TNBC
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + nab-paclitaxel	TNBC neoadj
	T + Avastin	HCC adj
	T + Avastin	1L RCC
	T ± chemo	1L mUC

RG7446/RG7853/ RG6268	Tecentriq or Alecensa or entrectinib	1LNSCLC Dx+
RG7601	Venclexta	r/r MM t(11:14)
	Venclexta + HMA	1L AML
RG7853	Alecensa	ALK+ NSCLC adj
RG3648	Xolair	food allergy
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
RG7314	balovaptan	autism
RG6321	port delivery system with ranibizumab	wAMD
	port delivery system with ranibizumab	DME
RG7716	faricimab	DME
	faricimab	wAMD

Registration (5 NMEs + 6 AIs)

RG6264	Perjeta + Herceptin FDC SC	HER2+ BC
RG6268	Rozlytrek (entrectinib) [1]	ROS1+ NSCLC
	Rozlytrek (entrectinib) [1]	NTRK+ tumor-agnostic
RG7446	Tecentriq Dx+	1L sq + non-sq NSCLC
	Tecentriq+ Avastin	1L HCC
RG7601	Venclexta + Gazyva [1]	1L CLL
RG3648	Xolair [2]	nasal polyps
RG6152	Xofluza [1]	influenza
	Xofluza [1]	influenza, high risk
RG6168	satralizumab	NMOSD
RG7916	risdiplam [2]	SMA

[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 January 30, 2020

NME submissions and their additional indications

Projects in phase II and III

2019		2020		2021		2022 and beyond					
RG7916	**Risdiplam (US) ✓** SMA	**RG6321**	**Port Delivery System with ranibizumab** wAMD							**RG6321**	**Port Delivery System with ranibizumab** DME
RG6168	**satralizumab ✓** NMOSD	**RG7413**	**etrolizumab** ulcerative colitis			**RG6058**	**tiragolumab + Tecentriq** NSCLC	**RG6042**	**HTT ASO** Huntington's	**RG6152**	**Xofluza** influenza, hospitalized pts
RG6152	**Xofluza (EU) ✓** influenza	**RG6152**	**Xofluza** influenza, pediatric			**RG6180**	**iNeST*** oncology	**RG1450**	**gantenerumab** Alzheimer's	**RG6149**	**ST2 Mab** asthma
RG6152	**Xofluza (EU) ✓** influenza, high risk	**RG6152**	**Xofluza** influenza post-exposure prophylaxis			**RG7388**	**idasanutlin** AML fit 1L	**RG1662**	**basmisanil CIAS**	**RG6173**	**NME** asthma
RG6264	**Perjeta + Herceptin FDC SC ✓** HER2+ BC	**RG7388**	**idasanutlin + chemo** AML			**RG7388**	**idasanutlin** polycythemia vera	**RG6100**	**semorinemab (Tau MAb)** Alzheimer's	**RG7413**	**etrolizumab**) Crohn's
RG6268	**Rozlytrek (entrectinib) (EU) ✓** ROS1+ NSCLC	**RG7440**	**ipatasertib + abiraterone** 1L CRPC	**RG7716**	**faricimab** DME	**RG7440**	**ipatasertib + fulv + palbociclib** 1L HR+ mBC	**RG7314**	**balovaptan** autism	**RG7845**	**fenebrutinib** autoimmune diseases
RG6268	**Rozlytrek (entrectinib) (EU) ✓** NTRK+ tumor-agnostic	**RG7440**	**ipatasertib + chemo** 1L TNBC / HR+ BC	**RG7716**	**faricimab** wAMD	**RG7440**	**ipatasertib + Tecentriq + taxane** 1L TNBC	**RG7935**	**prasinezumab** Parkinson's	**RG7880**	**IL22-Fc** inflammatory 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 January 30, 2020

AI submissions for existing products

Projects in phase II and III

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

2019

RG3648	**Xolair (US) ✓** nasal polyps
RG3502	**Kadcyla✓** HER2+ eBC
RG7601	**Venclexta + Gazyva ✓** 1L CLL
RG7446	**Tecentriq ✓** 1L non-sq + sq NSCLC Dx+

2020

RG3502	**Kadcyla + Perjeta** HER2+ eBC
RG7421	**Cotellic + Tecentriq + Zelboraf** 1L BRAFmut melanoma
RG7446	**Tecentriq + nab-paclitaxel** TNBC neoadj
RG7446	**Tecentriq + Avastin** 1L RCC
RG7446	**Tecentriq + paclitaxel** 1L TNBC
RG7446	**Tecentriq** MIBC adj
RG7446	**Tecentriq ± chemo** 1L mUC
RG7446	**Tecentriq + chemo + Avastin** 1L ovarian cancer
RG7446	**Tecentriq + Avastin ✓** 1L HCC
RG7853	**Alecensa** 1L NSCLC Dx+

2021

RG3648	**Xolair** Food allergy
RG7601	**Venclexta + HMA** 1L AML
RG7446/ RG6268	**Tecentriq or Rozlytrek (entrectinib)** 1L NSCLC Dx+
RG7596	**Polivy (polatuzumab vedotin)** 1L DLBCL

2022 and beyond

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

Status as of January 30, 2020

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

Major pending approvals 2019 and YTD 2020

US		EU		China		Japan-Chugai	
RG6152	**Xofluza** Influenza, high risk pts Filed Dec. 2018	RG6268	**Rozlytrek (entrectinib)** ROS1+ NSCLC Filed Jan 2019	RG99	**CellCept** lupus nephritis Filed Aug 2018	RG3502	**Kadcyla** HER2+ eBC adj Filed Aug 2019
RG6168	**satralizumab** NMOSD Filed Aug 2019	RG6268	**Rozlytrek (entrectinib)** NTRK+ tumor-agnostic Filed Jan 2019	RG105	**MabThera** CLL Filed Apr 2019	RG6268	**Rozlytrek (entrectinib)** ROS1+ NSCLC Filed Mar 2019
RG7916	**risdiplam** SMA Filed Nov 2019	RG7601	**Venclexta+Gazyva** 1L CLL Filed Jul 2019	RG105	**MabThera** FL Filed Apr 2019	RG7853	**Alecensa** r/r ALK+ ALCL Filed Jun 2019
RG3648	**Xolair** nasal polyps Filed Sept 2019	RG6168	**satralizumab** NMOSD Filed Aug 2019	RG405	**Avastin** 1L/2L gliobastoma Filed Jan 2019	RG6168	**satralizumab** NMOSD Filed Nov 2019
RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+ Filed Dec 2019	RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+ Filed Nov 2019	RG405	**Avastin + Tarceva** NSCLC Filed Aug 2019		
RG7446	**Tecentriq + Avastin** HCC Filed Jan 2020	RG6152	**Xofluza** influenza Filed Nov 2019	RG3502	**Kadcyla** HER2+ eBC Filed Feb 2019		
RG6264	**Perjeta+Herceptin FDC SC** Her2+BC Filed Dec 2019	RG6152	**Xofluza** influenza, high risk Filed Nov 2019	RG7159	**Gazyva** 1L FL Filed Sept 2019		
		RG7446	**Tecentriq +Avastin** HCC Filed Jan 2020	RG7159	**Gazyva** r/r FL Filed Sept 2019		
		RG6264	**Perjeta+Herceptin FDC SC** Her2+BC Filed Jan 2020	RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Filed Feb 2019		

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

Status as of January 30, 2020

Major granted approvals 2019 and YTD 2020

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
RG6268	**Rozlytrek (entrectinib)** ROS1+ NSCLC Aug 2019	RG7596	**Polivy (polatuzumab vedotin)** r/r DLBCL January 2020	RG1273	**Perjeta** HER2+ eBC neoadj Dec 2018	RG1569	**Actemra** CRS Mar 2019
RG6268	**Rozlytrek (entrectinib)** NTRK+ tumor-agnostic Aug 2019	RG6013	**Hemlibra** hemophilia A FVIII non-inh Mar 2019	RG6264	**Perjeta + Herceptin** 1L HER2+ mBC Dec 2019	RG1569	**Actemra** Adult Onset Still's disease May 2019
RG7446	**Tecentriq + nab-paclitaxel** 1L TNBC Mar 2019	RG6013	**Hemlibra** Q4W hemophilia A Mar 2019			RG6268	**Rozlytrek** NTRK+ tumor-agnostic June 2019
RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Mar 2019	RG7446	**Tecentriq + chemo + Avastin** 1L non-sq NSCLC Mar 2019			RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Aug 2019
RG7446	**Tecentriq + nab-paclitaxel** **1L non sq NSCLC** Dec 2019	RG7446	**Tecentriq + nab-paclitaxel** 1L non sq NSCLC Sept 2019			RG7446	**Tecentriq + nab-paclitaxel** 1L TNBC Sept 2019
RG7601	**Venclexta + Gazyva** 1L CLL May 2019	RG7446	**Tecentriq + nab-paclitaxel** 1L TNBC Aug 2019			RG7446	**Tecentriq + pemetrexed** 1L non-sq NSCLC Nov 2019
RG3502	**Kadcyla** HER2+ eBC May 2019	RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Sept 2019				
RG7596	**Polivy (polatuzumab vedotin)** r/r DLBCL June 2019	RG3502	**Kadcyla** HER2+EBC Dec 2019				
RG105	**Rituxan** GPA/MPA (pediatrics) Sept 2019						

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

Status as of January 30, 2020

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group 2019 results

Diagnostics

Foreign exchange rate information

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

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

In collaboration with Chugai

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

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients without inhibitors to factor VIII	Hemophilia A patients with and without inhibitors to Factor VIII, dosing every 4 weeks
Phase/study	**Phase III HAVEN 3**	**Phase III HAVEN 4**
# of patients	N=135	N=46
Design	Patients on FVIII episodic treatment prior to study entry: ▪ **ARM A:** Hemlibra prophylaxis qw ▪ **ARM B:** Hemlibra prophylaxis q2w ▪ **ARM C:** Episodic FVIII treatment; switch to Hemlibra prophylaxis possible after 24 weeks Patients on FVIII prophylaxis prior to study entry: ▪ **ARM D:** Hemlibra prophylaxis qw	Multicenter, open-label, non-randomized study to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of Hemlibra administered every 4 weeks. ▪ **Part 1:** Pharmacokinetic (PK) run-in part (N=6) ▪ **Part 2:** Expansion part (N=40)
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 24 weeks
Status	▪ FPI Q3 2016, recruitment completed Q2 2017 ▪ Study met primary and key secondary endpoints Q4 2017 ▪ FDA granted Breakthrough Therapy Designation April 2018 ▪ Data presented at WFH 2018 ▪ Filed in US (priority review) and EU in Q2 2018 ▪ Data published in *NEJM* 2018; 379: 811-822	▪ FPI Q1 2017, recruitment completed Q2 2017 ▪ PK run-in data at ASH 2017 ▪ Positive interim analysis outcome reported Q4 2017 ▪ Data presented at WFH 2018 ▪ Interim data filed in US and EU in Q2 2018 ▪ Data published in Lancet Haematology 2019 Jun;6(6):e295-e305
	▪Approved in US Q4 2018 and EU Q1 2019	
CT Identifier	NCT02847637	NCT03020160

In collaboration with Chugai

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

Alecensa

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK-positive advanced NSCLC	Adjuvant ALK+ NSCLC
Phase/study	**Phase III** **ALEX**	**Phase III** **ALINA**
# of patients	N=286	N=255
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 600 mg BID ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Progression-free survival	▪ Disease-free survival
Status	▪ Recruitment completed Q3 2015 ▪ Primary endpoint met Q1 2017 ▪ Data presented at ASCO 2017, 2018, ESMO 2017, 2018 ▪ Data published in *NEJM* 2017; 377:829-838 ▪ CNS data presented at ESMO 2017 ▪ Final PFS and updated OS presented at ESMO 2019 ▪ Approved in US Q4 2017 (priority review) and in EU Q4 2017	▪ FPI Q3 2018
CT Identifier	NCT02075840	NCT03456076

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

Cotellic

Selective small molecule inhibitor of MAPK kinase

Indication	First-line metastatic triple negative breast cancer	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 arms 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; 377:1331-1344
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 and filed in EU Q1 2019 ▪ Approved in US Q2 2019 and in EU Q4 2019 ▪ Data published in *NEJM* 2019; 380:617-628	▪ 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
Phase/study	**Phase III** **APHINITY**	**Phase II** **BERENICE**
# of patients	N=4,803	N=401
Design	▪ **ARM A:** Perjeta (840mg loading, 420 q3w) + Herceptin for 52 weeks plus chemotherapy (6-8 cycles) ▪ **ARM B:** Placebo + Herceptin (52 weeks) plus chemotherapy (6-8 cycles)	*Neoadjuvant treatment:* ▪ **ARM A:** ddAC q2w x4 followed by wkly paclitaxel for 12 wks, with P+H 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
Primary endpoint	▪ Invasive disease-free survival	▪ Safety
Status	▪ Primary endpoint met Q1 2017 ▪ Data presented at ASCO 2017 and published in *NEJM* 2017; 377:122-131 ▪ Filed in US and EU Q3 2017 ▪ Approved in US Q4 2017 (priority review) and EU Q2 2018 ▪ Six year iDFS data presented at SABCS 2019	▪ Recruitment completed Q3 2015 ▪ Data presented at SABCS 2016 ▪ Data published in Ann Oncol. 2018 Mar 1; 29(3): 646-653
CT Identifier	NCT01358877	NCT02132949

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

Perjeta

First-in-class HER2 dimerization inhibitor

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

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; 378:2288-2301 ▪ 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 ▪ Approved in EU Q3 2019 and US Q4 2019	▪ FPI Q2 2016 ▪ Recruitment completed Q2 2017 ▪ Study met co-primary endpoint of PFS in Q2 2018 ▪ Data presented at WCLC 2018
CT Identifier	NCT02366143	NCT02367781	NCT02657434

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous and squamous NSCLC PD-L1-selected patients	1L 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	▪ IMpower111 consolidated into IMpower110 Q3 2016 ▪ Recruitment completed Q1 2018 ▪ Study met primary end point in PD-L1 high (IC3/TC3) Q3 2019 ▪ Data presented at ESMO and ESMO-IO 2019 ▪ Filed in EU and US Q4 2019 (US: FDA acceptance pending)	▪ 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 and final OS at WCLC 2019	▪ FPI Q2 2016 ▪ Orphan drug designation granted by FDA Q3 2016 ▪ Study met endpoints of OS and PFS in Q2 2018 ▪ Primary data presented at WCLC 2018 ▪ Data published in *NEJM* 2018; 379:2220-2229 ▪ Filed with the US and EU Q3 2018 ▪ Approved in US Q1 2019 and EU Q3 2019
CT Identifier	NCT02409342	NCT02367794	NCT02763579

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	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	Stage IV non-small cell lung cancer
Phase/study	**Phase II/III** **B-FAST**	**Phase Ib/II** **IMscin001**
# of patients	N=598	N=260
Design	▪ **Cohort A:** ALK + (Alecensa) ▪ **Cohort B:** ROS1 + (entrectinib) ▪ **Cohort C:** bTMB-high (Tecentriq)	▪ Part 1: dose finding, atezo SC followed by atezo IV ▪ Part 2: non inferiority of atezo SC + Avastin + chemo vs atezo IV + Avastin+ chemo
Primary endpoint	▪ Cohort A/B: Objective response rate ▪ Cohort C: Progression-free survival	▪ Observed concentration of atezolizumab in serum at cycle 1
Status	▪ FPI Q3 2017 ▪ Recruitment completed for cohort A Q3 2018 and Cohort C Q3 2019 ▪ Study met primary end point in cohort A (ALK+) Q3 2019 and presented at ESMO 2019	▪ FPI Q4 2018
CT Identifier	NCT03178552	NCT03735121

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – SCCHN

Indication	Adjuvant squamous cell carcinoma of the head and neck
Phase/study	**Phase III** **IMvoke010**
# of patients	N=400
Design	▪ **ARM A:** Tecentriq 1200mg q3w ▪ **ARM B:** Placebo
Primary endpoint	▪ Event-free survival and overall survival
Status	▪ FPI Q1 2018
CT Identifier	NCT03452137

SCCHN=squamous cell carcinoma of the head and neck

Tecentriq

Anti-PD-L1 cancer immunotherapy – UC

Indication	1L metastatic urothelial carcinoma	Adjuvant high-risk muscle-invasive urothelial cancer	High-risk non-muscle-invasive bladder cancer
Phase/study	**Phase III IMvigor130**	**Phase III IMvigor010**	**Phase III ALBAN**
# of patients	N=1,200	N=800	**N=614**
Design	▪ **ARM A:** Tecentriq plus gemcitabine and carboplatin or cisplatin ▪ **ARM B:** Tecentriq monotherapy ▪ **ARM C:** Placebo plus gemcitabine and carboplatin or cisplatin	After cystectomy: ▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Observation	▪ **ARM A**: BCG induction and maintenance ▪ **ARM B:** Tecentriq+ BCG induction and maintenance
Primary endpoint	▪ Progression-free survival, overall survival and safety	▪ Disease-free survival	▪ Recurrence-free survival
Status	▪ FPI Q3 2016 ▪ FPI for arm B (amended study) Q1 2017 ▪ Recruitment completed Q3 2018 ▪ Study met co-primary endpoint of PFS Q3 2019 ▪ Data presented at ESMO 2019	▪ FPI Q4 2015 ▪ Recruitment completed Q3 2018 ▪ Primary endpoint was not met Jan 2020	▪ FPI Q4 2018
CT Identifier	NCT02807636	NCT02450331	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 ▪ Data published in the Lancet. 2019 Jun 15;393(10189):2404-2415	▪ 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 – CRC and HCC

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

Cotellic in collaboration with Exelixis

Tecentriq

Anti-PD-L1 cancer immunotherapy – solid tumors

Indication	Solid tumors
Phase/study	**Phase I**
# of patients	N=430
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)
Primary endpoint	▪ Safety
Status	▪ FPI Q2 2016 ▪ FPI arm E Q1 2017 ▪ FPI arm F Q2 2018 ▪ Breakthrough Therapy Designation granted by FDA for HCC Jul 2018 ▪ HCC data presented at ESMO 2018, APPLE, ILCA and ESMO 2019
CT Identifier	NCT02715531

HCC=hepatocellular carcinoma; GC=gastric cancer; PaC=pancreatic cancer; mEC=metastatic esophageal cancer; CRC=colorectal cancer; TNBC=triple-negative breast cancer; GBM=glioblastoma multiforme; ESMO=European Society for Medical Oncology; APPLE= Asia-Pacific primary liver cancer expert meeting; ILCA=International liver cancer association

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	▪ Recruitment completed Q2 2017 ▪ Study met co-primary endpoint of PFS in both PDL1+ and ITT populations Jul 2018 ▪ Primary PFS and interim OS data presented at ESMO 2018 and ASCO 2019 ▪ Data published in *NEJM* 2018; 379:2108-2121 ▪ US accelerated approval Q1 2019 ▪ Approved in the EU Q3 2019	▪ FPI Q3 2017 ▪ Recruitment completed Q3 2019	▪ FPI Q1 2018
CT Identifier	NCT02425891	NCT03125902	NCT03371017

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – breast cancer

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

[1] In collaboration with ImmunoGen, Inc.
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=453
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	Previously untreated metastatic melanoma BRAF mutation-positive	BRAF-WT metastatic or unresectable locally advanced melanoma after immunotherapy
Phase/study	**Phase III IMspire150 TRILOGY**	**Phase I**	**Phase Ib**
# of patients	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]	▪ 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	▪ Safety and PK	▪ Objective response rate and disease control rate
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2018 ▪ Primary endpoint met Q4 2019	▪ FPI Q4 2012 ▪ Data presented at ESMO 2016 ▪ Published in Nature Medicine 2019 Jun;25(6):929-935	▪ FPI Q2 2017 ▪ Recruitment completed Q4 2018 ▪ Cohort C (Tecentriq monotherapy) data presented at SMR 2019
CT Identifier	NCT02908672	NCT01656642	NCT03178851

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – hematology

Indication	1L FL and 1L DLBCL	Relapsed or refractory FL	Relapsed or refractory AML
Phase/study	**Phase I**	**Phase I**	**Phase I**
# of patients	N=92	N=38	N=21
Design	▪ Tecentriq plus Gazyva plus bendamustine ▪ Tecentriq plus Rituxan plus CHOP	▪ Tecentriq plus Gazyva plus lenalidomide	▪ Tecentriq plus anti-CD47
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ Safety and efficacy
Status	▪ FPI Q4 2015	▪ FPI Q4 2015 ▪ Data presented at ASH 2018	▪ FPI Q4 2019
CT Identifier	NCT02596971	NCT02631577	NCT03922477

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; AML=acute myeloid leukemia; ASH=American Society of Hematology

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	▪ Study met primary endpoint at pre-specified interim analysis Q4 2018 ▪ BTD granted by FDA Q1 2019 ▪ US filing completed under RTOR Q1 2019, approved Q2 2019 ▪ Filed in EU Q2 2019 ▪ Data presented at ASCO 2019 and ASH 2019 ▪ Data published in *NEJM* 2019; 380:2225-2236	▪ Study met primary endpoint at interim analysis ▪ Data presented at ASH 2017 ▪ Filed in US Q4 2017 and EU Q1 2018 ▪ Data published in *NEJM* 2018; 378:1107–20 ▪ Updated data presented at ASCO 2018 and ASH 2019 ▪ Approved in US Q2 2018 (priority review) ▪ EU approval Q4 2018
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; NEJM=New England Journal of Medicine

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 2019; 133(18):1964-1976
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 I**	**Phase Ib/II**	**Phase III CANOVA**
# of patients	N=166	N=100	N=244
Design	▪ **Dose escalation cohort:** Venclexta dose escalation ▪ **Safety expansion cohort (t11:14):** Venclexta expansion ▪ **Combination:** Venclexta plus dexamethasone	▪ Venclexta plus carfilzomib plus dexamethasone in t(11;14) positive r/r MM	▪ Venclexta plus dexamethazone vs pomalidomide plus dexamethasone in t(11;14) positive r/r MM
Primary endpoint	▪ Safety and maximum tolerated dose	▪ Safety, objective response rate, PK, PD	▪ Progression-free survival
Status	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016 and ASH 2016	▪ FPI Q1 2017	▪ FPI Q4 2018
CT Identifier	NCT01794520	NCT02899052	NCT03539744

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Treatment-naïve AML not eligible for standard induction therapy	
Phase/study	**Phase III** **Viale-A**	**Phase III** **Viale-C**
# of patients	N=400	N=175
Design	▪ **ARM A:** Venclexta plus azacitidine ▪ **ARM B:** Azacitidine	▪ **ARM A:** Venclexta plus low-dose cytarabine ▪ **ARM B:** Low-dose cytarabine
Primary endpoint	▪ Overall survival and percentage of participants with complete remission	▪ Overall survival
Status	▪ FPI Q1 2017	▪ FPI Q2 2017
CT Identifier	NCT02993523	NCT03069352

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 ▪ Data published in Blood. 2019 Jan 3;133(1):7-17	▪ FPI Q1 2015 ▪ Initial data presented at ASCO 2016, updated data presented at ASH 2016 and ASH 2017 ▪ Breakthrough Therapy Designation granted by FDA Q3 2017
	▪ Filed in US Jul 2018 ▪ US accelerated approval Q4 2018	
CT Identifier	NCT02203773	NCT02287233

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Relapsed or refractory AML	Relapsed or refractory AML not eligible for cytotoxic therapy	Relapsed or refractory hematological malignancies
Phase/study	**Phase I**	**Phase Ib/II**	**Phase I**
# of patients	N=52	N=140	N=86
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	▪Venclexta plus AMG176 dose escalation ▪ Dose expansion phase to confirm safety and preliminary RPTD
Primary endpoint	▪ Dose and composite complete remission (CRc) Rate	▪ Safety and efficacy	▪ Maximum tolerated dose and safety
Status	▪ FPI Q4 2018 ▪ Initial data presented at ASH 2019	▪ FPI Q1 2016 ▪ Data presented at ASH 2017 ▪ Arm A closed Q2 2019 ▪ Updated data on Arm B presented at ASH 2019	▪ FPI Q2 2019 ▪ Study on clinical hold
CT Identifier	NCT03625505	NCT02670044	NCT03797261

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

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 ▪ Data presented at ASH 2019
CT Identifier	NCT02966782	NCT02942290

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – breast cancer

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

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

Polivy (polatuzumab vedotin)

ADC targeting CD79b to treat B cell malignancies

Indication	Relapsed or refractory FL and DLBCL	1L DLBCL
Phase/study	**Phase Ib/II**	**Phase III POLARIX**
# of patients	N=329	N=875
Design	▪ **PIb:** Dose escalation ▪ **PhII:** Polatuzumab vedotin plus BR vs. BR ▪ **PhII expansion:** Polatuzumab vedotin plus Gazyva (non-randomized)	▪ **ARM A:** Polatuzumab vedotin plus R-CHP ▪ **ARM B:** R-CHOP
Primary endpoint	▪ Safety and response by PET/CT	▪ Progression-free survival
Status	▪ FPI Q4 2014 ▪ 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 and in EU Jan 2020	▪ 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=134	N=128
Design	▪ **Dose escalation cohort:** Polatuzumab vedotin plus Gazyva plus Venclexta[1] ▪ **Expansion cohort DLBCL:** Polatuzumab vedotin plus Rituxan plus Venclexta[1] ▪ **Expansion cohort FL:** Polatuzumab vedotin plus Gazyva plus Venclexta[1]	▪ **Dose escalation cohort:** Polatuzumab vedotin plus Gazyva plus lenalidomide ▪ **Expansion cohort DLBCL:** Polatuzumab vedotin plus Rituxan plus lenalidomide ▪ **Expansion cohort FL:** Polatuzumab vedotin plus Gazyva plus lenalidomide
Primary endpoint	▪ Percentage of participants with CR	▪ Percentage of participants with CR
Status	▪ FPI Q1 2016	▪ FPI Q1 2016 ▪ Interim data in FL presented at ASCO, EHA and ICML 2019 ▪ Primary data presented at ASH 2019
CT Identifier	NCT02611323	NCT02600897

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

Rozlytrek (entrectinib)

CNS-active and selective inhibitor of NTRK/ROS1

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

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

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 2x300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	120-week treatment period: ▪ **ARM A:** Ocrelizumab 2x300 mg iv every 24 weeks ▪ **ARM B:** Placebo
Primary endpoint	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Sustained disability progression versus placebo by Expanded Disability Status Scale (EDSS)
Status	▪ Primary endpoint met Q2 2015, OLE ongoing ▪ Primary data presented at ECTRIMS 2015 ▪ Updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM* 2017; 376:221-234		▪ Primary endpoint met Q3 2015 ▪ Primary data presented at ECTRIMS 2015, updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM* 2017; 376:209-220
	▪ Approved in US Q1 2017 and EU Q1 2018		
CT Identifier	NCT01247324	NCT01412333	NCT01194570

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

MabThera/Rituxan

Immunology development program

Indication	Moderate to severely active pemphigus vulgaris
Phase/study	**Phase III** **PEMPHIX**
# of patients	N=132
Design	▪ **ARM A:** Rituxan ▪ **ARM B:** Mycophenolate mofetil
Primary endpoint	▪ Proportion of patients who achieve sustained complete remission
Status	▪ Breakthrough Therapy Designation granted by FDA in Q1 2017 ▪ Recruitment completed Q4 2017 ▪ Study met primary endpoint Q2 2019 ▪ Data presented at EADV 2019 ▪ Approved in US Q2 2018 and in EU Q1 2019 based on Roche-supported IST Ritux 3
CT Identifier	NCT02383589

IST=Investigator sponsored trial

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	▪ Recruitment completed Q4 2017 ▪ Primary endpoint met Q2 2019 ▪ Breakthrough therapy designation granted by the FDA Q3 2019 ▪ Data presented at ASN and ACR 2019
CT Identifier	NCT02550652

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

Xolair

Humanized mAb that selectively binds to IgE

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

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

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza	
Phase/study	**Phase III CAPSTONE-1**	**Phase III CAPSTONE-2**
# of patients	N=1,436	N=2,184
Design	▪ Randomized, double-blind study of a single dose of Xofluza compared with placebo or Tamiflu 75 mg twice daily for 5 days in otherwise healthy patients with influenza	▪ Randomized, double-blind study of a single dose of Xofluza compared with placebo or Tamiflu 75 mg twice daily for 5 days in patients with influenza at high risk of influenza complications
Primary endpoint	▪ Time to alleviation of symptoms	▪ Time to improvement of influenza symptoms
Status	▪ FPI Q4 2016, recruitment completed Q1 2017 ▪ Primary endpoint met Q3 2017 (time to alleviation of symptoms versus placebo) ▪ Filed in US Q2 2018 (priority review), approval Q4 2018 ▪ Data published in *NEJM* 2018; 379:913-923 ▪ Filed in EU Q4 2019	▪ FPI Q1 2017, recruitment completed Q1 2018 ▪ Primary endpoint met Q3 2018 (time to improvement of influenza symptoms versus placebo) ▪ Data presented at IDweek 2018 ▪ Filed in US Q1 2019, approval Q4 2019 ▪ Filed in EU Q4 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=366	N=30	N=176
Design	▪ Xofluza + neuraminidase inhibitor vs placebo + neuraminidase inhibitor in hospitalized patients with influenza	▪ Xofluza on Day 1 (based on body weight and age) in healthy pediatric patients from birth to <1 year with influenza-like symptoms	▪ Xofluza vs Tamiflu in healthy pediatric patients 1 to <12 years of age with influenza-like symptoms
Primary endpoint	▪ Time to clinical improvement	▪ Safety	▪ Safety
Status	▪ FPI Jan 2019	▪ FPI Q1 2019	▪ FPI Q4 2018 ▪ Recruitment completed Q1 2019 ▪ Primary endpoint met Q2 2019 ▪ Data presented at OPTIONS X 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 Q4 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)

Spark

Roche Group 2019 results

Diagnostics

Foreign exchange rate information

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	Advanced prostate cancer and solid tumors
Phase/study	**Phase III** **IPATential150**	**Phase Ib**
# of patients	N=1,100	N=54
Design	▪ **ARM A:** Ipatasertib plus abiraterone ▪ **ARM B:** Placebo plus abiraterone	▪ Ipatasertib plus rucaparib **Stage 1:** Dose escalation in advanced breast, ovarian and prostate cancer ▪ **Stage 2:** Dose expansion in prostate cancer
Primary endpoint	▪ Progression-free survival	▪ Safety and efficacy
Status	▪ FPI Q2 2017 ▪ Recruitment completed Jan 2019	▪ FPI Q2 2019
CT Identifier	NCT03072238	NCT03840200

In collaboration with Array BioPharma

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L TNBC and HR+ breast cancer	1L TNBC	TNBC
Phase/study	**Phase III** **IPATunity130**	**Phase II** **LOTUS**	**Phase Ib**
# of patients	N=450	N=120	N=114
Design	Cohort 1: Dx+ 1L TNBC (N=249): ▪ **ARM A:** Ipatasertib+paclitaxel ▪ **ARM B:** Placebo+paclitaxel Cohort 2: Dx+ HR+ mBC (N=201): ▪ **ARM A:** Ipatasertib+paclitaxel ▪ **ARM B:** Placebo+paclitaxel	▪ **ARM A:** Ipatasertib+paclitaxel ▪ **ARM B:** Placebo+paclitaxel	▪ **ARM A:** Ipatasertib+Tecentriq +paclitaxel ▪ **ARM B:** Ipatasertib+Tecentriq+nab-paclitaxel
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Safety and efficacy
Status	▪ FPI Q1 2018	▪ Recruitment completed Q1 2016 ▪ Data presented at ASCO 2017 and ASCO 2018 ▪ Data published in Lancet Oncology 2017 Aug 8. pii: S1470-2045(17)30450-3	▪ FPI Q1 2018 ▪ Data presented at AACR 2019
CT Identifier	NCT03337724	NCT02162719	NCT03800836

In collaboration with Array BioPharma

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

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

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

In collaboration with Array BioPharma

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 ▪ Recruitment completed Q3 2019	▪ 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:** PSEN1 E280A mutation carriers recieve crenezumab SC ▪ **ARM B:** PSEN1 E280A mutation carriers receive placebo ▪ **ARM C:** non-mutation carriers receive placebo
Primary endpoint	▪ Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score
Status	▪ FPI Q4 2013 ▪ Recruitment completed Q1 2017
CT Identifier	NCT01998841

In collaboration with AC Immune
Aβ=amyloid-beta

Gantenerumab (RG1450)

Fully human mAb binding aggregated forms of Aβ

Indication	Prodromal to mild Alzheimer's disease	
Phase/study	**Phase III GRADUATE 1**	**Phase III GRADUATE 2**
# of patients	N=1,016	N=1,016
Design	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo
Primary endpoint	▪ Change in CDR-SOB at 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-SOB=Clinical Dementia Rating Scale Sum of Boxes

Gantenerumab (RG1450)

Fully human mAb binding aggregated forms of Aβ

Indication	Prodromal Alzheimer's disease	Mild Alzheimer's disease
Phase/study	**Phase II/III** **SCarlet RoAD**	**Phase III** **Marguerite RoAD**
# of patients	N=799	N=389
Design	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab (225 mg) ▪ **ARM B:** Gantenerumab (105 mg) ▪ **ARM C:** Placebo	104-week subcutaneous treatment period: ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo
Primary endpoint	▪ Change in CDR-SOB at 2 years ▪ Sub-study: change in brain amyloid by PET at 2 years	▪ Change in ADAS-Cog and CDR-SOB at 2 years (co-primary)
Status	▪ Phase I PET data: *Archives of Neurology*, 2012 Feb;69(2):198-207 ▪ Recruitment completed Q4 2013 ▪ Dosing stopped due to futility Q4 2014 ▪ FPI in open label extension study Q4 2015 ▪ OLE data presented at CTAD 2017, AD/PD and AAN 2018 and 2019	▪ FPI Q1 2014 ▪ Recruitment stopped Q4 2015 ▪ FPI Q1 2016 for open label extension ▪ OLE data (MRI) presented at CTAD 2017, AD/PD, AAIC 2018 and AAN 2018 and 2019
CT Identifier	NCT01224106	NCT02051608

In collaboration with MorphoSys AG

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

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=166
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 ▪ 104 week data presented at Action Duchenne 2019	▪ FPI Q3 2017 ▪ Recruitment completed July 2019 ▪ Discontinued after a pre-planned futility analysis indicated study was unlikely to meet primary endpoint Q4 2019
CT Identifier	NCT02515669	NCT03039686

BPNA=British Paediatric Neurology Association; AAN=American Academy of Neurology; NSAA=North Star Ambulatory Assessment

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	▪ Recruitment completed for part 2 Q4 2018 ▪ 12 month data from Part 1 presented at AAN, CureSMA and EAN 2019; 16 month data presented at WMS 2019 ▪ Study met primary endpoint in part 2 Jan 2020	▪ Recruitment completed for part 2 Q3 2018 ▪ 12 month data from Part 1 presented at AAN, CureSMA and EAN 2019; 16 month data presented at WMS 2019 ▪ Study met primary endpoint in part 2 Q4 2019	▪ FPI Q1 2017 ▪ Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019 and WMS 2019
	Orphan drug designation granted by FDA Q1 2017 and EU Jan 2019, PRIME designation in Q4 2018, filed in US Q4 2019		
CT Identifier	NCT02913482	NCT02908685	NCT03032172

In collaboration with PTC Therapeutics and SMA Foundation

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

Risdiplam (RG7916)

Oral SMN2 splicing modifier

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

In collaboration with PTC Therapeutics and SMA Foundation

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

In collaboration with Ionis Pharmaceuticals

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

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=800	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

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

Satralizumab (RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Neuromyelitis optica spectrum disorder (NMOSD)	
Phase/study	**Phase III** **Sakura Star**	**Phase III** **Sakura Sky**
# of patients	N=90	N=70 (adults); N=6 (adolescents)
Design	Satralizumab as monotherapy: ▪ **Group A:** Satralizumab 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 ▪ Data presented at ECTRIMS 2019	▪ FPI Q3 2017 ▪ Primary endpoint met Q3 2018 ▪ Data presented at ECTRIMS 2018 and AAN 2019 ▪ Published in NEJM 2019; 381:2114-2124
	▪ BTD granted Q4 2018 ▪ Filed in EU Q3 2019; US acceptance of filing Q4 2019	
CT Identifier	NCT02073279	NCT02028884

*Trials managed by Chugai (Roche opted-in)

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

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

Indication	Ulcerative colitis patients who are TNF-naïve		
Phase/study	**Phase III** **HIBISCUS I** Induction study	**Phase III** **HIBISCUS II** Induction study	**Phase III** **GARDENIA** Sustained remission study
# of patients	N=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 ▪ Recruitment completed Q4 2019	▪ FPI Q4 2014 ▪ Recruitment completed Q4 2019	▪ FPI Q4 2014 ▪ Recruitment completed Q2 2019
CT Identifier	NCT02163759	NCT02171429	NCT02136069

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

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

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

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

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

UEGW=United European Gastroenterology Week

Crovalimab (RG6107; SKY59)

A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH)
Phase/study	**Phase I/II** **COMPOSER**
# of patients	N=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 and 2019
CT Identifier	NCT03157635

In collaboration with Chugai
ASH=American Society of Hematology

Faricimab (RG7716)

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

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

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

Faricimab (RG7716)

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

Indication	Center-involving diabetic macular edema (CI-DME)	
Phase/study	**Phase III YOSEMITE**	**Phase III RHINE**
# of patients	N=900	N=900
Design	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab (RG7716) q8w/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 ▪ Recruitment completed Q3 2019	▪ FPI Oct 2018 ▪ Recruitment completed Q3 2019
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 ▪ Recruitment completed Q4 2019	▪ FPI Q1 2019 ▪ Recruitment completed Q4 2019
CT Identifier	NCT03823287	NCT03823300

BCVA=best corrected visual acuity

Port Delivery System with ranibizumab

First eye implant to achieve sustained delivery of a biologic medicine

Indication	wAMD		DME
Phase/study	**Phase III Archway**	**Phase II+III extension Portal**	**Phase III Pagoda**
# of patients	N=418	N=500	N=545
Design	▪ **ARM A:** PDS with ranibizumab every 24 weeks ▪ **ARM B:** Intravitreal ranibizumab every 4 weeks	▪ Patients from LADDER or Archway will receive refills of 100 mg/mL ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)	▪ **ARM A:** PDS with ranibizumab every 24 weeks ▪ **ARM B:** Intravitreal ranibizumab every 4 weeks
Primary endpoint	▪ Change in BCVA from baseline at the average of week 36 and week 40	▪ Safety and long term efficacy	Change in BCVA from baseline at the average of week 48 and week 52
Status	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2019	▪ FPI Q3 2018	▪ FPI Q3 2019
CT Identifier	NCT03677934	NCT03683251	NCT04108156

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

Roche pRED

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group 2019 results

Diagnostics

Foreign exchange rate information

Oncology development programs

Bispecific 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

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

Oncology development programs

Bispecific antibodies

Molecule	FAP-IL2v FP (RG7461)		FAP-4-1BBL FP (RG7827)
Indication	**1L Renal call carcinoma**	**1L/2L+ Melanoma**	**Solid tumors**
Phase/study	**Phase Ib**	**Phase Ib**	**Phase I**
# of patients	N=110	N=40	N=200
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	▪ **Part 1:** Single agent dose escalation ▪ **Part 2:** Combo dose escalation with Tecentriq ▪ **Part 3:** Combo expansion with Tecentriq
Primary endpoint	▪ Safety, PD and efficacy	▪ Safety	▪ Safety, efficacy, PK and PD
Status	▪ FPI Q1 2017	▪ FPI Q2 2019	▪ FPI Q2 2018
CT Identifier	NCT03063762	NCT03386721	

Oncology development programs

Bispecific antibody

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

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

Oncology development programs

Bispecific antibody

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, ICML 2019, ASH 2019	▪ FPI Q2 2018 ▪ Data presented at ASH 2019	▪ FPI Q1 2018
CT Identifier	NCT03075696	NCT03533283	NCT03467373

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

Oncology development programs

Bispecific antibodies

Molecule	PD1-TIM3 (RG7769)	PD1-LAG3 (RG6139)
Indication	Advanced and metastatic solid tumors	Advanced and metastatic solid tumors
Phase/study	Phase Ia/b	Phase I
# of patients	N=280	N=200
Design	▪ **Part A1**: Dose escalation (Q2W) ▪ **Part A2**: Dose escalation (Q3W) ▪ **Part B1**: Dose expansion metastatic melanoma ▪ **Part B2**: Dose expansion NSCLC 2L+ ▪ **Part B3**: Dose expansion NSCLC 1L (PD-L1 high cohort)	Open-label, multicenter, multiple-ascending dose (MAD) study ▪ **Part A**: Dose escalation (Q2W or Q3W) ▪ **Part B**: Tumor specific dose expansion
Primary endpoint	▪ Safety, PK/PD and efficacy	▪ Safety, PK/PD and efficacy
Status	▪ FPI Q4 2018	▪ FPI Q4 2019
CT Identifier	NCT03708328	NCT04140500

NSCLC=non-small cell lung cancer

Oncology development programs

Monoclonal antibodies and antibody fusion protein

Molecule	selicrelumab (CD40 MAb, RG7876)	Anti-CD25 (RG6292)	CD19-4-1BBL (RG6076)
Indication	**Solid tumors**	**Advanced and metastatic solid tumors**	**Relapsed or refractory B cell non-Hodgkin's lymphoma**
Phase/study	**Phase Ib**	**Phase I**	**Phase I**
# of patients	N=94	N=110	N=207
Design	▪ **Part I:** Selicrelumab dose escalation in combination with vanucizumab ▪ **Part II:** Selicrelumab dose expansion in combination with Avastin in PROC, HNSCC and CPI exp. NSCLC	▪ **Part A**: Dose escalation Q3W ▪ **Part B**: Tumor specific expansion cohorts	▪ **Part 1**: Dose-escalation in combination with Gazyva ▪ **Part 2**: Dose-escalation in combination with CD20-TCB
Primary endpoint	▪ Safety, PD and efficacy	▪ Safety, PK/PD and efficacy	▪ Safety, PK/PD and efficacy
Status	▪ FPI Q1 2016 ▪ Part II FPI Q2 2018 ▪ Selicrelumab+vanucizumab no longer recruiting	▪ FPI Q4 2019	▪ FPI Q3 2019
CT Identifier	NCT02665416	NCT04158583	NCT04077723

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

Neuroscience development programs

Molecule	**basmisanil** ($GABA_A$α5 NAM, RG1662)	**brain shuttle gantenerumab** (RG6102)
Indication	**Cognitive impairment associated with schizophrenia**	**Alzheimer's disease**
Phase/study	**Phase II**	**Phase I**
# of patients	N=180	N~60
Design	For 24 weeks patients will receive: ▪ **ARM A:** RG1662 80mg twice daily ▪ **ARM B:** RG1662 240mg twice daily ▪ **ARM C:** Placebo	▪ Single and multiple ascending dose study with healthy volunteer and patient cohorts
Primary endpoint	▪ Efficacy (cognitive function), PK, safety and tolerability	▪ Safety, tolerability, PK
Status	▪ FPI Q4 2016 ▪ Recruitment completed Q2 2019 ▪ Primary endpoint not met Q4 2019	▪ FPI Q3 2019
CT Identifier	NCT02953639	NCT04023994

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 ▪ LPI July 2019	▪ 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)	CpAM (RG7907)
Indication	Chronic hepatitis B	Chronic hepatitis B
Phase/study	Phase I	Phase I/II
# of patients	N=140	N=175
Design	▪ Healthy volunteer and chronic hepatitis B patient study	▪ **Part 1:** Healthy volunteers ▪ **Part 2:** Chronic hepatitis B patients, 4 week dosing ▪ **Part 3:** Chronic hepatitis B patients, 48 week on top of SoC
Primary endpoint	▪ Safety, PK and PD	▪ Safety, PK and PD and efficacy
Status	▪ FPI Q4 2016 ▪ Data presented at APASL 2019	▪ FPI Q4 2016 ▪ Data presented at EASL 2018 and 2019
CT Identifier	NCT02956850	NCT02952924

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

Infectious diseases development programs

Chronic hepatitis B

Molecule	NME (RG6217)	NME (RG6084)
Indication	Chronic hepatitis B	Chronic hepatitis B
Phase/study	Phase I	Phase I
# of patients	N=75	N=27
Design	▪ Healthy volunteer and chronic hepatitis B patient study	▪ Chronic hepatitis B patient study
Primary endpoint	▪ Safety	▪ Safety
Status	▪ FPI Q4 2018	▪ FPI Q1 2019
CT Identifier	NCT03762681	

Immunology development programs

Molecule	IgG-IL2 FP (RG7835)	
Indication	**Autoimmune diseases**	**Ulcerative Colitis**
Phase/study	**Phase I**	**Phase 1b**
# of patients	N=49	N=50
Design	▪ 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	▪ Safety, PK and PD	▪ Safety, tolerability, PK/PD, efficacy
Status	▪ FPI Q3 2017 ▪ Recruitment completed Q3 2018	▪ FPI Q2 2019
CT Identifier	NCT03221179	NCT03943550

Ophthalmology development programs

Molecule	NME (RG6179)
Indication	DME
Phase/study	**Phase I**
# of patients	N~50
Design	**Part 1:** Open label, multiple ascending dose study evaluating safety, tolerability and pharmacokinetics (PK) of intravitreal monotherapy **Part 2:** Safety, tolerability and pharmacodynamics of RG6179 in combination with anti-VEGF (ranibizumab) treatment
Primary endpoint	Safety, tolerability, PK
Status	▪ FPI July 2019
CT Identifier	
Collaborator	Sensen

DME=diabetic macular edema

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group 2019 results

Diagnostics

Foreign exchange rate information

Oncology development programs

Bispecific antibodies

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

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

Oncology development programs

Bispecific antibodies

Molecule	FcRH5 X CD3 (RG6160)	HER2 x CD3 (RG6194)
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

Monoclonal antibodies

Molecule	**tiragolumab** (anti-TIGIT, RG6058, MTIG7192A)		
Indication	**Solid tumors**	**NSCLC**	**R/R Multiple Myeloma (MM) or R/R B-cell NHL**
Phase/study	**Phase I**	**Phase II CITYSCAPE**	**Phase I**
# of patients	N=300	N=135	N=52
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	▪ Phase Ia: Tiragolumab monotherapy ▪ Phase Ib: Tiragolumab plus daratumumab (r/r MM) or rituximab (r/r NHL)
Primary endpoint	▪ Safety, tolerability, PK variability and preliminary efficacy	▪ Overall response rate and progression-free survival	▪ Safety, tolerability, PK/PD and preliminary efficacy
Status	▪ FPI Q2 2016	▪ FPI Q3 2018 ▪ Recruitment completed Q2 2019	▪ FPI Q2 2019
CT Identifier	NCT02794571	NCT03563716	NCT04045028

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

Oncology development programs

Small molecules

Molecule	SERD (3) (RG6171, GDC-9545)		PI3K inhibitor (RG6114, GDC-0077)
Indication	**Metastatic ER+ HER2-neg breast cancer**	**ER+ HER2-neg Stage I-III operable breast cancer**	**PIK3CA mutant solid tumors and metastatic ER+ HER2-neg breast cancer**
Phase/study	**Phase I**	**Phase I**	**Phase I**
# of patients	N=130	N=45	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	▪ Open-label, pre-operative administration ▪ Dose escalation	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/PD	▪ Safety, tolerability and PK
Status	▪ FPI Q4 2017 ▪ Data presented at SABCS 2019	▪ FPI Q3 2019	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017
CT Identifier	NCT03332797	NCT03916744	NCT03006172

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

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

Immunology development programs

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

UC=Ulcerative Colitis

Immunology development programs

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

FeNO=Fractional exhaled nitric oxide

Immunology development programs

gRED Genentech Research & Early Development

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

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

Immunology development programs

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

MTX=methotrexate

Immunology development programs

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 ▪ Recruitment completed Q3 2019
CT Identifier	NCT03162250
Collaborator	Seattle Genetics, Symphogen

TAC=THIOMAB™ antibiotic conjugate

Ophthalmology development programs

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

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

Metabolic diseases development programs

gRED Genentech Research & Early Development

Molecule	FGFR1 X KLB (RG7992)		
Indication	**Metabolic diseases**		**NASH**
Phase/study	**Phase Ia**	**Phase Ib**	**Phase II**
# of patients	N=79	N=140	N=260
Design	Healthy volunteer study ▪ Randomized, blinded, placebo-controlled, single ascending dose of RG7992	Obese type 2 diabetes ▪ Randomized, blinded, placebo-controlled, multiple ascending dose of RG7992	Non-Alcoholic Steatohepatitis (NASH) ▪ Randomized, blinded, placebo-controlled study of RG7992
Primary endpoint	▪ Safety and tolerability	▪ Safety, tolerability and PK	▪ Proportion of Participants with NASH Resolution on Overall Histopathological Reading Without Worsening of Fibrosis at Week 52, Safety and PK
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q1 2017	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2019	▪ FPI expected Q1 2020
CT Identifier	NCT02593331	NCT03060538	NCT04171765

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

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group 2019 results

Diagnostics

Foreign exchange rate information

Hemophilia A

Unique gene therapy platform

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

Choroideremia

Unique gene therapy platform

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

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group 2019 results

Diagnostics

Foreign exchange rate information

Geographical sales split by Divisions and Group*

CHFm	2018	2019	% change CER
Pharmaceuticals Division	**43,967**	**48,516**	**+11**
United States	23,233	26,711	**+13**
Europe	8,693	8,453	**+1**
Japan	3,701	4,143	**+9**
International	8,340	9,209	**+15**
Diagnostics Division	**12,879**	**12,950**	**+3**
United States	2,866	2,932	**+1**
Europe	4,059	3,938	**+1**
Japan	502	509	**-2**
International	5,452	5,571	**+6**
Group	**56,846**	**61,466**	**+9**
United States	26,099	29,643	**+12**
Europe	12,752	12,391	**+1**
Japan	4,203	4,652	**+8**
International	13,792	14,780	**+12**

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

Pharma Division sales 2019

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Avastin	7,073	4	3,019	2	1,794	2	871	0	1,389	13
MabThera	6,477	-4	4,488	3	590	-33	109	-44	1,290	-1
Herceptin	6,039	-12	2,707	-8	1,013	-43	243	-5	2,076	10
Ocrevus	3,708	57	3,049	44	495	148	-	-	164	161
Perjeta	3,522	29	1,528	13	1,092	24	280	90	622	71
Actemra / RoActemra	2,311	8	944	8	705	4	398	9	264	14
Xolair	1,969	1	1,969	1	-	-	-	-	-	-
Tecentriq	1,875	143	1,180	148	349	138	188	126	158	138
Lucentis	1,826	8	1,826	8	-	-	-	-	-	-
Kadcyla	1,393	45	635	74	432	19	82	7	244	56
Hemlibra	1,380	*	943	*	165	308	232	*	40	*
TNKase / Activase	1,332	2	1,278	2	-	-	-	-	54	2
Esbriet	1,129	9	806	5	263	18	-	-	60	34
Alecensa	876	38	329	14	212	123	217	12	118	86
Pulmozyme	751	2	527	2	132	3	1	23	91	-1
CellCept	656	0	83	-23	173	0	85	3	315	7
Mircera	591	10	-	-	67	-9	202	-4	322	28
Gazyva	552	43	249	25	174	32	66	397	63	47
Xeloda	406	-4	22	-38	17	2	73	-36	294	14
Tamiflu	377	0	43	-75	81	234	97	-1	156	75

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

Pharma Division sales 2019

New products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Erivedge	279	10	185	14	62	-10	-	-	32	38
Perjeta	3,522	29	1,528	13	1,092	24	280	90	622	71
Kadcyla	1,393	45	635	74	432	19	82	7	244	56
Gazyva	552	43	249	25	174	32	66	397	63	47
Esbriet	1,129	9	806	5	263	18	-	-	60	34
Cotellic	57	-2	11	-25	31	-9	-	-	15	50
Alecensa	876	38	329	14	212	123	217	12	118	86
Tecentriq	1,875	143	1,180	148	349	138	188	126	158	138
Ocrevus	3,708	57	3,049	44	495	148	-	-	164	161
Hemlibra	1,380	*	943	*	165	308	232	*	40	*
Xofluza	10	-29	8	-42	-	-	-	-	2	-
Polivy	51	-	51	-	-	-	-	-	-	-
Rozlytrek	7	-	7	-	-	-	-	-	-	-
Total	**14,839**	**57**	**8,981**	**52**	**3,275**	**50**	**1,065**	**97**	**1,518**	**81**

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

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q1/18	Q2/18	Q3/18	Q4/18	Q1/19	Q2/19	Q3/19	Q4/19
Avastin	-2	1	6	5	9	6	8	-6
MabThera	-8	-11	-7	-6	-3	-5	-1	-6
Herceptin	2	2	1	-3	-6	-12	-7	-24
Ocrevus	-	195	104	83	67	59	48	55
Perjeta	18	28	27	35	41	29	33	16
Actemra / RoActemra	13	13	9	14	6	10	9	5
Xolair	7	14	9	12	1	2	3	0
Tecentriq	29	44	71	89	135	146	154	136
Lucentis	6	27	2	47	11	9	7	7
Kadcyla	6	11	8	7	24	42	54	57
Hemlibra	-	-	-	*	*	*	*	313
TNKase / Activase	8	10	1	4	7	-3	5	0
Esbriet	13	15	21	26	10	13	6	9
Alecensa	81	98	62	69	61	41	50	11
Pulmozyme	0	6	1	3	6	0	7	-5
CellCept	-8	-4	4	-9	4	-4	3	-3
Mircera	5	4	16	-4	16	10	11	5
Gazyva	27	38	51	44	35	38	45	51
Xeloda	-2	-11	-2	-8	5	-2	-4	-13
Tamiflu	11	-75	-63	-67	-40	110	369	104

CER=Constant Exchange Rates; * over 500%; [1] Q1-Q4/18 vs Q1-Q4/17; Q1-Q4/19 vs. Q1-Q4/18;

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Avastin	12	7	1	-11	1	3	4	1	2	4	9	-13	16	10	29	0
MabThera	9	-1	4	1	-38	-35	-26	-33	-50	-42	-45	-37	-4	8	3	-11
Herceptin	3	-8	-6	-24	-44	-47	-42	-39	-9	6	-1	-15	26	17	20	-16
Ocrevus	54	46	35	44	232	149	154	112	-	-	-	-	261	173	118	155
Perjeta	36	9	8	4	27	28	18	21	74	99	125	67	83	73	122	19
Actemra / RoActemra	5	11	11	6	4	8	3	3	13	11	13	1	10	15	16	15
Xolair	1	2	3	0	-	-	-	-	-	-	-	-	-	-	-	-
Tecentriq	91	158	198	146	158	112	113	172	-	169	66	68	262	127	132	109
Lucentis	11	9	7	7	-	-	-	-	-	-	-	-	-	-	-	-
Kadcyla	39	62	87	108	9	18	20	28	12	11	10	-5	32	62	78	50
Hemlibra	*	*	*	302	450	*	211	202	-	*	*	472	-	-	*	*
TNKase / Activase	7	-4	5	-1	-	-	-	-	-	-	-	-	-10	6	2	8
Esbriet	7	9	0	6	14	18	26	16	-	-	-	-	37	49	20	31
Alecensa	14	5	15	23	182	154	164	58	24	16	14	-1	278	177	154	-64
Pulmozyme	6	-1	9	-4	8	3	2	-2	43	38	-	14	4	0	5	-15
CellCept	-20	-25	-30	-15	2	-2	3	-1	8	7	1	-1	13	-1	17	-1
Mircera	-	-	-	-	-11	-7	-8	-8	3	4	-6	-14	35	21	27	28
Gazyva	22	8	24	48	31	31	30	38	-	-	390	145	31	101	31	43
Xeloda	10	-41	-63	-53	-13	0	16	7	-14	-30	-44	-53	13	15	17	10
Tamiflu	-86	*	-	*	38	*	*	145	-6	153	-	50	55	30	270	86

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

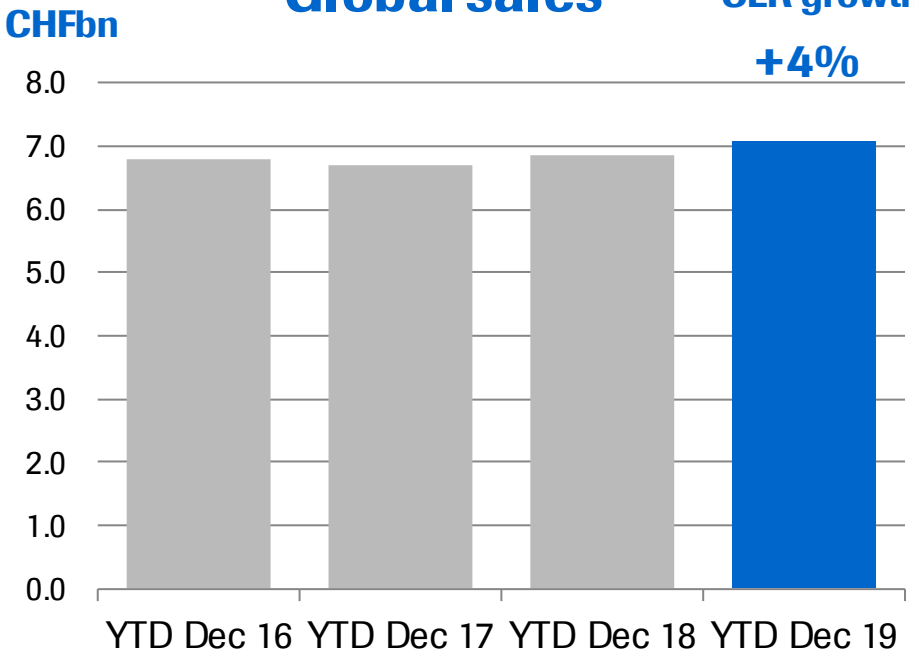
CER sales growth (%)
Quarterly development

	2018 vs. 2017				2019 vs. 2018			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmaceuticals Division	**7**	**7**	**7**	**8**	**10**	**11**	**15**	**8**
United States	15	15	12	14	14	13	14	11
Europe	-7	-8	-7	-6	-6	-2	5	6
Japan	0	0	0	-5	7	12	14	3
International	5	6	14	14	17	16	27	2
Diagnostics Division	**5**	**7**	**6**	**10**	**1**	**4**	**6**	**1**
Roche Group	**6**	**7**	**7**	**9**	**8**	**9**	**13**	**6**

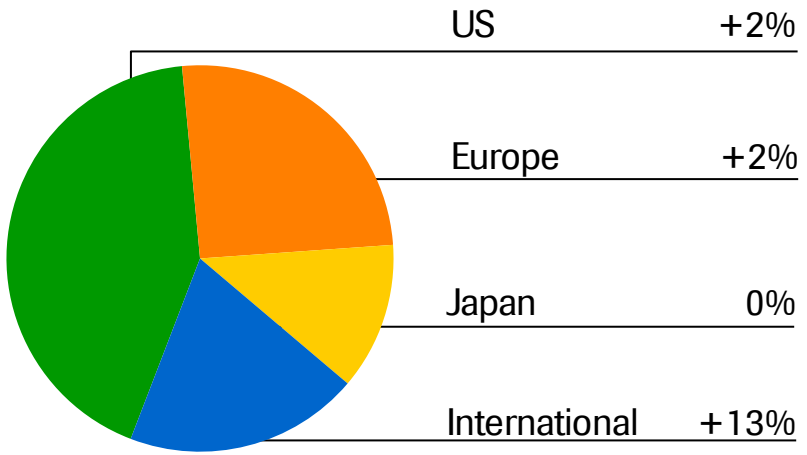
CER=Constant Exchange Rates

Avastin

Global sales



Regional sales



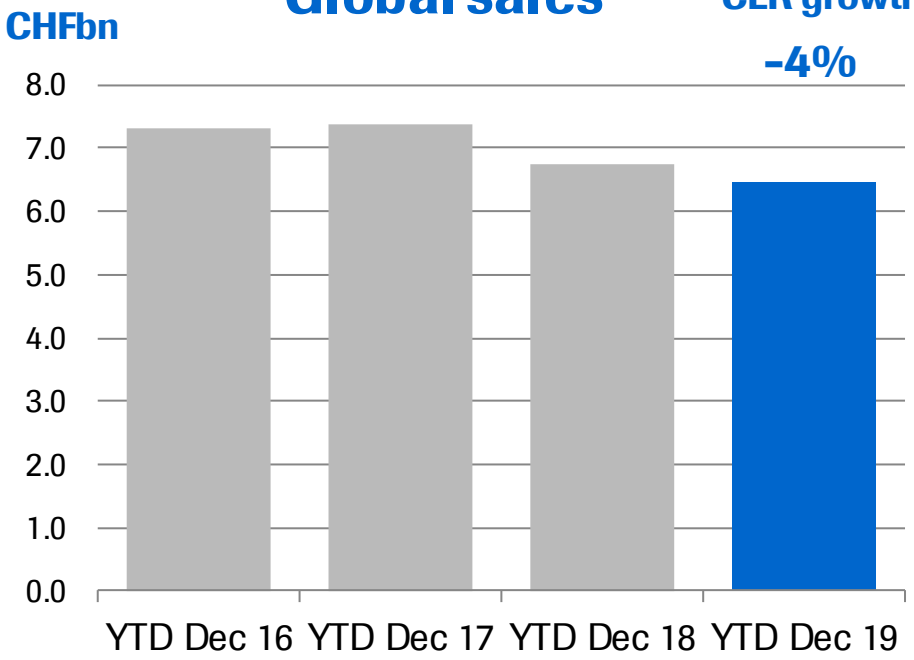
2019 sales of CHF 7,073m

- US: Demand growth driven by various indications; first biosimilar launched in Q3
- EU: Growth driven by various indications
- International: Growth driven by China in 1L CRC and 1L NSCLC and by longer duration of treatment

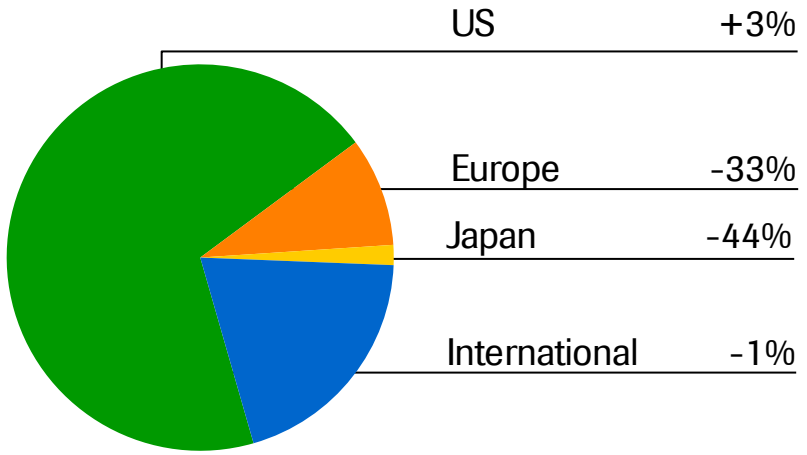
CER=Constant Exchange Rates

MabThera / Rituxan

Global sales



Regional sales

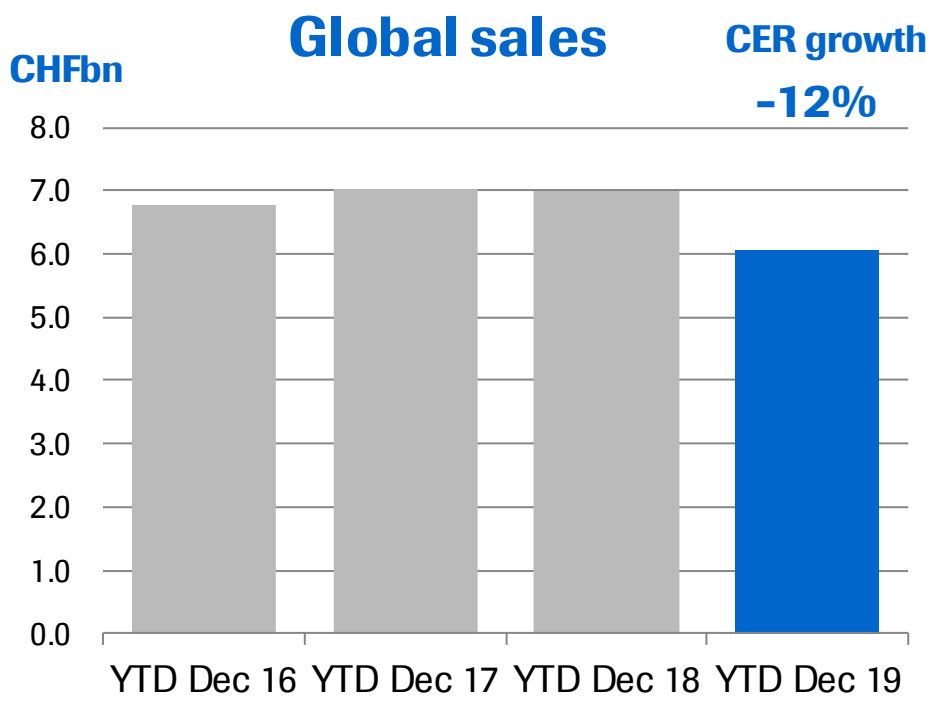


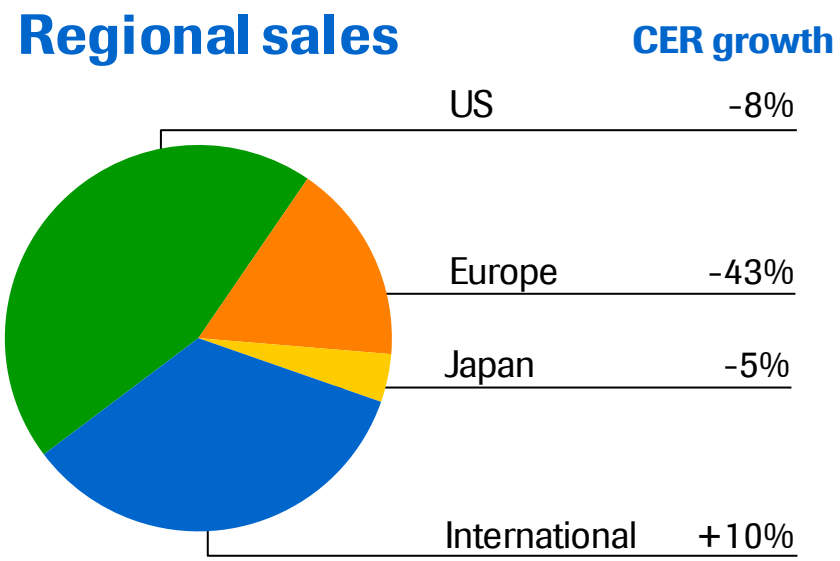
2019 sales of CHF 6.477m

- US: Growth driven by approved oncology/immunology indications; first biosimilar launched in Q4
- EU: Biosimilar erosion rate softening
- Japan: Decline due to biosimilars
- International: Volume growth in China compensates for biosimilar erosion

CER=Constant Exchange Rates

Herceptin



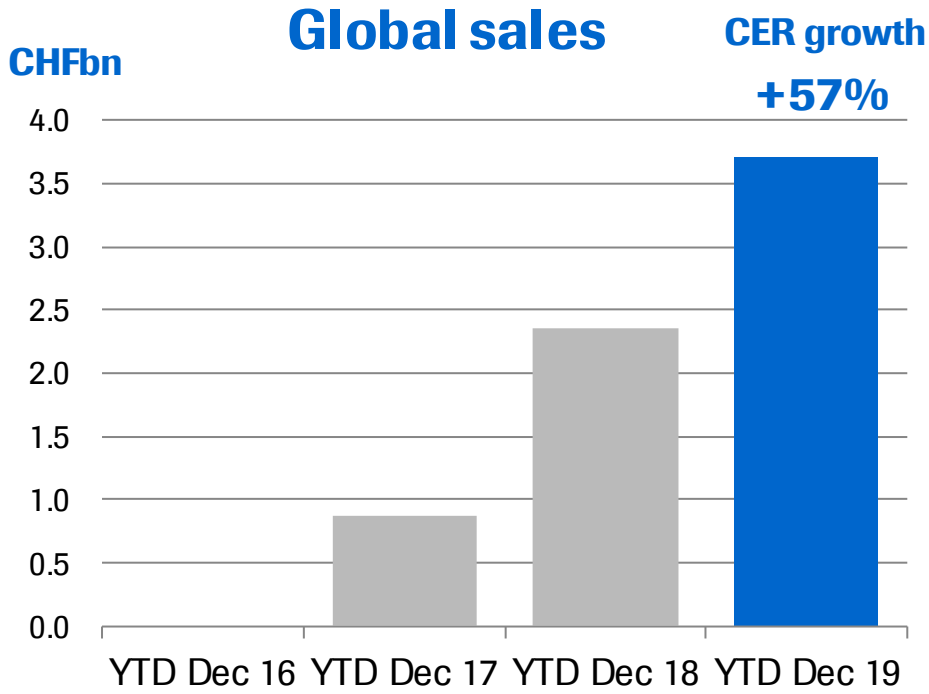


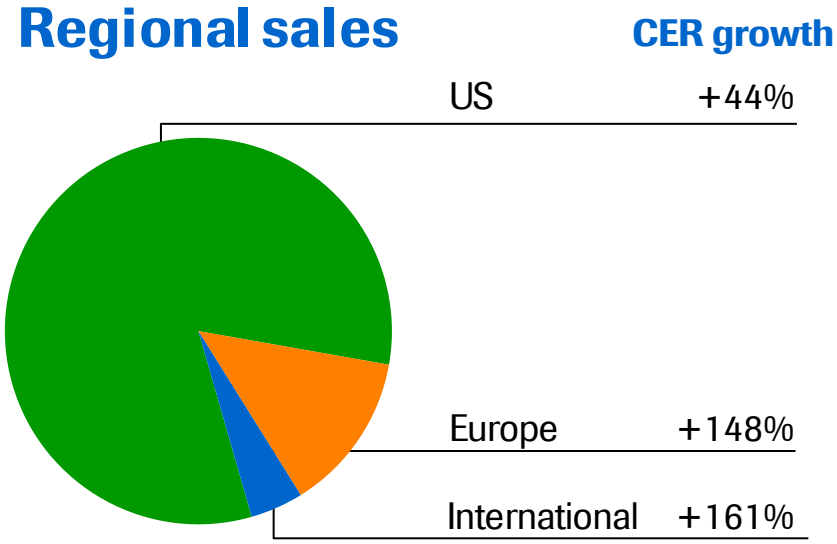
2019 sales of CHF 6,039m

- US: Switching of eligible adjuvant patients to Kadcyla and first biosimilars launched in H2
- 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

Ocrevus



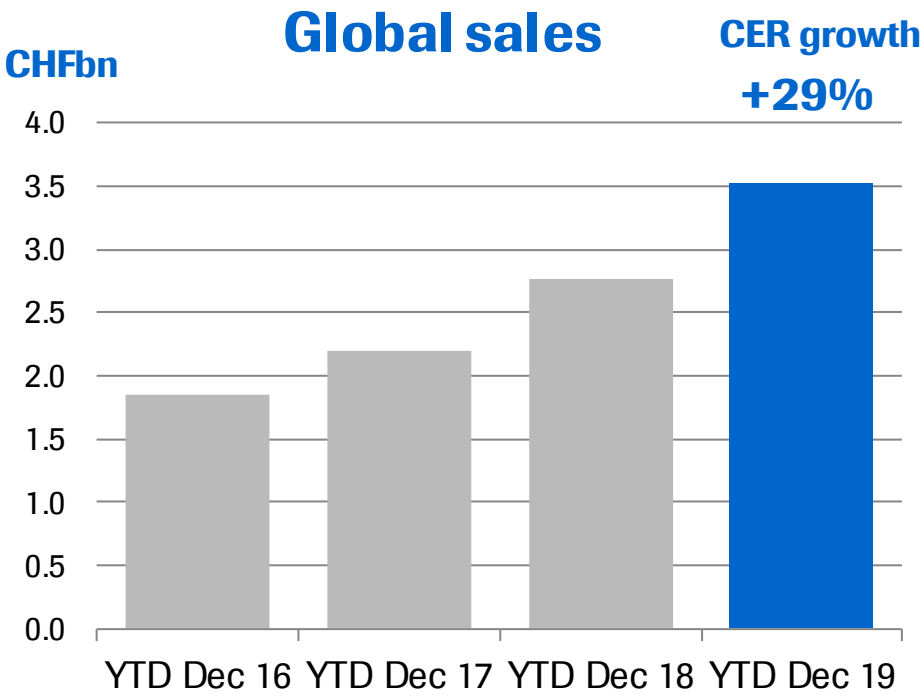


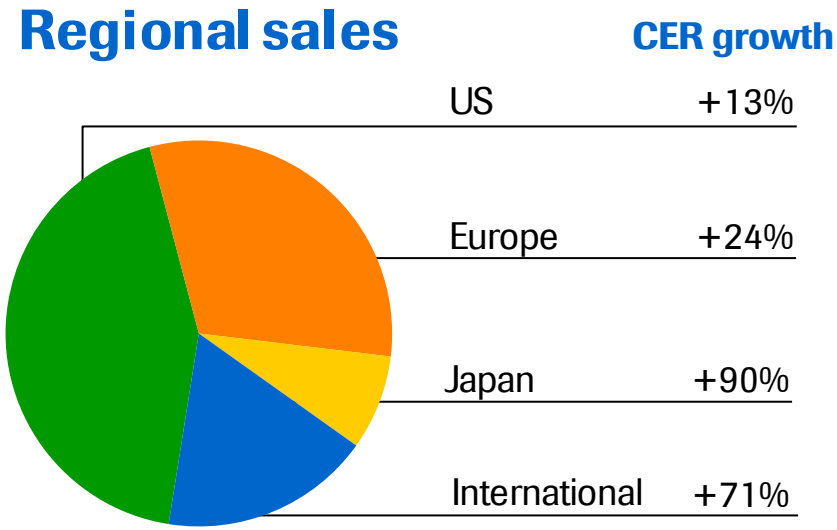
2019 sales of CHF 3,708m

- 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

Perjeta





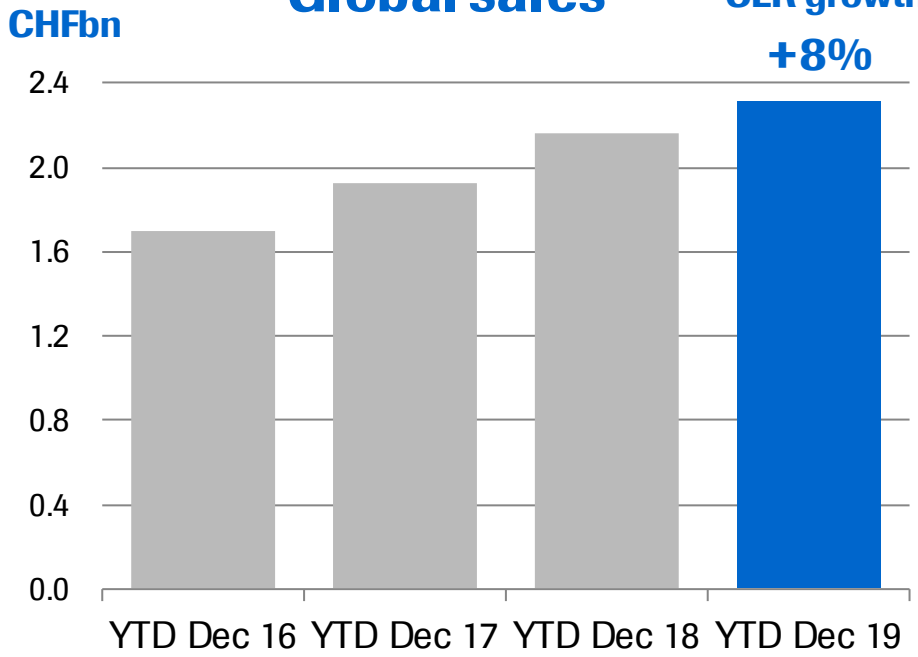
2019 sales of CHF 3,522m

- US: Growth driven by eBC adjuvant setting despite patients with residual disease being switched to Kadcyla
- EU: Growth driven by eBC adjuvant setting
- International: Accelerated growth in all regions (especially China) driven by eBC adjuvant setting
- Japan: Growth driven by eBC adjuvant setting

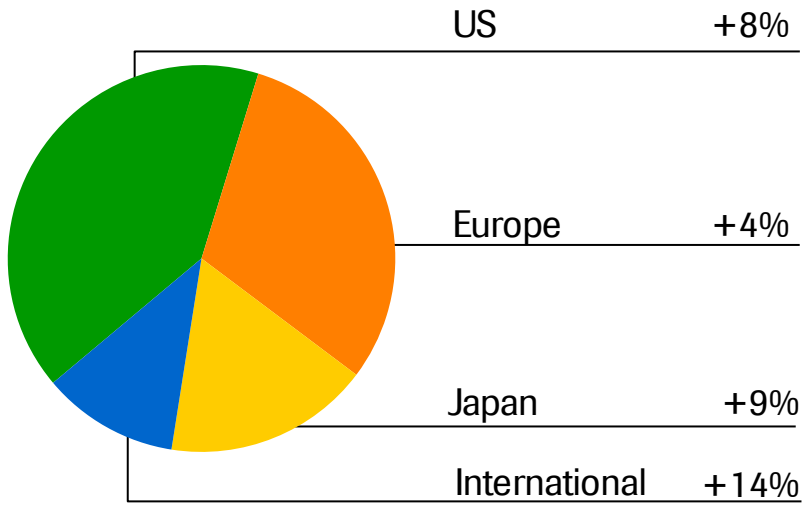
CER=Constant Exchange Rates

Actemra / RoActemra

Global sales



Regional sales

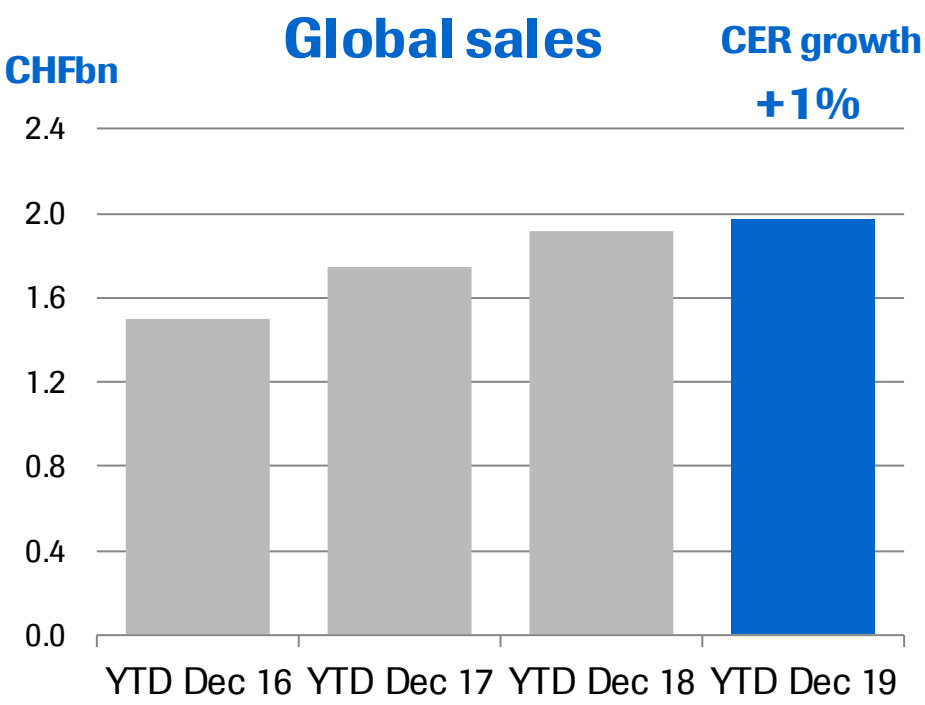


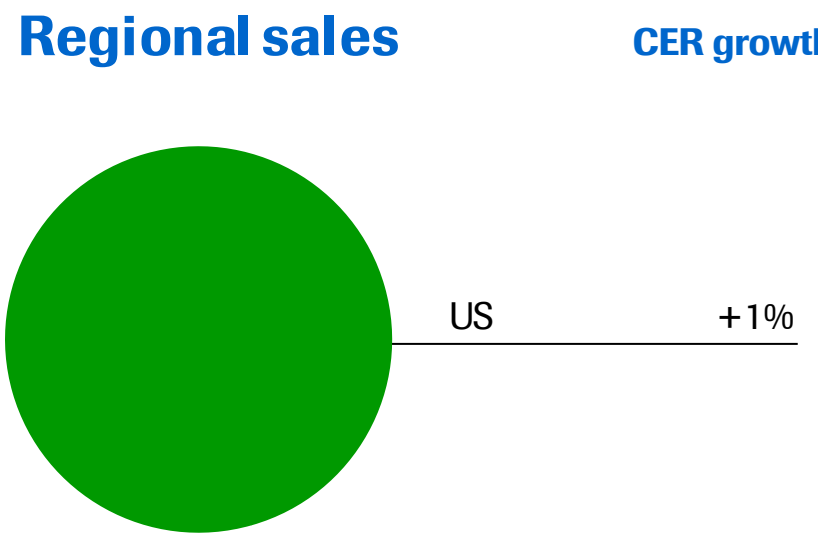
2019 sales of CHF 2,311m

- 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

Xolair





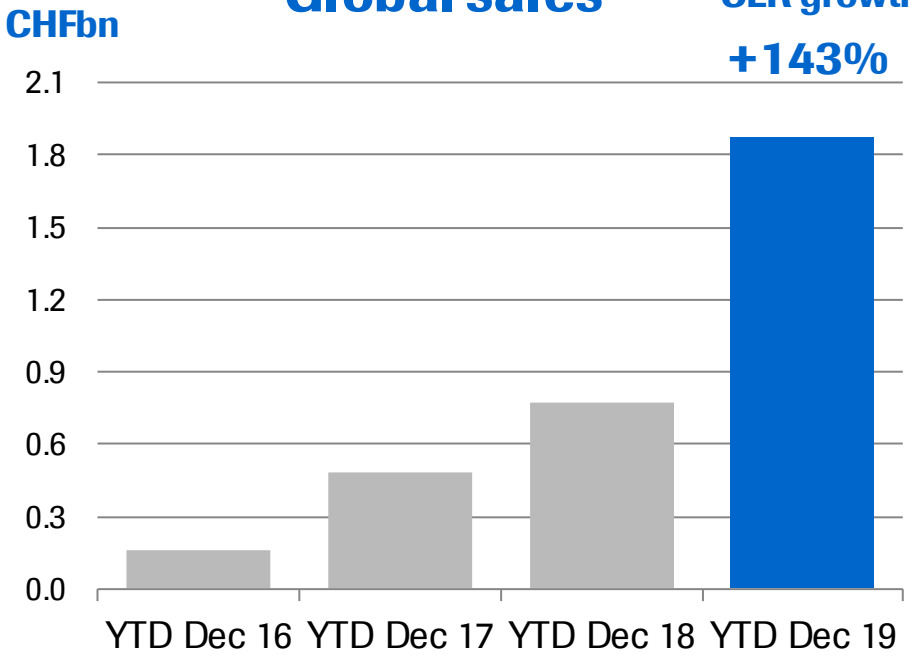
2019 sales of CHF 1,969m

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

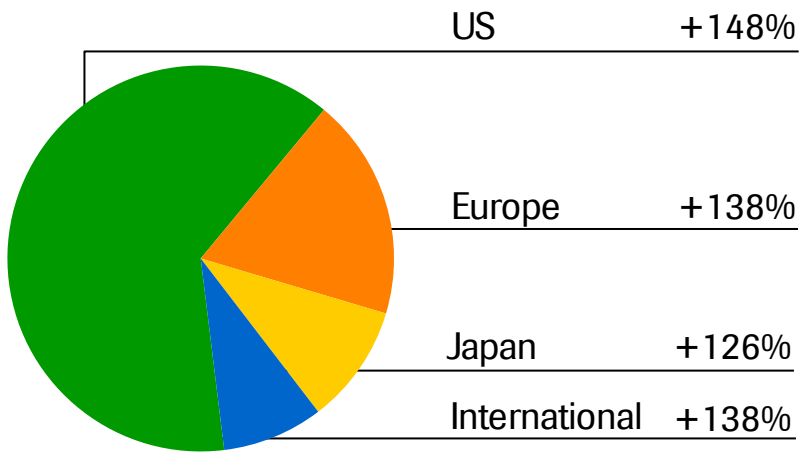
CER=Constant Exchange Rates

Tecentriq

Global sales



Regional sales

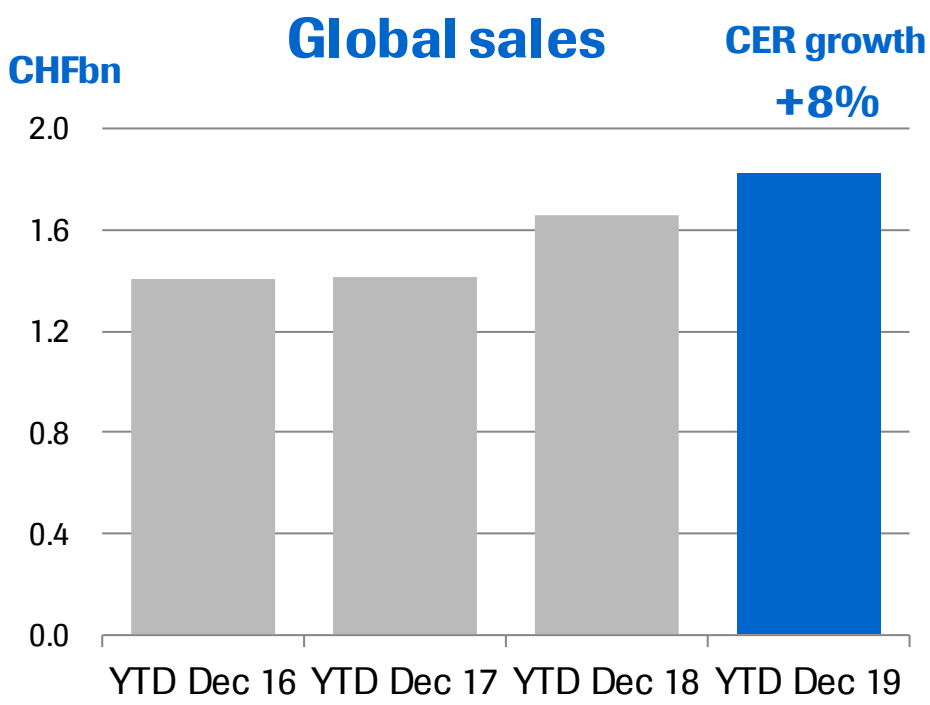


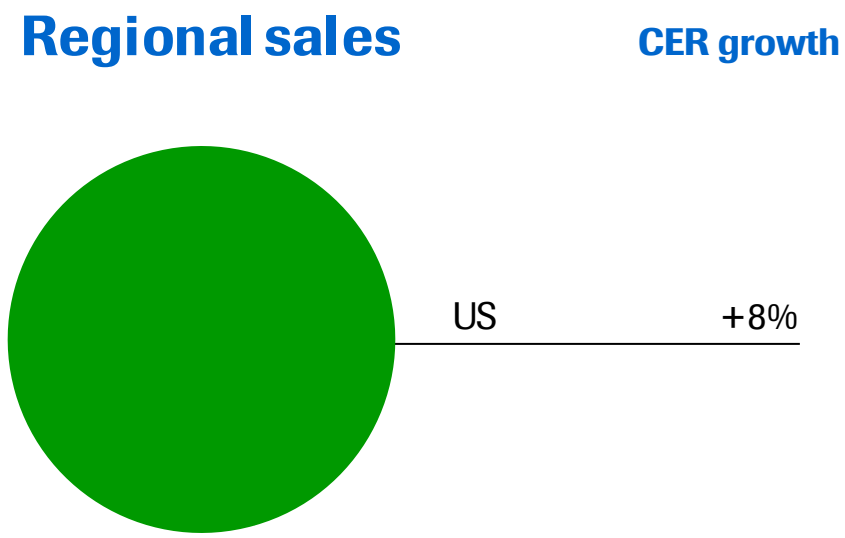
2019 sales of CHF 1,875m

- 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

Lucentis



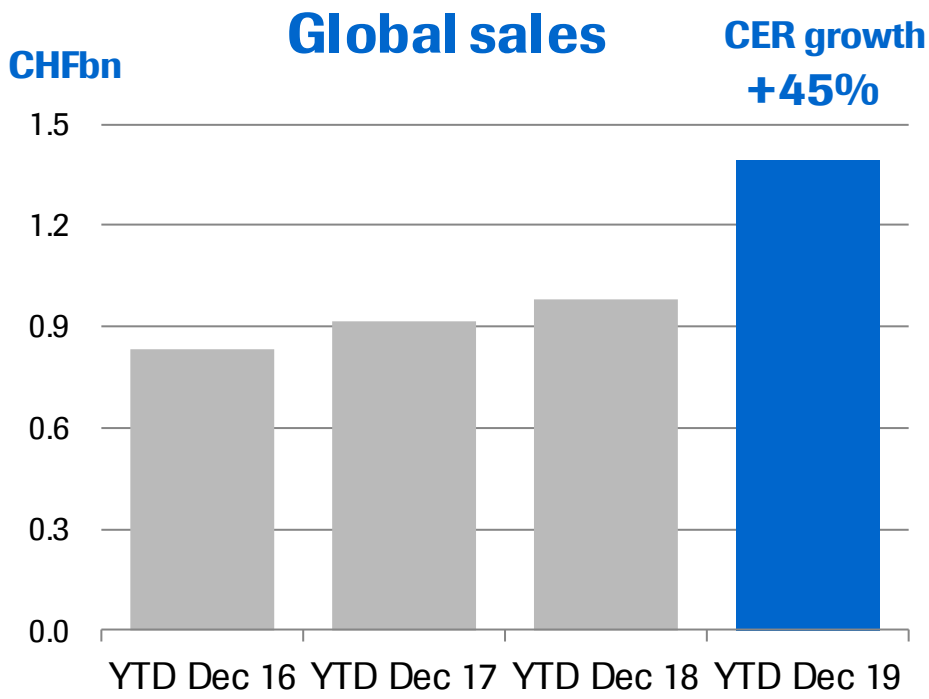


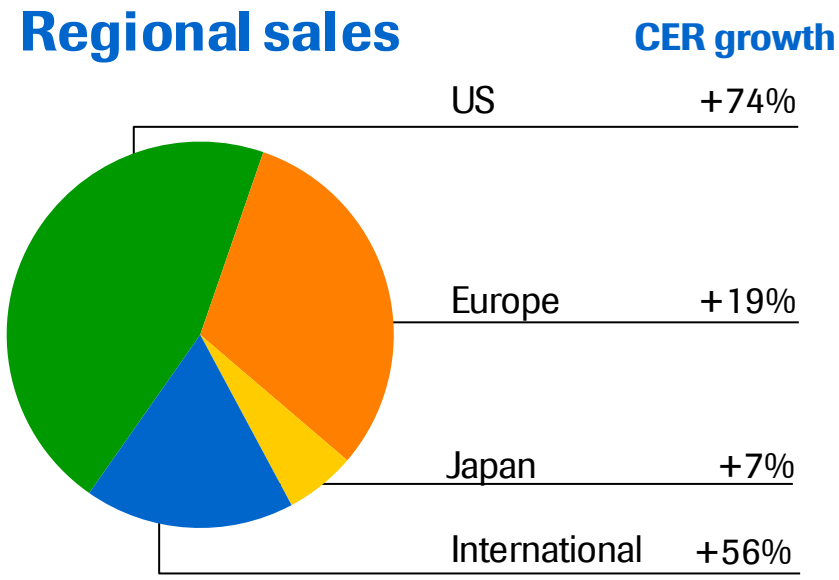
2019 sales of CHF 1,826m

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

CER=Constant Exchange Rates

Kadcyla



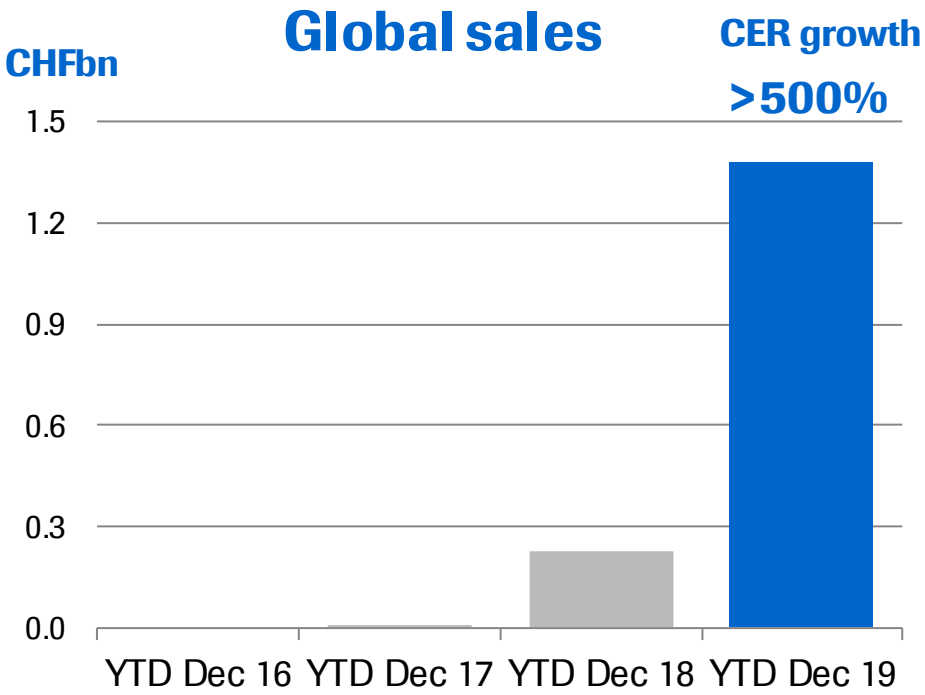


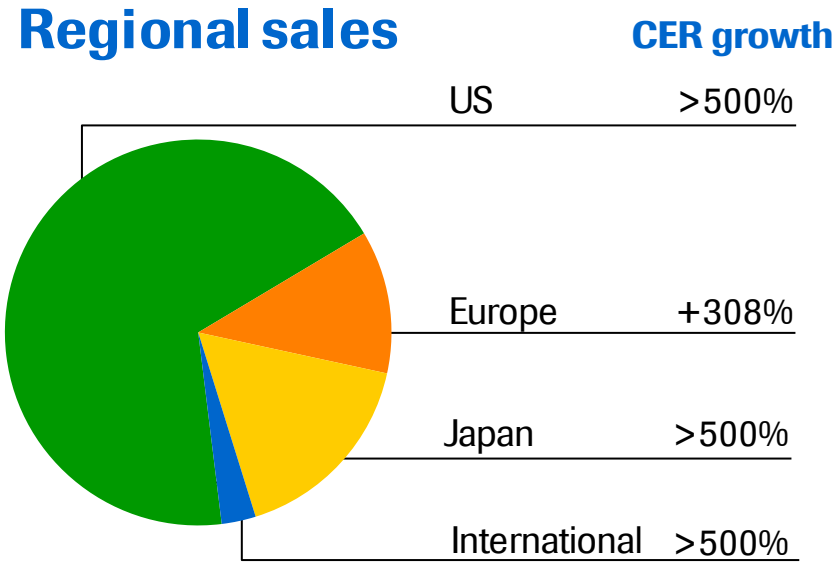
2019 sales of CHF 1,393m

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

CER=Constant Exchange Rates

Hemlibra





2019 sales of CHF 1,380m

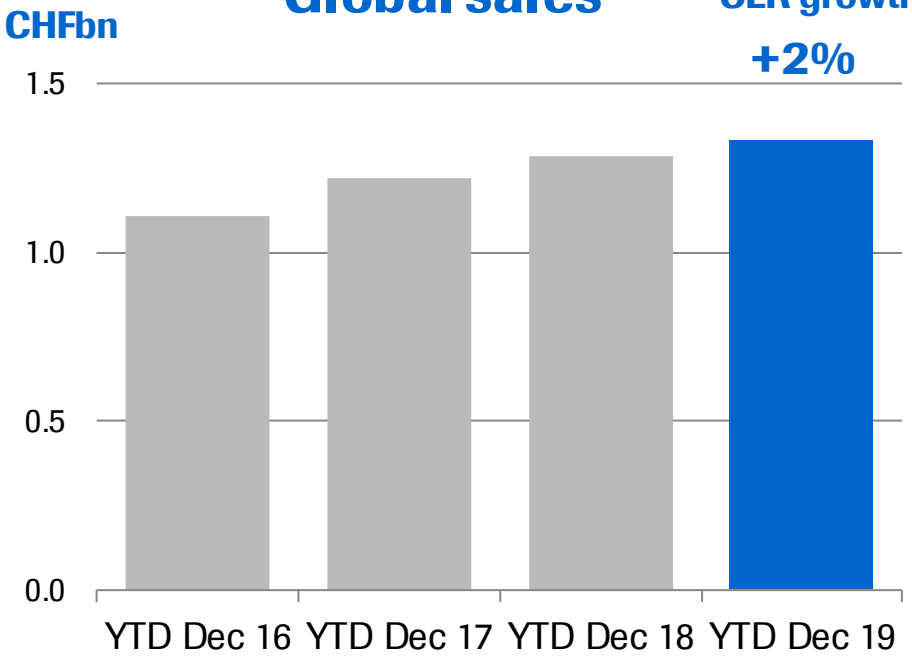
- US: Strong uptake in non-inhibitors and continued market share gains in inhibitors
- EU: Growth mainly driven by non-inhibitors; first non-inhibitor launches in H2
- Japan: Very strong uptake in non-inhibitors

CER=Constant Exchange Rates

TNKase / Activase

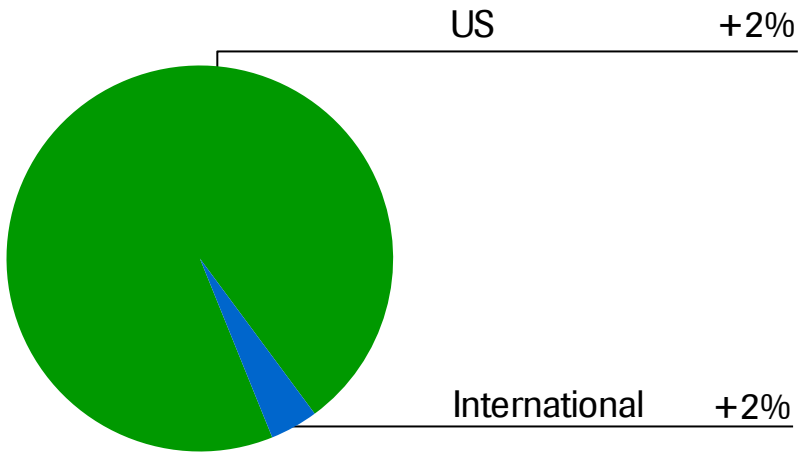
Global sales

CER growth +2%



Regional sales

CER growth

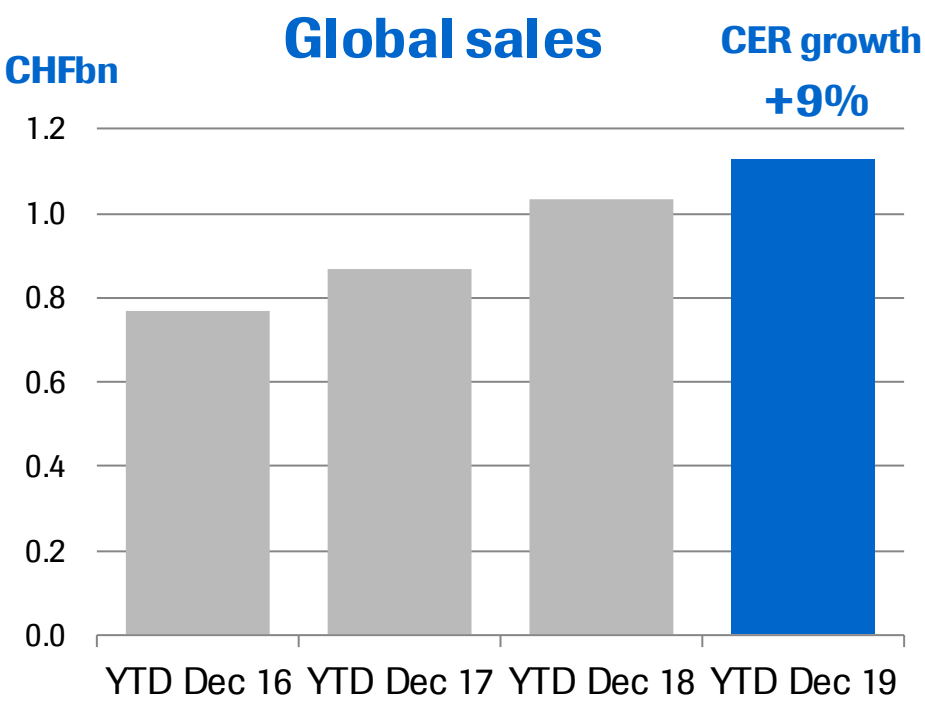


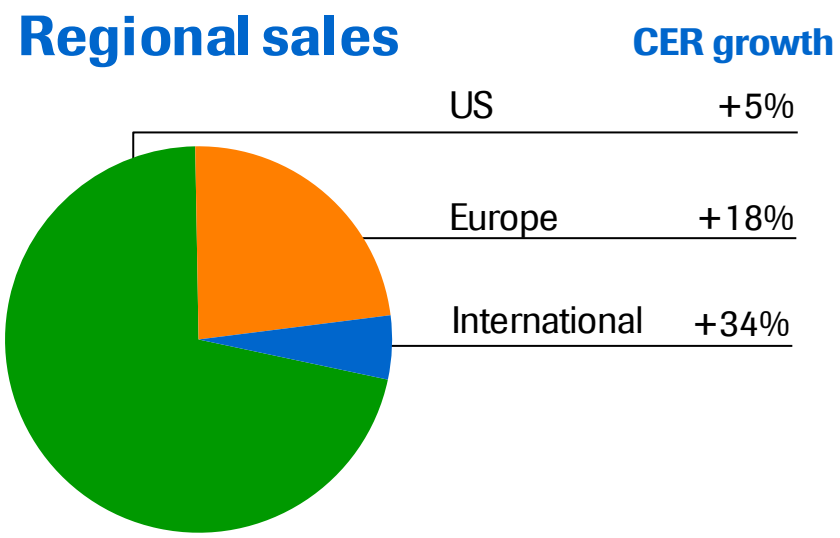
2019 sales of CHF 1,332m

- US: Growth driven by demand

CER=Constant Exchange Rates

Esbriet





2019 sales of CHF 1,129m

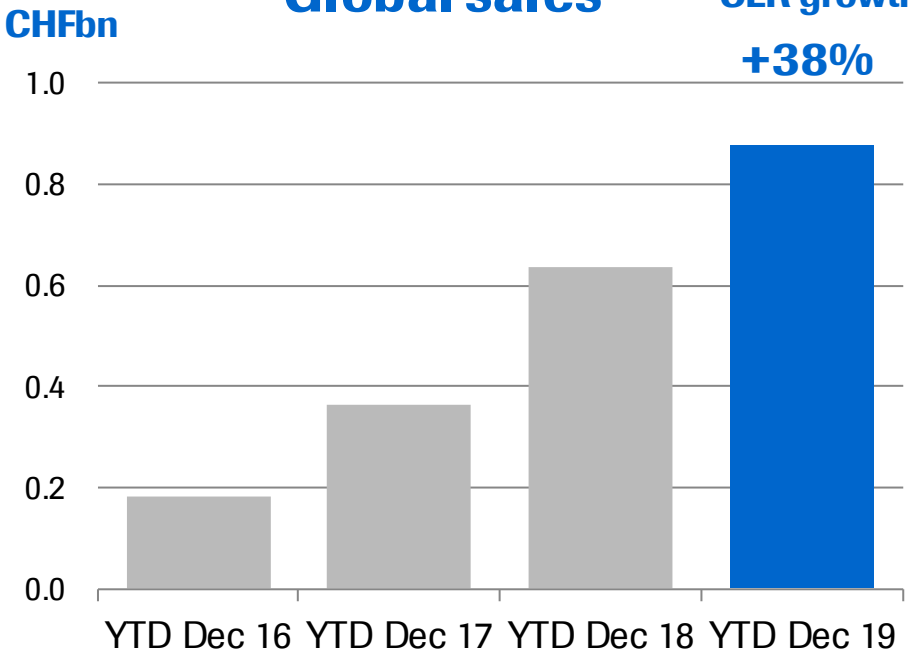
- US: Growth driven by continued penetration in moderate and mild patients; improved patient compliance
- EU: Growth driven by continued penetration in moderate and mild patients

CER=Constant Exchange Rates

Alecensa

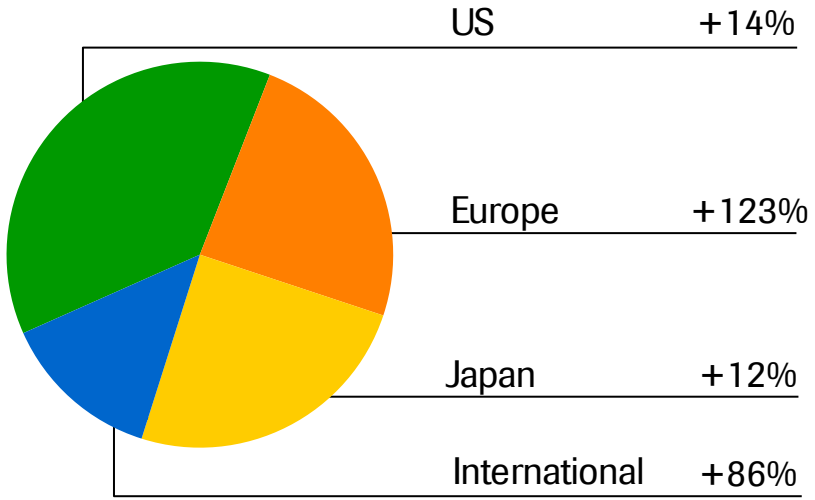
Global sales

CER growth +38%



Regional sales

CER growth

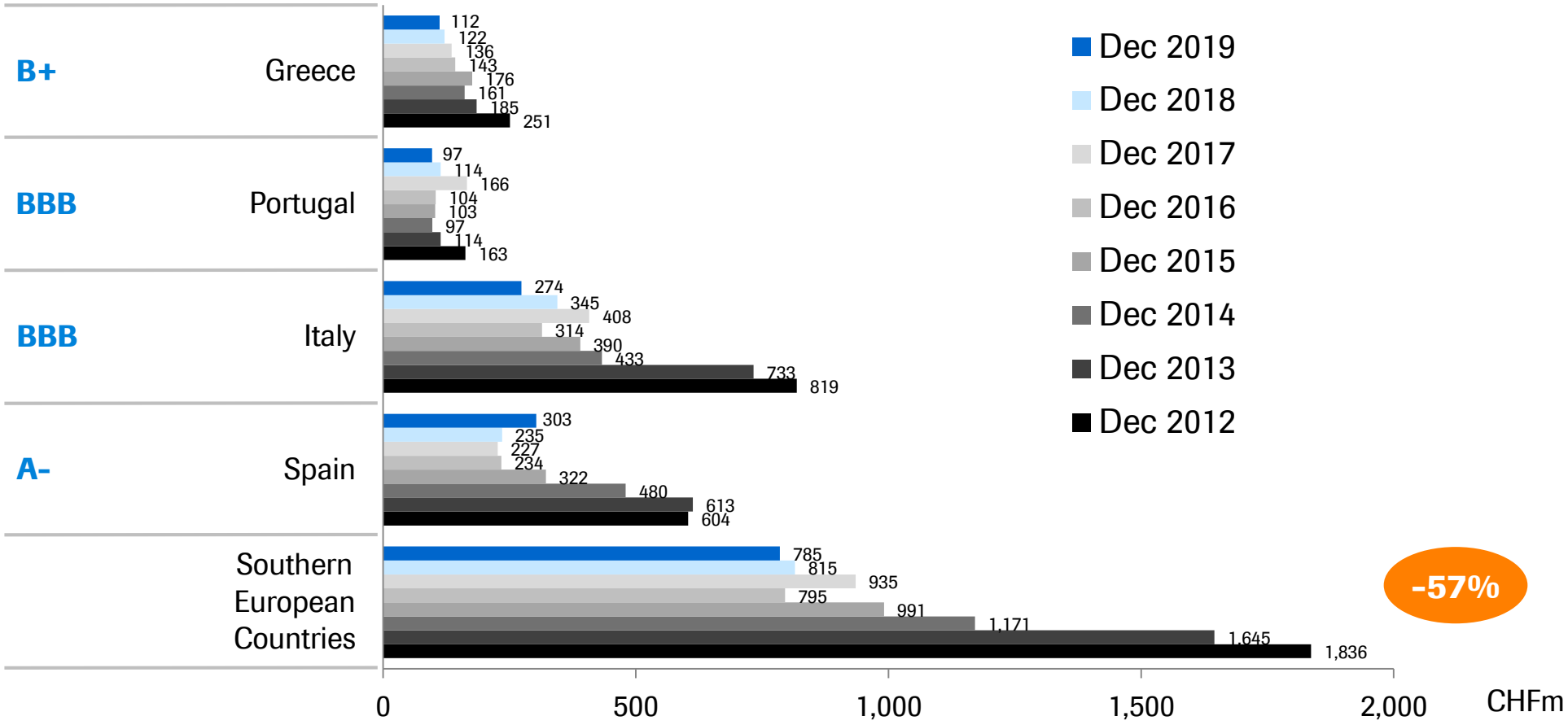


2019 sales of CHF 876m

- 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

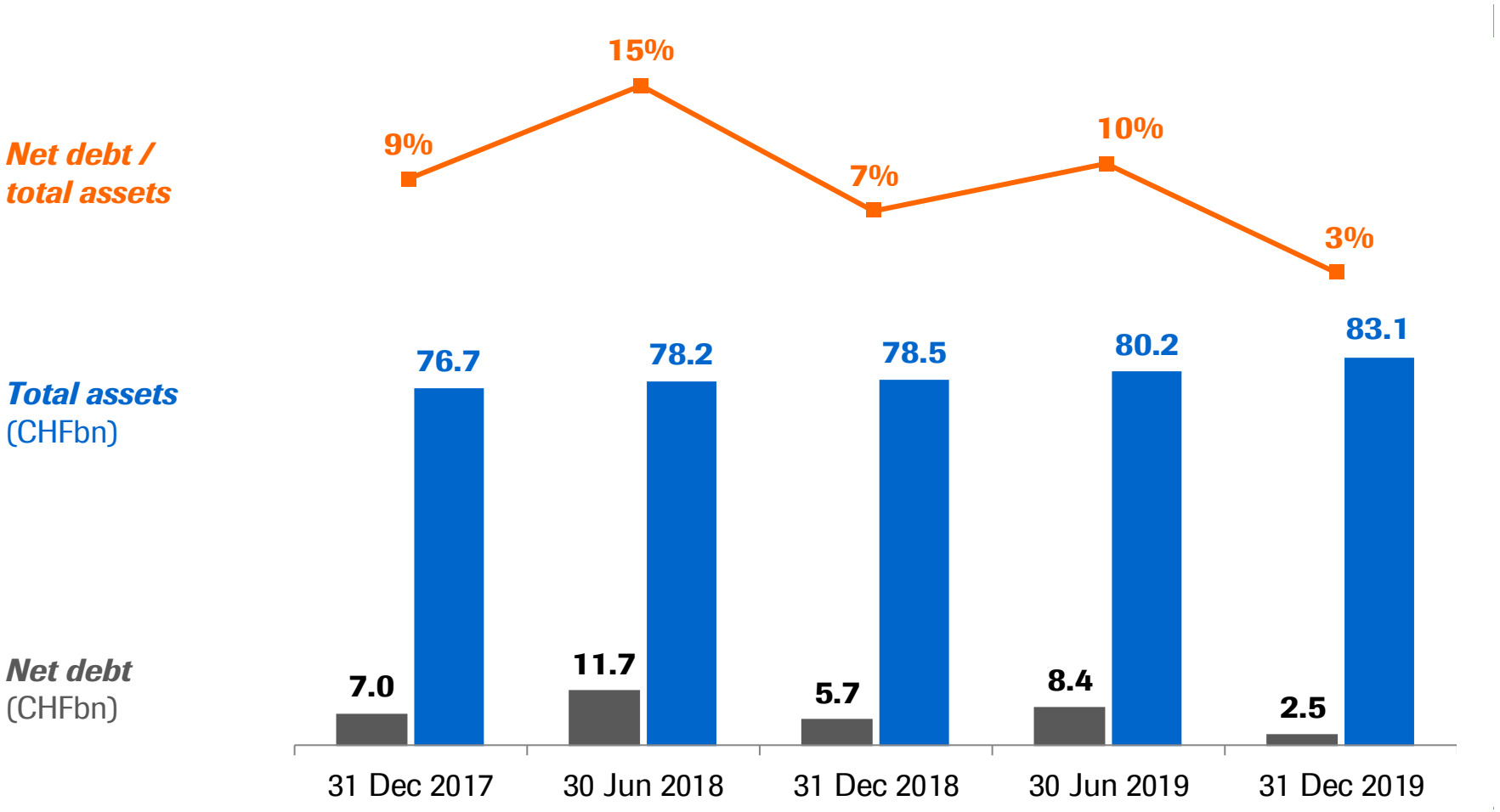
CER=Constant Exchange Rates

2019: Accounts receivable in Southern Europe decreased by –57% since Dec 2012

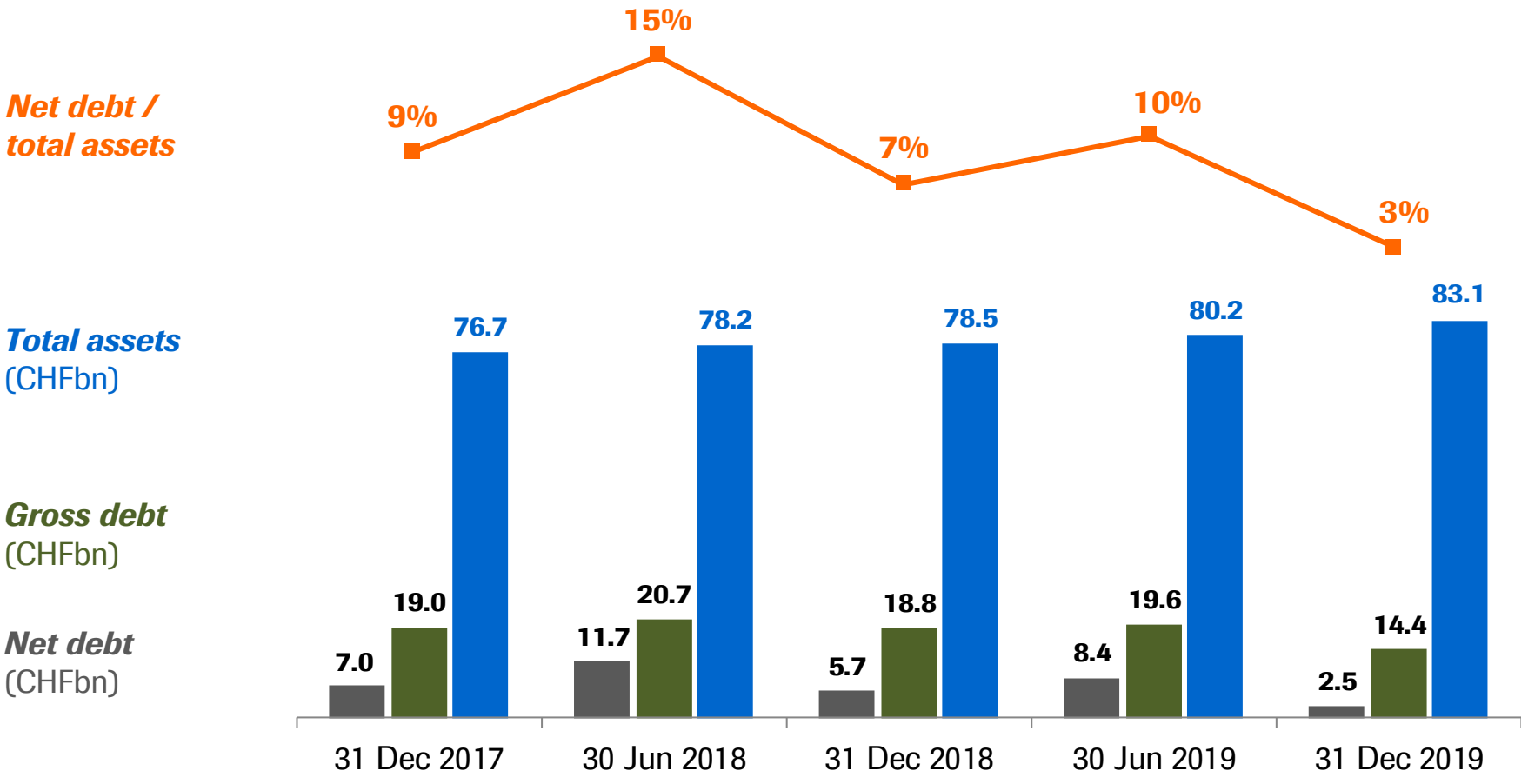


Sovereign country ratings from Standard & Poor's, as of 7 January 2020

Balance sheet: Net debt to total assets



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



Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Spark

Roche Group 2019 results

Diagnostics

Foreign exchange rate information

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	7,819	3	1,523	-3	2,714	3	3,582	5
Molecular Diagnostics	2,109	6	807	4	783	6	519	10
Diabetes Care	1,918	1	309	15	1,120	-5	489	5
Tissue Diagnostics	1,104	0	614	-6	280	4	210	13
Diagnostics Division	**12,950**	**3**	**3,253**	**0**	**4,897**	**2**	**4,800**	**6**

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

Diagnostics Division quarterly sales and CER growth[1]

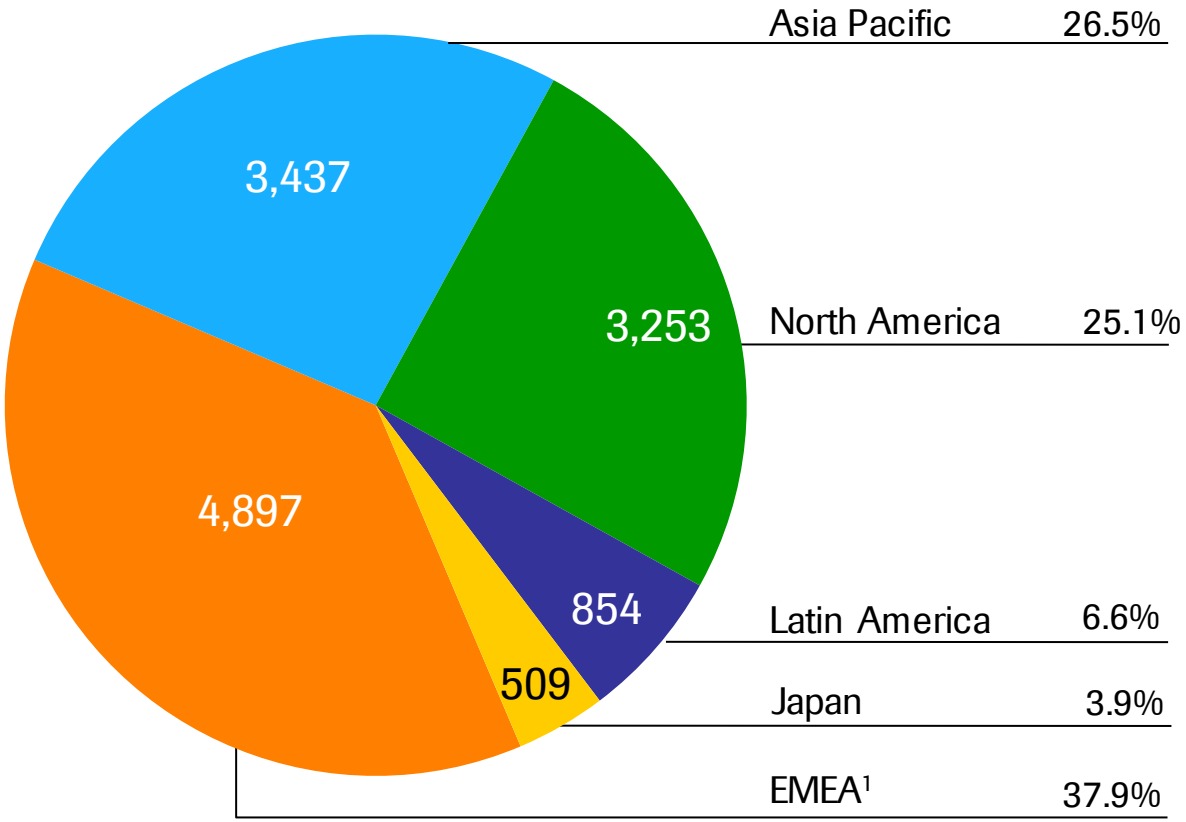
	Q1 18		Q2 18		Q3 18		Q4 18		Q1 19		Q2 19		Q3 19		Q4 19	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Centralised and Point of Care Solutions	1,716	4	2,039	9	1,870	8	2,143	12	1,681	-1	2,081	5	2,004	9	2,053	-2
Molecular Diagnostics	468	6	511	4	489	5	551	6	502	7	527	6	518	8	562	4
Diabetes Care	478	5	513	-3	493	1	496	5	465	1	493	0	437	-8	523	9
Tissue Diagnostics	249	7	290	15	262	4	311	13	251	-1	275	-4	273	6	305	-1
Diagnostics Division	**2,911**	**5**	**3,353**	**7**	**3,114**	**6**	**3,501**	**10**	**2,899**	**1**	**3,376**	**4**	**3,232**	**6**	**3,443**	**1**

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

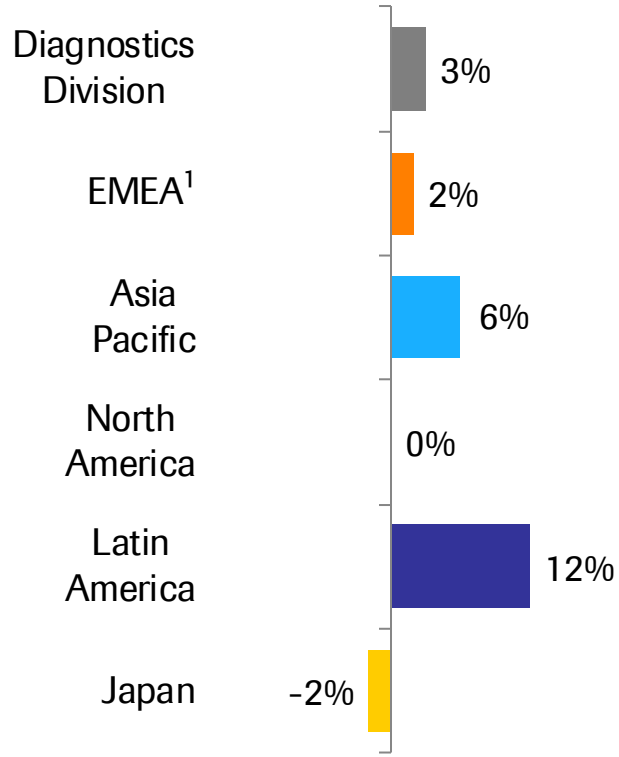
2019: Diagnostics Division sales

Growth driven by Asia Pacific and Latin America

CHF 12,950m



CER sales growth

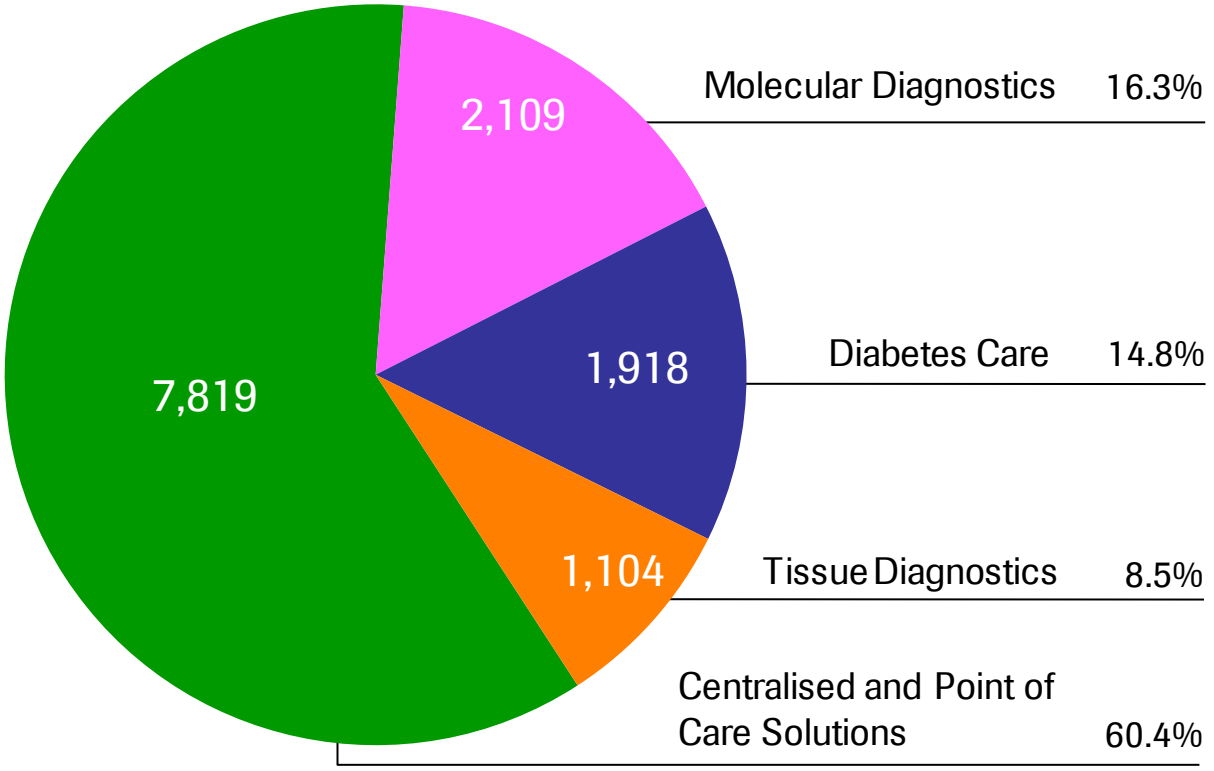


CER=Constant Exchange Rates; [1] Europe, Middle East and Africa

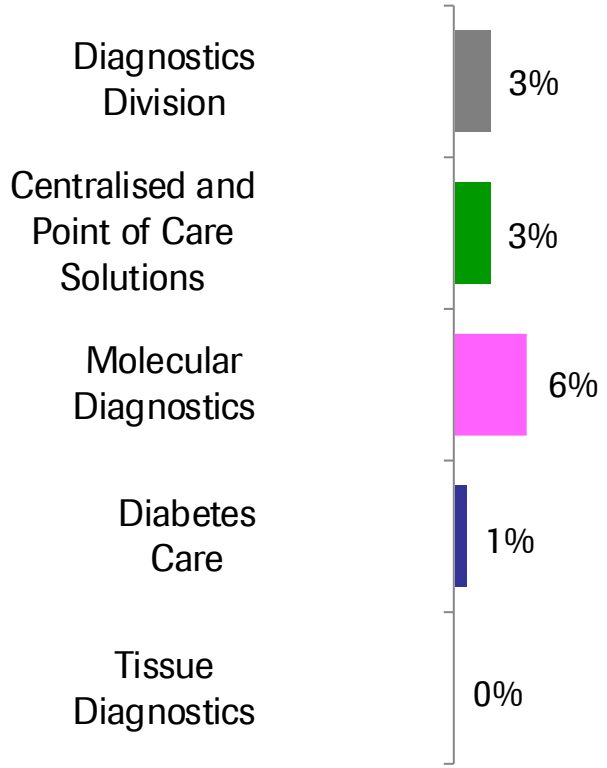
2019: Diagnostics Division sales

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

CHF 12,950m

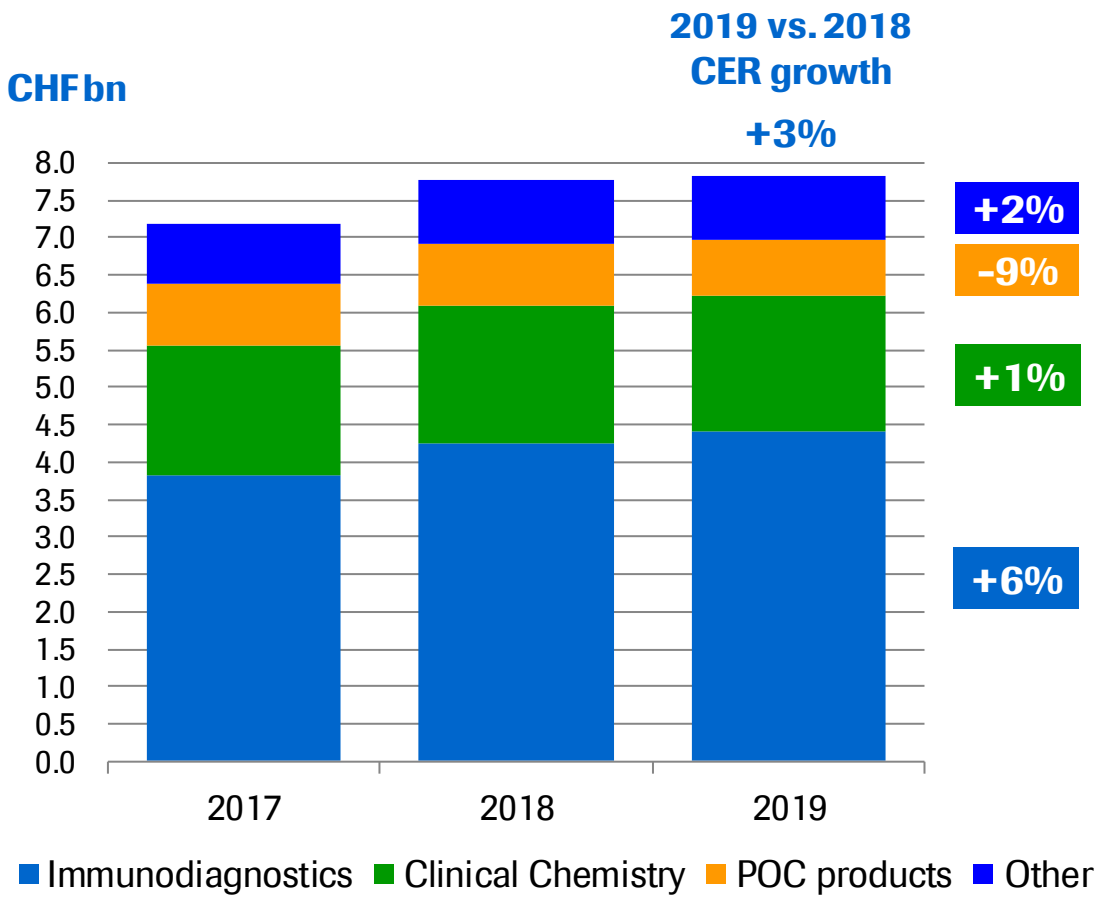


CER sales growth



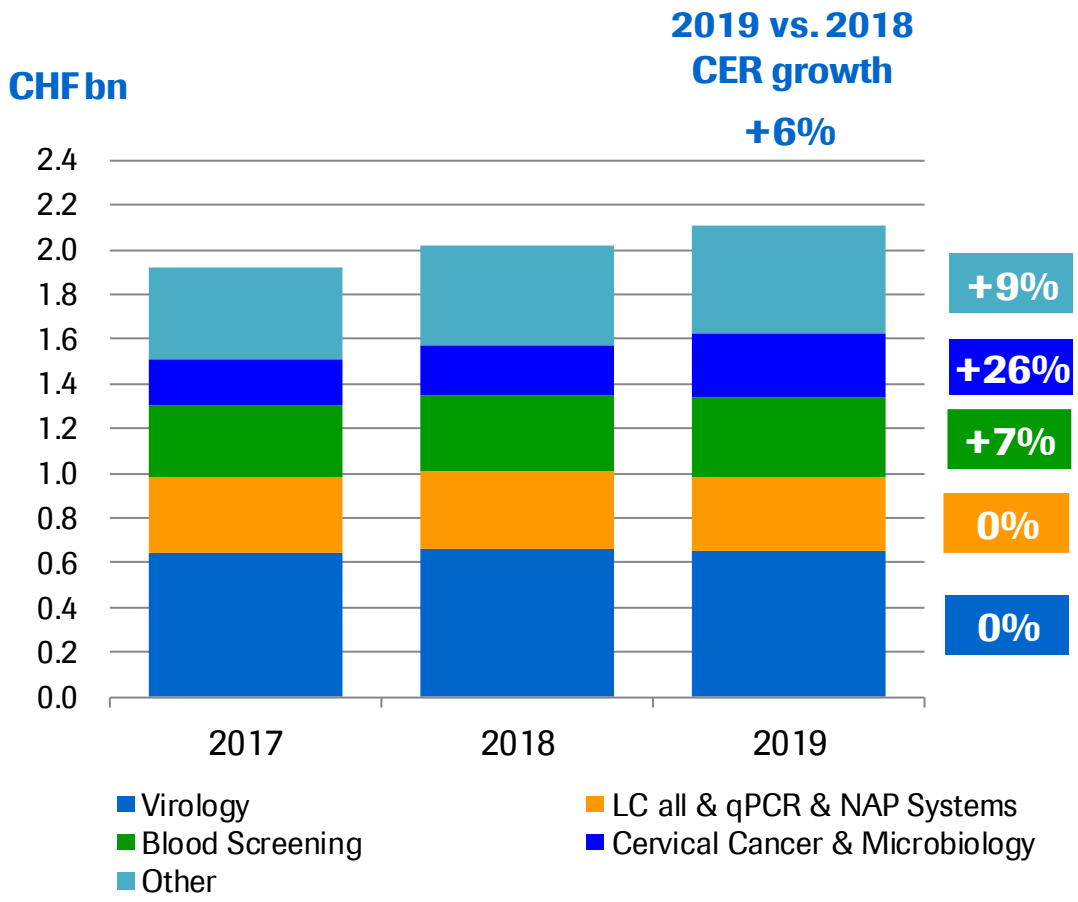
CER=Constant Exchange Rates

Centralised and Point of Care Solutions



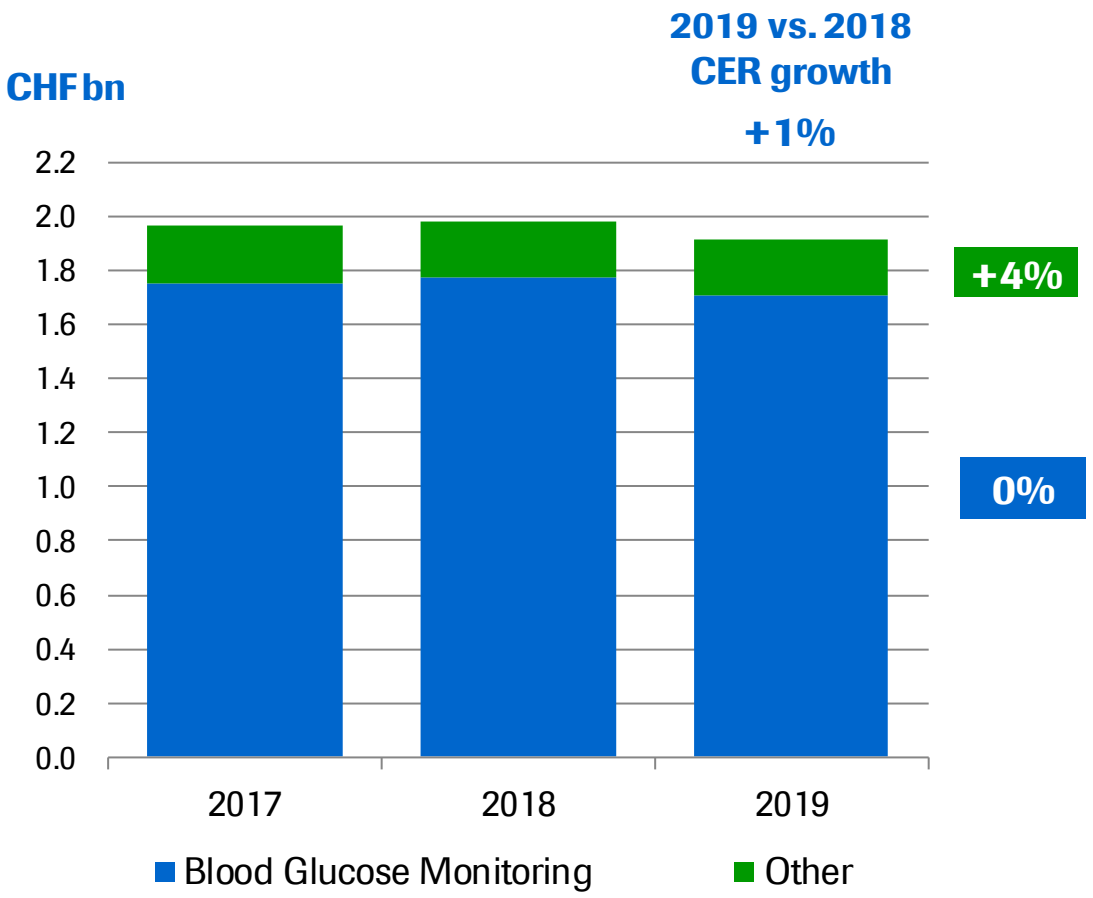
CER=Constant Exchange Rates

Molecular Diagnostics



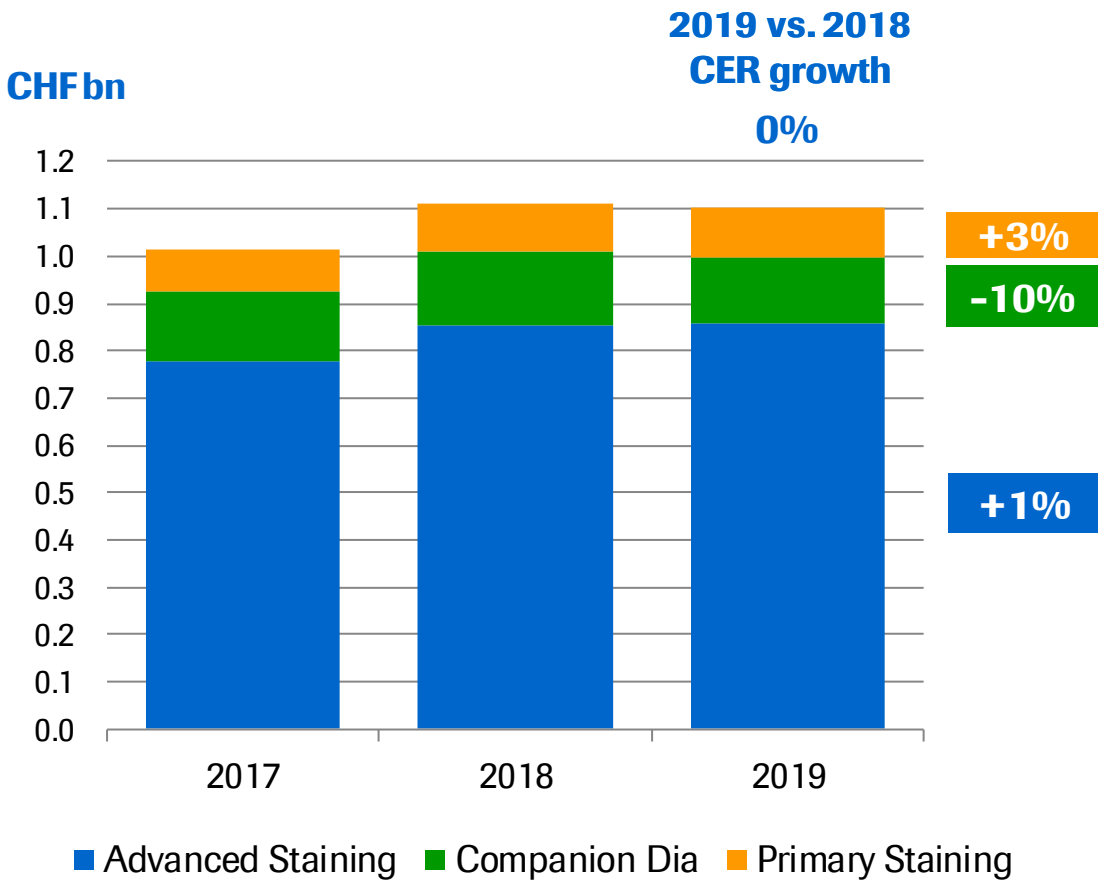
CER=Constant Exchange Rates

Diabetes Care



CER=Constant Exchange Rates

Tissue Diagnostics



CER=Constant Exchange Rates

Pipeline summary

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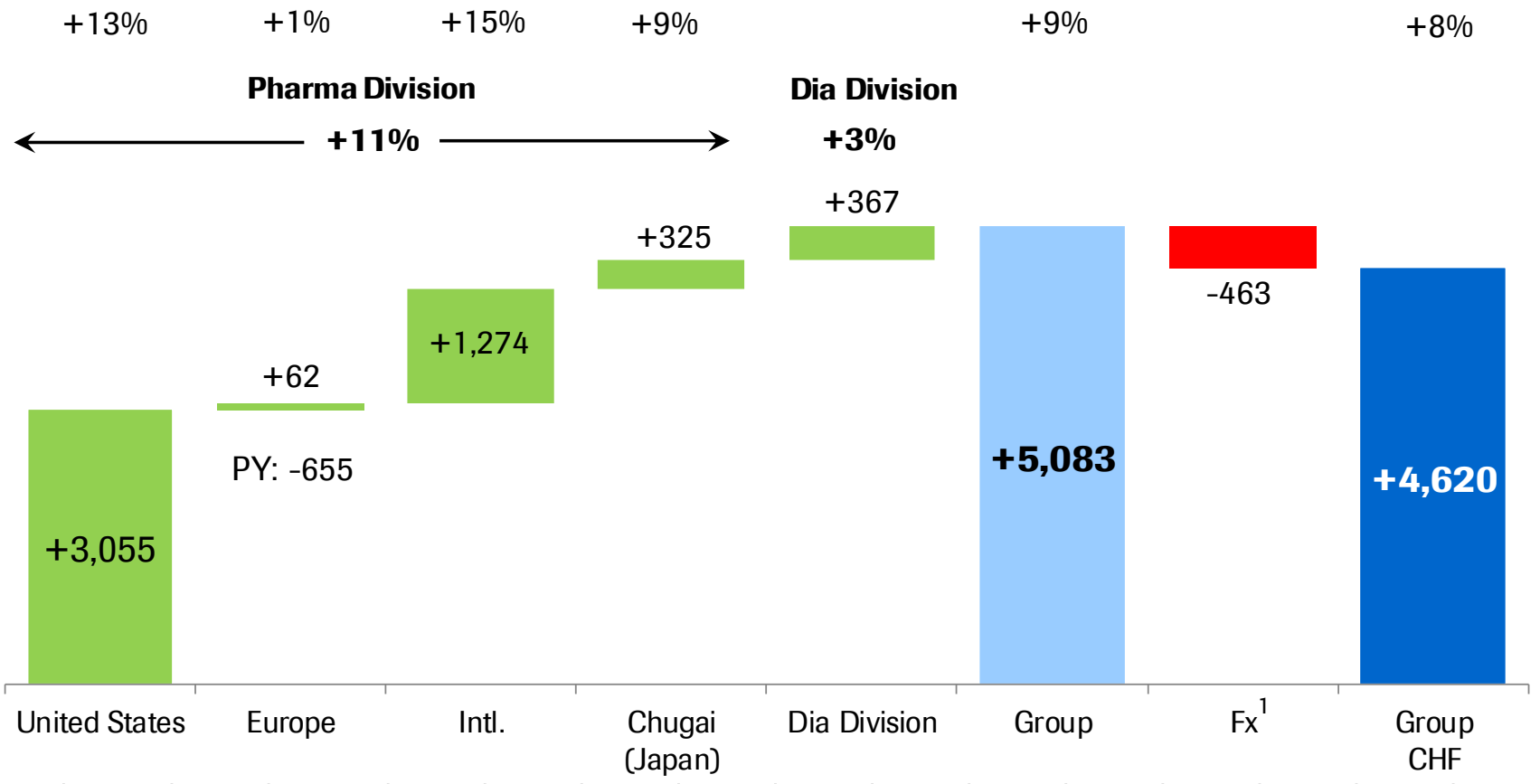
Roche Group 2019 results

Diagnostics

Foreign exchange rate information

Group sales 2019

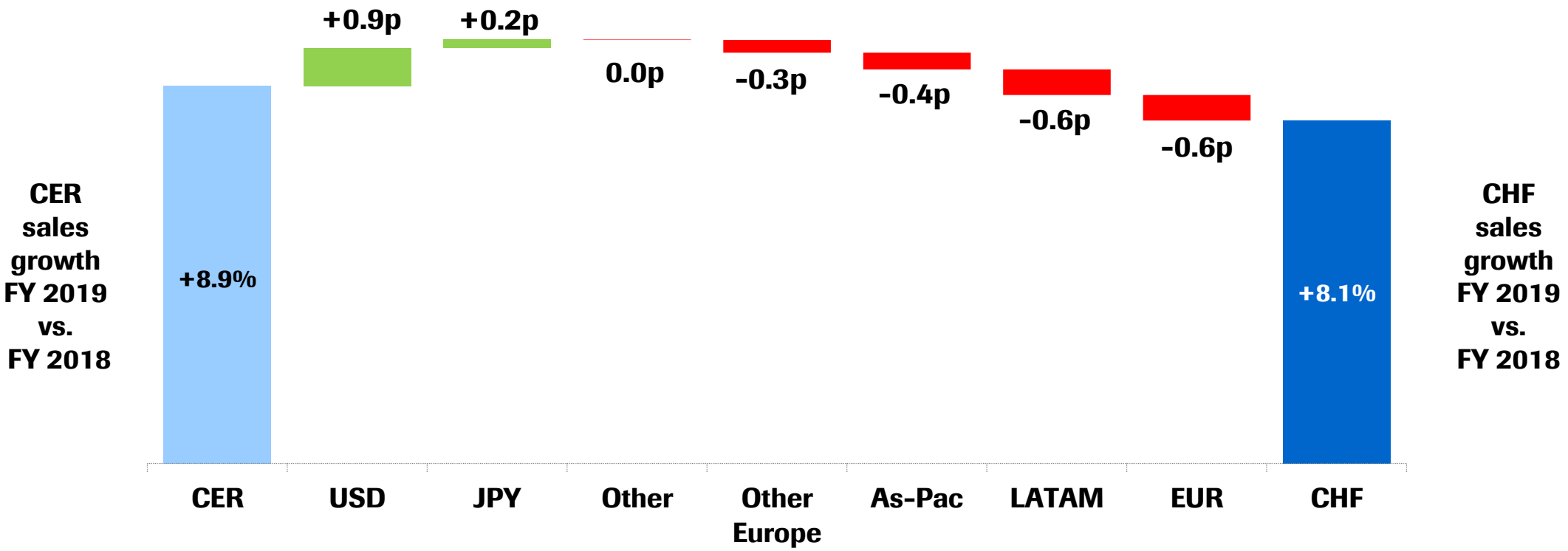
CER sales increase of +9% driven by US and International



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

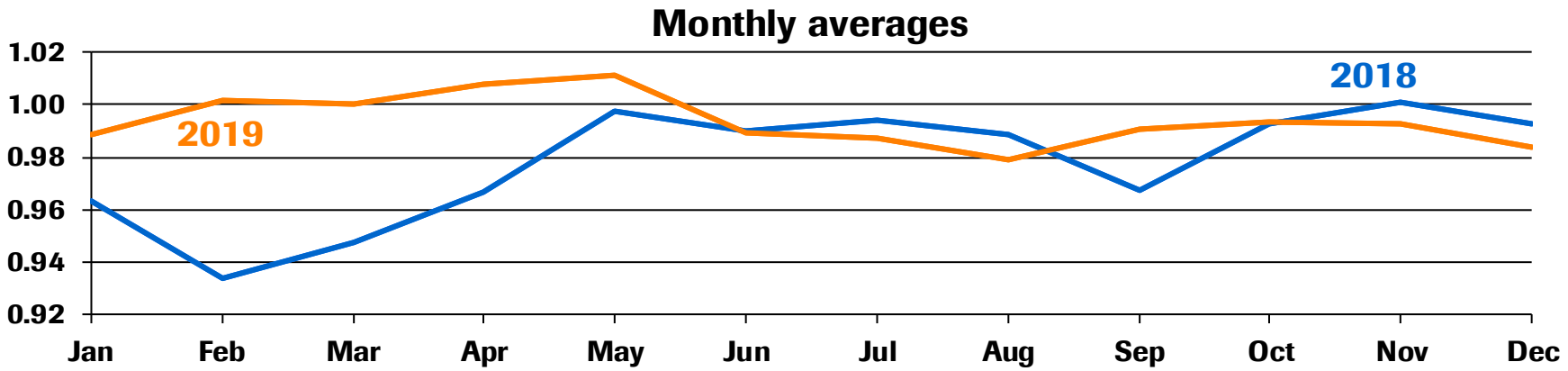
Exchange rate impact on sales growth

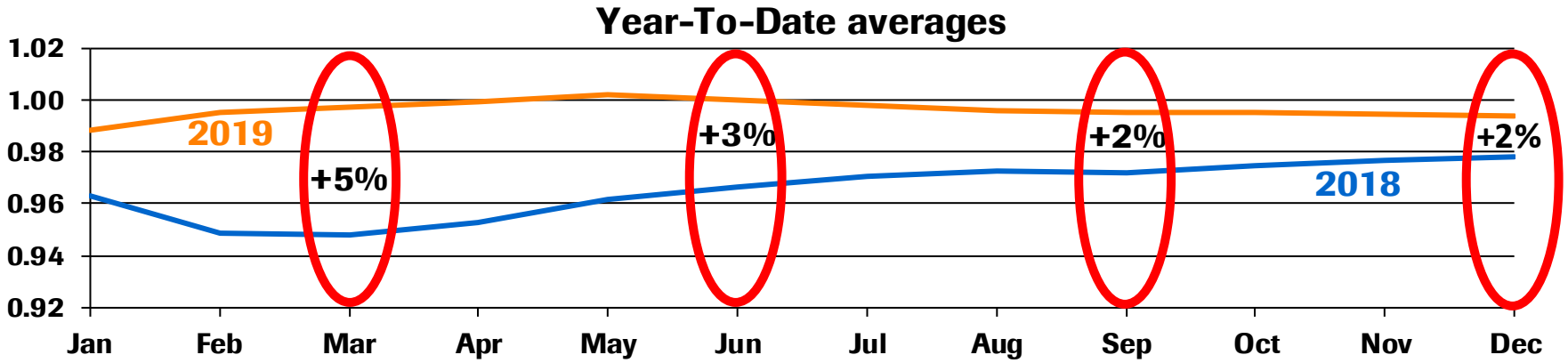
Negative impact driven by EUR and LATAM currencies, partially offset by USD



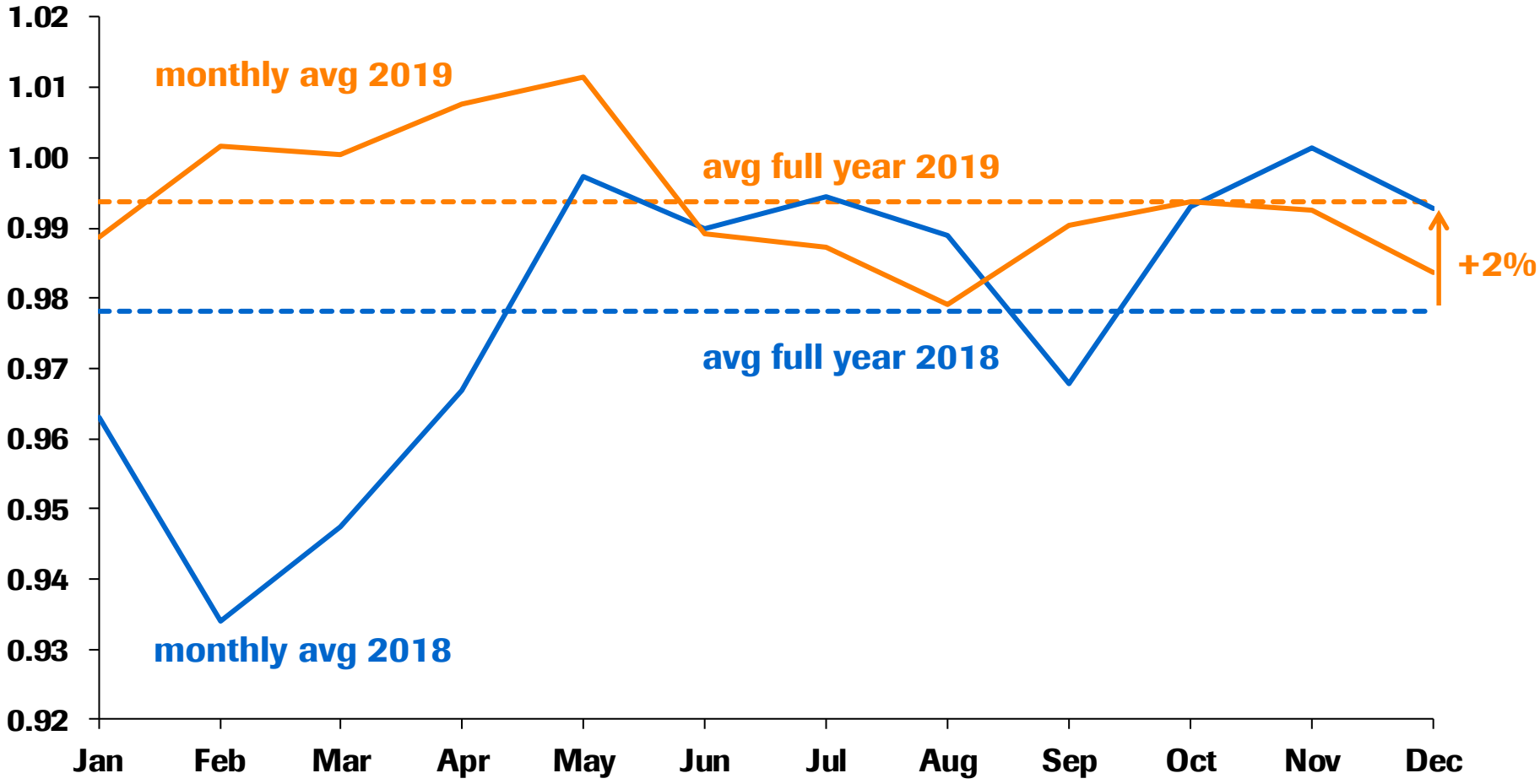
CER=Constant Exchange Rates (avg full year 2018)

CHF / USD

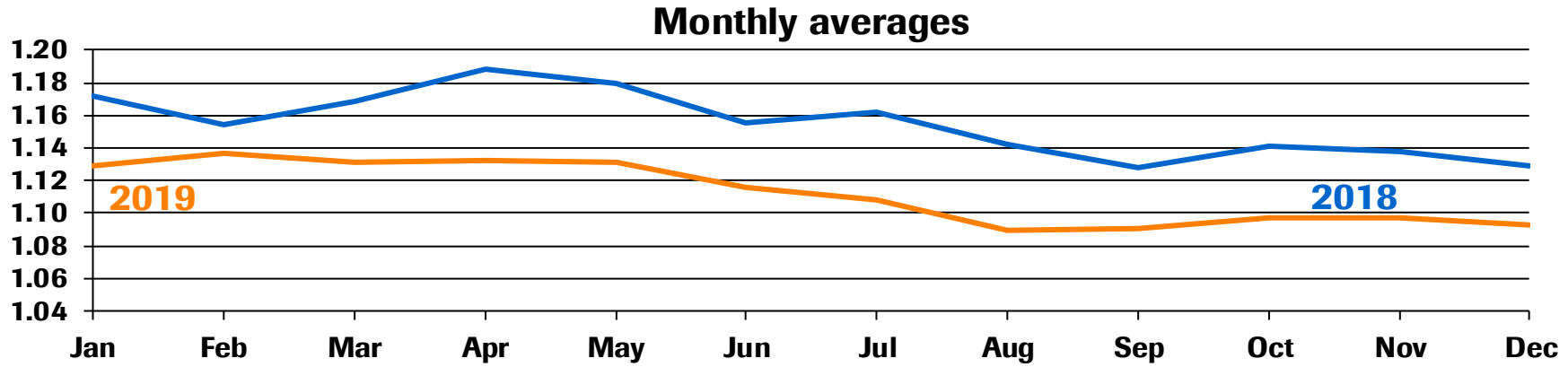

Monthly averages
1.02
1.00
0.98
0.96
0.94
0.92
2019
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

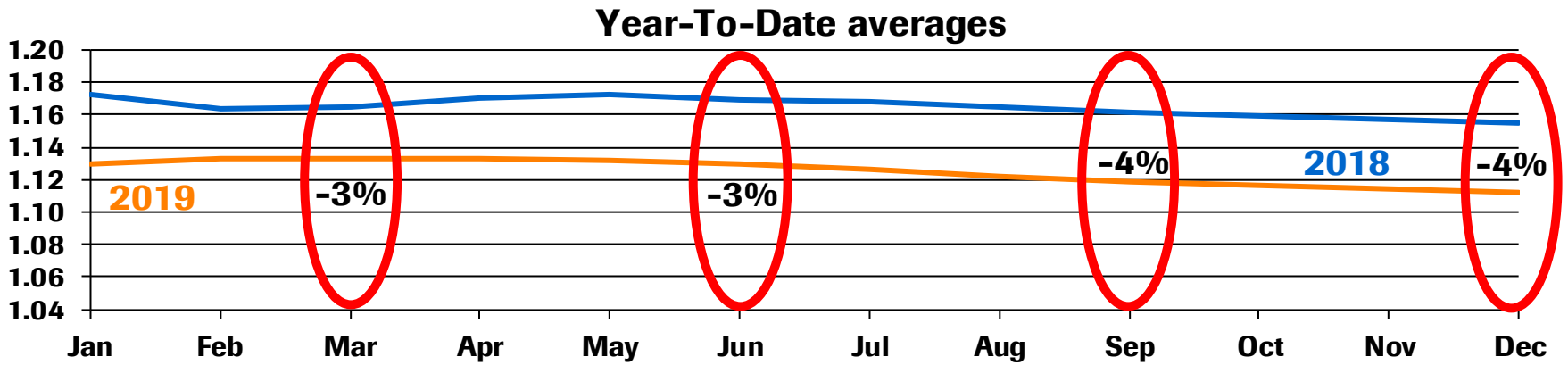

Year-To-Date averages
1.02
1.00
0.98
0.96
0.94
0.92
2019
+5%
+3%
+2%
+2%
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / USD

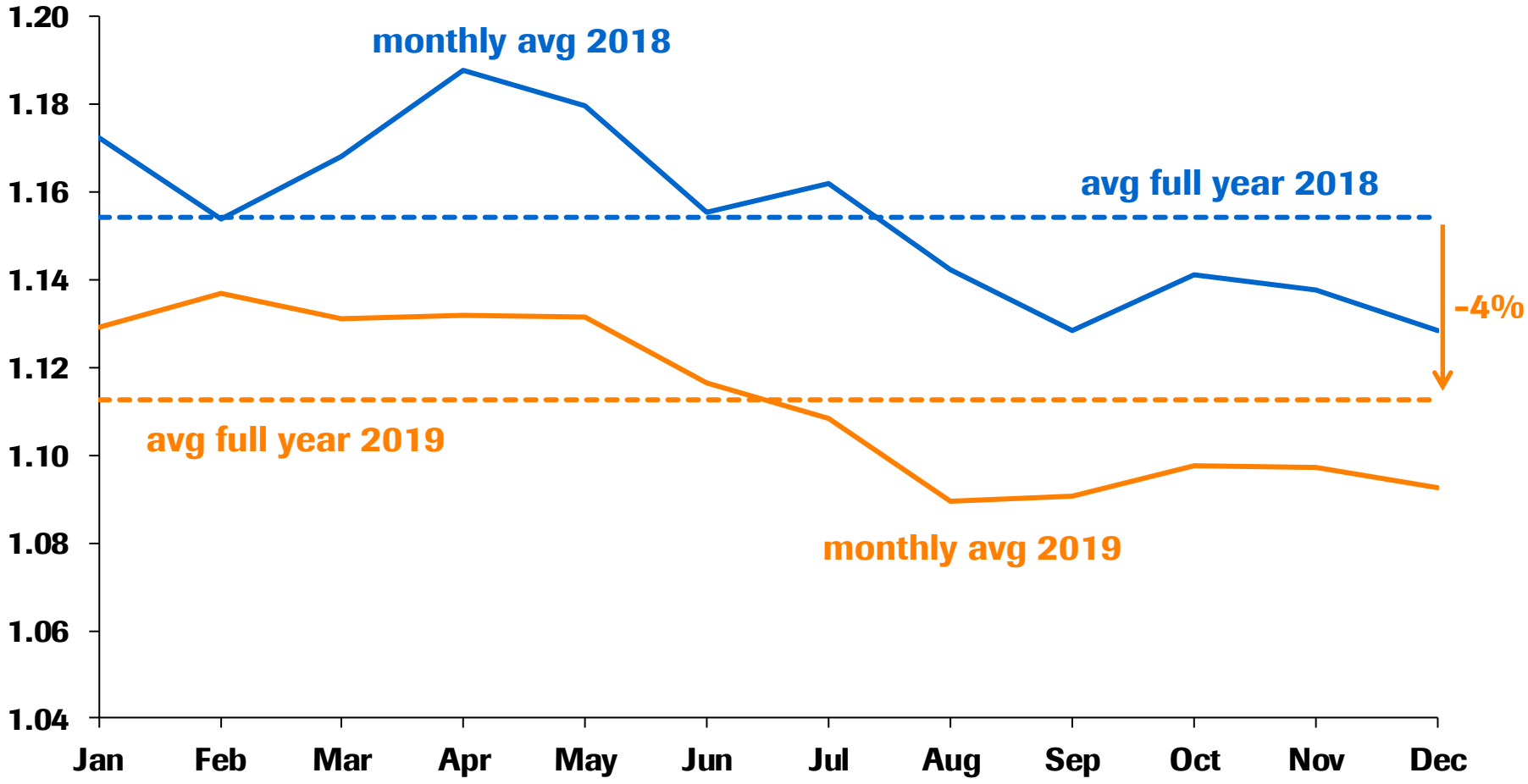

1.02
1.01
1.00
0.99
0.98
0.97
0.96
0.95
0.94
0.93
0.92
monthly avg 2019
avg full year 2019
+2%
avg full year 2018
monthly avg 2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

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

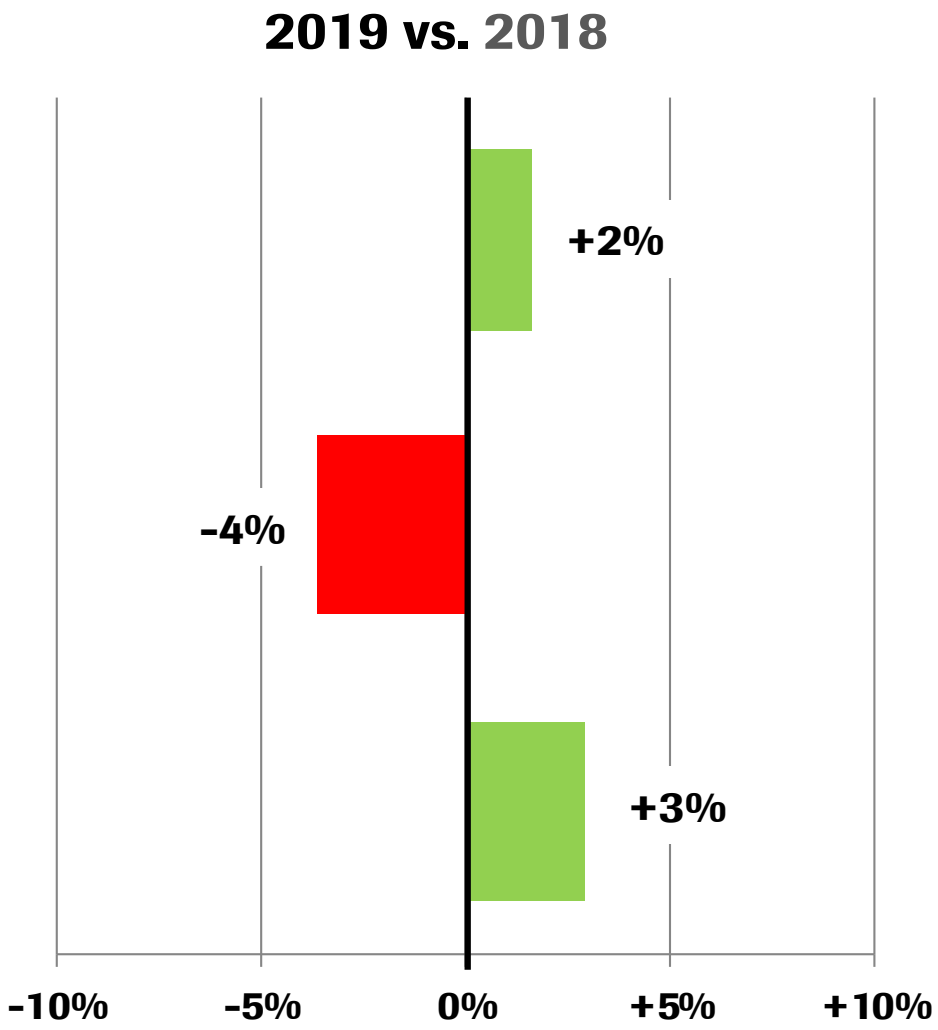

Year-To-Date averages
1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
2019
-3%
-3%
-4%
2018
-4%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

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
-4%
avg full year 2019
monthly avg 2019
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

Average CHF exchange rates

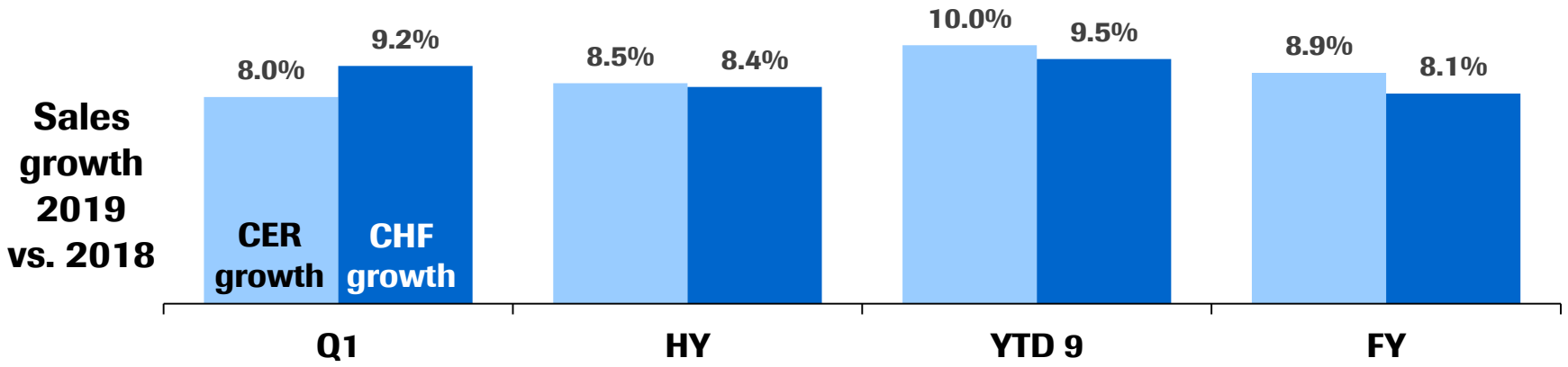
	2019	2018
USD	0.99	0.98
EUR	1.11	1.15
JPY	0.91	0.89



Exchange rate impact on sales growth

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

Development of average exchange rates versus prior year period				
CHF / USD	+5.1%	+3.5%	+2.4%	+1.6%
CHF / EUR	-2.8%	-3.4%	-3.7%	-3.6%
CHF / JPY	+3.4%	+2.2%	+2.8%	+2.9%
Difference in CHF / CER growth	+1.2%p	-0.1%p	-0.5%p	-0.8%p

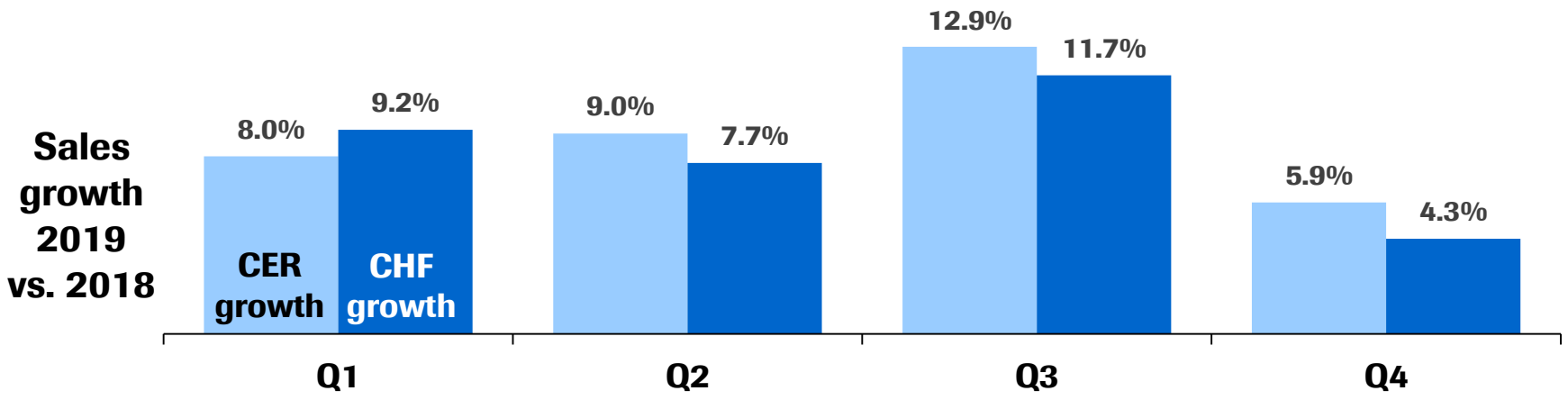


CER=Constant Exchange Rates (avg full year 2018)

Exchange rate impact on sales growth

In Q4 2019 negative impact of EUR and USD and positive impact of JPY

Development of average exchange rates versus prior year period				
CHF / USD	+5.1%	+1.8%	+0.2%	-0.6%
CHF / EUR	-2.8%	-4.1%	-4.2%	-3.5%
CHF / JPY	+3.4%	+1.0%	+4.1%	+3.0%
Difference in CHF / CER growth	+1.2%p	-1.3%p	-1.2%p	-1.6%p



CER=Constant Exchange Rates (avg full year 2018)

Doing now what patients need next