
Roche

Roche

Q1 2019 Sales

Basel, 17 April 2019

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

Group

Severin Schwan
Chief Executive Officer

Q1 2019 performance

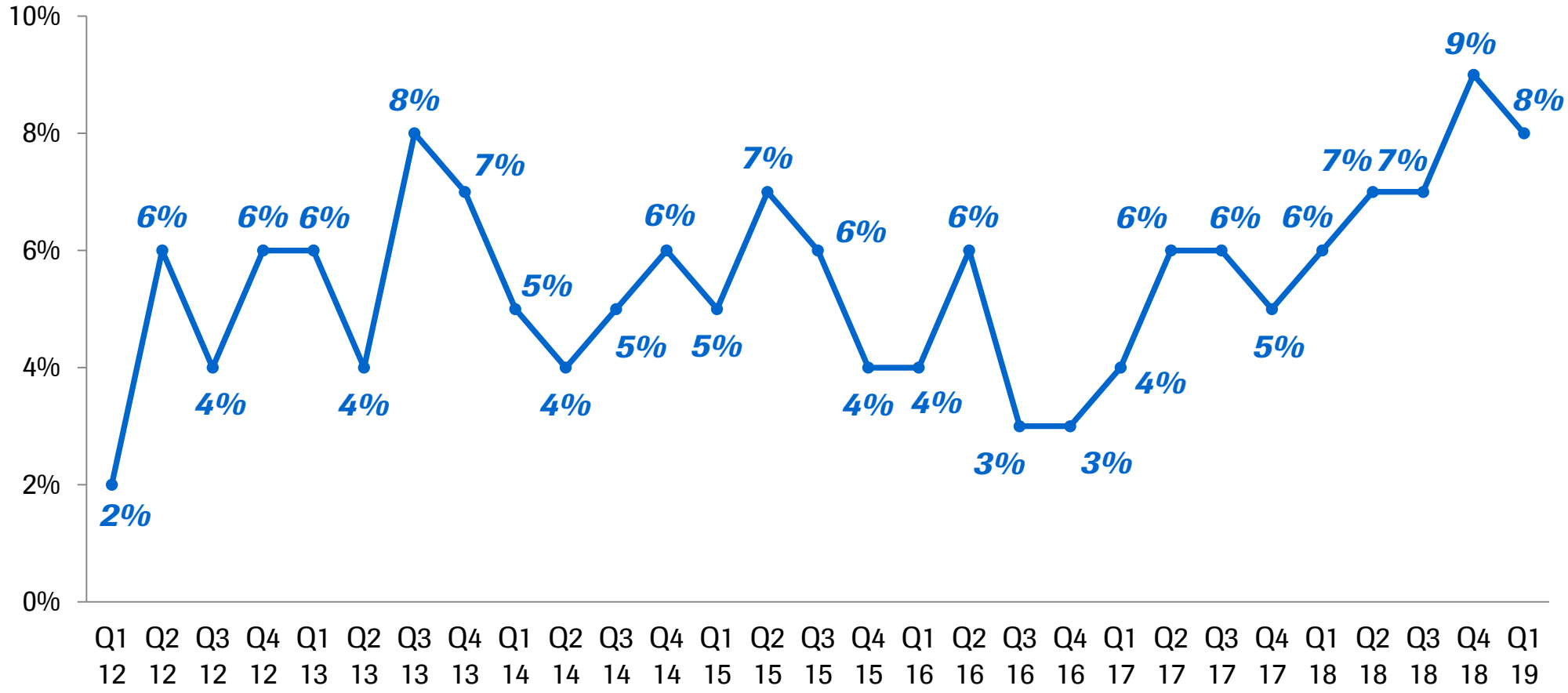
Outlook

Q1 2019: Strong sales growth

	2019 CHFbn	2018 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	**11.9**	10.7	**12**	**10**
Diagnostics Division	**2.9**	2.9	**0**	**1**
Roche Group	**14.8**	13.6	**9**	**8**

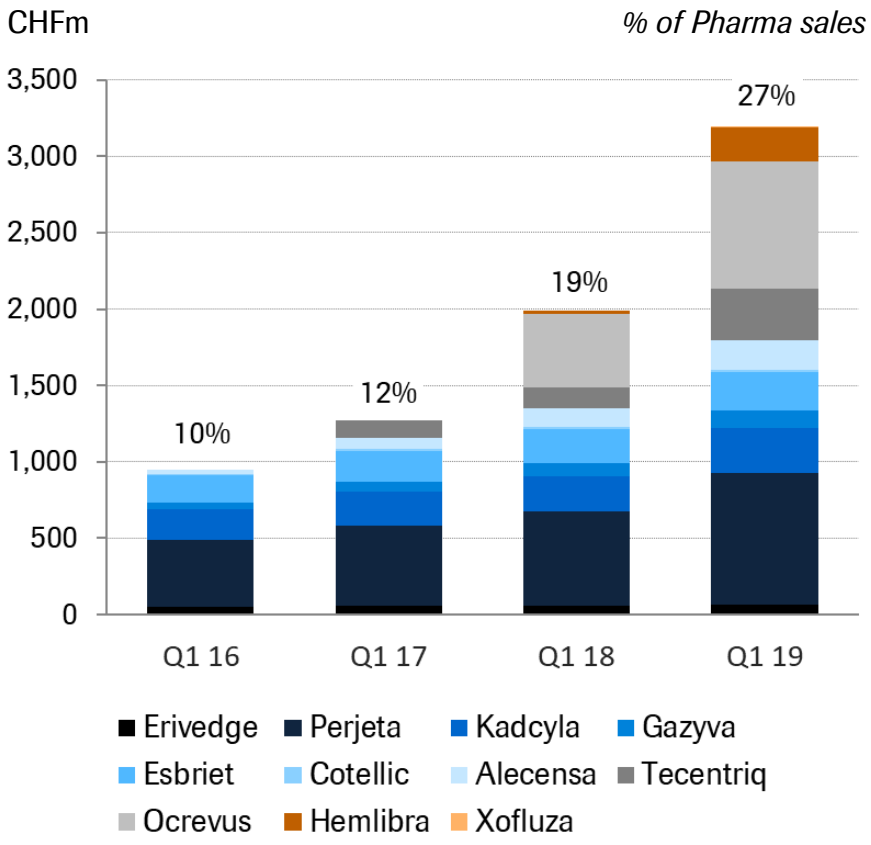
CER=Constant Exchange Rates

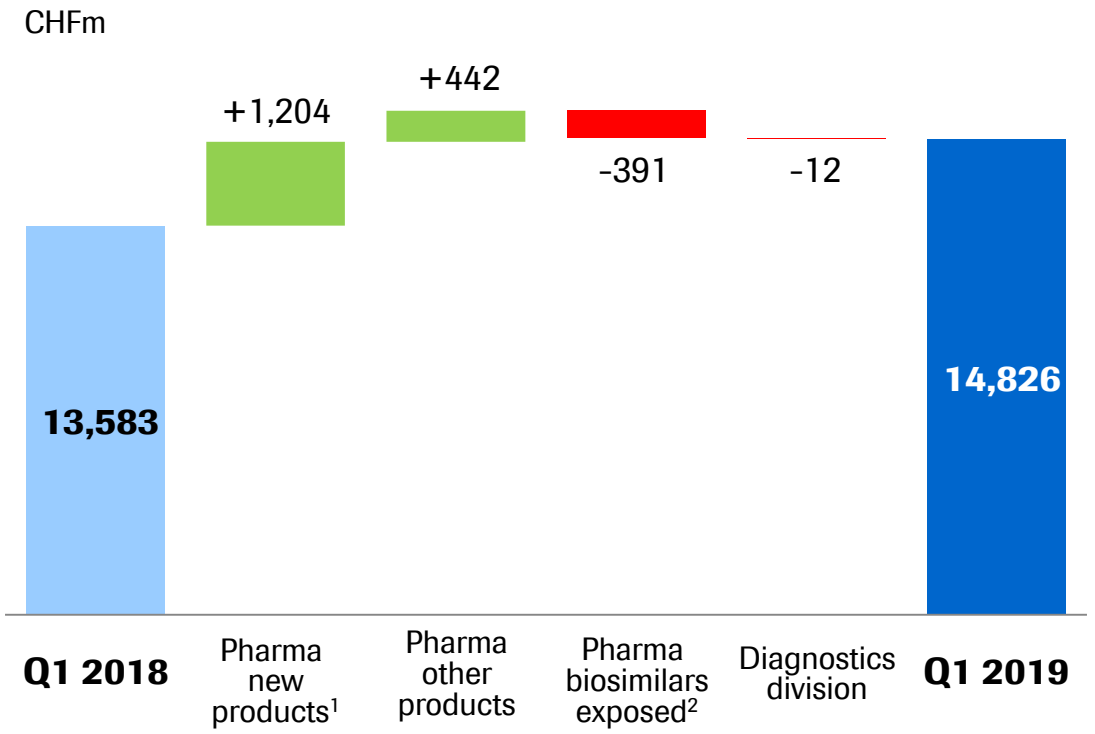
Q1 2019: Group sales growth for the eighth consecutive year



All growth rates at Constant Exchange Rates (CER)

New products with strong momentum





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

Roche significantly advancing patient care

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

26 *Breakthrough Therapy Designations (BTD)*

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

7 *Breakthrough Device Designations (BDD)*

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

Spark acquisition
Growing our pipeline and adding new technologies

- Pioneer of gene therapy, founded in 2013, as a spin off of the Children's Hospital of Philadelphia
- Focus on key therapeutic areas: Ophthalmology, hemophilia, neuroscience, and others
- Launched first in vivo gene therapy, Luxturna, in 2018 (US)
- Full gene therapy value chain including only FDA approved manufacturing facility, established pay for performance scheme
- Transaction value: USD 4.3 billion on a fully diluted basis

Replace and extend the business: Excellent start into the year

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

Achievements 2019

Entering new franchises

AAN (Amercian Academy of Neurology)

Ocrevus: Treat early and with full dose to max benefit, good safety sustained

satralizumab: Ph III combination data

risdiplam: 1 year data in type 1/2/3 SMA

Hemlibra: EU approval in Hemophilia A (non-inhibitors)

polatuzumab: US filing acceptance in aNHL

Replace/extend existing businesses

Gazyva+Ven: US filing acceptance in 1L CLL

Kadcyla: US filing acceptance in adj. HER2+ BC

Tecentriq: EU approval in 1L NSCLC with Avastin
US approval in 1L SCLC & 1L TNBC

Herceptin: US approval Hylecta (SC formulation)

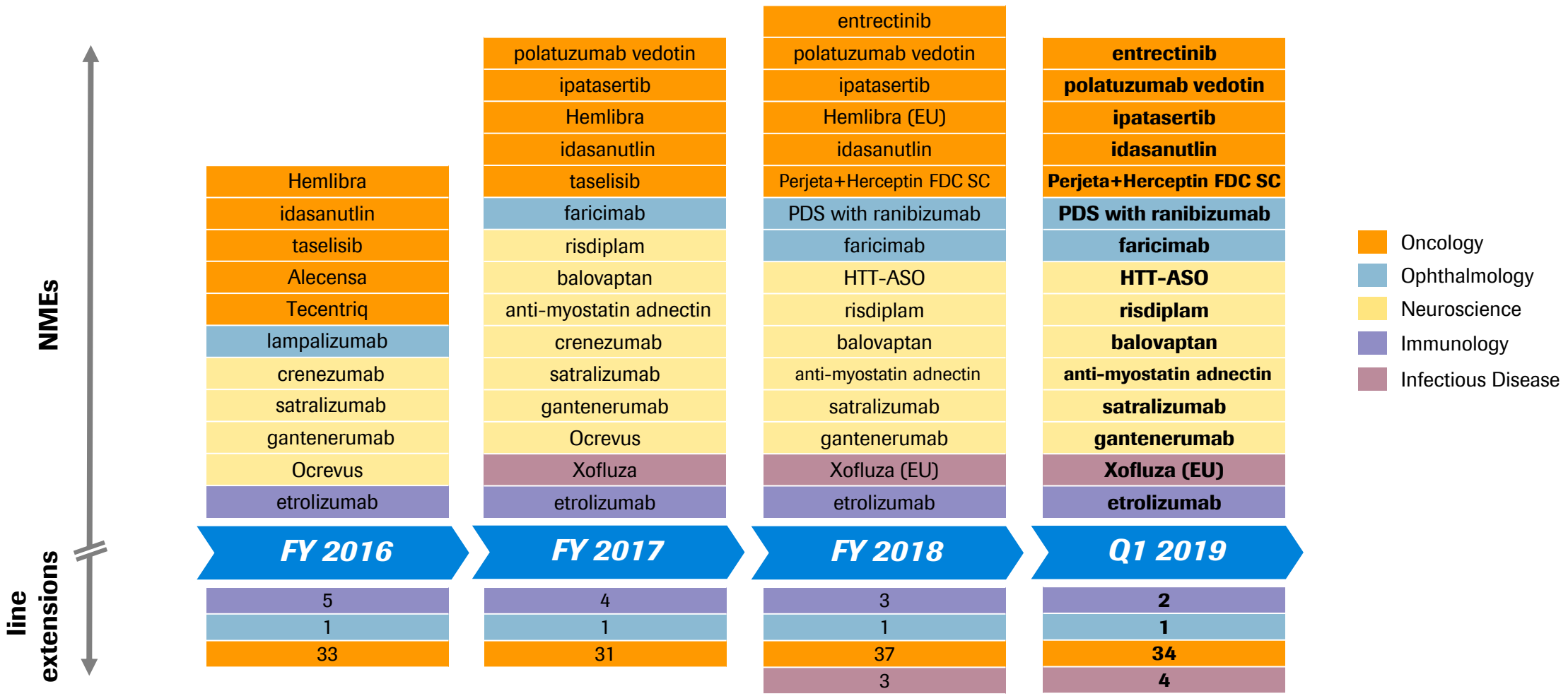
entrectinib: US priority review ROS1+ NSCLC & NTRK+

Xofluza: US filing acceptance in high risk patients

SMA=spinal muscular atrophy; NMOSD=neuromyelitis optica spectrum disorder; aNHL=advanced non-Hodgkin's lymphoma; CLL=chronic lymphocytic leukemia; BC=breast cancer; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; TNBC=triple-negative breast cancer

Outlook

Q1 2019: Record number of NMEs at pivotal stage



NME=new molecular entities; FDC=Fixed dose combination; SC=Subcutaneous; PDS=Port delivery system; For details on the indications and line extensions please consult the pipeline appendix

2019 outlook raised

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

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

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Bill Anderson
CEO Roche Pharmaceuticals

Q1 2019: Pharmaceuticals Division sales

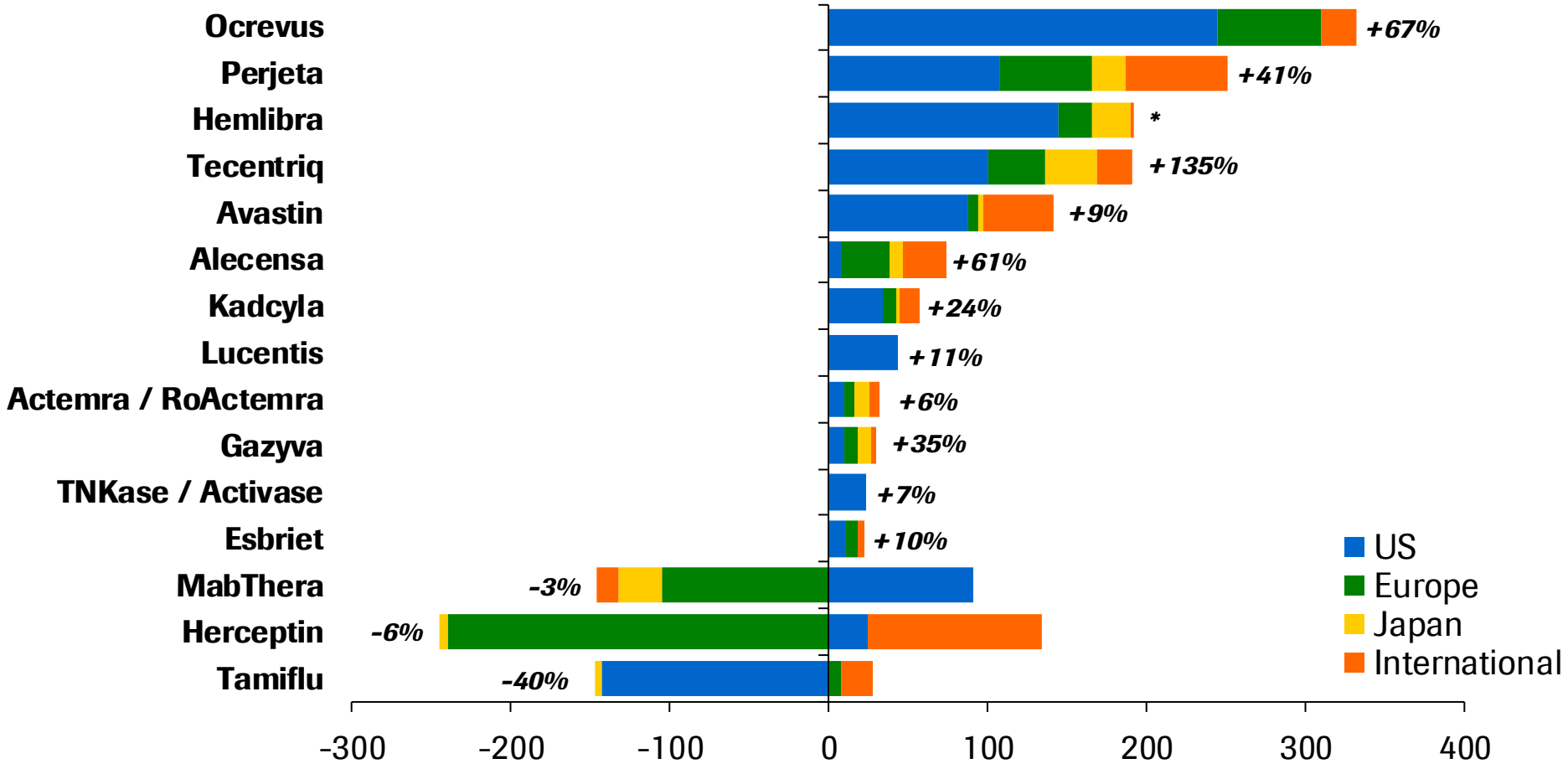
Strong growth driven by US, International, and Japan

	2019 CHFm	2018 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**11,927**	**10,672**	**12**	**10**
United States	6,623	5,516	20	14
Europe	2,101	2,287	-8	-6
Japan	941	851	11	7
International	2,262	2,018	12	17

CER=Constant Exchange Rates

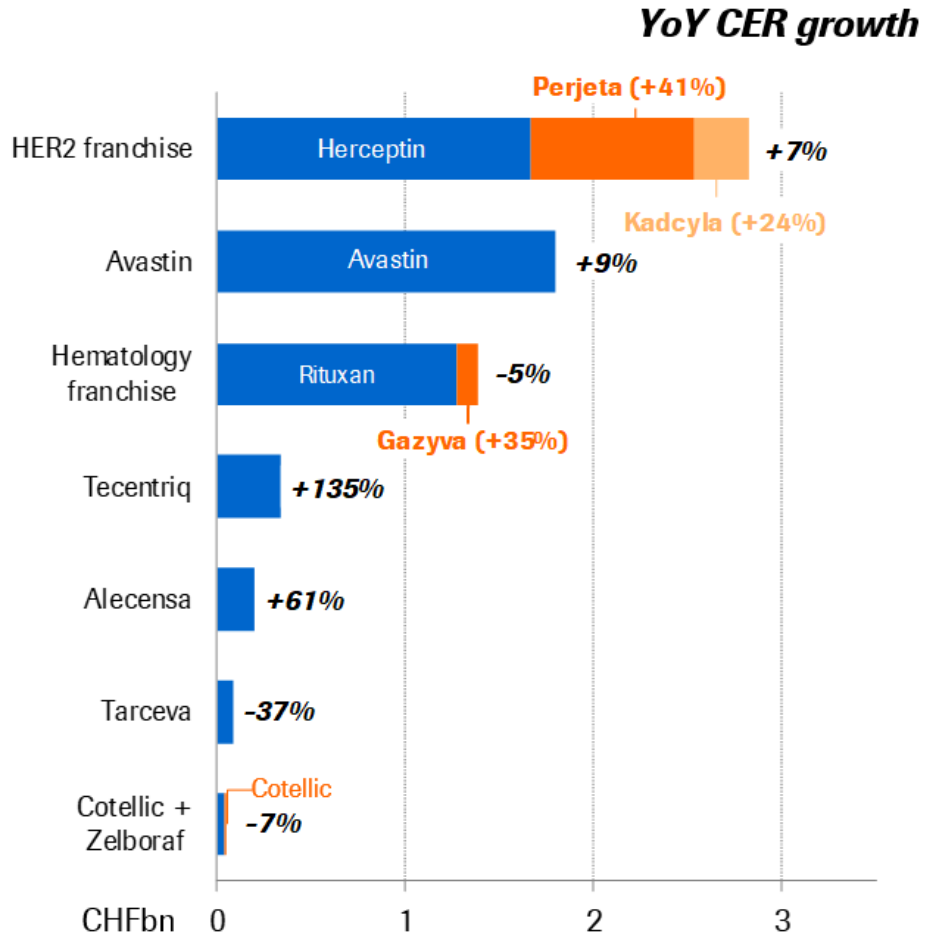
Q1 2019: Portfolio rejuvenation on-going

Strong growth from new products



Absolute values and growth rates at Constant Exchange Rates (CER); * over 500%

Q1 2019: Oncology sales +7% driven by breast and lung franchises



Oncology Q1 update

HER2 franchise

- Perjeta: Accelerated global growth driven by eBC adjuvant
- Kadcyla: Spontaneous use in eBC and growth in 2L mBC

Hematology franchise

- Venclexta:* Accelerated momentum due to 1L AML and R/R CLL
- Gazyva: Global growth driven by approved indications

Tecentriq

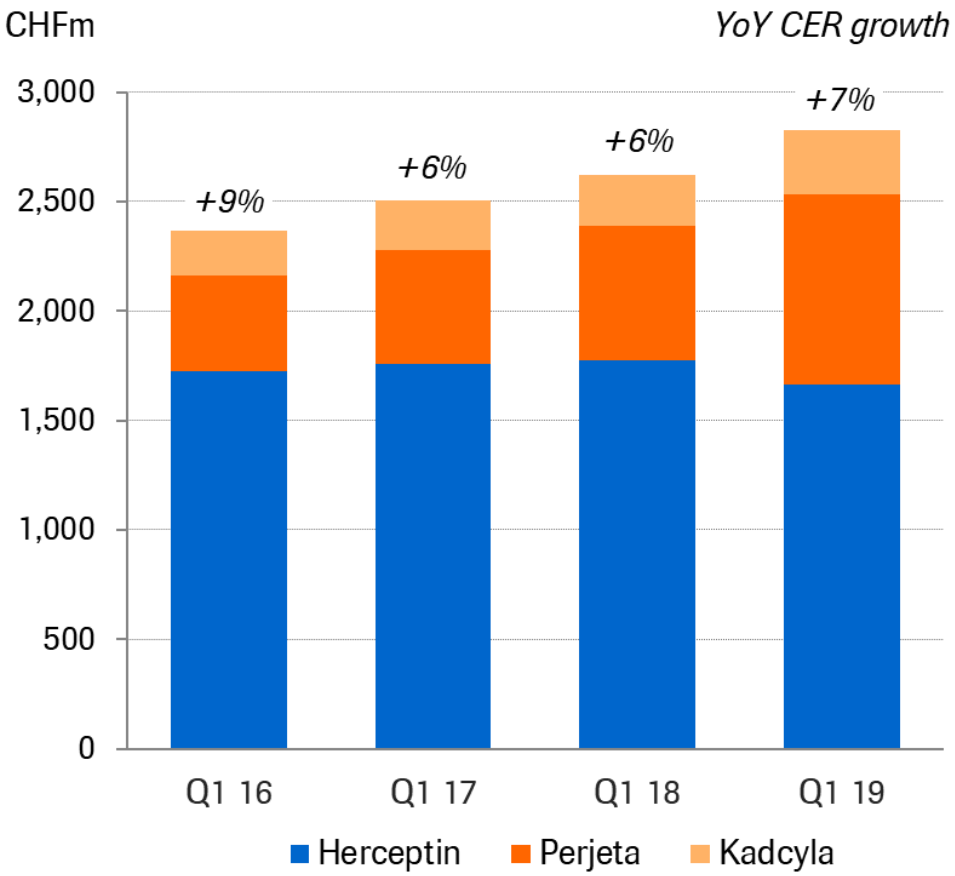
- Growth driven by first in class launches in 1L SCLC and 1L TNBC and 1L NSCLC

Alecensa

- Strong 1L launch momentum in key markets

* Venclexta sales booked by partner AbbVie and therefor not included; Q1 2019 Oncology sales: CHF 6.9bn; CER growth +7%; eBC=early breast cancer; mBC=metastatic breast cancer; AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; NSCLC=non-small cell lung cancer; SCLC=small cell lung cancer; TNBC=triple negative breast cancer

HER2 franchise: Accelerated growth driven by Perjeta and Kadcyla



HER2 franchise Q1 update

- Perjeta US (+36%): Growth remains driven by eBC (APHINITY)
- Perjeta EU (+27%): Accelerated growth due to first adjuvant launches (APHINITY) and extended 1L duration of treatment
- Kadcyla US (+39%): Spontaneous use in the adjuvant setting for patients with residual disease (KATHERINE)
- KATHERINE included in NCCN and AGO guidelines

Outlook 2019

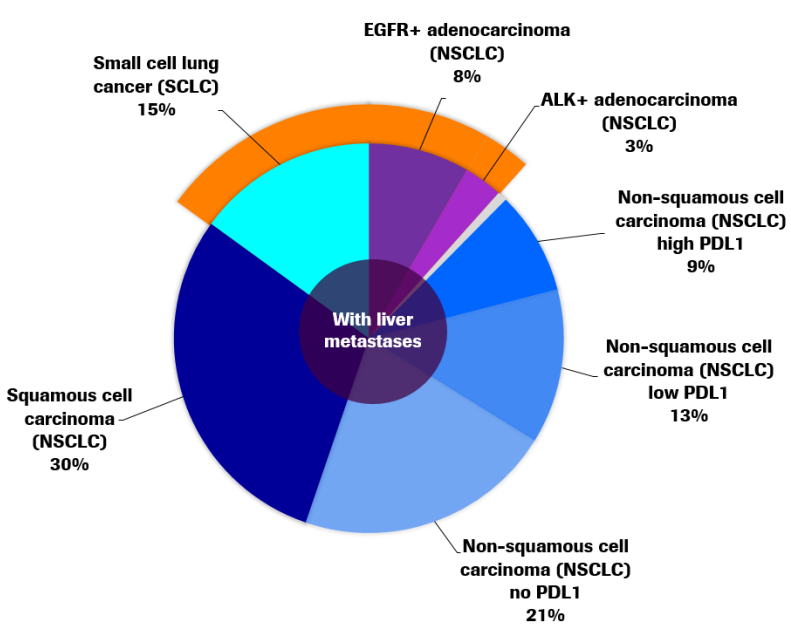
- US: Kadcyla KATHERINE approval
- US/EU: Continued Perjeta uptake (APHINITY)
- US: Market entry of Herceptin biosimilars

CER=Constant Exchange Rates; eBC=early breast cancer; NCCN=National Comprehensive Cancer Network; AGO=Arbeitsgemeinschaft Gynäkologische Onkologie

Lung cancer franchise

Broad coverage with differentiated growth opportunities

Lung cancer market (Incidence rates[1])



C = Roche with first CIT combination FDA-approved in 1L SCLC and EU-approved in 1L NSCLC incl. EGFR+ or ALK+ patients *

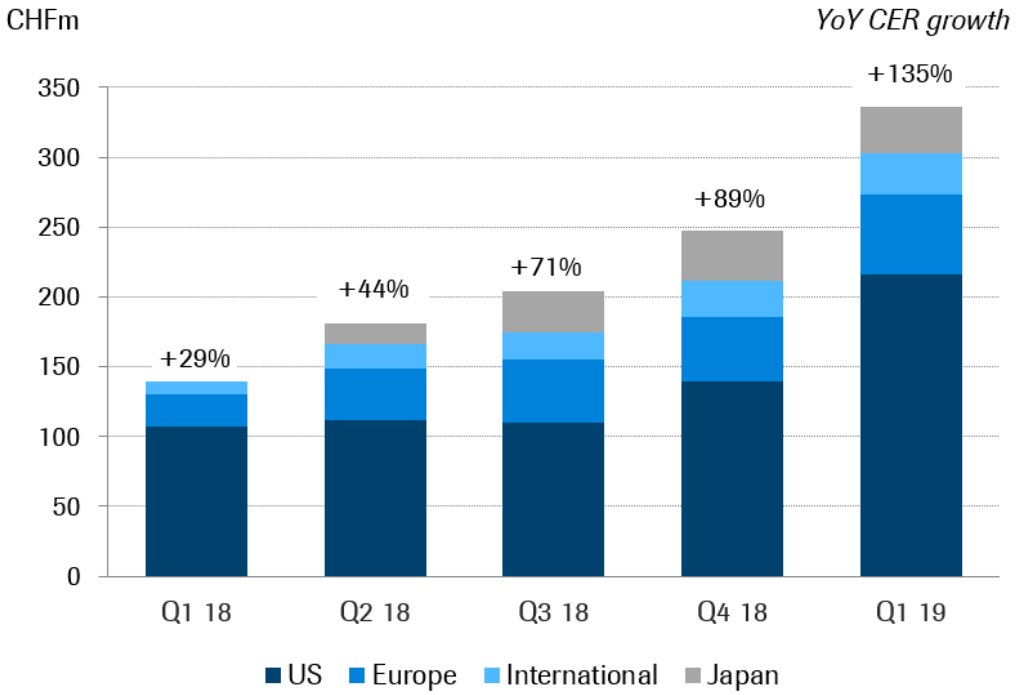
1L NSq NSCLC	• Tecentriq: 3 positive Ph III trials, including multiple chemos • Uniquely differentiated with abraxane and Avastin combinations • Strong efficacy in patients with liver metastases (~20% pts)
1L SCLC	• Tecentriq new standard of care and first CIT combination with chemo in 1L SCLC
1/2L ALK+ NSCLC	• Alecensa rapidly established as market leader in 1L ALK+
2L+ EGFR+/ALK+ NSCLC	• Tecentriq + Avastin: Only CIT combination with positive data in EGFR+/ALK+ patients progressing after targeted therapy
1L ROS1+ NSCLC	• Entrectinib new standard of care in 1L ROS1+ NSCLC and NTRK+ pan tumor

Total lung cancer market growing from USD ~14bn in 2017 to ~33bn in 2024[2]

[1] Datamonitor: incidence rates includes the 7 major markets (US, JP, FR, DE, IT, ES, UK); [2] Evaluate Pharma; CIT=Cancer Immunotherapy; SCLC=small cell lung cancer; NSCLC=non-small cell lung cancer;
* CIT combination has been filed in the EU for 1L SCLC, but not yet approved, and CIT combination approved in US for 1L NSCLC with no EGFR or ALK genomic tumor aberrations.

Lung cancer franchise: Tecentriq

Strong US launch in 1L SCLC; 2L NSCLC share gains in EU



Tecentriq Q1 update

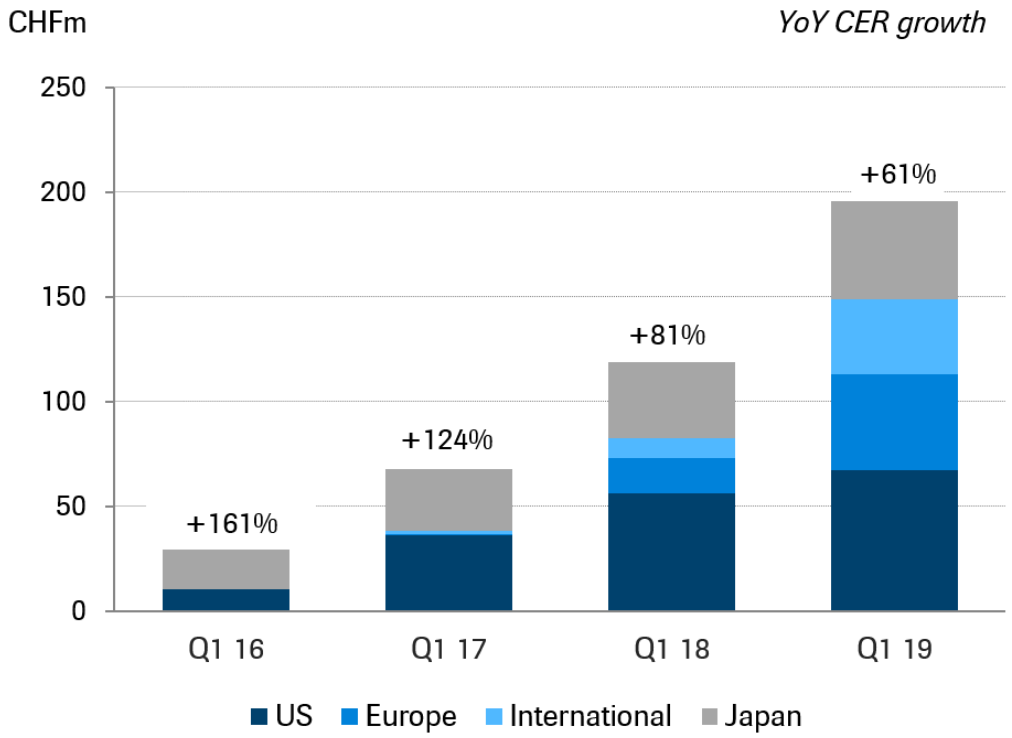
- US (+91%): Growth driven by 1L SCLC and by 1L TNBC
- EU (+158%): Increasing shares in 2L NSCLC; approval in 1L NSCLC achieved, launches on-going
- Japan: Strong launch in 1L NSCLC

Outlook 2019

- EU approval in 1L SCLC and 1L TNBC

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

Lung cancer franchise: Alecensa
Strong 1L momentum in all markets



Alecensa Q1 update

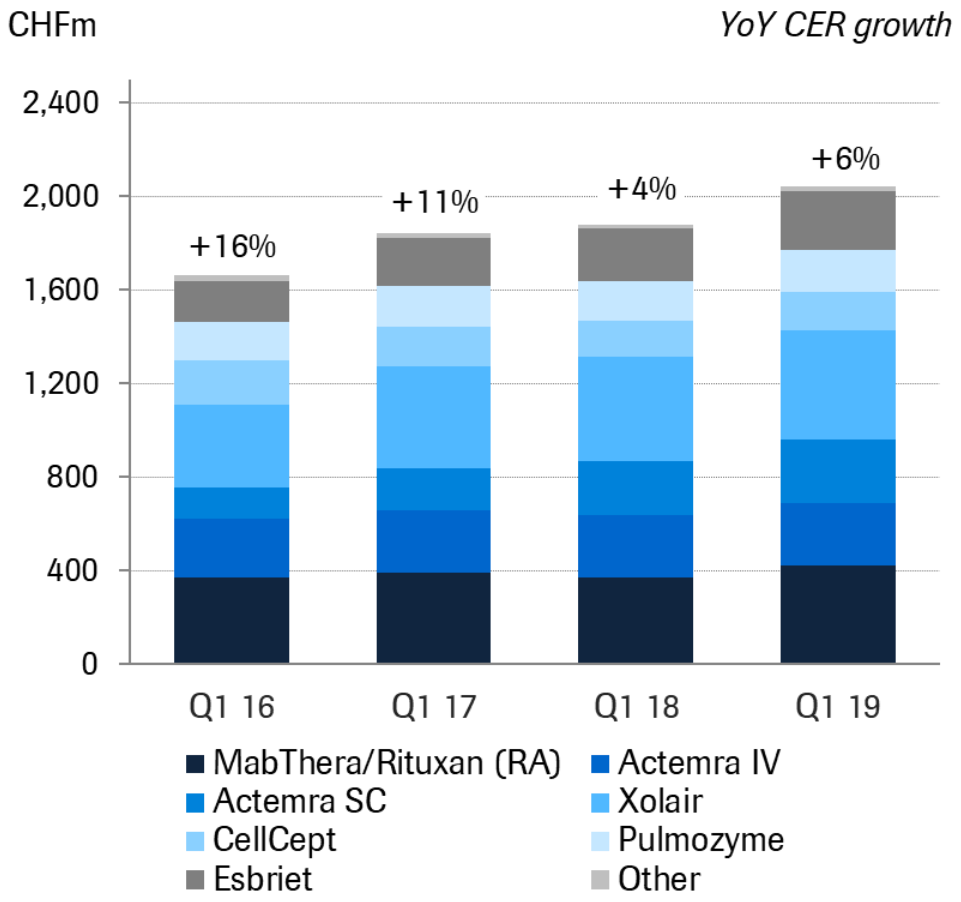
- US (+14%): 1L New patient share at 70%
- EU (+182%): 1L launches ongoing
- Japan (+24%): 1L New patient share close to 70%
- Strong launch momentum in China

Outlook 2019

- Updated ALEX data expected at ESMO
- NRDL listing in China expected

CER=Constant Exchange Rates; NRDL=national reimbursement drug list

Immunology franchise
Annualized sales exceed CHF 8bn



Immunology Q1 update

Esbriet (+10%)

- Strong growth in mild to moderate patient segments

Actemra (+6%)

- EU: Remains leader in overall and 1L monotherapy RA
- Growth driven by giant cell arteritis (GCA)

Xolair (+1%)

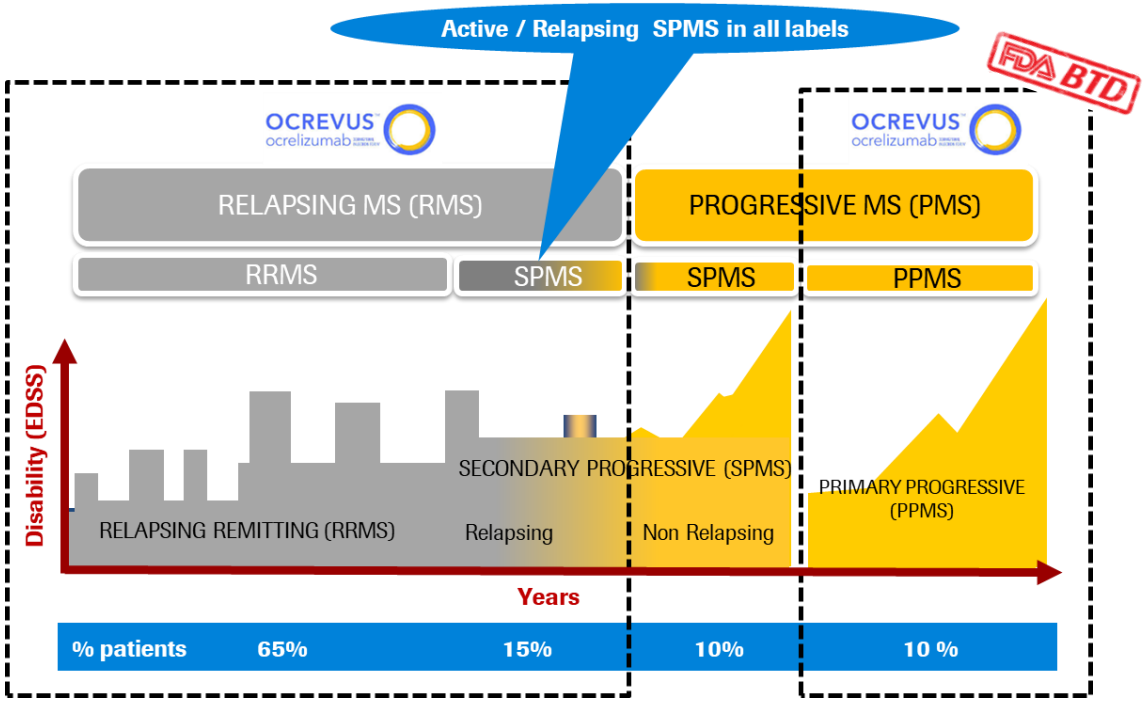
- Growth driven by CIU
- Pivotal Ph III (OUtMATCH) in food allergy to start in Q2
- Ph III (POLYP I/II) results in nasal polyps expected mid year

CER=Constant Exchange Rates; RA=rheumatoid arthritis; CIU=chronic idiopathic urticaria

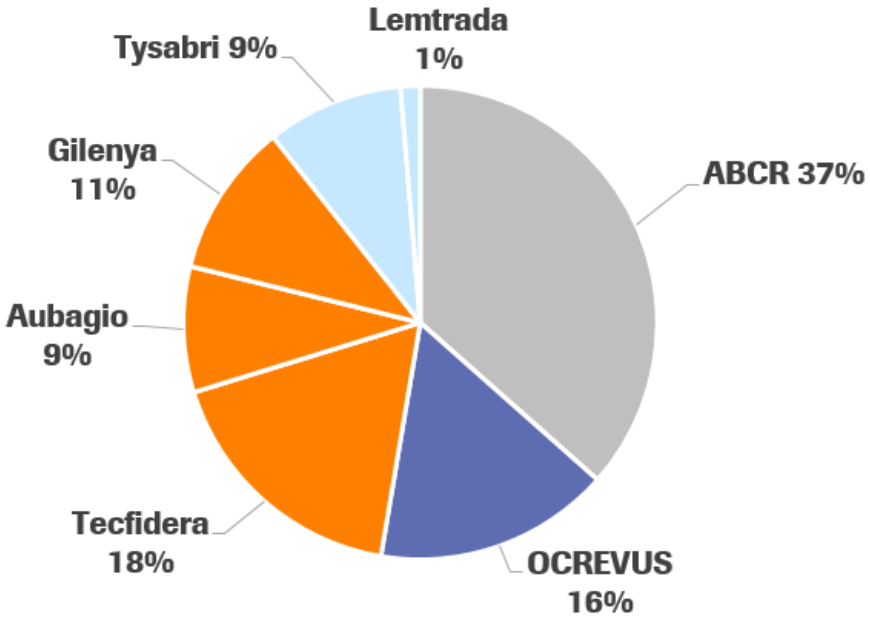
Neuroscience franchise: Ocrevus in MS

US label covers ~90% of MS patients including "active SPMS"

MS spectrum[1] and US label



US market shares[2]

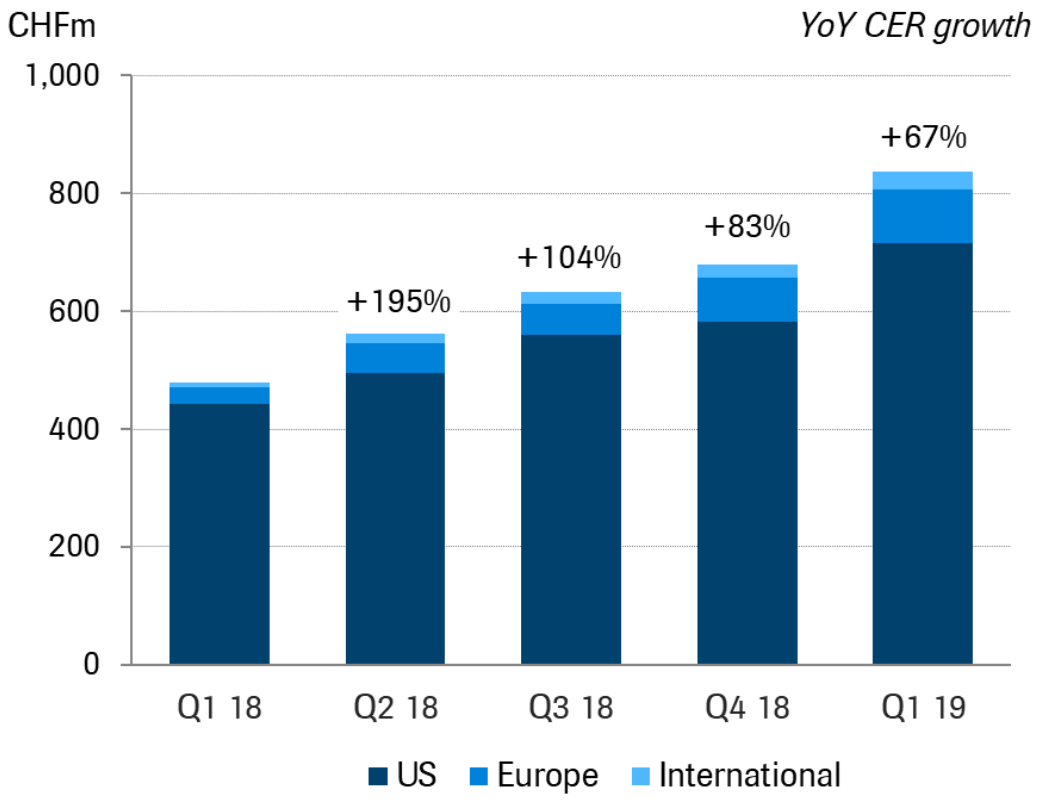


Total global MS market USD ~22 bn in 2024[3]

Source: [1] Roche analysis of MS prevalence epidemiological studies; [2] US SHA claims of MS licensed therapies. ABCR's refers to Avonex®, Betaferon®/Betaseron®, Copaxone®, Rebif®, Extavia®, Plegridy®; [3] EvaluatePharma

Neuroscience franchise

Ocrevus growth increasingly driven by earlier lines



Ocrevus Q1 update

- US (+54%) driven by earlier lines
- Progress in shortening retreatment intervals
- Further strong launches in EU and International

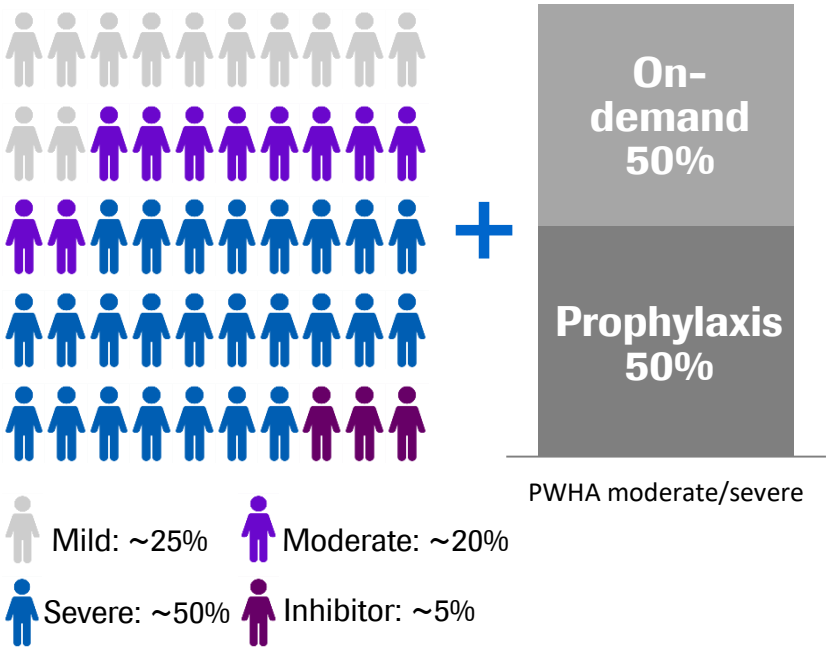
Outlook 2019

- Continue moving into earlier lines displacing orals
- AAN: PK/PD data highlighting importance of higher exposure and lower B-cell levels in slowing disease progression
- AAN: >5 years OLE data (OPERA; ORATORIO)
- Continued fast enrollment in 13 Ph III/IV studies expected

CER=Constant Exchange Rates; AAN=conference of the Amercian Academy of Neurology; PK=Pharmacokinetics; PD=Pharmacodynamic; OLE=open label extension

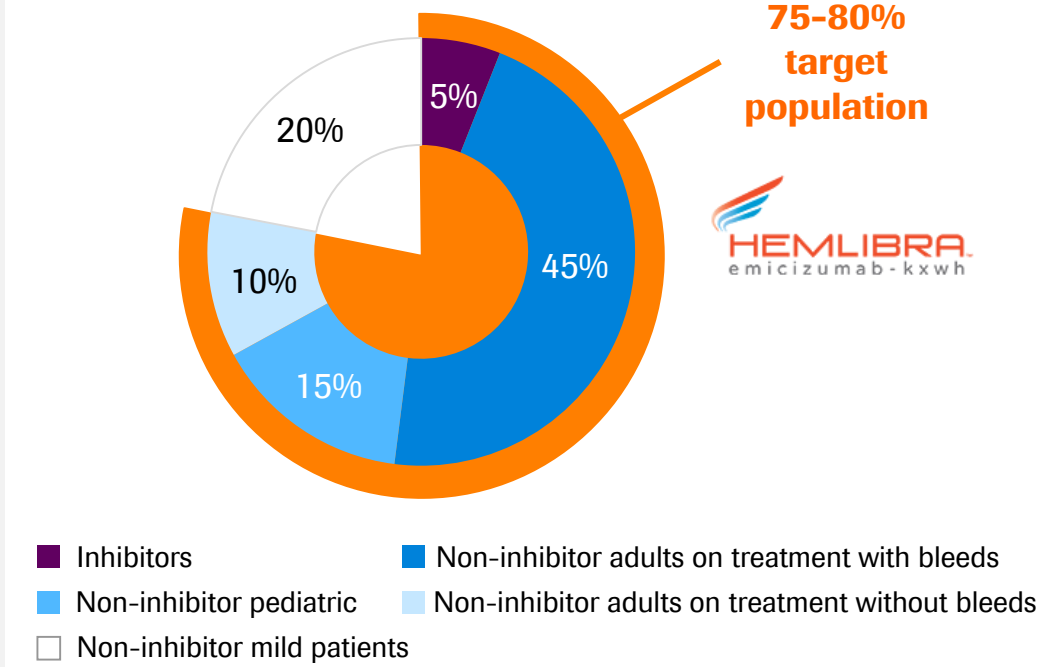
Hemophilia A franchise
Transforming the market

Severity & treatment-based segmentation



Needs-based segmentation[1]

FDA BTD

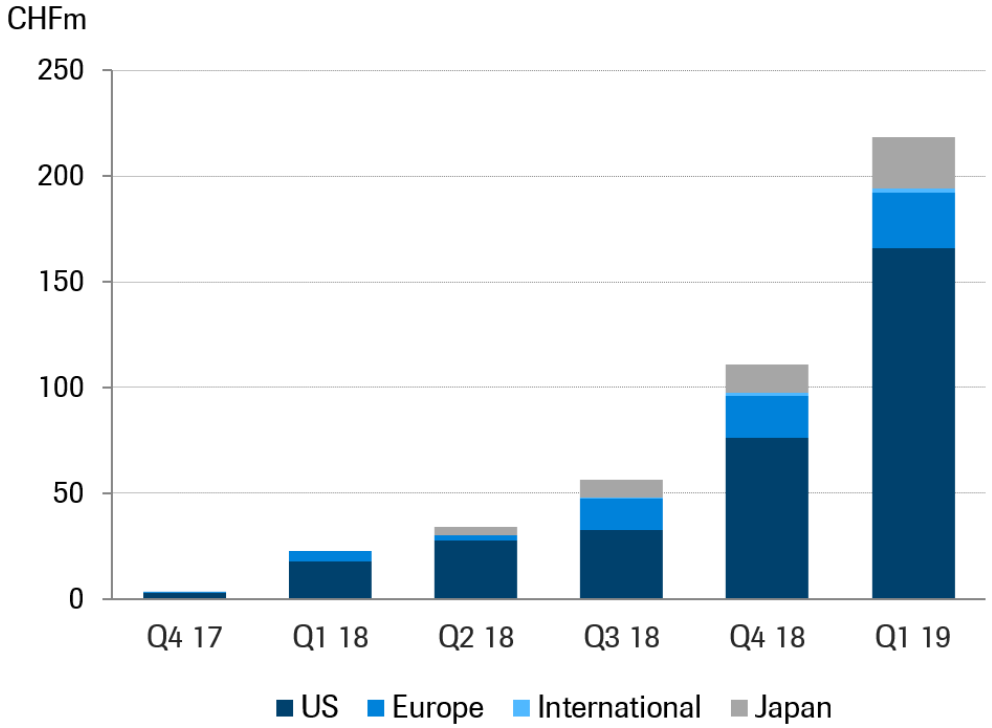


Total hemophila A market growing to USD 13bn by 2024[2]

PWHA=People with Hemophilia A; Source: Treated patients MORSE 2017 (prevalence), UKHCDO Annual Report 2016 and internal assumptions (treatment rate); [1] Target population based on the US label; [2] Source: Evaluate Pharma

Hemophilia A franchise

Hemlibra with strong uptake in non-inhibitors



Hemlibra Q1 update

- US: Strong uptake in non-inhibitors driven by large centers and patient requests
- EU: Non-inhibitor approval for severe hemophilia A achieved in March
- Overall >2,500 patients treated globally

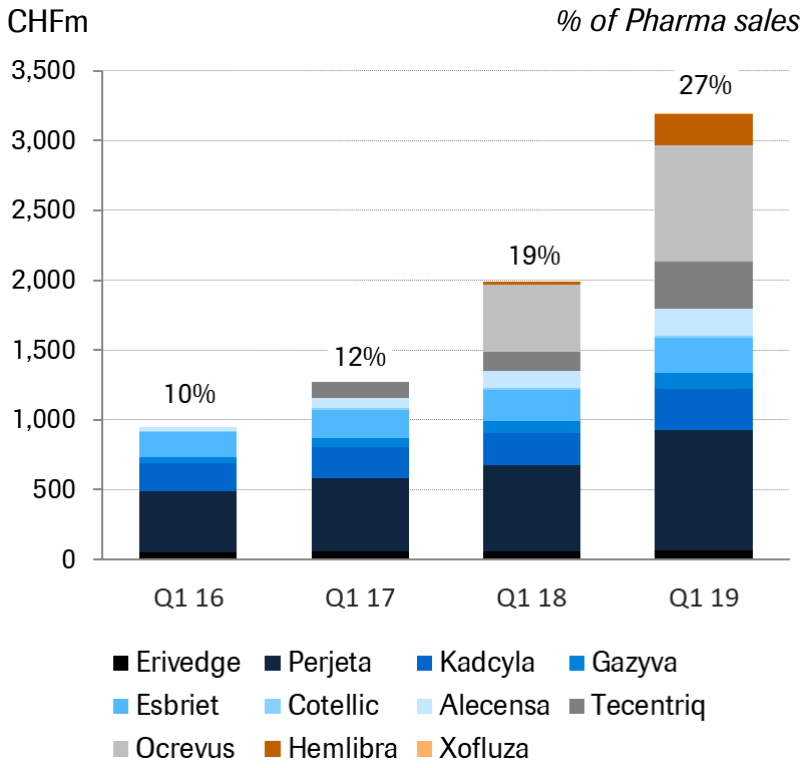
Outlook 2019

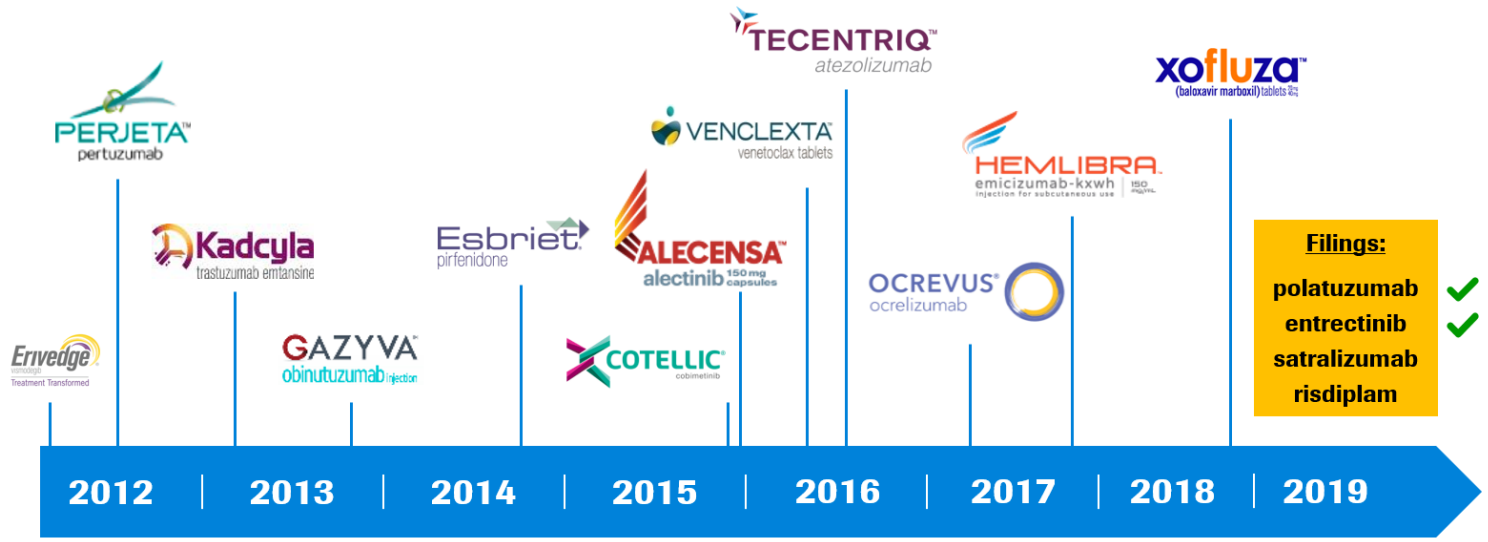
- US/EU: Uptake in non-inhibitors and inhibitors

CER=Constant Exchange Rates

New products close to annualized sales of CHF 13bn*

Additional 4 NMEs approaching launch





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

Upcoming conferences 2019*

AAN 2019 Annual Meeting

Philadelphia, 4-10 May

- **risdiplam:** Ph II/III (*FIREFISH*) and (*SUNFISH*) 1-year data in type 1/2/3 SMA
- **satralizumab:** Ph III (*SakuraSky*) in Neuromyelitis optica spectrum disorders (NMOSD)
- **HTT-ASO:** OLE PhI/IIa data in Huntington's disease
- **Ocrevus:** OLE Ph III (*OPERA I/II*) in RMS & OLE Ph III (*ORATORIO I/II*) in PPMS including long-term CDP reduction after >5 yrs
- **Ocrevus:** New PK/PD data and exposure-response analyses in MS patients (high exposure and greater B cell depletion important for CDP control, confirming dosing schedule)
- **Ocrevus:** Safety update: Long-term safety continues to support risk/benefit profile

Roche Virtual Pipeline Event

Monday, 13 May 2019
17:00 to 18:15 CEST

2019 ASCO ANNUAL MEETING

Chicago, 31 May - 4 June

Hematology:

- **Venclexta + Gazyva:** Ph III (*CLL14*) in 1L CLL

Breast cancer:

- **Tecentriq:** Ph III (*IMpassion130*) OS update in 1L mTNBC
- **Perjeta + Herceptin:** Final Ph III OS data *(CLEOPATRA)* in 1L mHER2+ BC

Lung & pan-tumor:

- **Tecentriq + Avastin:** Ph III (*IMpower150*) liver metastases in 1L NSCLC
- **entrectinib:** Ph I/Ib (*STARTRK-NG*) update in NTRK1/2/3+, ROS1+ CNS tumors in pediatrics

Roche Analyst Event at ASCO 2019

Monday, 3 June 2019
6.00pm to 7.15pm CDT (Chicago)

* Submitted / pending acceptance; OLE=open label extension; CDP=clinical disease progression

2019: Key late-stage news flow *

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

Additional 2019 news flow:

- **MabThera/Rituxan**: EU approval of pemphigus vulgaris
- **Herceptin Hylecta**: US approval SC formulation
- **Venclexta + Gazyva**: Early filing in 1L unfit CLL under RTOR pilot program

* 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 observed in the Venclexta arm; Further analysis on-going.; IA=interim analysis; RTOR=real time oncology review

Diagnostics Division

Michael Heuer
CEO Roche Diagnostics

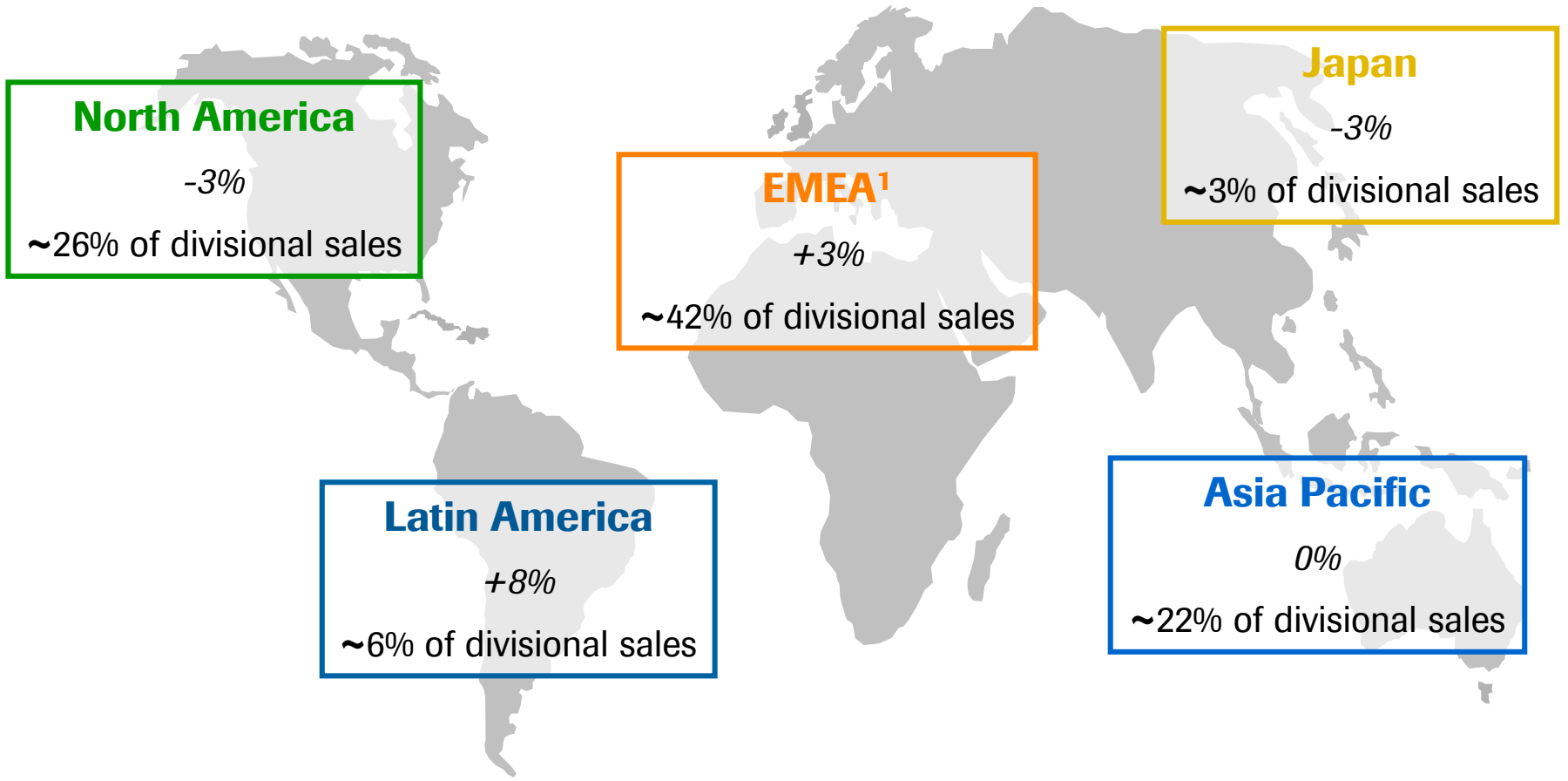
Q1 2019: Diagnostics Division sales

	2019 CHFm	2018 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**2,899**	**2,911**	**0**	**1**
Centralised and Point of Care Solutions	1,681	1,716	-2	-1
Molecular Diagnostics	502	468	7	7
Diabetes Care	465	478	-3	1
Tissue Diagnostics	251	249	1	-1

CER=Constant Exchange Rates; Underlying growth of Molecular Diagnostics excluding sequencing business: +7%

Q1 2019: Diagnostics Division regional sales

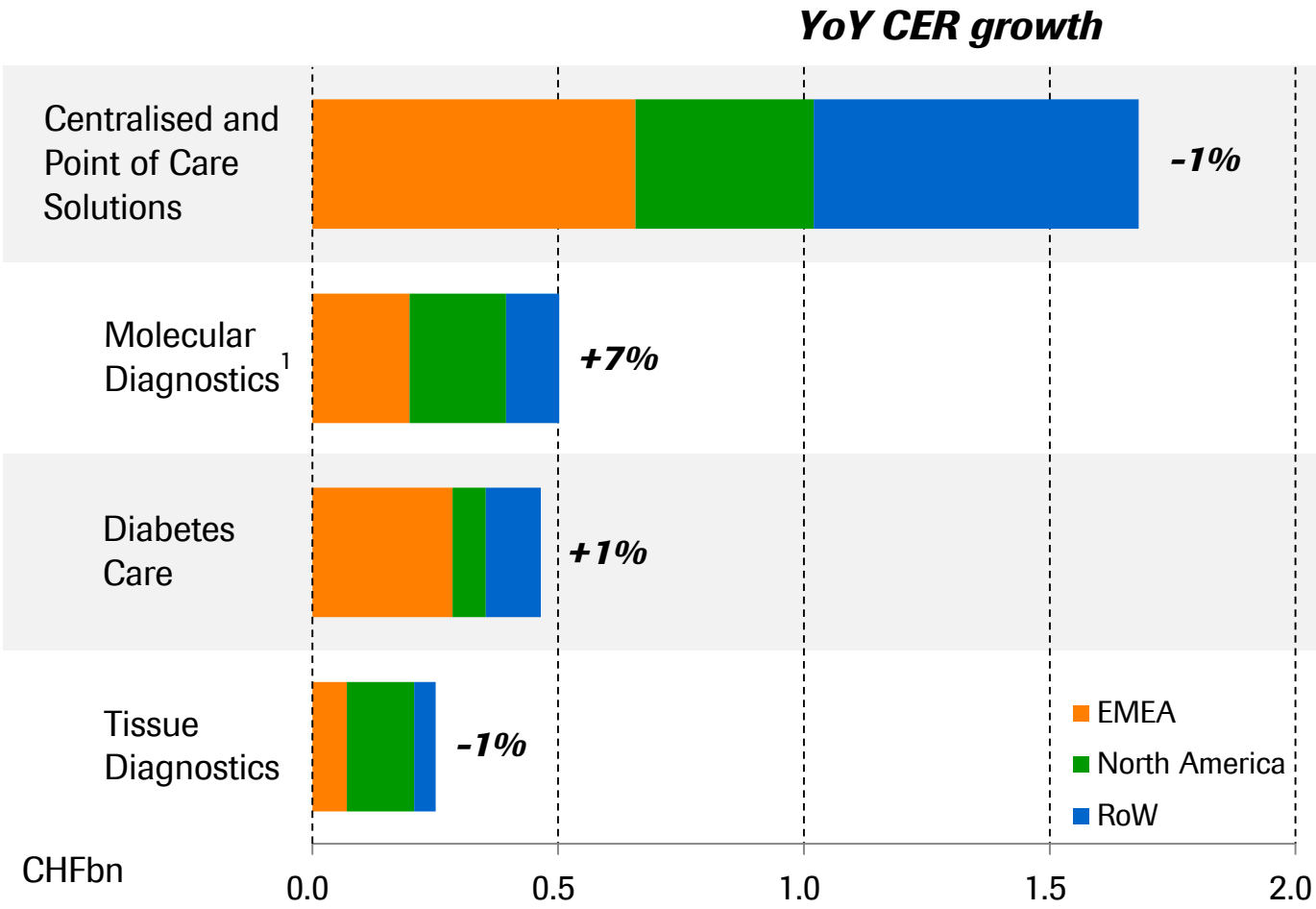
Growth in EMEA and Latin America



+1% growth in E7 countries[2]

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

Q1 2019: Diagnostics Division highlights
Growth due to Molecular Diagnostics



- Immunodiagnostics (+3%); Clinical chemistry (-2%)
- Sales affected by reduction of distributor inventories in China

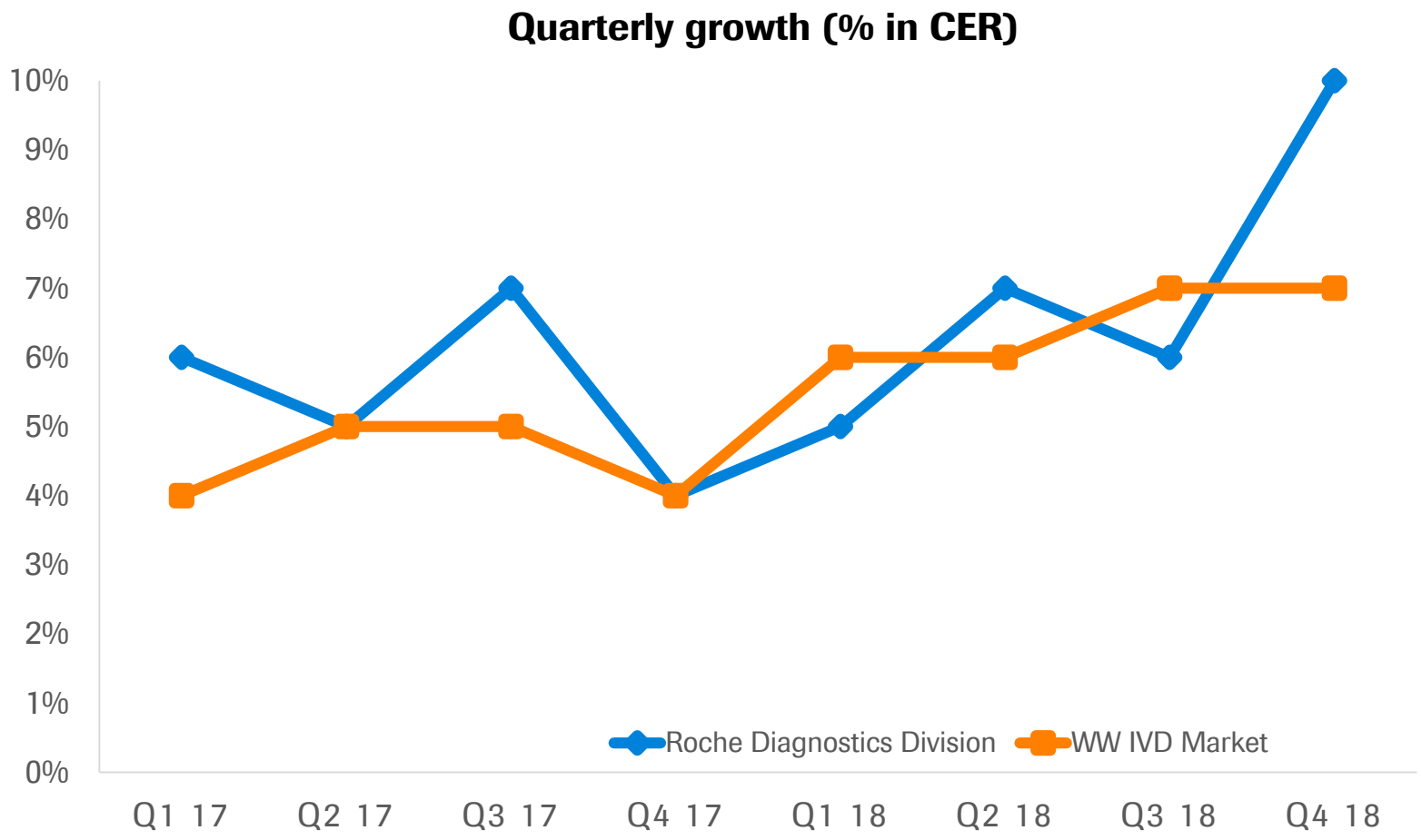
- Cervical cancer (+52%); Blood screening (+14%); Microbiology (+40%); POC MDx (+18%); Virology (0%)

- Blood glucose monitoring (+1%); Insulin delivery systems (-4%)

- Advanced staining (+2%); Primary staining (0%); Companion diagnostics (-19%)
- BenchMark and Discovery Ultra shipment delays

[1] Underlying growth of Molecular Diagnostics excluding sequencing business: +7%; CER=Constant Exchange Rates; EMEA=Europe, Middle East and Africa

Roche increasing market leadership

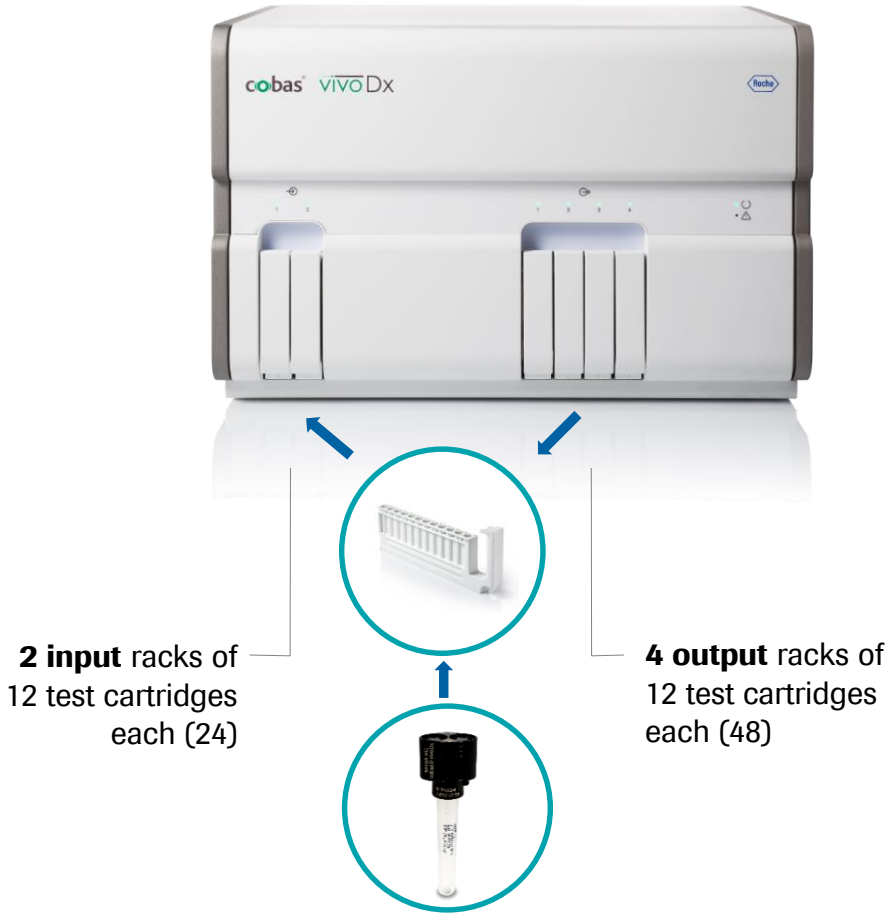


- Strong commercial presence
- Broadest test menu

Source: 3rd party IVD consultancy, Q4 2018 IVD is weighted estimate

Launch of cobas vivoDx System for antibiotic resistance testing

Delivers fast phenotypic results in an automated workflow



- Results in <6 hours (vs 5 days for culture testing)
- 96 tests per 8 hours shift
- Single and multi sampling processing possible
- First launched with MRSA test

VENTANA PD-L1 (SP142) Assay

First FDA companion diagnostic approval for use in TNBC

The VENTANA PD-L1 (SP142) Assay is a system…

IHC platform

VENTANA
BenchMark ULTRA

Antibody

VENTANA
SP142 Antibody

Detection kit

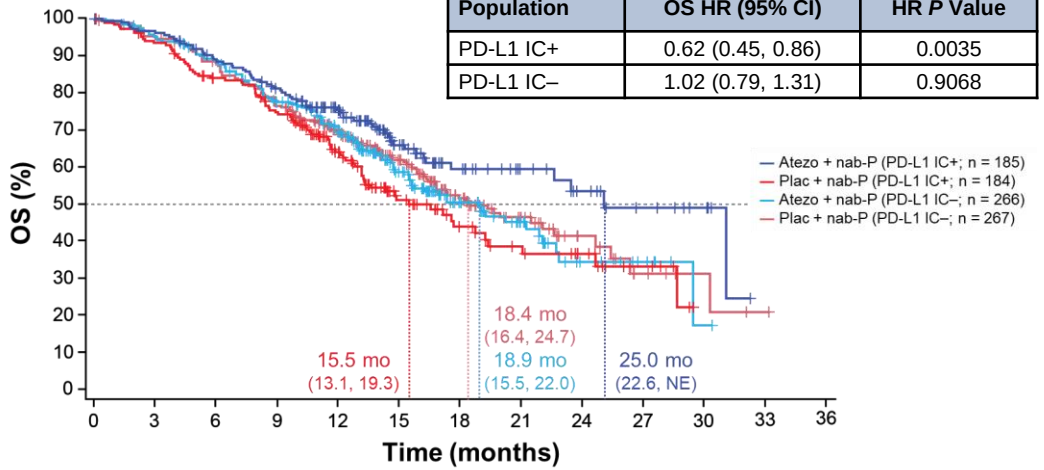
VENTANA
OptiView Detection Kit
+ Amplification Kit

Scoring algorithm

PD-L1 (SP142)
Scoring System

…that identifies TNBC patients eligible for treatment with Tecentriq + nab-paclitaxel[1]

Population	OS HR (95% CI)	HR *P* Value
PD-L1 IC+	0.62 (0.45, 0.86)	0.0035
PD-L1 IC–	1.02 (0.79, 1.31)	0.9068



Patients with 1L mTNBC should be routinely tested for PD-L1 IC status to determine whether they might benefit from Tecentriq + nab-paclitaxel

[1] Emens LA, et al. IMpassion130 biomarkers. SABCS 2018 (program #GS1-04); TNBC=triple-negative breast cancer

Launch of cobas infinity laboratory solution, version 3.0

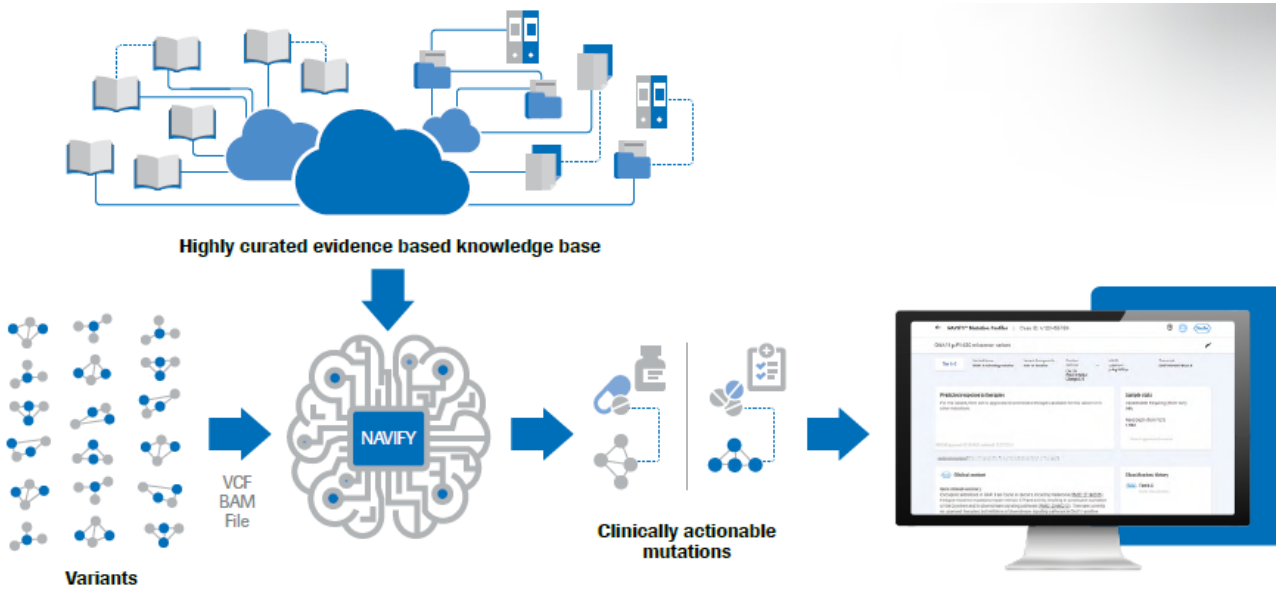
Software management solution for diagnostic laboratories

New features to ensure the delivery of high quality and reliable results:

- New and improved Quality Control module
- Intelligent routing of samples in high volume testing labs
- Addition of more work areas and clinical disciplines in the lab environment
- Easy-to-use and customizable interface

Launch of NAVIFY mutation profiler and therapy matcher[1]

Clinical decision support solution for next generation sequencing labs



NAVIFY mutation profiler:

- Provides annotation, interpretation and clinical reporting of NGS[2] tests

NAVIFY therapy matcher:

- Helps clinicians to link clinically actionable mutations to relevant therapy options

[1] CE-IVD marked software for comprehensive genomic profiling as a medical device; [2] NGS: next generation sequencing

Key launches 2019

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

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

Finance

Alan Hippe
Chief Financial Officer

Q1 2019: Highlights

Sales

- Strong Group sales growth (+8%)
- Strong growth in Pharmaceuticals (+10%); Diagnostics (+1%)

M&A

- Definitive merger agreement to acquire Spark Therapeutics for USD 114.50 per share
- All-cash transaction will be financed by available funds and commercial paper
- Transaction is not expected to have an impact on the financial guidance for 2019

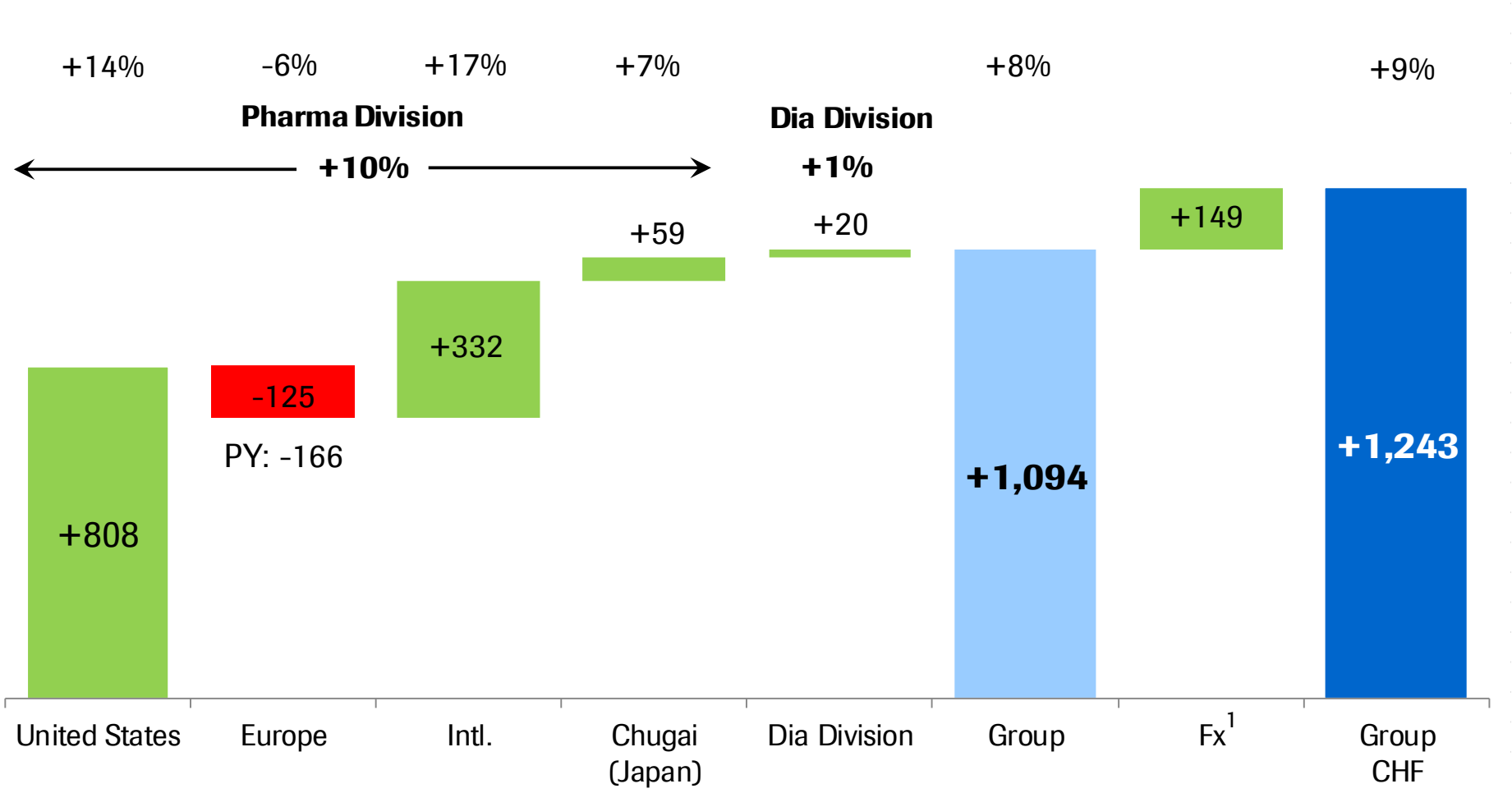
Currency impact on sales

- Overall slightly positive – positive impact from USD partially offset by LATAM currencies and EUR

All growth rates at Constant Exchange Rates (CER)

Group sales 2019

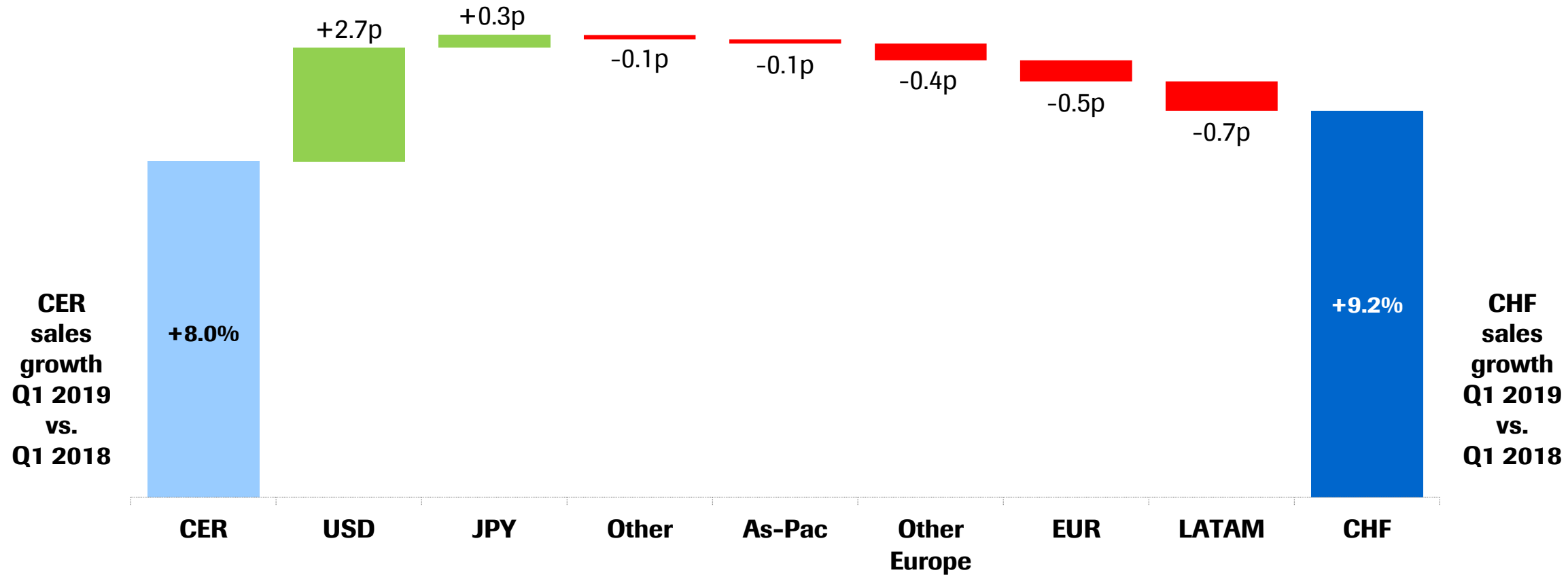
CER sales increase of +8% driven by US and International, partially offset by Europe



Absolute values in CHFm at Constant Exchange Rates (avg full year 2018); [1] avg full year 2018 to avg Q1 2019 fx

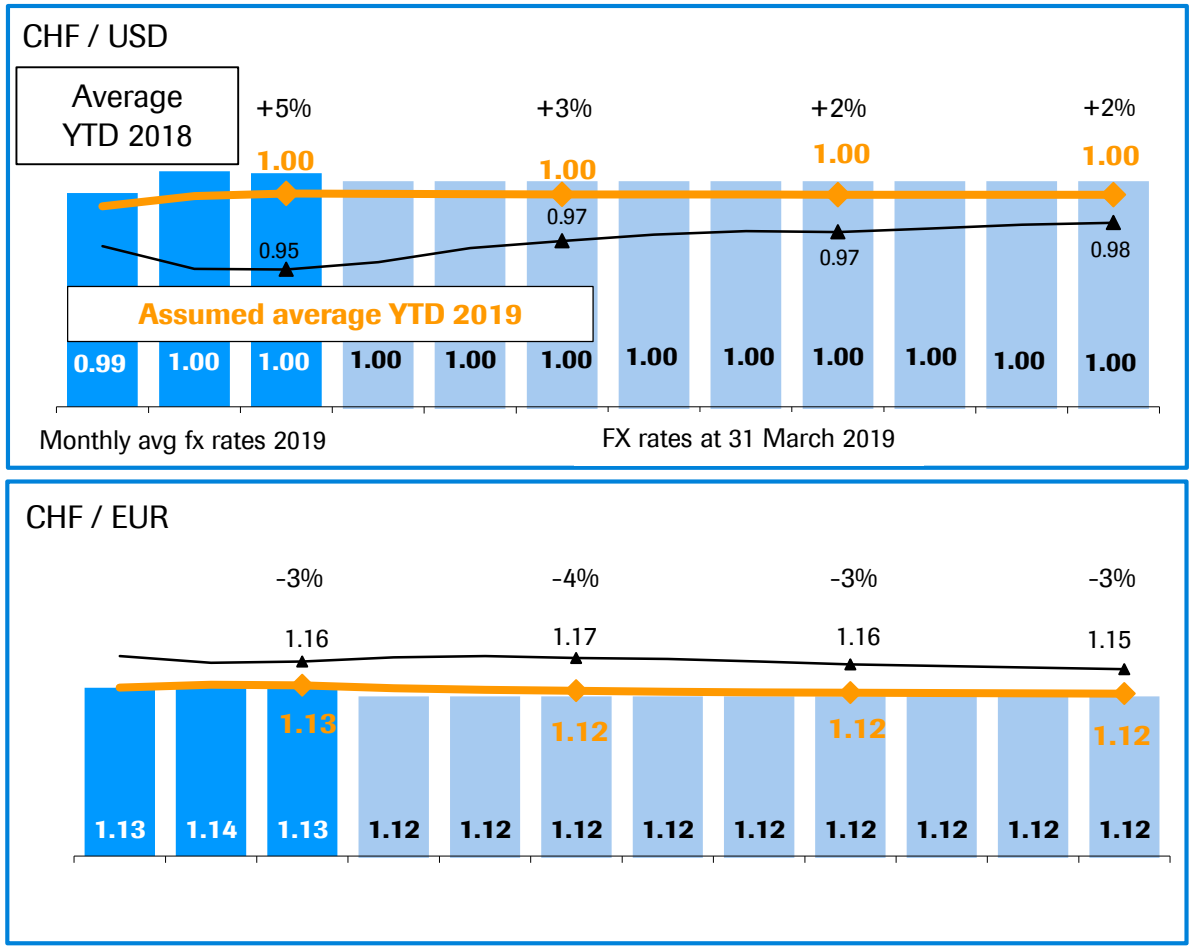
Exchange rate impact on sales growth

Positive impact from USD partially offset by LATAM currencies & EUR



CER=Constant Exchange Rates (avg full year 2018)

Low currency impact expected in 2019



Assuming the 31 March 2019 exchange rates remain stable until end of 2019, 2019 impact[1] is expected to be (%p):

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

[1] on Group growth rates

2019 outlook raised

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

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

[1] At Constant Exchange Rates (CER)

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group Q1 2019 sales

Diagnostics

Foreign exchange rate information

Changes to the development pipeline
Q1 2019 update

New to phase I

1 NMEs:
RG6084 – HBV

New to phase II

1 AI:
RG7388 idasanutlin – AML fit 1L

New to phase III

1 AI transitioned from Ph2:
RG7716 faricimab – wAMD

1 AI:
RG6152 Xofluza – influenza post-exposure prophylaxis

New to registration

1 AI transitioned from Ph3 following filing in EU and US:

RG3502 Kadcyla – HER2+ eBC

2 AIs transitioned from Ph3 following filing in US:
RG6152 Xofluza – influenza high risk patients
RG7601 Venclexta + Gazyva – 1L CLL

Removed from phase I

1 NME:
RG6049 – neurodegenerative disorders
2 AIs:
RG7446 Tecentriq ± daratumumab– MM
RG7446 Tecentriq – NMIBC

Removed from phase II

Removed from phase III

Removed from registration

4 AIs following EU approval:

RG7446 Tecentriq + Chemo+ Avastin – 1L non-squamous NSCLC
RG6013 Hemlibra – hemophilia A w/o FVIII inhibitors
RG6013 Hemlibra – hemophilia A Q4W
RG105 MabThera – pemphigus vulgaris

Status as of April 17, 2019

Roche Group development pipeline

Phase I (40 NMEs + 19 AIs)

RG6026	CD20 x CD3 ± chemo ± T	heme tumors
RG6109	-	AML
RG6114	mPI3K alpha inh	HR+ BC
RG6123	-	solid tumors
RG6146	BET inh combos	solid & heme tumors
RG6148	-	HER2 expressing BC
RG6160	-	multiple myeloma
RG6171	SERD (3)	ER+ (HER2-) mBC
RG6180	iNeST*± T	solid tumors
RG6185	pan-RAF inh + Cotellic	solid tumors
RG6194	HER2 x CD3	BC
RG7159	anti-CD20 combos	heme tumors
RG7421	Cotellic + Zelboraf + T	melanoma
	Cotellic + T	2L BRAF WT mM
	Cotellic + T	RCC, bladder, head & neck ca
RG7440	ipatasertib + Taxane + T	TNBC
RG7446	Tecentriq (T)	solid tumors
	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chemo	HCC, GC, PaC
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + radium 223	mCRPC
	T + rucaparib	ovarian ca
RG7461	FAP IL2v FP combos	solid tumors
RG7601	Venclexta + idasanutlin	AML
	Venclexta ± azacitidine	r/r MDS
	Venclexta + gilteritinib	r/r AML
	Venclexta + Cotellic + T	MM

RG7769	PD1-TIM3 biMAb	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab ± T	heme tumors
RG7876	selicrelumab + Avastin	solid tumors
CHU	Raf/MEK dual inh	solid tumors
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
RG6107	crovalimab (C5 inh MAb)	PNH
RG6151	-	asthma
RG6173	-	asthma
RG6174	-	inflammatory diseases
RG7835	-	autoimmune diseases
RG7880	IL-22Fc	inflammatory diseases
RG6004	HBV LNA	HBV
RG6084	-	HBV
RG6217	-	HBV
RG7854	TLR7 agonist (3)	HBV
RG7861	anti-S. *aureus* TAC	infectious diseases
RG7907	HBV CpAM (2) (Capsid)	HBV
RG7992	FGFR1/KLB MAb	metabolic diseases
RG6000	-	ALS
RG6237	-	neuromuscular disorders
RG7816	GABA Aa5 PAM	autism
RG6147	-	geographic atrophy
RG7774	-	retinal disease
CHU	PTH1 recep. ago	hypoparathyroidism
CHU	-	hyperphosphatemia
CHU	-	endometriosis

Phase II (13 NMEs + 10 AIs)

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

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

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

Status as of April 17, 2019

Roche Group development pipeline

Phase III (11 NMEs + 34 AIs)

RG3502	Kadcyla + Perjeta	HER2+ eBC
RG6264	Perjeta + Herceptin FDC SC	HER2+ BC
RG7388	idasanutlin + chemo	AML
RG7440	ipatasertib + abiraterone	1L CRPC
	ipatasertib + chemo	1L TNBC/HR+ BC
RG7421	Cotellic + Zelboraf + T	1L BRAFm melanoma
	Cotellic + T	1L BRAF WT melanoma
RG7596	polatuzumab vedotin	1L DLBCL
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq	NMIBC, high risk
	Tecentriq Dx+	1L sq + non-sq NSCLC
	Tecentriq	RCC adj
	T + chemo + Avastin	1L ovarian cancer
	T + pemetrexed	1L non-sq NSCLC
	T + nab-paclitaxel	1L sq NSCLC
	T ± chemo	SCCHN adj
	Tecentriq	HER2+ BC neoadj
	T + paclitaxel	1L TNBC
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + nab-paclitaxel	TNBC neoadj
	T + Avastin	1L HCC
	T + Avastin	1L RCC
	T ± chemo	1L mUC
	T + enzalutamide	mCRPC
RG7446/RG7853/RG6268	Tecentriq or Alecensa or entrectinib	1LNSCLC Dx+
RG7601	Venclexta + bortezomib	MM
	Venclexta	r/r MM t(11:14)
	Venclexta + HMA	1L AML
RG7853	Alecensa	NSCLC adj
RG3648	Xolair	nasal polyps
RG7413	etrolizumab	ulcerative colitis
	etrolizumab	Crohn's
RG6152	Xofluza	influenza, hospitalized pts
	Xofluza	influenza, pediatric
	Xofluza	influenza post exposure prophylaxis
RG1450	gantenerumab	Alzheimer's
RG6042	HTT ASO	Huntington's
RG6168	satralizumab	NMOSD
RG6206	anti-myostatin adnectin	DMD
RG7314	balovaptan	autism
RG6321	port delivery system with ranibizumab	wAMD
RG7716	faricimab	DME
	faricimab	wAMD

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

Registration (3 NMEs + 7AIs)

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

[1] Approved in US
[2] Filed in US

Status as of April 17, 2019

NME submissions and their additional indications

Projects currently in phase II and III

2019		2020		2021		2022 and beyond					
RG7916	**risdiplam** SMA	RG6152	**Xofluza** influenza post-exposure prophylaxis	RG7413	**etrolizumab** ulcerative colitis	RG6058	**tiragolumab + Tecentriq** NSCLC	RG6152	**Xofluza** influenza, hospitalized pts	RG7716	**faricimab** wAMD
RG6168	**satralizumab** NMOSD	RG6152	**Xofluza** influenza, pediatric	RG6321	**Port Delivery System with ranibizumab** wAMD	RG6180	**iNeST** oncology	RG6042	**HTT ASO** Huntington's	RG7716	**faricimab** DME
RG6152	**Xofluza (EU)** influenza	RG6206	**anti-myostatin adnectin** DMD	RG7596	**polatuzumab vedotin** 1L DLBCL	RG7388	**idasanutlin** AML fit 1L	RG1450	**gantenerumab** Alzheimer's	RG6149	**ST2 MAb** asthma
RG6152	**Xofluza (EU)** influenza, high risk	RG6264	**Perjeta + Herceptin FDC SC** HER2+ BC			RG7388	**idasanutlin** polycythemia vera	RG1662	**basmisanil** CIAS	RG7413	**etrolizumab** Crohn's
RG6268	**entrectinib (EU)** ✓ NSCLC ROS1+	RG7388	**idasanutlin + chemo** AML			RG7440	**ipatasertib** TNBC neoadj	RG6100	**Tau MAb** Alzheimer's	RG7625	**petesicatib** autoimmune diseases
RG6268	**entrectinib (EU)** ✓ NTRK1 pantumor	RG7440	**ipatasertib + abiraterone** 1L CRPC			RG7596	**polatuzumab vedotin** r/r FL	RG7314	**balovaptan** autism	RG7845	**fenebrutinib** autoimmune diseases
		RG7440	**ipatasertib +chemo** 1L TNBC / HR+ BC					RG7935	**prasinezumab** Parkinson's		

✓ 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
Immunology
Infectious Diseases

CardioMetabolism
Neuroscience
Ophthalmology
Other

FDC =fixed-dose combination

Status as of April 17, 2019

AI submissions for existing products

Projects currently in phase II and III

2019

RG3648	**Xolair** nasal polyps
RG3502	**Kadcyla✓** HER2+ eBC
RG7446	**Tecentriq + Avastin** 1L HCC
RG7421	**Cotellic + Tecentriq** 1L BRAF WT melanoma
RG7421	**Cotellic + Tecentriq + Zelboraf** 1L BRAFmut melanoma
RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+
RG7446	**Tecentriq + nab-paclitaxel** 1L sq NSCLC
RG7601	**Venclexta + Gazyva* ✓** 1L CLL

2020

RG3502	**Kadcyla + Perjeta** HER2+ eBC
RG7446	**Tecentriq + nab-paclitaxel** TNBC neoadj
RG7446	**Tecentriq + pemetrexed** 1L non-sq NSCLC
RG7446	**Tecentriq + Avastin** 1L RCC
RG7446	**Tecentriq + paclitaxel** 1L TNBC
RG7446	**Tecentriq** MIBC adj
RG7446	**Tecentriq ± chemo** 1L mUC
RG7446	**Tecentriq + enzalutamide** mCRPC
RG7446	**Tecentriq + chemo + Avastin** 1L ovarian cancer

2021

RG7601	**Venclexta + HMA** 1L AML
RG7446/ RG7853/ RG6268	**Tecentriq or Alecensa or entrectinib** 1L NSCLC Dx+

2022 and beyond

RG7446	**Tecentriq** NMIBC
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
RG7159	**Gazyva** lupus nephritis
RG7421	**Cotellic + Tecentriq ± taxane** TNBC
RG7601	**Venclexta** r/r MM t(11:14)
RG7601	**Venclexta + Rituxan** DLBCL
RG7601	**Venclexta + azacitidine** 1L MDS
RG7601	**Venclexta + fulvestrant** 2L HR+BC
RG7853	**Alecensa** NSCLC adj

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

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

Status as of April 17, 2019

Cancer immunotherapy pipeline overview

Phase I (10 NMEs + 22 AIs)

RG6026	CD20 x CD3 ± chemo ± T	heme tumors
RG6123	-	solid tumors
RG6160	-	multiple myeloma
RG6180	iNeST ± T	solid tumors
RG6194	HER2 x CD3	BC
RG7421	Cotellic + Zelboraf + T	melanoma
	Cotellic + T	2L BRAF WT mM
	Cotellic + T	RCC, bladder, head & neck ca
RG7440	ipatasertib + Taxane + T	TNBC
RG7446	Tecentriq (T)	solid tumors
	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chem	HCC, GC, PaC
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + radium 223	mCRPC
	T + rucaparib	ovarian ca
RG7461	FAP IL2v FP combos	solid tumors
RG7601	Venclexta + Cotellic + T	MM
RG7769	PD1-TIM3 biMAb	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab ± T	heme tumors
RG7876	selicrelumab + Avastin	solid tumors
AMGN**	Tecentriq + talimogene laherp	TNBC, CRC
BLRX**	Tecentriq + BL-8040	AML, solid tumors
CRVS**	Tecentriq + CPI-444	solid tumors
EXEL**	Tecentriq + cabozantinib	solid tumors
HALO**	Tecentriq + PEGPH20	CCC, GBC
INO**	Tecentriq + INO5401+INO9012	bladder ca
KITE**	Tecentriq + KTE-C19	r/r DLBCL

MORPHEUS Platform - Phase Ib/II (7 AIs)

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

Phase II (2 NMEs + 5 AIs)

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

Phase III (22 AIs)

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

Registration (4 AIs)

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

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

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

RG-No Roche/Genentech

T=Tecentriq

Status as of April 17, 2019

Major pending approvals 2019

Pending Approval

US		EU		Japan-Chugai	
RG7596	**polatuzumab vedotin** r/r DLBCL Filed Dec 2018	**RG7596**	**polatuzumab vedotin** r/r DLBCL Filed Dec 2018	**RG1569**	**Actemra** Adult Onset Still's disease, Filed May 2018
RG7446	**Tecentriq + nab-paclitaxel** 1L non sq NSCLC Filed Nov 2018	**RG7446**	**Tecentriq + nab-paclitaxel** 1L non sq NSCLC Filed Oct 2018	**RG7446**	**Tecentriq + nab-paclitaxel** 1L TNBC Filed Dec 2018
RG6268	**entrectinib** NSCLC ROS1+ Filed Dec 2018	**RG7446**	**Tecentriq + nab-paclitaxel** 1L TNBC Filed Sep.2018	**RG7446**	**Tecentriq + chemo** 1L extensive stage SCLC Filed Dec 2018
RG6268	**entrectinib** NTRK1 pan-tumor Filed Dec 2018	**RG7446**	**Tecentriq + chemo** 1L extensive stage SCLC Filed Sep. 2018	**RG6268**	**entrectinib** NTRK+ solid tumors Filed Dec 2018
RG7601	**Venclexta+Gazyva** 1L CLL Filed Mar 2019	**RG6268**	**entrectinib** NSCLC ROS1+ Filed Jan 2019	**RG6268**	**entrectinib** NSCLC ROS1+ Filed Mar 2019
RG3502	**Kadcyla** HER2+EBC Filed Feb 2019	**RG6268**	**entrectinib** NTRK1 pantumor Filed Jan 2019		
RG6152	**Xofluza** Influenza, high risk pts Filed Dec. 2018	**RG3502**	**Kadcyla** HER2+EBC Filed Feb 2019		

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

Status as of April 17, 2019

Major granted approvals 2019

Approved

US		EU		Japan-Chugai	
RG597	**Herceptin SC Hylecta** Feb 2019	RG105	**MabThera** pemphigus vulgaris, Mar 2019	RG1569	**Actemra** CRS, Mar 2019
RG7446	**Tecentriq + nab-paclitaxel** 1L TNBC Mar 2019	RG6013	**Hemlibra** hemophilia A FVIII non-inh, Mar 2019		
RG7446	**Tecentriq + chemo** 1L extensive stage SCLC Mar 2019	RG6013	**Hemlibra** Q4W hemophilia A, Mar 2019		
		RG7446	**Tecentriq + chemo + Avastin** 1L non-sq NSCLC Mar 2019		

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

Status as of April 17, 2019

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group Q1 2019 sales

Diagnostics

Foreign exchange rate information

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A		
Phase/study	**Phase I** Study in Japan	**Phase I/II** Study in Japan	**Non-interventional study**
# of patients	N=82	N=18	N=221
Design	▪ Enrolled 64 healthy volunteers and 18 patients	▪ Extension study in patients from ph 1	Non-interventional study evaluating bleeding incidence, health-related quality of life and safety in patients with hemophilia A and inhibitors to factor VIII under SoC treatment ▪ **Cohort A:** Adults and adolescents with FVIII Inhibitors ▪ **Cohort B:** Children with FVIII Inhibitors ▪ **Cohort C:** Adults and adolescents without FVIII Inhibitors
Primary endpoint	▪ Exploratory safety and efficacy	▪ Exploratory safety and efficacy	▪ Number of bleeds over time, sites of bleed, type of bleed
Status	▪ Recruitment completed Q2 2014 ▪ Data presented at ASH 2014	▪ Recruitment completed Q4 2014 ▪ Data presented at ISTH 2015 ▪ Extension data presented at WFH 2016	▪ Inhibitor cohort closed Q4 2015, except China ▪ FPI in non-inhibitor and pediatric subjects in Q1 2016 ▪ Cohort A presented at ASH 2016 and EAHAD 2017; Cohort B presented at ASH 2017 and WFH 2018; Cohort C presented at EAHAD and WFH 2018 ▪ Study completed
	▪ Breakthrough Therapy Designation granted by FDA Q3 2015		
CT Identifier	JapicCTI-121934	JapicCTI-132195	NCT02476942

In collaboration with Chugai

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

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients with inhibitors to factor VIII	Hemophilia A pediatric patients with inhibitors to factor VIII
Phase/study	**Phase III HAVEN 1**	**Phase III HAVEN 2**
# of patients	N=118	N=88
Design	Patients on episodic treatment prior to study entry: ▪ **ARM A:** Hemlibra prophylaxis ▪ **ARM B:** Episodic treatment (no prophylaxis) Patients on prophylaxis prior to study entry: ▪ **ARM C:** Hemlibra prophylaxis Patients on episodic treatment previously on non-interventional study: ▪ **ARM D:** Hemlibra prophylaxis	Patients on prophylactic or episodic treatment prior to study entry: ▪ **Cohort A:** Hemlibra prophylaxis qw ▪ **Cohort B:** Hemlibra prophylaxis q2w ▪ **Cohort C:** Hemlibra prophylaxis q4w
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 52 weeks
Status	▪ FPI Q4 2015, recruitment completed in arms A and B Q2 2016 ▪ Primary and all secondary endpoints met Q4 2016 ▪ Data published in *NEJM* 2017 Aug 31;377(9):809-818	▪ FPI Q3 2016, recruitment completed Q2 2017 ▪ Positive interim data in Q2 2017 ▪ FPI cohorts B/C Q4 2017 ▪ Full primary data at ASH 2018
	▪ Data presented at ISTH 2017, updated data presented at ASH 2017 ▪ Filed in US and EU in Q2 2017; granted accelerated assessment (EMA) and priority review (FDA) ▪ Approved in US Q4 2017 and EU Q1 2018	
CT Identifier	NCT02622321	NCT02795767

In collaboration with Chugai

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

Hemlibra

Factor VIII mimetic for treatment of hemophilia A

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

In collaboration with Chugai

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

Alecensa

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK-positive advanced NSCLC	ALK-positive advanced NSCLC in ALK inhibitor-naïve patients who are chemotherapy-naïve or have received one previous line of chemotherapy	Adjuvant ALK+ NSCLC
Phase/study	**Phase III** **ALEX**	**Phase III** **J-ALEX/Japic CTI-132316** Japanese study	**Phase III** **ALINA**
# of patients	N=286	N=207	N=255
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 300mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 600 mg BID ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Disease-free survival
Status	▪ Recruitment completed Q3 2015 ▪ Primary endpoint met Q1 2017 ▪ Data presented at ASCO 2017, ESMO 2017, ASCO 2018 and ESMO 2018 ▪ Data published in *NEJM* 2017 June; 377:829-838 ▪ CNS data presented at ESMO 2017	▪ Primary data analysis positive ▪ Data presented at ASCO 2016 and 2017 ▪ Breakthrough Therapy Designation granted by FDA Q3 2016 ▪ Data published in *Lancet* 2017 Jul; 390(10089):29–39	▪ FPI Q3 2018
	▪ Approved in US Q4 2017 (priority review) and in EU Q4 2017		
CT Identifier	NCT02075840	JapicCTI-132316	NCT03456076

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

Cotellic

Selective small molecule inhibitor of MAPK kinase

Indication	First-line metastatic triple negative breast cancer	Recurrent or advanced solid tumors
Phase/study	**Phase II** **COLET**	**Phase Ib** **COTEST**
# of patients	N=160	N=250
Design	▪ **ARM A:** Cotellic plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel ▪ **ARM C:** Cotellic plus Tecentriq plus nab-paclitaxel ▪ **ARM D:** Cotellic plus Tecentriq plus paclitaxel	Cotellic plus Tecentriq in head and neck, bladder and renal cancer (cohorts for each cancer type in CPI naive and CPI experienced patients)
Primary endpoint	▪ Progression-free survival and safety	▪ Objective response rate
Status	▪ FPI Q1 2015 ▪ FPI arms C and D: Q4 2016 ▪ Data from arm A and B presented at SABCS 2017	▪ FPI Q4 2017
CT Identifier	NCT02322814	NCT03264066

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

Cotellic

Selective small molecule inhibitor of MAPK kinase

Indication	First-line BRAFv600 mutation-positive metastatic or unresectable locally advanced melanoma	First-line BRAF-WT metastatic or unresectable locally advanced melanoma	Previously untreated metastatic melanoma BRAF mutation-positive	BRAF-WT metastatic or unresectable locally advanced melanoma after immunotherapy
Phase/study	**Phase III IMspire150 TRILOGY**	**Phase III IMspire170**	**Phase I**	**Phase Ib**
# of patients	N=500	N=500	N=67	N=152
Design	Double-blind, randomized, placebo-controlled study ▪ **ARM A:** Tecentriq plus Cotellic plus Zelboraf[1] ▪ **ARM B:** Placebo plus Cotellic plus Zelboraf[1]	▪ **ARM A:** Cotellic plus Tecentriq ▪ **ARM B:** Pembrolizumab	▪ Dose-finding study of Cotellic plus Tecentriq plus Zelboraf[1] and Tecentriq plus Zelboraf[1] combinations	▪ Preliminary efficacy of Cotellic plus Tecentriq in patients who have progressed on prior aPD-1 therapy
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival and overall survival	▪ Safety and PK	▪ Objective response rate and disease control rate
Status	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2018	▪ FPI Q4 2017 ▪ Recruitment completed Q4 2018	▪ FPI Q4 2012 ▪ Data presented at ESMO 2016	▪ FPI Q2 2017 ▪ Recruitment completed Q4 2018
CT Identifier	NCT02908672	NCT03273153	NCT01656642	NCT03178851

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

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

In collaboration with Biogen

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

Kadcyla

First ADC for HER2-positive breast cancer

Indication	HER2-positive early breast cancer high-risk patients	Operable HER2-positive early breast cancer
Phase/study	**Phase III KATHERINE**	**Phase III KAITLIN**
# of patients	N=1,484	N=1,850
Design	▪ **ARM A:** Kadcyla 3.6mg/kg Q3W ▪ **ARM B:** Herceptin	Following surgery and antracycline-based therapy: ▪ **ARM A:** Herceptin 6mg/kg Q3W plus Perjeta 420 mg/kg Q3W plus chemo ▪ **ARM B:** Kadcyla 3.6mg/kg Q3W plus Perjeta 420mg/kg Q3W plus chemo
Primary endpoint	▪ Invasive disease-free survival	▪ Invasive disease-free survival
Status	▪ Recruitment complete 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	▪ Recruitment completed Q2 2015 ▪ Data expected in 2020
CT Identifier	NCT01772472	NCT01966471

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

Perjeta

First-in-class HER2 dimerization inhibitor

Indication	Adjuvant HER2-positive breast cancer	Neoadjuvant/adjuvant HER2-positive breast cancer	HER2-positive early breast cancer subcutaneous co-formulation
Phase/study	**Phase III APHINITY**	**Phase II BERENICE**	**Phase III FeDeriCa**
# of patients	N=4,803	N=401	N=500
Design	▪ **ARM A:** Perjeta (840mg loading, 420 q3w) + Herceptin for 52 weeks plus chemotherapy (6-8 cycles) ▪ **ARM B:** Placebo + Herceptin (52 weeks) plus chemotherapy (6-8 cycles)	*Neoadjuvant treatment:* ▪ **ARM A:** ddAC q2w x4 followed by wkly paclitaxel for 12 wks, with P+H x4 cycles ▪ **ARM B:** FEC plus P+H x4 followed by docetaxel plus P+H x4 *Adjuvant treatment:* ▪ P+H q3w to complete 1 year of HER2 therapy ▪ Hormonal and radiation therapy as indicated	Fixed-dose combination (FDC) of Perjeta (P) and Herceptin (H) for subcutaneous administration in combination with chemotherapy in the neoadjuvant/adjuvant setting ▪ **ARM A:** P IV+H IV+chemotherapy ▪ **ARM B:** FDC of PH SC+chemotherapy
Primary endpoint	▪ Invasive disease-free survival (IDFS)	▪ Safety	▪ Trough Serum Concentration (Ctrough) of Pertuzumab During Cycle 7
Status	▪ Primary endpoint met Q1 2017 ▪ Data presented at ASCO 2017 ▪ Filed in US and EU Q3 2017 ▪ Approved in US Q4 2017 (priority review) and EU Q2 2018	▪ Recruitment completed Q3 2015 ▪ Data presented at SABCS 2016 ▪ Data published Ann Oncol. 2018 Mar 1; 29(3): 646-653	▪ FPI Q2 2018 ▪ Recruitment completed Q4 2018
CT Identifier	NCT01358877	NCT02132949	NCT03493854

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous NSCLC		
Phase/study	**Phase III IMpower150**	**Phase III IMpower130**	**Phase III IMpower132**
# of patients	N=1,202	N=650	N=568
Design	▪ **ARM A:** Tecentriq plus paclitaxel plus carboplatin ▪ **ARM B:** Tecentriq plus Avastin plus paclitaxel plus carboplatin ▪ **ARM C:** Avastin plus paclitaxel plus carboplatin	▪ **ARM A:** Tecentriq plus nab-paclitaxel plus carboplatin ▪ **ARM B:** Nab-paclitaxel plus carboplatin	▪ **ARM A:** Tecentriq plus carboplatin or cisplatin plus pemetrexed ▪ **ARM B:** Carboplatin or cisplatin plus pemetrexed
Primary endpoint	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival
Status	▪ FPI Q2 2015 ▪ Recruitment completed Q4 2016 ▪ Study met co-primary endpoint of PFS in Q4 2017 and OS in Q1 2018 ▪ PFS data presented at ESMO IO 2017 ▪ PFS subgroup data presented at AACR 2018 ▪ Filed in US Q1 2018 (priority review) and EU (Q1 2018) ▪ Data published in NEJM 2018 Jun 14;378(24):2288-2301 ▪ Approved in US Q4 2018 and EU Q1 2019	▪ FPI Q1 2015 ▪ Recruitment completed Q1 2017 ▪ Study met co-primary endpoint of OS and PFS in Q2 2018 ▪ Filed in US and EU	▪ FPI Q2 2016 ▪ Recruitment completed Q2 2017 ▪ Study met co-primary endpoint of PFS in Jul 2018 ▪ Data presented at WCLC 2018
CT Identifier	NCT02366143	NCT02367781	NCT02657434

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous and squamous NSCLC PD-L1-selected patients	1L squamous NSCLC	1L extensive-stage SCLC
Phase/study	**Phase III IMpower110**	**Phase III IMpower131**	**Phase III IMpower133**
# of patients	N=570	N=1,025	N=400
Design	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** *NSq*: carboplatin or cisplatin plus pemetrexed *Sq:* carboplatin or cisplatin plus gemcitabine	▪ **ARM A:** Tecentriq plus paclitaxel plus carboplatin ▪ **ARM B:** Tecentriq plus nab-paclitaxel plus carboplatin ▪ **ARM C:** Nab-paclitaxel plus carboplatin	▪ **ARM A:** Tecentriq plus carboplatin plus etoposide ▪ **ARM B:** Placebo plus carboplatin plus etoposide
Primary endpoint	▪ Overall survival	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival
Status	▪ FPI Q3 2015 ▪ IMpower111 consolidated into IMpower110 Q3 2016 ▪ Recruitment completed Q1 2018	▪ FPI Q2 2015 ▪ Recruitment completed Q1 2017 ▪ Study met co-primary endpoint of PFS in Q1 2018 ▪ Primary PFS data presented at ASCO 2018 ▪ Interim OS data presented at ESMO 2018	▪ FPI Q2 2016 ▪ Orphan drug designation granted by FDA Q3 2016 ▪ Study met endpoints of OS and PFS in Q2 2018 ▪ Primary data presented at WCLC ▪ Data published at NEJM 2018 Sep 25 2018 2018; 379:2220-2229 ▪ Filed with the US and EU Q3 2018 ▪ Approved in US Q1 2019
CT Identifier	NCT02409342	NCT02367794	NCT02763579

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	Adjuvant NSCLC	Neoadjuvant NSCLC
Phase/study	**Phase III** **IMpower010**	**Phase III** **IMpower030**
# of patients	N=1,127	N=302
Design	Following adjuvant cisplatin-based chemotherapy ▪ **ARM A:** Tecentriq ▪ **ARM B:** Best supportive care	▪ **ARM A:** Tecentriq + platinum-based chemotherapy ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Disease-free survival	▪ Major pathological response (MPR)
Status	▪ FPI Q3 2015 ▪ Trial amended from PD-L1 selected patients to all-comers ▪ FPI for all-comer population Q4 2016 ▪ Recruitment completed Q3 2018	▪ FPI Q2 2018
CT Identifier	NCT02486718	NCT03456063

Tecentriq

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L non-squamous NSCLC	NSCLC	Stage IV non-small cell lung cancer
Phase/study	**Phase II/III B-FAST**	**Phase I**	**Phase Ib/II IMnscin**
# of patients	N=580	N=53	
Design	▪ **Cohort A:** ALK + (Alecensa) ▪ **Cohort B:** ROS1 + (entrectinib) ▪ **Cohort C:** bTMB-high (Tecentriq)	▪ Tecentriq plus Tarceva[1] or Alecensa	▪ Part 1: dose finding, atezo SC followed by atezo IV ▪ Part 2: non inferiority of atezo SC + Avastin + chemo vs atezo IV + Avastin+ chemo
Primary endpoint	▪ Cohort A/B: Objective response rate ▪ Cohort C: Progression-free survival	▪ Safety	▪ Observed concentration of atezolizumab in serum at cycle 1
Status	▪ FPI Q3 2017 ▪ Recruitment completed for cohort A Q3 2018	▪ FPI Q1 2014 ▪ FPI in Alecensa arm Q3 2015 ▪ Recruitment completed in Tarceva arm Q3 2015 ▪ Data from Tarceva presented at WCLC and ESMO Asia 2016	▪ FPI Q4 2018
CT Identifier	NCT03178552	NCT02013219	NCT03735121

[1]Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a subsidiary of Astellas US, LLC;
NSCLC=non-small cell lung cancer; ESMO=European Society for Medical Oncology; ECC=European Cancer Congress; WCLC=World Conference on Lung Cancer

Tecentriq

Anti-PD-L1 cancer immunotherapy – SCCHN

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

SCCHN=squamous cell carcinoma of the head and neck

Tecentriq

Anti-PD-L1 cancer immunotherapy – UC

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

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – UC

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

UC=urothelial carcinoma

Tecentriq

Anti-PD-L1 cancer immunotherapy – UC

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

UC=urothelial carcinoma; BCG=Bacille Calmette-Guérin

Tecentriq

Anti-PD-L1 cancer immunotherapy – renal cell cancer

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

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – prostate cancer

Indication	Metastatic castration-resistant prostate cancer	Metastatic castration-resistant prostate cancer
Phase/study	**Phase Ib**	**Phase III** **IMbassador250**
# of patients	N=45	N=730
Design	▪ Tecentriq plus radium-223 dichloride	▪ **ARM A:** Tecentriq plus enzalutamide ▪ **ARM B:** Enzalutamide
Primary endpoint	▪ Safety and tolerability	▪ Overall survival
Status	▪ FPI Q3 2016 ▪ Recruitment completed Q3 2018	▪ FPI Q1 2017 ▪ Recruitment completed Q2 2018
CT Identifier	NCT02814669	NCT03016312

Tecentriq

Anti-PD-L1 cancer immunotherapy – CRC and HCC

Indication	2/3L metastatic colorectal cancer	1L hepatocellular carcinoma
Phase/study	**Phase I**	**Phase III** **IMbrave150**
# of patients	N=84	N=480
Design	Open-label, single-arm, two-stage study with Cotellic plus Tecentriq plus Avastin ▪ **Stage 1:** Safety run-in ▪ **Stage 2:** Dose-expansion with two cohorts; – Expansion – Biopsy	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Sorafenib
Primary endpoint	▪ Safety	▪ Overall survival and progression free survival
Status	▪ FPI Q3 2016	▪ FPI Q1 2018 ▪ Recruitment completed Jan 2019
CT Identifier	NCT02876224	NCT03434379

Cotellic in collaboration with Exelixis

Tecentriq

Anti-PD-L1 cancer immunotherapy – solid tumors

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

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Previously untreated metastatic triple negative breast cancer		
Phase/study	**Phase III IMpassion130**	**Phase III IMpassion131**	**Phase III IMpassion132**
# of patients	N=900	N=540	N=350
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel	▪ **ARM A:** Tecentriq plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel	▪ **ARM A:** Tecentriq plus capecitabine or carbo/gem ▪ **ARM B:** Placebo plus capecitabine or carbo/gem
Primary endpoint	▪ Progression-free survival and overall survival (co-primary endpoint)	▪ Progression-free survival	▪ Overall survival
Status	▪ FPI Q3 2015 ▪ Recruitment completed Q2 2017 ▪ Study met co-primary endpoint of PFS in both PDL1+ and ITT populations Jul 2018 ▪ Primary PFS and interim OS data presented at ESMO 2018 ▪ Filed in US and EU ▪ US accelerated approval Q1 2019	▪ FPI Q3 2017	▪ FPI Q1 2018
CT Identifier	NCT02425891	NCT03125902	NCT03371017

Tecentriq

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Neoadjuvant triple negative breast cancer	Adjuvant triple negative breast cancer
Phase/study	**Phase III IMpassion031**	**Phase III IMpassion030**
# of patients	N=204	N=2300
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)	▪ iDFS
Status	▪ FPI Q3 2017 ▪ Recruitment completed Q2 2018 ▪ Q1 2019 IDMC recommendation to expand study to recruit 120 more patients (all comers and PDL1-positive)	▪ FPI Q3 2018
CT Identifier	NCT03197935	NCT03498716

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Metastatic and locally advanced early breast cancer (HER2-positive)	Neoadjuvant HER2-positive breast cancer
Phase/study	**Phase I**	**Phase III** **IMpassion050**
# of patients	N=76	N=224
Design	▪ **Cohort 1A (mBC):** Tecentriq plus Perjeta plus Herceptin ▪ **Cohort 1B (mBC):** Tecentriq plus Kadcyla[1] ▪ **Cohort 1F (mBC):** Tecentriq plus Perjeta plus Herceptin plus docetaxel ▪ **Cohort 2A (eBC):** Tecentriq plus Perjeta plus Herceptin ▪ **Cohort 2B (eBC):** Tecentriq plus Kadcyla[1] ▪ **Cohort 2C (expansion on cohort 1B):** Tecentriq plus Kadcyla[1]	▪ **ARM A:** ddAC Herceptin/Perjeta + paclitaxel followed by surgery and chemotherapy ▪ **ARM B:** ddAC Herceptin/Perjeta + chemotherapy +Tecentriq followed by surgery and chemotherapy +Tecentriq
Primary endpoint	▪ Safety	▪ pCR
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q2 2018	▪ FPI Q4 2018
CT Identifier	NCT02605915	NCT03726879

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

Tecentriq

Anti-PD-L1 cancer immunotherapy – ovarian cancer

Indication	Front-line ovarian cancer	Advanced gynecological cancers and platinum-sensitive ovarian 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	▪ FPI Q2 2017
CT Identifier	NCT03038100	NCT03101280

[1]Rucaparib in collaboration with Clovis

Tecentriq

Anti-PD-L1 cancer immunotherapy – hematology

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

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor –

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	▪ FPI Q4 2014 ▪ Recruitment completed Q3 2016 ▪ Study met primary endpoint at pre-specified interim analysis Q4 2018 ▪ BTD granted by FDA Q1 2019 ▪ US filing completed under RTOR Q1 2019	▪ Recruitment completed Q3 2015 ▪ Study met primary endpoint at interim analysis ▪ Data presented at ASH 2017 ▪ Filed in US Q4 2017 and EU Q1 2018 ▪ Data published in *NEJM* 2018; 378:1107–20 ▪ Updated data presented at ASCO 2018 ▪ Approved in US Q2 2018 (priority review) ▪ EU approval Q4 2018
CT Identifier	NCT02242942	NCT02005471

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

CLL=chronic lymphocytic leukemia; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology; RTOR=Real time oncology review

Venclexta

Novel small molecule Bcl-2 selective inhibitor – CLL

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

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

CLL=chronic lymphocytic leukemia; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Venclexta

Novel small molecule Bcl-2 selective inhibitor – NHL

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

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

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – MM

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

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – MM

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

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Treatment-naïve AML not eligible for standard induction therapy	
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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

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

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Relapsed or Refractory AML	Relapsed or refractory AML not eligible for cytotoxic therapy
Phase/study	**Phase I**	**Phase Ib/II**
# of patients		N=140
Design	▪ Venetoclax in combination with gilteritinib	Phase I (dose escalation): ▪ **ARM A:** Cotellic[1] plus Venclexta ▪ **ARM B:** Idasanutlin plus Venclexta Phase II (expansion): ▪ **ARM A:** Cotellic[1] plus Venclexta ▪ **ARM B:** Idasanutlin plus Venclexta
Primary endpoint	▪ Dose and composite complete remission (CRc) Rate	▪ Safety and efficacy
Status	▪ FPI Q4 2018	▪ FPI Q1 2016 ▪ Data presented at ASH 2017
CT Identifier	NCT03625505	NCT02670044

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – MDS

Indication	Myelodysplastic syndromes after azacitidine failure	Treatment-naive myelodysplastic syndromes
Phase/study	**Phase Ib**	**Phase II**
# of patients	N=66	N=90
Design	Cohort 1: ▪ **ARM A:** Venclexta 400 mg ▪ **ARM B:** Venclexta 800 mg Cohort 2: ▪ **ARM A:** Venclexta plus azacitidine Study expansion: ▪ Venclexta or Venclexta plus azacitidine	▪ **ARM A:** Venclexta 400 mg plus azacitidine ▪ **ARM B:** Venclexta 800 mg plus azacitidine ▪ **ARM C:** Azacitidine
Primary endpoint	▪ Safety, efficacy, PK and PD	▪ Overall response rate
Status	▪ FPI Q1 2017	▪ FPI Q1 2017
CT Identifier	NCT02966782	NCT02942290

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

Venclexta

Novel small molecule Bcl-2 selective inhibitor – breast cancer

Indication	≥2L HR+ breast cancer
Phase/study	**Phase II**
# 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

Ocrevus

Humanized mAb selectively targeting CD20+ B cells

Indication	Relapsing multiple sclerosis (RMS)		Primary-progressive multiple sclerosis (PPMS)
Phase/study	**Phase III OPERA I**	**Phase III OPERA II**	**Phase III ORATORIO**
# of patients	N=821	N=835	N=732
Design	96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	96-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv followed by 600 mg iv every 24 weeks ▪ **ARM B:** Interferon β-1a	120-week treatment period: ▪ **ARM A:** Ocrelizumab 2x 300 mg iv every 24 weeks ▪ **ARM B:** Placebo
Primary endpoint	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Annualized relapse rate at 96 weeks versus Rebif	▪ Sustained disability progression versus placebo by Expanded Disability Status Scale (EDSS)
Status	▪ Primary endpoint met Q2 2015, OLE ongoing ▪ Primary data presented at ECTRIMS 2015 ▪ Updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM*, 2017 Jan 19;376(3):221-234		▪ Primary endpoint met Q3 2015 ▪ Primary data presented at ECTRIMS 2015, updated data presented at AAN and ECTRIMS 2017, AAN and EAN 2018 ▪ Data published in *NEJM*, 2017 Jan 19;376(3):209-220
	▪ Approved in US Q1 2017 and EU Q1 2018		
CT Identifier	NCT01247324	NCT01412333	NCT01194570

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

Actemra/RoActemra

Interleukin-6 receptor inhibitor

Indication	Giant cell arteritis
Phase/study	**Phase III** **GiACTA**
# of patients	N=250
Design	Part 1: 52-week blinded period ▪ **ARM A:** Actemra SC 162mg qw plus 26 weeks prednisone taper ▪ **ARM B:** Actemra SC 162mg q2w plus 26 weeks prednisone taper ▪ **ARM C:** Placebo plus 26 weeks prednisone taper ▪ **ARM D:** Placebo plus 52 weeks prednisone taper Part II: ▪ 104-wk open label extension: patients in remission followed off of the study drug; Patients with active disease receive open label Actemra SC 162mg qw
Primary endpoint	▪ Proportion of patients in sustained remission at week 52
Status	▪ Primary and key secondary endpoints met Q2 2016 ▪ Breakthrough Therapy Designation granted by FDA Q3 2016 ▪ Data presented at ACR 2016 ▪ Filed globally Q4 2016; approved in US Q2 2017 and in EU Q3 2017 ▪ Data published in *NEJM*, 2017 Jul 27;377(4):317-328
CT Identifier	NCT01791153

In collaboration with Chugai

ACR=American College of Rheumatology; *NEJM*=New England Journal of Medicine

MabThera/Rituxan

Immunology development program

Indication	Moderate to severely active pemphigus vulgaris		Relapsing ANCA-associated vasculitis
Phase/study	**Phase III PEMPHIX**	**Phase III Ritux 3**	**Phase III MAINRITSAN**
# of patients	N=132	N=90	N=117
Design	▪ **ARM A:** Rituxan ▪ **ARM B:** Mycophenolate mofetil	▪ **ARM A:** Rituxan ▪ **ARM B:** General corticotherapy	▪ **ARM A:** Rituxan ▪ **ARM B:** Azathioprine
Primary endpoint	▪ Proportion of patients who achieve sustained complete remission	▪ Number of patients with pemphigus controlled 24 months after the start of Rituxan treatment and with both cutaneous and mucosal lesions healing after 6 months of Rituxan treatment	▪ Number of major relapse at the end of the maintenance treatment (18 months + 10 months follow-up)
Status	▪ FPI Q2 2015 ▪ Breakthrough Therapy Designation granted by FDA in Q1 2017 ▪ Data published in *Lancet* 2017 Mar; 389(10083): p2031–2040 ▪ Recruitment completed Q4 2017	▪ FPI Q3 2009 ▪ Data published in *Lancet* 2017 May 20;389(10083):2031–2040	▪ FPI Q4 2008 ▪ Data published in *NEJM* 2014;371(19):1771–80 ▪ US and EU approval Q4 2018
	▪ Approved in US Q2 2018 based on Roche-supported randomized controlled IST Ritux 3		
CT Identifier	NCT02383589	NCT00784589	NCT00748644

IST=Investigator sponsored trial; ANCA=Antineutrophil cytoplasmic antibodies

Gazyva (obinutuzumab)

Immunology development program

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

In collaboration with Biogen

Xolair

Humanized mAb that selectively binds to IgE

Indication	Chronic rhinosinusitis with nasal polyps	
Phase/study	**Phase III** **POLYP 1**	**Phase III** **POLYP 2**
# of patients	N=120	N=120
Design	Placebo-controlled study of Xolair in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had an inadequate response to standard-of-care treatments: ▪ **ARM A:** Xolair every 2 weeks or every 4 weeks ▪ **ARM B:** Placebo	Placebo-controlled study of Xolair in adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had an inadequate response to standard-of-care treatments: ▪ **ARM A:** Xolair every 2 weeks or every 4 weeks ▪ **ARM B:** Placebo
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
Status	▪ FPI Q4 2017 ▪ Recruitment completed Q3 2018	▪ FPI Q4 2017 ▪ Recruitment completed Q3 2018
CT Identifier	NCT03280550	NCT03280537

In collaboration with Novartis

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

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

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

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza		
Phase/study	**Phase III** **FLAGSTONE (hospitalised patients)**	**Phase III** **miniSTONE 1 (0-1 year old)**	**Phase III** **miniSTONE 2 (1-12 years old)**
# of patients	n=240	n=30	n=120
Design	▪ Xofluza + neuraminidase inhibitor vs placebo + neuraminidase inhibitor in hospitalized patients with influenza	▪ Xofluza on Day 1 (based on body weight and age) in healthy pediatric patients from birth to <1 year with influenza-like symptoms	▪ Xofluza vs Tamiflu in healthy pediatric patients 1 to <12 Years of age with influenza-like symptoms
Primary endpoint	▪ Time to Clinical Improvement	▪ Safety	▪ Safety
Status	▪ FPI Jan 2019	▪ FPI Q1 2019	▪ FPI Q4 2018 ▪ Recruitment completed Q1 2019
CT Identifier	NCT03684044	NCT03653364	NCT03629184

In collaboration with Shionogi & Co., Ltd.

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group Q1 2019 sales

Diagnostics

Foreign exchange rate information

Entrectinib (RG6268, RXDX-101)

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 ▪ ROS-1 Data presented at WCLC 2018
	▪ Breakthrough Therapy Designation granted by FDA (Q2 2017), PRIME designation granted by EMA (Q1 2018) and Sakigake Designation granted by MHLW (Q4 2017) for NTRK fusion-positive, locally advanced or metastatic solid tumors ▪ Filed in US December 2018 and EU January 2019		
CT Identifier	NCT02568267	NCT02568267	NCT02650401

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

Idasanutlin (RG7388)

Small molecule MDM2 antagonist

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

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L castration-resistant prostate cancer	2L castration-resistant prostate cancer	1L metastatic gastric or gastroesophageal junction adenocarcinoma
Phase/study	**Phase III** **IPATential150**	**Phase II** **A.MARTIN**	**Phase II** **JAGUAR**
# of patients	N=1,100	N=262	N=153
Design	▪ **ARM A:** Ipatasertib plus abiraterone ▪ **ARM B:** Placebo plus abiraterone	▪ **ARM A:** Ipatasertib 400 mg plus abiraterone ▪ **ARM B:** Ipatasertib 200 mg plus abiraterone ▪ **ARM C:** Placebo plus abiraterone	▪ **ARM A:** Ipatasertib plus mFOLFOX6 ▪ **ARM B:** Placebo plus mFOLFOX6
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Progression-free survival
Status	▪ FPI Q2 2017 ▪ Recruitment completed Jan 2018	▪ Recruitment completed Q4 2014 ▪ ITT data presented at ASCO 2016 ▪ Biomarker data at ESMO 2016	▪ Recruitment completed Q4 2014 ▪ Data showed no benefit in treated vs control group Q2 2016
CT Identifier	NCT03072238	NCT01485861	NCT01896531

In collaboration with Array BioPharma

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

Ipatasertib (RG7440, GDC-0068)

Highly selective small molecule inhibitor of Akt

Indication	1L TNBC and HR+ breast cancer	1L TNBC	Neoadjuvant TNBC	TNBC
Phase/study	**Phase III IPATunity130**	**Phase II LOTUS**	**Phase II FAIRLANE**	**Phase Ib**
# of patients	N=450	N=120	N=150	N=114
Design	Cohort 1: Dx+ 1L TNBC (N=249) ▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel Cohort 2: Dx+ HR+ mBC (N=201) ▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel	▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel	▪ **ARM A:** Ipatasertib plus paclitaxel ▪ **ARM B:** Placebo plus paclitaxel	Study of ipatasertib plus Tecentriq plus taxane ▪ **ARM A:** Ipatasertib plus Tecentriq plus paclitaxel ▪ **ARM B:** Ipatasertib plus Tecentriq plus nab-paclitaxel
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Pathologic complete response (pCR)	▪ Safety and efficacy
Status	▪ FPI Q1 2018	▪ Recruitment completed Q1 2016 ▪ Data presented at ASCO 2017 and ASCO 2018 ▪ Data published in *Lancet Oncology* 2017 Aug 8. pii: S1470-2045(17)30450-3	▪ FPI Q1 2015 ▪ Recruitment completed Q2 2017 ▪ Data presented at AACR 2018	▪ FPI Q1 2018 ▪ Data presented at AACR 2019
CT Identifier	NCT03337724	NCT02162719	NCT02301988	NCT03800836

In collaboration with Array BioPharma

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

Polatuzumab vedotin (RG7596)

ADC targeting CD79b to treat B cell malignancies

Indication	Non-Hodgkin's lymphoma	Relapsed or refractory FL and DLBCL	1L DLBCL
Phase/study	**Phase II ROMULUS**	**Phase Ib/II**	**Phase III POLARIX**
# of patients	N=246	N=224	N=875
Design	▪ **ARM A:** Pinatuzumab vedotin plus Rituxan ▪ **ARM B:** Polatuzumab vedotin plus Rituxan ▪ **ARM C:** Polatuzumab vedotin plus Rituxan ▪ **ARMs E, G, H:** Polatuzumab vedotin plus Gazyva	▪ **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 anti-tumor activity	▪ Safety and response by PET/CT	▪ Progression-free survival
Status	▪ FPI in Gazyva arms Q1 2015 ▪ Recruitment completed Q3 2016 ▪ Updated data presented at ASCO, ICML and EHA 2015 ▪ Updated data presented at ASH 2016	▪ 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	▪ FPI Q4 2017
CT Identifier	NCT01691898	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

Polatuzumab vedotin (RG7596)

ADC targeting CD79b to treat B cell malignancies

Indication	Relapsed or refractory FL or DLBCL	
Phase/study	**Phase I/II**	**Phase I/II**
# of patients	N=116	N=116
Design	▪ **Dose escalation cohort:** Polatuzumab vedotin plus Gazyva plus Venclexta[1] ▪ **Expansion cohort DLBCL:** Polatuzumab vedotin plus Rituxan plus Venclexta[1] ▪ **Expansion cohort FL:** Polatuzumab vedotin plus Gazyva plus Venclexta[1]	▪ **Dose escalation cohort:** Polatuzumab vedotin plus Gazyva plus lenalidomide ▪ **Expansion cohort DLBCL:** Polatuzumab vedotin plus Rituxan plus lenalidomide ▪ **Expansion cohort FL:** Polatuzumab vedotin plus Gazyva plus lenalidomide
Primary endpoint	▪ Percentage of participants with CR	▪ Percentage of participants with CR
Status	▪ FPI Q1 2016	▪ FPI Q1 2016
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

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=300	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	▪ FPI Q4 2016	▪ FPI Q3 2018
CT Identifier	NCT01793441	NCT02901431	NCT03504917

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

Crenezumab (RG7412)

Humanized mAb targeting all forms of Aβ

Indication	Alzheimer's Prevention Initiative (API) Colombia
Phase/study	**Phase II** Cognition study
# of patients	N=252
Design	▪ **ARM A:** 100 carriers receive crenezumab SC ▪ **ARM B:** 100 carriers receive placebo ▪ **ARM C:** 100 non-carriers receive placebo
Primary endpoint	▪ Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score
Status	▪ FPI Q4 2013 ▪ Recruitment completed Q1 2017
CT Identifier	NCT01998841

In collaboration with AC Immune

Aβ=amyloid-beta; AAIC=Alzheimer's Association International Conference; CTAD= Clinical Trials on Alzheimer's Disease; AD/PD=Alzheimer's & Parkinson's Diseases Congress; AAN=American Academy of Neurology; MRI=Magnetic resonance imaging

Gantenerumab (RG1450)

Fully human mAb binding aggregated forms of Aβ

Indication	Prodromal to mild Alzheimer's disease	
Phase/study	**Phase III GRADUATE 1**	**Phase III GRADUATE 2**
# of patients	N=760	N=760
Design	104-week subcutaneous treatment period ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo	104-week subcutaneous treatment period ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo
Primary endpoint	▪ Change in CDR-SB at 2 years	▪ Change in CDR-SB at 2 years
Status	▪ FPI Q2 2018	▪ FPI Q3 2018
CT Identifier	NCT03443973	NCT03444870

In collaboration with MorphoSys AG

Aβ=amyloid-beta; CDR-SB=Clinical Dementia Rating, Sum of Boxes

Gantenerumab (RG1450)

Fully human mAb binding aggregated forms of Aβ

Indication	Prodromal Alzheimer's disease	Mild Alzheimer's disease
Phase/study	**Phase II/III** **SCarlet RoAD**	**Phase III** **Marguerite RoAD**
# of patients	N=799	N=1,000
Design	104-week subcutaneous treatment period ▪ **ARM A:** Gantenerumab (225 mg) ▪ **ARM B:** Gantenerumab (105 mg) ▪ **ARM C:** Placebo	104-week subcutaneous treatment period ▪ **ARM A:** Gantenerumab ▪ **ARM B:** Placebo
Primary endpoint	▪ Change in CDR-SB at 2 years ▪ Sub-study: change in brain amyloid by PET at 2 years	▪ Change in ADAS-Cog and CDR-SB at 2 years (co-primary)
Status	▪ Phase I PET data: *Archives of Neurology*, 2012 Feb;69(2):198-207 ▪ Recruitment completed Q4 2013 ▪ Dosing stopped due to futility Q4 2014 ▪ Data presented at AAIC 2015 ▪ FPI in open label extension study Q4 2015 ▪ OLE data presented at CTAD 2017, AD/PD and AAN 2018	▪ FPI Q1 2014 ▪ Recruitment stopped Q4 2015 ▪ FPI Q1 2016 for open label extension ▪ OLE data (MRI) presented at CTAD 2017, AD/PD, AAN and AAIC 2018
CT Identifier	NCT01224106	NCT02051608

In collaboration with MorphoSys AG

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

RG6206

Myostatin-inhibiting adnectin fusion protein

Indication	Duchenne muscular dystrophy	
Phase/study	**Phase I/II**	**Phase II/III**
# of patients	N=40	N=159
Design	▪ Randomized, double-blind, placebo-controlled, multiple ascending dose study in ambulatory boys with Duchenne muscular dystrophy	Randomized, double blind, placebo-controlled study in ambulatory boys age 6-11 years with duchenne muscular dystrophy ▪ **ARM A:** RG6206 low dose ▪ **ARM B:** RG6206 high dose ▪ **ARM C:** Placebo
Primary endpoint	▪ Safety	▪ Change from baseline in the 4 stair climb velocity after 48 weeks
Status	▪ FPI Q4 2015 ▪ 24 week data presented at BPNA and AAN 2018	▪ FPI Q3 2017
CT Identifier	NCT02515669	NCT03039686

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

Risdiplam (RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy		
Phase/study	**Phase II/III FIREFISH**	**Phase II/III SUNFISH**	**Phase II JEWELFISH**
# of patients	N=21 (Part 1), 41 (Part 2)	N=51 (Part 1), 180 (Part 2)	N=180
Design	Open-label study in infants with type 1 spinal muscular atrophy ▪ **Part 1 (dose-finding):** At least 4 weeks ▪ **Part 2 (confirmatory):** 24 months	Randomized, double-blind, placebo-controlled study in adult and pediatric patients with type 2 or type 3 spinal muscular atrophy ▪ **Part 1 (dose-finding):** At least 12 weeks ▪ **Part 2 (confirmatory):** 24 months	▪ Open-label single arm study adult and pediatric patients (0.5-60 years) with previously treated SMA type 1, 2 and 3
Primary endpoint	▪ Safety, tolerability, PK, PD and efficacy	▪ Safety, tolerability, PK, PD and efficacy	▪ Safety, tolerability and PK/PD
Status	▪ FPI Q4 2016, FPI Part 2 Q1 2018 ▪ Recruitment completed for part 2 Q4 2018 ▪ Data of Part 1 presented at International SMA, AAN, Cure SMA and WMS 2018	▪ FPI Q4 2016, FPI Part 2 Q4 2017 ▪ Recruitment completed for part 2 Q3 2018 ▪ Data of Part 1 presented at Cure SMA, WMS 2017, AAN 2018, Cure SMA and WMS 2018	▪ FPI Q1 2017 ▪ Data presented at WMS 2017, AAN 2018 and WMS 2018
	Orphan drug designation granted by FDA Q1 2017 and EU Jan 2019, PRIME designation in Q4 2018		
CT Identifier	NCT02913482	NCT02908685	NCT03032172

In collaboration with PTC Therapeutics and SMA Foundation

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

Risdiplam (RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy
Phase/study	**Phase II** **RAINBOWFISH**
# of patients	n=25
Design	Open-label, single-arm, multicenter study in infants aged from birth to 6 weeks who have been genetically diagnosed with SMA but are not yet presenting with symptoms
Primary endpoint	▪ Proportion who are sitting without support after 12 months of treatment
Status	▪ FPI expected Q2 2019
CT Identifier	NCT03779334

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

RG6042 (HTT ASO)

Antisense oligonucleotide (ASO) targeting human HTT mRNA

Indication	Huntington's disease		
Phase/study	**Phase I/IIa**	**Phase II OLE**	**Phase III Generation HD1**
# of patients	N=46	N=46	N=660
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	▪ **ARM A**: RG6042 120mg bi-monthly ▪ **ARM B**: RG6042 120mg every four months ▪ **ARM C**: Placebo bi-monthly
Primary endpoint	▪ Safety, tolerability, PK and PD	▪ Longer term safety, tolerability, PK, PD.	▪ cUHDRS Globally ▪ TFC USA only
Status	▪ FPI Q3 2015 ▪ Data presented at CHDI 2018 and AAN 2018 ▪ PRIME designation granted 2018	▪ FPI Q1 2018	▪ FPI Jan 2019 ▪ Q1 2019 protocol modified to allow for bi-monthly vs four-monthly dosing. FPI for new protocol expected Q2 2019
CT Identifier	NCT02519036	NCT03342053	NCT03761849

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

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

Indication	Ulcerative colitis patients who are TNF-naïve		
Phase/study	**Phase III** **HIBISCUS I** Induction study	**Phase III** **HIBISCUS II** Induction study	**Phase III** **GARDENIA** Sustained remission study
# of patients	N=350	N=350	N=390
Design	▪ **ARM A:** Etrolizumab 105mg SC q4w plus adalimumab placebo SC ▪ **ARM B:** Etrolizumab placebo SC plus adalimumab SC ▪ **ARM C:** Etrolizumab placebo SC plus adalimumab placebo SC	▪ **ARM A:** Etrolizumab 105mg SC q4w plus adalimumab placebo SC ▪ **ARM B:** Etrolizumab placebo SC plus adalimumab SC ▪ **ARM C:** Etrolizumab placebo SC plus adalimumab placebo SC	Time on treatment 54 weeks ▪ **ARM A:** Etrolizumab 105mg SC q4w plus placebo IV ▪ **ARM B:** Placebo SC q4w plus inflixumab IV
Primary endpoint	▪ Induction of remission compared with placebo as determined by the Mayo Clinic Score (MCS) at week 10	▪ Induction of remission compared with placebo as determined by the Mayo Clinic Score (MCS) at week 10	▪ Proportion of patients in sustained clinical remission as determined by Mayo Clinic Score (MCS) at weeks 10, 30 and 54
Status	▪ FPI Q4 2014	▪ FPI Q4 2014	▪ FPI Q4 2014
CT Identifier	NCT02163759	NCT02171429	NCT02136069

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

Indication	Ulcerative colitis patients who are TNF-naïve and refractory or intolerant to immunosuppressant and/or corticosteroid treatment	Ulcerative colitis patients who are refractory or intolerant of TNF inhibitors	Moderate to severe ulcerative colitis patients
Phase/study	**Phase III** **LAUREL** Maintenance study	**Phase III** **HICKORY** Induction and maintenance study	**Phase III** **COTTONWOOD** Open label extension study
# of patients	N=350	N=800	N=2,625
Design	Induction phase: ▪ **ARM A:** Open label etrolizumab 105mg SC q4w Maintenance study: ▪ **ARM B:** Etrolizumab 105mg SC q4w ▪ **ARM C:** Placebo	Cohort 1 (open-label): ▪ **ARM A:** Etrolizumab induction + placebo maintenance ▪ **ARM B:** Etrolizumab induction + maintenance Cohort 2 (blinded): ▪ **ARM A:** Etrolizumab induction + maintenance ▪ **ARM B:** Placebo induction + maintenance	▪ Patients who were previously enrolled in etrolizumab phase II and phase III studies and meet recruitment criteria will receive etrolizumab 105 SC q4w
Primary endpoint	▪ Maintenance of remission (at week 62) among randomized patients in remission at Week 10 as determined by the Mayo Clinic Score (MCS)	▪ Clinical Remission (Mayo Clinic Score, MCS) at Week 14 ▪ Remission maintenance (by MCS, at Week 66) among patients with remission at Week 14	▪ Long-term efficacy as determined by partial Mayo Clinic Score (pMCS), incidence of adverse events
Status	▪ FPI Q3 2014 ▪ Recruitment completed Q1 2019	▪ FPI Q2 2014 ▪ First data presented at ECCO 2017 ▪ Open label induction and endoscopy data presented at UEGW 2017 ▪ Recruitment completed Q1 2019	▪ FPI Q3 2014
CT Identifier	NCT02165215	NCT02100696	NCT02118584

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

Etrolizumab (RG7413)

Humanized mAb against beta 7 integrin

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

UEGW=United European Gastroenterology Week

Crovalimab (RG6107; SKY59)

A humanized monoclonal antibody against complement C5

Indication	paroxysmal nocturnal hemoglobinuria (PNH)
Phase/study	**Phase I/II** **COMPOSER**
# of patients	N=49
Design	Healthy volunteers and treatment naïve and pretreated patients with PNH ▪ Part 1: single ascending dose study in healthy subjects ▪ Part 2: intra-patient single ascending dose study in PNH patients ▪ Part 3: Multiple-dose study in PNH patients ▪ Part 4: Dose confirmation in PNH patients
Primary endpoint	▪ Safety, PK, PD
Status	▪ Part 1: FPI Q4 2016 ▪ Part 2/3: FPI Q2 2017 ▪ Nonclinical data published in Scientific Reports 2017 Apr; 7(1):1080 ▪ Data presented for Part 2 and 3 at ASH 2018
CT Identifier	NCT03157635

In collaboration with Chugai

Faricimab (RG7716)

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

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

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

Faricimab (RG7716)

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

Indication	Center-involving diabetic macular edema (CI-DME)	
Phase/study	**Phase III YOSEMITE**	**Phase III RHINE**
# of patients	N=900	N=900
Design	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab (RG7716) q8w/PRN ▪ **ARM C:** Aflibercept, q8w	▪ **ARM A:** Faricimab q8w ▪ **ARM B:** Faricimab (RG7716) q8w/PRN ▪ **ARM C:** Aflibercept, q8w
Primary endpoint	▪ Change from baseline in BCVA at 1 year	▪ Change from baseline in BCVA at 1 year
Status	▪ FPI Q3 2018	▪ FPI Oct 2018
CT Identifier	NCT03622580	NCT03622593

BCVA=best corrected visual acuity

Faricimab (RG7716)

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

Indication	Neovascular age related macular degeneration (nAMD)	
Phase/study	**Phase III TENAYA**	**Phase III LUCERNE**
# of patients	N=640	N=640
Design	▪ **ARM A:** Faricimab 6.0mg Q16 flex after 4 initiating doses (IDs) ▪ **ARM B:** Aflibercept 2.0mg Q8 after 3 IDs	▪ **ARM A:** Faricimab 6.0mg Q16 flex after 4 initiating doses (IDs) ▪ **ARM B:** Aflibercept 2.0mg Q8 after 3 IDs
Primary endpoint	▪ Change From Baseline in BCVA Week 40, 44 & 48	▪ Change From Baseline in BCVA Week 40, 44 & 48
Status	▪ FPI Q1 2019	▪ FPI Q1 2019
CT Identifier	NCT03823287	NCT03823300

BCVA=best corrected visual acuity

Port Delivery System with ranibizumab

First eye implant to achieve sustained delivery of a biologic medicine

Indication	wAMD		
Phase/study	**Phase II LADDER**	**Phase III Archway**	**Phase II+III extension Portal**
# of patients	N=220	N=360	N=500
Design	▪ Four-arm study: Lucentis monthly intravitreal control vs three ranibizumab formulations delivered via implant	▪ **ARM A:** PDS with ranibizumab every 24 weeks ▪ **ARM B:** Intravitreal ranibizumab every 4 weeks	▪ Patients from LADDER or Archway will receive refills of 100 mg/mL ranibizumab q24w (patients without the PDS will receive the PDS and subsequent refills)
Primary endpoint	▪ Time to first refill	▪ Change in BCVA from baseline at the average of week 36 and week 40	▪ Safety
Status	▪ FPI Q3 2015 ▪ Recruitment completed Q3 2017 ▪ Positive primary data presented at ASRS 2018	▪ FPI Q3 2018	▪ FPI Q3 2018
CT Identifier	NCT02510794	NCT03677934	NCT03683251

In collaboration with Forsight and Novartis
wAMD=wet age-related macular degeneration

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group Q1 2019 sales

Diagnostics

Foreign exchange rate information

Oncology development programs

Small molecules

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

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

Oncology development programs

Monoclonal antibodies

Molecule	FAP-IL2v FP (RG7461)		
Indication	**Solid tumors**	**1L Renal call carcinoma**	**Solid tumors**
Phase/study	**Phase I**	**Phase Ib**	**Phase Ib**
# of patients	N=60	N=110	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)	**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	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	▪ Safety, PD and efficacy
Status	▪ FPI Q4 2015 ▪ FPI Part B/C Q4 2017	▪ FPI Q1 2017	▪ FPI Q1 2018
CT Identifier	NCT02627274	NCT03063762	NCT03386721

Oncology development programs

Monoclonal antibodies

Molecule	cibisatamab (CEA x CD3, RG7802)	
Indication	**CEA-positive solid tumors**	
Phase/study	**Phase Ia**	**Phase Ib**
# of patients	N≈286	N=410
Design	▪ **Part I:** Dose escalation of RG7802 ▪ **Part II:** Dosing strategy ▪ **Part III:** Assessment of schedule ▪ **Part IV:** Dose and schedule expansion	▪ **Part I:** RG7802 dose escalation plus Tecentriq ▪ **Part II:** Expansion at defined dose and schedule
Primary endpoint	▪ Safety, Efficacy, PK and PD	▪ Safety, Efficacy, PK and PD
Status	▪ FPI Q4 2014 ▪ Data presented at ASCO 2017	▪ FPI Q1 2016 ▪ Data presented at ASCO 2017
CT Identifier	NCT02324257	NCT02650713

ASCO=American Society of Clinical Oncology

Oncology development programs

Monoclonal antibodies

Molecule	CD20 x CD3 (RG6026)		
Indication	**Relapsed or refractory B cell non-Hodgkin's lymphoma**		**Non-Hodgkin's lymphoma**
Phase/study	**Phase I**	**Phase Ib**	**Phase Ib**
# of patients	N=260	N=140	Part I: 15-60 Part II: ~66-104
Design	**Cohort 1:** Single-agent dose escalation study ▪ Initial dose escalation ▪ Expansion cohort in r/r DLBCL ▪ Expansion cohort in r/r FL *All patients will receive pretreatment with a single dose of Gazyva (1000mg)* **Cohort 2:** RG6026 + Gazyva (i.e. continuous treatment with Gazyva	▪ Dose escalation and expansion of RG6026 plus Tecentriq	▪ **Part I:** Dose-finding for the combination of RG6026 plus G/R CHOP in r/r indolent NHL ▪ **Part II:** Dose expansion RG6026 plus G/R-CHOP or R-CHOP in 1L DLBCL
Primary endpoint	▪ Safety	▪ Safety	▪ Safety
Status	▪ FPI Q1 2017 ▪ Data presented at ASH 2018	▪ FPI Q2 2018	▪ FPI Q1 2018
CT Identifier	NCT03075696	NCT03533283	NCT03467373

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

Oncology development programs

Monoclonal antibodies

Molecule	**selicrelumab** (CD40 MAb, RG7876)	
Indication	**Solid tumors**	**Solid tumors**
Phase/study	**Phase Ib**	**Phase Ib**
# of patients	N=270	N=170
Design	▪ **Part I:** Selicrelumab single dose escalation in combination with Tecentriq ▪ **Part II:** Selicrelumab plus Tecentriq combination extension in CRC, HNSCC and cpi-experienced NSCLC	▪ **Part I:** Selicrelumab dose escalation in combination with vanucizumab ▪ **Part II:** Selicrelumab dose expansion in combination with Avastin in PROC, HNSCC and CPI exp. NSCLC
Primary endpoint	▪ Safety, PD and efficacy	▪ Safety, PD and efficacy
Status	▪ FPI Part 1 Q4 2014 ▪ FPI Part 2 Q4 2017	▪ FPI Q1 2016 ▪ Part II FPI Q2 2018 ▪ Selicrelumab + vanucizumab arm is no longer recruiting patients
CT Identifier	NCT02304393	NCT02665416

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

Oncology development programs

Monoclonal antibodies

Molecule	NME (RG6123)	FAP-4-1BBL FP (RG7827)	PD1-TIM3 (RG7769)
Indication	**Solid tumors**	**Solid tumors**	**advanced and metastatic solid tumors**
Phase/study	**Phase I**	**Phase I**	**Phase Ia/b**
# of patients	N=125	N=200	n=280
Design	▪ Dose escalation of single agent RG6123	▪ **Part 1:** Single agent dose escalation ▪ **Part 2:** Combo dose escalation with Tecentriq ▪ **Part 3:** Combo expansion with Tecentriq	▪ **Part 1a**: Dose escalation (Q2W) ▪ **Part 1b**: Dose escalation (Q3W) ▪ **Part 2a**: Dose expansion Metastatic Melanoma ▪ **Part 2b**: Dose expansion NSCLC ▪ **Part 2c**: Dose expansion NSCLC (PD-L1 high cohort)
Primary endpoint	▪ Safety, efficacy, PK and PD	▪ Safety, efficacy, PK and PD	▪ Safety, PD and efficacy
Status	▪ FPI Jul 2018	▪ FPI Q2 2018	▪ FPI Q4 2018
CT Identifier	NCT03539484		NCT03708328

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

Neuroscience development programs

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

NAM= negative allosteric modulator

Neuroscience development programs

Molecule	NME (RG7906)		
Indication	**Psychiatric disorders**	**Schizophrenia**	
Phase/study	**Phase I**	**Phase II**	**Phase II**
# of patients	N=164	N=36	N=500
Design	▪ **Part 1:** Adaptive single ascending dose in healthy volunteers. Single-center, randomized, placebo-controlled, parallel study ▪ **Part 2:** Adaptive multiple ascending dose in healthy volunteers. Single-center, randomized, double-blind, placebo-controlled, parallel study	▪ 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	▪ Safety, tolerability, PK and PD	▪ Effects on dopamine synthesis capacity	▪ Effects on negative symptoms (Brief Negative Symptoms Scale, BNSS)
Status	▪ FPI Q1 2016 ▪ Part 1 completed, Part 2 completed	▪ FPI Q4 2018	▪ FPI Q4 2018
CT Identifier	NCT02699372		NCT03669640

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

Neuroscience development programs

Parkinson's disease and autism

Molecule	**prasinezumab** (anti-αSynuclein, RG7935, PRX002)	**GABA-Aa5 PAM** (RG7816)	
Indication	**Parkinson's disease**	**Autism**	
Phase/study	**Phase II PASADENA**	**Phase I**	**Phase I**
# of patients	N=316	N=105	N=15
Design	▪ Randomized, double-blind, placebo-controlled study to evaluate the efficacy of prasinezumab in participants with early PD (52 weeks plus a 52-week blinded extension)	▪ Randomized, double-blind, adaptive single-ascending-dose SAD/MAD/FE study in healthy volunteers	▪ PET study to assess occupancy of brain alpha5-Containing GABAA receptors of RG7816 using [11C] Ro15-4513 following single oral doses in healthy participants
Primary endpoint	▪ Change from baseline in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) total score (sum of Parts I, II, and III) at week 52	▪ Safety and tolerability	▪ Percentage of brain alpha5-Containing GABA-A receptors occupied by RG7816, plasma concentrations of RG7816
Status	▪ FPI Q2 2017 ▪ Recruitment completed Q4 2018 ▪ Ph1 data published online in *JAMA Neurol.* 2018 Jun 18	▪ FPI Q4 2017	▪ FPI Q2 2018
CT Identifier	NCT03100149		NCT03507569
Collaborator	Prothena		

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

Infectious diseases development programs

Chronic hepatitis B

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

LNA=locked nucleic acid

Infectious diseases development programs

Chronic hepatitis B

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

LNA=locked nucleic acid

Immunology development programs

Molecule	**petesicatib** (CAT-S inh, RG7625)	**IgG-IL2 FP** (RG7835)
Indication	**Psoriasis**	**Autoimmune diseases**
Phase/study	**Phase II**	**Phase I**
# of patients	N=30	N=56
Design	▪ An open label phase 2a trial assessing the clinical efficacy and safety of RO5459072 in moderate to severe psoriasis	▪ A randomized, adaptive, investigator/subject blind, single ascending dose, placebo-controlled study of subcutaneously administered RO7049665 (RG7835) in healthy volunteers
Primary endpoint	▪ Proportion of patients achieving a PASI75 response after twelve weeks	▪ Safety, PK and PD
Status	▪ FPI Q4 2018	▪ FPI Q3 2017 ▪ Recruitment completed Q3 2018
CT Identifier		NCT03221179

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

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group Q1 2019 sales

Diagnostics

Foreign exchange rate information

Oncology development programs

Monoclonal antibodies

Molecule	mosunetuzumab (CD20 x CD3, RG7828)			
Indication	**Hematologic tumors**	**1L DLBCL & R/R NHL**	**R/R DLBCL & FL**	**1L DLBCL & 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 RG7828 as single agent and in combination with Tecentriq ▪ Expansion cohorts for r/r FL, r/r DLBCL and r/r MCL	▪ Mosunetuzumab plus CHOP ▪ Mosunetuzumab plus CHP + polatuzumab vedotin	▪ Mosunetuzumab monotherapy ▪ Mosunetuzumab + polatuzumab vedotin	▪ Mosunetuzumab monotherapy (after a response to prior systemic chemotherapy) ▪ Mosunetuzumab monotherapy (1L treatment)
Primary endpoint	▪ Safety, tolerability, dose/schedule, PK, and response rates ▪ First data in R/R NHL presented at ASH 2018	▪ Safety/tolerability and response	▪ Safety/tolerability and response	▪ Safety/tolerability and response
Status	▪ FPI Q3 2015	▪ FPI Q1 2019	▪ FPI Q3 2018	▪ FPI expected Q2 2019
CT Identifier	NCT02500407	NCT03677141	NCT03671018	NCT03677154

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

Oncology development programs

Monoclonal antibodies

Molecule	**tiragolumab** (anti-TIGIT, RG6058, MTIG7192A)	
Indication	**Solid tumors**	**NSCLC**
Phase/study	**Phase I**	**Phase II**
# of patients	N=300	N=120
Design	▪ **Phase Ia:** Dose escalation and expansion of tiragolumab ▪ **Phase Ib:** Dose escalation and expansion Tecentriq plus tiragolumab	▪ Tecentriq plus tiragolumab
Primary endpoint	▪ Safety, tolerability, PK variability and preliminary efficacy	▪ Overall response rate and progression-free survival
Status	▪ FPI Q2 2016	▪ FPI Q3 2018
CT Identifier	NCT02794571	NCT03563716

NSCLC=Non-small cell lung cancer

Oncology development programs

Monoclonal antibodies

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

Oncology development programs

Antibody–drug conjugates

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

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

Oncology development programs

Small molecules

Molecule	SERD (3) (RG6171, GDC-9545)	PI3K inhibitor (RG6114, GDC-0077)
Indication	**Metastatic ER+ HER2-neg. breast cancer**	**PIK3CA mutant solid tumors and metastatic ER+ HER2- breast cancer**
Phase/study	**Phase I**	**Phase I**
# of patients	N=130	N=156
Design	▪ Dose escalation and expansion at recommended phase II dose (RP2D) ▪ Single agent and in combination with palbociclib and/or luteinizing hormone–releasing hormone (LHRH) agonist	Monotherapy and in combination with SoC (letrozole; letrozole plus palbociclib; fulvestrant) ▪ **Stage 1:** Dose escalation ▪ **Stage 2:** Expansion
Primary endpoint	▪ Safety	▪ Safety, tolerability and PK
Status	▪ FPI Q4 2017	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017
CT Identifier	NCT03332797	NCT03006172

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

Oncology development programs

Individualized Neoantigen-Specific Therapy

Molecule	**Individualized Neoantigen-Specific Therapy, iNeST (Personalized Cancer Vaccine, PCV)** (RG6180)	
Indication	**Locally advanced or metastatic solid tumors**	**1L Advanced Melanoma**
Phase/study	**Phase Ia/Ib**	**Phase II IMcode001**
# of patients	N=572	N=132
Design	Open-label, multicenter, global study ▪ **Phase Ia:** Dose escalation of RG6180 as single agent ▪ **Phase Ib:** Dose escalation, exploration and expansion trial of RG6180 in combination with Tecentriq	▪ **ARM A:** Pembrolizumab ▪ **ARM B:** iNeST in combination with pembrolizumab
Primary endpoint	▪ Safety, tolerability, PK and immune response	▪ Progression free survival and objective response rate
Status	▪ FPI Q4 2017	▪ FPI Q1 2019
CT Identifier	NCT03289962	NCT03815058
Collaborator	BioNTech	

Neuroscience development programs

gRED Genentech Research & Early Development

Molecule	DLK inhibitor (RG6000, GDC-0134)	Anti-Tau (RG6100)	
Indication	**Amyotrophic lateral sclerosis**	**Prodromal to mild Alzheimer's disease**	**Moderate Alzheimer's disease**
Phase/study	**Phase I**	**Phase II Tauriel**	**Phase II**
# of patients	N=82	N=360	N=260
Design	▪ Randomized, double-blind, placebo-controlled, multicenter, single and multiple ascending dose study	▪ Randomized, double-blind, placebo-controlled, multi-center efficacy and safety study	▪ Randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety study
Primary endpoint	▪ Safety, tolerability, and PK of single and multiple doses	▪ Safety, CDR-SB score from baseline to week 72	▪ Safety, ADAS-Cog11 and ADCS-ADL from baseline to week 49
Status	▪ FPI Q2 2016	▪ FPI Q4 2017	▪ FPI Q1 2019
CT Identifier	NCT02655614	NCT03289143	NCT03828747
Collaborator		AC Immune	

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

Immunology development programs

Molecule	IL-22Fc (RG7880)		
Indication	**Inflammatory diseases**	**Diabetic foot ulcer**	**Inflammatory bowel disease**
Phase/study	**Phase Ib**	**Phase Ib**	**Phase II**
# of patients	N=90	N=72	N=270
Design	▪ Multiple ascending dose study with healthy volunteer and patient cohorts	▪ Multiple ascending dose study in patients with neuropathic diabetic foot ulcers that do not respond adequately to standard wound care	IL-22 FC compared with vedolizumab and with placebo in the treatment of participants with moderate to severe UC ▪ **Part A:** Induction of clinical remission ▪ **Part B:** Durability of clinical remission
Primary endpoint	▪ Safety and tolerability	▪ Safety and tolerability	▪ Percentage of participants with clinical remission at week 8
Status	▪ FPI Q2 2016	▪ FPI Q4 2016 ▪ Recruitment completed Q2 2018	▪ FPI Q4 2018
CT Identifier	NCT02749630	NCT02833389	NCT03558152

UC=Ulcerative Colitis

Immunology development programs

gRED Genentech Research & Early Development

Molecule	NME (RG6151, GDC-0214)	NME (RG6173, MTPS9579A)	ST2 MAb (RG6149, AMG 282, MSTT1041A)
Indication	**Asthma**		
Phase/study	**Phase I**	**Phase I**	**Phase IIb ZENYATTA**
# of patients	N=84	N=70	N=515
Design	▪ Single and multiple ascending dose study with healthy volunteer and patient cohorts	▪ Single and multiple ascending dose study of MTPS9579A in healthy adult subjects	Add-on therapy for the treatment of high-need, uncontrolled asthma in adults (50-week subcutaneous treatment period): ▪ **ARM A:** RG6149 (70 mg) ▪ **ARM B:** RG6149 (210mg) ▪ **ARM C:** RG6149 (490mg) ▪ **ARM D:** Placebo
Primary endpoint	▪ Safety, tolerability and biomarker for target engagement (FeNO reduction)	▪ Safety, tolerability and PK	▪ Percentage of participants with asthma exacerbations
Status	▪ FPI Q4 2017 ▪ Recruitment completed Q1 2018	▪ FPI Q1 2018	▪ FPI Q3 2016 ▪ Recruitment completed Apr 2018
CT Identifier	ACTRN12617001227381p		NCT02918019
Collaborator			Amgen

Immunology development programs

gRED Genentech Research & Early Development

Molecule	NME (RG6174, GDC-0334)	fenebrutinib (BTKi, RG7845, GDC-0853)	
Indication	**Inflammatory disease**	**Rheumatoid arthritis**	
Phase/study	**Phase I**	**Phase II ANDES**	**Phase II Open label extension**
# of patients	N=106	N=578	N=578
Design	▪ Single and multiple ascending dose study of GDC-0334 and the effect of food on the pharmacokinetics of GDC-0334 in healthy adult participants	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	▪ Safety, tolerability, PK of single doses and multiple doses	▪ ACR 50 at week12 and safety	▪ ACR 50 at week12 and safety
Status	▪ FPI Q4 2017	▪ FPI Q3 2016 ▪ Recruitment completed Q1 2018	▪ FPI Q4 2016 ▪ Recruitment completed Q2 2018
CT Identifier	NCT03381144	NCT02833350	NCT02983227

MTX=methotrexate

Immunology development programs

gRED Genentech Research & Early Development

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

Immunology development programs

gRED Genentech Research & Early Development

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=24
Design	▪ Establish safety and PK in patients (*S. aureus* bacteremia)
Primary endpoint	▪ Safety and PK
Status	▪ FPI Q3 2017
CT Identifier	NCT03162250
Collaborator	Seattle Genetics, Symphogen

TAC=THIOMAB™ antibiotic conjugate

Ophthalmology development programs

Molecule	**NME** (RG6147)
Indication	**Geographic atrophy**
Phase/study	**Phase I**
# of patients	N≈44
Design	Open-label study of RG6417 following single and multiple intravitreal administrations in patients with GA secondary to AMD ▪ **Stage 1:** Single dose-escalation (SAD) ▪ **Stage 2:** Multiple-dose (MD) stages
Primary endpoint	▪ Safety and tolerability
Status	▪ FPI Q3 2017
CT Identifier	NCT03295877

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

Metabolic diseases development programs

Molecule	FGFR1/KLB MAb (RG7992)	
Indication	**Metabolic diseases**	
Phase/study	**Phase Ia**	**Phase Ib**
# of patients	N=79	N=140
Design	Healthy volunteer study ▪ Randomized, blinded, placebo-controlled, single ascending dose of RG7992	Obese type 2 diabetes ▪ Randomized, blinded, placebo-controlled, multiple ascending dose of RG7992
Primary endpoint	▪ Safety and tolerability	▪ Safety, tolerability and PK
Status	▪ FPI Q4 2015 ▪ Recruitment completed Q1 2017	▪ FPI Q1 2017
CT Identifier	NCT02593331	NCT03060538

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

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development

Genentech research and early development

Roche Group Q1 2019 sales

Diagnostics

Foreign exchange rates information

Q1 2019: Geographical sales split by divisions and Group*

CHFm	Q1 2018	Q1 2019	% change CER
Pharmaceuticals Division	**10,672**	**11,927**	**+10**
United States	5,516	6,623	**+14**
Europe	2,287	2,101	**-6**
Japan	851	941	**+7**
International	2,018	2,262	**+17**
Diagnostics Division	**2,911**	**2,899**	**+1**
United States	678	699	**-2**
Europe	1,015	996	**+1**
Japan	93	94	**-3**
International	1,125	1,110	**+2**
Group	**13,583**	**14,826**	**+8**
United States	6,194	7,322	**+12**
Europe	3,302	3,097	**-4**
Japan	944	1,035	**+6**
International	3,143	3,372	**+12**

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

Pharma Division sales Q1 2019

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Avastin	1,798	9	824	12	461	1	194	2	319	16
MabThera	1,694	-3	1,168	9	171	-38	28	-50	327	-4
Herceptin	1,666	-6	791	3	300	-44	56	-9	519	26
Perjeta	868	41	412	36	267	27	51	74	138	83
Ocrevus	836	67	715	54	92	232	-	-	29	261
Actemra / RoActemra	534	6	212	5	174	4	86	13	62	10
Xolair	469	1	469	1	-	-	-	-	-	-
Lucentis	457	11	457	11	-	-	-	-	-	-
TNKase / Activase	362	7	351	7	-	-	-	-	11	-10
Tecentriq	336	135	216	91	57	158	33	-	30	262
Kadcyla	291	24	125	39	97	9	18	12	51	32
Esbriet	250	10	174	7	62	14	-	-	14	37
Hemlibra	219	*	166	*	26	450	25	-	2	-
Alecensa	196	61	67	14	46	182	47	24	36	278
Pulmozyme	182	6	119	6	35	8	-	43	28	4
Tamiflu	179	-40	24	-86	28	38	71	-6	56	55
CellCept	163	4	21	-20	44	2	19	8	79	13
Mircera	142	16	-	-	17	-11	45	3	80	35
Gazyva	115	35	55	22	38	31	8	-	14	31
Xeloda	108	5	9	10	4	-13	22	-14	73	13

CER=Constant Exchange Rates; * over 500%

Pharma Division sales Q1 2019

New products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Erivedge	62	2	39	3	17	-9	-	-	6	25
Perjeta	868	41	412	36	267	27	51	74	138	83
Kadcyla	291	24	125	39	97	9	18	12	51	32
Gazyva	115	35	55	22	38	31	8	-	14	31
Esbriet	250	10	174	7	62	14	-	-	14	37
Cotellic	15	-1	3	-23	9	0	-	-	3	44
Alecensa	196	61	67	14	46	182	47	24	36	278
Tecentriq	336	135	216	91	57	158	33	-	30	262
Ocrevus	836	67	715	54	92	232	-	-	29	261
Hemlibra	219	*	166	*	26	450	25	-	2	-
Xofluza	6	-	6	-	-	-	-	-	-	-
Total	**3,194**	**57**	**1,978**	**52**	**711**	**48**	**182**	**118**	**323**	**92**

CER=Constant Exchange Rates; * over 500%

Pharma Division CER sales growth[1] in %

Global top 20 products

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

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

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Avastin	-1	5	3	12	-1	-1	1	1	4	2	2	2	9	21	15	16
MabThera	3	5	7	9	-50	-49	-46	-38	-33	-40	-54	-50	4	18	12	-4
Herceptin	11	11	0	3	-7	-21	-34	-44	-19	-19	-17	-9	4	13	32	26
Perjeta	36	34	38	36	8	15	25	27	12	12	35	74	56	42	46	83
Ocrevus	163	82	59	54	-	*	*	232	-	-	-	-	*	*	459	261
Actemra / RoActemra	17	8	17	5	2	11	8	4	18	16	13	13	25	-4	24	10
Xolair	14	9	12	1	-	-	-	-	-	-	-	-	-	-	-	-
Lucentis	27	2	47	11	-	-	-	-	-	-	-	-	-	-	-	-
TNKase / Activase	11	1	4	7	-	-	-	-	-	-	-	-	4	-1	3	-10
Tecentriq	-7	-4	21	91	*	*	286	158	-	-	-	-	434	*	458	262
Kadcyla	12	6	1	39	1	7	9	9	12	8	3	12	35	13	14	32
Esbriet	12	21	33	7	19	15	14	14	-	-	-	-	43	40	-5	37
Hemlibra	-	-	*	*	-	-	*	450	-	-	-	-	-	-	-	-
Alecensa	107	56	44	14	349	137	217	182	36	26	20	24	403	289	343	278
Pulmozyme	7	2	4	6	5	8	8	8	7	32	26	43	4	-11	-8	4
Tamiflu	-100	-86	-100	-86	118	-33	-77	38	-96	-77	-73	-6	-59	-4	11	55
CellCept	-14	16	-24	-20	-4	-1	0	2	3	0	-4	8	-1	4	-11	13
Mircera	-	-	-	-	-17	-7	-8	-11	-5	-4	-4	3	25	44	-3	35
Gazyva	29	24	25	22	66	79	52	31	-	-	-	-	10	58	24	31
Xeloda	-54	50	183	10	-33	-52	-27	-13	6	5	1	-14	-3	-3	-17	13

CER=Constant Exchange Rates; * over 500%; [1] Q2-Q4/18 vs Q2-Q4/17; Q1/19 vs. Q1/18

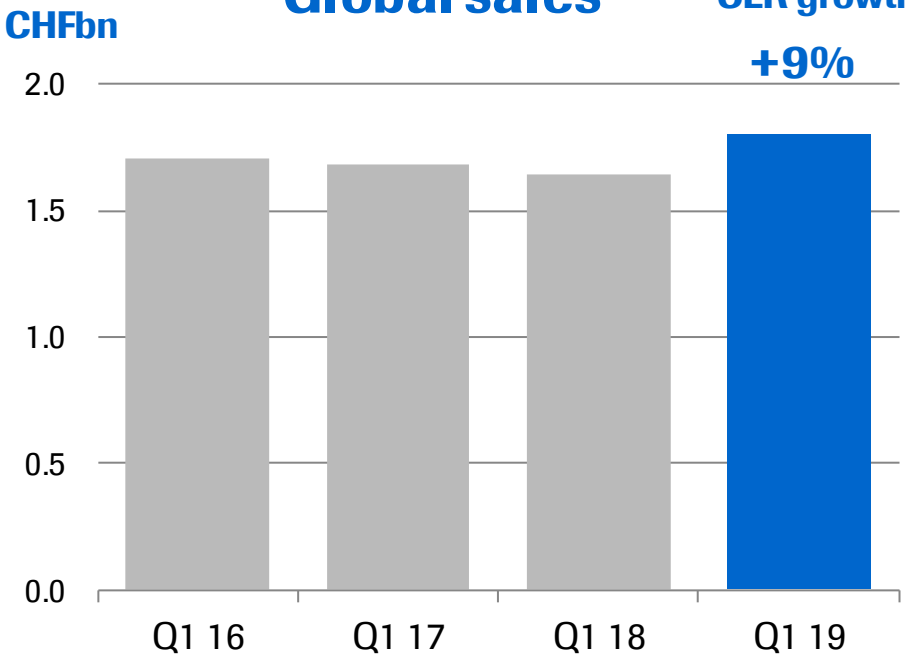
CER sales growth (%)
Quarterly development

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

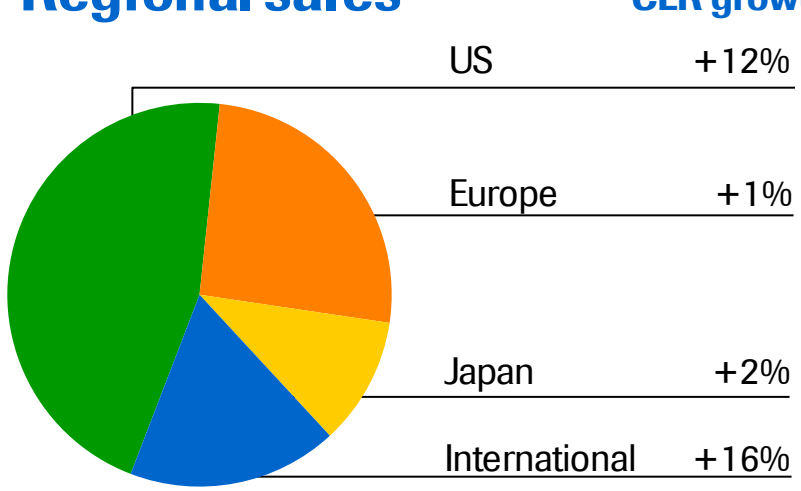
CER=Constant Exchange Rates

Avastin

Global sales



Regional sales



Q1 2019 sales of CHF 1,798m

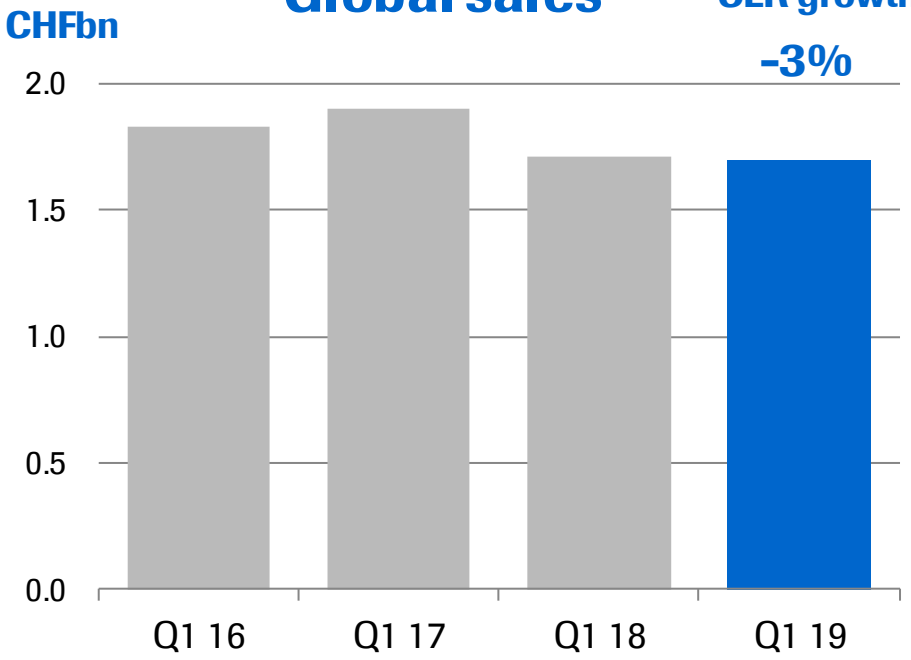
- US: Demand growth driven by 1L CRC, 1L OC, 1L NSCLC and some phasing
- EU: Growth driven by 1L CRC and 1L OC
- International: Growth driven by China in 1L CRC and 1L NSCLC and by longer duration of treatment

CER=Constant Exchange Rates

MabThera/Rituxan

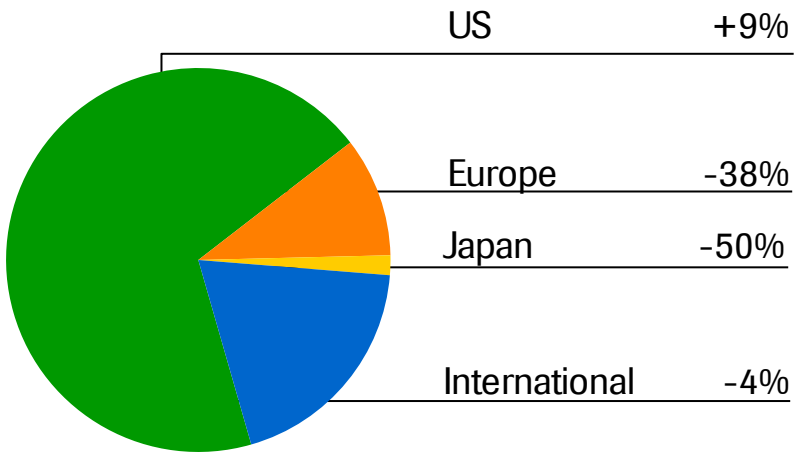
Global sales

CER growth -3%



Regional sales

CER growth



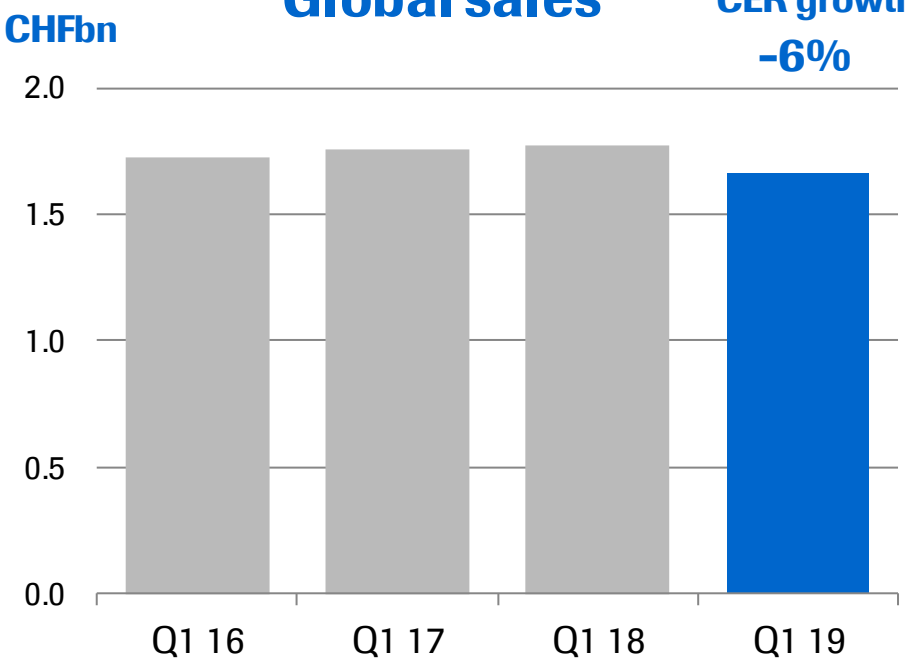
Q1 2019 sales of CHF 1,694m

- US: Growth driven by all approved oncology and immunology indications
- EU: Biosimilars decline rate softening
- Japan: Decline due to biosimilars
- International: Sales impacted by phasing in LATAM; China with continued strong growth

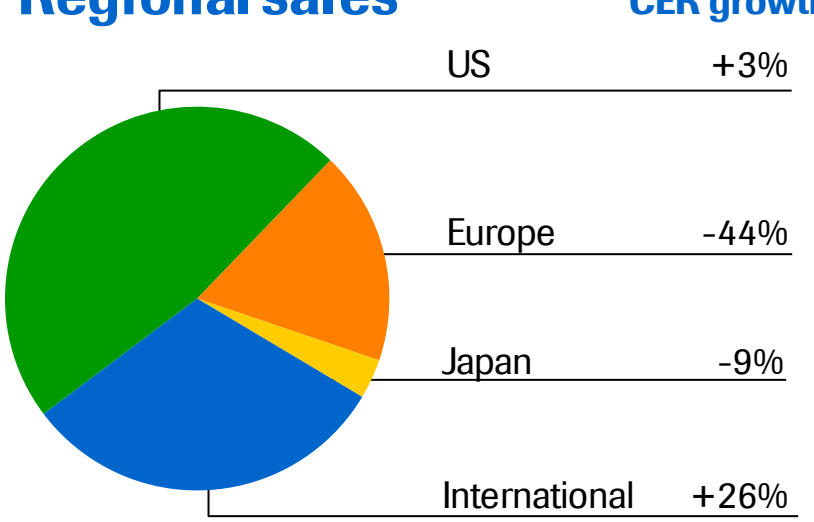
CER=Constant Exchange Rates

Herceptin

Global sales



Regional sales

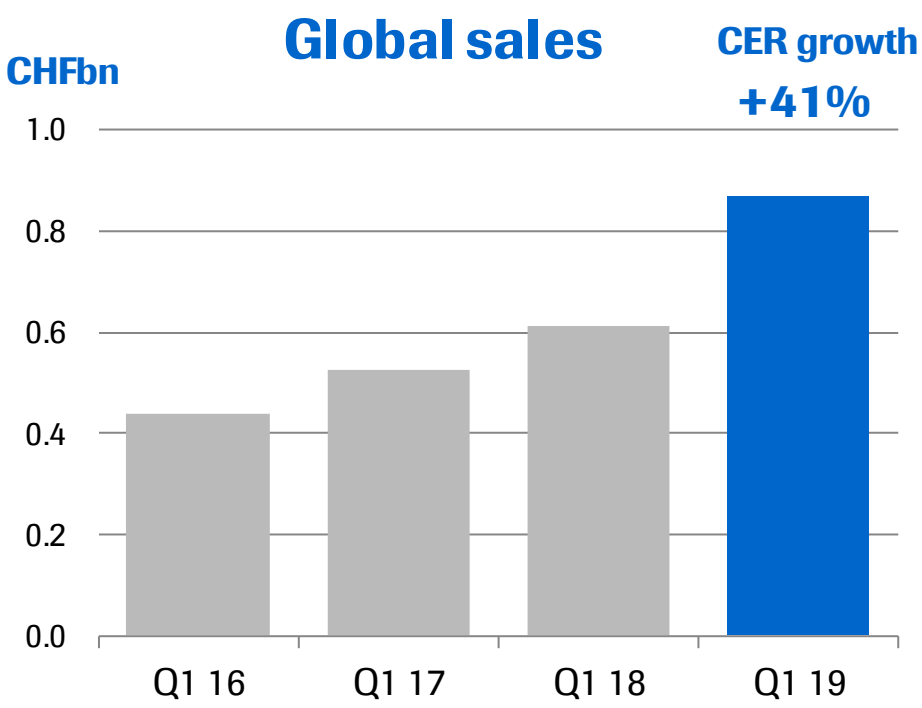


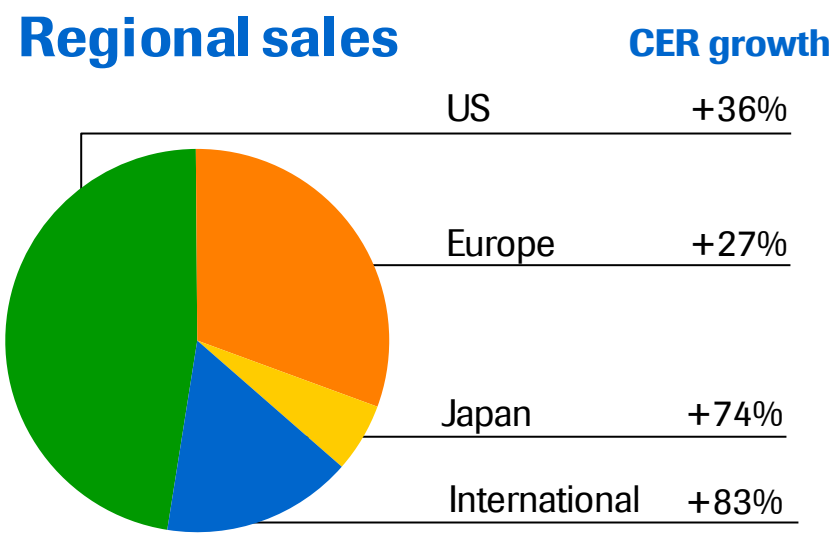
Q1 2019 sales of CHF 1,666m

- US: Volume growth mainly driven by longer duration
- EU: Decline due to biosimilars
- Japan: Decline due to biosimilars
- International: Growth driven by volume demand in China

CER=Constant Exchange Rates

Perjeta



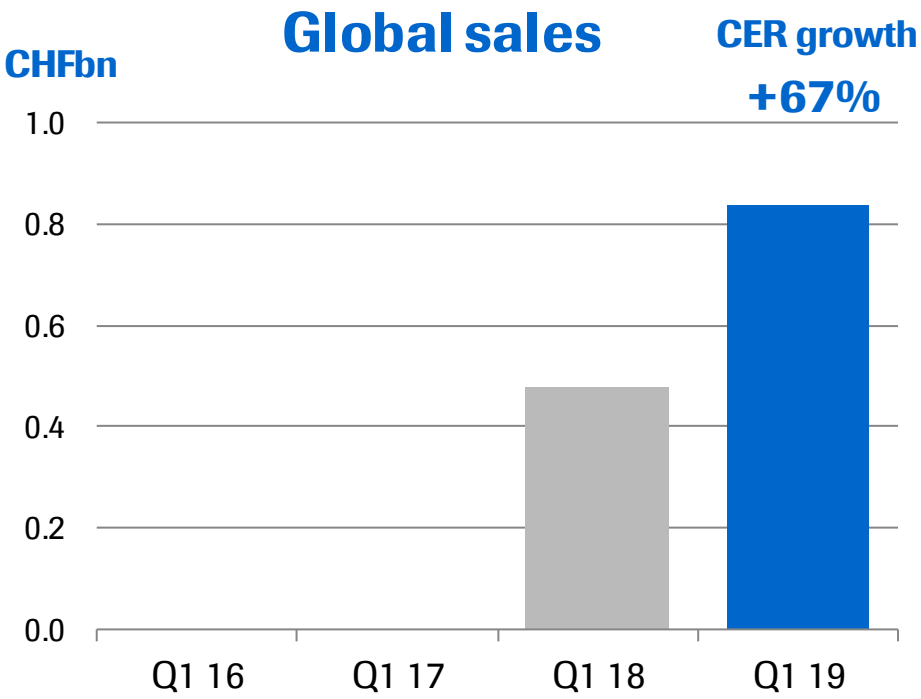


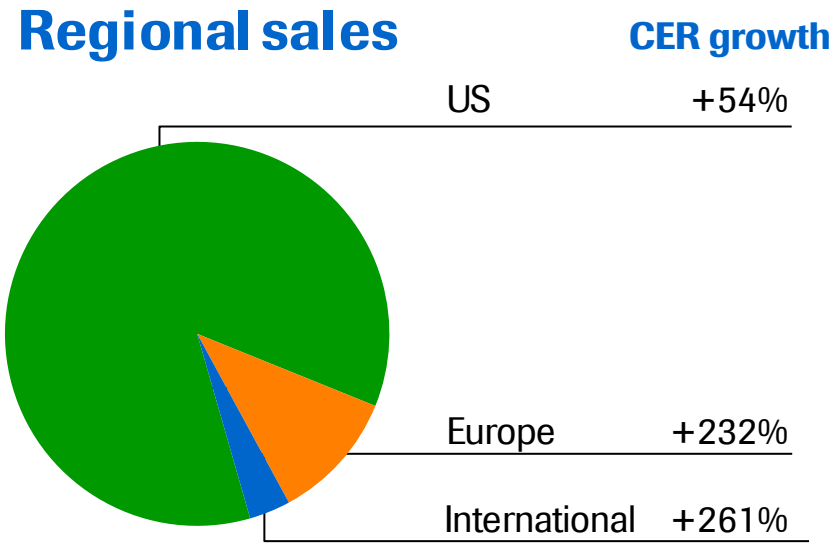
Q1 2019 sales of CHF 868m

- US: High growth remains driven by eBC adjuvant setting following APHINITY approval in Q4 17
- EU: Growth in 1L mBC and increasingly in eBC adjuvant setting following APHINITY approval in Q2 18
- International: Accelerated growth in all regions driven by eBC adjuvant setting and launch in China
- Japan: Growth driven by eBC adjuvant setting following APHINITY approval in Q4 18

CER=Constant Exchange Rates

Ocrevus





Q1 2019 sales of CHF 836m

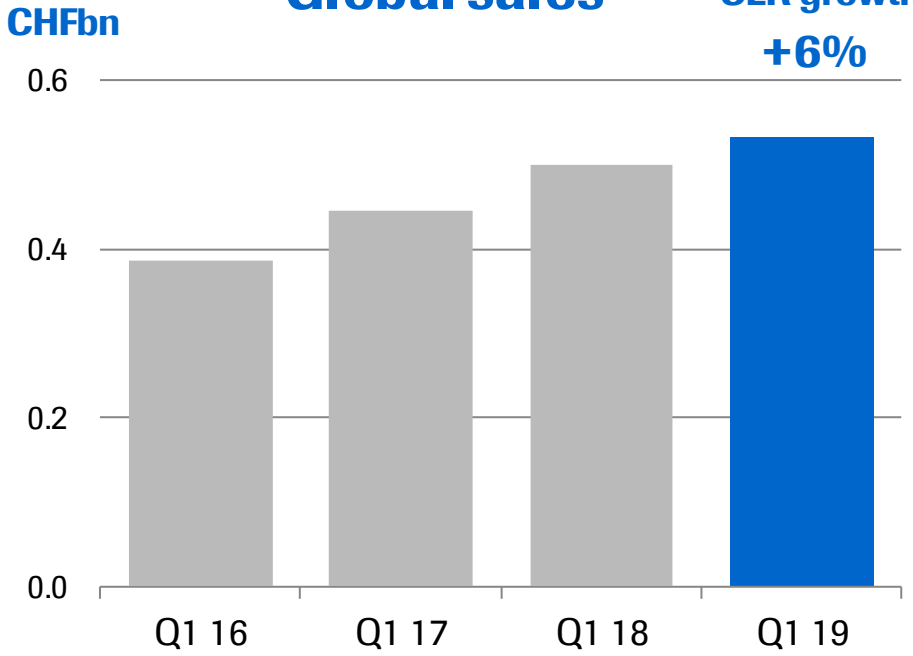
- US: Moving into earlier lines displacing orals
- EU: All EU-5 have now launched. Uptake dynamics in early launch countries similar to the US

CER=Constant Exchange Rates

Actemra/RoActemra

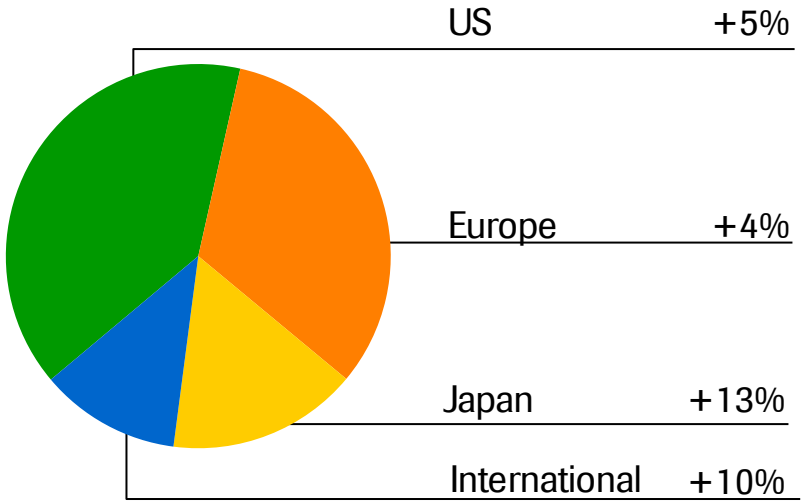
Global sales

CER growth +6%



Regional sales

CER growth

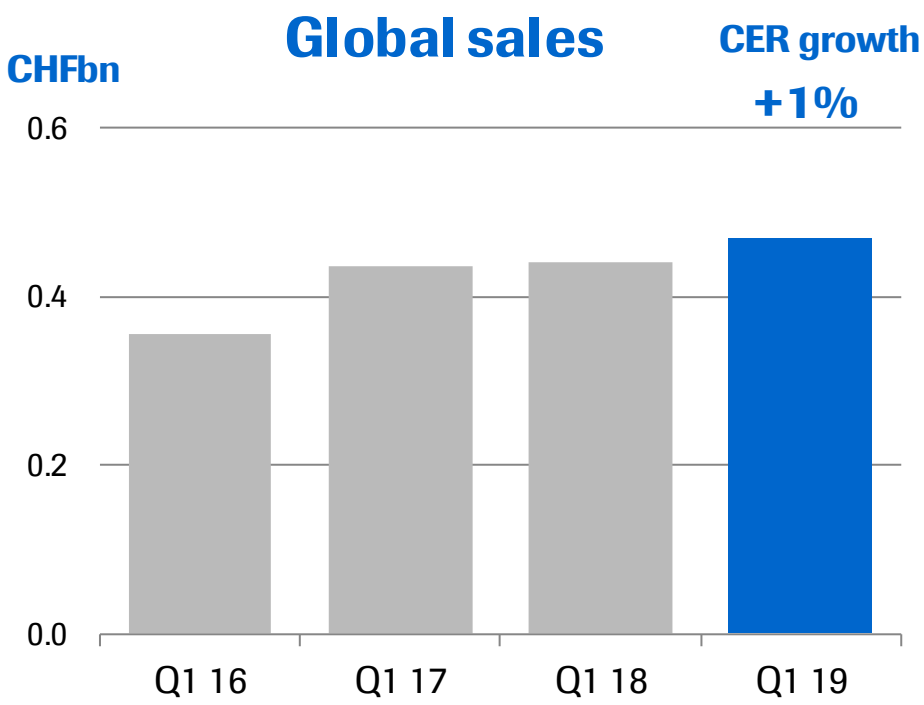


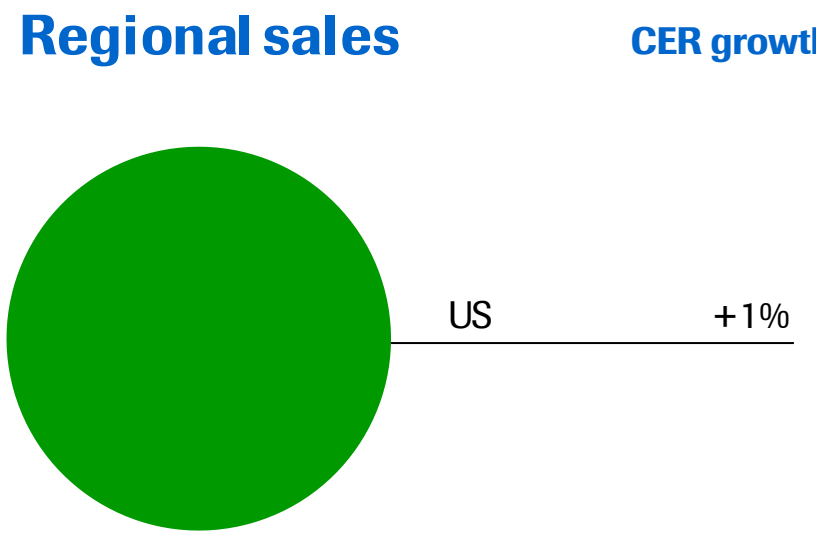
Q1 2019 sales of CHF 534m

- US: Growth driven by Giant Cell Arteritis (GCA) launch and continued SC uptake
- EU: Market leadership in monotherapy achieved; Growth driven by GCA
- International: Growth driven by all regions

CER=Constant Exchange Rates

Xolair



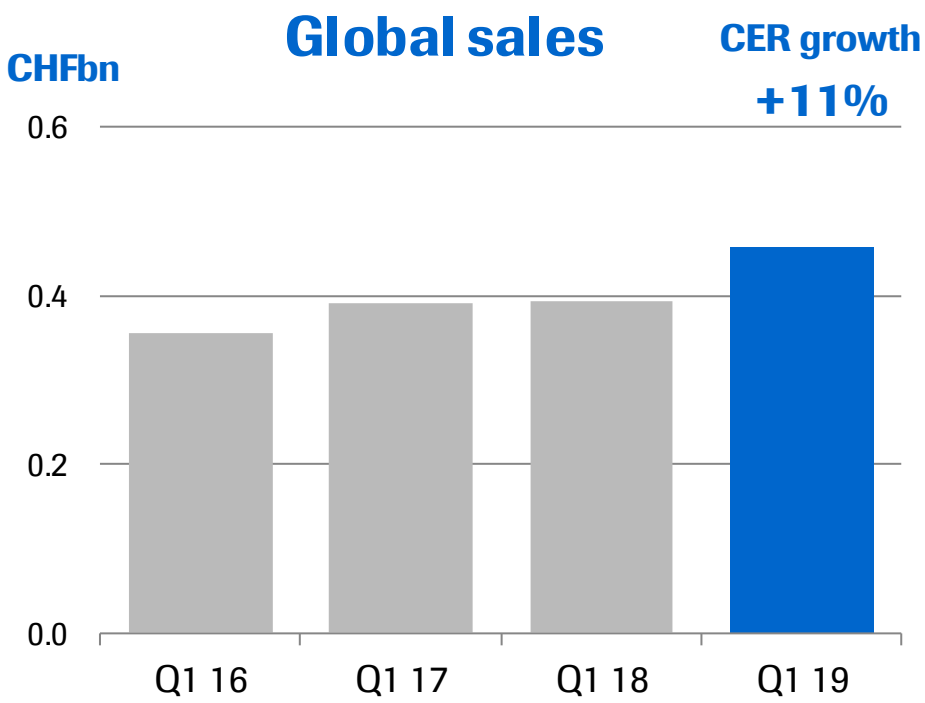


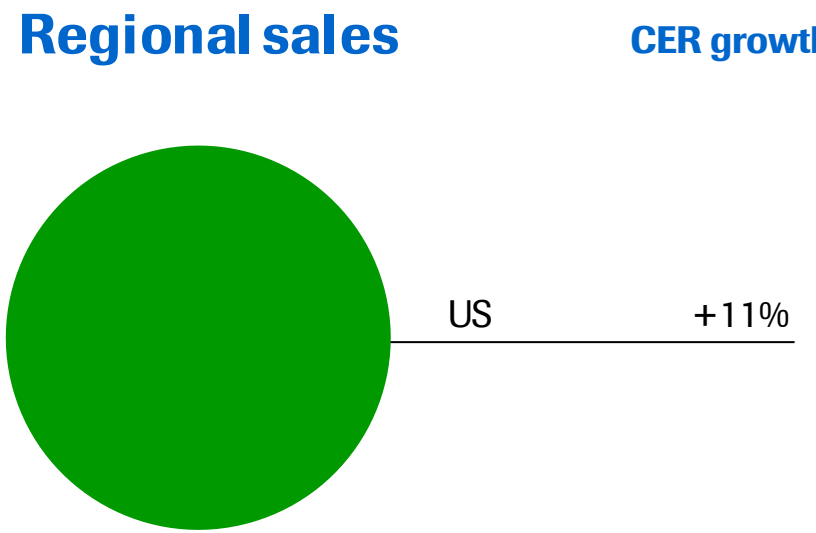
Q1 2019 sales of CHF 469m

- Xolair remains market leader in growing biologics asthma market
- Growth due to chronic idiopathic urticaria
- Pre-filled syringe approved in Q3 18

CER=Constant Exchange Rates

Lucentis





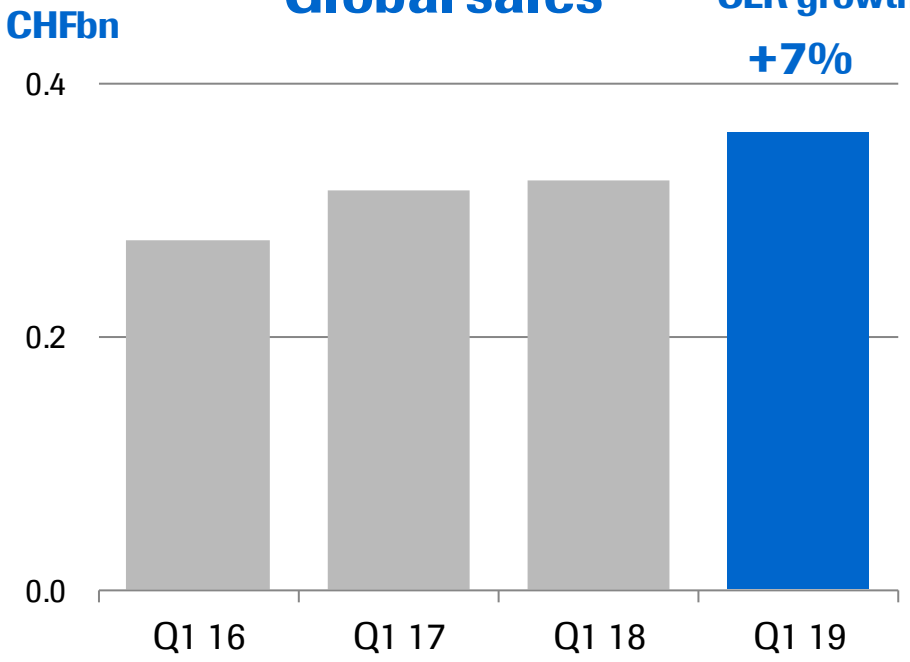
Q1 2019 sales of CHF 457m

- Strong growth after first prefilled syringe launched for wAMD and macular edema after retinal vein oclusion
- First-in-class launches in mCNV and DR w/o DME on-going
- Stable market shares in all approved indications

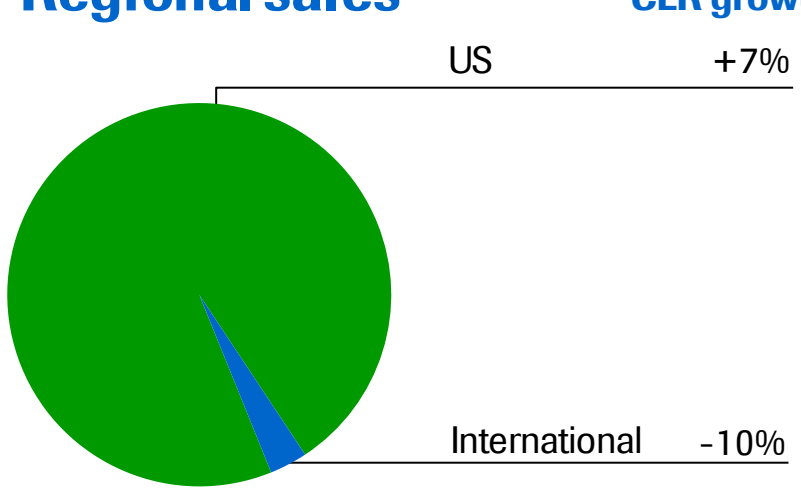
CER=Constant Exchange Rates

TNKase / Activase

Global sales



Regional sales

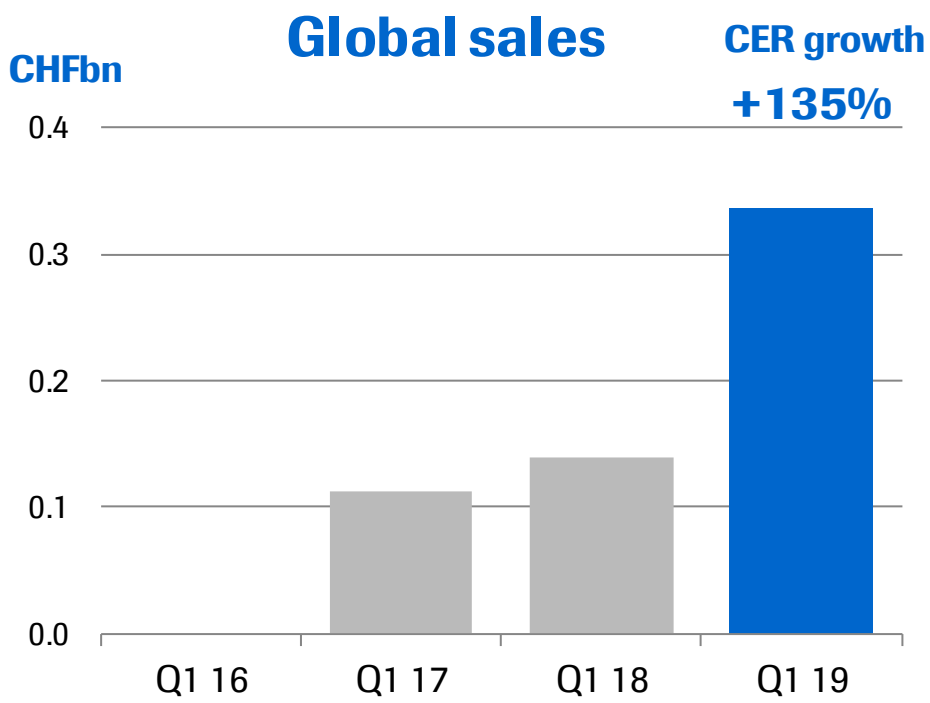


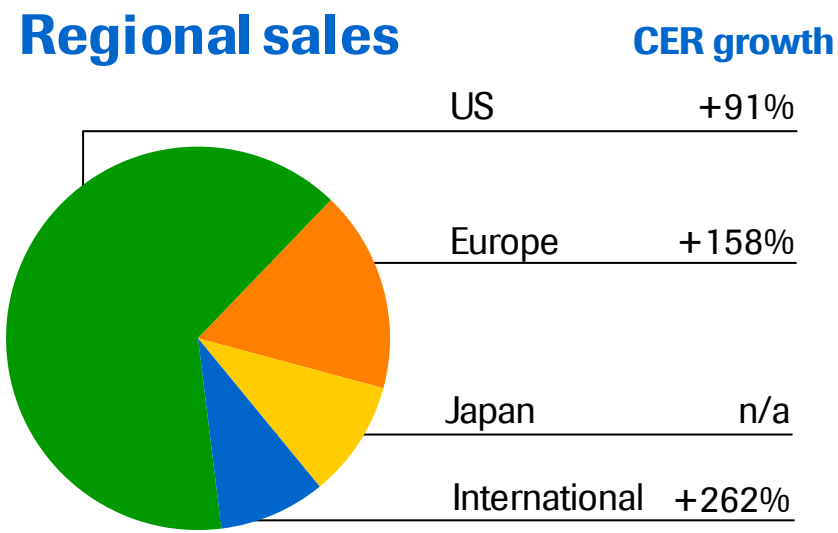
Q1 2019 sales of CHF 362m

- US: Growth driven by demand

CER=Constant Exchange Rates

Tecentriq



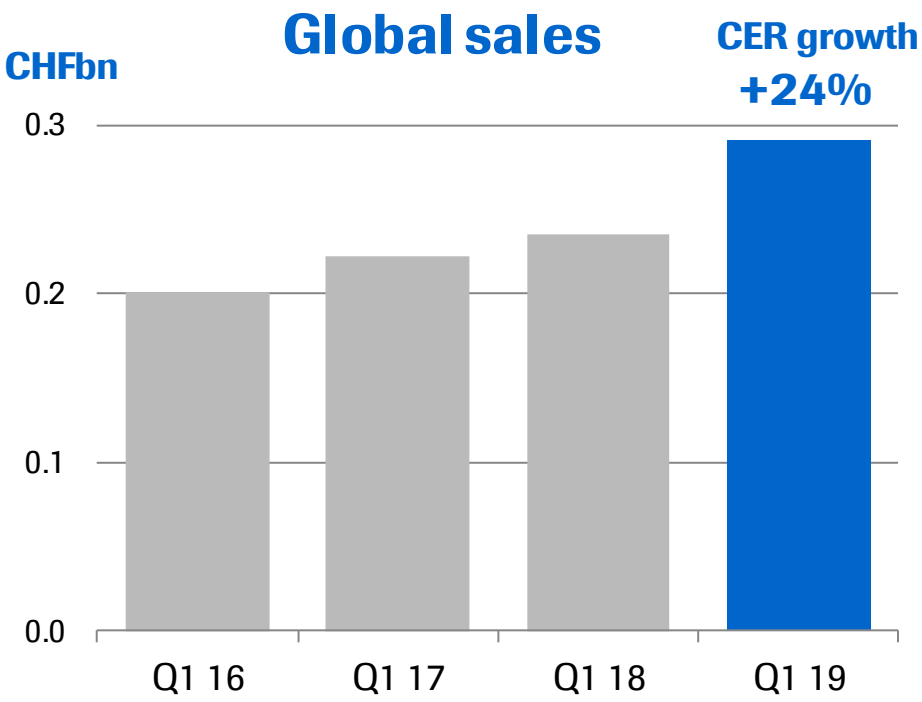


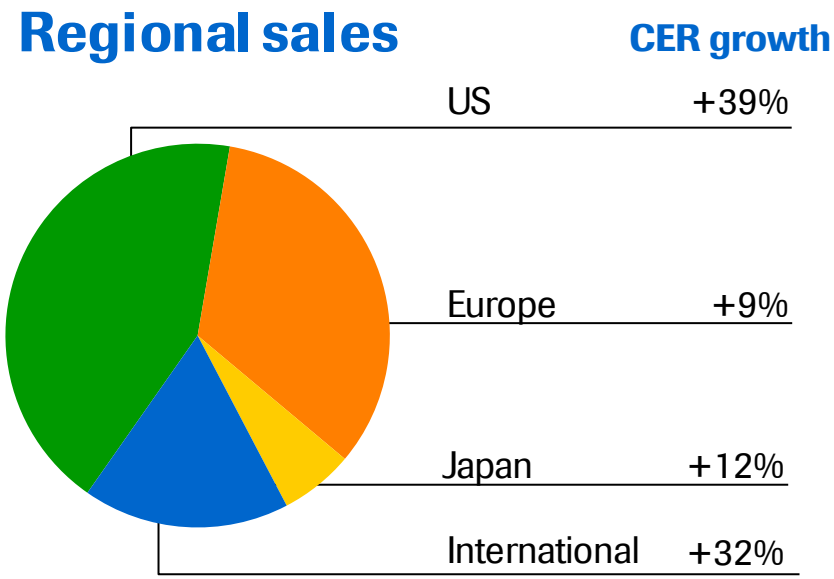
Q1 2019 sales of CHF 336m

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

CER=Constant Exchange Rates

Kadcyla



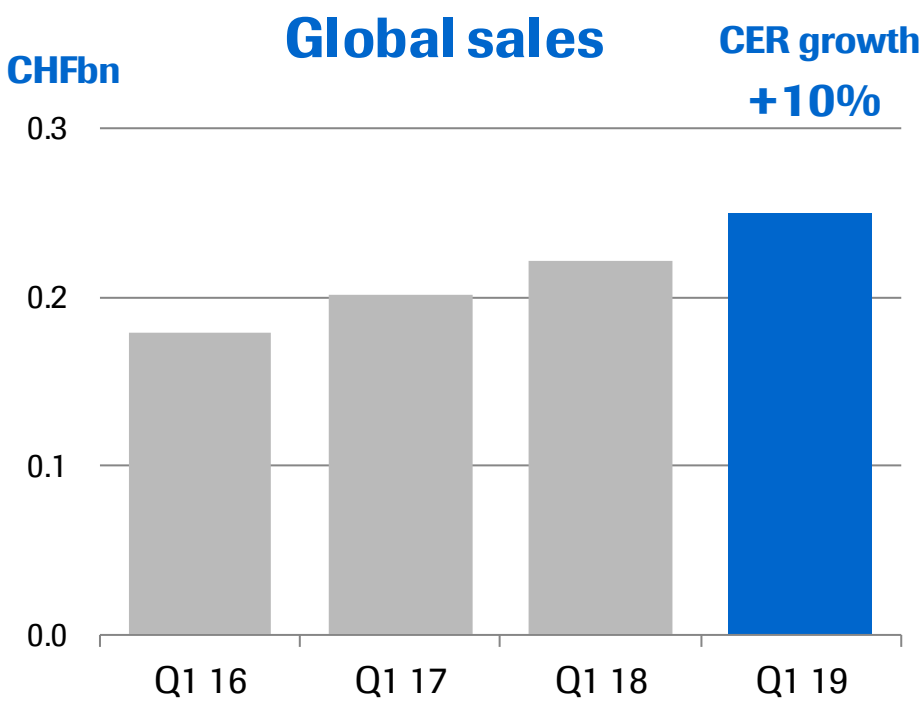


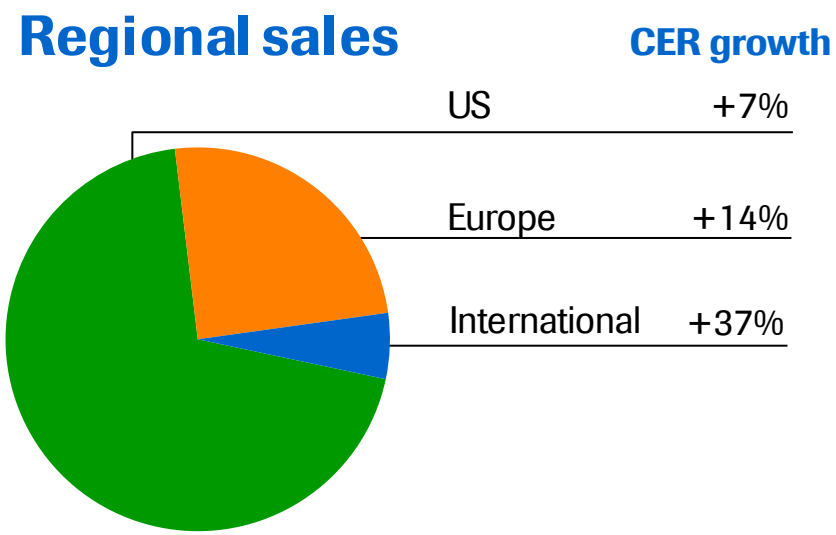
Q1 2019 sales of CHF 291m

- US: Spontaneous uptake in Her2+ eBC with residual disease after neoadjuvant treatment (KATHERINE)
- EU: Increasing patient shares in 2L mBC
- International: Growth driven by all regions as 2L mBC roll-out progresses

CER=Constant Exchange Rates

Esbriet



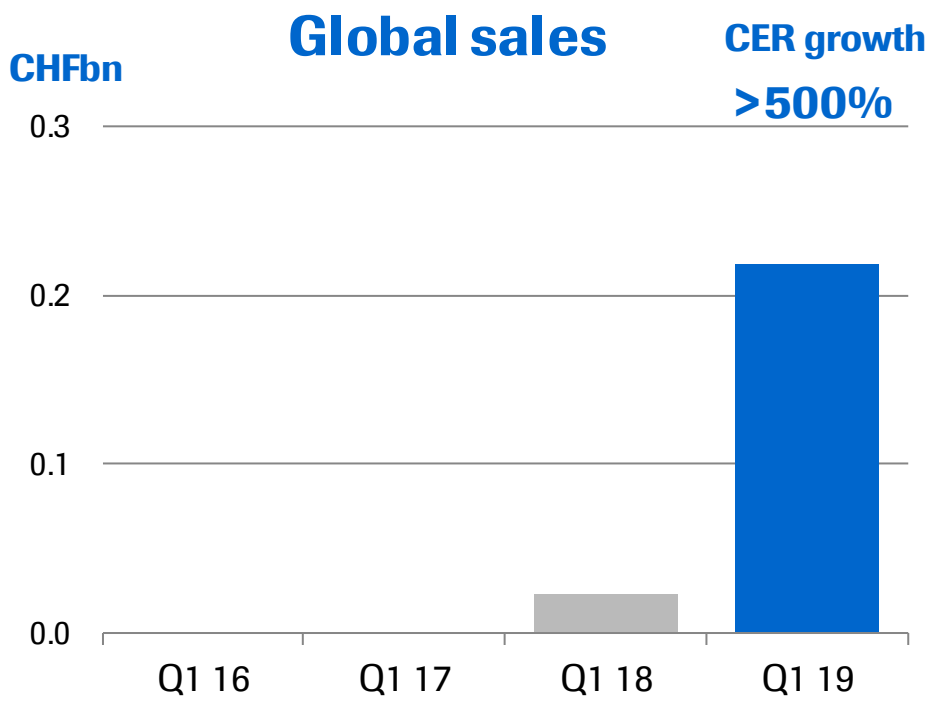


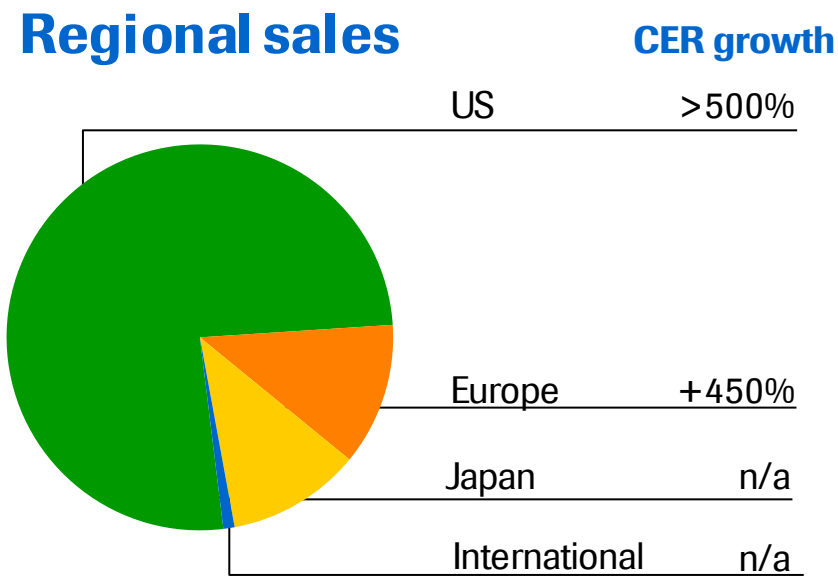
Q1 2019 sales of CHF 250m

- 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

Hemlibra





Q1 2019 sales of CHF 219m

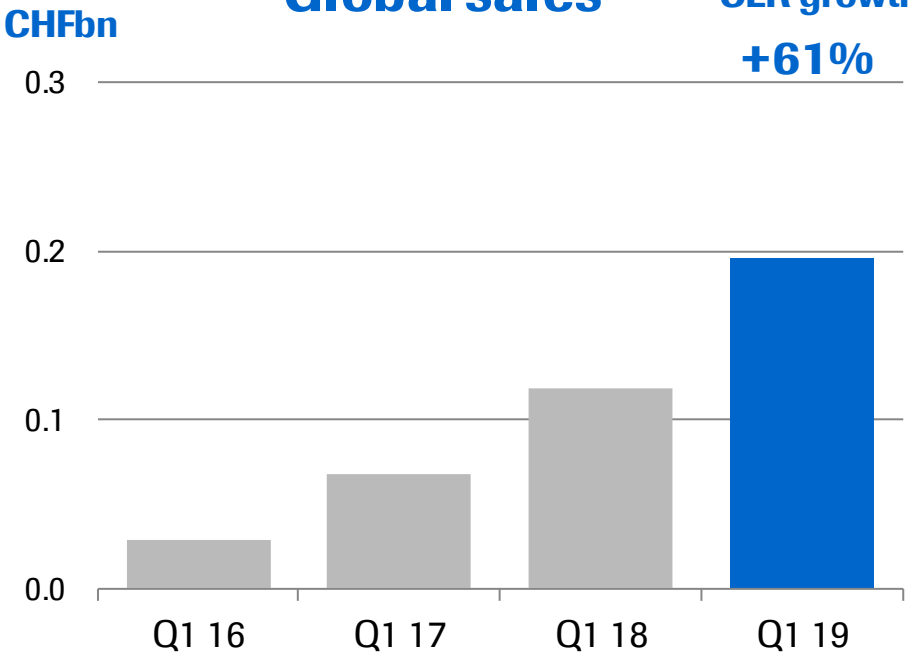
- US: Growth due to non-inhibitor approval in Q4 18
- Europe: Growth due to non-inhibitor approval in Q1 19
- Japan: Growth due to non-inhibitor approval in Q4 18

CER=Constant Exchange Rates

Alecensa

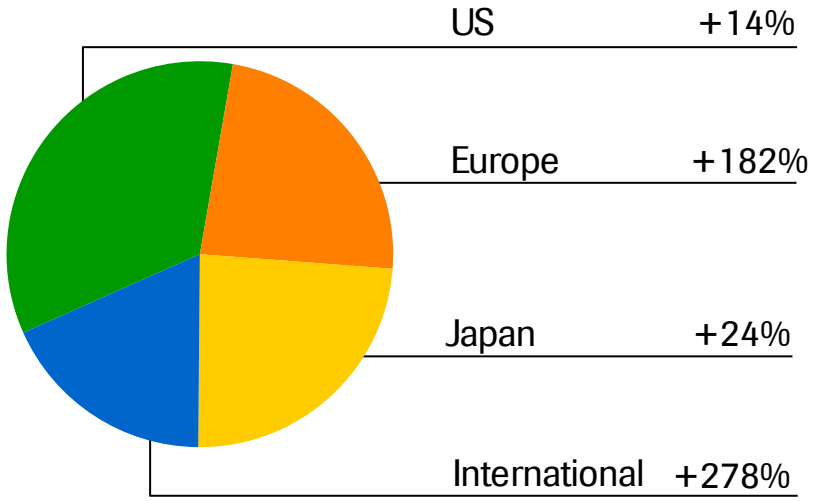
Global sales

CER growth +61%



Regional sales

CER growth



Q1 2019 sales of CHF 196m

- US: Growth due to 1L new patient share reaching 70%
- EU: Growth driven by on-going 1L launches
- Japan: Growth due to 1L new patient share approaching 70%
- International: Growth driven by launch in China

CER=Constant Exchange Rates

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group Q1 2019 sales

Diagnostics

Foreign exchange rates information

Q1 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	1,681	-1	363	-6	657	2	661	-1
Molecular Diagnostics	502	7	196	0	198	9	108	18
Diabetes Care	465	1	68	18	285	-2	112	-1
Tissue Diagnostics	251	-1	137	-7	70	6	44	11
Diagnostics Division	**2,899**	**1**	**764**	**-3**	**1,210**	**3**	**925**	**1**

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

Diagnostics Division quarterly sales and CER growth[1]

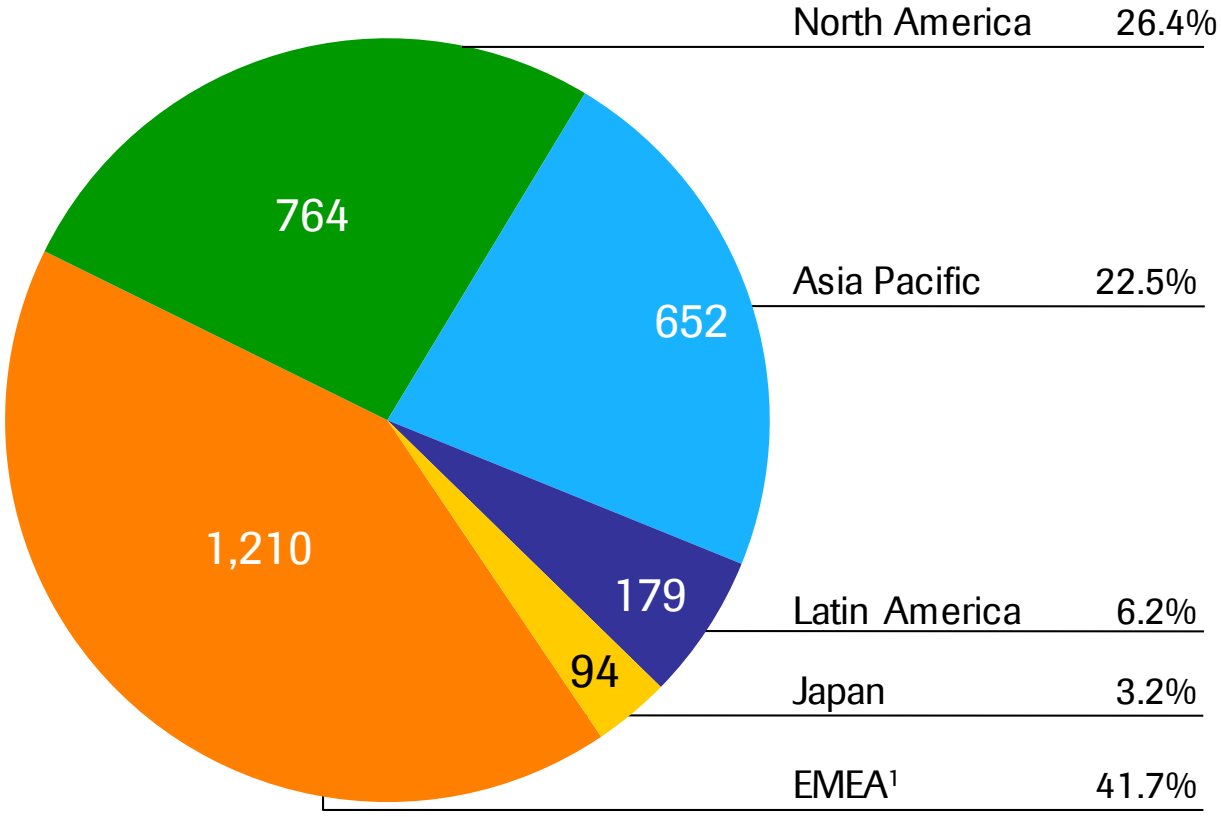
	Q4 17		Q1 18		Q2 18		Q3 18		Q4 18		Q1 19	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Centralised and Point of Care Solutions	1,968	7	1,716	4	2,039	9	1,870	8	2,143	12	1,681	-1
Molecular Diagnostics	532	5	468	6	511	4	489	5	551	6	502	7
Diabetes Care	501	-9	478	5	513	-3	493	1	496	5	465	1
Tissue Diagnostics	280	6	249	7	290	15	262	4	311	13	251	-1
Dia Division	**3,281**	**4**	**2,911**	**5**	**3,353**	**7**	**3,114**	**6**	**3,501**	**10**	**2,899**	**1**

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

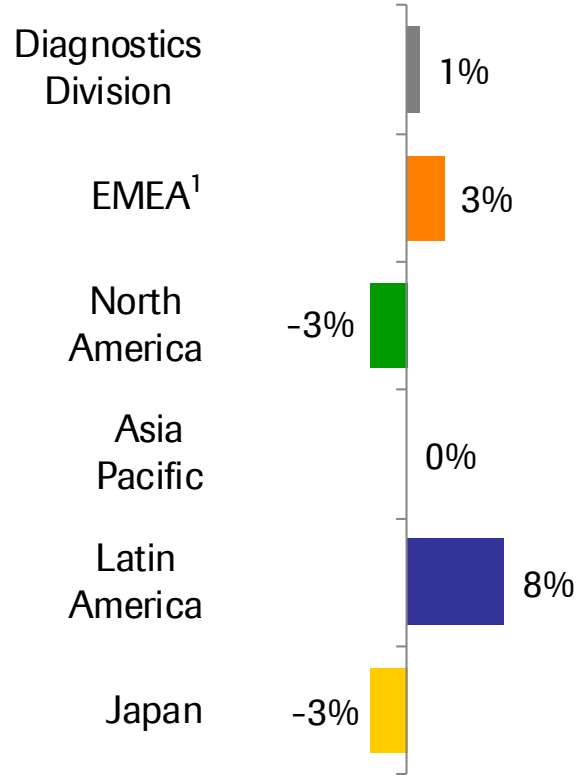
Q1 2019: Diagnostics Division sales

Growth driven by EMEA and Latin America

CHF 2,899m



CER sales growth

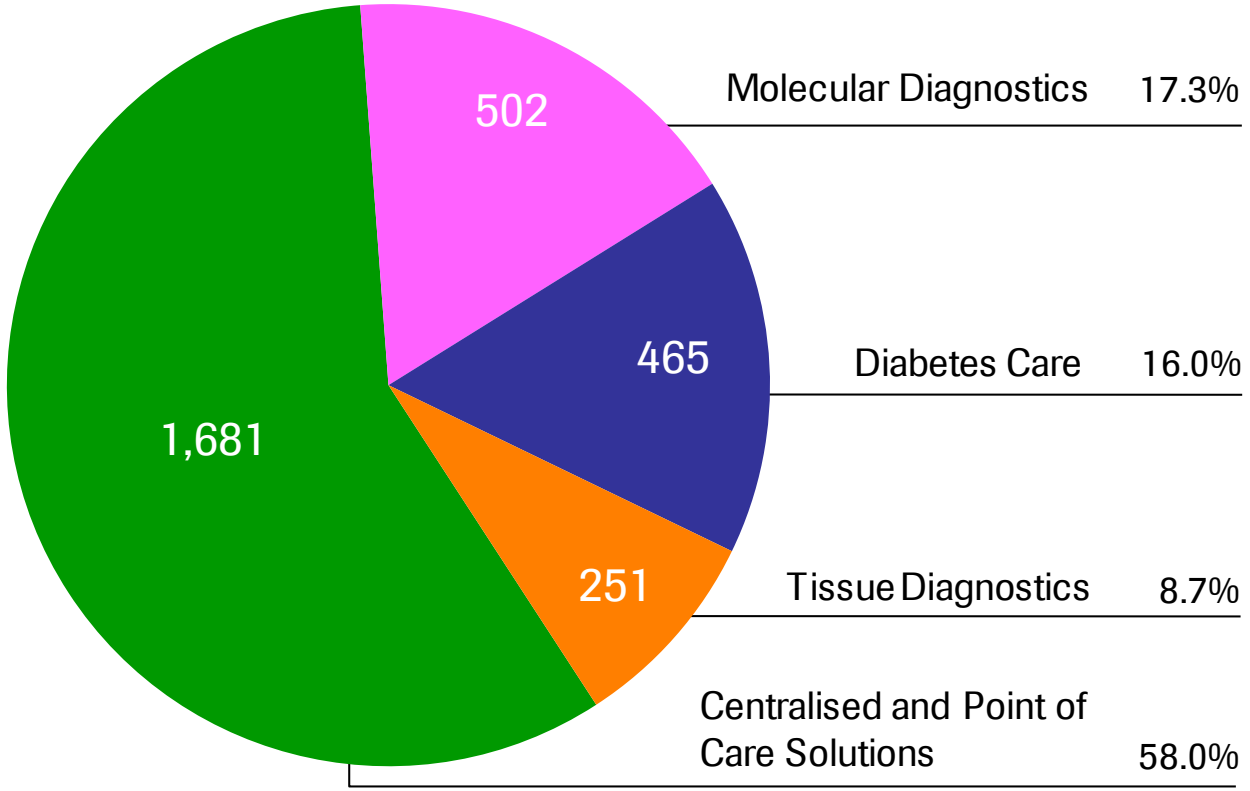


CER=Constant Exchange Rates; [1] Europe, Middle East and Africa

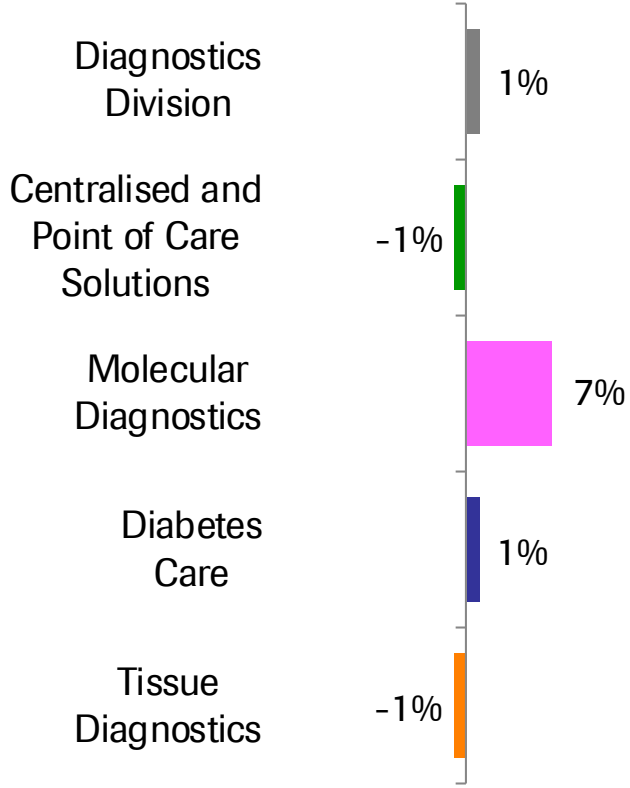
Q1 2019: Diagnostics Division sales

Growth driven by Molecular Diagnostics

CHF 2,899m

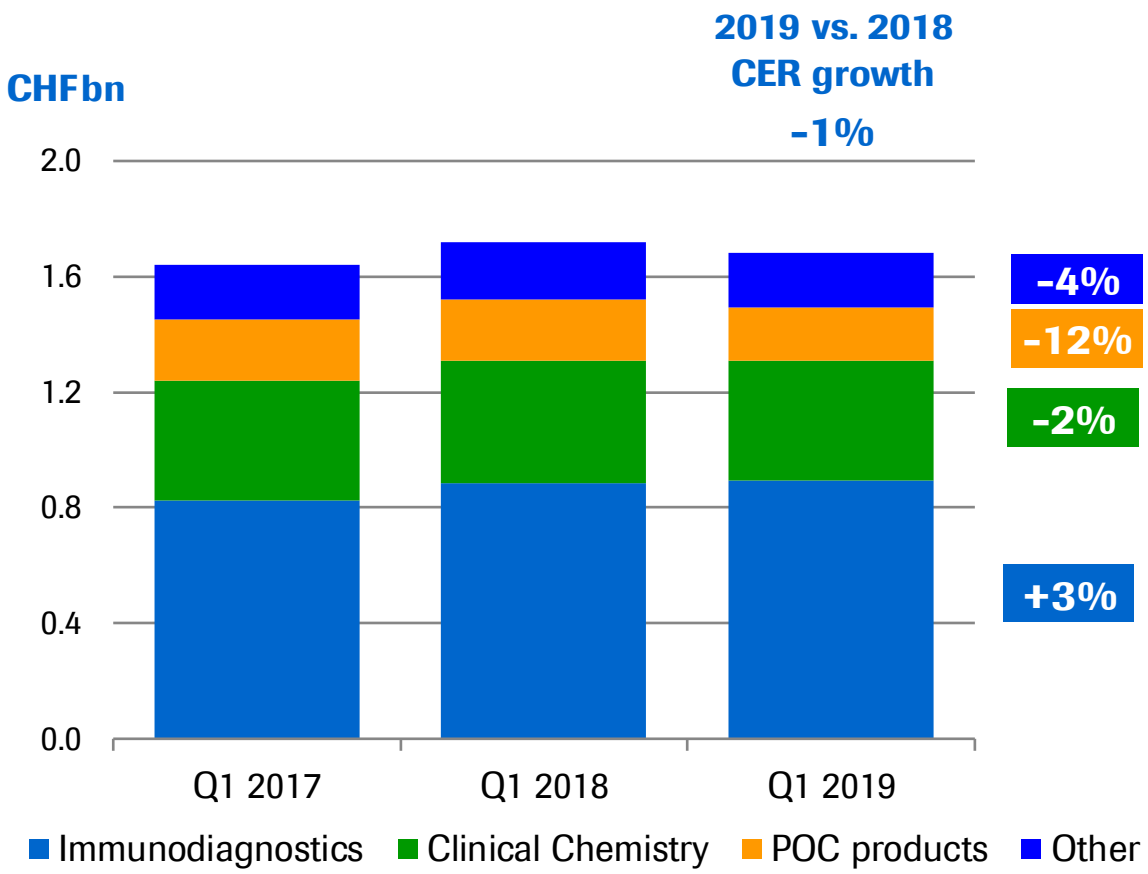


CER sales growth



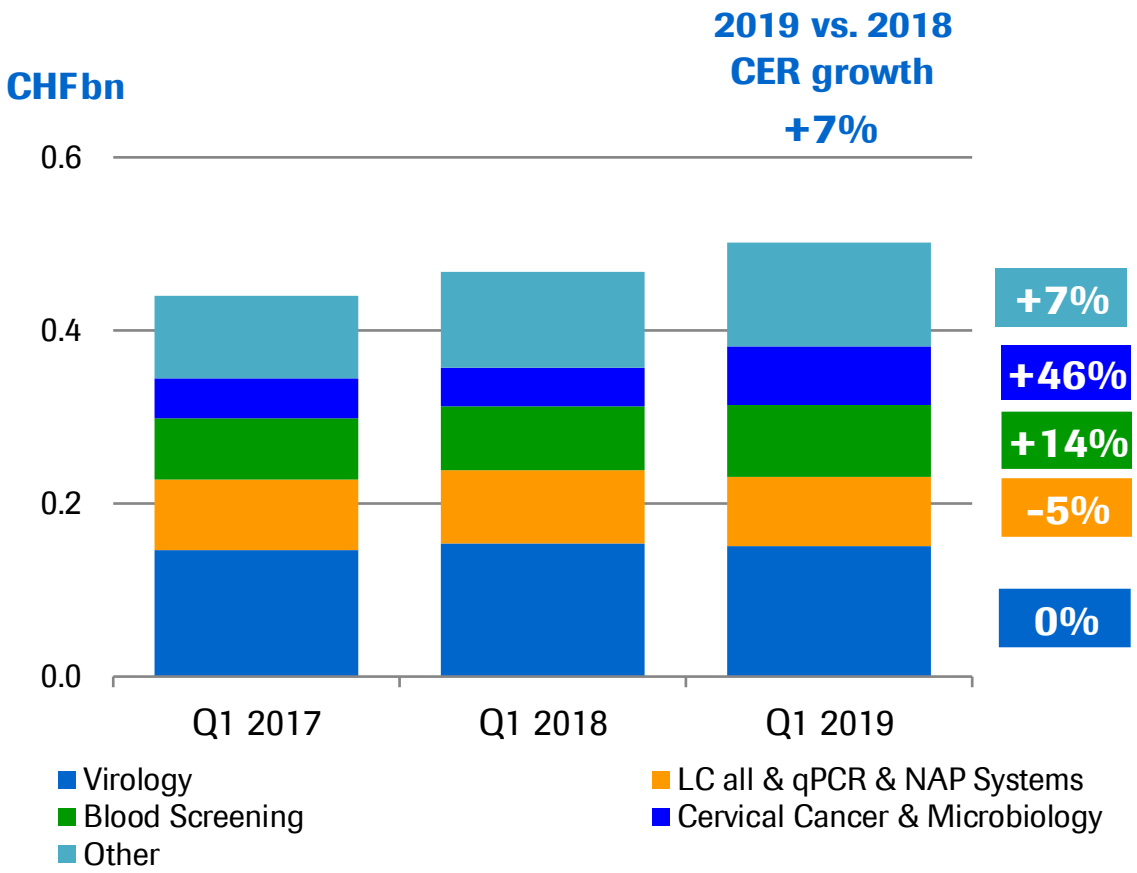
CER=Constant Exchange Rates

Centralised and Point of Care Solutions



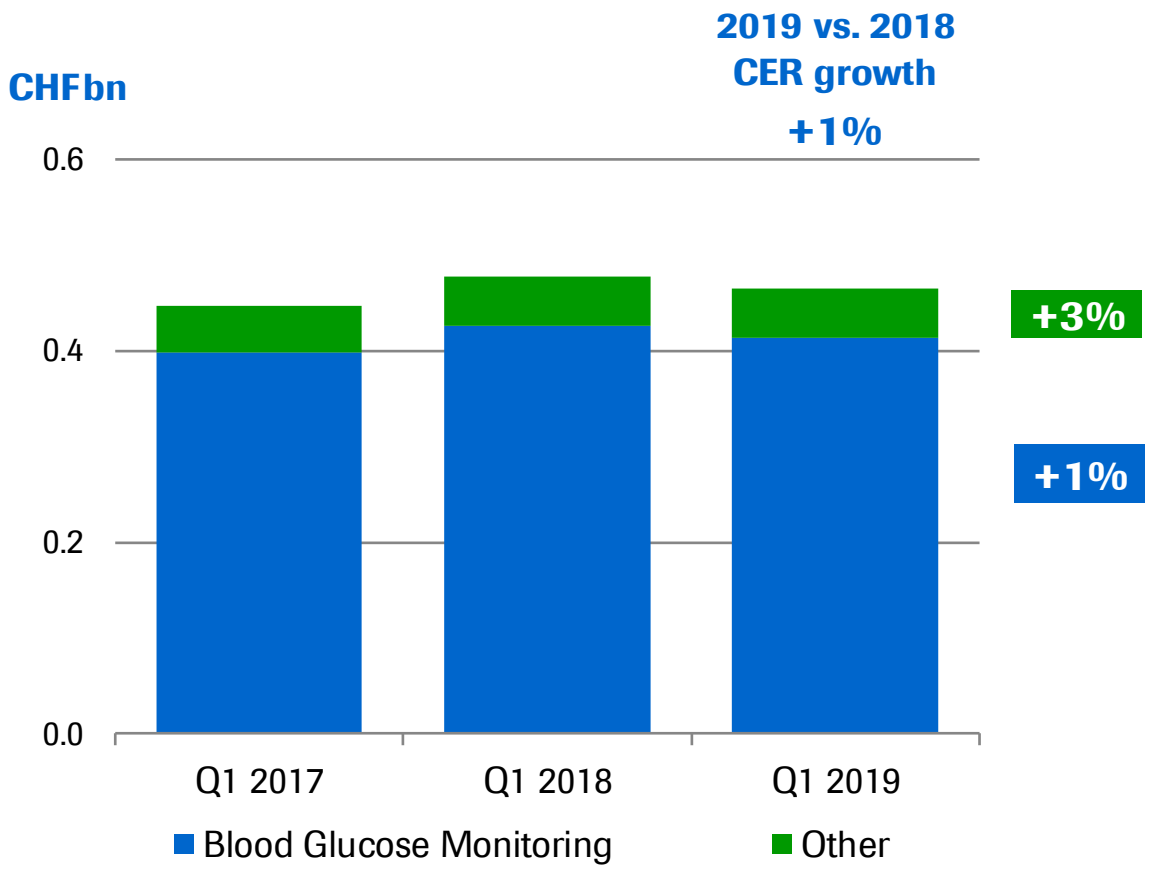
CER=Constant Exchange Rates

Molecular Diagnostics



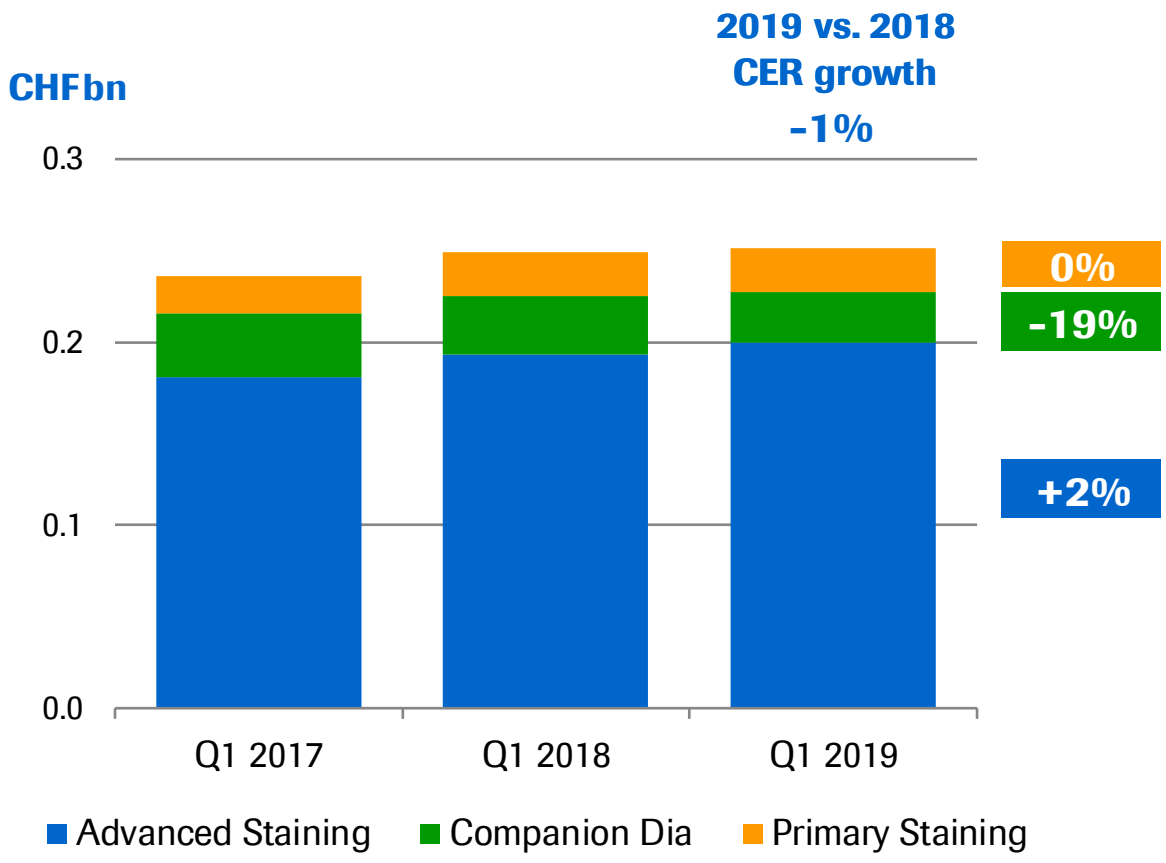
CER=Constant Exchange Rates

Diabetes Care



CER=Constant Exchange Rates

Tissue Diagnostics



CER=Constant Exchange Rates

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

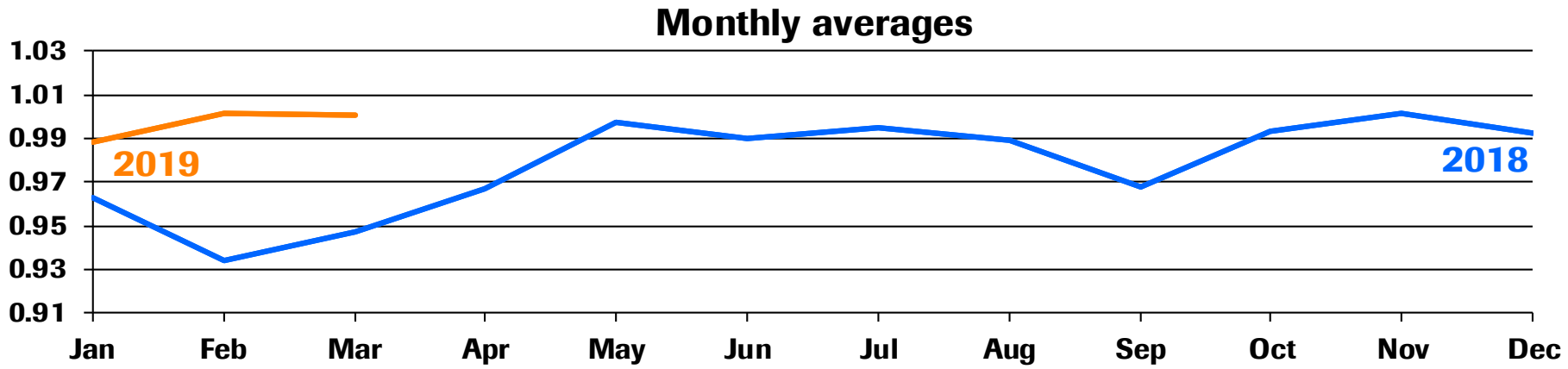
gRED (Genentech Research & Early Development)

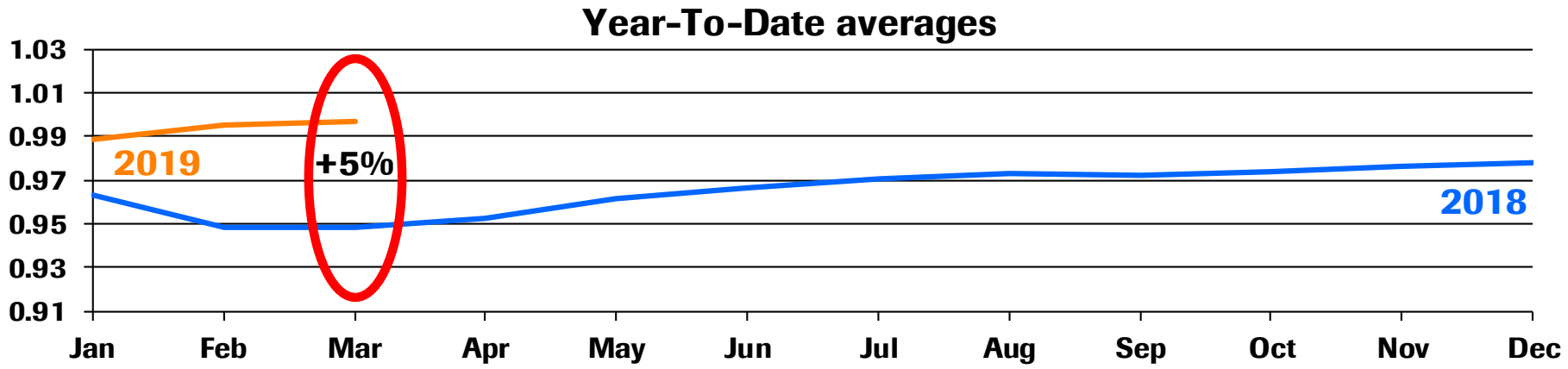
Roche Group Q1 2019 sales

Diagnostics

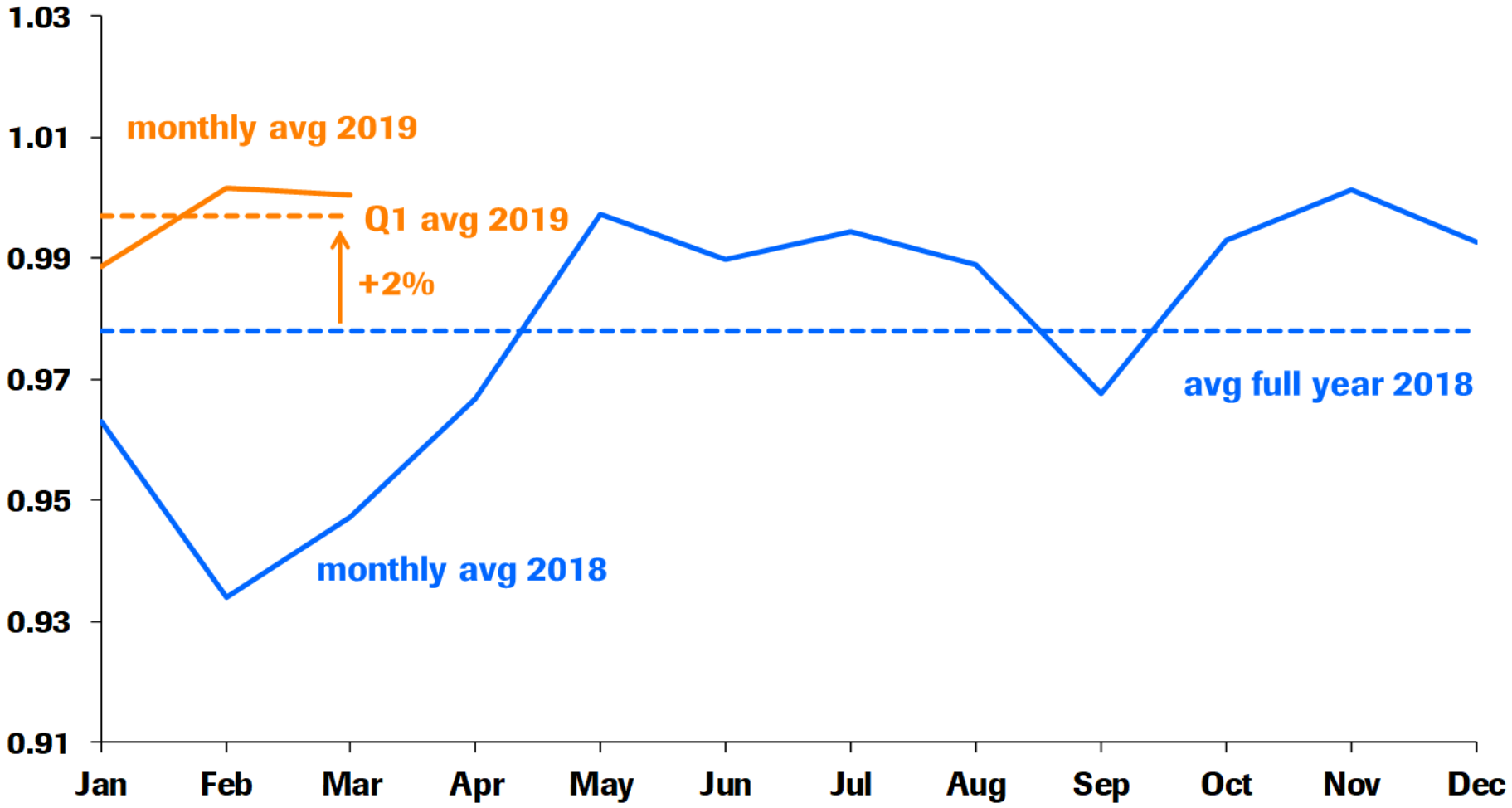
Foreign exchange rates information

CHF / USD

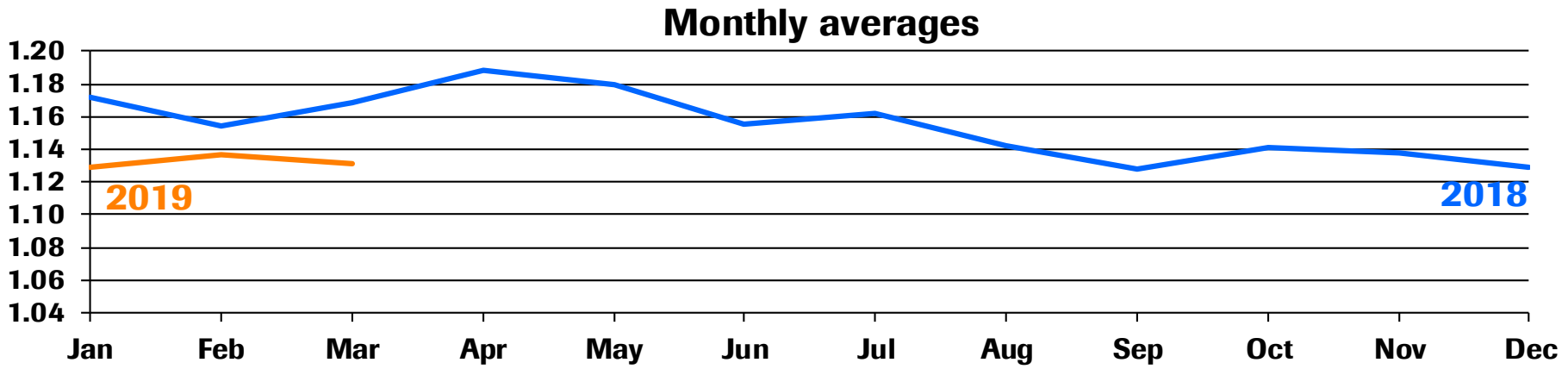

Monthly averages
1.03
1.01
0.99
0.97
0.95
0.93
0.91
2019
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

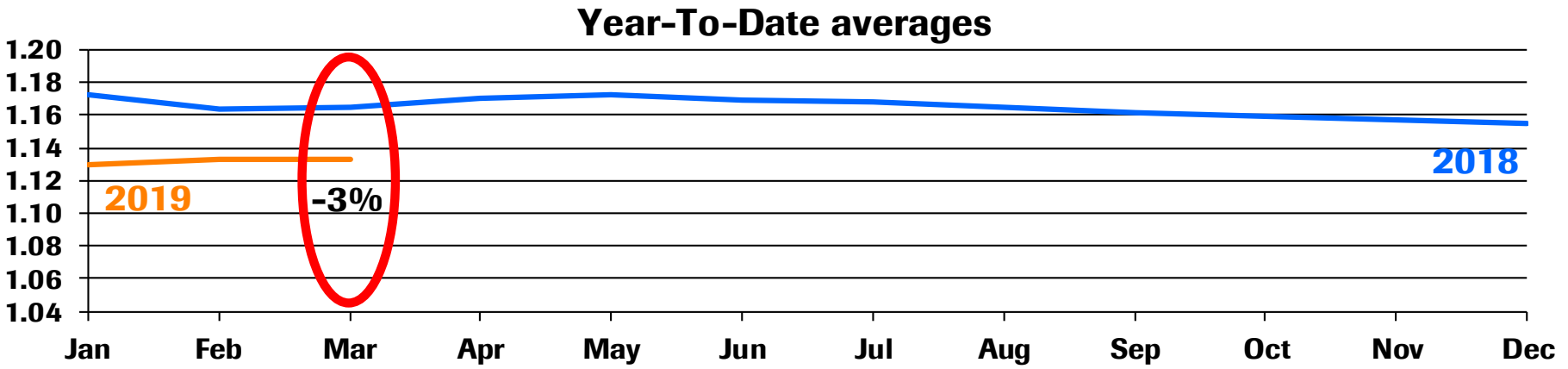

Year-To-Date averages
1.03
1.01
0.99
0.97
0.95
0.93
0.91
2019
+5%
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / USD

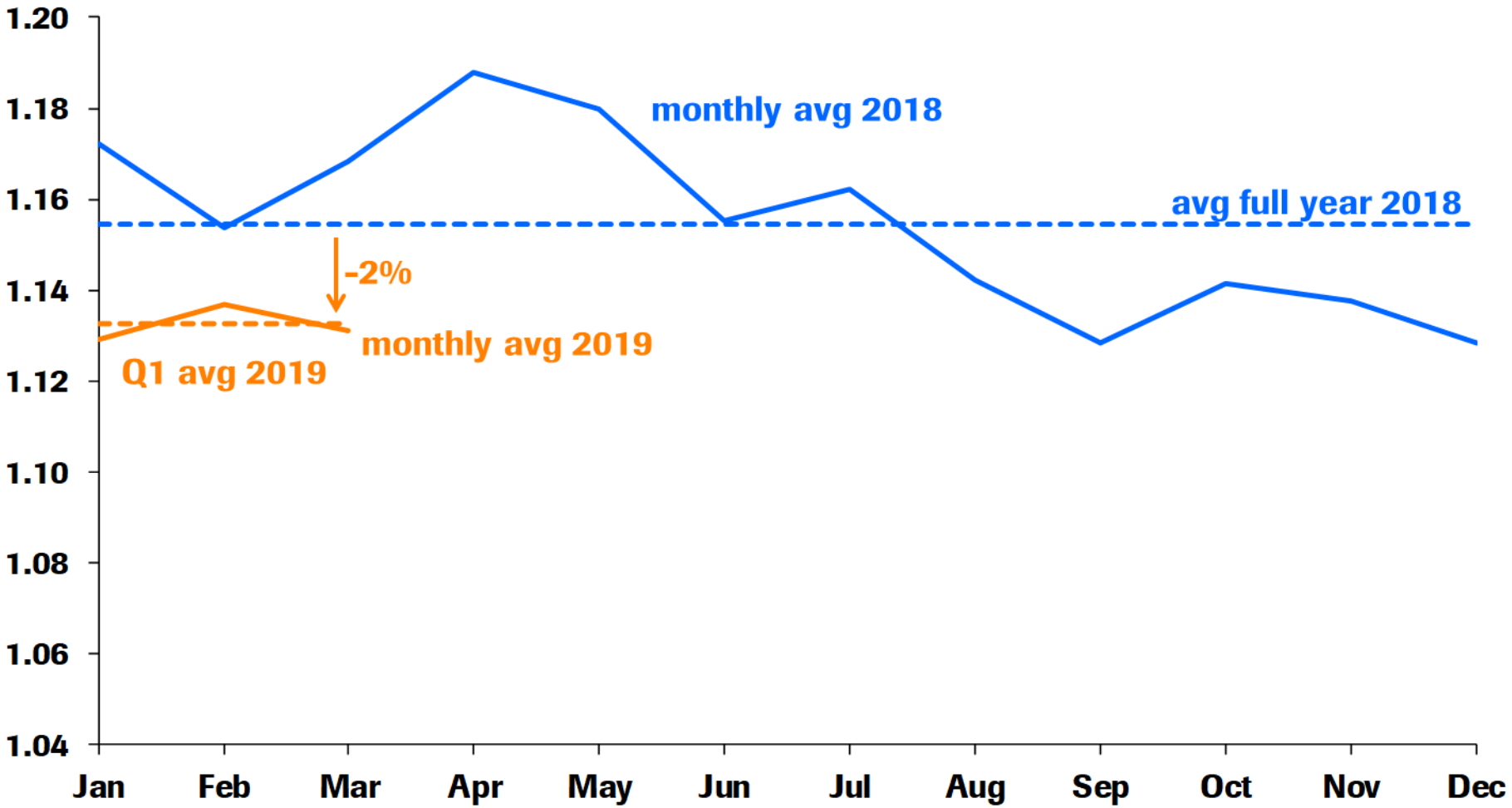

1.03
1.01
0.99
0.97
0.95
0.93
0.91
monthly avg 2019
Q1 avg 2019
+2%
avg full year 2018
monthly avg 2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / EUR


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

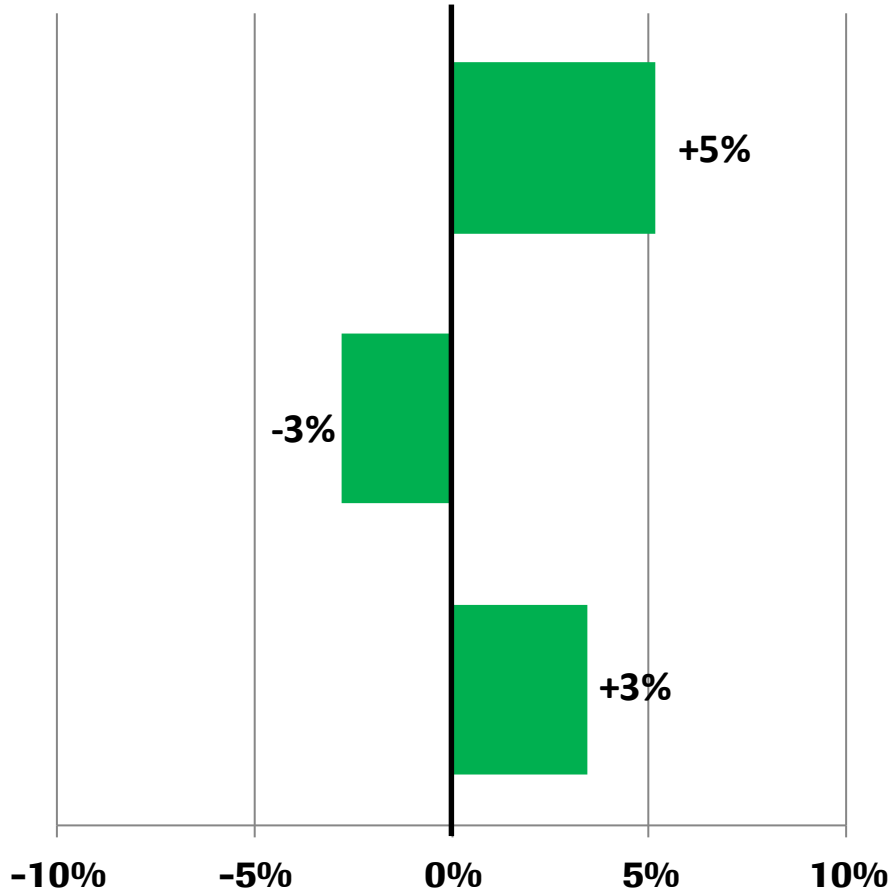

Year-To-Date averages
1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
2019
-3%
2018
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

CHF / EUR


1.20
1.18
1.16
1.14
1.12
1.10
1.08
1.06
1.04
monthly avg 2018
avg full year 2018
-2%
monthly avg 2019
Q1 avg 2019
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

Average CHF exchange rates

	Q1 2019	Q1 2018
USD	1.00	0.95
EUR	1.13	1.16
JPY	0.90	0.87

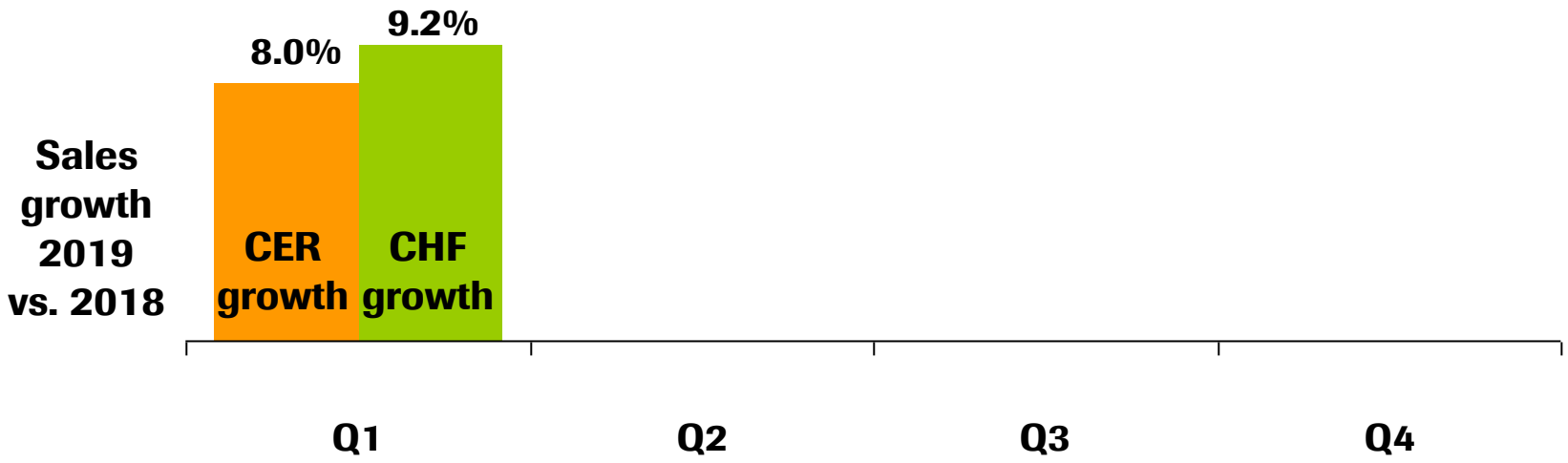


Exchange rate impact on sales growth

In Q1 2019 positive impact of USD and JPY, partially offset by EUR

Development of average exchange rates versus prior year period

CHF / USD	+5.1%
CHF / EUR	-2.8%
CHF / JPY	+3.4%
Difference in CHF / CER growth	+1.2%p



CER=Constant Exchange Rates

Doing now what patients need next