
Roche

Roche

Q1 2017 sales

Basel, 27 April 2017

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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;
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Group

Severin Schwan

Chief Executive Officer

Q1 2017 performance

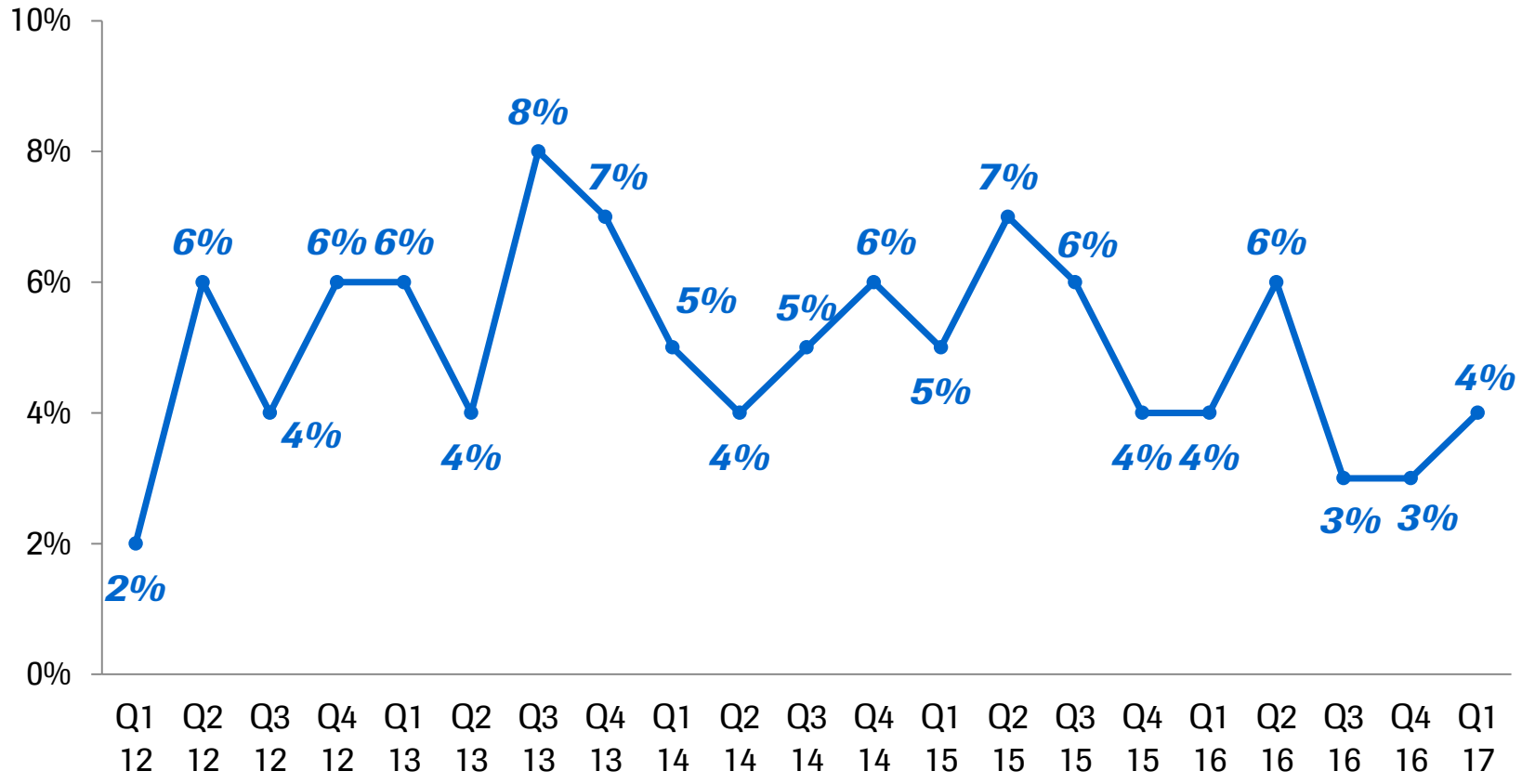
Outlook

Q1 2017: Strong sales growth in both divisions

	2017 CHFbn	2016 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	**10.2**	9.8	**4**	**3**
Diagnostics Division	**2.8**	2.6	**6**	**6**
Roche Group	**12.9**	12.4	**4**	**4**

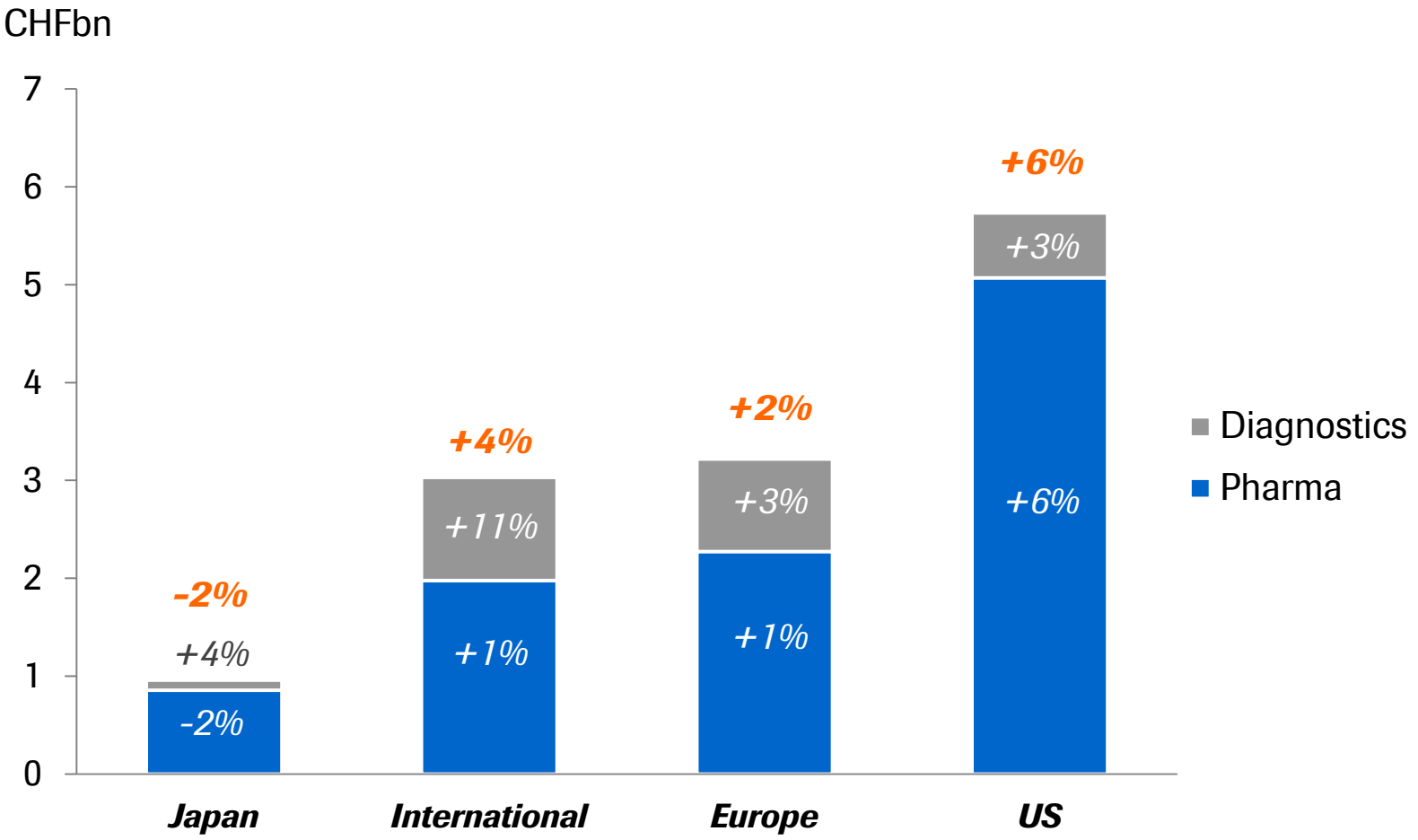
CER=Constant Exchange Rates

Q1 2017: Sales growth for the sixth consecutive year



All growth rates at Constant Exchange Rates (CER)

Q1 2017: Strong sales growth in US, International and Europe



All growth rates at Constant Exchange Rates (CER)

Roche significantly advancing patient care

Recognition for innovation 2013-present

15 *Breakthrough Therapy Designations*

Rank	Company	#
1	**Roche**	**15**
2	Novartis	11
3	BMS	10
3	Merck	9
4	AbbVie	7
4	Pfizer	7

Year	Molecule
2017	***Rituxan*** *(Pemphigus vulgaris)*
2016	***Actemra*** *(Giant cell arteritis)*
	Alecensa *(1L ALK+ NSCLC)*
	Ocrevus *(PPMS)*
	Venclexta *(AML)*
	Venclexta *+* ***Rituxan*** *(R/R CLL)*
2015	***Actemra*** *(Systemic sclerosis)*
	Tecentriq *(NSCLC)*
	Venclexta *(R/R CLL 17p del)*
	Emicizumab*/ACE 910 (Hemophilia A)*
2014	***Esbriet*** *(IPF)*
	Lucentis *(Diabetic retinopathy)*
	Tecentriq *(Bladder)*
2013	***Alecensa*** *(2L ALK+ NSCLC)*
	Gazyva *(1L CLL)*

Source: http://www.focr.org/breakthrough-therapies as of March 2017; PPMS=Primary Progressive Multiple Sclerosis; CLL=Chronic Lymphocytic Leukemia; NSCLC=Non-Small Cell Lung Cancer; IPF=Idiopathic Pulmonary Fibrosis

Q1 2017: Major launch activities started

Ocrevus (RMS and PPMS)	• First medicine in PPMS, first B-cell targeted in RMS • Indications granted w/o limitations* • No black box warning • No extra requirements for screening or monitoring
Lucentis (Diabetic Retinopathy[1])	• First in class
Tecentriq (1L bladder cancer[2])	• First in class
Diagnostics	• FDA approval of cobas e 801

* for example line of therapy, patient population etc., [1] DR independent of macular edema; [2] 1L cisplatin-ineligible

Q1 2017: Major read-outs securing future growth

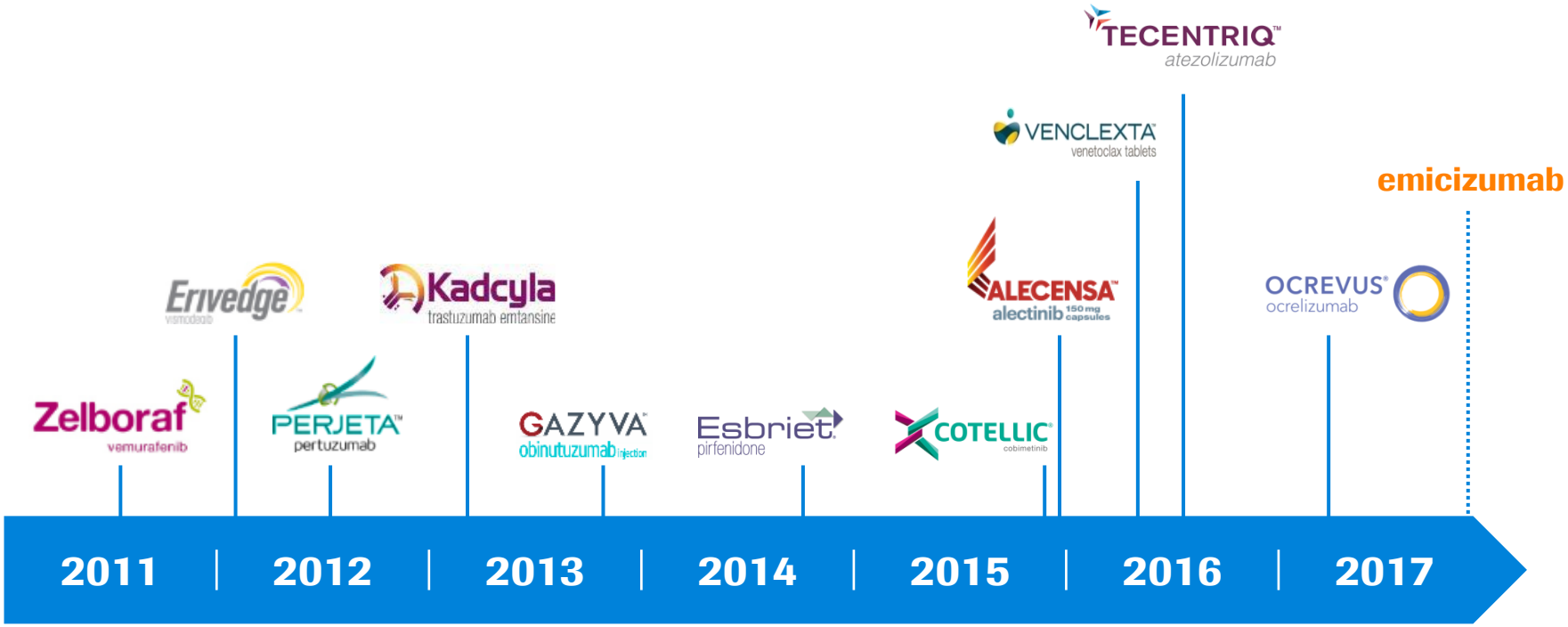
Perjeta (Early breast cancer)	• APHINITY: Best in class, reducing risk recurrence of invasive cancer or death
emicizumab (Hem. A inhibitors)	• HAVEN1 (Adults): Superiority vs Standard of Care • HAVEN2 (Pediatric): Positive interim result
Alecensa (ALK+ lung cancer)	• ALEX: Superiority in 1L vs Standard of Care • ALUR: Superiority in 2/3L vs Standard of Care
Rituxan (SC, Pemphigus vulgaris)	• SC: Positive ODAC vote (11:0) • Pemphigus vulgaris: BTD granted

SC=Subcutaneous; ODAC=Oncologic Drug Advisory Committee; BTD=Breakthrough Therapy Designation

Q1 2017 performance

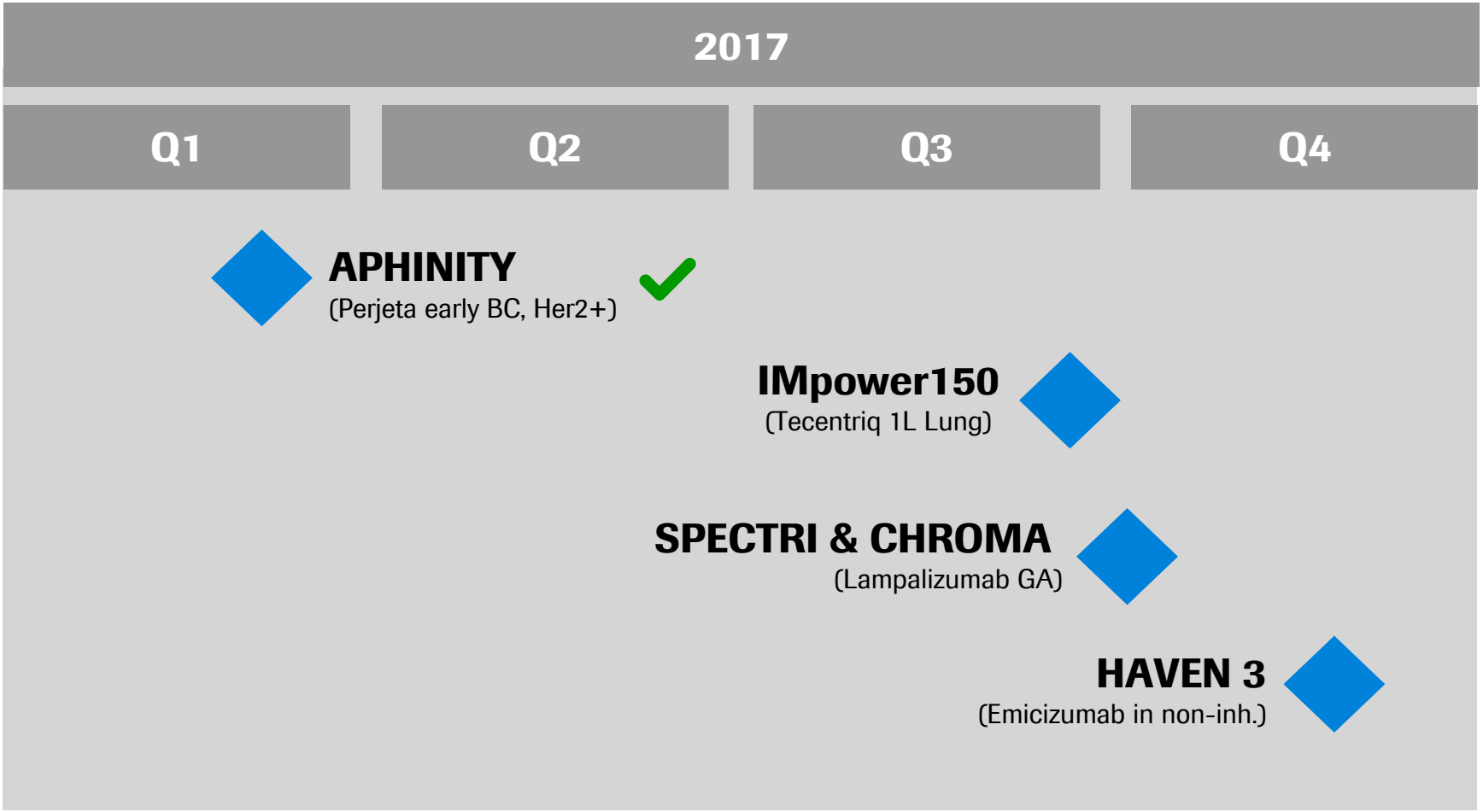
Outlook

Launch of new medicines at a record high



2017: Another important year for our pipeline

Key read-outs



Outcome studies are event-driven: timelines may change

2017 outlook

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

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Daniel O'Day

CEO Roche Pharmaceuticals

Q1 2017 sales

Innovation

Outlook

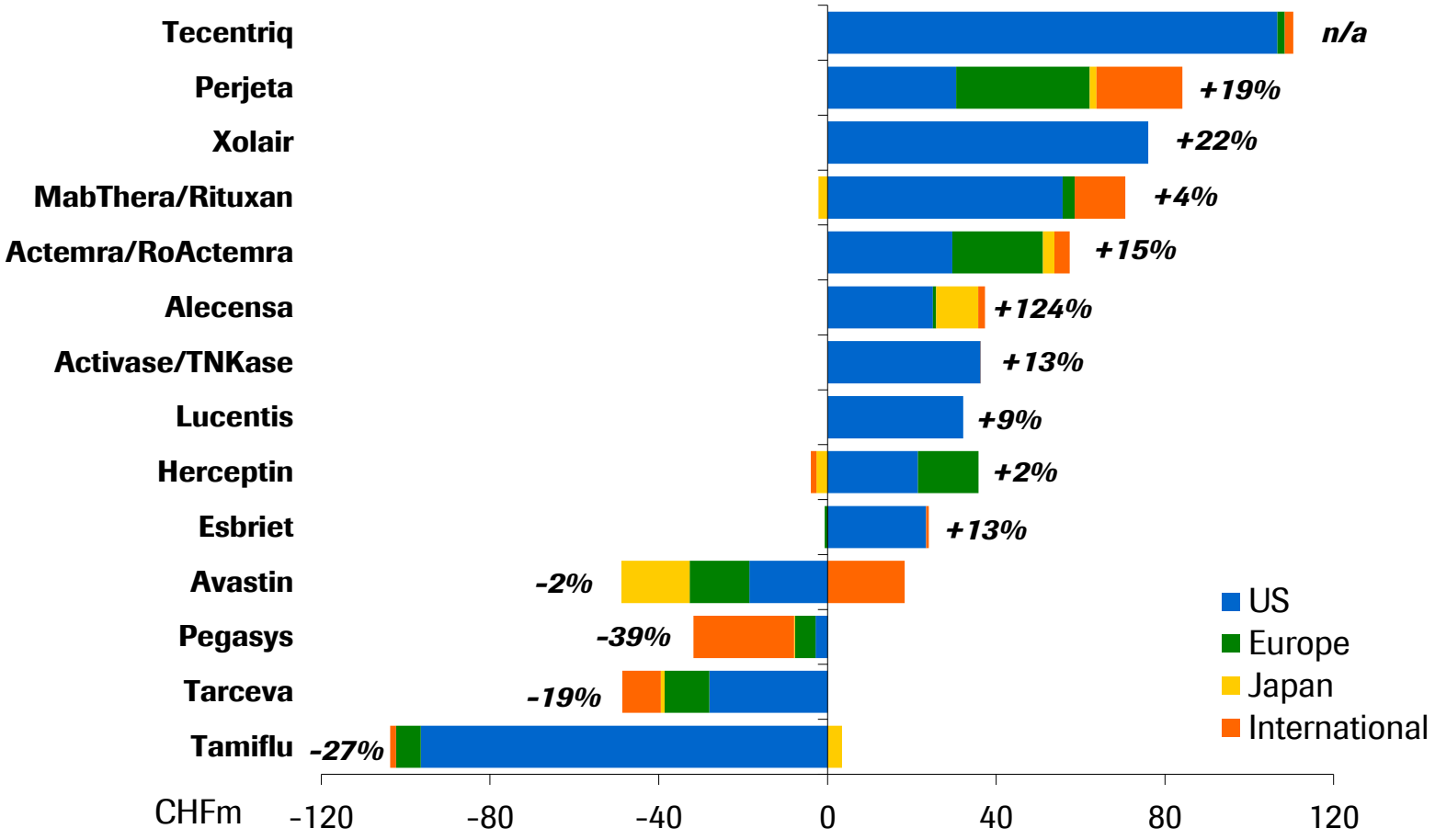
Q1 2017: Pharma sales

Strong growth in the US due to ongoing launches

	2017 CHFm	2016 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**10,177**	**9,800**	**4**	**3**
United States	5,070	4,716	8	6
Europe	2,273	2,319	-2	1
Japan	856	853	0	-2
International	1,978	1,912	3	1

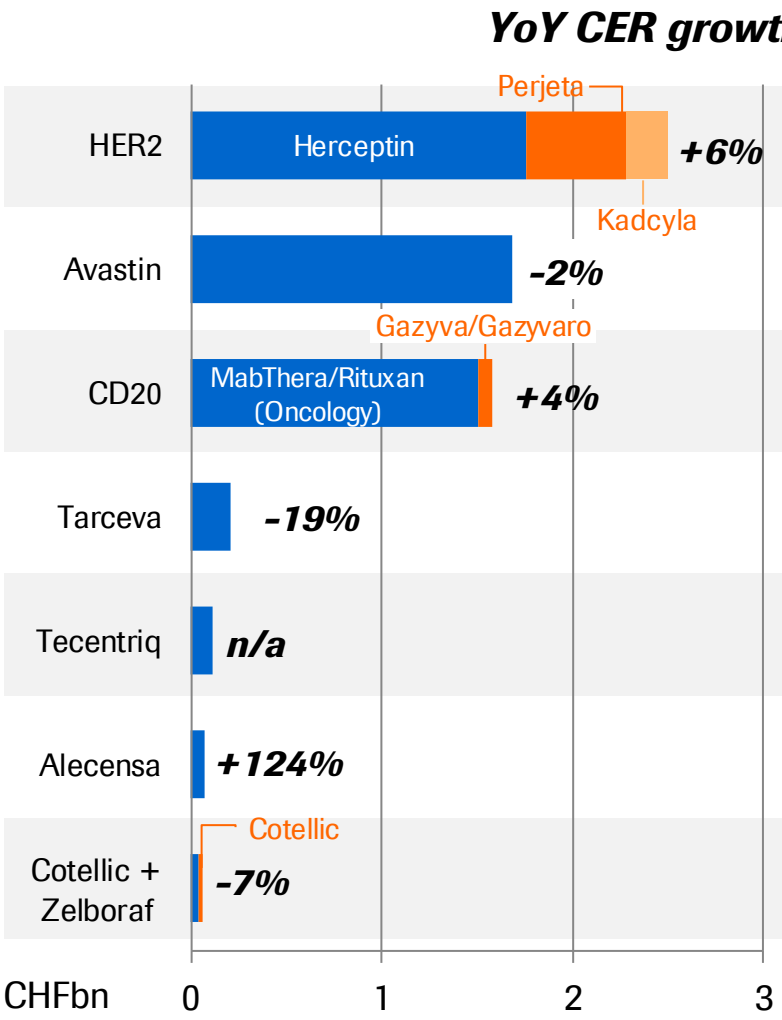
CER=Constant Exchange Rates

Q1 2017: Strong sales performance with increasing contribution from new launches



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

Q1 2017: Oncology +4% growth



- Perjeta: Strong sales growth in all regions
- Kadcyla: Strong sales growth in US, EU and International

- Growth impacted by competition and pricing in Japan

- Gazyva in R/R FL (iNHL) (GADOLIN) off to a good start
- Gazyva in 1L FL (iNHL) (GALLIUM) on NCCN guidelines

- Increased competition

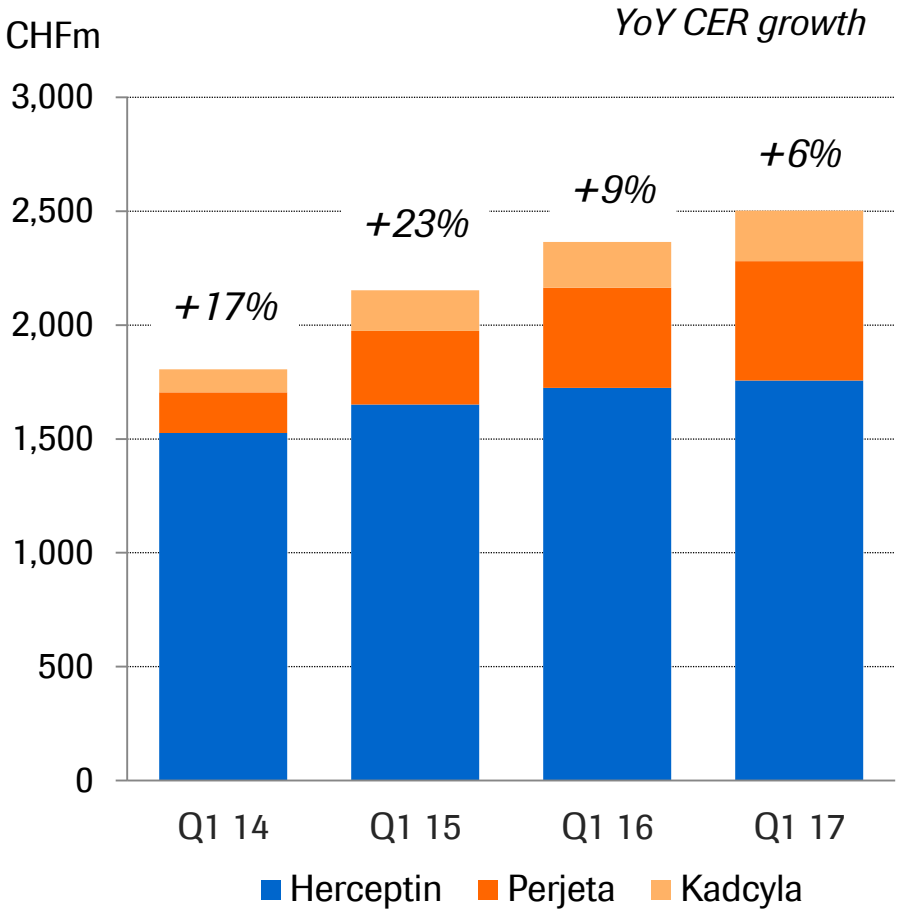
- US: 2L bladder gaining market share
- US: 1L cisplatin-ineligible bladder approved
- US: Gaining share in 2/3L lung (all-comers label)

- US: 2L market leadership achieved after 12 months
- US/EU: 1L positive ALEX data at ASCO

- Cotellic+Zelboraf stable market share in 1L and 2L

CER=Constant Exchange Rates
Q1 2017 Oncology sales: CHF 6.4bn; CER growth +4%

HER2 franchise: Growth driven by Perjeta



HER2 franchise Q1 2017

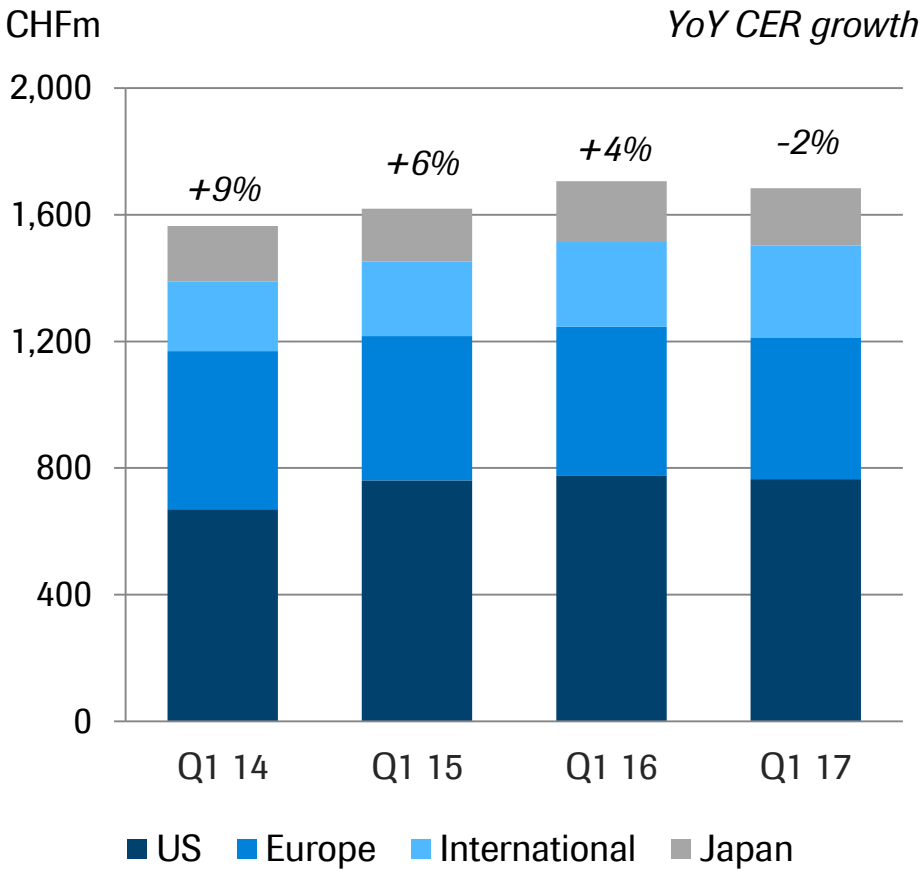
- Perjeta (+19%): Strong demand driven by all regions
- Herceptin (+2%): Volume growth in EU due to longer treatment duration
- Kadcyla (+11%): Growth in US, EU and International

Outlook 2017

- US/EU filing of APHINITY (adj. BC)
- Herceptin: Further SC conversion
- Perjeta: Further increasing penetration

CER=Constant Exchange Rates

Avastin: International growth partly offsets performance in developed markets



Avastin Q1 2017

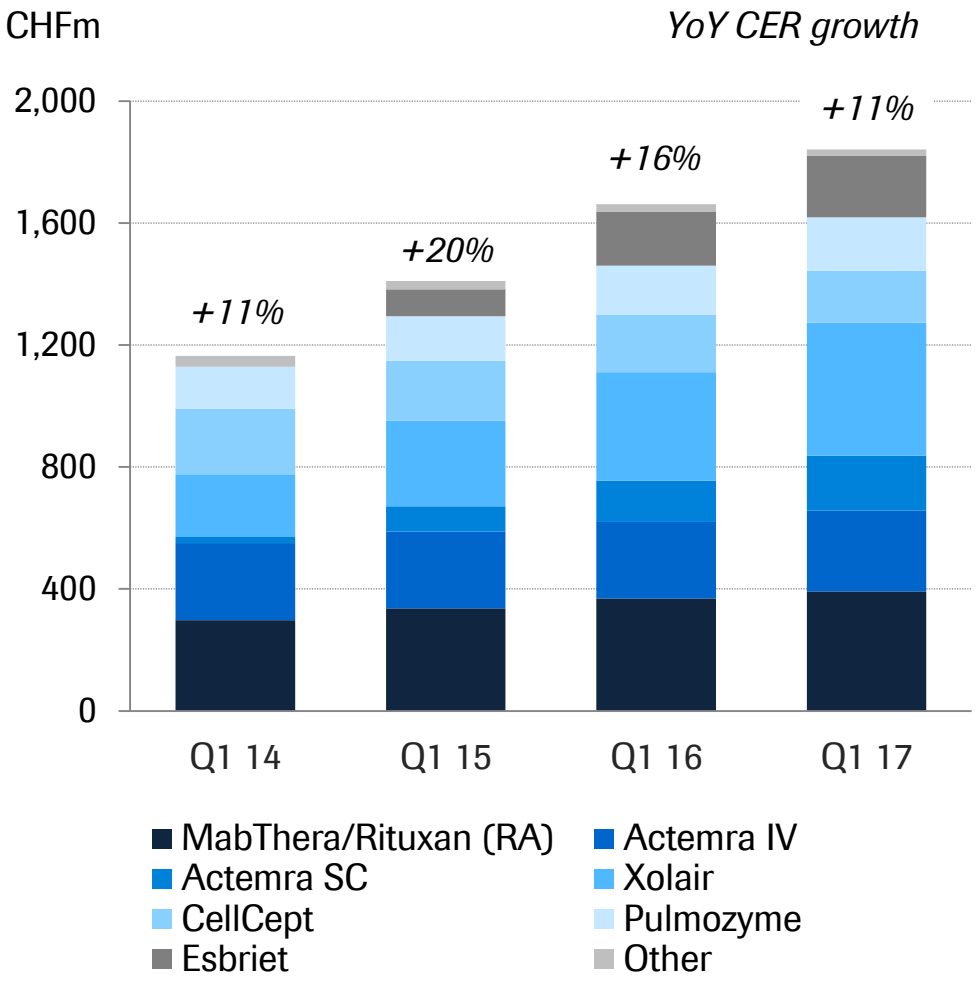
- US (-2%): Competition in lung from cancer immunotherapies
- Japan (-8%): Base effect from mandatory price cut in Japan
- International (+7%): Growth driven by launches in China

Outlook 2017

- Continued uptake in ovarian cancer
- Ph III (IMpower150) results in 1L lung for Tecentriq+Avastin+chemo expected in Q3/4

CER=Constant Exchange Rates

Immunology franchise growing above CHF 7bn annualised; further launches in 2017



Immunology Q1 2017

Xolair (+22%)

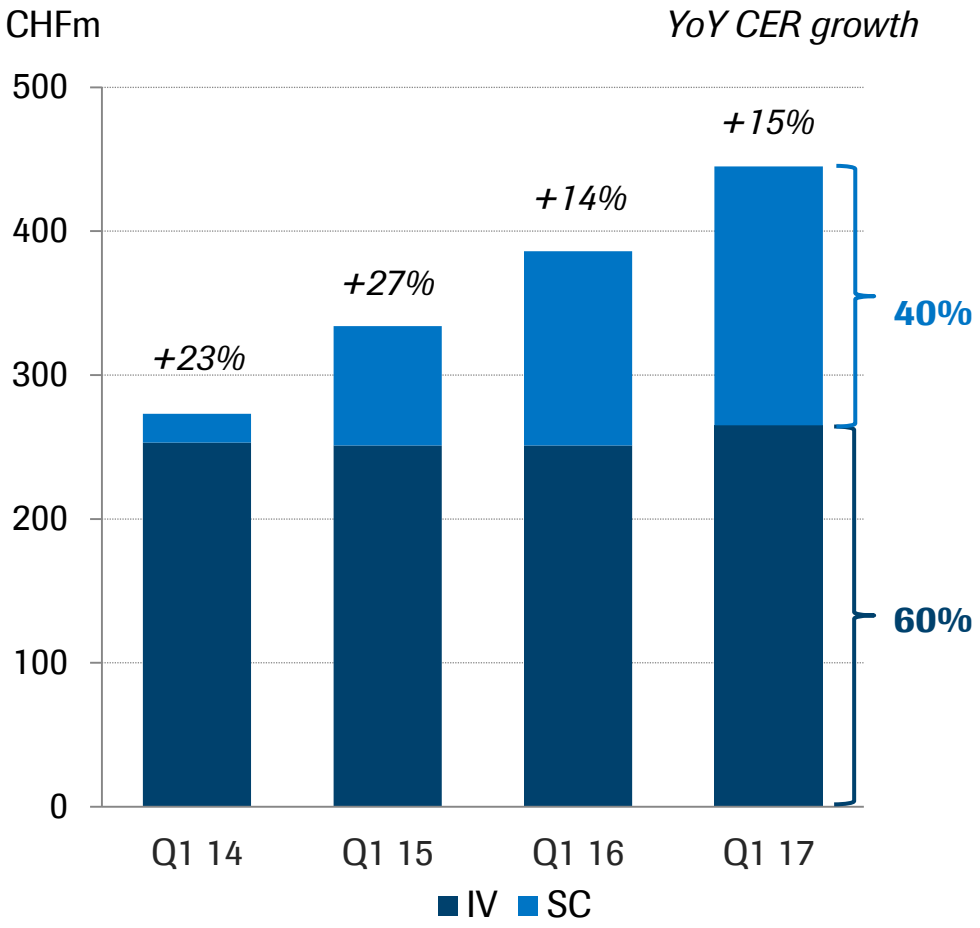
- Allergic asthma & chronic idiopathic urticaria driving growth
- Asthma: US pediatrics launch on-going; only biologic approved for children

MabThera/Rituxan (+7%)

- Continues to grow in rheumatoid arthritis and vasculitis (GPA and MPA)
- BTD for pemphigus vulgaris

CER=Constant Exchange Rates; GPA=granulomatosis with polyangiitis; MPA=microscopic polyangiitis; BTD=breakthrough therapy designation

Actemra/RoActemra: Strong growth driven by SC formulation and 1L monotherapy



PDUFA date
Giant cell arteritis
May 22

Actemra Q1 2017

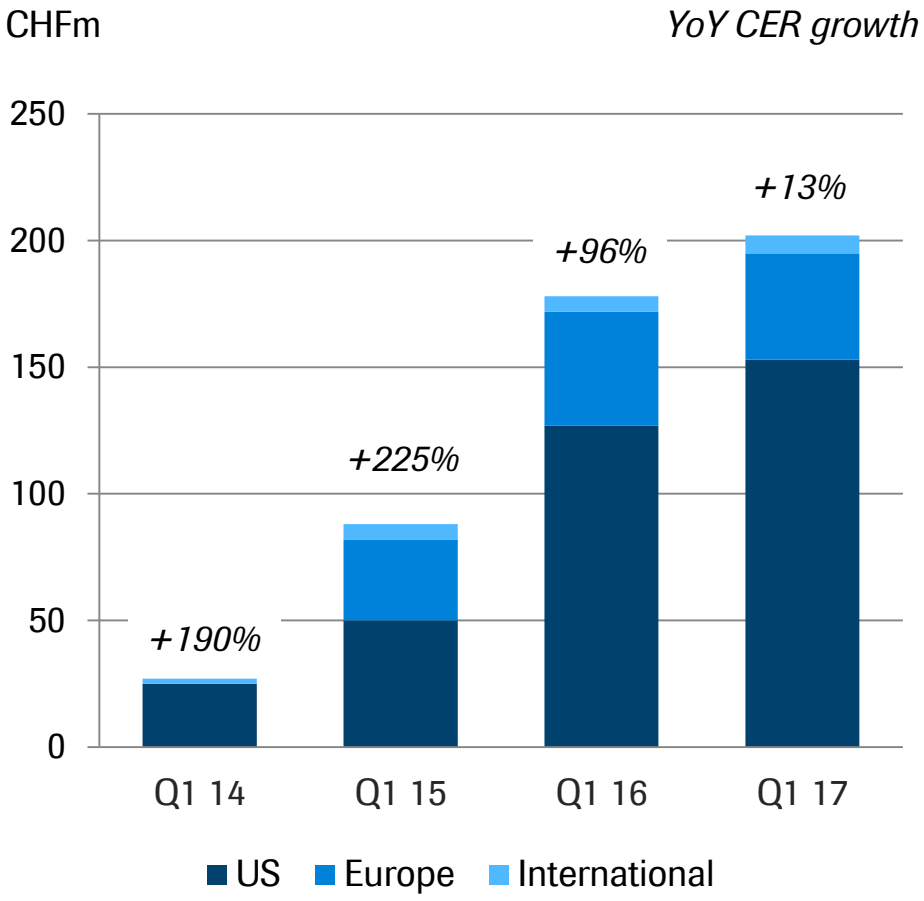
- US (+21%): Increasing SC uptake
- EU (+17%): Increasing monotherapy market share, also in 1L

Outlook 2017

- Increasing 1L monotherapy leadership
- US/EU approval in giant cell arteritis (2nd BTD and priority review for Actemra)

CER=Constant Exchange Rates; IV=intravenous; SC=subcutaneous; BTD=breakthrough therapy designation

Esbriet: Continuing to target mild to moderate patient populations



Esbriet Q1 2017

- Market leadership in the US and EU5
- US (+19%): Growth driven by penetration into moderate and severe patient segments
- EU (-2%): Overall market leadership in EU5 markets, increased competition

Outlook 2017

- Increased investments in patient education regarding benefits of earlier treatment

CER=Constant Exchange Rates

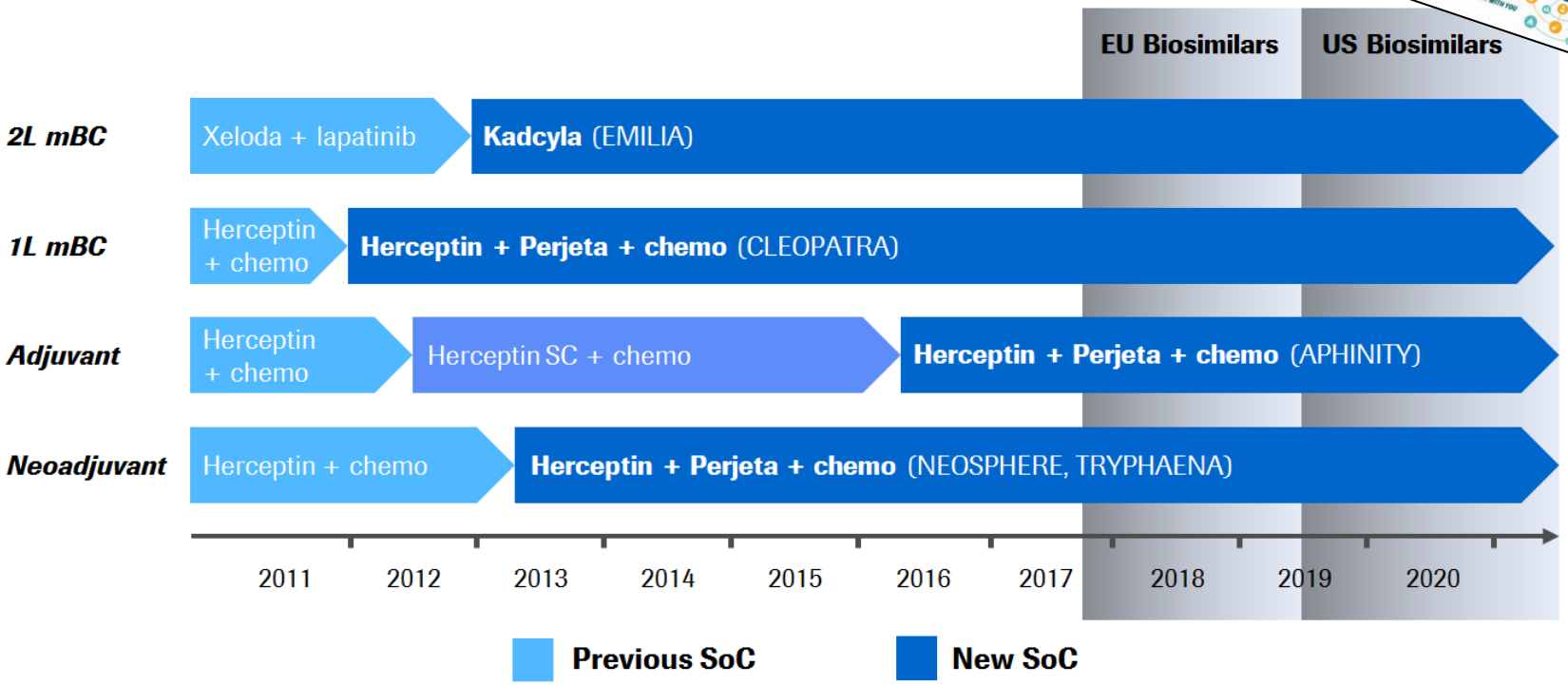
Q1 2017 sales

Innovation

Outlook

Herceptin+Perjeta: Positive results in adjuvant BC

Keeping the HER2 franchise growing



- Phase III study (APHINITY) met primary endpoint (improvement in invasive disease-free survival)
- Results to be presented at ASCO on June 5th and to be filed in the US/EU
- SC co-formulation of Herceptin + Perjeta in development

BC=breast cancer; mBC=metastatic breast cancer; L=line of treatment; SoC=standard of care; SC=subcutaneous

Alecensa: Positive results in 1L ALK+ NSCLC

ALKi with proven strong activity in the brain

Phase III ALEX

- Second Phase III head-to-head study showed Alecensa was superior to crizotinib in 1L ALK+ lung cancer
- Patients receiving Alecensa lived significantly longer without their disease progressing (PFS)
- Safety profile was consistent with previous studies
- Results to be presented at ASCO

1L lung

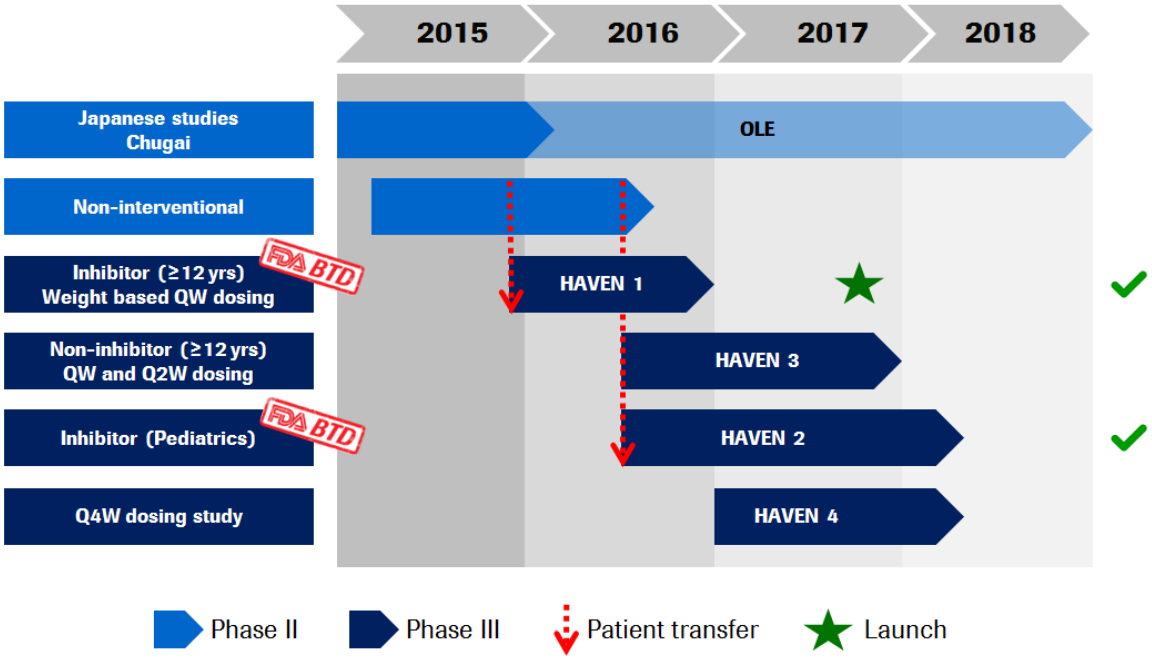
- Phase III data (ALEX) to be filed in the US/EU
- Breakthrough therapy designation
- Japanese market share >60%

2L lung

- Positive Phase III study ALUR supports use in chemo/crizotinib failed patients
- EU approval achieved in Q1
- US market share of 50% after 12 months

Alecensa in collaboration with Chugai; NSCLC=non-small cell lung cancer; Xalkori® (crizotinib); PFS=progression free survival; BTD=breakthrough therapy designation

Emicizumab: Positive results in adult & pediatric inhibitor patients

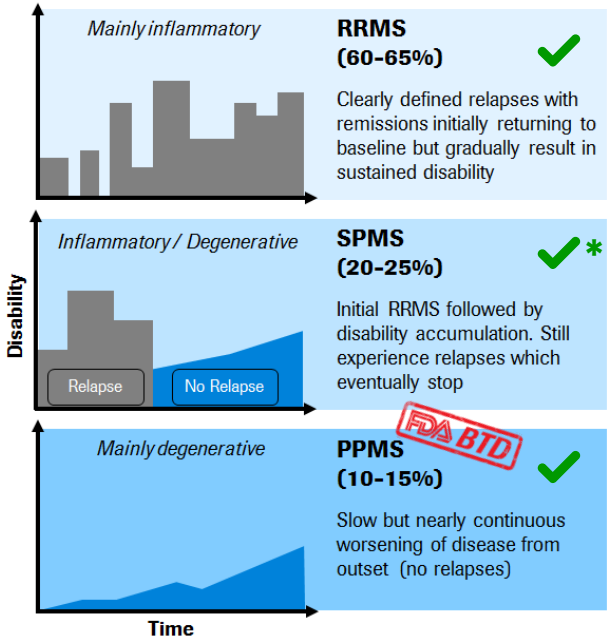


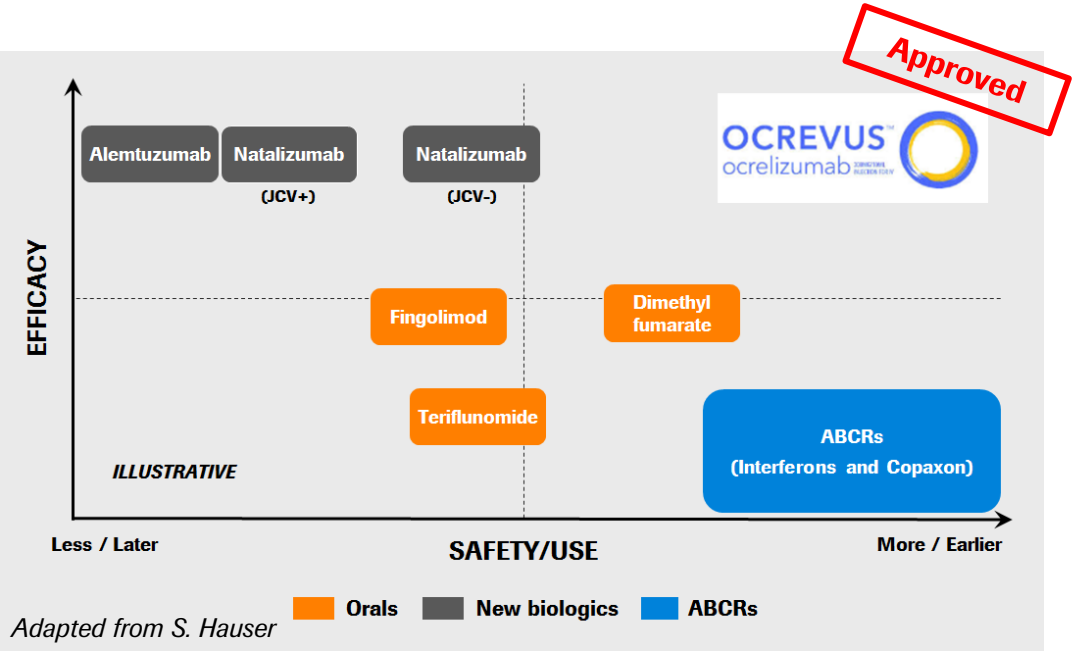
- Positive phase III results in inhibitor patients ≥12 years (HAVEN 1) to be presented at ISTH
- Positive phase III interim results in inhibitor pediatrics (HAVEN 2) to be presented at ISTH
- Global filing based on HAVEN1 and HAVEN2 interim results and launch preparations on track

Emicizumab (ACE910) in collaboration with Chugai; QW=weekly dosing; Q2W=dosing every 2 weeks; Q4W=dosing every 4 weeks; OLE=open label extension; BTD=breakthrough therapy designation

Ocrevus approved in the US

First treatment for both RMS and PPMS





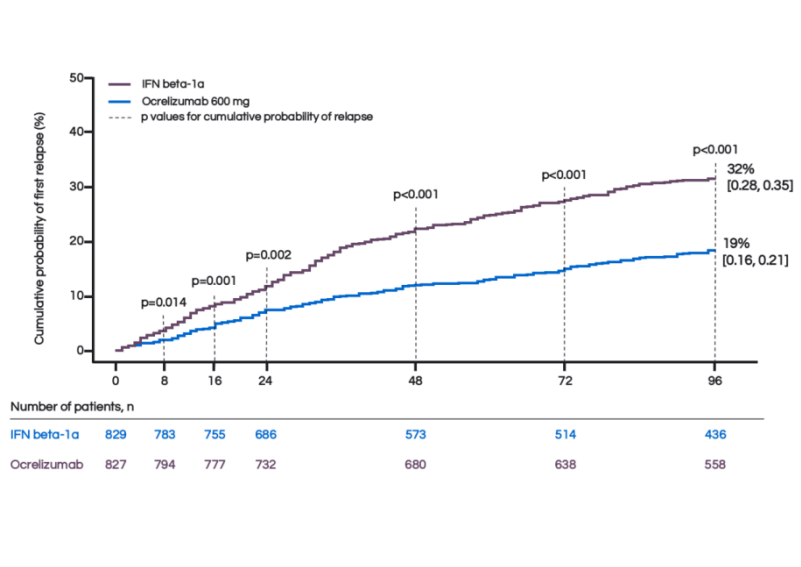
- Broad label includes RMS (RRMS, relapsing SPMS) and PPMS without any limitations
- No black box warning, no additional screening or monitoring

RMS=relapsing forms of multiple sclerosis (MS) including patients with RRMS and SPMS with superimposed relapses; RRMS= relapsing-remitting MS; SPMS=secondary progressive MS; PPMS=primary progressive MS; Adapted from Lublin 1996, Arnold 2004; *=relapsing SPMS included in the label

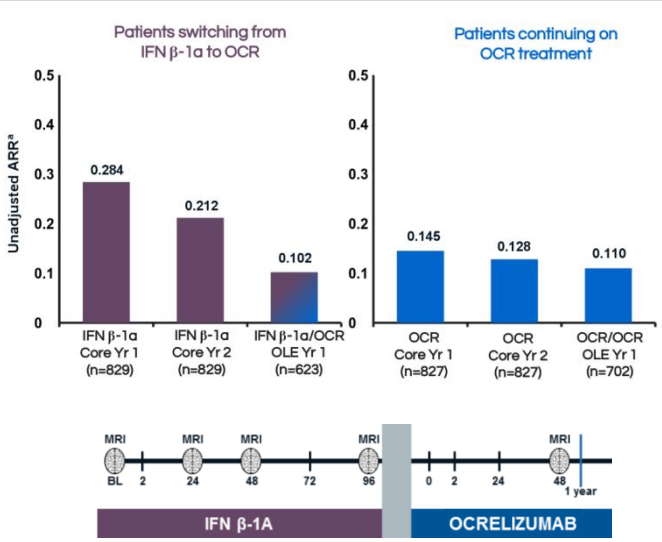
Ocrevus: New data presented at AAN

Rapid and sustained strong disease control

OPERA I & II (RMS)
Onset of disease control



OPERA I & II OLE (RMS)
Switching from IFN β-1a to Ocrevus



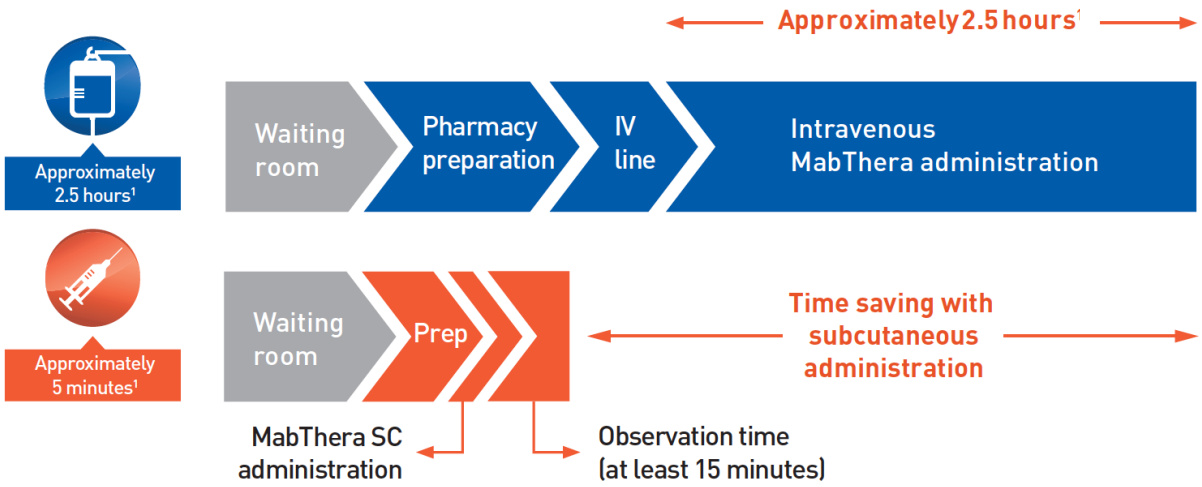
- Findings support early treatment with Ocrevus in RMS due to rapid onset of disease control after 8 weeks
- Strong sustained benefit of Ocrevus in RMS after three years with no new safety findings
- Findings support switching from Rebif® (interferon beta-1a) to Ocrevus in RMS

IFN β-1a=interferon beta-1a; OLE=open-label extension; Naismith RT. *et al*, presented at AAN 2017; Hauser SL. *et al*, presented at AAN 2017

MabThera/Rituxan SC in hematologic cancers

FDA advisory committee recommends approval

PDUFA date June 26

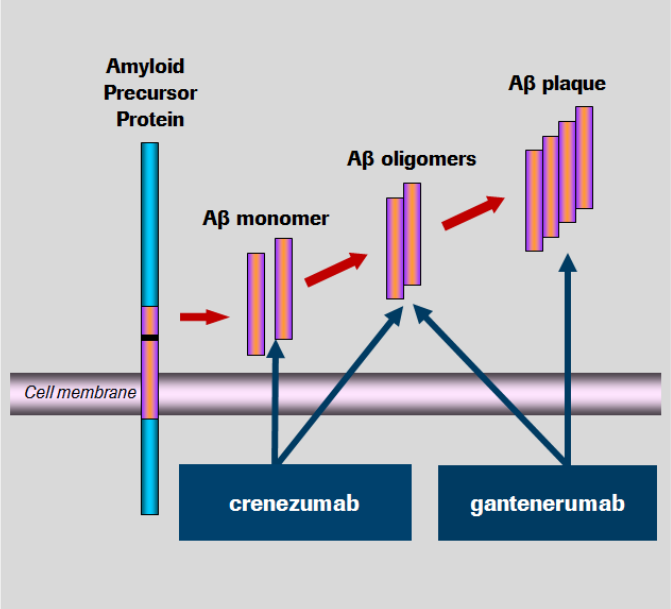


- ODAC voted unanimously (11:0) that the benefit-risk of rituximab/hyaluronidase for SC injection was favorable for the treatment of certain blood cancers
- Approved in the EU in NHL and CLL
- Encouraging initial uptake in the EU markets, comparable to Herceptin SC

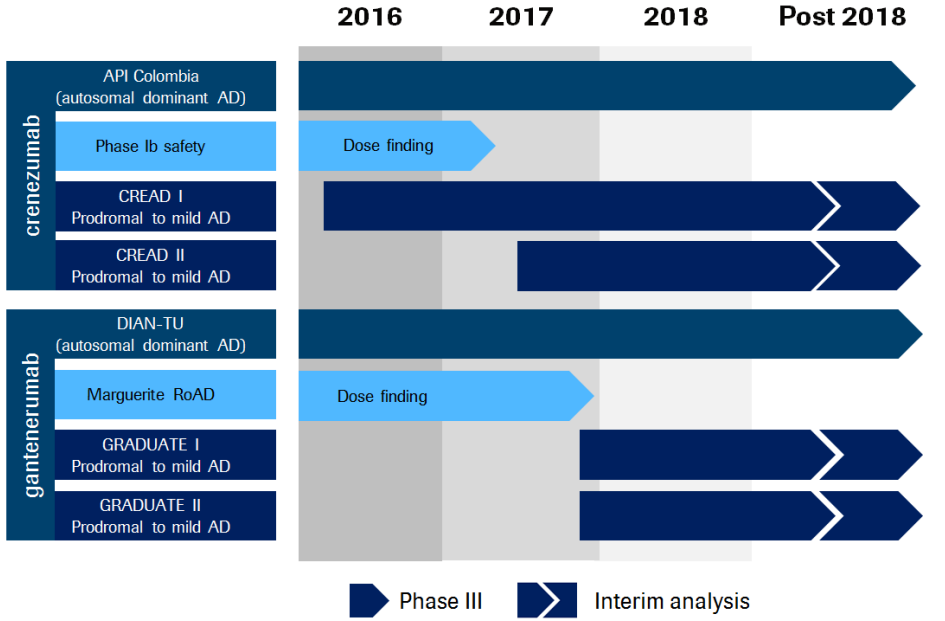
MabThera/Rituxan SC partnered with Halozyme; SC=subcutaneous; ODAC=Oncologic Drug Advisory Committee of the FDA; NHL=non-hodgkin's lymphoma; CLL=chronic lymphoid leukemia

Crenezumab and gantenerumab in Alzheimer's
Phase III programs starting

Amyloid pathway and targets



AD development plan



- Second Phase III trial (CREAD II) for crenezumab started
- Phase III development program for gantenerumab to start in 2017

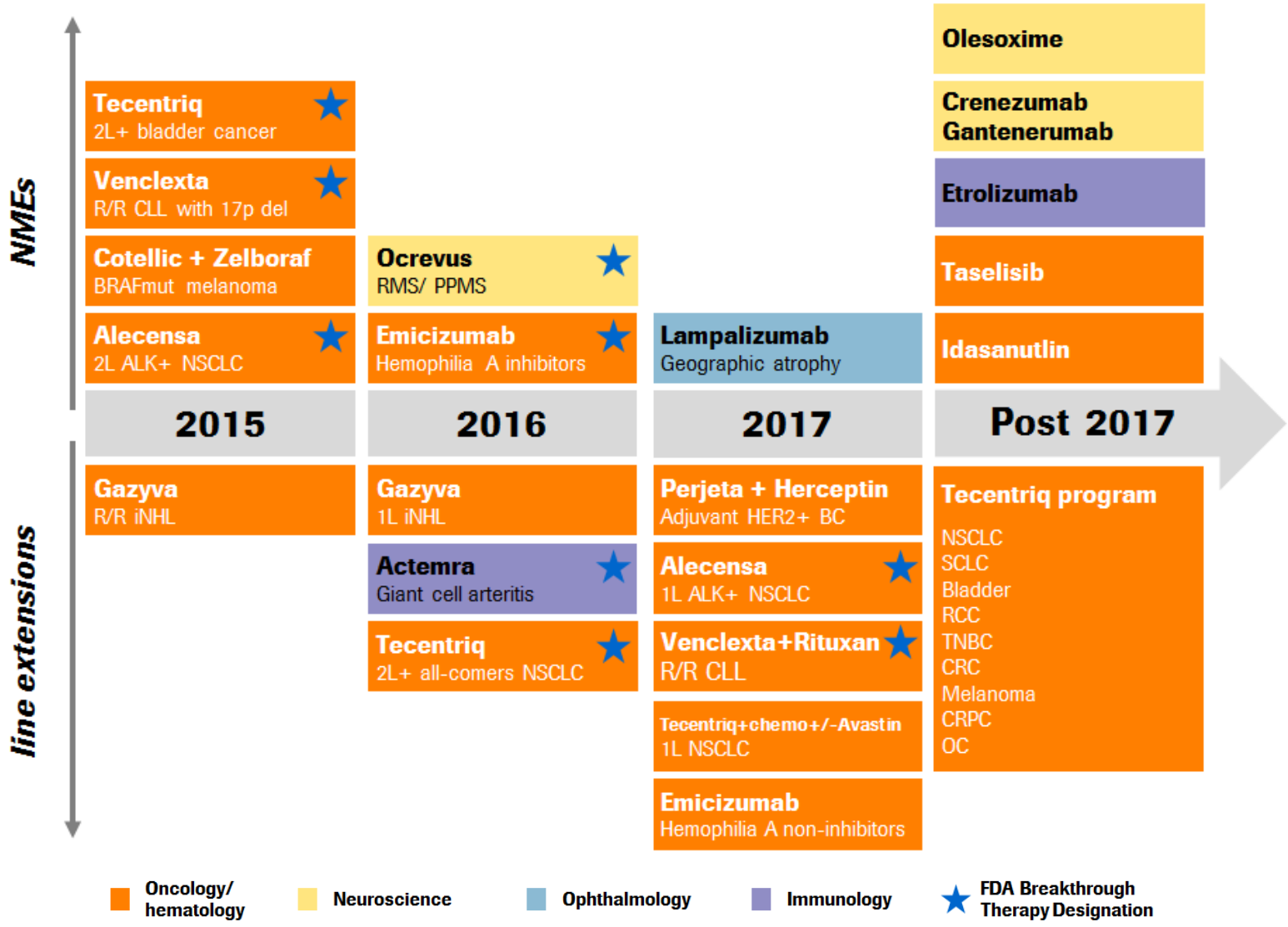
AD=Alzheimer`s disease; NME=new molecular entity

Q1 2017 sales

Innovation

Outlook

2017 onwards: Key data read-outs

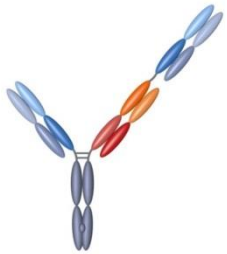


Outcome studies are event-driven: timelines may change

ASCO 2017: Major oral presentations

Tumor type	Trials
Breast	• Herceptin + Perjeta: Ph III (APHINITY) in adjuvant HER2+ BC
Lung	• Alecensa: Ph III (ALEX) in 1L ALK+ NSCLC • Tecentriq: Ph III (OAK) in 2L NSCLC
Colorectal	• aCEA/CD3 TCB +/- Tecentriq: Ph I in 3L CRC
Solid tumors	• Tecentriq + IDOi: Ph I
Renal	• Tecentriq + Avastin: Update Ph II (IMmotion150) in 1L RCC

Novel mode of action:



aCEA/CD3 TCB

Simultaneous binding to tumor and T cells results in:

- T cell engagement, activation and killing of tumor cells by delivery of cytotoxic granules
- T-cell engagement independent of specificity and activation status

IDOi in collaboration with NewLink Genetics; Alecensa in collaboration with Chugai

2017: Key late-stage news flow

	Compound	Indication	Milestone	
Regulatory	**Alecensa**	2L ALK+ NSCLC	EU approval	✓
	Ocrevus	RMS / PPMS	US/EU launch	
	Tecentriq	1L Bladder cancer cis-ineligible	US approval	✓
	Tecentriq	2/3L NSCLC and 2L Bladder cancer	EU approval	
	Gazyva	1L FL (iNHL)	US/EU filing	
	Actemra	Giant cell arteritis	US/EU approval	
	emicizumab	Hemophilia A inhibitors	US/EU filing	
Phase III readouts*	**Perjeta + Herceptin**	Adjuvant HER2+ BC	Ph III APHINITY	✓
	Alecensa	1L ALK+ NSCLC	Ph III ALEX	✓
	Venclexta + Rituxan	R/R CLL	Ph III MURANO	
	Tecentriq + chemo/ Tecentriq + chemo + Avastin	1L NSCLC	Ph III IMpower150	
	lampalizumab	Geographic atrophy	Ph III SPECTRI and CHROMA	
	emicizumab	Hemophilia A non-inhibitors	Ph III HAVEN3	

Additional Q1 2017 news flow:

- Lucentis: Approval in diabetic retinopathy
- MabThera/Rituxan SC in blood cancers: Positive FDA advisory committee vote (11:0)
- Emicizumab: Interim results in pediatric inhibitors (HAVEN2)

* Outcome studies are event-driven: Timelines may change

Diagnostics Division

Roland Diggelmann

CEO Roche Diagnostics

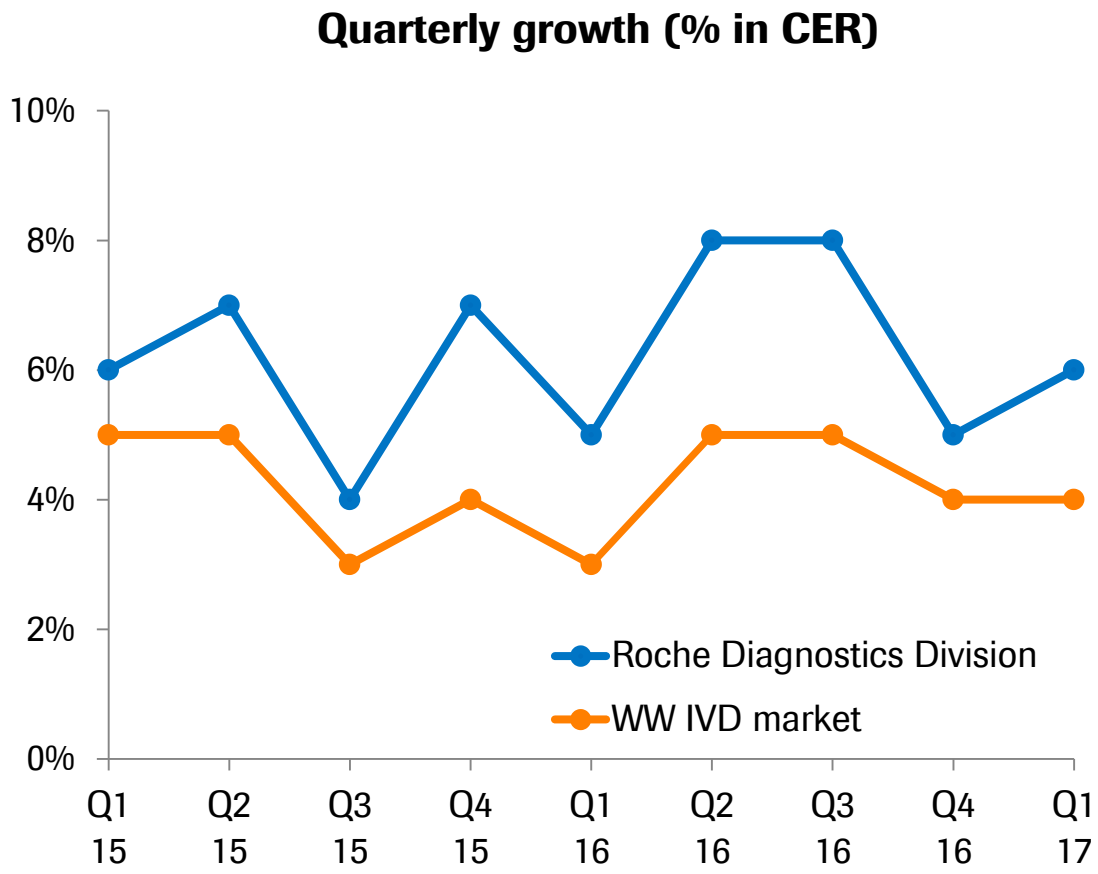
Q1 2017: Diagnostics sales growth driven by Centralised and Point of Care and Tissue Diagnostics

	2017 CHFm	2016 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**2,765**	**2,614**	**6**	**6**
Centralised and Point of Care Solutions	1,641	1,519	8	9
Diabetes Care	447	443	1	1
Molecular Diagnostics	441	446	-1	-2
Tissue Diagnostics	236	206	15	15

CER=Constant Exchange Rates
Underlying growth of Molecular Diagnostics excluding sequencing business: 0%

Roche continuously outgrowing the market

Increasing market leadership

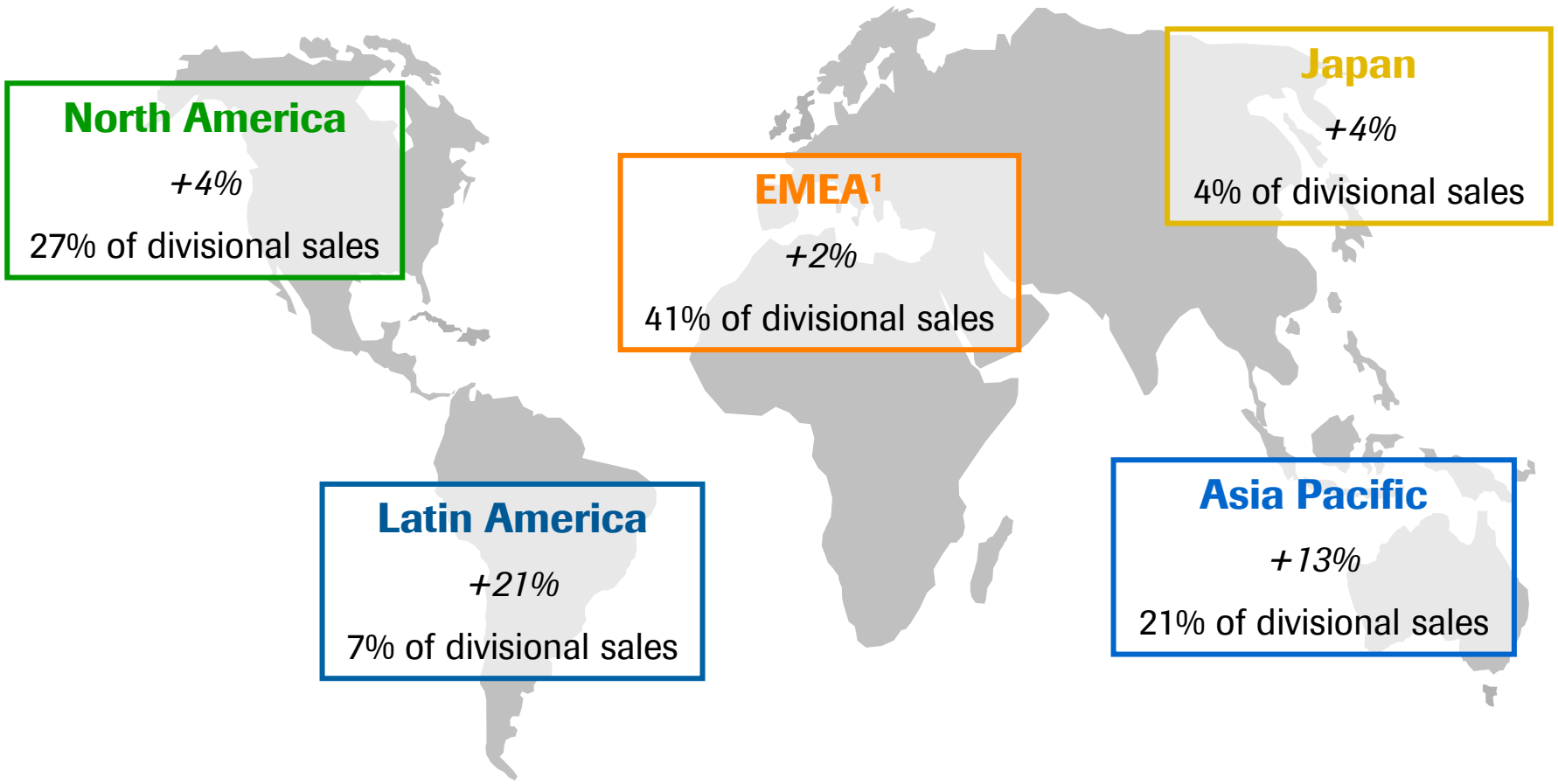


- Strong commercial presence
- Broadest test menu

Source: 3rd party IVD consultancy; Q1 2017 market growth is an estimate

Q1 2017: Diagnostics regional sales

Growth driven by all regions

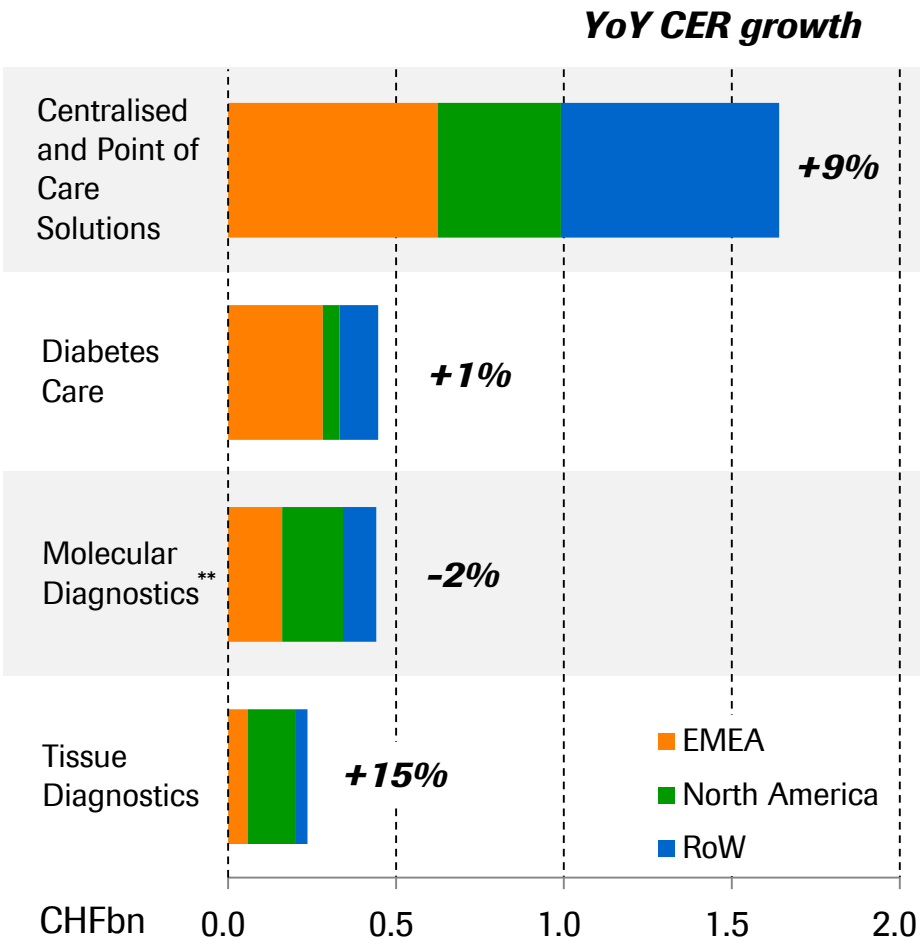


+18% growth in E7 countries[2]

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

Q1 2017: Diagnostics Division highlights

Growth driven by integrated laboratory solutions



- Driven by immunodiagnostics (+13%), clinical chemistry (3%) and PoC* (+4%)
- Driven by blood glucose monitoring (+2%)
- Virology (-6%) and blood screening (-4%)
- Advanced staining portfolio (+11%); primary staining (+14%) and companion diagnostics (+40%)

* PoC =Point of Care; ** Underlying growth of Molecular Diagnostics excluding sequencing business: 0%
CER=Constant Exchange Rates; EMEA=Europe, Middle East and Africa

Further expanding the industry's broadest menu

FDA approval of cobas e 801

New launches of Immunoassays	
GDF-15	IGFBP-3
Active B-12*	Androstenedione
HIV Duo	17-OH-Progesteron
IGF-1*	
Chagas	
PIVKA	
HCV Duo	

- Part of the cobas 8000 family
- Double throughput on same footprint
- Installed base of 252

Launched in 2016
Launch planned in 2017
Launch planned in 2018
Launch planned in 2019

* Assays will be available on the cobas e 801 by 2018-2019

GDF 15 = growth-differentiation factor 15; Active B-12 = Vitamin B12; HIV Duo = HIV-1 and HIV-2 (HIV Antigen and HIV Antibody); IGF-1 = Insulin like growth factor; Pivka = Protein Induced by Vitamin K Absence or Antagonist II; HCV Duo (HCV Antigen and HCV antibody) IGFBP-3 = Insulin-like growth factor-binding protein 3; B2MG urine = Human β2 Microglobulin; AMH CDx = Anti-Müllerian hormone companion diagnostic; AB-42 = A beta Alzheimer marker; t-Tau p-Tau = Tau protein Alzheimer marker

Market leader in women's health

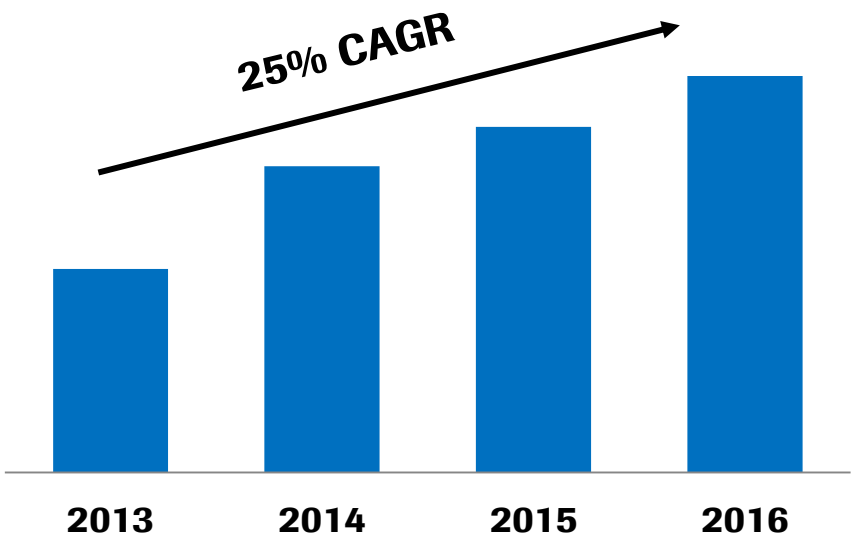
CE mark for HPV test on cobas 6800/8800

FDA clearance of CINtec Histology assay

Portfolio

Immunoassays	Molecular & sequencing	Tissue
Fertility	Cervical cancer*	Cervical cancer*
Prenatal testing	Virology	Breast cancer
Osteoporosis	Prenatal testing	
Ovarian cancer		
Breast cancer		
Sexually Transmitted Diseases		

Sales



* New 2017 launches

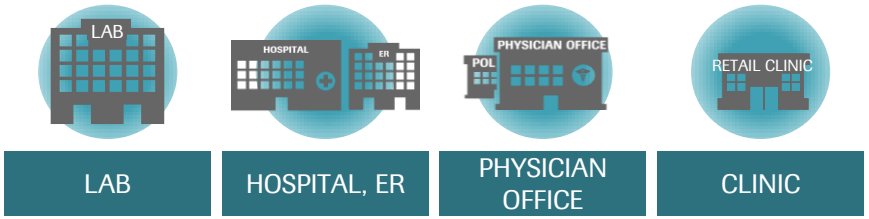
Menu expansion for the cobas Liat system

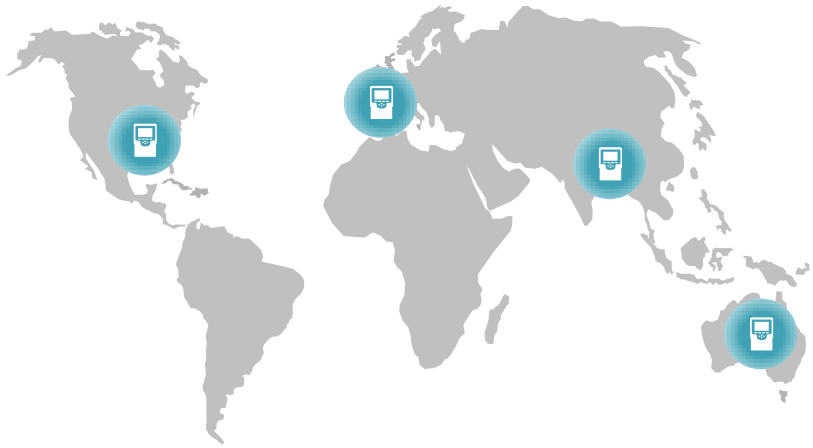
Global launch of respiratory & infectious disease menu

Growing menu

Available Globally	Upcoming Launches
Influenza A/B	MRSA/SA EU launch (2017)
Influenza A/B & RSV	Infectious Disease assays (forthcoming)
Strep A	
Cdiff*	

Solutions across all segments and regions





* Qualitative IVD test, that utilizes real-time PCR, for the direct detection of the tcdB gene of toxigenic *C. difficile* in unformed stool specimens; Not available yet in the US; RSV = Respiratory syncytial virus; Strep A = group A streptococcal infection; Cdiff = C. difficile; MRSA = methicillin-resistant Staphylococcus aureus; SA = Staphylococcus aureus

Key Launch List 2017

	Area	Product	Market
Instruments/ Devices	Central Laboratory	cobas 8000 <e 801> – High throughput immunochemistry analyser	US ✓
		CCM High Speed – cobas connection module (CCM) for up to 6000 samples/hour	WW
	Coagulation Testing	cobas t 511 / t 711 – Medium and high volume coagulation systems	EU
	Point of Care	CoaguChek Vantus – Hand-held coagulation monitoring system for Patient Self-Testing	US
	Diabetes Care	Accu-Chek Instant bG System – Effortless, accurate and affordable bG system for price sensitive markets	EU ✓
Tests/ Assays	HPV	cobas HPV – Next generation HPV DNA test leveraging 68/8800 Automation to detect 14 hrHPV with simultaneous detection of genotypes 16 and 18	EU ✓
		CINtec Histology – Diagnostic component of the Roche Cervical Cancer portfolio	US ✓
	Virology	cobas HIV 1&2 Qual – For use on the cobas 6800/8800 Systems; for diagnosis of acute HIV 1 or 2 infection and for confirmation of HIV 1 or 2 infection	EU
	Sequencing	AVENIO ctDNA panels - Liquid biopsy for circulating tumor DNA, 3 panels: targeted panel (17 genes for cancer therapy selection), expanded panel (77 genes for cancer therapy selection), surveillance panel (197 genes)	EU/US
	cobas Liat	cobas Liat C.diff – Qualitative IVD test, that utilizes real-time PCR, for the direct detection of the tcdB gene of toxigenic *C. difficile* in unformed stool specimens	EU ✓
		cobas Liat MRSA/SA – Qualitative IVD test, that utilizes real-time PCR, for the direct detection of MRSA and *Staphylococcus aureus* DNA from nasal swabs	EU
	Women's Health	AMH – Immunoassay for the in vitro quantitative determination of anti-Mullerian hormone (AMH) in human serum and plasma for the assessment of the ovarian reserve in women presenting to fertility clinics	US ✓
	Companion Diagnostics	PD-L1 (SP142) for Bladder Cancer* – complementary diagnostic for Tecentriq	EU
		PD-L1 (SP142) for NSCLC* – complementary diagnostic for Tecentriq	EU

* = Achieve commercial readiness, dependent on Pharma label and approval

Finance

Alan Hippe

Chief Financial Officer

Q1 2017: Highlights

Sales

- Good sales growth in both divisions

Guidance for FY 2017

- 2016 core EPS base is CHF 14.67 for outlook 2017 at CER

Currency impact

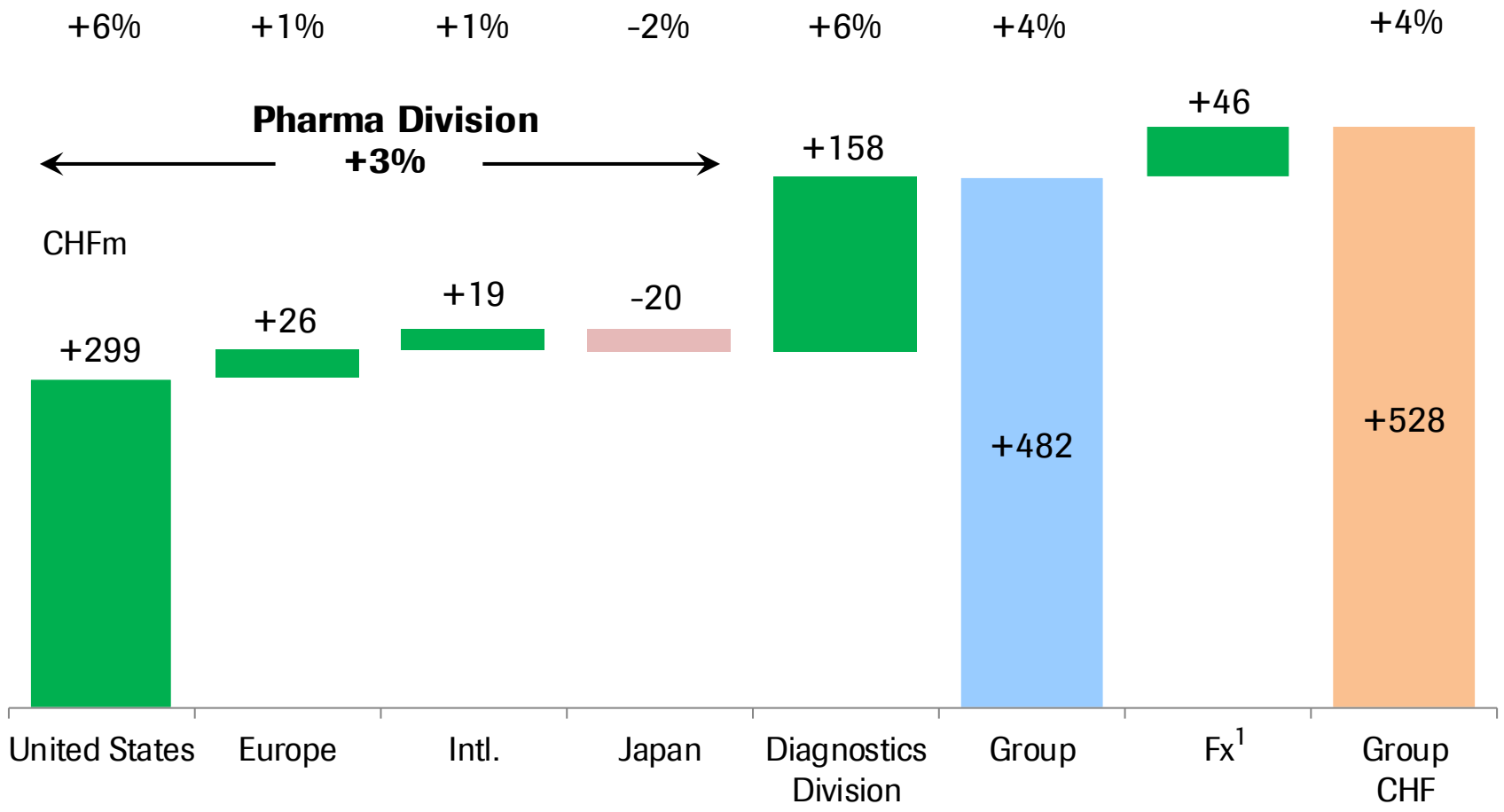
- Slight positive impact mainly from USD and BRL, offset by EUR and GBP

Capital markets update

- Bond issuance in March 2017: CHF 1.5bn in total
  - CHF: 0.4bn maturity in Sept 2018 - coupon 0.0%
  - CHF: 0.75bn maturity in Sept 2024 - coupon 0.1%
  - CHF: 0.35bn maturity in Mar 2029 - coupon 0.45%

Q1 2017: Group sales

Sales increase driven by US and Diagnostics Division

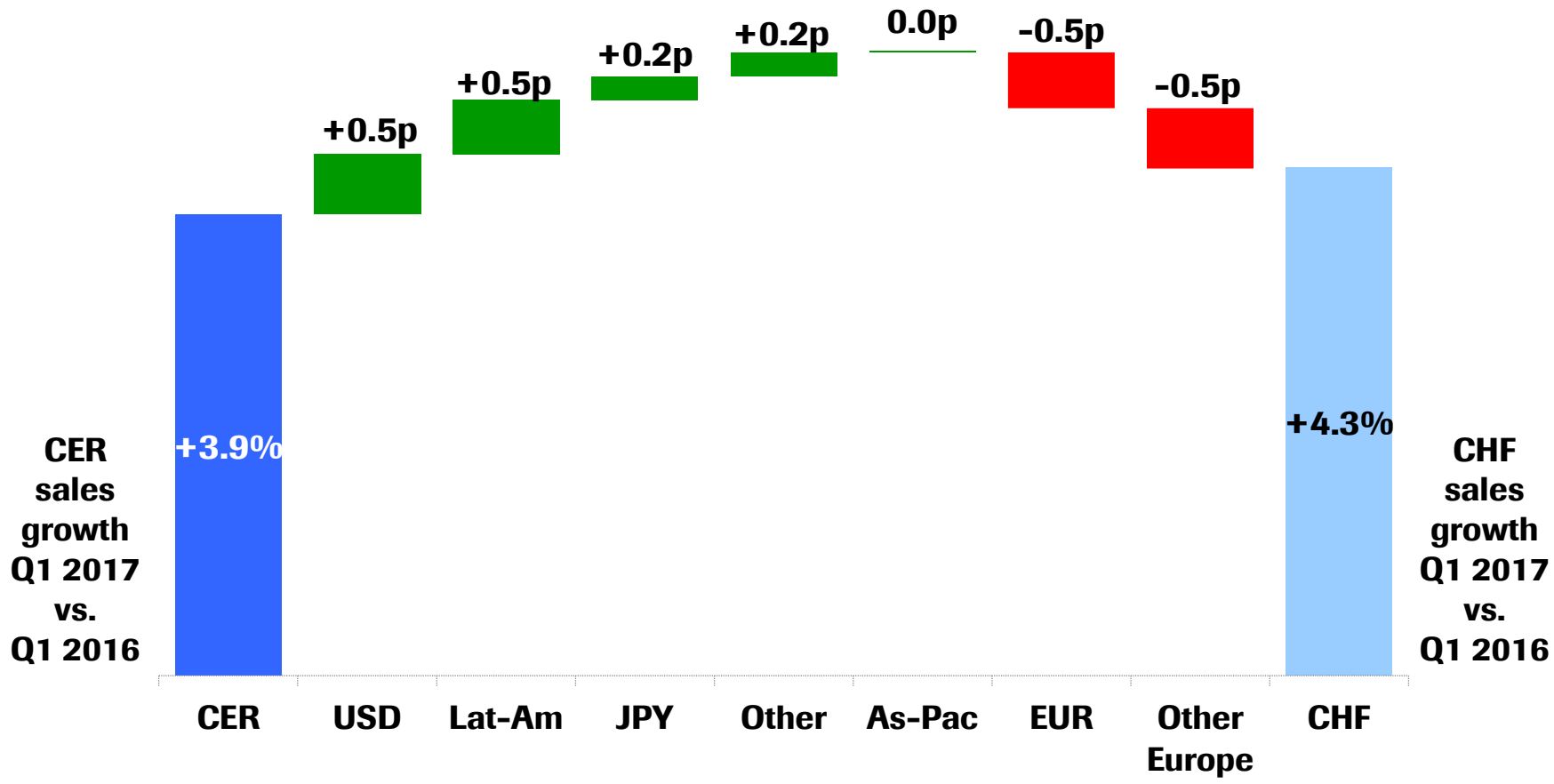


Absolute values and growth rates at Constant Exchange Rates (CER)

[1] average Full Year 2016 to average Q1 2017 Fx

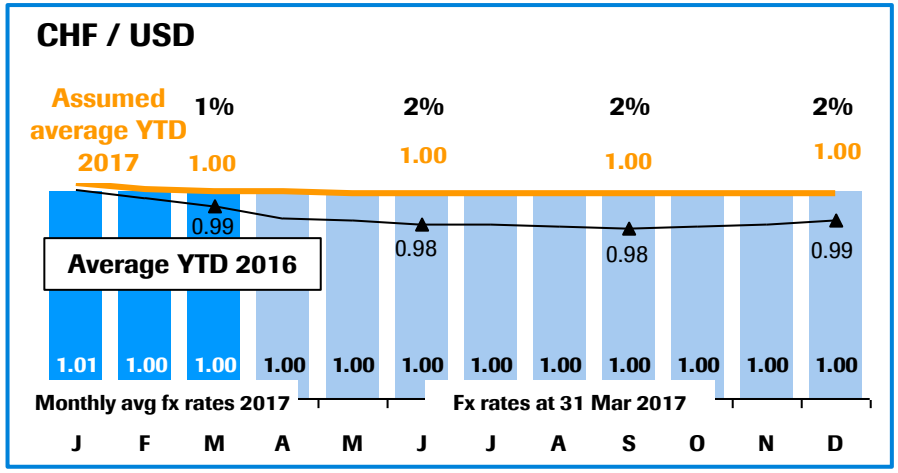
Exchange rate impact on sales growth

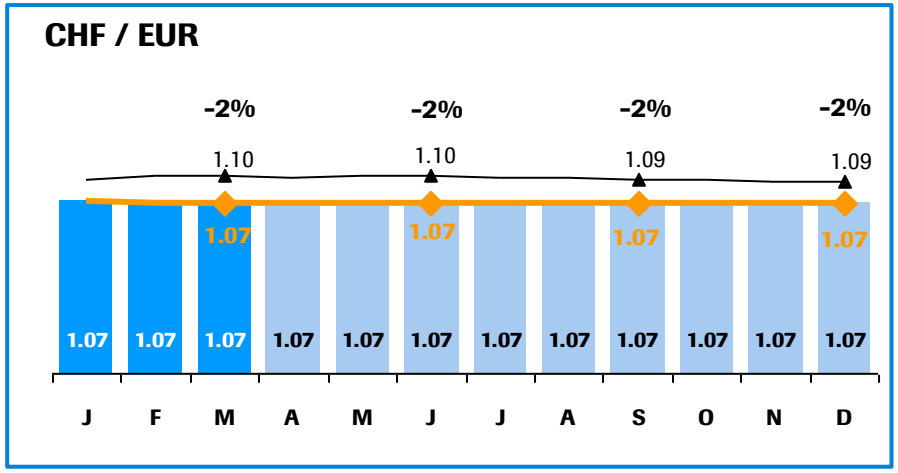
USD and Lat-Am offset by EUR and other Europe



CER = Constant Exchange Rates (avg full year 2016)

Low currency impact expected in 2017





Assuming the 31 March 2017 exchange rates remain stable until end of 2017, 2017 impact is expected to be (%p):

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

2017 outlook

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

[1] At Constant Exchange Rates (CER)

Pipeline summary

Changes to the development pipeline
Q1 2017 update

New to phase I

2 NMEs:

RG6026 CD20 CD3 TCB – hematopoietic tumors

RG6004 HBV LNA – HBV

1 AI:

RG7601 Venclexta ± HMA – r/r MDS

New to phase II

1 AI:

RG7601 Venclexta + HMA – 1L MDS

New to phase III

2 AIs:

RG7446 Tecentriq + chemo + Avastin – 1L ovarian cancer

RG7601 Venclexta + HMA – 1L AML

New to registration

1 AI following filing in the EU and US (rolling submission):

RG7853 Alecensa – 1L ALK+ NSCLC

1 AI transitioned following filing in the US:

RG435 Avastin – GBM

Removed from phase I

2 NMEs:

RG7800 SMN2 splicer – SMA

RG7834 – HBV

Removed from phase II

2 NMEs:

RG6046 SERD – ER+(HER-neg) mBC

RG7227 danoprevir – HCV

1 AI:

RG3637 lebrikizumab – COPD

Removed from phase III

1 AI:

RG435 Avastin – mesothelioma

Removed from registration

1 NME following EU approval:

RG7853 Alecensa – 2L ALK+ NSCLC

1 AI following US approval:

RG3645 Lucentis – diabetic retinopathy w/o DME

Status as of April 27, 2017

Roche Group development pipeline

Phase I (42 NMEs + 27 AIs)

RG6016	LSD1 inh	SCLC
RG6026	CD20 CD3 TCB	hematopoietic tumors
RG6047	SERD (2)	ER+ (HER2-neg) mBC
RG6058	TIGIT ± Tecentriq	solid tumors
RG6061	HIF1 alpha LNA	solid tumors
RG6078	IDO inh	solid tumors
	IDO inh + Tecentriq	solid tumors
RG6114	mPI3K alpha inh	HR+ BC
RG6146	BET inh	solid + heme tumors
RG6180	personalised cancer vaccine	oncology
RG6185	pan-RAF inh	oncology
RG7155	emactuzumab + Tecentriq	solid tumors
	emactuzumab + CD40 iMAb	solid tumors
RG7159	anti-CD20 multiple combos	heme tumors
RG7386	FAP-DR5 biMAb	solid tumors
RG7421	Cotellic + Tecentriq + Avastin	2/3L CRC
RG7446	Tecentriq	solid tumors
	Tecentriq	NMIBC
	T + Zelboraf ± Cotellic	melanoma
	T ± Avastin ± chemo	HCC, GC, PaC
	T ± Avastin ± chemo	solid tumors
	T + Cotellic	solid tumors
	T + ipi/IFN	solid tumors
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 multiple combos	lymphoma
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T + HMA	MDS
	T + radium 223	mCRPC
	T + guadecitabine	AML
RG7461	FAP IL2v FP + Tecentriq ± Avastin	RCC
RG7601	Venclexta multiple combos	NHL
	Venclexta + Gazyva	CLL
	Venclexta + Cotellic/idasanutlin	AML
	Venclexta ± HMA	r/r MDS
RG7741	ChK1 inh	solid tumors
RG7802	CEA CD3 TCB ± Tecentriq	solid tumors
RG7813	CEA IL2v FP* + Tecentriq	solid tumors
RG7828	CD20/CD3 TDB	heme tumors
RG7876	CD40 iMAb + Tecentriq	solid tumors
	CD40 iMAb + vanucizumab	solid tumors
RG7882	ADC	ovarian ca
RG7888	OX40 MAb	solid tumors
	OX40 MAb + Tecentriq	solid tumors
RG7986	ADC	r/r NHL
CHU	Raf/MEK dual inh	solid tumors
CHU	glypican-3/CD3 biMAb	solid tumors
RG3616	Erivedge + Esbriet	IPF
	Erivedge + ruxolitinib	myelofibrosis
RG6069	anti-fibrotic agent	fibrosis
RG6107	C5 inh MAb	PNH
RG7159	obinutuzumab	renal transplant
RG7880	IL-22Fc	inflammatory diseases
RG7990	-	asthma
RG6004	HBV LNA	HBV
RG6080	nacubactam (DBO β-lactamase inh)	bact.infections
RG7854	TLR7 agonist (3)	HBV
RG7861	*S. aureus* TAC	infectious diseases
RG7907	HBV Capsid (2)	HBV
RG7992	FGFR1/KLB MAb	metabolic diseases
RG6000	-	ALS
RG6029	Nav1.7 inh (2)	pain
RG6100	Tau MAb	Alzheimer's
RG7203	PDE10A inh	schizophrenia
RG7906	-	psychiatric disorders
RG7935	α-synuclein MAb	Parkinson's
IONIS	ASO	Huntington's
CHU	PTH1 recep. ago	hypoparathyroidism
CHU	-	hyperphosphatemia

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

RG-No Roche/Genentech
CHU Chugai managed
IONIS IONIS managed
PRO Proximagen managed
NOV Novimmune managed

*INN: cergutuzumab amunaleukin
**Ph3 in preparation
***out-licensed to Galderma and Maruho
T=Tecentriq

Phase II (20 NMEs + 12 AIs)

RG3502	Kadcyla + Tecentriq	2L HER2+ mBC
RG7221	vanucizumab	mCRC
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7440	ipatasertib**	CRPC
	ipatasertib	1L TNBC
	ipatasertib	TNBC neoadj
RG7596	polatuzumab vedotin	1L DLBCL
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + Rituxan	r/r FL
	Venclexta + HMA	1L MDS
RG7604	taselisib + letrozole	(HER2-neg) BC neoadj
RG7686	codrituzumab	liver cancer
RG3637	lebrikizumab	atopic dermatitis
	lebrikizumab ± Esbriet	IPF
RG6125	Cadherin-11 MAb	RA
RG6149	ST2 MAb	asthma
RG7159	obinutuzumab	lupus
RG7625	Cat-S antag	autoimmune diseases
RG7845	BTK inh	autoimmune diseases
CHU	nemolizumab***	atopic dermatitis
CHU	nemolizumab	pruritus in dialysis pts
PRO	VAP-1 inh	inflammatory disease
NOV	TLR4 MAb	autoimmune diseases
RG6152	CAP endonuclease inh	influenza
RG7745	Flu A MAb	influenza A
CHU	URAT1 inh	gout
RG1662	basmisanil	CIAS, post-stroke recovery
RG6083	olesoxime	SMA
RG7314	V1a receptor antag	autism
RG7916	SMN2 splicer(2)	SMA
RG3645	ranibizumab PDS	wAMD
RG7716	VEGF-ANG2 biMAb	wAMD, DME

Status as of April 27, 2017

Roche Group development pipeline

Phase III (8 NMEs + 32 AIs)

RG1273	Perjeta + Herceptin	HER2+ BC adj
	Perjeta + Herceptin	HER2+1L gastric ca
RG3502	Kadcyla	HER2+ BC adj
	Kadcyla + Perjeta	HER2+ BC adj
RG6013	emicizumab	hemophilia A FVIII inh
	emicizumab	pediatric hemophilia A FVIII inh
	emicizumab	hemophilia A w/o FVIII inh
	emicizumab	Q4W hemophilia A
RG7204	Zelboraf	BRAFmut melanoma adj
RG7388	idasanutlin	AML
RG7421	Cotellic + Tecentriq	3L CRC
	Cotellic + T + Zelboraf	BRAFmut melanoma
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq Dx+	1L sq + non-sq SCLC
	Tecentriq	RCC adj
	T + Abraxane	1L non-sq NSCLC
	T + chemo+Avastin	1L ovarian cancer
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
	T + Abraxane	1L sq NSCLC
	T + Abraxane	TNBC
	T + Avastin	RCC
	T ± chemo	1L mUC
	T + chemo	1L extens. stage SCLC
	T + enzalutamide	CRPC
RG7601	Venclexta + Rituxan	r/r CLL
	Venclexta + Gazyva	1L CLL
	Venclexta + bortezomib	MM
	Venclexta + HMA	1L AML
RG7604	taselisib + fulvestrant	ER+(HER2-neg) mBC
RG105	MabThera	pemphigus vulgaris
RG1569	Actemra	systemic sclerosis
RG7413	etrolizumab	ulcerative colitis
	etrolizumab	Crohn's
RG1450	gantenerumab	Alzheimer's
RG6168	IL-6R Mab (SA237)	neuromyelitis optica
RG7412	crenezumab	Alzheimer's
RG7417	lampalizumab	geographic atrophy
RG3645	Lucentis 0,3mg PFS[1]	DME

Registration (2 NMEs + 8 AIs)

RG105	SC Rituxan[1]	NHL/CLL
RG435	Avastin[2]	GBM
	Avastin[3]	rel. ovarian ca. Pt-sensitive
RG7159	Gazyva[4]	1L FL
RG7446	Tecentriq[5]	2L mUC
	Tecentriq[6]	2L+ NSCLC
RG7853	Alecensa[7]	1L ALK+ NSCLC
RG1569	Actemra	giant cell arteritis
CHU	Actemra	large-vessel vasculitis
RG1594	OCREVUS®[6]	PPMS + RMS

1. Approved in EU – Filed in US
2. US only
3. Approved in US, filed in EU for chemo backbone extension
4. Filed in EU
5. Filing based on IMvigor210; accelerated approval in US for 1L & 2L; phase III in 2L ongoing
6. Approved in US
7. Filed in EU, rolling submission in US

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

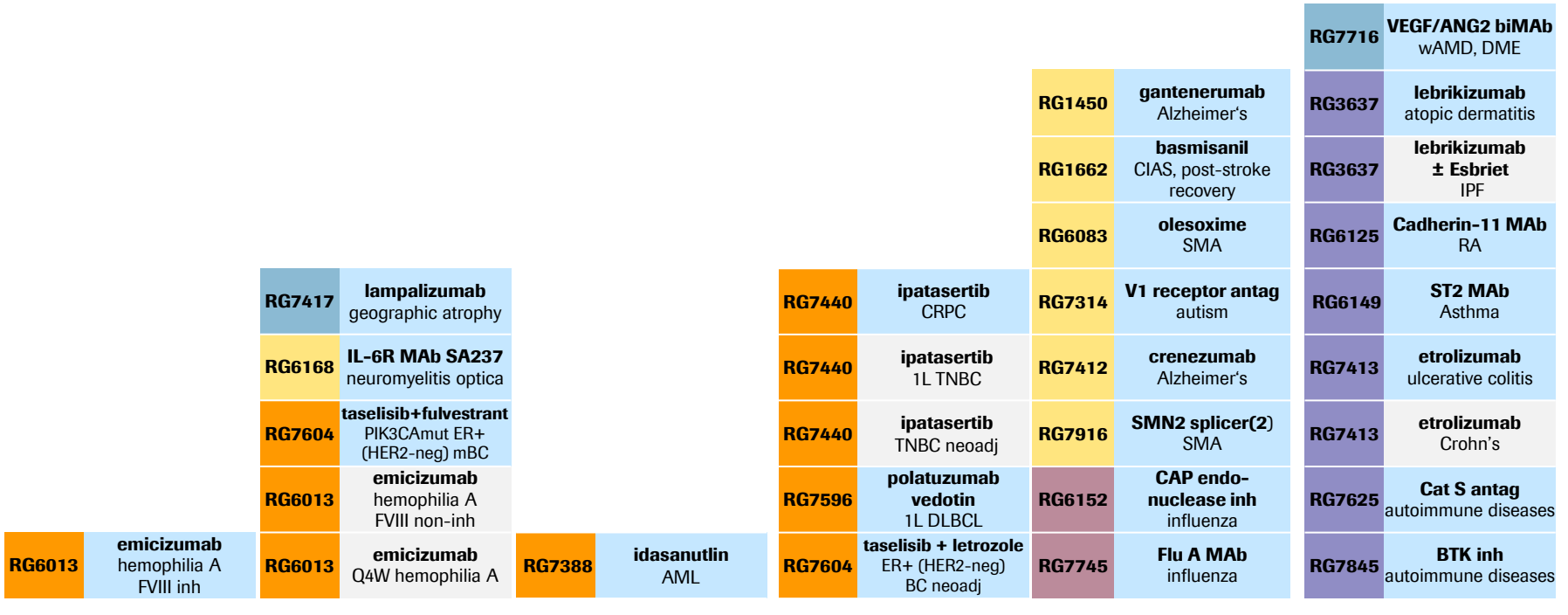
RG-No Roche/Genentech
CHU Chugai managed
RG105 Branded as Rituxan (US, Japan)
RG1569 Branded as RoActemra (EU)
RG7159 Branded as Gazyvaro (EU)

T=Tecentriq

Status as of April 27, 2017

NME submissions and their additional indications

Projects currently in phase II and III



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

Status as of April 27, 2017

AI submissions for existing products

Projects currently in phase II and III

2017		2018		2019		2020 and beyond	
RG3645	**Lucentis 0.3mg PFS (US)** DME	RG105	**MabThera** pemphigus vulgaris	RG7421	**Cotellic + Tecentriq** 3L CRC	RG3502	**Kadcyla + Tecentriq** 2L Her2+ mBC
RG435	**Avastin (US) ✓** GBM	RG1569	**Actemra** systemic sclerosis	RG7421	**Cotellic + Tecentriq + Zelboraf** BRAFmut melanoma	RG3502	**Kadcyla + Perjeta** HER2+ BC adj.
RG1273	**Perjeta + Herceptin** 1L HER2+ gastric cancer	RG7446	**Tecentriq + chemo + Avastin** 1L non-sq NSCLC	RG7446	**Tecentriq** 1L non-sq + sq NSCLC (Dx+)	RG3502	**Kadcyla** HER2+ BC adj.
RG1273	**Perjeta + Herceptin** HER2+ BC adj.	RG7446	**Tecentriq + Abraxane** 1L sq NSCLC	RG7446	**Tecentriq + chemo + pemetrexed** 1L non-sq NSCLC	RG7446	**Tecentriq + enzalutamide** CRPC
RG7159	**Gazyva (US)** 1L FL	RG7446	**Tecentriq + Abraxane** 1L non-sq NSCLC	RG7601	**Venclexta + Gazyva** 1L CLL	RG7446	**Tecentriq** RCC adj
RG7204	**Zelboraf** BRAFmut melanoma adj.	RG7446	**Tecentriq + chemo** 1L extens. stage SCLC	RG7601	**Venclexta + bortezomib** MM	RG7446	**Tecentriq + chemo + Avastin** 1L ovarian cancer
RG7601	**Venclexta + Rituxan** r/r CLL	RG7446	**Tecentriq + Avastin** RCC			RG7601	**Venclexta + Rituxan** r/r FL
RG7853	**Alecensa[1] ✓** 1L ALK+ NSCLC	RG7446	**Tecentriq + Abraxane** TNBC			RG7601	**Venclexta + Rituxan** DLBCL
						RG7601	**Venclexta + HMA** 1L AML
						RG7601	**Venclexta + HMA** 1L MDS
						RG3645	**ranibizumab PDS** wAMD
						RG7159	**obinutuzumab** lupus nephritis
						RG7421	**Cotellic + Tecentriq ± taxane** TNBC
						RG7446	**Tecentriq ± chemo** 1L mUC
						RG7446	**Tecentriq** NSCLC adj
						RG7446	**Tecentriq** MIBC adj

✓ Indicates submission to health authorities has occurred
1 Filed in EU, rolling submission in US
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

Status as of April 27, 2017

Major granted and pending approvals 2017

	US		EU		Japan-Chugai	
Approved	RG1594	**OCREVUS®** PPMS & RMS March 2017	RG7853	**Alecensa** 2L ALK+ NSCLC February 2017		
	RG3645	**Lucentis** mCNV January 2017				
	RG3645	**Lucentis** diabetic retinopathy w/o DME April 2017				
	RG7446	**Tecentriq** 1L bladder cancer cis-ineligible April 2017				
Pending Approval	RG435	**Avastin** GBM	RG7853	**Alecensa** 1L ALK+ NSCLC Filed March 2017	RG7446	**Tecentriq** NSCLC 2L+ Filed February 2017
	RG7853	**Alecensa** 1L ALK+ NSCLC Rolling submission March 2017	RG7446	**Tecentriq** mUC 2L Filed April 2016	CHU	**Actemra** large-vessel vasculitis Filed November 2016
	RG1569	**Actemra** giant cell arteritis Filed November 2016	RG7446	**Tecentriq** NSCLC 2L+ Filed April 2016		
			RG7159	**Gazyva** follicular lymphoma 1L Filed October 2016		
			RG1594	**OCREVUS®** PPMS & RMS Filed April 2016		
			RG1569	**Actemra** giant cell arteritis Filed November 2016		

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

Status as of April 27, 2017

Roche Group Development pipeline
Combinations

Phase I (6 NMEs + 23 AIs)

RG6058	TIGIT ± Tecentriq	solid tumors
RG6078	IDO inh +Tecentriq	solid tumors
RG7155	emactuzumab + Tecentriq	solid tumors
	emactuzumab + CD40 iMAb	solid tumors
RG7159	anti-CD20 multiple combos	heme tumors
RG7421	Cotellic + Tecentriq + Avastin	2/3L CRC
RG7446	T + Zelboraf ± Cotellic	melanoma
	T ± Avastin ± chemo	HCC, GC, PaC
	T ± Avastin ± chemo	solid tumors
	T + Cotellic	solid tumors
	T + ipi/IFN	solid tumors
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 multiple combos	lymphoma
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T + HMA	MDS
	T + radium 223	mCRPC
RG7461	FAP IL2v FP + Tecentriq ± Avastin	RCC
RG7601	Venclexta multiple combos	NHL
	Venclexta + Gazyva	CLL
	Venclexta + Cotellic/idasanutlin	AML
	Venclexta ± HMA	r/r MDS
RG7802	CEA CD3 TCB ± Tecentriq	solid tumors
RG7813	CEA* IL2v FP + Tecentriq	solid tumors
RG7876	CD40 iMAb + Tecentriq	solid tumors
	CD40 iMAb + vanucizumab	solid tumors
RG7888	OX40 Mab + Tecentriq	solid tumors
RG3616	Erivedge + Esbriet	IPF
	Erivedge + ruxolitinib	myelofibrosis

Phase II (7 AIs)

RG3502	Kadcyla + Tecentriq	2L HER2+ mBC
RG7421	Cotellic + Tecentriq taxane	TNBC
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + Rituxan	r/r FL
	Venclexta + HMA	1L MDS
RG7604	taselisib + letrozole	(HER2-) BC neoadj
RG3637	lebrikizumab ± Esbriet	IPF

Phase III (1 NMEs + 19 AIs)

RG1273	Perjeta + Herceptin	HER2+ BC adj
	Perjeta + Herceptin	1L HER2+ gastric ca
RG3502	Kadcyla + Perjeta	HER2+ BC adj
RG7421	Cotellic + Tecentriq	3 L CRC
	Cotellic + T + Zelboraf	BRAFm melanoma
RG7446	T + Abraxane	1L non-sq NSCLC
	T + chemo + Avastin	1L ovarian cancer
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
	T + Abraxane	1L sq NSCLC
	T + Abraxane	TNBC
	T + Avastin	RCC
	T ± chemo	1L mUC
	T + chemo	1L extens. stage SCLC
	T + enzalutamide	CRPC
RG7601	Venclexta + Rituxan	r/r CLL
	Venclexta + Gazyva	1L CLL
	Venclexta + bortezomib	MM
	Venclexta + HMA	1L AML
RG7604	taselisib + fulvestrant	ER+ (HER2-neg) mBC

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

RG-No Roche/Genentech
CHU Chugai managed
*INN: cergutuzumab amunaleukin
T=Tecentriq

Status as of April 27, 2017

Cancer immunotherapy pipeline overview

Phase I (11 NMEs + 28 AIs)

RG6026	CD20 CD3 TCB	hematopoietic tumors
RG6058	TIGIT ± Tecentriq	solid tumors
RG6078	IDO inh	solid tumors
	IDO inh + Tecentriq	solid tumors
RG6180	personalized cancer vaccine	oncology
RG7155	emactuzumab + Tecentriq	solid tumors
	emactuzumab + CD40 iMAb	solid tumors
RG7421	Cotellic + Tecentriq + Avastin	2/3L CRC
RG7446	Tecentriq	solid tumors
	Tecentriq	NMIBC
	T + Zelboraf ± Cotellic	melanoma
	T ± Avastin ± chemo	HCC-GC-PaC
	T ± Avastin ± chemo	solid tumors
	T + Cotellic	solid tumors
	T + Ipi/IFN	solid tumors
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 multiple combos	lymphoma
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T + HMA	MDS
	T + radium 223	mCRPC
	T + guadecitabine	AML
RG7461	FAP IL2v FP + Tecentriq ± Avastin	RCC
RG7802	CEA CD3 TCB ± Tecentriq	solid tumors
RG7813	CEA* IL2v FP+Tecentriq	solid tumors
RG7828	CD20/CD3 TDB	heme tumors
RG7876	CD40 iMAb + Tecentriq	solid tumors
	CD40 iMAb + vanucizumab	solid tumors
RG7888	OX40 iMAb	solid tumors
	OX40 iMAb + Tecentriq	solid tumors
INCY**	Tecentriq + epacadostat	solid tumors
CLDX**	Tecentriq + varlilumab	solid tumors
CRVS**	Tecentriq + CPI-444	solid tumors
KITE**	Tecentriq + KTE-C19	r/r DLBCL
AMGN**	Tecentriq + talimogene laherp	TNBC, CRC
JNJ**	Tecentriq ± daratumumab	solid tumors
CLVS**	Tecentriq + rucaparib	ovarian ca
EPZM**	Tecentriq + tazemetostat	r/r DLBCL
BLRX**	Tecentriq + BL-8040	AML, solid tumors

Phase II (4 AIs)

RG3502	Kadcyla + Tecentriq	HER2+ 2L mBC
RG7421	Cotellic + Tecentriq ± taxane	TNBC
IMDZ**	Tecentriq + NY-ESO-1	soft tissue sarcoma
SNDX**	Tecentriq + entinostat	TNBC

Phase III (15 AIs)

RG7421	Cotellic + Tecentriq	3 L CRC
	Cotellic + T + Zelboraf	BRAFm melanoma
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	T + Abraxane	1L non-sq NSCLC
	T + chemo+Avastin	1L ovarian cancer
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
	T + Abraxane	1L sq NSCLC
	T + Abraxane	TNBC
	T + Avastin	RCC
	T ± chemo	1L mUC
	T + chemo	1L extens. stage SCLC
	T + enzalutamide	CRPC
	Tecentriq Dx+	1L sq+non-sq SCLC
	Tecentriq	RCC adj

Registration (1 NMEs + 1 AIs)

RG7446	Tecentriq[1]	2L mUC
	Tecentriq[2]	2L+ NSCLC

1. Filing based on IMvigor210, accelerated approval in US for 1L & 2L; phase III in 2L ongoing
2. Approved in US

** External collaborations: INCY- Incyte IDO inh; CLDX – Celldex CD27 MAb; CRVS – Corvus ADORA2A antag; KITE – Kite KTE-C19; AMGN – Amgen oncolytic virus; JNJ – Janssen CD38 MAb; CLVS – Clovis PARP inh; EPZM – Epizyme EZH2 inh; BLRX - BioLine Rx CXCR4 antag; IMDZ – Immune Design CMB305; SNDX – Syndax HDAC inh

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

RG-No Roche/Genentech
*INN: cergutuzumab amunaleukin
T=Tecentriq

Status as of April 27, 2017

Doing now what patients need next