
Roche

Roche

YTD September 2016 sales

Basel, 20 October 2016

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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;
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;
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9 litigation;
10 loss of key executives or other employees; and
11 adverse publicity and news coverage.

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Group

Severin Schwan

Chief Executive Officer

YTD Sept 2016: Highlights

Growth

Sales	• Group sales +4%[1] driven by HER2 (+9%), CD20 (+4%), and Immunology franchises (+12%), new launches, and Professional Diagnostics (+9%) • Good growth[1] in all regions

Portfolio progress Q3

Oncology	• Cancer immunotherapy: Tecentriq launched in bladder cancer (US), sales off to a good start, approved in lung cancer (US) with broad label • Tecentriq in 2/3L NSCLC: OAK data with survival benefit (ESMO) • Alecensa: 1st line ALK – BTD granted (US) • Perjeta: APHINITY read out expected in Q1 2017
Hematology	• Emicizumab (ACE 910): Ph III in patients without FVIII inhibitors trial started
Neuroscience	• OCREVUS: Filings accepted in EU and US; PDUFA date Dec 28, 2016
Immunology	• Actemra: Ph III in giant cell arteritis met primary end point – BTD granted • Lucentis: Priority Review for myopic choroidal neovascularization granted (US)
Diagnostics	• Successful launch of cobas e 801, high throughput immunodiagnostics analyser

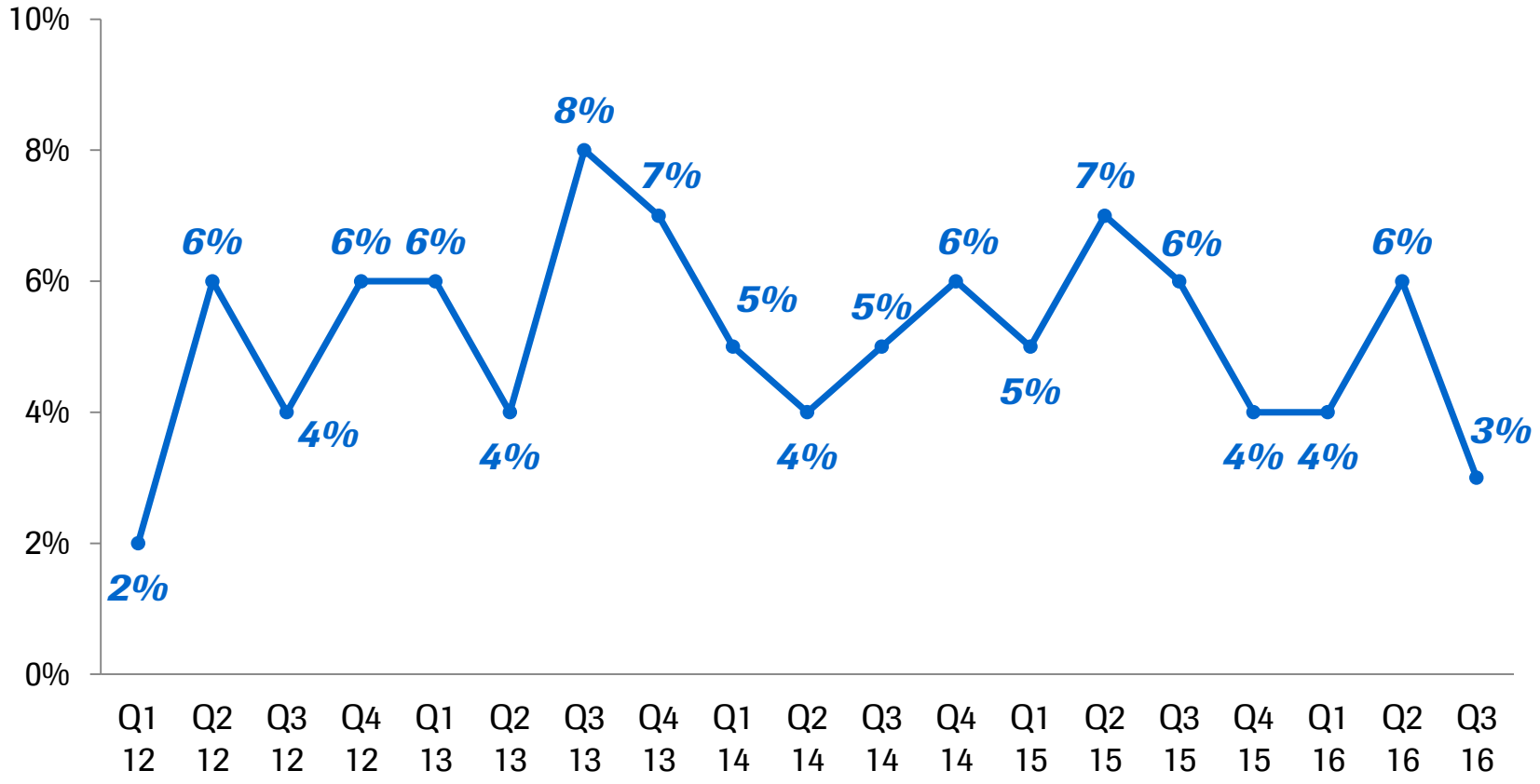
[1] All growth rates at constant exchange rates (CER)

YTD Sept 2016: Good sales growth in both divisions

	2016 CHFbn	2015 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	**29.1**	27.7	**5**	**4**
Diagnostics Division	**8.4**	7.8	**7**	**7**
Roche Group	**37.5**	35.5	**6**	**4**

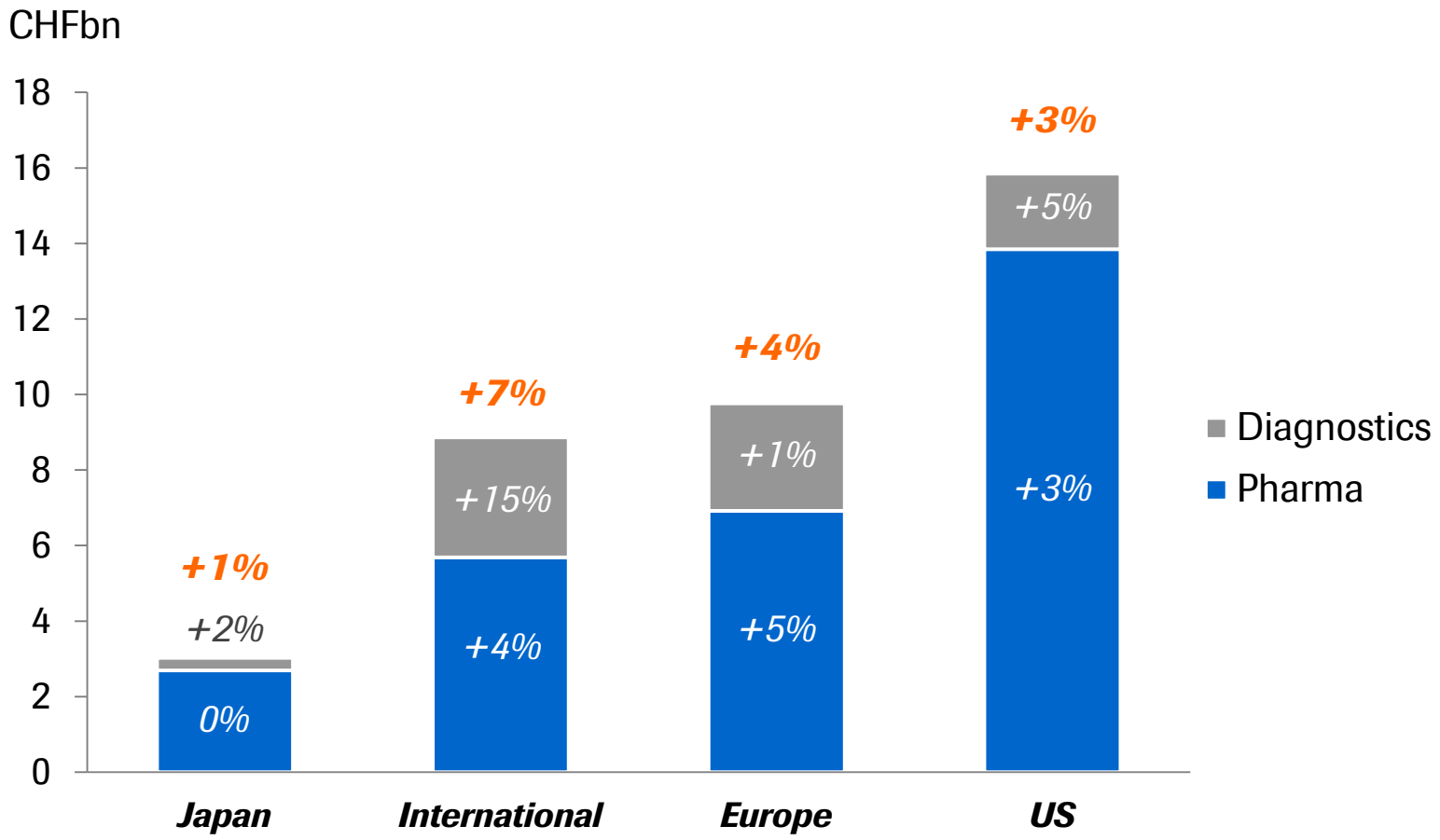
CER=Constant Exchange Rates

Q3 2016: Sales growth for fifth consecutive year



All growth rates at Constant Exchange Rates (CER)

YTD Sept 2016: Good sales growth in International, US and Europe

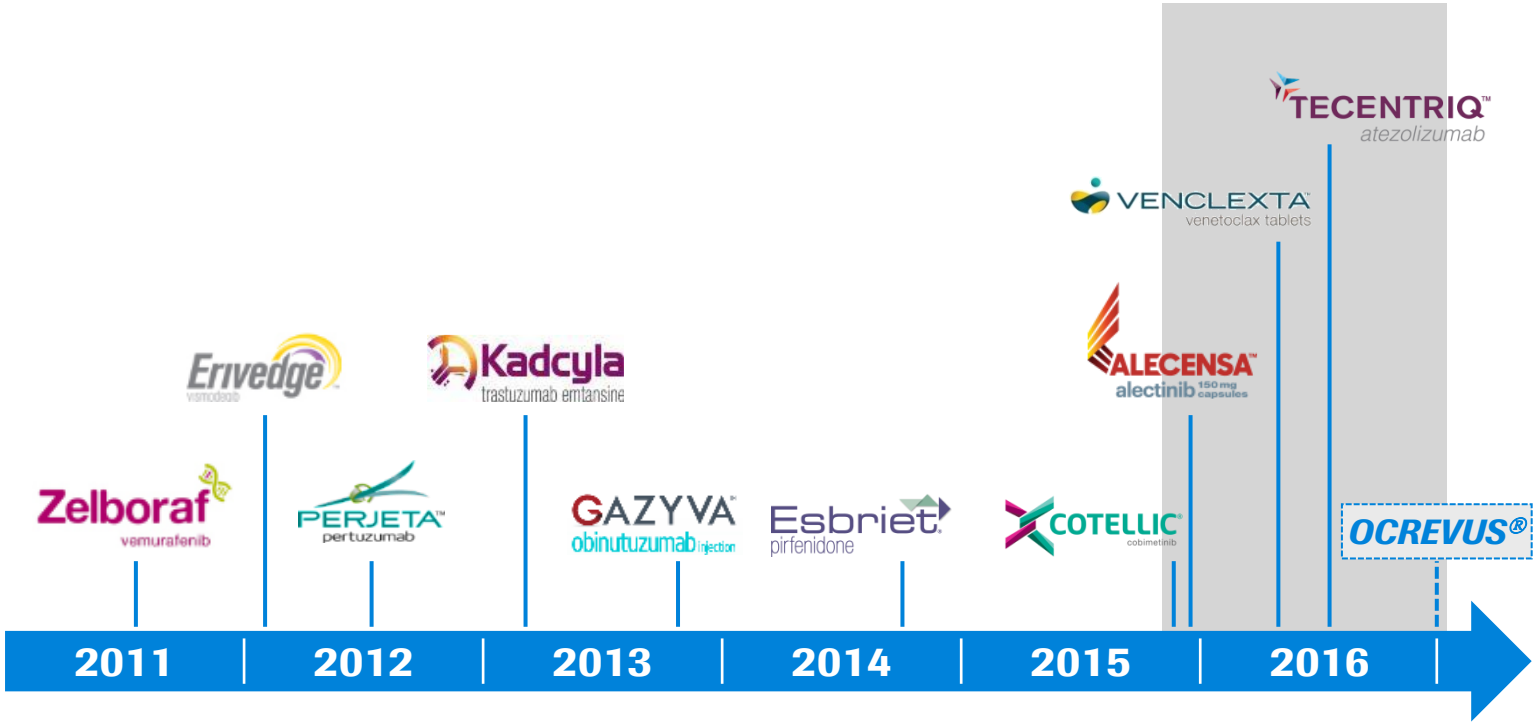


All growth rates at Constant Exchange Rates (CER)

Continued leadership in innovation

Launches at historical high

5 NME launches in a year



Roche significantly advancing patient care

Recognition for innovation 2013-present

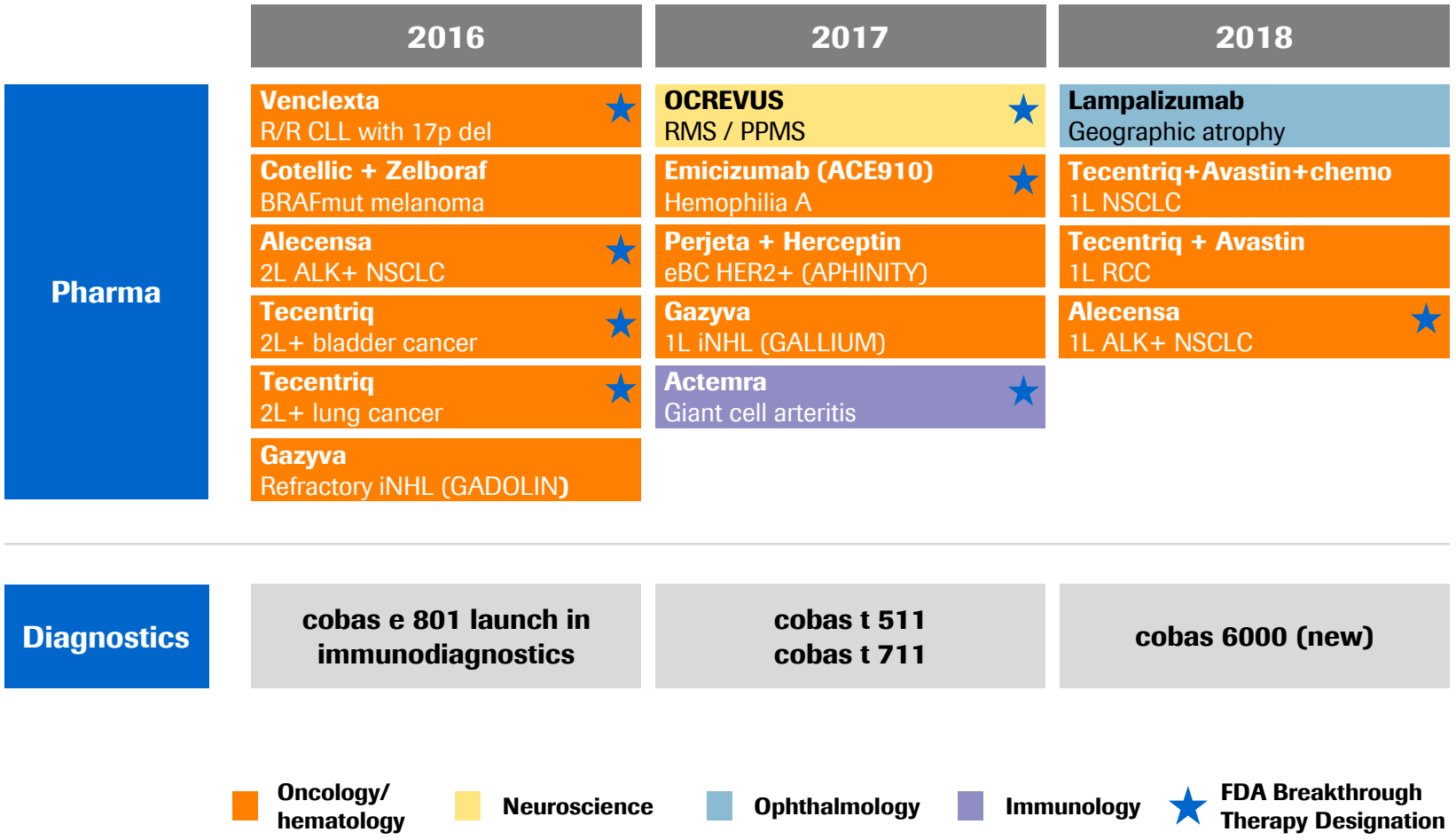
14 *Breakthrough Therapy Designations*

Rank	Company	#
1	**Roche**	**14**
2	Novartis	11
3	BMS	10
4	Merck	9
5	AbbVie	7
6	Pfizer	7

Year	Molecule
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 at Oct 2016; PPMS=Primary Progressive Multiple Sclerosis; CLL=Chronic Lymphocytic Leukemia; NSCLC=Non-Small Cell Lung Cancer; IPF=Idiopathic Pulmonary Fibrosis

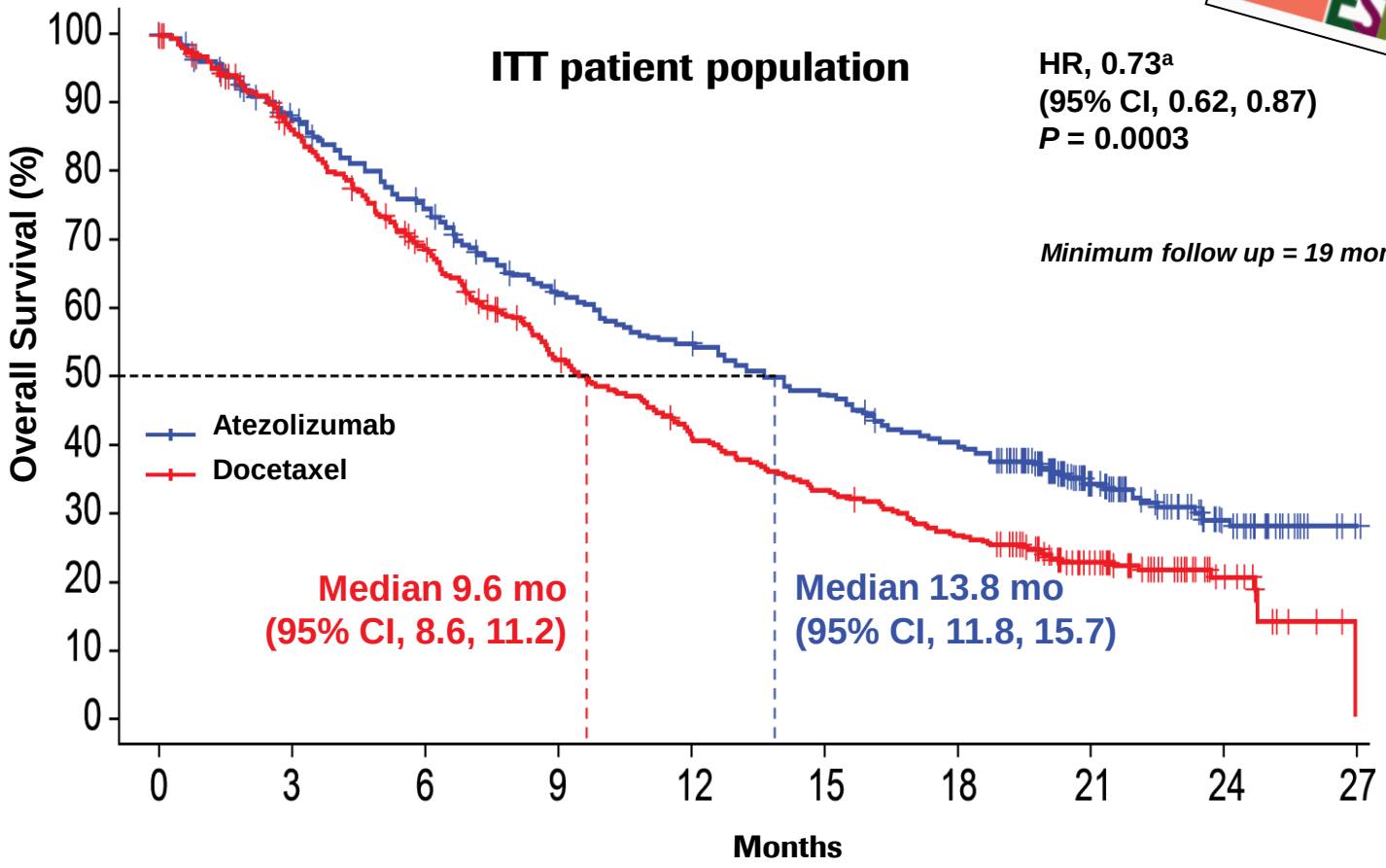
Q3 2016: Pipeline / launch activities on track



Outcome studies are event-driven: timelines may change. Standard approval timelines of 1 year assumed.

Tecentriq in 2L+ non-small cell lung cancer

Survival benefit regardless of PD-L1 status



No. at Risk																									
Atezolizumab	425	407	382	363	342	326	305	279	260	248	234	223	218	205	198	188	175	163	157	141	116	74	54	41	28	15	4	1
Docetaxel	425	390	365	336	311	286	263	236	219	195	179	168	151	140	132	123	116	104	98	90	70	51	37	28	16	6	3	

Barlesi et al, ESMO 2016; [a] Stratified HR; HR=hazard ratio; ITT=intention-to-treat

2016 outlook

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

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Daniel O'Day

CEO Roche Pharmaceuticals

YTD Sept 2016 sales

Innovation

Outlook

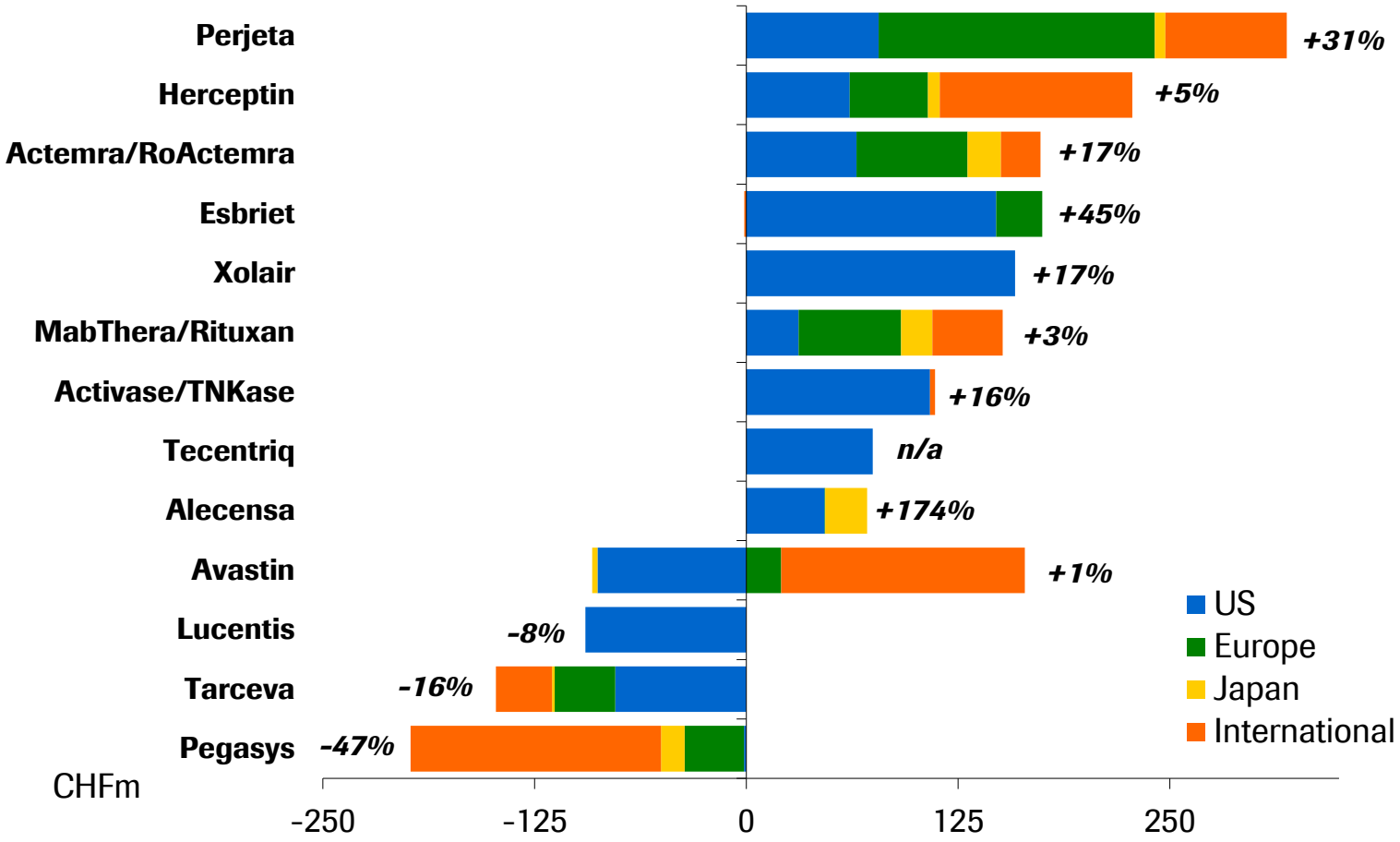
YTD Sept 2016: Pharma sales

Strong growth in US, Europe and International

	2016 CHFm	2015 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**29,140**	**27,690**	**5**	**4**
United States	13,850	13,047	6	3
Europe	6,916	6,476	7	5
Japan	2,690	2,341	15	0
International	5,684	5,826	-2	4

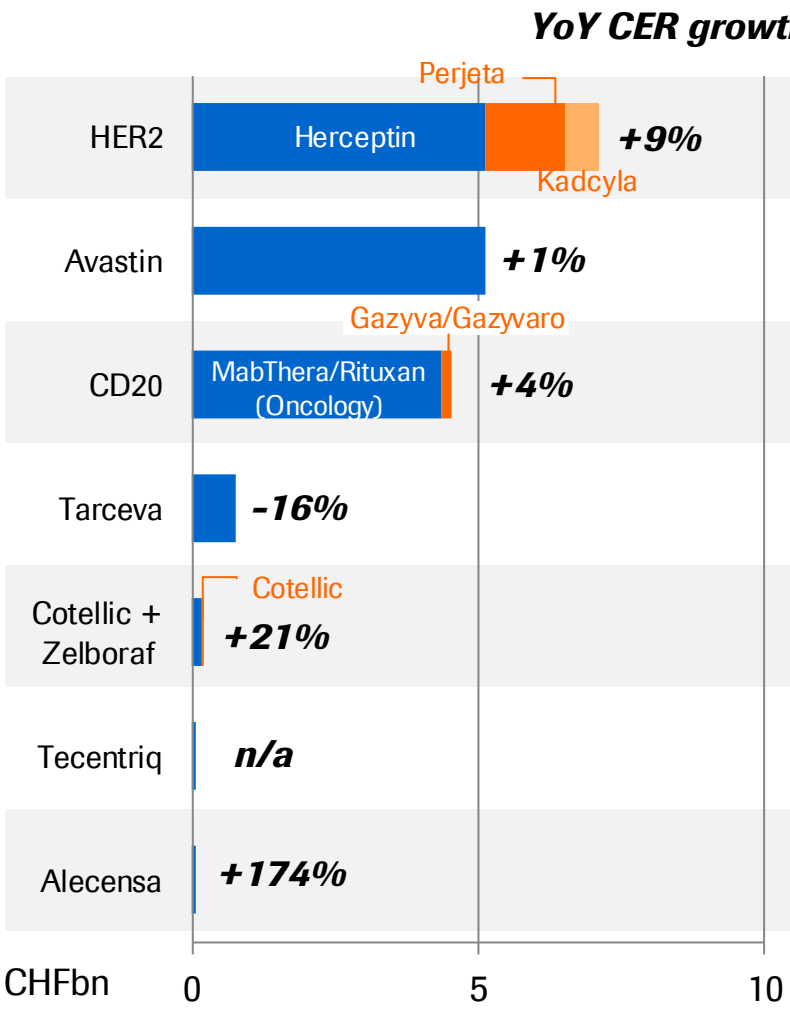
CER=Constant Exchange Rates

YTD Sept 2016: Strong performance with increasing contribution from new launches



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

YTD Sept 2016: Oncology with +4% growth



- Strong uptake of Perjeta and Kadcyla
- Growth of Herceptin due to longer treatment

- Growth impacted by decline in the US
- Outside US growth driven by ovarian and cervical

- Gazyva in R/R iNHL (GADOLIN), off to a good start
- GALLIUM data in 1L iNHL to be presented at ASH

- Increased competition
- EU: Avastin+Tarceva in 1L NSCLC approved

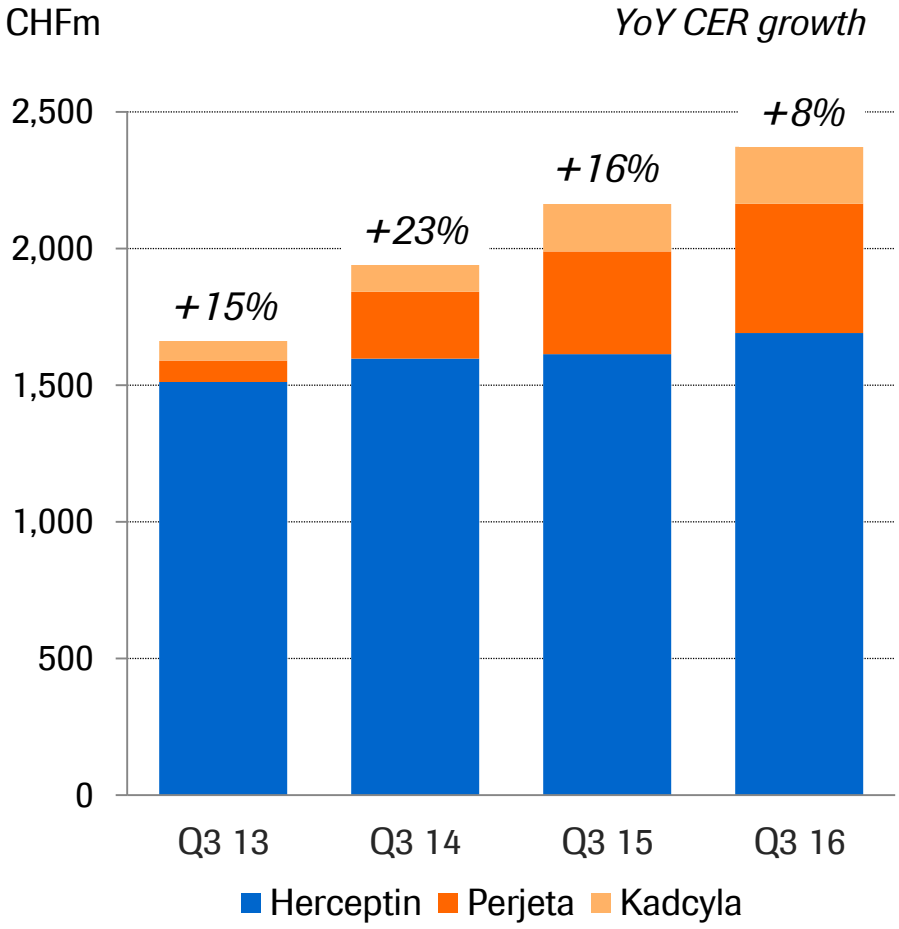
- Back to growth post launch of Cotellic

- US: Launch in bladder off to very strong start
- US approval in 2/3L lung (all-comers label)

- US: Launch in 2L off to a strong start
- BTD for 1L granted based on J-ALEX

CER=Constant Exchange Rates; BTD=breakthrough therapy designation
YTD Sep 2016 Oncology sales: CHF 18.6bn; CER growth +4%

HER2 franchise: Growth driven by Perjeta and Herceptin



HER2 franchise Q3 2016

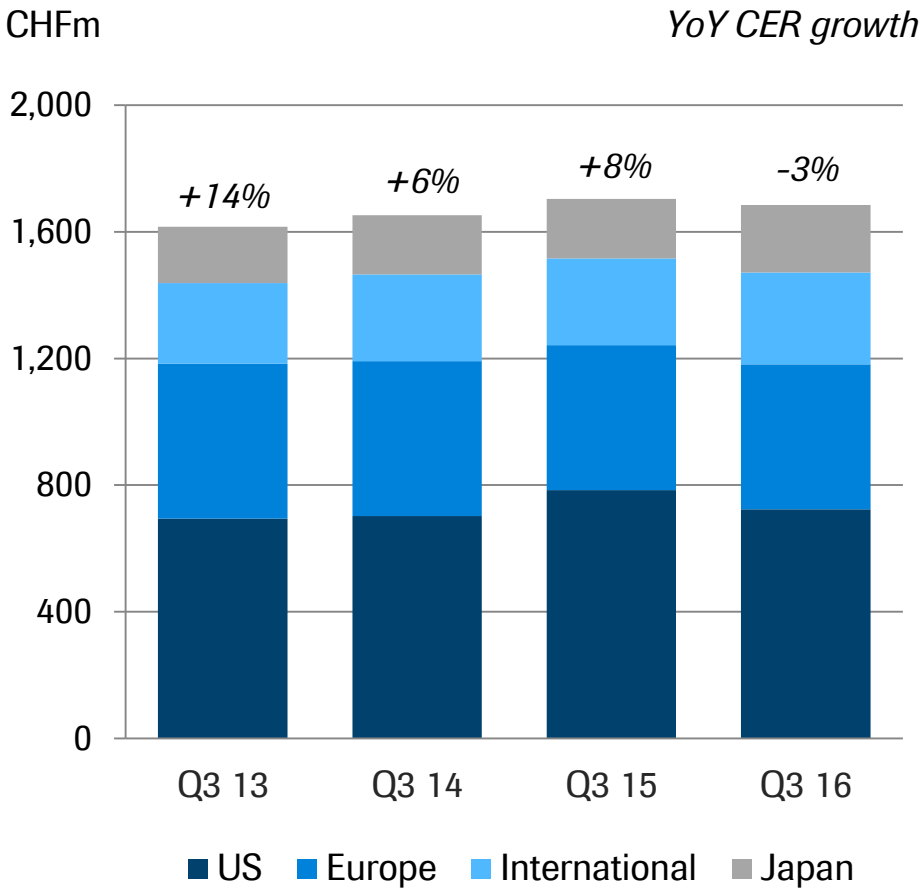
- Perjeta (+24%): Strong demand due to neoadjuvant and mBC uptake in the EU
- Herceptin (+5%): Strong volume momentum in the EU due to longer treatment duration
- Kadcyla (+5%): Growth driven by International and Japan

Outlook 2016

- Herceptin: Further SC conversion
- Perjeta: Further increasing penetration
- APHINITY (adj BC) expected in Q1 2017

CER=Constant Exchange Rates

Avastin: Growth in International



Avastin Q3 2016

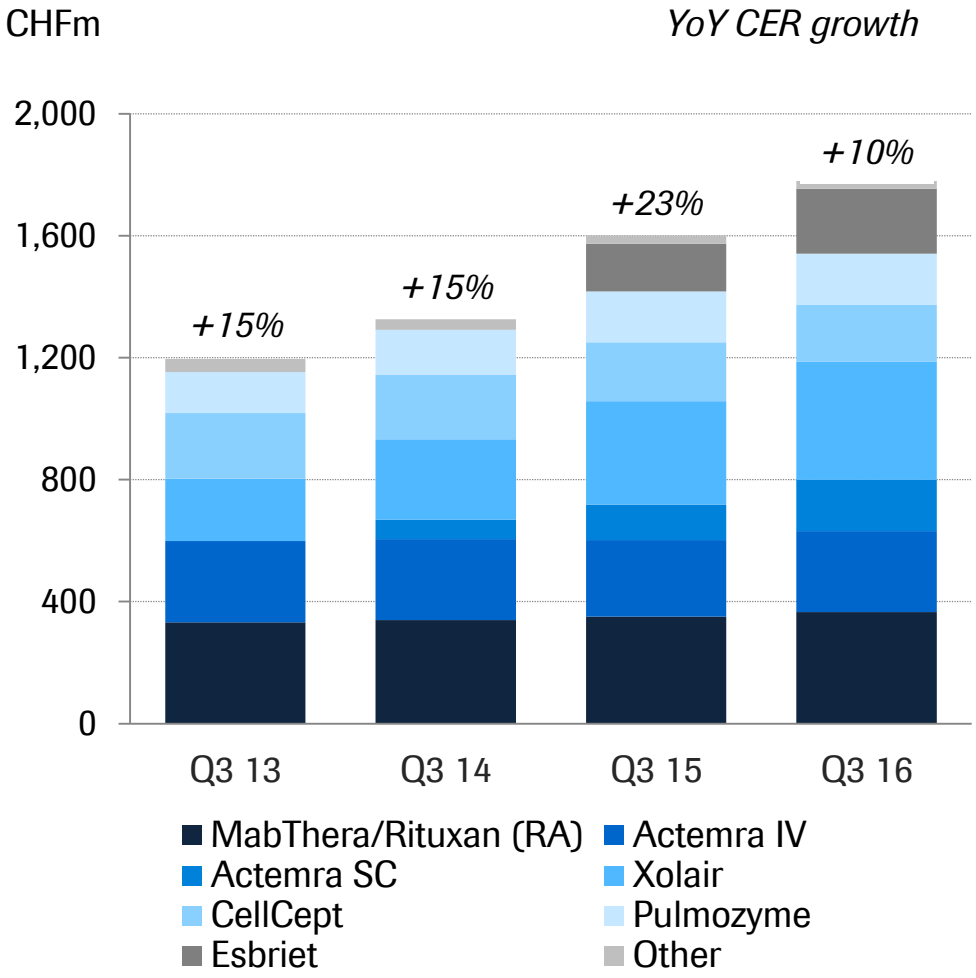
- International (+18%): growth driven by China (1L lung) and LATAM
- EU (-1%): Strong growth in Germany, UK delistings in certain indications
- US (-9%): Softness in niche areas, 340b impact
- Japan (-6%): Impacted by -10.9% mandatory price cut in April

Outlook 2016

- Continued uptake in ovarian and cervical
- Mesothelioma: Filing underway

CER=Constant Exchange Rates

Immunology: Franchise approaching CHF 8bn sales annualised



Immunology Q3 2016

Xolair (+13%)

- Allergic asthma & chronic idiopathic urticaria driving growth
- Paediatrics US approval in asthma

Actemra (+15%)

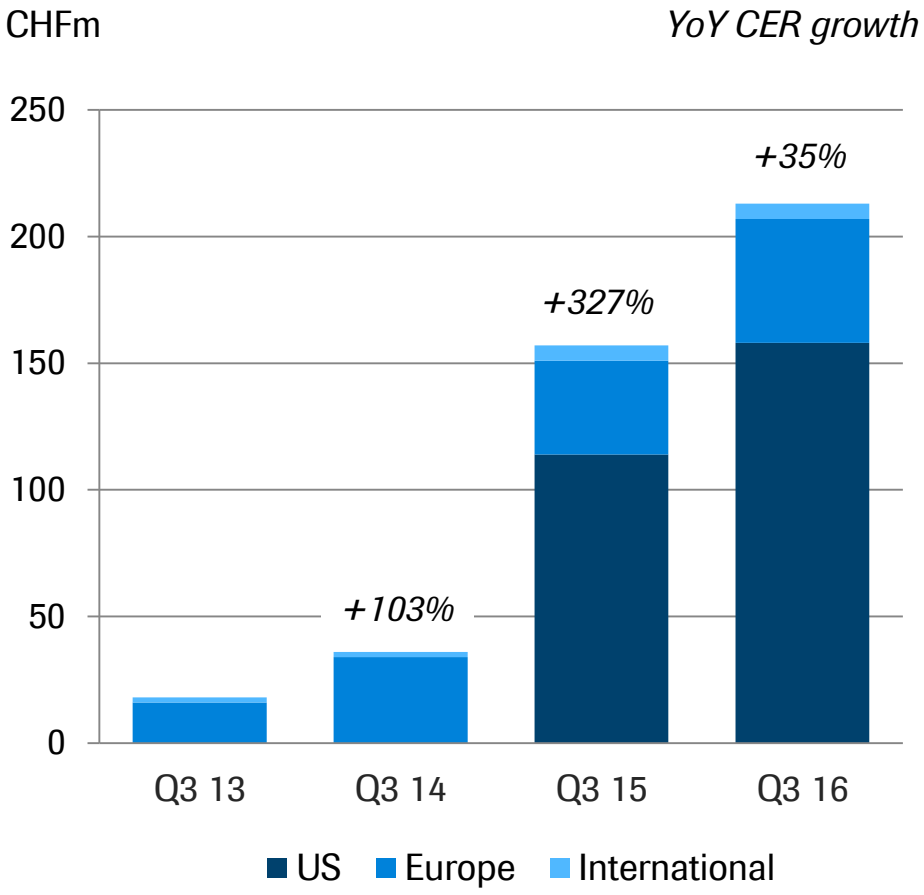
- Increasing 1L monotherapy leadership
- 2nd BTD granted after positive Ph3 results in giant cell arteritis

MabThera/Rituxan (+4%)

- Continues to grow in rheumatoid arthritis and vasculitis (GPA and MPA)

CER=Constant Exchange Rates; BTD=breakthrough therapy designation

Esbriet: Growth driven by moderate and severe patients



Esbriet Q3 2016

US (+38%)

- Growth driven by continued penetration into moderate and severe patient segments, first entries into mild segment

EU (+33%)

- Increasing differentiation due to strengthened label including the pooled 1 year mortality data
- Market leadership in EU5 maintained

Outlook 2016

- Targeting mild and moderate patient segments

Q3 2016 sales

Innovation

Outlook

Roche significantly advancing patient care
Recognition for innovation 2013-present

14 *Breakthrough Therapy Designations*

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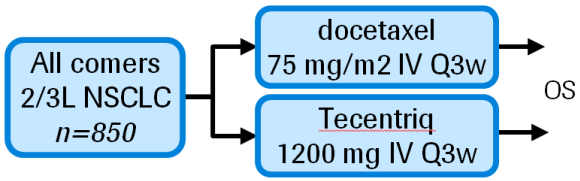
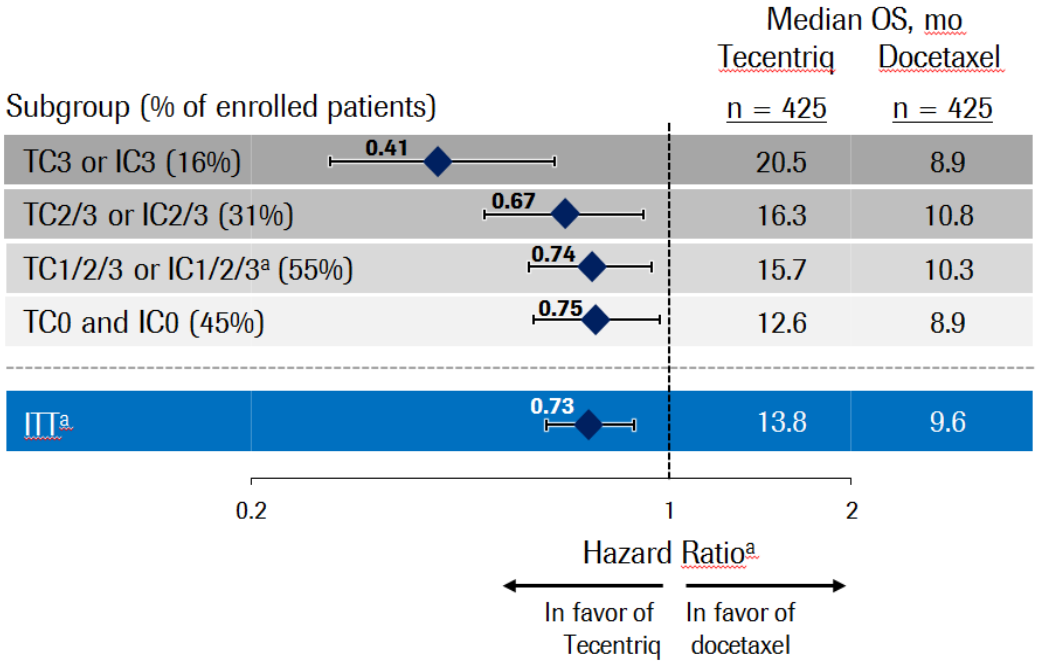
Tecentriq approved in 2L+ NSCLC
OAK data with OS benefit in all-comers

TECENTRIQ™ atezolizumab INJECTION FOR INTRAVENOUS USE 1200 mg

Phase III OAK study design





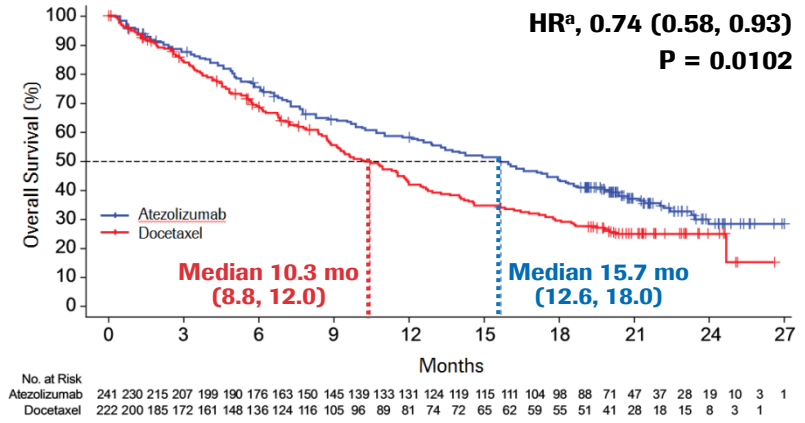
- Approved for all-comers, only aPD-L1 in 2L+ NSCLC
- First CIT agent efficacious irrespective of PD-L1 status including low/no PD-L1 expression
- Showed efficacy in important sub-groups such as never smokers, patients with brain metastases
- Active in squamous and non-squamous

Barlesi et al, ESMO 2016

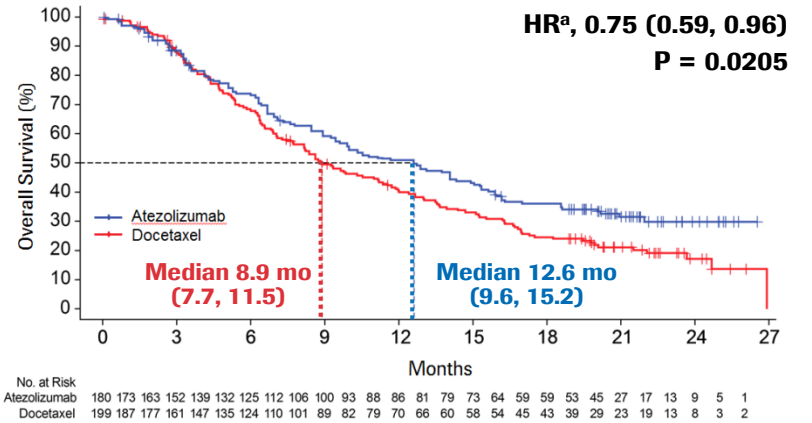
Tecentriq in 2L+ NSCLC

Survival benefit regardless of PD-L1 status

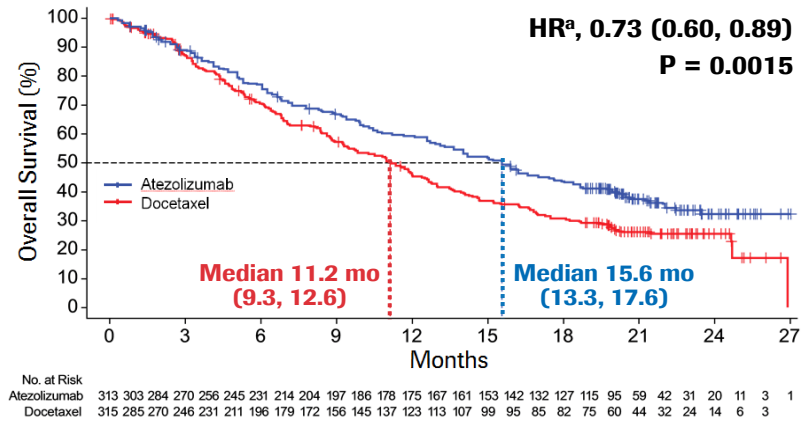
TC1/2/3 or IC1/2/3 (55% of patients)



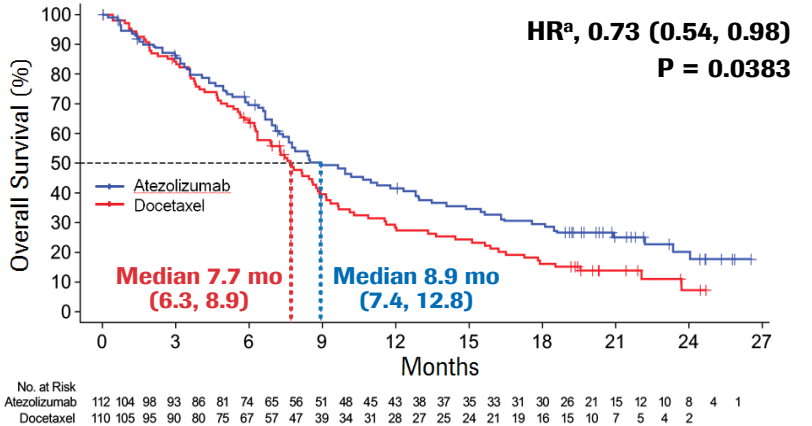
TC0 and IC0 (45% of patients)



Non-squamous (74% of patients)



Squamous (26% of patients)



Barlesi et al, ESMO 2016; [a] Stratified HR; HR=hazard ratio; TC=tumor cells; IC=tumor-infiltrating immune cells; Minimum follow up=19 months

CIT development program by tumor type

Solid tumors

Solid tumors

Tecentriq		Ph1
Tecentriq	±chemo ±Avastin	Ph1
Tecentriq	+Cotellic	Ph1
aOX40	±Tecentriq	Ph1
aCEA/CD3 TCB	±Tecentriq	Ph1
IDOi	±Tecentriq	Ph1
emactuzumab	±Tecentriq	Ph1
aCEA-IL2v FP	±Tecentriq	Ph1
aFAP-IL2v FP		Ph1
aCD40	±Tecentriq	Ph1
emactuzumab	±aCD40	Ph1
aCD40	+vanucizumab	Ph1
Tecentriq	+vanucizumab	Ph1
aTIGIT	±Tecentriq	Ph1
Tecentriq	+daratumumab*	Ph1
Tecentriq	+IFN or ipilimumab*	Ph1
Tecentriq	+A2Ai (CPI-444)*	Ph1
Tecentriq	+varlilumab*	Ph1
Tecentriq	+CXCR4 (BL8040)*	Ph1
Tecentriq	+mRNA vaccines*	Ph1

Colon

Tecentriq	+Cotellic (3L+)	**Ph3**
Tecentriq	+Cotellic+Avastin (2L+)	Ph1
Tecentriq	+T-VEC*	Ph1

Ovarian

Tecentriq	+rucaparib*	Ph1

Lung (NSCLC & SCLC)

Tecentriq	(2L/3L)	✓
Tecentriq	(1L Dx+)	**Ph3**
Tecentriq	+chemo (3x 1L trials)	**Ph3**
Tecentriq	+chemo ±Avastin (1L)	**Ph3**
Tecentriq	(adjuvant)	**Ph3**
Tecentriq	+Tarceva or Alecensa	Ph1
Tecentriq	+chemo (SCLC)	**Ph3**
Tecentriq	+epacadostat*	Ph1

Bladder

Tecentriq	(2L+ UBC)	✓
Tecentriq	+BCG (NMIBC)	Ph1
Tecentriq	(2L+ UBC)	**Ph3**
Tecentriq	(Dx+ adjuvant MIBC)	**Ph3**
Tecentriq	+ chemo (1L mUC)	**Ph3**

Breast (TNBC & HER2+)

Tecentriq	+chemo (TNBC)	**Ph3**
Tecentriq	+Kadcyla or Herceptin+ Perjeta (HER2+)	Ph1
Tecentriq	+Kadcyla (HER2+ 2L)	Ph2
Tecentriq	+T-VEC*	Ph1
Tecentriq	+entinostat*	Ph2

RCC

Tecentriq	±Avastin	Ph2
Tecentriq	+Avastin	**Ph3**

Sarcoma

Tecentriq	+NY-ESO-1 (CMB305)*	Ph2

Melanoma

Tecentriq	+Zelboraf±Cotellic	Ph1

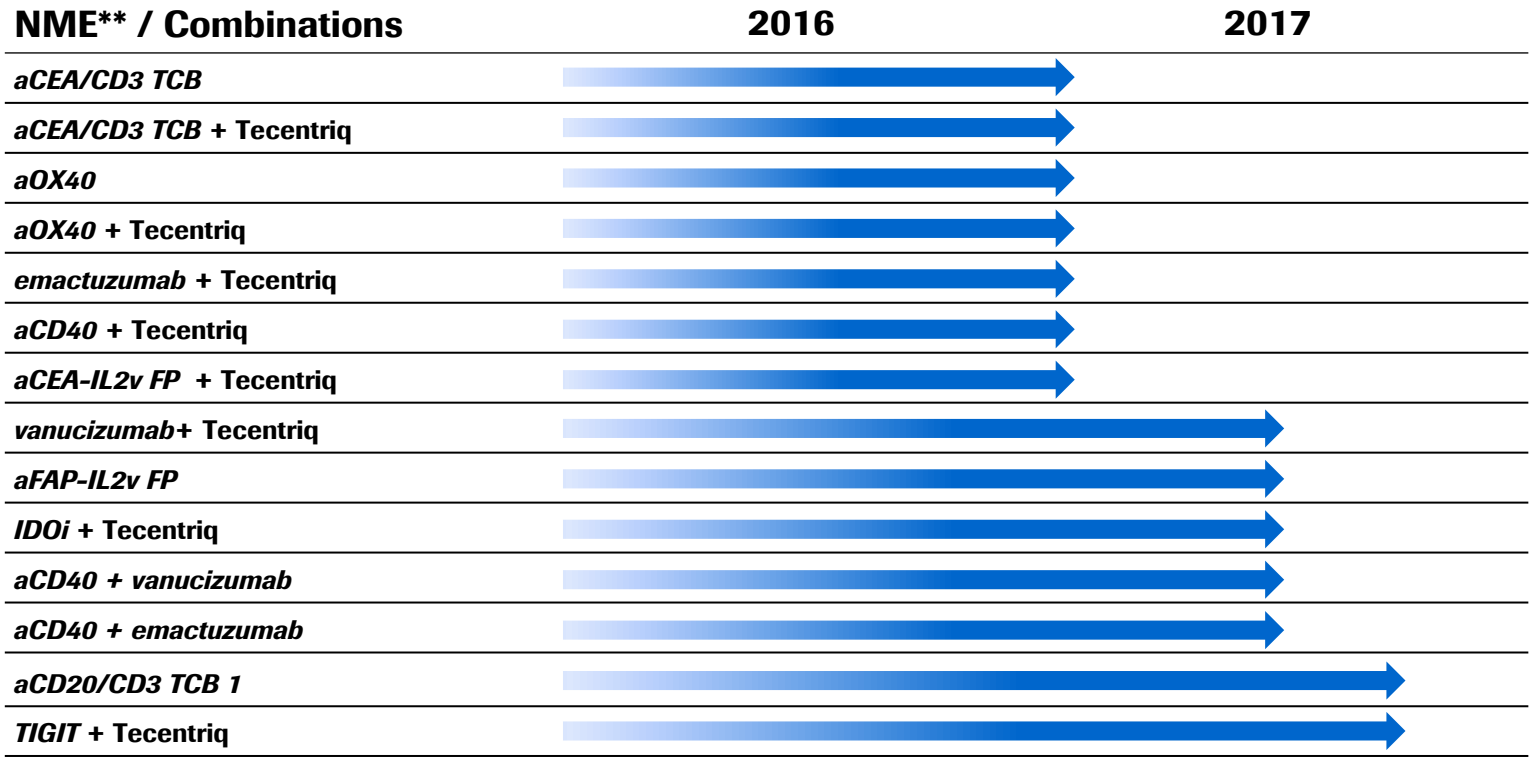
Hematological tumors

Tecentriq	±lenalidomide ±daratumumab*	(R/R MM)	Ph1
Tecentriq	±azacitidine	(MDS)	Ph1
Tecentriq	+Gazyva/Rituxan +tazemetostat*	(R/R FL and DLBCL)	Ph1
Tecentriq	+Gazyva/Rituxan+polatuzumab	(R/R FL and DLBCL)	Ph2
Tecentriq	+Gazyva/Rituxan+lenalidomide	(R/R FL and DLBCL)	Ph1
Tecentriq	+Gazyva/Rituxan+bendamustine/CHOP	(1L FL and DLBCL)	Ph1
aCD20/CD3 TCB 1			Ph1
Tecentriq	+CD19 CAR-T (KTE-C19)*	(refractory aNHL)	Ph1
Tecentriq	+guadecitabine*	AML	Ph1
Tecentriq	+CXCR4 (BL8040)*	AML	Ph1

✓ = approved; *External collaborations; Other CIT NMEs besides Tecentriq

As of Oct 20th

Cancer immunotherapy: 10 NMEs with near-term monotherapy and combination read-outs*



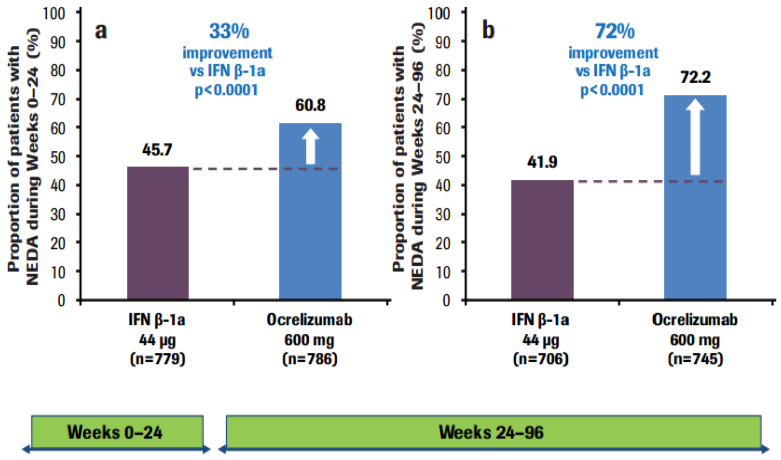
** NMEs: aCD40; aOX40; aFAP-IL2v FP; aCEA-IL2v FP; vanucizumab (aAng2/VEGF); aCEA/CD3 TCB; aCD20/CD3 TCB 1; emactuzumab (aCSF-1R); IDOi (NewLink); aTIGIT

NME=new molecular entity; * Outcome studies are event driven, timelines may change

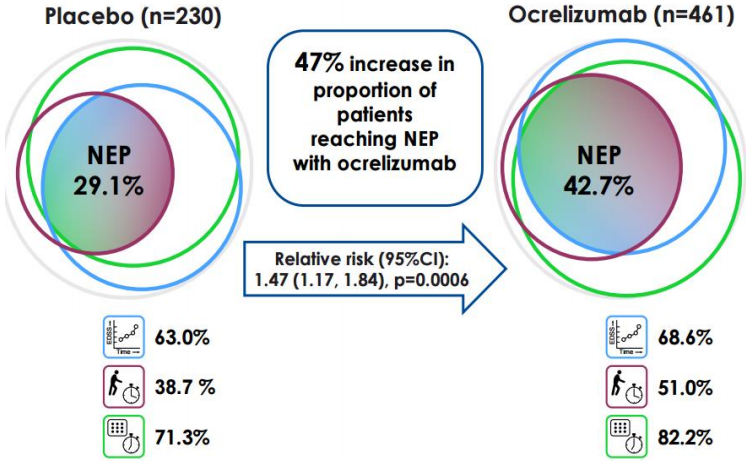
OCREVUS: First drug active in both RMS & PPMS

Strong share of voice at ECTRIMS

OPERA I & II (RMS)
No evidence of disease activity (NEDA)



ORATORIO (PPMS)
No evidence of progression (NEP)

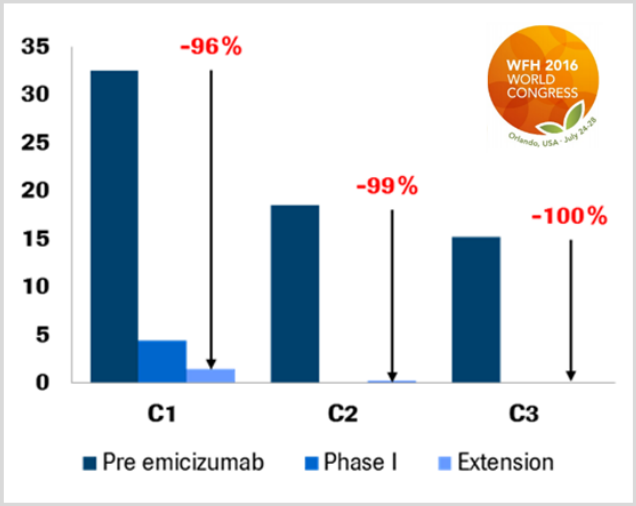


- New endpoint analysis focusing on disease progression as treatment goal
- Regulatory review by FDA/EMA for both RMS and PPMS on-going; PDUFA date: Dec 28th

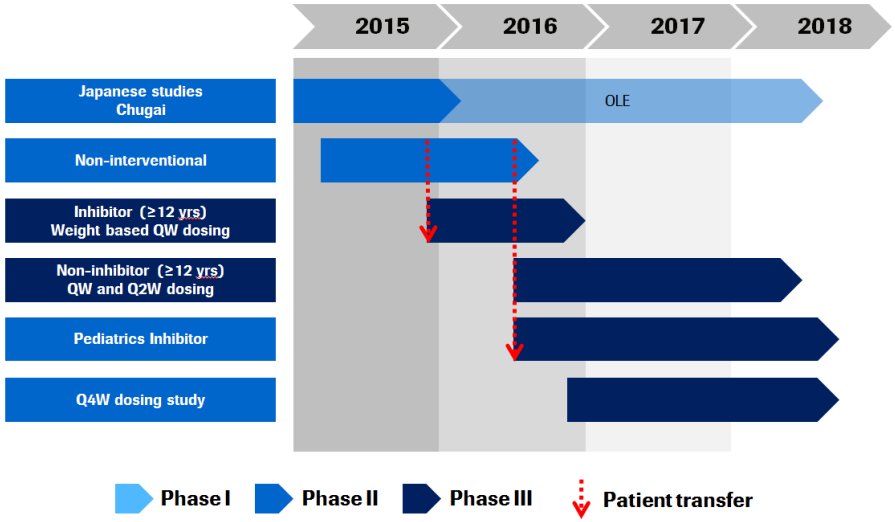
RMS=relapsing forms of multiple sclerosis (MS) which includes patients with RRMS and SPMS with superimposed relapses; RRMS=relapsing-remitting MS; SPMS=secondary progressive MS; PPMS=primary progressive MS; Giovannoni G. *et al*, presented at ECTRIMS 2016; Montalban X. *et al*, presented at ECTRIMS 2016

Emicizumab in hemophilia A

Long term follow-on data presented at WFH



Cohorts		Median follow up (Months)
C1 (0.3mg/kg)	n=6	32.6
C2 (1mg/kg)	n=6*	27.0
C3 (3mg/kg)	n=6**	21.4



- Two year follow-on data confirm efficacy and safety profile
- Additional Phase III studies in non-inhibitors and paediatrics have started
- Phase III Inhibitor results expected in Q4

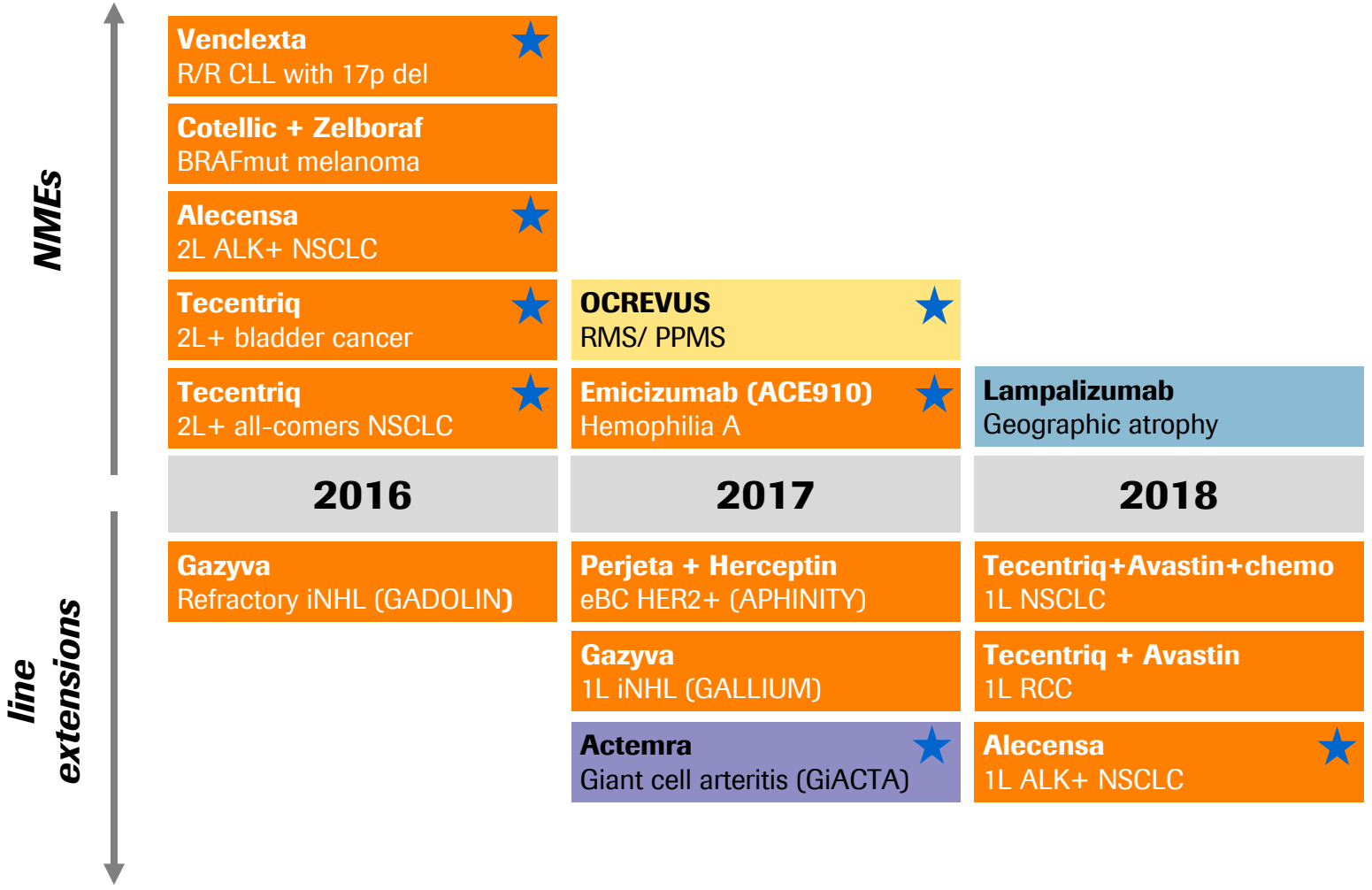
Nogami K. *et al*, presented at WFH 2016 ; ABR=annual bleeding rate; OLE=open label extension; *1 patient discontinued administration due to mild injection site erythema; **1 patient did not participate in the extension study since prior treatment was sufficiently efficacious

Q3 2016 sales

Innovation

Outlook

2016 onwards: Significant launch activities



Outcome studies are event-driven: timelines may change. Standard approval timelines of 1 year assumed.

ASH 2016

*61 abstracts, 1 plenary and 21 orals**

Gazyva

- **Gazyva:** P3 ***(GALLIUM)*** in 1L FL; Plenary session
- **Gazyva+bendamustine:** P3 **(*GADOLIN*)** in R/R FL (OS update); Oral
- **Gazyva:** P3 **(*GOYA*)** in 1L DLBCL; Oral

Polatuzumab vedotin

- **Pola+Gazyva:** P2 **(*ROMULUS*)** in R/R FL/DLBCL
- **Pola+Gazyva+CHP:** P1 in 1L DLBCL
- **Pola+Rituxan+CHP:** P1/2 in 1L DLBCL
- **Pola+Gazyva/Rituxan+bendamustine:** P1/2 in R/R FL/DLBCL

MabThera SC

- **MabThera SC:** P3 **(*SABRINA*)** pivotal study in FL (PFS update); Oral

Venclexta**

- **Venclexta+Rituxan+bendamustine:** P2 **(*CONTRALTO*)** in R/R FL
- **Venclexta+LDAC:** P1/2 in 1L unfit AML; Oral

ASH: Roche analyst briefing on Monday, Dec 5th (6PM)

* As of Oct 10th; ** Venclexta in collaboration with AbbVie; Gazyva in collaboration with Biogen; FL (iNHL)=follicular lymphoma; DLBCL (aNHL)=diffuse large B-cell lymphoma; CLL=chronic lymphoid leukemia; SC=subcutaneous

2016: Key late-stage news flow

	Compound	Indication	Milestone	
Regulatory	***Gazyva***	Rituxan-refractory iNHL	US/EU approval	✓
	Venclexta	R/R CLL with 17p deletion	US approval	✓
	OCREVUS	RMS/PPMS	US/EU filing	✓
	Tecentriq	Bladder cancer	US approval	✓
	Tecentriq	2/3L NSCLC (all-comers)	US approval	✓
	Alecensa	2L ALK+ NSCLC	EU CHMP opinion	
Phase III readouts*	***lebrikizumab***	Severe asthma	Ph III LAVOLTA I/II	✗
	Tecentriq	2/3L NSCLC	Ph III OAK	✓
	Gazyva	1L aNHL	Ph III GOYA	✗
	Gazyva	1L FL (iNHL)	Ph III GALLIUM	✓
	Perjeta + Herceptin	Adjuvant HER2+ BC	Ph III APHINITY	Q1 2017
	Actemra	Giant cell arteritis	Ph III GiACTA	✓
	Alecensa	1L ALK+ NSCLC	Ph III ALEX	early 2017
Phase II readouts*	***lebrikizumab***	Atopic dermatitis	Ph II TREBLE, ARBAN	✓
	Tecentriq	Bladder cancer	Ph II IMvigor210 (1L)	✓
	Tecentriq + Avastin	1L Renal cancer	Ph II IMmotion150	
	Venclexta + Rituxan	R/R FL (iNHL)	Ph II CONTRALTO	
	Venclexta + Rituxan/Gazyva	1L aNHL	Ph II CAVALLI	✓

* Outcome studies are event driven, timelines may change

Diagnostics Division

Roland Diggelmann

CEO Roche Diagnostics

YTD Sept 2016: Diagnostics Division sales

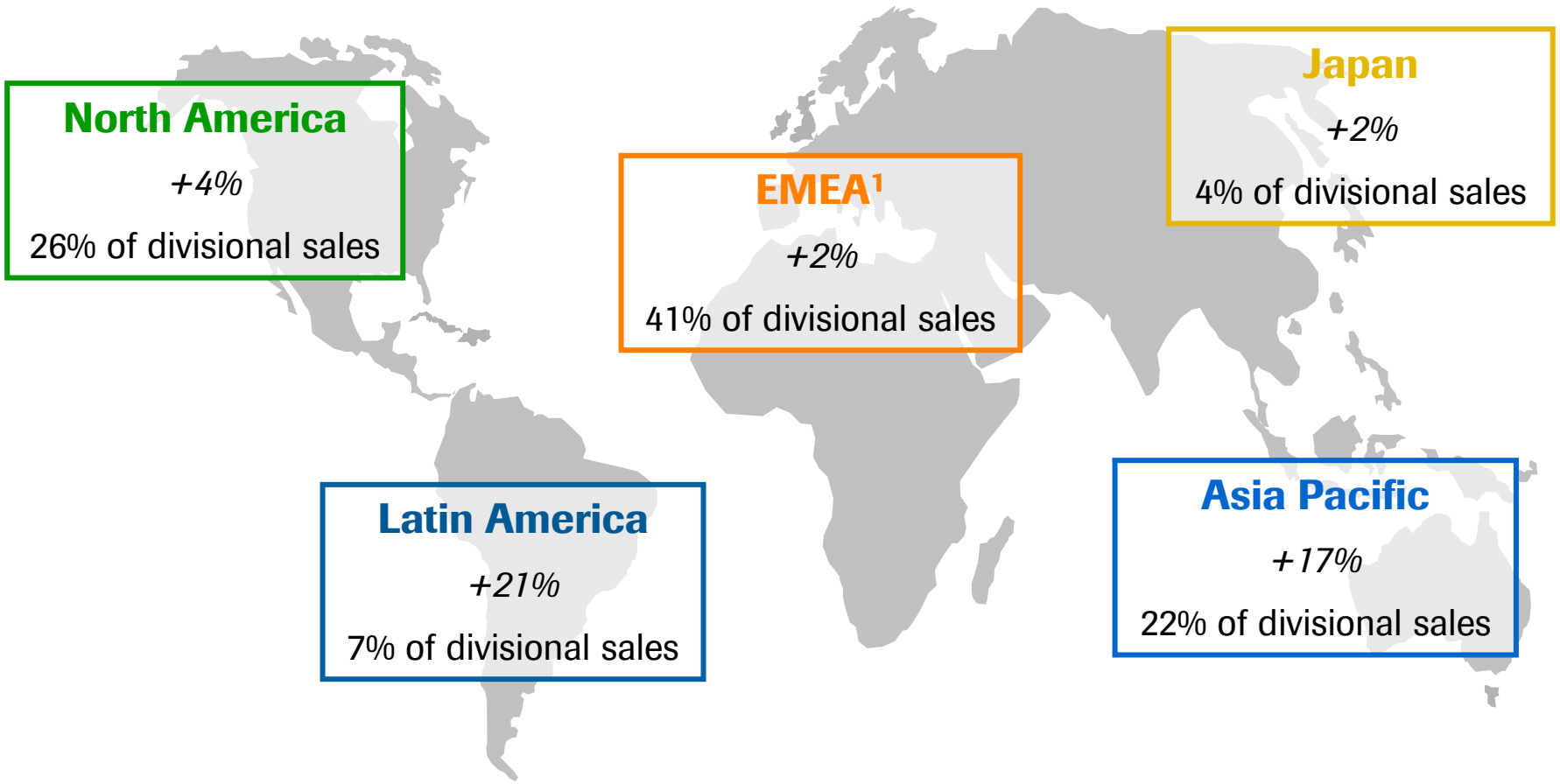
Strong growth driven by clinical diagnostics

	2016 CHFm	2015 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**8,365**	**7,835**	**7**	**7**
Professional Diagnostics	4,884	4,487	9	9
Diabetes Care	1,484	1,533	-3	-2
Molecular Diagnostics	1,345	1,248	8	7
Tissue Diagnostics	652	567	15	13

CER=Constant Exchange Rates; Underlying growth of Molecular Diagnostics excluding sequencing business: +2%

YTD Sept 2016: Diagnostics regional sales

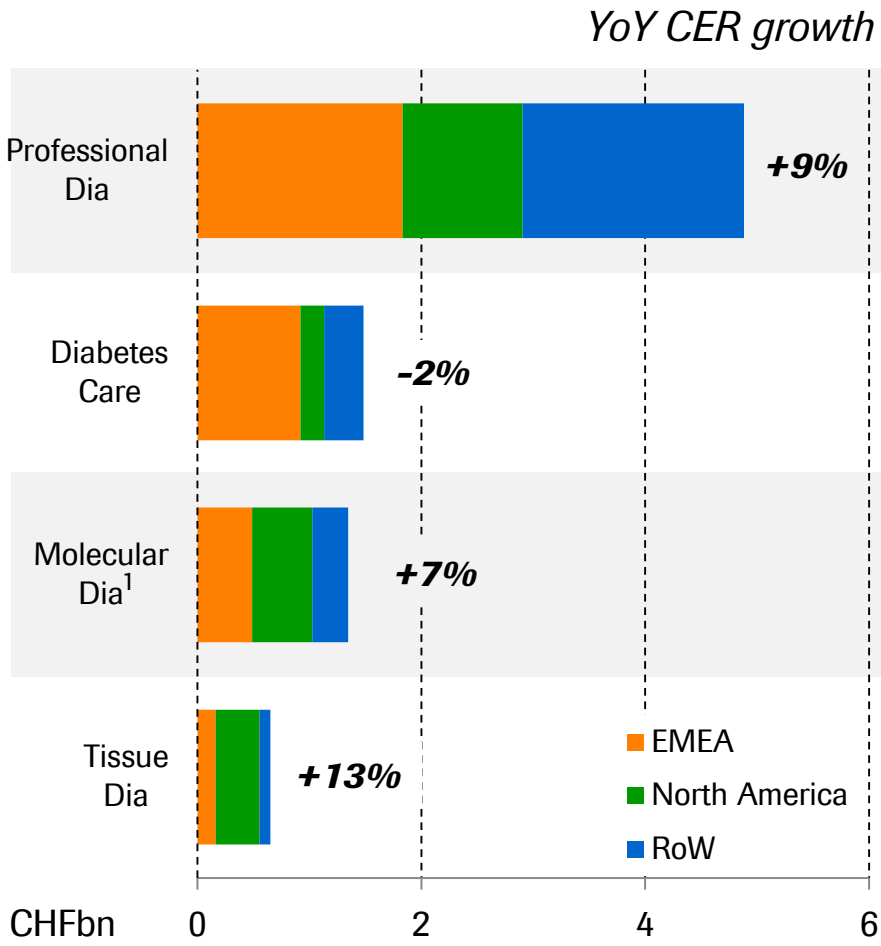
Growth driven by all regions



+21% 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

YTD Sept 2016: Diagnostics highlights
Growth driven by immunodiagnostic products

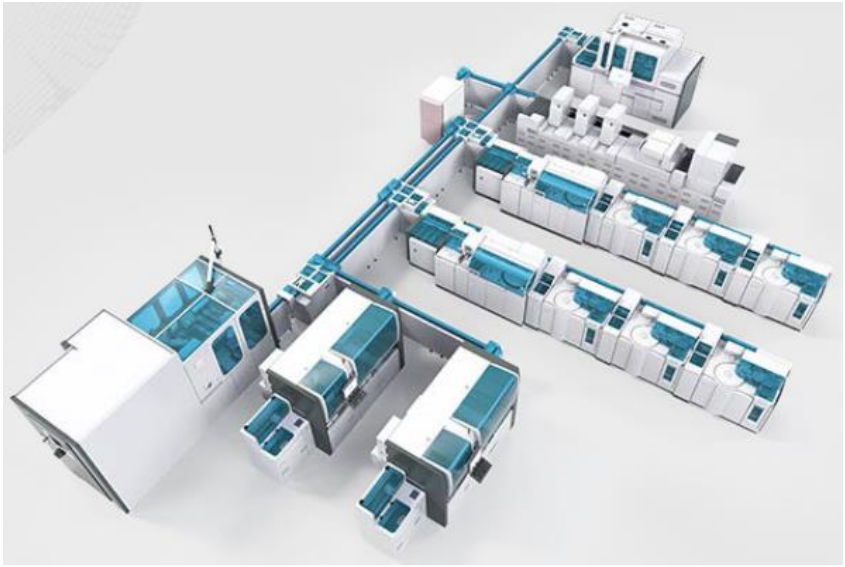


- Driven by immunodiagnostics (+14%) and clinical chemistry (+6%)
- Spillover of US reimbursement cuts to private sector
- Virology (+11%), HPV (+13%) and blood screening (+3%)
- Advanced staining portfolio (+9%); primary staining (+18%)

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

The connected core laboratory

Launch of next generation immunoassay analyser cobas e 801



- Latest addition to the cobas 8000 family
- Dedicated to high throughput laboratories
- Modularity and expansion potential
- Over 100 instruments delivered 3 months after launch

Meeting the molecular testing needs
Expanding virology solutions

cobas®
4800 System

Virology test menu

- HIV-1
- HBV
- HCV
- HCV GT
- CMV*
- HPV

cobas®
6800/8800 System

Virology test menu

- HIV-1
- HBV
- HCV
- CMV
- HIV-1/2 Qual*

Growth drivers

- Increased HCV testing due to new treatment options
- Increased HBV testing driven by APAC
- Increased HIV testing due to Global Access Program in Sub-Saharan Africa
- Only CE marked and FDA approved CMV virology test
- Increased HPV testing driven by FDA approval for primary screening

* In Development

HBV: hepatitis B virus; HCV GT: hepatitis C virus genotyping; CMV: cytomegalovirus; HPV: human papillomavirus

Rapid Zika assay development in 2016

Fast response and broadest solution

cobas® Zika test	LightMix® Zika rRT-PCR Test	
	 	
March 30	**June 20**	**August 29**
• FDA - Investigational New Drug Application • Use with cobas® 6800/8800 Systems • FDA expands testing recommendation to all of US and its territories	• Available in markets accepting the CE mark • For use with Roche's LightCycler® 480 or cobas z 480	• FDA – Emergency Use Authorization

cobas® Influenza A/B & RSV* test approved

Point of care lab quality PCR results in ~20 min

cobas® Influenza A/B & RSV test

cobas® Liat System

- Full test menu of Strep A, Influenza A/B and Influenza A/B & RSV*
- Plans to extend menu in MRSA and C. difficile
- Manufacturing process ramped up

* RSV: respiratory cyncytial virus

Key launches 2016

	Area	Product	Market
Instruments / Devices	***Central Laboratory***	cobas 8000 <e 801> – high throughput immunochemistry analyzer	EU ✓
		cobas c 513 – high throughput dedicated HbA1c analyzer	US
	Point of Care	CoaguChek INRange (Zenith) – modified analyzer for intuitive self testing with full blue tooth connectivity	EU ✓
	Sequencing	Roche SMRT Sequencer – single molecule sequencer for clinical research (in collaboration with Pacific Biosciences)	WW
	Diabetes Care	Accu-Chek Guide – next-generation blood glucose monitoring system	EU ✓
		Accu-Chek Insight CGM – new high-performance continuous glucose monitoring system	EU
Tests / Assays	***Virology***	cobas 6800/8800 HIV Qual – early Infant Diagnosis and Confirmatory HIV Test	EU
	HPV / Microbiology	cobas 6800/8800 CT/NG – fully automated solution for screening and diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae in symptomatic & asymptomatic patients*	EU
	Point of Care	cobas Liat Influenza A/B plus RSV (CLIA) – automated multiplex real time RT-PCR assay for qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV)	US ✓
	Sequencing	ctDNA oncology panels – liquid biopsy for circulating tumor DNA for cancer therapy selection	US
	Companion Diagnostics	PD-L1 (SP142) for Bladder Cancer* – complementary diagnostic for Tecentriq	US ✓
		PD-L1 (SP142) for NSCLC* – complementary diagnostic for Tecentriq	US ✓

* achieve commercial readiness, dependent on Pharma label and approval

Finance

Alan Hippe

Chief Financial Officer

Q3 2016: Highlights

Sales

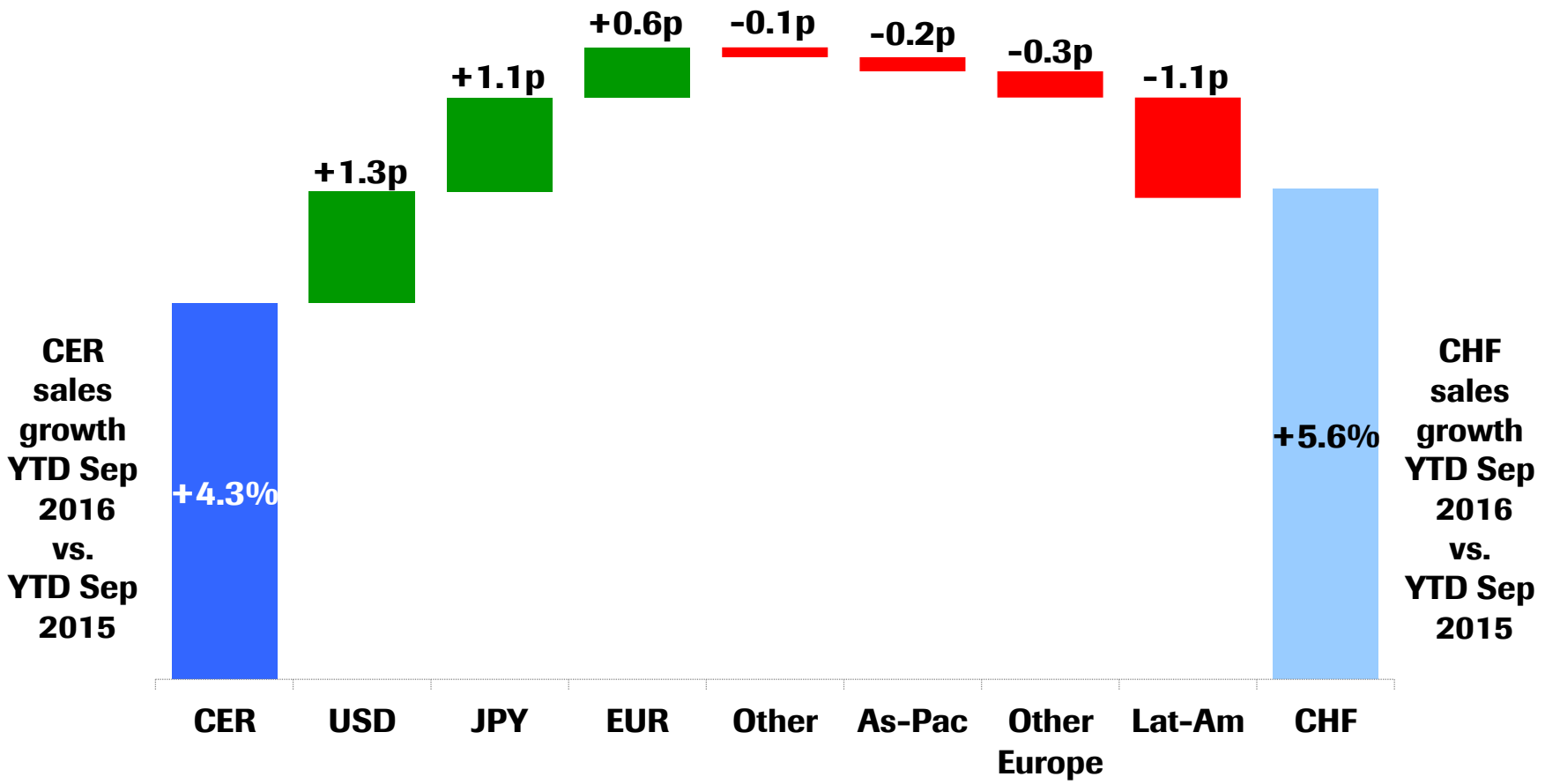
- Good underlying sales growth in all regions and both divisions

Currency impact

- Positive impact from USD, JPY and EUR currencies partly offset by Latin America

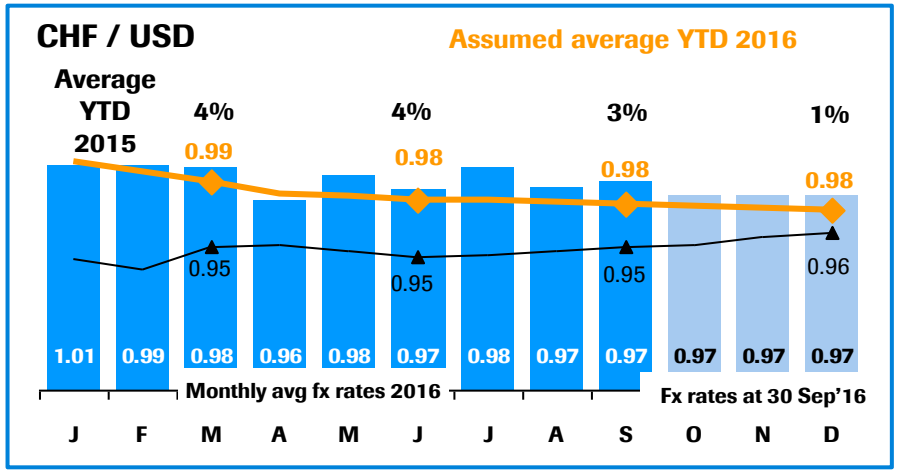
Exchange rate impact on sales growth

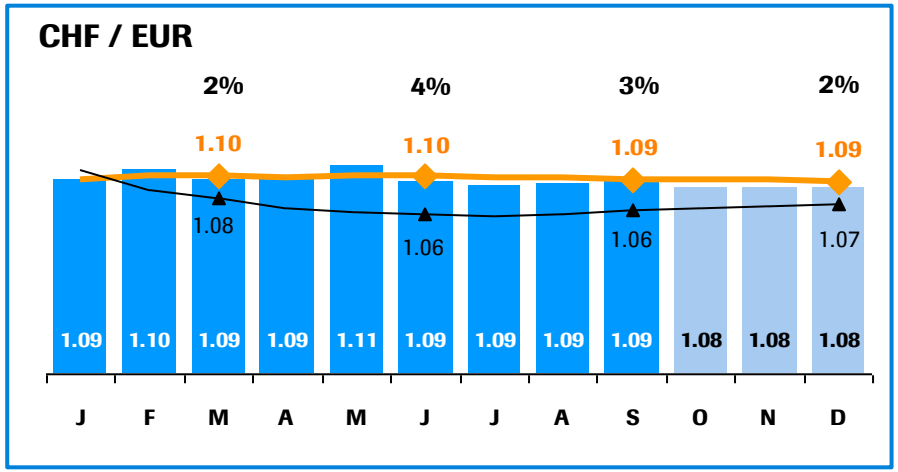
Positive impact from USD, JPY and EUR



CER = Constant Exchange Rates (avg full year 2015)

Low currency impact expected in 2016





Assuming the 30 September 2016 exchange rates remain stable until end of 2016, 2016 impact is expected to be (%p):

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

2016 outlook

Group sales growth[1]	Low to mid-single digit
Core EPS growth[1]	Ahead of sales growth
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 YTD Sept 2016 sales

Diagnostics

Foreign exchange rate information

Changes to the development pipeline
Q3 2016 update

New to Phase I	New to Phase II	New to Phase III	New to Registration
2 AIs: **RG7421** Cotellic+Tecentriq+Avastin – CRC 2L/3L **RG7446** Tecentriq + radium 223 - mCRPC	**2 NMEs transitioned from Ph1 :** **RG6149** ST2 MAb – asthma **RG7845** BTK inh – autoimmune diseases **1 AI:** **RG3502** Kadcyla + Tecentriq – Her2+ 2L mBC	**2 AIs:** **RG6013** emicizumab – hemophilia A, pediatric patients with FVIII inhibitors **RG6013** emicizumab – hemophilia A, adults and adolescents without FVIIII inhibitors	**1 AI:** **RG3645** Lucentis - myopic CNV
Removed from Phase I	**Removed from Phase II**	**Removed from Phase III**	**Removed from Registration**
4 NMEs: **RG7775** MDM2 (4) IV prodrug – AML **RG4929** – glaucoma **RG7842** ERK inh + Cotellic – solid tumors **RG7944** therapeutic vaccine – HBV	**1 NME:** **RG7795** TLR7 agonist – HBV		

Status as of October 20, 2016

Roche Group development pipeline

Phase I
(39 NMEs+25 AIs)

RG6016	LSD1 inh	AML
RG6047	SERD (2)	ER+(HER2-neg) mBC
RG6058	TIGIT ± Tecentriq	solid tumors
RG6061	HIF1 alpha LNA	solid tumors
RG6078	IDO inh	solid tumors
RG6078	IDO inh+Tecentriq	solid tumors
RG6146	BET inh	solid and heme tumors
RG7155	emactuzumab+Tecentriq	solid tumors
RG7155	emactuzumab+CD40 iMAb	s. tumors
RG7159	Gazyva multiple combos	heme indications
RG7304	Raf /MEK dual inh	solid tumors
RG7386	FAP-DR5 biMAb	solid tumors
RG7421	Cotellic+Tecentriq+Avastin	CRC 2L/3L
RG7446	Tecentriq	solid tumors
RG7446	Tecentriq+Zelboraf±Cotellic	melanoma
RG7446	Tecentriq±Avastin±chemo	HCC-GC-PaC
RG7446	Tecentriq±Avastin±chemo	s. tumors
RG7446	Tecentriq+Cotellic	solid tumors
RG7446	Tecentriq+ipi/IFN	solid tumors
RG7446	Tecentriq+Tarceva/Alecensa	NSCLC
RG7446	Tecentriq-Gazyva	lymphoma
RG7446	Tecentriq±lenalidomide±daratumumab	MM
RG7446	Tecentriq+K/HP	HER2+ BC
RG7446	Tecentriq	NMIBC
RG7446	Tecentriq+HMA	MDS
RG7446	Tecentriq+radium 223	mCRPC
RG7461	FAP IL2v FP	solid tumors
RG7601	Venclexta	heme indications
RG7601	Venclexta + Gazyva	CLL
RG7601	Venclexta+Cotellic/idasanutlin	AML
RG7741	ChK1 inh	solid tumors, lymphoma
RG7802	CEACD3 TCB± Tecentriq	solid tumors
RG7813	*CEA IL2v FP+Tecentriq	solid tumors
RG7828	CD20/CD3 biMAb	heme tumors
RG7841	Ly6E ADC	solid tumors
RG7876	CD40 iMAb+Tecentriq	solid tumors
RG7876	CD40 iMAb+vanucizumab	solid tumors
RG7882	ADC	ovarian ca
RG7888	OX40 MAb	solid tumors
RG7888	OX40 MAb + Tecentriq	solid tumors
RG7986	ADC	r/r NHL
RG3616	Erivedge+Esbriet	IPF
RG3616	Erivedge+ruxolitinib	myelofibrosis
RG6069	-	fibrosis
RG6125	Cadherin-11 MAb	RA
RG7159	obinutuzumab	renal transplant
RG7880	IL-22Fc	inflammatory diseases
RG7990	-	asthma
RG6080	DBO β-lactamase inh	bact. infections
RG7834	-	HBV
RG7861	S. aureus TAC	infectious diseases
RG7992	FGFR1/KLB MAb	metabolic diseases
RG6000	-	ALS
RG6029	Nav1.7 inh (2)	pain
RG6100	Tau MAb	Alzheimer's disease
RG7203	PDE10A inh	schizophrenia
RG7800	SMN2 splicer	spinal muscular atrophy
RG7893	Nav1.7 inh	pain
RG7906	-	psychiatric disorders
RG7916	SMN2 splicer(2)	spinal muscular atrophy
RG7935	α-synuclein MAb	Parkinson's Disease
IONIS	ASO	Huntington's Disease
CHU	PTH1 recep. ago	hypoparathyroidism
CHU	-	hyperphosphatemia

Phase II
(19 NMEs+12 AIs)

RG3502	Kadcyla	HER2+ NSCLC
RG3502	Kadcyla + Tecentriq	Her2+ 2L mBC
RG6046	SERD	ER+(HER2-neg) BC
RG7221	vanucizumab	mCRC
RG7421	Cotellic+paclitaxel	TNBC
RG7440	ipatasertib	solid tumors
RG7596	polatuzumab vedotin	heme tumors
RG7601	Venclexta	DLBCL
RG7601	Venclexta + Rituxan	FL rel/ref
RG7604	taselisib	NSCLC sq 2L
RG7604	taselisib+letrozole	(HER2-) BC neoadj
RG7686	codrituzumab	liver cancer
RG3637	lebrikizumab +/- Esbriet	IPF
RG3637	lebrikizumab	atopic dermatitis
RG3637	lebrikizumab	COPD
RG6149	ST2 MAb	asthma
RG7159	obinutuzumab	lupus nephritis
RG7625	Cat-S antag	autoimmune diseases
RG7845	BTK inh	autoimmune diseases
CHU**	nemolizumab (IL-31R)	atopic dermatitis
CHU	nemolizumab (IL-31R)	pruritus dialysis pts
PRO	VAP-1 inh	inflammatory disease
RG6152	CAP endonuclease inh	influenza
RG7227	danoprevir	HCV
RG7745	Flu A MAb	influenza A
CHU	URAT1 inh	gout
RG1662	basmisanil	cognitive disorders
RG6083	olesoxime	spinal muscular atrophy
RG7314	V1 receptor antag	autism
RG3645	ranibizumab PDS	wAMD
RG7716	VEGF-ANG2 biMAb	wAMD, DME

New Molecular Entity (NME)
Additional Indication (AI)

Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

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

*NN: cergutuzumab amunaleukin
**outlicensed to Galderma and Maruho

Status as of October 20, 2016

Roche Group development pipeline

Phase III
(8 NMEs + 31 AIs)

RG435[1]	Avastin	glioblastoma 1L
RG435	Avastin	mesothelioma
RG1273	Perjeta+Herceptin	HER2+ BC adj
RG1273	Perjeta+Herceptin	HER2+gastric ca 1L
RG3502	Kadcyla	HER2+ BC adj
RG3502	Kadcyla+Perjeta	HER2+ BC adj
RG6013	emicizumab	hemophilia A FVIII inhibitors
RG6013	emicizumab	pediatric hemophilia A FVIII inh
RG6013	emicizumab	hemophilia A without FVIII inh
RG7159	Gazyva	follicular lymphoma 1L
RG7204	Zelboraf	melanoma adj
RG7388	idasanutlin	AML
RG7421	Cotellic + Tecentriq	CRC 3L
RG7446	Tecentriq+Abraxane	NSCLC non-sq. 1L
RG7446	Tecentriq+chemo+Avastin	NSCLC non-sq.1L
RG7446	Tecentriq+chemo+pemetrexed	NSCLC non-sq.1L
RG7446	Tecentriq+Abraxane	NSCLC sq. 1L
RG7446	Tecentriq Dx+	NSCLC sq. & non sq. 1L
RG7446	Tecentriq	NSCLC adj
RG7446	Tecentriq+Abraxane	TNBC
RG7446	Tecentriq+Avastin	RCC
RG7446	Tecentriq	muscle inv. bladder ca adj
RG7446	Tecentriq±chemo	mUC 1L
RG7446	Tecentriq+chemo	extens. stage SCLC 1L
RG7601	Venclexta+Rituxan	CLL rel/refract
RG7601	Venclexta+Gazyva	CLL 1L
RG7601	Venclexta+bortezomib	MM
RG7604	taselisib+fulvestrant	PIK3CAmut ER+(HER2-)mBC
RG7853	Alecensa	ALK+ NSCLC 1L

RG105	MabThera	pemphigus vulgaris
RG1569	Actemra	giant cell arteritis
RG1569	Actemra	systemic sclerosis
RG7413	etrolizumab	ulcerative colitis
RG7413	etrolizumab	Crohn's disease
CHU	Actemra	large-vessel vasculitis
RG1450	gantenerumab	Alzheimer's
RG6168	IL-6R Mab (SA237)	neuromyelitis optica
RG7412	crenezumab	Alzheimer's
RG7417	lampalizumab	geographic atrophy

Registration
(3 NMEs + 4 AIs)

RG105[2]	MabThera SC	CLL
RG435[3]	Avastin	rel. ovarian ca. Pt-sensitive
RG7446[4]	Tecentriq	mUC 2L
RG7446[5]	Tecentriq	NSCLC 2L+
RG7853[6]	Alecensa	ALK+ NSCLC 2L
RG1594	OCREVUS®	PPMS & RMS
RG3645[1]	Lucentis	myopic CNV

1 US only
2 Approved in EU – Filing US pending
3 EU chemo backbone extension filing pending
4 Phase 3 ongoing – Approved in US
5 Approved in US
6 Approved in US and Japan

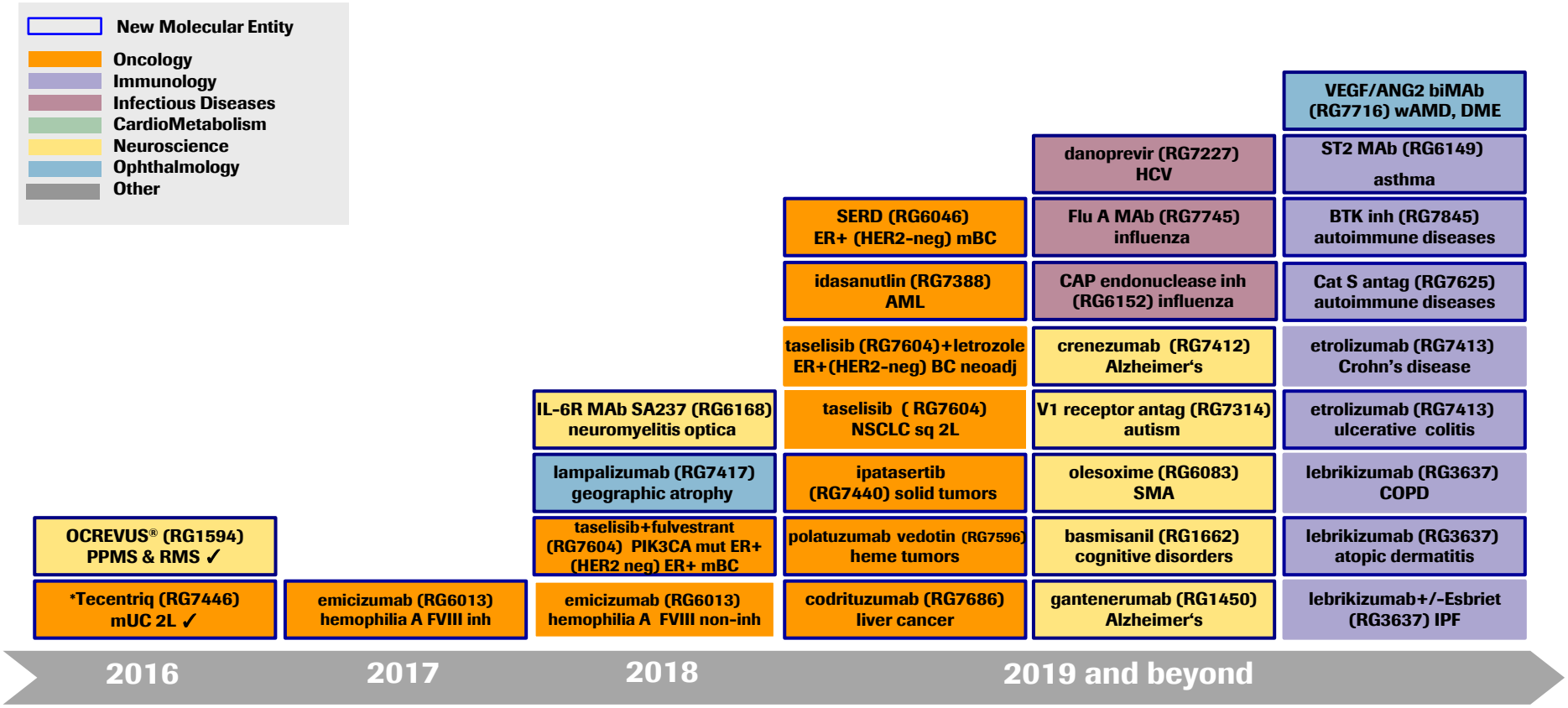
New Molecular Entity (NME)
Additional Indication (AI)
Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other

RG-No Roche/Genentech managed
CHU Chugai managed
IONIS IONIS managed
PRO Proximagen managed
RG105 MabThera is branded as Rituxan in US and Japan
RG1569 Actemra is branded as RoActemra in EU
RG7159 Gazyva is branded as Gazyvaro in EU

Status as of October 20, 2016

NME submissions and their additional indications

Projects currently in phase 2 and 3



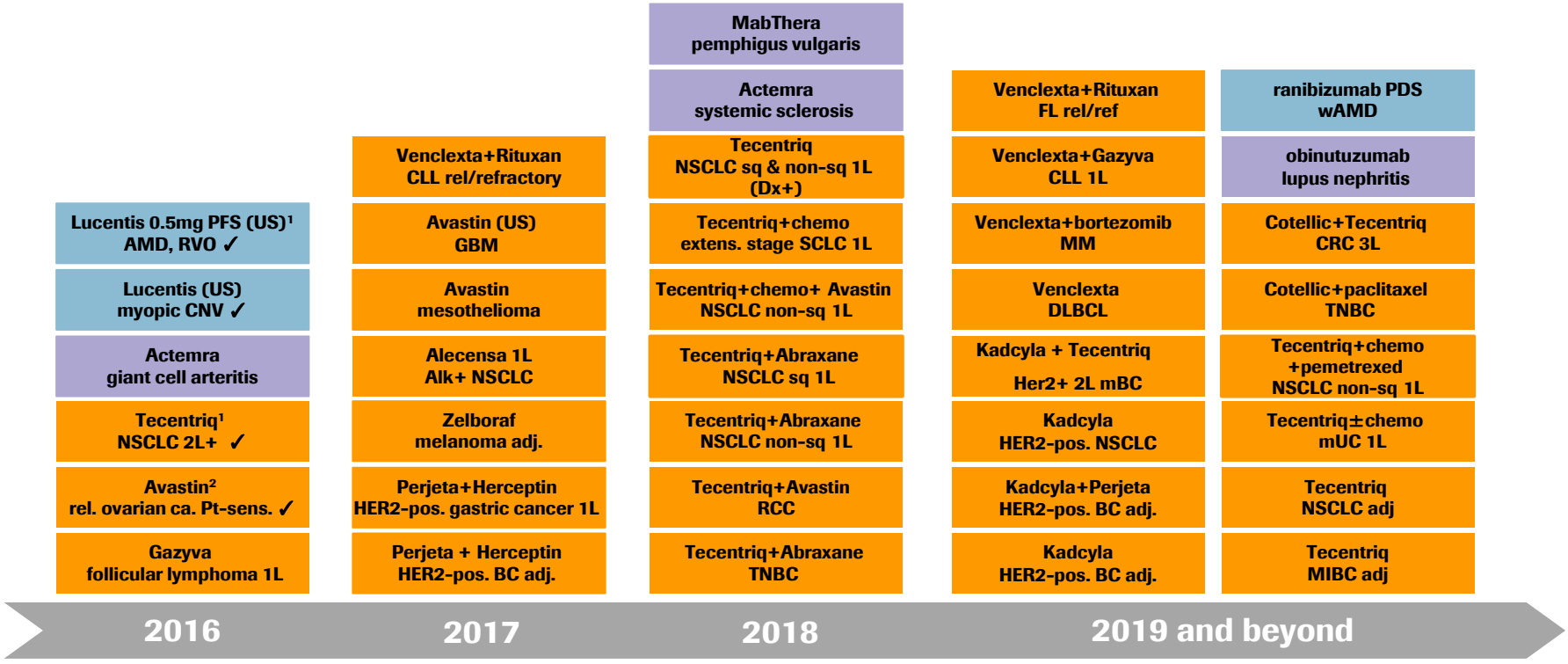
Unless stated otherwise, submissions are planned to occur in US and EU

✓indicates a submission which has occurred with regulatory action pending ; *approved in US

Status as of October 20, 2016

Submissions of additional indications for existing products

Projects currently in phase 2 and 3

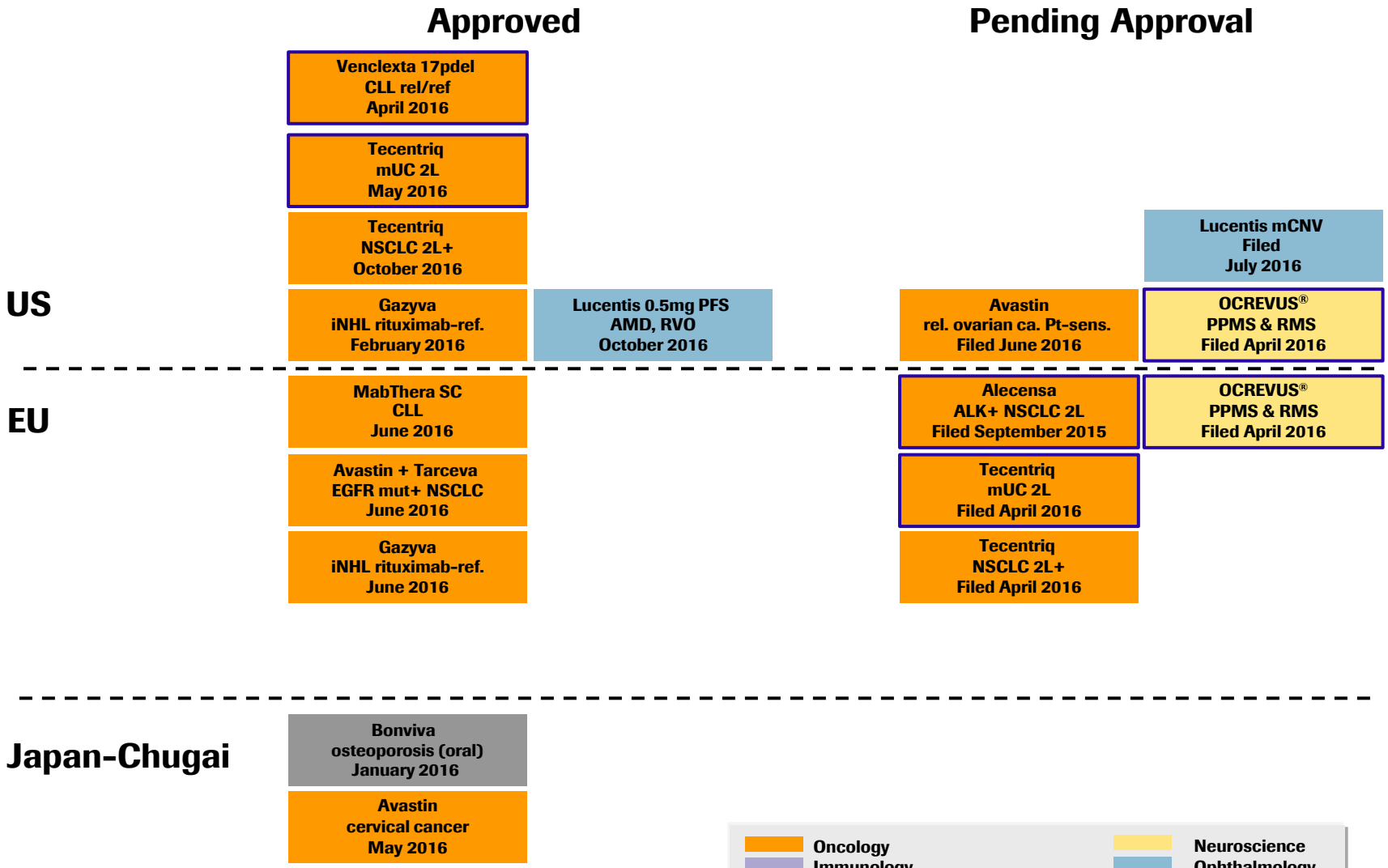


✓ indicates submission to health authorities has occurred
1 Approved in US
2 Approved in EU
Unless stated otherwise, submissions are planned to occur in US and EU.

Oncology
Immunology
Infectious Diseases
CardioMetabolism
Neuroscience
Ophthalmology
Other
NME

Status as of October 20, 2016

Major granted and pending approvals 2016



Status as of October 20, 2016

Roche Group Development pipeline
Combinations

Phase I
(5 NMEs + 21 AIs)

RG6058	TIGIT ± Tecentriq	solid tumors
RG6078	IDO inh+Tecentriq	solid tumors
RG7155	emactuzumab+Tecentriq	solid tumors
RG7155	emactuzumab+CD40 iMAb	s. tumors
RG7159	Gazyva multiple combos	heme indications
RG7421	Cotellic+Tecentriq+Avastin	CRC 2L/3L
RG7446	Tecentriq+Zelboraf±Cotellic	melonama
RG7446	Tecentriq±Avastin±chemo	HCC-GC-PaC
RG7446	Tecentriq±Avastin±chemo	s. tumors
RG7446	Tecentriq+Cotellic	solid tumors
RG7446	Tecentriq+ipi/IFN	solid tumors
RG7446	Tecentriq+Tarceva/Alecensa	NSCLC
RG7446	Tecentriq-Gazyva	lymphoma
RG7446	Tecentriq±lenalidomide±daratumumab	MM
RG7446	Tecentriq+K/HP	HER2+ BC
RG7446	Tecentriq+HMA	MDS
RG7446	Tecentriq +radium 223	mCRPC
RG7601	Venclexta + Gazyva	CLL
RG7601	Venclexta+Cotellic/idasanutlin	AML
RG7802	CEACD3 TCB±Tecentriq	solid tumors
RG7828	*CEA IL2v FP+Tecentriq	solid tumors
RG7876	CD40 iMAb+Tecentriq	solid tumors
RG7876	CD40 iMAb+vanucizumab	solid tumors
RG7888	OX40 MAb + Tecentriq	solid tumors
RG3616	Erivedge+Esbriet	IPF
RG3616	Erivedge+ruxolitinib	myelofibrosis

Phase II
(5 AIs)

RG3502	Kadcyla + Tecentriq	Her2+ 2L mBC
RG7421	Cotellic+paclitaxel	TNBC
RG7601	Venclexta + Rituxan	FL rel/ref
RG7604	taselisib+letrozole	(HER2-) BC neoadj
RG3637	lebrikizumab +/- Esbriet	IPF

Phase III
(1 NME + 15 AIs)

RG1273	Perjeta+Herceptin	HER2+ BC adj
RG1273	Perjeta+Herceptin	HER2+gastric ca 1L
RG3502	Kadcyla + Perjeta	HER2+ BC adj
RG7421	Cotellic + Tecentriq	CRC 3L
RG7446	Tecentriq+Abraxane	NSCLC non-sq.1L
RG7446	Tecentriq+chemo+Avastin	NSCLC non-sq.1L
RG7446	Tecentriq+chemo+pemetrexed	NSCLC non-sq.1L
RG7446	Tecentriq+Abraxane	NSCLC sq. 1L
RG7446	Tecentriq+Abraxane	TNBC
RG7446	Tecentriq+Avastin	RCC
RG7446	Tecentriq±chemo	mUC 1L
RG7446	Tecentriq+chemo	extens. stage SCLC 1L
RG7601	Venclexta+Rituxan	CLL rel/refract
RG7601	Venclexta+Gazyva	CLL 1L
RG7601	Venclexta+bortezomib	MM
RG7604	taselisib+fulvestrant	PIK3CAmut ER+(HER2-)mBC

New Molecular Entity (NME)
Additional Indication (AI)

Oncology
Immunology

RG-No **Roche Genentech managed**

*INN: cergutuzumab amunaleukin

Status as of October 20, 2016

Cancer immunotherapy pipeline overview

Phase I
(9 NMEs + 28 AIs)

RG6058	TIGIT+Tecentriq	solid tumors
RG6078	IDO inh	solid tumors
RG6078	IDO inh+Tecentriq	solid tumors
RG7155	emactuzumab+Tecentriq	solid tumors
RG7155	emactuzumab+CD40 iMAb	s. tumors
RG7421	Cotellic+Tecentriq+Avastin	CRC 2L/3L
RG7446	Tecentriq	solid tumors
RG7446	Tecentriq+Zelboraf±Cotellic	melonama
RG7446	Tecentriq±Avastin±chemo	HCC-GC-PaC
RG7446	Tecentriq±Avastin±chemo	s. tumors
RG7446	Tecentriq+Cotellic	solid tumors
RG7446	Tecentriq+ipi/IFN	solid tumors
RG7446	Tecentriq+Tarceva/Alecensa	NSCLC
RG7446	Tecentriq+Gazyva	lymphoma
RG7446	Tecentriq±lenalidomide±daratumumab	MM
RG7446	Tecentriq+K/HP	HER2+ BC
RG7446	Tecentriq	NMIBC
RG7446	Tecentriq+HMA	MDS
RG7446	Tecentriq +radium 223	mCRPC
RG7461	FAP IL2v FP	solid tumors
RG7802	CEACD3 TCB± Tecentriq	solid tumors
RG7828	*CEA IL2v FP+Tecentriq	solid tumors
RG7828	CD20/CD3 biMAb	heme tumors
RG7876	CD40 iMAb+Tecentriq	solid tumors
RG7876	CD40 iMAb+vanucizumab	solid tumors
RG7888	OX40 MAb	solid tumors
RG7888	OX40 MAb + Tecentriq	solid tumors
*INCY	Tecentriq+IDO inh	solid tumors
*CLDX	Tecentriq+varlilumab	s. tumors
*CRVS	Tecentriq+CPI-4444	s. tumors
*KITE	Tecentriq+KTE-019	r/r DLBCL
*AMGN	Tecentriq+talimogene laherp	TNBC, CRC
*JNJ	Tecentriq ±daratumumab	s. tumors
*CLVS	Tecentriq+rucaparib	ovarian ca
Epizyme	Tecentriq+tazemetostat	r/r DLBCL
Astex [1]	Tecentriq+guadecitabine	AML
BioLine Rx	Tecentriq + BL-8040	AML & s. tumors

Phase II
(3 AIs)

RG3502	Kadcyla + Tecentriq	Her2+ 2L mBC
IMDZ	Tecentriq+NY-ESO-1	soft tissue sarcoma
SNDX	Tecentriq+entinostat	TNBC

Phase III
(12 AIs)

RG7421	Cotellic + Tecentriq	CRC 3L
RG7446	Tecentriq+chemo	NSCLC non-sq. 1L
RG7446	Tecentriq+chemo+Avastin	NSCLC non-sq.1L
RG7446	Tecentriq+chemo+pemetrexed	NSCLC non-sq.1L
RG7446	Tecentriq+chemo	NSCLC sq. 1L
RG7446	Tecentriq Dx+	NSCLC sq. & non sq. 1L
RG7446	Tecentriq	NSCLC adj
RG7446	Tecentriq+Abraxane	TNBC
RG7446	Tecentriq+Avastin	RCC
RG7446	Tecentriq	muscle inv. bladder ca adj
RG7446	Tecentriq±chemo	mUC 1L
RG7446	Tecentriq+chemo	extens. stage SCLC 1L

Registration
(1 NME + 1 AI)

RG7446 [2]	Tecentriq	mUC 2L
RG7446[3]	Tecentriq	NSCLC 2L+

1 FPI expected Q4 2016
2 Phase 3 ongoing - Approved in US
3 Approved in US

New Molecular Entity (NME)
Additional Indication (AI)

Oncology

RG-No Roche Genentech managed

*external collaborations: INCY- Incyte INCB024360, CLDX - Celldex CD27 MAb; CLVS – Clovis PARPi, CRVS – Corvus CPI-444, KITE – Kite KTE-C19, AMGN – Amgen oncolytic virus, JNJ – Janssen CD38 MAb., IMDZ – Immune Design CMB305, SNDX – Syndax HDACi

Status as of October 20, 2016

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group YTD Sept 2016 sales

Diagnostics

Foreign exchange rate information

Alecensa (alectinib, RG7853, AF802)

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK-positive advanced non-small cell lung cancer (NSCLC)	ALK-positive advanced NSCLC in ALK inhibitor-naïve patients who are chemotherapy-naïve or have received one previous line of chemotherapy	ALK-positive crizotinib-naïve advanced NSCLC
Phase/study	**Phase III** **ALEX**	**Phase III** **J-ALEX/Japic CTI-132316** **Japanese study**	**Phase I/II** **AF-001JP** Japanese study
# of patients	N=286	N=207	N=70
Design	▪ **ARM A**: Alecensa 600mg BID ▪ **ARM A**: crizotinib 250mg BID	▪ **ARM A**: Alecensa 300mg BID ▪ **ARM A**: crizotinib 250mg BID	▪ **Part 1**: Dose escalation monotherapy ▪ **Part 2**: Monotherapy, dose selected based on the results of Part 1
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Phase I: Determination of recommended dose ▪ Phase II: Safety and efficacy
Status	▪ Recruitment completed Q3 2015 ▪ Data expected in 2017	▪ Primary analysis positive ▪ Data presented at ASCO 2016 ▪ Breakthrough therapy designation granted by US FDA Q3 2016	▪ Results published in Lancet Oncology 2013 Jun;14(7):590-8 ▪ Approved in Japan July 2014

In collaboration with Chugai; ASCO=American Society of Clinical Oncology

Alecensa (alectinib, RG7853, AF802)

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	ALK-positive advanced NSCLC after progression on crizotinib treatment	ALK-positive advanced NSCLC after progression on crizotinib treatment
Phase/study	**Phase I/II** **AF-002JG/NP28761** US study	**Phase I/II** **ACCALIA/NP28673** Global study
# of patients	Phase I: N=36 Phase II: N=85	N=130
Design	▪ **Part 1**: Dose escalation monotherapy ▪ **Part 2**: Monotherapy, dose selected based on the results of Part 1	▪ **Part 1**: Dose escalation monotherapy ▪ **Part 2**: Monotherapy, dose selected based on the results of Part 1
Primary endpoint	▪ Phase I: Determination of recommended dose ▪ Phase II: Safety and efficacy	▪ Phase I: Determination of recommended dose ▪ Phase II: Safety and efficacy
Status	▪ Phase I data presented at ECC 2013 ▪ Phase I full cohort, including CNS data, published in *Lancet Oncology* 2014, Sept.15(10):1119-28 ▪ Phase II FPI Q3 2013 ▪ Primary analysis positive Q1 2015 ▪ Data presented at ASCO 2015 ▪ Updated data presented at WCLC 2015	▪ Phase II FPI Q3 2013 ▪ Primary analysis positive Q4 2014 ▪ Updated analysis in Q1 2015 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ECC 2015 ▪ Updated data presented at ESMO 2016
	▪ Filed Q2 (US) and Q3 (EU) 2015 ▪ Priority review granted by FDA Q3 2015 ▪ Breakthrough therapy designation granted by US FDA June 2013 ▪ Approved in US Q4 2015	

In collaboration with Chugai

ECC=European Cancer Congress; ASCO=American Society of Clinical Oncology; WCLC=World Conference on Lung Cancer

Avastin

Ovarian cancer clinical development programme

Indication	Relapsed platinum-sensitive ovarian cancer	
Phase/study	**Phase III OCEANS**	**Phase III GOG-0213**
# of patients	N=484	N=674
Design	▪ **ARM A:** Carboplatin, gemcitabine, and concurrent placebo for 6 - 10 cycles, followed by placebo alone until disease progression ▪ **ARM B:** Carboplatin, gemcitabine, and concurrent Avastin for 6 - 10 cycles, followed by Avastin alone until disease progression.	▪ **ARM A**: carboplatin and paclitaxel ▪ **ARM B**: carboplatin, paclitaxel and Avastin (from cycle 2 onwards until disease progression).
Avastin dose	▪ 15 mg/kg q3 weeks	▪ 15 mg/kg q3 weeks
Primary endpoint	▪ Progression-free survival	▪ Overall survival
Status	▪ Primary endpoint met Q1 2011 ▪ EMA approval received Q4 2012 ▪ Final data presented at SGO 2014 ▪ Filed with US FDA June 2016	▪ Study showed a 4.9 mo overall survival benefit ▪ Presented SGO Q1 2015 ▪ Filed with US FDA June 2016

SGO=Society of Gynecologic Oncology

Avastin

Brain cancer clinical development programmes

Indication	Newly diagnosed glioblastoma
Phase/study	**Phase III** **AVAglio**
# of patients	N=920
Design	▪ **ARM A:** Concurrent radiation and temozolomide plus placebo; followed by maintenance TMZ plus placebo for 6 cycles; then placebo until disease progression ▪ **ARM B:** Concurrent radiation and TMZ plus Avastin; followed by maintenance TMZ plus Avastin for 6 cycles; then Avastin (15mg/kg q3 weeks) monotherapy until disease progression
Avastin dose	▪ 10 mg/kg q2 weeks or 15 mg/kg q3 weeks
Primary endpoint	▪ Progression-free survival ▪ Overall survival
Status	▪ Co-primary endpoint of PFS met Q3 2012 ▪ Overall survival data presented at ASCO 2013 ▪ Filed in EU Q1 2013 ▪ Negative CHMP opinion Q3 2014 ▪ US filing pending

TMZ=temozolomide
ASCO=American Society of Clinical Oncology

Cotellic (cobimetinib)

Selective small molecule inhibitor of mitogen-activated protein kinase kinase

Indication	Third-line advanced or metastatic colorectal cancer	2L/3L metastatic colorectal cancer	Locally advanced or metastatic tumours
Phase/study	**Phase III IMblaze370 COTEZO**	**Phase I**	**Phase I**
# of patients	N=360	N=33	N=151
Design	▪ **ARM A:** Tecentriq ▪ **ARM B:** Cotellic plus Tecentriq ▪ **ARM C:** regorafenib	▪ 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 – (1) expansion, (2) biopsy	▪ **ARM A:** Dose-finding - Cotellic plus Tecentriq ▪ **ARM B:** Dose-expansion - Cotellic plus Tecentriq
Primary endpoint	▪ Overall survival	▪ Safety	▪ Safety
Status	▪ FPI Q2 2016	▪ FPI Q3 2016	▪ FPI Q4 2013 ▪ CRC data presented at ASCO, ESMO 2016

In collaboration with Exelixis
ESMO=European Society for Medical Oncology

Cotellic (cobimetinib)

Selective small molecule inhibitor of mitogen-activated protein kinase kinase

Indication	First-line metastatic triple negative breast cancer	Previously untreated metastatic melanoma BRAF mutation positive	Relapsed or refractory AML not eligible for cytotoxic therapy
Phase/study	**Phase II COLET**	**Phase I**	**Phase I/II**
# of patients	N=150	N=70	N=140
Design	▪ **ARM A:** Cotellic plus paclitaxel ▪ **ARM B:** placebo plus paclitaxel	▪ Dose-finding study of Cotellic + Tecentriq (PD-L1 MAb) + Zelboraf[1] and Tecentriq (PD-L1 MAb) +Zelboraf[1] combinations	Phase I (dose escalation) ▪ **ARM A:** Cotellic plus Venclexta ▪ **ARM B:** idasanutlin plus Venclexta Phase II (expansion) ▪ **ARM A:** Cotellic plus Venclexta ▪ **ARM B:** idasanutlin plus Venclexta
Primary endpoint	▪ Progression-free survival, safety	▪ Safety/PK	▪ Safety and efficacy
Status	▪ FPI Q1 2015	▪ FPI Q4 2012 ▪ Data presented at ESMO 2016	▪ FPI Q1 2016

In collaboration with Exelixis

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

Erivedge

A novel small molecule inhibitor of the hedgehog signalling pathway

Indication	Locally advanced or metastatic basal cell carcinoma	Idiopathic pulmonary fibrosis	Intermediate- or high-risk myelofibrosis (MF)
Phase/study	**Phase II STEVIE**	**Phase Ib ISLAND 2**	**Phase Ib MYLIE**
# of patients	N=1,200	N=20	N=20
Design	▪ **Single ARM:** 150 mg Erivedge orally once daily	▪ Erivedge plus Esbriet	▪ Erivedge plus ruxolitinib
Primary endpoint	▪ Safety: Incidence of adverse events	▪ Safety and tolerability	▪ Safety and efficacy
Status	▪ FPI Q2 2011 ▪ Recruitment completed Q3 2014 ▪ Interim data presented at SMR 2014	▪ FPI Q1 2016	▪ FPI Q1 2016

In collaboration with Curis; SMR=Society for Melanoma Research

Gazyva/Gazyvaro (obinutuzumab)

Oncology development programme

Indication	Diffuse large B-cell lymphoma (DLBCL)	Indolent non-Hodgkin's lymphoma MabThera/Rituxan refractory	Front-line indolent non-Hodgkin's lymphoma
Phase/study	**Phase III GOYA**	**Phase III GADOLIN** Induction and maintenance study	**Phase III GALLIUM** Induction and maintenance study
# of patients	N=1,418	N=411	N=1,401
Design	▪ **ARM A:** Gazyva 1000mg IV plus CHOP ▪ **ARM B:** MabThera/Rituxan plus CHOP	▪ **ARM A:** Gazyva 1000mg IV plus bendamustine followed by Gazyva mainteinance ▪ **ARM B:** bendamustine	▪ **ARM A:** Gazyva 1000mg IV + chemo followed by Gazyva maintenance ▪ **ARM B:** MabThera/Rituxan + chemo followed by MabThera/Rituxan maintenance ▪ Chemotherapy: ▪ For follicular lymphoma (FL): CHOP, CVP or bendamustine ▪ For non-follicular lymphoma: physician's choice
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Progression-free survival in FL patients (N=1202)
Status	▪ Final analysis: Primary endpoint not met July 2016 ▪ Data to be presented at upcoming medical conference	▪ Trial stopped at interim for efficacy Q1 2015 ▪ Approved by the FDA Q1 2016 after priority review and by EMA Q2 2016 ▪ Data update to be presented at upcoming medical conference	▪ Trial stopped at interim for efficacy (May 2016) ▪ Data to be presented at upcoming medical conference

In collaboration with Biogen

CHOP=Cyclophosphamide, Doxorubicin, Vincristine and Prednisone; CVP=Cyclophosphamide, Vincristine and Prednisolone;

Kadcyla

Evaluating new treatment options in HER2-positive breast and lung cancer

Indication	HER2-positive neoadjuvant breast cancer	HER2-positive early breast cancer high-risk patients	Operable HER2-positive early breast cancer	HER2-positive 2L metastatic breast cancer	HER2-positive advanced (2L+) NSCLC
Phase/study	**Phase III KRISTINE**	**Phase III KATHERINE**	**Phase III KAITLIN**	**Phase II KATE2**	**Phase II**
# of patients	N=444	N=1,484	N=1,850	N=200	N=40
Design	Before surgery patients will receive 6 cycles of: ▪**ARM A:** Herceptin plus Perjeta plus docetaxel plus carboplatin ▪**ARM B:** Kadcyla plus Perjeta After surgery patients will receive: ▪**ARM A:** Herceptin plus Perjeta ▪**ARM B:** Kadcyla plus Perjeta	▪ **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	▪ **ARM A:** Kadcyla plus Tecentriq ▪ **ARM B:** Kadcyla plus placebo	▪ Single-agent Kadcyla 3.6 mg/kg
Primary endpoint	▪ Pathologic Complete Response (pCR)	▪ Invasive disease-free survival (IDFS)	▪ Invasive disease-free survival (IDFS)	▪ Progression-free survival	▪ Overall response rate and safety
Status	▪ Enrolment completed Q2 2015 ▪ Primary endpoint not met ▪ Data presented at ASCO 2016	▪ Enrolment completed Q4 2015 ▪ Data expected in 2018	▪ Enrolment completed Q2 2015 ▪ Data expected in 2019	▪ FPI Q3 2016	▪ FPI Q4 2014 ▪ Enrolment completed Q2 2016

In collaboration with ImmunoGen, Inc.; ASCO American Society of Clinical Oncology

MabThera/Rituxan

Oncology and immunology development programmes

Indication	Previously untreated chronic lymphocytic leukemia	Moderate to severely active pemphigus vulgaris
Phase/study	**Phase Ib** **SAWYER** Subcutaneous study (ex-US)	**Phase III** **PEMPHIX**
# of patients	N=225	N=124
Design	▪ Two-stage design: - Stage 1 (dose-finding, N=55) - Stage 2 (N=170): CLL dose confirmation: ▪ **ARM A**: MabThera IV plus chemotherapy (fludarabine and cyclophosphamide) ▪ **ARM B**: MabThera 1600mg SC plus chemotherapy (fludarabine and cyclophosphamide)	▪ **ARM A:** Rituxan ▪ **ARM B:** mycophenolate mofetil
Primary endpoint	▪ Part 1: PK (dose selection) ▪ Part 2: PK of MabThera IV versus MabThera SC (arm A vs. arm B)	▪ Proportion of patients who achieve a sustained complete remission
Status	▪ Stage 2 data confirmed non-inferior PK and comparable safety/efficacy of MabThera 1600mg SC vs. MabThera IV ▪ Presented at ASH 2014 ▪ EMA approval granted May 2016	▪ FPI Q2 2015

Subcutaneous MabThera : applies Enhanze technology, partnered with Halozyme
ASH=American Society of Hematology

Perjeta

First-in-class HER2 dimerisation inhibitor

Indication	Adjuvant HER2-positive breast cancer	Neoadjuvant/adjuvant HER2-positive breast cancer	Advanced HER2-positive gastric cancer
Phase/ study	**Phase III APHINITY**	**Phase II BERENICE**	**Phase III JACOB**
# of patients	N=4,803	N=401	N=780
Design	▪ **ARM A:** Perjeta (840mg loading, 420 q3w) plus Herceptin for 52 weeks plus chemotherapy (6-8 cycles) ▪ **ARM B**: placebo plus Herceptin (52 weeks) plus chemotherapy (6-8 cycles)	Neoadjuvant treatment: ▪**ARM A:** ddAC q2w x4 cycles followed by weekly paclitaxel for 12 weeks, with P+H x4 cycles ▪**ARM B:** FEC+P+H x4 cycles followed by docetaxel+P+H x4 cycles Adjuvant treatment: ▪P+H q3w to complete 1 year of HER2 therapy ▪Hormonal and radiation therapy as indicated	▪ **ARM A:** Perjeta (840mg loading, 420mg q3w) plus Herceptin and chemotherapy ▪ **ARM B:** placebo plus Herceptin and chemotherapy
Primary endpoint	▪ Invasive disease-free survival (IDFS)	▪ Safety	▪ Overall survival
Status	▪ Recruitment completed Q3 2013 ▪ Data expected in Q1 2017	▪ Enrollment completed Q3 2015 ▪ Data in-house	▪ Recruitment completed Q1 2016 ▪ Data expected in 2017

•ddAC=dose-dense doxorubicin plus cyclophosphamide; FEC = fluorouracil, epirubicin, and cyclophosphamide

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – lung cancer

Indication	1L non-squamous and squamous NSCLC PD-L1-selected patients	1L non-squamous NSCLC	1L non-squamous NSCLC	1L non-squamous NSCLC
Phase/study	**Phase III IMpower 110**	**Phase III IMpower 150**	**Phase III IMpower 130**	**Phase III IMpower 132**
# of patients	N=570	N=1,200	N=650	N=568
Design	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B**: (NSq) carboplatin or cisplatin + pemetrexed (Sq) carboplatin or cisplatin +gemcitabine	▪ **ARM A:** Tecentriq + paclitaxel + carboplatin ▪ **ARM B**: Tecentriq + Avastin + paclitaxel + carboplatin ▪ **ARM C**: Avastin + paclitaxel + carboplatin	▪ **ARM A:** Tecentriq + nab-paclitaxel + carboplatin ▪ **ARM B**: nab-paclitaxel + carboplatin	▪ **ARM A:** Tecentriq + carboplatin or cisplatin + pemetrexed ▪ **ARM B**: carboplatin or cisplatin + pemetrexed
Primary endpoint	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival
Status	▪ FPI Q3 2015 ▪ IMpower 111 con-solidated into IMpower 110 Q3 2016	▪ FPI Q2 2015	▪ FPI Q1 2015	▪ FPI April 2016

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – lung cancer

Indication	Adjuvant NSCLC	1L squamous NSCLC	1L extensive-stage SCLC
Phase/study	**Phase III IMpower 010**	**Phase III IMpower 131**	**Phase III IMpower 133**
# of patients	N=1127	N=1025	N=400
Design	Following adjuvant cisplatin-based chemotherapy ▪ **ARM A:** Tecentriq ▪ **ARM B**: best supportive care	▪ **ARM A:** Tecentriq + paclitaxel + carboplatin ▪ **ARM B**: Tecentriq + nab-paclitaxel + carboplatin ▪ **ARM C**: nab-paclitaxel + carboplatin	▪ **ARM A:** Tecentriq + carboplatin + etoposide ▪ **ARM B**: Placebo + carboplatin + etoposide
Primary endpoint	▪ Disease-free survival	▪ Progression-free survival and overall survival	▪ Progression-free survival and overall survival
Status	▪ FPI Q3 2015 ▪ Trial amended from PD-L1-selected patients to all-comers ▪ Expect FPI for all-comer population Q4 2016	▪ FPI Q2 2015	▪ FPI Q2 2016 ▪ Orphan drug designation granted by FDA in October, 2016

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – lung cancer

Indication	Metastatic NSCLC 2L	Locally advanced or metastatic NSCLC PD-L1 positive	Locally advanced or metastatic NSCLC PD-L1 positive	Locally advanced or metastatic NSCLC (2L/3L)	Non-small cell lung cancer
Phase/study	**Phase III OAK**	**Phase II FIR**	**Phase II BIRCH**	**Phase II POPLAR**	**Phase I**
# of patients	N=1,225	N=130	N=667	N=287	N=53
Design	▪ **ARM A:** Tecentriq 1200mg q3w ▪ **ARM B:** docetaxel	Single arm study: ▪Tecentriq 1200mg q3w	Single arm study: ▪Tecentriq 1200mg q3w	▪ **ARM A**: Tecentriq 1200mg q3w ▪ **ARM B**: docetaxel	▪ Tecentriq plus Tarceva[1] or Alecensa
Primary endpoint	▪ Overall survival	▪ Overall response rate	▪ Objective response rate	▪ Overall survival	▪ Safety
Status	▪ Recruitment completed Q2 2015 ▪ Initial read-out in Q3 2016 ▪ Data presented at ESMO 2016 ▪ Data filed with US FDA Q3 2016	▪ Recruitment completed Q2 2014 ▪ Data presented at ASCO 2015	▪ Recruitment completed Q4 2014 ▪ Primary analysis presented at ECC 2015	▪ Recruitment completed Q2 2014 ▪ Interim data presented at ASCO 2015 ▪ Primary analysis presented at ECC 2015 ▪ Results published in *Lancet*, 9 March 2016 ▪ Updated data presented at ASCO 2016	▪ FPI Q1 2014 ▪ FPI in Alecensa arm Q3 2015
		▪ Filed with the FDA Q1 2016 ▪ Priority review granted Q1 2016 ▪ Approved in US October 2016			

[1]Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a subsidiary of Astellas US, LLC
ASCO=American Society of Clinical Oncology; ECC=European Cancer Congress

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – UC

Indication	Adjuvant high risk muscle invasive bladder cancer PD-L1-positive patients	Locally advanced or metastatic urothelial bladder cancer	
Phase/study	**Phase III IMvigor 010**	**Phase III IMvigor 211**	**Phase II IMvigor 210**
# of patients	N=440	N=932	N=439
Design	After cystectomy: ▪**ARM A:** Tecentriq monotherapy ▪**ARM B**: observation	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	▪ Disease-free survival	▪ Overall survival	▪ Objective response rate
Status	▪ FPI October 2015	▪ Enrolment completed Q1 2016	▪ US accelerated approval Q2 2016 ▪ Filed in EU Q2 2016 ▪ Cohort 2 results published in *Lancet*, 4 Mar 2016 ▪ Updated data (Cohorts 1 and 2) presented at ESMO 2016

UC=urothelial carcinoma; ASCO=American Society of Clinical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – UC

Indication	1L metastatic urothelial carcinoma	High-risk non-muscle-invasive bladder cancer
Phase/study	**Phase III** **IMvigor 130**	**Phase Ib/II**
# of patients	N=1200	N=70
Design	▪**ARM A:** Tecentriq plus gemcitabine and carboplatin or cisplatin ▪**ARM B**: placebo plus gemcitabine and carboplatin or cisplatin ▪**ARM C**: Tecentriq monotherapy	▪**Cohort 1a:** Tecentriq (BCG-unresponsive NMIBC) ▪**Cohort 1b:** Tecentriq + BCG (BCG-unresponsive NMIBC) ▪**Cohort 2:** Tecentriq + BCG (BCG-relapsing NMIBC) ▪**Cohort 3:** Tecentriq + BCG (BCG-naive NMIBC)
Primary endpoint	▪ Progression-free survival, overall survival, safety	▪ Safety, objective response rate
Status	▪ FPI Q3 2016 ▪ Trial currently being modified to include patients who are eligible for a cisplatin-containing regimen (patients ineligible for cisplatin continue to be enrolled), and to add a third arm evaluating atezolizumab monotherapy	▪ FPI Q2 2016

UC=urothelial carcinoma; BCG = Bacille Calmette-Guérin; NMIBC=non-muscle invasive bladder cancer

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – renal cell cancer

Indication	Untreated advanced renal cell carcinoma		Metastatic castration-resistant prostate cancer
Phase/study	**Phase III** **IMmotion 151**	**Phase II** **IMmotion 150**	**Phase Ib**
# of patients	N=900	N=305	N=45
Design	▪ **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	▪ Tecentriq plus radium-223 dichloride
Primary endpoint	▪ Progression-free survival and overall survival co-primary	▪ Progression-free survival	▪ Safety and tolerability
Status	▪ FPI Q2 2015	▪ Recruitment completed Q1 2015 ▪ Data expected in-house in 2016	▪ FPI Q3 2016

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – CRC

Indication	Third-line advanced or metastatic colorectal cancer	2/3L metastatic colorectal cancer
Phase/study	**Phase III** **IMblaze370 COTEZO**	**Phase I**
# of patients	N=360	N=33
Design	▪ **ARM A**: Tecentriq ▪ **ARM B**: Cotellic + Tecentriq ▪ **ARM C**: regorafenib	Open-label, single-arm, two-stage study with Cotellic + Tecentriq + Avastin ▪ Stage 1: Safety run-in ▪ Stage 2: Dose-expansion with two cohorts – (1) expansion, (2) biopsy
Primary endpoint	▪ Overall survival	▪ Safety
Status	▪ FPI Q2 2016	▪ FPI Q3 2016

Cotellic in collaboration with Exelixis;
SMR=Society for Melanoma Research

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – solid tumours

Indication	Previously untreated metastatic triple negative breast cancer	Metastatic breast cancer and locally advanced early breast cancer HER2-positive	Previously untreated metastatic melanoma BRAF mutation positive
Phase/study	**Phase III IMpassion 130**	**Phase I**	**Phase I**
# of patients	N=900	N=66	N=70
Design	▪ **ARM A**: Tecentriq plus nab-paclitaxel ▪ **ARM B**: placebo plus nab-paclitaxel	▪ Cohort 1A (metastatic): Tecentriq + Perjeta +Herceptin ▪ Cohort 1B (metastatic): Tecentriq + Kadcyla ▪ Cohort 2A (neoadjuvant): Tecentriq + Perjeta +Herceptin followed by docetaxel + carboplatin + Perjeta +Herceptin ▪ Cohort 2B (neoadjuvant): Tecentriq + Kadcyla followed by docetaxel + carboplatin + Perjeta +Herceptin ▪ Cohort 2C (expansion on cohort 1B): Tecentriq + Kadcyla	▪ Dose-finding study of Tecentriq + Zelboraf[1] and Tecentriq + Zelboraf[1] + Cotellic (MEK inhibitor)[2] combinations
Primary endpoint	▪ Progression-free survival and overall survival co-primary	▪ Safety	▪ Safety/PK
Status	▪ FPI Q3 2015	▪ FPI Q4 2015	▪ FPI Q4 2012 ▪ Zelboraf combination data presented at SMR 2015

[1]Zelboraf in collaboration with Plexxikon, a member of Daiichi Sankyo Group; [2]Cotellic in collaboration with Exelixis; SMR=Society for Melanoma Research

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – solid tumours

Indication	Solid tumours	Solid tumours	Solid tumours	Solid tumours
Phase/study	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=86	N=225	N=160	N=162
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 - randomised to Tecentriq + vanucizumab or Tecentriq + Avastin	▪ **ARM A**: Tecentriq + Avastin ▪ **ARM B**: Tecentriq + Avastin + FOLFOX ▪ **ARM C**: Tecentriq + carboplatin + paclitaxel ▪ **ARM D**: Tecentriq + carboplatin+ pemetrexed ▪ **ARM E**: Tecentriq + carboplatin+ nab-paclitaxel ▪ **ARM F**: Tecentriq + nab-paclitaxel	▪ **Part I:** sequential and single concomitant administration of Tecentriq and RG7876 (CD40 MAb, i.v. and s.c., dose escalation) ▪ **Part II:** multiple doses of concomitant Tecentriq and RG7876 (CD40 MAb), recommended dose and route per Part I ▪ **Part III:** study drugs schedule in specific indication per Part II	Tecentriq in combination with emactuzumab (CSF-1R MAb) ▪ **Part 1**: dose escalation ▪ **Part 2**: expansion
Primary endpoint	▪ Safety	▪ Safety/PK	▪ Safety	▪ Safety
Status	▪ FPI April 2016 ▪ Expect FPI ARM D Q4 2016	▪ FPI Q2 2012 ▪ Updated CRC data presented at AACR 2016 ▪ Updated TNBC data (ARM F) presented at ASCO 2016	▪ FPI Q4 2014	▪ FPI Q1 2015

AACR=American Association for Cancer Research; ASCO=American Society of Clinical Oncology; HCC=hepatocellular carcinoma; PaC=pancreatic cancer

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – solid tumours

Indication	Solid tumours	Solid tumours	Solid tumours	Solid tumours
Phase/study	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=224	N=400	N=151	N=300
Design	▪ Tecentriq in combination with RG6078 (IDO inhibitor), dose escalation and expansion cohorts	▪ **Stage 1**: Dose escalation of Tecentriq plus RG7888 (OX40 MAb) ▪ **Stage 2:** Expansion Tecentriq plus RG7888 (OX40 MAb)	▪ **ARM A:** Dose-finding Tecentriq plus Cotellic ▪ **ARM B:** Dose-exspansion Tecentriq plus Cotellic	▪ **Phase Ia:** Dose escalation and expansion MTIG7192A, RG6058 (TIGIT) ▪ **Phase 1b**: Dose escalation and expansion Tecentriq plus MTIG7192A, RG6058 (TIGIT)
Primary endpoint	▪ Safety and tolerability	▪ Safety	▪ Safety	▪ Safety, tolerability, PK variability, preliminary efficacy
Status	▪ FPI Q3 2015	▪ FPI Q2 2015 ▪ Dose escalation data presented at ASCO 2016	▪ FPI Q4 2013 ▪ CRC cohort data presented at ASCO 2016, ESMO 2016	▪ FPI Q2 2016

ASCO=American Society of Clinical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – solid tumours

Indication	Locally advanced or metastatic solid tumours	CEA-positive solid tumours	Locally advanced or metastatic solid tumours
Phase/study	**Phase I**	**Phase Ib**	**Phase I**
# of patients	N=200	N=100	N=689
Design	▪ **ARM A:** Tecentriq plus ipilimumab ▪ **ARM B:** Tecentriq plus interferon alpha-2b	▪ Tecentriq plus RG7802 (CEA CD3 TCB)	▪ Dose escalation study
Primary endpoint	▪ Safety	▪ Safety, PK/PD, imaging, biomarkers	▪ Safety/PK
Status	▪ FPI Q3 2014	▪ FPI Q1 2016	▪ FPI Q2 2011 ▪ Initial efficacy data presented at ASCO 2013 ▪ Data from bladder cohort presented at ASCO and ESMO 2014 ▪ Data from TNBC cohort presented at AACR 2015 ▪ Updated lung and bladder data presented at ASCO 2015 ▪ GBM data presented at SNO 2015

ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; AACR=American Association for Cancer Research; SNO=Society for Neuro-Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – hematology

Indication	Relapsed/refractory follicular lymphoma and DLBCL	Multiple myeloma	Myelodysplastic syndromes
Phase/study	**Phase I**	**Phase I**	**Phase I**
# of patients	N=46	N=214	N=46
Design	**Stage 1:** Safety evaluation ▪Tecentriq plus Gazyva **Stage 2:** expansion ▪Tecentriq plus Gazyva **Stage 3:** new cohort ▪Tecentriq plus tazemetostat[1]	▪ Tecentriq monotherapy ▪ Tecentriq +lenalidomide ▪ Tecentriq + daratumumab[2] ▪ Tecentriq + lenalidomide + daratumumab[2]	▪ Tecentriq monotherapy and azacitidine combination cohorts
Primary endpoint	▪ Safety	▪ Safety	▪ Safety
Status	▪ FPI Q4 2014 ▪ Expect FPI Stage 3 Q4 2016	▪ FPI Q3 2015 ▪ FPI daratumumab[2] cohorts Q3 2016	▪ FPI Q3 2015

[1] Tazemetostat tested for r/r DLBCL in collaboration with Epizyme; [2] daratumumab cohorts in collaboration with Janssen; DLBCL=diffuse large B cell lymphoma

Tecentriq (atezolizumab, RG7446)

Anti-PDL1 cancer immunotherapy – hematology

Indication	1L FL and 1L DLBCL	Relapsed or refractory FL	Relapsed or refractory FL or DLBCL
Phase/study	**Phase I**	**Phase I**	**Phase I/II**
# of patients	N=92	N=46	N=86
Design	▪ Tecentriq + Gazyva + bendamustine ▪ Tecentriq + Gazyva + CHOP	▪ Tecentriq + Gazyva + lenalidomide	▪ Dose escalation: Tecentriq + Gazyva + polatuzumab vedotin ▪ Expansion: Tecentriq + Gazyva + polatuzumab vedotin
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ Safety and efficacy
Status	▪ FPI Q4 2015	▪ FPI Q4 2015	▪ Expect FPI for FL Q4 2016 ▪ Study to be amended to change from Gazayva to Rituxan for DLBCL with FPI expected Q1 2017

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

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – CLL

Indication	Untreated CLL patients with coexisting medical conditions	Relapsed or refractory CLL	Relapsed or refractory CLL with 17p deletion
Phase/study	**Phase III CLL14**	**Phase III MURANO**	**Phase II**
# of patients	N=432	N=391	N=100
Design	▪ **ARM A**: Venclexta plus Gazyva ▪ **ARM B**: chlorambucil plus Gazyva	▪ **ARM A**: Venclexta plus Rituxan ▪ **ARM B**: Rituxan plus bendamustine	▪ Single-agent Venclexta
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Safety/MTD
Status	▪ Enrolment completed Q3 2016	▪ Recruitment completed Q3 2015 ▪ Data expected in 2017	▪ Breakthrough therapy designation granted by US FDA in Q2 2015 ▪ Approved by US FDA April 2016 after priority review ▪ CHMP opinion in October 2016

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
CLL=chronic lymphocytic leukemia

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – CLL

Indication	Relapsed or refractory CLL	Relapsed CLL and SLL	Relapsed or refractory or previously untreated CLL	Relapsed or refractory or previously untreated CLL
Phase/study	**Phase II**	**Phase Ib**	**Phase Ib**	**Phase Ib**
# of patients	N=120	N=50	N=100	N=90
Design	▪ Venclexta after ibrutinib therapy ▪ Venclexta after idelalisib therapy	▪ Dose-escalation study in combination with MabThera/Rituxan	▪ Venclexta in combination with MabThera/Rituxan and bendamustine	▪ Venclexta in combination with Gazyva
Primary endpoint	▪ Overall response rate	▪ Safety/MTD	▪ Safety/MTD	▪ Safety/MTD
Status	▪ FPI Q3 2014 ▪ Data presented at ASH 2015 ▪ Updated data presented at ASCO 2016	▪ Recruitment completed Q1 2015 ▪ Data presented at ASCO 2014 and EHA 2015 ▪ Updated data presented at ASH 2015, ASCO 2016	▪ FPI Q2 2013 ▪ Data presented at ASH 2015	▪ FPI Q1 2014 ▪ Data presented at ASH 2015

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
CLL=chronic lymphocytic leukemia; SLL=small lymphocytic lymphoma
ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology; EHA=European hematology association

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – NHL

Indication	Relapsed or refractory follicular NHL	B cell NHL, front-line DLBCL
Phase/study	**Phase II** **CONTRALTO**	**Phase I/II** **CAVALLI**
# of patients	N=165	N=248
Design	▪ **ARM A:** Venclexta plus Rituxan ▪ **ARM B:** Venclexta plus Rituxan plus bendamustine ▪ **ARM C:** Rituxan plus bendamustine	Phase I (dose finding, patients with B cell NHL): ▪ **ARM A:** Venclexta+R-CHOP ▪ **ARM B:** Venclexta+G-CHOP Phase II (expansion, patients with 1L DLBCL): ▪ Venclexta+R/G-CHOP
Primary endpoint	▪ Overall response rate	▪ Safety and efficacy
Status	▪ FPI Q4 2014 ▪ Data to be presented at ASH 2016	▪ FPI Q2 2014 ▪ Data presented at ASCO 2016

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
NHL=non-Hodgkin's lymphoma; DLBCL=diffuse large B cell lymphoma
ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – NHL

Indication	Relapsed or refractory FL or DLBCL	Relapsed or Refractory NHL	Relapsed or Refractory CLL and NHL
Phase/study	**Phase I/II**	**Phase I**	**Phase I**
# of patients	N=116	N=60	N=211
Design	▪ Dose escalation cohort: polatuzumab vedotin + Gazyva + Venclexta ▪ Expansion cohort: DLBCL polatuzumab vedotin + Gazyva + Venclexta ▪ Expansion cohort: FL polatuzumab vedotin + Gazyva + Venclexta	▪ Dose escalation of Venclexta in combination with Rituxan and bendamustine	▪ Dose-escalation study ▪ **ARM A:** CLL and SLL patients ▪ **ARM B:** NHL and SLL
Primary endpoint	▪ Percentage of participants with CR	▪ Overall response rate	▪ Safety/PK/Response rate
Status	▪ FPI Q1 2016	▪ FPI Q2 2012 ▪ Study resumed Q3 2013 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASH 2015	▪ Updated CLL, SLL and NHL (DLBCL and FL) data presented at ASCO 2014 ▪ Updated data presented at ASH 2015 ▪ Arm A filed for r/r CLL indications Q4 2015 ▪ Updated data presented at ASCO 2016

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

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – MM

Indication	Relapsed or refractory multiple myeloma		
Phase/study	**Phase III**	**Phase I**	**Phase I**
# of patients	N=240	N=30	N=84
Design	▪ **ARM A**: Venclexta+ bortezomib and dexamethasone ▪ **ARM B**: Placebo + bortezomib and dexamethasone	▪ Patients receiving bortezomib and dexamethasone as standard therapy: ▪ Dose escalation cohort: Venclexta+bortezomib+dexamethasone ▪ Safety expansion cohort: Venclexta+bortezomib+dexamethasone	▪ Dose escalation cohort ▪ Safety expansion cohort
Primary endpoint	▪ PFS	▪ Safety/MTD	▪ Safety/MTD
Status	▪ FPI July 2016	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016	▪ FPI Q4 2012 ▪ Data presented at ASCO 2015 ▪ Updated data presented at ASCO 2016

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

MM=multiple myeloma; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology

Venclexta (venetoclax, RG7601, ABT-199)

Novel small molecule Bcl-2 selective inhibitor – AML

Indication	Acute myelogenous leukemia (AML)		Treatment-naïve acute myelogenous leukemia (AML)	Relapsed or refractory AML not eligible for cytotoxic therapy
Phase/study	**Phase II**	**Phase Ib**	**Phase I/II**	**Phase I/II**
# of patients	N=54	N=160	N=65	N=140
Design	▪ Dose escalation of Venclexta	▪ Venclexta (dose escalation) +decitabine ▪ Venclexta (dose escalation) +azacitidine	▪ Venclexta + low-dose cytarabine	Phase I (dose escalation) ▪ **ARM A:** Cotellic+ Venclexta ▪ **ARM B:** idasanutlin+ Venclexta Phase II (expansion) ▪ **ARM A:** Cotellic + Venclexta ▪ **ARM B:** idasanutlin+ Venclexta
Primary endpoint	▪ Overall response rate	▪ Safety	▪ Safety, PK/PD, efficacy	▪ Safety and efficacy
Status	▪ FPI Q4 2013 ▪ Data presented at ASH 2014 ▪ Updated data presented at ASCO 2016	▪ FPI Q4 2014 ▪ Data to be presented at ASH 2015 ▪ Updated data presented at ASCO 2016	▪ FPI Q1 2015 ▪ Initial data presented at ASCO 2016 ▪ Updated data to be presented at ASH 2016	▪ FPI Q1 2016

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

Zelboraf

A selective novel small molecule that inhibits mutant BRAF

Indication	Adjuvant therapy in patients with resected cutaneous BRAF mutation positive melanoma
Phase/study	**Phase III** **BRIM8**
# of patients	N=475
Design	▪ 52-week treatment ▪ **ARM A:** Zelboraf 960mg bid ▪ **ARM B:** Placebo
Primary endpoint	▪ Disease-free survival
Status	▪ Enrolment completed Q2 2015 ▪ Data expected in 2017

In collaboration with Plexxikon, a member of Daiichi Sankyo Group
See also combinations with Cotellic (MEK inhibitor) and Tecentriq (PD-L1 MAb)

Actemra/RoActemra

Interleukin-6 receptor inhibitor

Indication	Systemic sclerosis		Giant cell arteritis
Phase/study	**Phase II** **faSScinate** Proof-of-concept study	**Phase III** **focuSSced**	**Phase III** **GiACTA**
# of patients	N=86	N=210	N=250
Design	Blinded 48-week treatment with weekly dosing: ▪**ARM A:** Actemra SC 162mg ▪**ARM B:** Placebo SC Open-label weekly dosing at weeks 49 to 96: ▪Actemra SC 162mg	Blinded 48-week treatment with weekly dosing: ▪**ARM A:** Actemra SC 162mg ▪**ARM B:** Placebo SC Open-label weekly dosing at weeks 49 to 96: ▪Actemra SC 162mg	Part 1: 52-week blinded period ▪**ARM A:** Actemra SC 162mg qw + 26 weeks prednisone taper ▪**ARM B:** Actemra SC 162mg q2w + 26 weeks prednisone taper ▪**ARM C:** Placebo+ 26 weeks prednisone taper ▪**ARM D:** Placebo+ 52 weeks prednisone taper Part II: ▪104-week 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	▪ Change in modified Rodnan skin score (mRSS) at week 24 ▪ Safety	▪ Change in modified Rodnan skin score (mRSS) at week 48	▪ Proportion of patients in sustained remission at week 52
Status	▪ 48 week data presented at EULAR 2015 ▪ Primary and all key secondary endpoints showed trend for improved efficacy ▪ Breakthrough designation granted Q1 2015 ▪ 96-week data to be presented at ACR 2016	▪ FPI Q4 2015	▪ Recruitment completed Q2 2015 ▪ Primary and key secondary endpoints met Q2 2016 ▪ Breakthrough designation granted Q3 2016 ▪ Data to be presented at ACR 2016

In collaboration with Chugai; EULAR=European League Against Rheumatism; ACR=American College of Rheumatology

Lucentis

Anti-VEGF antibody fragment for ocular diseases

Indication	AMD port delivery device (Ranibizumab Port Delivery System)
Phase/study	**Phase II** **LADDER**
# of patients	N=220
Design	▪ Four arm study: Lucentis monthly intravitreal control vs. 3 ranibizumab formulations delivered via implant
Primary endpoint	▪ Time to first refill
Status	▪ FPI Q3 2015

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

Obinutuzumab (GA101, RG7159)

Immunology development programme

Indication	Lupus nephritis	Hypersensitized adult participants with end-stage renal disease awaiting transplantation
Phase/study	**Phase II NOBILITY**	**Phase I**
# of patients	N=120	N=25
Design	▪ **ARM A:** obinutuzumab 1000mg IV plus mycophenolate mofetil ▪ **ARM B:** placebo IV plus mycophenolate mofetil	▪ Cohort 1: single dose of obinutuzumab ▪ Cohort 2: repeated doses of obinutuzumab
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Safety
Status	▪ FPI Q4 2015	▪ FPI Q4 2015 ▪ Enrolment completed Q3 2016

In collaboration with Biogen

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group YTD Sept 2016 sales

Diagnostics

Foreign exchange rate information

Emicizumab (RG6013, ACE910)

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>90
Design	▪ Enrolled 64 healthy volunteers and 18 patients	▪ Extension study in patients from phase 1	▪ A single arm, multicenter, non-interventional study evaluating bleeding incidence, health-related quality of life and safety in patients with Hemophilia A and inhibitors to factor VIII under standard-of-care treatment
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

In collaboration with Chugai

ASH=American Society of Hematology, ISTH=International Society on Thrombosis and Haemostasis; WFH=World Federation of Hemophilia

Emicizumab (RG6013, ACE910)

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	Hemophilia A patients without inhibitors to factor VIII
Phase/study	**Phase III Haven 1**	**Phase III Haven 2**	**Phase III Haven 3**
# of patients	N=118	N=40	N=135
Design	Patients on episodic treatment prior to study entry: ▪ **ARM A:** episodic treatment + emicizumab prophylaxis ▪ **ARM B:** episodic treatment (no prophylaxis); switch to emicizumab prophylaxis possible after 24 weeks Patients on prophylactic treatment with bypassing agents prior to study entry: ▪ **ARM C:** emicizumab prophylaxis + episodic treatment Patients on episodic treatment previously on non-interventional study: ▪ **ARM D:** emicizumab prophylaxis + episodic treatment	Patients on prophylactic or episodic treatment prior to study entry: ▪ Emicizumab prohylaxis+episodic treatment	Patients on FVIII episodic treatment prior to study entry: ▪ **Arm A**: emicizumab prophylaxis qw ▪ **Arm B**: emicizumab prophylaxis q2w ▪ **Arm C**: episodic FVIII treatment; switch to emicizumab prophylaxis possible after 24 weeks Patients on FVIII prophylaxis prior to study entry: ▪ **Arm D**: emicizumab prophylaxis qw
Primary endpoint	▪ Number of bleeds over 24 week period	▪ Number of bleeds over 52 weeks	▪ Number of bleeds over 24 weeks
Status	▪ FPI Q4 2015 ▪ Enrolment completed in Arms A and B Q2 2016	▪ FPI Q3 2016	▪ FPI Q3 2016

In collaboration with Chugai

Polatuzumab vedotin (RG7596)

Antibody–drug conjugate targeting CD79b for the treatment of B cell malignancies

Indication	Non-Hodgkin's lymphoma	B cell non-Hodgkin's lymphoma, 1L DLBCL	Relapsed or refractory follicular lymphoma and DLBCL
Phase	**Phase II ROMULUS**	**Phase Ib/II**	**Phase Ib/II**
# of patients	N=233	N=83	N=213
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	▪ PhIb: dose escalation ▪ PhII: polatuzumab vedotin in combination with Rituxan or Gazyva and CHP non-randomized	▪ PIb: dose escalation ▪ PhII: polatuzumab vedotin + BR vs. BR ▪ PhII expansion: polatuzumab vedotin +Gazyva non-randomized
Primary endpoint	▪ Safety and anti-tumour activity	▪ Safety and response by PET/CT	▪ Safety and response by PET/CT
Status	▪ Recruitment in arms A&B completed Q1 2014 ▪ FPI in Gazyva arms E, G, H Q1 2015 ▪ Updated data presented at ASCO, ICML and EHA 2015 ▪ Updated data on Gazyva arms to be presented at ASH 2016	▪ FPI Q4 2013 ▪ Initial data presented at ASH 2015 ▪ Updated data to be presented at ASH 2016	▪ FPI Q4 2014 ▪ Enrolment completed Q3 2016 ▪ Updated data to be presented at ASH 2016

In collaboration with Seattle Genetics

ASCO=American Society of Clinical Oncology; ICML=international conference on malignant lymphoma; EHA=European Hematology Association; ASH=American Society of Hematology; BR=bendamustine and Rituxan; CHP=Cyclophosphamide, Hydroxydoxorubicin, Prednisone; DLBCL=diffuse large B cell lymphoma

Polatuzumab vedotin (RG7596)

Antibody–drug conjugate targeting CD79b for the treatment of B cell malignancies

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

In collaboration with Seattle Genetics; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma

Taselisib (RG7604, GDC-0032)

Mutant-selective PI3 kinase inhibitor

Indication	HER2-negative ER-positive metastatic breast caner patients who progressed after aromatase inhibitor therapy	Neoadjuvant HER2-negative ER-positive breast cancer
Phase	**Phase III** **SANDPIPER**	**Phase II** **LORELEI**
# of patients	N=600	N=330
Design	▪ **ARM A**: taselisib plus fulvestrant ▪ **ARM B:** placebo plus fulvestrant	▪ **ARM A**: taselisib plus letrozole ▪ **ARM B:** placebo plus letozole
Primary endpoint	▪ Progression-free survival	▪ Response rate and pCR
Status	▪ FPI Q2 2015	▪ Enrolment completed Q3 2016

ER=estrogen receptor

Taselisib (RG7604, GDC-0032)

Mutant-selective PI3 kinase inhibitor

Indication	Solid tumours and HER2-negative HR-positive breast cancer	HER2-negative HR-positive locally recurrent or metastatic breast cancer	PI3KCAmut-pos. 2L squamous NSCLC Lung Master Protocol
Phase	**Phase I/II**	**Phase I**	**Phase II Lung-MAP**
# of patients	N=320	N=65	N=120
Design	▪ **Phase I** ▪ taselisib ▪ taselisib plus letrozole or fulvestrant ▪ **Phase II** ▪ taselisib (multiple doses) plus letrozole or fulvestrant	▪ taselisib plus docetaxel ▪ taselisib plus paclitaxel	▪ taselisib vs. chemo
Primary endpoint	▪ Safety/PK/efficacy	▪ Safety	▪ Progression-free survival
Status	▪ Recruitment completed Q2 2014 ▪ Updated data presented at SABCS 2014	▪ FPI Q2 2013	▪ FPI Q2 2014

SABCS=San Antonio Breast Cancer Symposium; HR=hormone receptor

Crenezumab (RG7412)

A humanized monoclonal antibody designed to target all forms of amyloid-beta

Indication	Prodromal to mild Alzheimer's disease	Alzheimer's disease	
Phase/study	**Phase III** **CREAD**	**Phase II** **ABBY** Cognition study	**Phase II** **BLAZE** Biomarker study
# of patients	N=750	N=446	N=91
Design	▪ **ARM A:** crenezumab IV 60mg/kg q4w ▪ **ARM B:** placebo IV q4w	▪ **ARM A**: crenezumab SC ▪ **ARM B**: crenezumab IV ▪ **ARM C:** placebo	▪ **ARM A**: crenezumab SC ▪ **ARM B**: crenezumab IV ▪ **ARM C:** placebo
Primary endpoint	▪ CDR-SB at 105 weeks	▪ Change in cognition (ADAS-cog) and Clinical Dementia Rating, Sum of Boxes (CDR-SOB) score from baseline to week 73	▪ Change in brain amyloid load from baseline to week 69
Status	▪ FPI Q1 2016	▪ Enrolment completed Q3 2012 ▪ Positive trend in cognition was observed in higher dose for people with milder disease consistently across both studies (ABBY/BLAZE) and across endpoint ▪ Data presented at AAIC 2014	▪ Enrolment completed Q3 2012 ▪ Cognition data presented at AAIC 2014 ▪ Exploratory amyloid PET analysis suggests reduced amyloid accumulation in ARM B ▪ Biomarker data presented at CTAD 2014

In collaboration with AC Immune

AAIC=Alzheimer's Association International Conference; CTAD=Clinical Trials on Alzheimer's Disease

Crenezumab (RG7412)

A humanized monoclonal antibody designed to target all forms of amyloid-beta

Indication	Mild to moderate Alzheimer's disease	Alzheimer's Prevention Initiative (API) Colombia
Phase/study	**Phase I**	**Phase II** Cognition study
# of patients	N=72	N=300
Design	▪ **ARM A/B**: crenezumab dose level I & placebo ▪ **ARM C/D**: crenezumab dose level II & placebo ▪ **ARM E/F**: crenezumab dose level III & placebo	▪ **ARM A**: 100 carriers receive crenezumab SC ▪ **ARM B**: 100 carriers receive placebo ▪ **ARM C:** 100 non-carriers receive placebo
Primary endpoint	▪ Safety (incidence and nature of MRI safety findings) and PK	▪ Change on Alzheimer's Prevention Initiative (API) Composite Cognitive Test total score
Status	▪ Enrolment completed Q3 2016	▪ FPI Q4 2013

In collaboration with AC Immune

Gantenerumab (RG1450)

Fully human monoclonal antibody designed to bind to aggregated forms of amyloid-beta

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-SOB 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 ▪ Enrolment completed Q4 2013 ▪ Dosing stopped due to futility Q4 2014 ▪ Data presented at AAIC 2015 ▪ FPI in open label extension study Q4 2015	▪ FPI Q1 2014 ▪ FPI Q1 2016 for open label extension

In collaboration with Morphosys

CDR-SOB=Clinical Dementia Rating scale Sum of Boxes; AAIC=Alzheimer's Association International Conference

OCREVUS (ocrelizumab, RG1594)

Humanized monoclonal antibody designed to selectively target CD20-positive 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 ▪ Data presented at ECTRIMS 2015 ▪ Filed globally in 2016	▪ Primary endpoint met Q2 2015 ▪ Data presented at ECTRIMS 2015 ▪ Filed globally in 2016	▪ Primary endpoint met Q3 2015 ▪ Data presented at ECTRIMS 2015 ▪ Filed globally in 2016

Olesoxime (RG6083)

Novel small molecule neuroprotectant that preserves mitochondrial function

Indication	Spinal muscular atrophy	
Phase/study	**Phase II** Registrational study	**Open-label study**
# of patients	N=165	N=165
Design	▪ **ARM A:** olesoxime ▪ **ARM B:** placebo	▪ Olesoxime
Primary endpoint	▪ Motor function measure	▪ Motor function measure
Status	▪ Study completed Q4 2013 ▪ Presented at AAN 2014	▪ FPI Q4 2015
Collaborator	Trophos acquisition	

AAN=Annual Meeting of the American Academy of Neurology

Etrolizumab (RG7413)

Humanized monoclonal antibody 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=720
Design	▪ **ARM A**: etrolizumab 105mg SC q4w + adalimumab placebo SC ▪ **ARM B**: etrolizumab placebo SC + adalimumab SC ▪ **ARM C**: etrolizumab placebo SC + adalimumab placebo SC	▪ **ARM A**: etrolizumab 105mg SC q4w + adalimumab placebo SC ▪ **ARM B**: etrolizumab placebo SC + adalimumab SC ▪ **ARM C**: etrolizumab placebo SC + adalimumab placebo SC	Time on treatment 54 weeks ▪**ARM A**: etrolizumab 105mg SC q4w + placebo IV ▪**ARM B**: placebo SC q4w + 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

Etrolizumab (RG7413)

Humanized monoclonal antibody against beta 7 integrin

Indication	UC patients who are TNF naïve and refractory or intolerant to immunosuppressant and/or corticosteroid treatment	UC patients who are refractory or intolerant of TNF inhibitors
Phase/study	**Phase III** **LAUREL** Maintenance study	**Phase III** **HICKORY** Induction and maintenance study
# of patients	N=350	N=800
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
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
Status	▪ FPI Q3 2014	▪ FPI Q2 2014

UC=ulcerative colitis

Etrolizumab (RG7413)

Humanized monoclonal antibody against beta 7 integrin

Indication	Moderate to severe ulcerative colitis	Moderate to severe ulcerative colitis
Phase/study	**Phase II** **SPRUCE** Open label extension study	**Phase III** **COTTONWOOD** Open label extension study
# of patients	N=116	N=2,600
Design	▪ Patients who were enrolled in EUCALYPTUS study and meet enrolment criteria will receive etrolizumab 105 SC q4w	▪ Patients who were previously enrolled in etrolizumab phase III studies and meet enrolment criteria will receive etrolizumab 105 SC q4w
Primary endpoint	▪ Safety	▪ Long-term efficacy as determined by partial Mayo Clinic Score (pMCS) ▪ Incidence of adverse events
Status	▪ Recruitment completed	▪ FPI Q3 2014

Etrolizumab (RG7413)

Humanized monoclonal antibody 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=1,250	N=900
Design	▪ **ARM A**: etrolizumab SC 210 mg (induction only) ▪ **ARM B**: etrolizumab SC 105 mg and maintainance ▪ **ARM C**: placebo	▪ Etrolizumab SC 105mg q4w
Primary endpoint	▪ Induction and maintenance of clinical remission	▪ Safety
Status	▪ FPI Q1 2015	▪ FPI Q2 2015

Lampalizumab (RG7417)

Antibody fragment to selectively block activation of alternative complement pathway

Indication	Geographic atrophy (GA) secondary to age-related macular degeneration		
Phase/study	**Phase III CHROMA**	**Phase III SPECTRI**	**Phase II**
# of patients	N=936	N=936	N=90
Design	▪ **ARM A:** lampalizumab 10mg q4w ▪ **ARM B:** lampalizumab 10mg q6w ▪ **ARM C:** placebo	▪ **ARM A:** lampalizumab 10mg q4w ▪ **ARM B:** lampalizumab 10mg q6w ▪ **ARM C:** placebo	▪ **ARM A:** lampalizumab 10mg q2w ▪ **ARM B:** lampalizumab 10mg q4w ▪ **ARM C:** placebo
Primary endpoint	▪ Primary: change in GA area ▪ Secondary: change in BCVA and in additional measures of visual function	▪ Primary: change in GA area ▪ Secondary: change in BCVA and in additional measures of visual function	▪ Change in GA area
Status	▪ FPI Q3 2014 ▪ Fast track designation received Q4 2014	▪ FPI Q3 2014 ▪ Fast track designation received Q4 2014	▪ FPI Q4 2014

Lebrikizumab (RG3637)

Humanized monoclonal antibody designed to bind specifically to IL-13

Indication	Idiopathic pulmonary fibrosis	Moderate to severe atopic dermatitis		Moderate to very severe COPD
Phase/study	**Phase II** **RIFF**	**Phase II** **TREBLE**	**Phase II** **ARBAN** Safety Study	**Phase II** **VALETA**
# of patients	N=480	N=200	N=50	N=300
Design	▪ **ARM A:** lebrikizumab SC q4w ▪ **ARM B:** placebo ▪ **ARM C:** lebrikizumab SC q4w + Esbriet ▪ **ARM D:** Esbriet	Patients on topical corticosteroids ▪**ARM A:** lebrikizumab dose 1 ▪**ARM B:** lebrikizumab dose 2 ▪**ARM C:** lebrikizumab dose 3 ▪**ARM D:** placebo	▪ **ARM A:** lebrikizumab ▪ **ARM B:** topical corticosteroids	Patients on background SOC during study ▪**ARM A:** lebrikizumab SC q4w ▪**ARM B:** placebo
Primary endpoint	▪ Change in FVC at week 52	▪ Percentage of patients achieving a 50% reduction in Eczema Area and Severity Index (EASI) score (EASI-50) from baseline to week 12	▪ Safety comparison of lebrikizumab vs. TCS	▪ Week 24 change from baseline in pre-bronchodilator forced expiratory volume (FEV-1)
Status	▪ FPI Q4 2013 (arms A&B) ▪ Data in-house for Arms A&B ▪ FPI in arms C and D in Q3 2015 ▪ LPI in arms C and D in Q3 2016 ▪ Interim data in-house for arms C and D	▪ Enrolment completed Q4 2015 ▪ Data in-house	▪ Enrolment completed Q4 2015 ▪ Data in-house	▪ FPI Q3 2015

COPD=chronic obstructive pulmonary diesease; SOC=standard of care

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group YTD Sept 2016 sales

Diagnostics

Foreign exchange rate information

Oncology development programmes
Small molecules

Molecule	Idasanutlin (MDM2 antagonist, RG7388)		
Indication	**Relapsed or refractory acute myeloid leukemia**	**Relapsed or refractory FL and DLBCL**	**Relapsed or refractory AML not eligible for cytotoxic therapy**
Phase	**Phase III**	**Phase Ib/II**	**Phase I**
# of patients	N=440	N=116	N=140
Design	▪ **ARM A:** Idasanutlin plus cytarabine ▪ **ARM B:** placebo plus cytarabine	▪ Dose escalation of idasanutlin plus Gazyva ▪ **ARM A:** Dose expansion of idasanutlin plus Gazyva in FL ▪ **ARM B:** Dose expansion of idasanutlin plus Gazyva in DLBCL	Phase I (dose escalation) ▪ **ARM A:** Cotellic plus Venclexta ▪ **ARM B:** idasanutlin plus Venclexta Phase II (expansion) ▪ **ARM A:** Cotellic plus Venclexta ▪ **ARM B:** idasanutlin plus Venclexta
Primary endpoint	▪ Overall survival	▪ Safety and efficacy	▪ Safety and efficacy
Status	▪ FPI Q4 2015	▪ FPI Q4 2015	▪ FPI Q1 2016

Oncology development programmes
Small molecules

Roche pRED

Molecule	**LSD1 inhibitor** (RG6016)
Indication	**Acute Leukemia**
Phase	**Phase I**
# of patients	N=41
Design	▪ Multiple ascending dose-escalation cohort ▪ Extension cohort at recommended dose
Primary endpoint	▪ Safety, efficacy and PK
Status	▪ FPI Q1 2014 ▪ Extension in MLL-AML initiated Q3 2015 ▪ Data presented at AACR 2016
Collaborator	Oryzon Genomics, S.A.

Oncology development programmes
Small molecules

Molecule	BET inhibitor (RG6146, TEN-010)		Raf/MEK inhibitor (RG7304, CKI27)	HIF1 alpha LNA (RG6061)
Indication	**Solid tumors**	**Acute Leukemia**	**Solid tumours**	**Hepatocellular carcinoma (HCC)**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=100	N=89	N=52	N=12
Design	▪ Dose escalation and expansion study	▪ Dose escalation and cohort expansion study	▪ Dose-escalation to MTD	▪ RG6061, 13 mg/kg/week, 2-hour IV infusion every week in a 6-week cycle, after two loading doses in week 1 of cycle 1 on day 1 and day 4
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ MTD and tumour assessment	▪ Change from baseline to week 6 in HIF1A mRNA level in tumour tissue
Status	▪ FPI Q4 2013	▪ FPI Q4 2014	▪ Initiated Q4 2008 ▪ Enrolment stopped Q4 2010	▪ FPI Q1 2016
Collaborator	Tensha acquisition		Chugai	Santaris acquisition

Oncology development programmes
Monoclonal antibodies

Molecule	Codrituzumab (Glypican-3 MAb, GC33, RG7686)	
Indication	**Metastatic liver cancer (hepatocellular carcinoma)**	**2L metastatic liver cancer (hepatocellular carcinoma)**
Phase	**Phase Ib**	**Phase II**
# of patients	N= 40-50	N=185
Design	▪ Study US monotherapy ▪ Study Japan monotherapy ▪ Dose escalation study in combo with SOC	▪ Adaptive design study Double blind randomized 2:1 RG7686: placebo ▪ Patients are stratified according to the level of GPC-3 expression in tumour
Primary endpoint	▪ Safety and tolerability	▪ Progression-free survival
Status	▪ Recruitment completed Q4 2013 ▪ Data presented at ASCO 2014 ▪ Further steps under evaluation	▪ Recruitment completed Q1 2013 ▪ Data presented at ASCO 2014 ▪ Further steps under evaluation
Collaborator	Chugai	

SOC=standard of care; ASCO=American Society of Clinical Oncology

Oncology development programmes
Monoclonal antibodies

Roche pRED

Molecule	Vanucizumab (ANG2-VEGF biMAb, RG7221)		
Indication	**Solid tumours**	**Metastatic colorectal cancer**	**Solid tumours**
Phase	**Phase I**	**Phase II McCAVE**	**Phase I**
# of patients	N≈160	N=192	N=170
Design	▪ Multiple ascending dose study with extension cohorts in solid tumours to assess the PD effects and platinum-resistant ovarian cancer ▪ Dose escalation of vanucizumab plus Tecentriq	▪ **ARM A**: Induction: Avastin+mFOLFOX-6; followed by maintenance: Avastin+5-FU/LV ▪ **ARM B**: Induction: RG7221+mFOLFOX-6; followed by maintenance: RG7221+5-FU/LV	▪ Vanucizumab in combination with RG7876 (CD40 MAb)
Primary endpoint	▪ Safety, PK	▪ Progression-free survival	▪ Safety, PD, efficacy
Status	▪ FPI Q4 2012 ▪ Dose escalation data presented at ASCO 2014 ▪ Ovarian cancer cohort data presented at ASCO 2015 ▪ Biomarker/imaging data presented at ECC 2015 ▪ FPI in combination arm Q2 2016	▪ Recruitment completed Q2 2016 ▪ Data in house Q3 2016	▪ FPI Q1 2016

ASCO=American Society of Clinical Oncology; ECC=European Cancer Congress

Oncology development programmes
Monoclonal antibodies

Roche pRED

Molecule	Emactuzumab (CSF-1R MAb, RG7155)			Cergutuzumab amunaleukin (CEA-IL2v, RG7813)	
Indication	**Solid tumours**			**Solid tumours**	
Phase	**Phase I/II**	**Phase I**	**Phase I**	**Phase I**	**Phase Ib**
# of patients	N=216	N=162	N≈120	N=113	N=75
Design	▪ Multiple ascending dose study +/- paclitaxel with extension cohorts	RG7155 in combination with Tecentriq (PD-L1 MAb) ▪ Part 1: dose escalation ▪ Part 2: expansion	Emactuzumab in combination with RG7876 (CD40 Mab) ▪ Part 1: dose escalation ▪ Part 2: expansion	▪ Single and multiple dose escalation study with extension cohorts	▪ Part 1: dose escalation of RG7813 in combination with Tecentriq (PD-L1 MAb) ▪ Part 2: dose expansion RG7813 in combination with Tecentriq (PD-L1 MAb)
Primary endpoint	▪ Safety, PK, PD, preliminary clinical activity	▪ Safety	▪ Safety, PK, PD	▪ Safety, PK, PD	▪ Safety, Efficacy, PK, PD
Status	▪ FPI Q4 2011 ▪ Biomarker data presented at AACR 2013 and 2014 ▪ Data presented at ASCO 2014 ▪ Updated data presented at ASCO 2015 ▪ Recruitment completed Q1 2016	▪ FPI Q1 2015	▪ FPI Q2 2016	▪ Recruitment completed Q1 2016 ▪ Imaging data presented at ASCO 2015 ▪ Biomarker/imaging data presented at ECC 2015 ▪ Final imaging data presented at ESMO 2016	▪ FPI in Q2 2015

AACR=American Association for Cancer Research; ASCO=American Society of Clinical Oncology; ECC=European Cancer Congress; ESMO=European Society for Medical Oncology

Oncology development programmes
Monoclonal antibodies

Roche pRED

Molecule	CEA CD3 T-cell bispecific (TCB) (RG7802)		CD40 MAb (RG7876)	
Indication	**CEA-positive solid tumours**		**Solid tumours**	**Solid tumours**
Phase	**Phase Ia**	**Phase I**	**Phase I**	**Phase I**
# of patients	N~300-350 (DE & DF)	N~200-250	N=160	N=170
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 plus Tecentriq ▪ Part II: Expansion at defined ds and schedule	▪ Part I: sequential and single concomitant administration of RG7876 (CD40 MAb, i.v. and s.c., dose escalation) and Tecentriq ▪ Part II: multiple doses of concomitant RG7876 (CD40 MAb) and Tecentriq, recom-mended dose and route per Part I ▪ Part III: study drugs schedule in specific indications per Part II	▪ RG7876 dose escalation in combination with vanucizumab (ANG2-VEGF biMAb)
Primary endpoint	▪ Safety, Efficacy, PK, PD	▪ Safety, Efficacy, PK, PD	▪ Safety, PD, efficacy	▪ Safety, PD, efficacy
Status	▪ FPI Q4 2014	▪ FPI Q1 2016	▪ FPI Q4 2014	▪ FPI Q1 2016

Oncology development programmes
Monoclonal antibodies

Molecule	FAP-DR5 biMAB (RG7386)	FAP-IL2v FP (RG7461)
Indication	Solid tumours	Solid tumours
Phase	Phase I	Phase I
# of patients	N=120	N=60
Design	▪ Part I: Dose escalation ▪ Part II: Tumour biopsy and imaging evaluation for assessment of treatment-induced pharmacodynamic (PD) effects ▪ Part III: Evaluation of antitumour activity of single-agent RO6874813 (RG7386) in patients with histologically confirmed recurrent or metastatic, non-resectable FAP+ sarcomas with two or fewer prior regimens for advanced disease	▪ Dose escalation study
Primary endpoint	▪ Parts I & II – safety and tolerability ▪ Part III – antitumour activity	▪ Safety, PK/PD
Status	▪ FPI Q3 2015	▪ FPI Q4 2015

Neuroscience development programmes

Roche pRED

Molecule	Basmisanil (GABRA5 NAM, RG1662)	
Indication	**Cognitive impairment associated with schizophrenia**	**Stroke recovery**
Phase	**Phase II**	**Phase II**
# of patients	N=150	N=80 (95 enrolled)
Design	▪ For 24 weeks patients will receive: ▪ **ARM A**: RG1662 80mg twice daily ▪ **ARM B**: RG1662 240mg twice daily ▪ **ARM C**: Placebo	Starting on day 5-7 post stroke patients will receive treatment for 90-days. ▪ **ARM A**: RG1662 240mg twice daily ▪ **ARM B**: Placebo
Primary endpoint	▪ Efficacy (cognitive function), PK, safety and tolerability	▪ PK, PD, safety and tolerability
Status	▪ Expect FPI Q4 2016	▪ Expect FPI Q4 2016

NAM=Negative allosteric modulator

Neuroscience development programmes

Roche pRED

Molecule	NME (RG7906)	PDE10A inhibitor (RG7203)	
Indication	**Psychiatric disorders**	**Schizophrenia**	
Phase	**Phase I**	**Phase I**	**Phase I**
# of patients	N=164	N=26	N=48
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-blinded, placebo-controlled study of multiple doses of RG7203 administered orally to psychiatrically stable patients with schizophrenia receiving risperidone ▪ **ARM A:** RG7203 plus risperidone ▪ **ARM B:** placebo plus risperidone	▪ Multicenter, randomized, double-blind, placebo-controlled, crossover study to evaluate the effects of RO5545965 in participants with mild to moderate negative symptoms of schizophrenia treated with antipsychotics.
Primary endpoint	▪ Safety, tolerability, PK, PD	▪ Safety, tolerability, PK	▪ Safety, tolerability, PK, PD
Status	▪ FPI Q1 2016	▪ Study completed Q3 2014 ▪ Next study in preparation	▪ FPI Q2 2016

Neuroscience development programmes

Spinal muscular atrophy

Molecule	SMN2 splicing modifier (RG7800)	SMN2 splicing modifier (2) (RG7916)
Indication	Spinal muscular atrophy	Spinal muscular atrophy
Phase	**Phase Ib MOONFISH**	**Phase I**
# of patients	N=48	N=33
Design	▪ Randomized, double-blind, 12-week, placebo-controlled multiple dose study in adult and pediatric patients	▪ Randomized, double-blind, adaptive single-ascending-dose (SAD), placebo-controlled study in healthy volunteers
Primary endpoint	▪ Safety and tolerability	▪ Safety and tolerability
Status	▪ Study on hold ▪ First cohort completed ▪ Healthy volunteer data presented at AAN and CureSMA 2015 ▪ SMA patient data from first cohort presented at WMS 2015	▪ FPI Q1 2016 ▪ Study completed Q3 2016 ▪ Data to be presented at Child Neurology Society conference, October 2016
Collaborator	PTC Therapeutics, SMA Foundation	

AAN=American Academy of Neurology; SMA=Spinal Muscular Atrophy; WMS=World Muscle Society

Neuroscience development programmes

Spinal muscular atrophy

Molecule	SMN2 splicing modifier (2) (RG7916)	SMN2 splicing modifier (2) (RG7916)
Indication	Spinal muscular atrophy	Spinal muscular atrophy
Phase	**Phase II SUNFISH**	**Phase II FIREFISH**
# of patients	N=186	N=48
Design	Randomised, double-blind, placebo- controlled study in adult and pediatric patients with type 2 or type 3 SMA ▪ Part 1 (dose-finding): at least 12 weeks ▪ Part 2 (confirmatory): 24 months	Open-label study in infants with type 1 SMA ▪ Part 1 (dose-finding): at least 4 weeks ▪ Part 2 (confirmatory): 24 months
Primary endpoint	▪ Safety and tolerability, pharmacokinetics, pharmacodynamics, efficacy	▪ Safety and tolerability, pharmacokinetics, pharmacodynamics, efficacy
Status	▪ Expect FPI Q4 2016	▪ Expect FPI Q4 2016
Collaborator	PTC Therapeutics, SMA Foundation	

SMA=Spinal Muscular Atrophy

Neuroscience development programmes

Roche pRED

Molecule	V1 receptor antagonist (RG7314)		Anti-αSynuclein (RG7935, PRX002)	
Indication	Autism		Parkinson's disease	
Phase	Phase II VANILLA	Phase II AVIATION	Phase I	Phase Ib
# of patients	N=225	N=300	N=40	N=80
Design	▪ Multi-center, randomized, double-blind, placebo-controlled proof-of-concept study in individuals with Autism Spectrum Disorder (ASD)	▪ Multi-center, randomized, double-blind, placebo-controlled proof-of-concept study in individuals with Autism Spectrum Disorder (ASD)	▪ Double-blind, placebo-controlled, single, ascending dose study of RG7935/PRX002 in healthy subjects	▪ Double-blind, placebo-controlled, multiple ascending dose study of RG7935/PRX002 in patients with Parkinson's disease
Primary endpoint	▪ Safety and efficacy	▪ Safety and efficacy	▪ Safety, tolerability and PK	▪ Safety, tolerability and PK
Status	▪ FPI Q3 2013	▪ FPI Q4 2016	▪ Study completed Q1 2015 ▪ Data presented at MDS 2015	▪ FPI Q3 2014 ▪ Enrolment completed ▪ Study ongoing
Collaborator			Prothena	

MDS=Movement Disorder Society

Infectious diseases development programmes

Roche pRED

Molecule	DBO beta lactamase inhibitor (RG6080)	NME (RG7834)
Indication	Infectious diseases	Chronic hepatitis B
Phase	Phase I	Phase I
# of patients	N=40	N=165
Design	▪ Randomized, double-blind, placebo-controlled, single-ascending dose study in healthy volunteers	▪ Healthy volunteer and chronic hepatitis B patient study
Primary endpoint	▪ Safety, PK	▪ Safety, PK/PD
Status	▪ Study completed	▪ FPI Q4 2015
Collaborator	Meiji and Fedora	

Ophthalmology development programmes

Roche pRED

Molecule	VEGF-Ang2 biMAb (RG7716)	
Indication	**Wet age-related macular degeneration**	**Center-involving diabetic macular edema (CI-DME)**
Phase/study	**Phase II AVENUE**	**Phase II BOULEVARD**
# of patients	N=271	N=150
Design	▪ **ARM A:** SoC (Lucentis, q4w ▪ **ARM B:** 1.5 mg VA2, q4w ▪ **ARM C:** 6mg VA2, q4w / q8w ▪ **ARM E:** Soc q4w x 3 doses, switch group to 6 mg VA2 q4w	▪ **ARM A:** SOC (Lucentis) 0.3 mg q4w ▪ **ARM B:** 1.5mg VA2, q4w ▪ **ARM C:** 6 mg VA2, q4w
Primary endpoint	▪ Visual acuity (change in BCVA) after 32 weeks	▪ Mean change from baseline in BCVA at week 24
Status	▪ FPI Q3 2015	▪ FPI Q2 2016

Immunology development programmes

Roche pRED

Molecule	Cathepsin S inhibitor (RG7625)	
Indication	**Primary Sjögren's syndrome**	**Celiac disease**
Phase/study	**Phase II**	**Phase I**
# of patients	N=70	N=19
Design	▪ **ARM A**: RG7625 ▪ **ARM B**: placebo	▪ **ARM A**: RG7625 ▪ **ARM B**: placebo
Primary endpoint	▪ Percentage of participants with a Clinically Relevant Decrease in European League Against Rheumatism (EULAR) Sjoören's Syndrome Disease Activity Index (ESSDAI) Score	▪ Overall numbers of participants who are Responders to the gluten challenge
Status	▪ FPI Q3 2016	▪ Enrolment completed Q3 2016

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group YTD Sept 2016 sales

Diagnostics

Foreign exchange rate information

Oncology development programmes
Monoclonal antibodies

gRED Genentech Research & Early Development

Molecule	OX40 MAb (RG7888, MOXR0916)		CD20/CD3 biMAb (RG7828)	Anti-TIGIT (RG6058, MTIG7192A)
Indication	**Solid tumours**	**Solid tumours**	**Hematologic tumours**	**Solid tumours**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=400	N=762	N=170	N=300
Design	▪ RG7888 dose escalation and expansion study	▪ Dose escalation and expansion of RG7888 + Tecentriq with or without Avastin	▪ Dose escalation and expansion	▪ Dose escalation and expansion as single agent and in combination with Tecentriq
Primary endpoint	▪ Safety	▪ Safety	▪ Safety, PK/PD	▪ Safety,PK/PD
Status	▪ FPI Q3 2014 ▪ Dose escalation data presented at AACR 2016	▪ FPI Q2 2015 ▪ Dose escalation data presented at ASCO 2016 ▪ FPI Avastin cohort Q3 2016	▪ FPI Q3 2015	▪ FPI Q2 2016

AACR=American Association for Cancer Research ; ASCO=American Society of Clinical Oncology

Oncology development programmes
Antibody–drug conjugates

gRED Genentech Research & Early Development

Molecule	NME ADC (RG7882)	Ly6E ADC (RG7841)	NME ADC (RG7986)
Indication	**Pt-resistant ovarian cancer or unresectable pancreatic cancer**	**HER2-neg. breast cancer and NSCLC**	**Relapsed or refractory B cell non-Hodgkin's lymphoma**
Phase	**Phase I**	**Phase I**	**Phase I**
# of patients	N=95	N=115	N=80
Design	▪ Dose escalation and expansion study	▪ Dose escalation and expansion study	▪ Dose escalation and expansion
Primary endpoint	▪ Safety/PK	▪ Safety	▪ Safety, PK
Status	▪ FPI Q2 2014	▪ FPI Q2 2014 ▪ Expansion study: FPI Q2 2015 ▪ Data presented at ESMO 2016	▪ FPI Q3 2015
Collaborator	Seattle Genetics		

ESMO=European Society for Medical Oncology

Oncology development programmes
Small molecules

gRED Genentech Research & Early Development

Molecule	Selective estrogen receptor degrader (SERD) (RG6046, GDC-0810/ARN-810)		Selective estrogen receptor degrader (SERD(2)) (RG6047, GDC-0927/SRN-927)
Indication	**Metastatic ER+ HER2-neg. breast cancer**	**Advanced or metastatic ER+ HER2-neg. breast cancer resistant to aromatase inhibitor therapy**	**Metastatic ER+ HER2-neg. breast cancer**
Phase	**Phase I/IIa**	**Phase II HydranGea**	**Phase I**
# of patients	N=195	N=152	N=90
Design	▪ Phase I: dose escalation ▪ Phase IIa: dose expansion ▪ Phase Ib: RG6046 plus palbociclib and/or an LHRH agonist	▪ **ARM A:** RG6046 ▪ **ARM B:** fulvestrant	▪ Dose escalation study
Primary endpoint	▪ Safety, PK, MTD	▪ Progression-free survival in all participants and for subset of participants with estrogen receptor (ESR)1 mutations	▪ Safety
Status	▪ FPI Q4 2014 ▪ Initial data presented at SABCS 2014 and AACR 2015 ▪ FPI in palbociclib arm Q1 2016	▪ FPI Q4 2015	▪ FPI Q1 2015
Collaborator	Seragon acquisition		

SABCS=San Antonio Breast Cancer Symposium; AACR=American Association for Cancer Research; LHRH=luteinizing hormone-releasing hormone

Oncology development programmes
Small molecules

gRED Genentech Research & Early Development

Molecule	Indoleamine 2, 3-dioxygenase (IDO) Inhibitor (RG6078, GDC-0919, NLG919)		ChK1 inhibitor (RG7741,GDC-0575)
Indication	**Solid tumours**	**Solid tumours**	**Solid tumours**
Phase	**Phase I**	**Phase I**	**Phase I**
# of patients	N=36	N=224	N=112
Design	▪ Dose escalation study	▪ Dose escalation and expansion study of RG6078 and Tecentriq combination	▪ Stage 1: Dose escalation ▪ Stage 2: Cohort expansion
Primary endpoint	▪ Safety	▪ Safety and tolerability	▪ Safety/PK
Status	▪ FPI Q1 2014 ▪ Safety and PK/PD data presented at ECC 2015	▪ FPI Q3 2015	▪ FPI Q2 2012
Collaborator	NewLink Genetics		Array BioPharma

ECC=European Cancer Congress

Oncology development programmes
Small molecules

Molecule	Ipatasertib (AKT inhibitor, RG7440, GDC-0068)			
Indication	**2L castration-resistant prostate cancer**	**1L metastatic gastric or gastroesophageal junction adenocarcinoma**	**1L TNBC**	**Neoadjuvant TNBC**
Phase	**Phase II A.MARTIN**	**Phase II JAGUAR**	**Phase II LOTUS**	**Phase II FAIRLANE**
# of patients	N=262	N=153	N=120	N=150
Design	▪ **ARM A**: ipatasertib (400mg) + abiraterone ▪ **ARM B**: ipatasertib (200mg) + abiraterone ▪ **ARM C**: placebo + abiraterone	▪ **ARM A:** ipatasertib + mFOLFOX6 ▪ **ARM B:** placebo + mFOLFOX6	▪ **ARM A:** ipatasertib + paclitaxel ▪ **ARM B:** placebo + paclitaxel	▪ **ARM A**: ipatasertib + paclitaxel ▪ **ARM B**: placebo + paclitaxel
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Progression-free survival	▪ Pathologic complete response (pCR)
Status	▪ Enrolment completed Q4 2014 ▪ Data in-house ▪ ITT data presented at ASCO 2016 ▪ Dx+ data presented at ESMO 2016	▪ Enrolment completed Q4 2014 ▪ Data showed no benefit for treatment group vs control Q2 2016	▪ Recruitment completed Q1 2016	▪ FPI Q1 2015
Collaborator	Array BioPharma			

mFOLFOX6=modified FOLFOX (folinic acid, fluorouracil, oxaliplatin); TNBC=triple-negative breast cancer

Immunology development programmes

gRED Genentech Research & Early Development

Molecule	IL22-Fc (RG7880)	NME (RG7990, BITS7201A)	NME (RG6069, GDC-3280)
Indication	**Inflammatory diseases**	**Asthma**	**Fibrosis**
Phase	**Phase Ib**	**Phase I**	**Phase I**
# of patients	N=48	N=80	N=88
Design	▪ Multiple ascending dose study with healthy volunteer and patient cohorts	▪ Single and multiple ascending dose study with healthy volunteer and patient cohorts	▪ Randomized, double-blind, placebo-controlled, ascending, single and multiple oral dose study
Primary endpoint	▪ Safety, tolerability	▪ Safety and tolerability	▪ Safety, tolerability, and PK
Status	▪ FPI Q2 2016	▪ FPI Q2 2016	▪ Study completed Q1 2016
Collaborator		Novimmune SA	

Immunology development programmes

gRED Genentech Research & Early Development

Molecule	BTKi (RG7845, GDC-0853)		ST2 MAb (RG6149, AMG 282, MSTT1041A)
Indication	**Autoimmune diseases**		**Asthma**
Phase	**Phase I**	**Phase II**	**Phase IIb ZENYATTA**
# of patients	N=123	N=580	N=500
Design	▪ Healthy volunteer single and multiple ascending dose study	▪ Randomized, double-blind, parallel group study in rheumatoid arthritis patients ▪ Cohort 1: RG7845 vs adalimumab ▪ in patients with IR to previous MTX ▪ Cohort 2: RG7845 vs placebo in patients with IR to previous TNF	▪ 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, PK	▪ ACR 50, safety	▪ Percentage of participants with asthma exacerbations
Status	▪ Last subject last visit Q4 2015 ▪ Favorable safety, PK and PD demonstrated ▪ Phase 2 study in rheumatoid arthritis to start in 2016	▪ FPI Q3 2016	▪ FPI Q3 2016
Collaborator			Amgen

Neuroscience development programmes

gRED Genentech Research & Early Development

Molecule	Nav1.7 (RG7893, GDC-0276)	Nav1.7 (2) (RG6029, GDC-0310)	NME (RG6000, GDC-0134)	Anti-Tau RG6100
Indication	**Pain**	**Pain**	**Amyotrophic lateral sclerosis**	**Prodromal to mild Alzheimer's disease**
Phase	**Phase I**	**Phase I**	**Phase I**	**Phase I**
# of patients	N=235	N=95	N=39	N=71
Design	▪ Randomized, placebo-controlled, double-blind study in healthy volunteers	▪ Randomized, placebo-controlled, double-blind study in healthy volunteers	▪ Randomized, double-blind, placebo-controlled, multicenter, single-ascending dose study	▪ Randomized, double-blind, placebo–controlled, single center study in healthy volunteers and patients
Primary endpoint	▪ Safety, tolerability, pharma-cokinetics; single and multiple doses	▪ Safety, tolerability, pharma-cokinetics; single and multiple doses	▪ Safety, tolerability, PK of single dose	▪ Safety, tolerability, PK of single doses and multiple doses
Status	▪ FPI Q3 2014	▪ FPI Q3 2015	▪ FPI Q2 2016	▪ FPI Q2 2016
Collaborator	Xenon Pharmaceuticals Inc.			AC Immune

Infectious diseases development programmes

gRED Genentech Research & Early Development

Molecule	Flu A MAb (RG7745)		Anti-S. aureus TAC (RG7861)
Indication	**Influenza A**	**Acute uncomplicated seasonal influenza A**	**Serious infections caused by *Staphylococcus aureus***
Phase	**Phase IIb**	**Phase II**	**Phase I**
# of patients	N~300	N=141	N=30
Design	Hospitalized patients requiring oxygen with severe influenza A ▪ **ARM A:** RG7745 + Tamiflu ▪ **ARM B**: placebo + Tamiflu	▪ **ARM A:** RG7745 dose level 1 ▪ **ARM B**: RG7745 dose level 2 ▪ **ARM C:** placebo	▪ Healthy volunteer study
Primary endpoint	▪ Safety and efficacy (time to normalization of respiratory function)	▪ Safety	▪ Safety
Status	▪ FPI Q1 2015	▪ FPI Q1 2016	▪ FPI Q4 2015
Collaborator			Seattle Genetics and Symphogen

TAC=THIOMAB™ antibiotic conjugate

Metabolic diseases development programmes

gRED Genentech Research & Early Development

Molecule	FGFR1/KLB Mab (RG7992)
Indication	Metabolic diseases
Phase	Phase I
# of patients	N=56
Design	▪ Healthy volunteer study ▪ **ARM A:** Single ascending dose of RG7992 ▪ **ARM B:** placebo
Primary endpoint	▪ Safety and tolerability
Status	▪ FPI Q4 2015

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group YTD Sept 2016 sales

Diagnostics

Foreign exchange rate information

YTD Sep 2016: Geographical sales split by divisions and Group*

CHFm	YTD Sep 2015	YTD Sep 2016	% change CER
Pharmaceuticals Division	**27,690**	**29,140**	**+4**
United States	13,047	13,850	**+3**
Europe	6,476	6,916	**+5**
Japan	2,341	2,690	**0**
International	5,826	5,684	**+4**
Diagnostics Division	**7,835**	**8,365**	**+7**
United States	1,857	1,999	**+5**
Europe	2,780	2,851	**+1**
Japan	286	334	**+2**
International	2,912	3,181	**+15**
Group	**35,525**	**37,505**	**+4**
United States	14,904	15,849	**+3**
Europe	9,256	9,767	**+4**
Japan	2,627	3,024	**+1**
International	8,738	8,865	**+7**

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

Pharma Division sales YTD Sep 2016

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
MabThera/Rituxan	5,484	3	2,933	1	1,429	4	211	11	911	5
Herceptin	5,125	5	1,898	3	1,569	3	225	4	1,433	8
Avastin	5,114	1	2,261	-4	1,402	2	611	-1	840	19
Perjeta	1,379	31	683	13	473	54	77	10	146	86
Actemra/RoActemra	1,247	17	474	16	416	19	205	12	152	17
Xolair	1,120	17	1,120	17	-	-	-	-	-	-
Lucentis	1,077	-8	1,077	-8	-	-	-	-	-	-
Activase/TNKase	807	16	773	17	-	-	-	-	34	9
Tarceva	765	-16	412	-16	135	-21	76	-2	142	-19
Kadcyla	616	9	238	1	250	5	55	16	73	51
Esbriet	571	45	419	56	135	25	-	-	17	-7
Cellcept	559	-5	134	-11	132	-1	51	13	242	-6
Pulmozyme	504	6	349	4	91	7	-	-	64	15
Tamiflu	503	-9	326	-23	38	211	76	25	63	13
Mircera	375	-4	-	-	65	-3	156	1	154	-9
Xeloda	350	-10	27	-40	25	-24	82	12	216	-8
NeoRec./Epogin	244	-10	-	-	107	-9	34	-13	103	-10
Rocephin	232	13	1	-	26	-10	21	-13	184	20
Valcyte / Cymevene	227	-15	52	-9	90	-23	-	-	85	-10
Madopar	214	6	-	-	74	1	12	-5	128	10

CER = Constant Exchange Rates (avg full year 2015)

Pharma Division sales YTD Sep 2016

Recently launched products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Zelboraf	160	2	35	4	92	-3	3	-2	30	17
Erivedge	148	25	97	13	39	48	-	-	12	68
Gazyva	142	54	87	55	38	156	-	-	17	-19
Alecensa	122	174	47	-	1	*	74	60	-	-
Tecentriq	77	-	76	-	1	-	-	-	-	-
Cotellic	30	-	8	-	22	-	-	-	-	-

CER = Constant Exchange Rates (avg full year 2015)
* over +500%

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q3/15	Q4/15	Q1/16	Q2/16	Q3/16
MabThera/Rituxan	4	4	3	5	0
Herceptin	7	10	4	5	4
Avastin	8	9	4	4	-3
Perjeta	57	50	33	35	24
Actemra/RoActemra	18	25	14	21	15
Xolair	21	22	22	17	13
Lucentis	-18	-17	-13	-10	-1
Activase/TNKase	14	36	21	17	12
Tarceva	-7	-9	-14	-17	-18
Kadcyla	44	36	11	10	5
Esbriet	-	296	96	24	35
Cellcept	-4	13	-4	-5	-5
Pulmozyme	14	8	7	10	0
Tamiflu	46	-67	-6	5	-23
Mircera	55	-1	0	7	-16
Xeloda	-11	-9	-17	-5	-6
NeoRec./Epogin	-8	-6	-14	-8	-7
Rocephin	-8	-1	5	18	18
Valcyte / Cymevene	-52	-41	-21	-6	-18
Madopar	10	-9	20	-4	4

CER = Constant Exchange Rates (avg full year 2015)
[1] Q3-Q4/15vs. Q3-Q4/14; Q1-Q3/16 vs. Q1-Q3/15

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
MabThera/Rituxan	7	0	6	-3	3	5	5	4	9	12	12	9	-2	11	3	0
Herceptin	13	4	6	0	4	2	3	4	3	5	4	2	16	7	8	10
Avastin	11	-2	0	-9	5	2	4	-1	12	7	-2	-6	7	27	18	14
Perjeta	31	15	16	8	74	65	56	42	14	18	10	4	131	65	121	78
Actemra/RoActemra	32	12	23	13	23	17	21	18	10	14	13	10	31	10	23	18
Xolair	22	22	17	13	-	-	-	-	-	-	-	-	-	-	-	-
Lucentis	-17	-13	-10	-1	-	-	-	-	-	-	-	-	-	-	-	-
Activase/TNKase	36	21	18	12	-	-	-	-	-	-	-	-	32	13	3	12
Tarceva	1	-15	-17	-16	-23	-18	-27	-19	-1	0	3	-9	-18	-14	-15	-27
Kadcyla	12	-2	7	-1	49	13	2	1	23	27	20	4	93	56	53	44
Esbriet	*	145	32	38	44	36	9	33	-	-	-	-	114	4	-8	-17
Cellcept	29	0	-18	-13	-1	-3	2	-1	11	11	16	12	16	-8	-4	-4
Pulmozyme	19	6	7	0	8	6	5	10	-	-	-	-	-22	22	38	-12
Tamiflu	-74	-15	-45	-39	455	78	*	*	-75	4	*	*	73	35	9	-24
Mircera	-	-	-	-	-4	-7	-2	0	9	4	2	-1	-13	0	18	-29
Xeloda	13	-71	-24	-21	-30	-31	-17	-23	10	12	16	8	-12	-13	-6	-6
NeoRec./Epogin	-	-	-	-	-6	-10	-11	-7	-9	-12	-12	-16	-5	-18	-5	-5
Rocephin	-	-	-	-	-27	-13	-13	2	-5	-10	-19	-11	0	12	30	22
Valcyte / Cymevene	-64	-25	15	-10	-16	-26	-21	-21	-	-	-	-	-22	-14	2	-18
Madopar	-	-	-	-	-1	-1	2	2	-2	-7	-2	-6	-13	39	-7	6

CER = Constant Exchange Rates (avg full year 2015)

[1] Q3-Q4/15 vs. Q3-Q4/14; Q1-Q3/16 vs. Q1-Q3/15

* over 500%

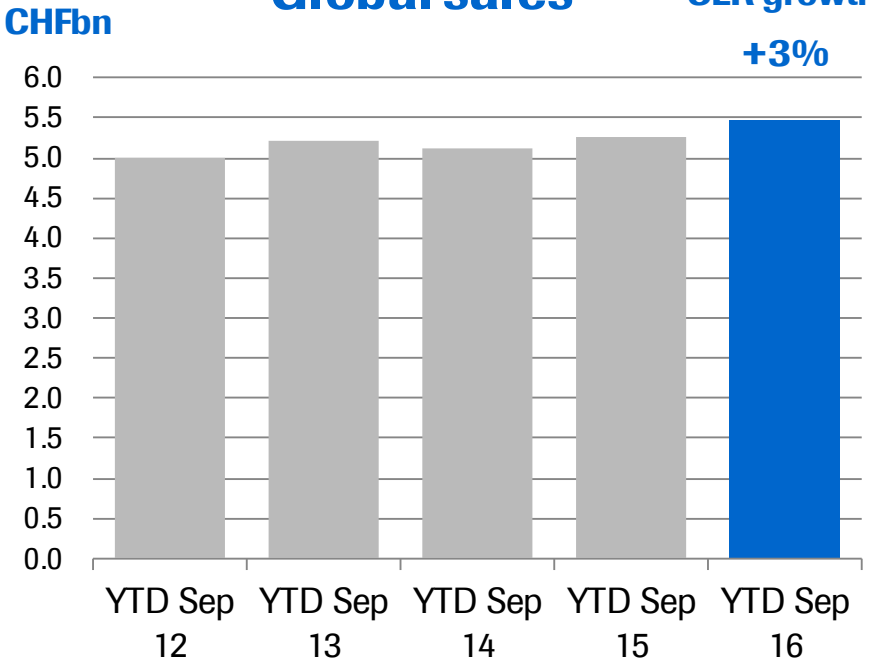
CER sales growth (%)
Quarterly development

	2015 vs. 2014				2016 vs. 2015		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Pharmaceuticals Division	**4**	**7**	**6**	**3**	**4**	**5**	**2**
United States	6	7	7	3	3	5	1
Europe	1	3	6	5	5	6	5
Japan	-2	18	8	2	4	1	-3
International	9	5	4	2	4	5	2
Diagnostics Division	**6**	**7**	**4**	**7**	**5**	**8**	**8**
Roche Group	**5**	**7**	**6**	**4**	**4**	**6**	**3**

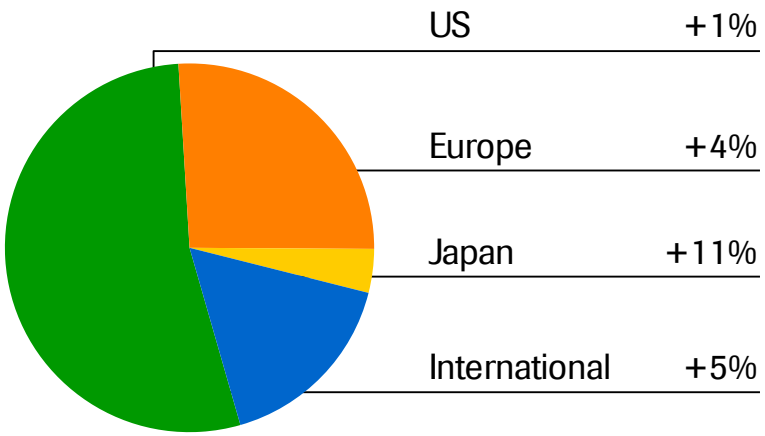
CER=Constant Exchange Rates

MabThera/Rituxan

Global sales



Regional sales



YTD Sep 2016 sales of CHF 5,484m

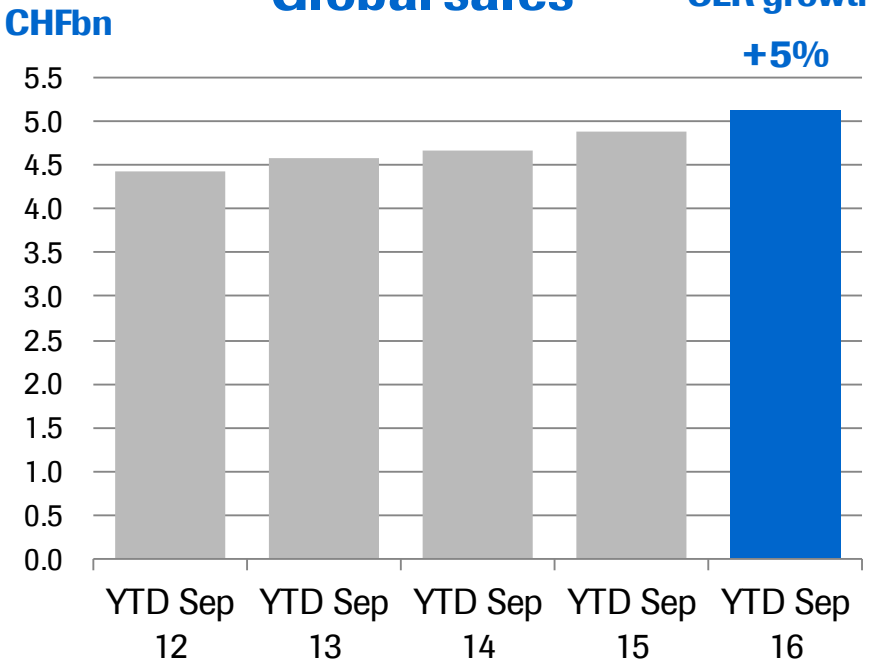
- Immunology sales grew +7% (driven by the US in 2L RA and GPA/MPA)
- Oncology sales grew +2% driven by 1L iNHL maintenance (US & EU)
- International: Growth driven by China (reimbursement obtained)

CER=Constant Exchange Rates

Herceptin

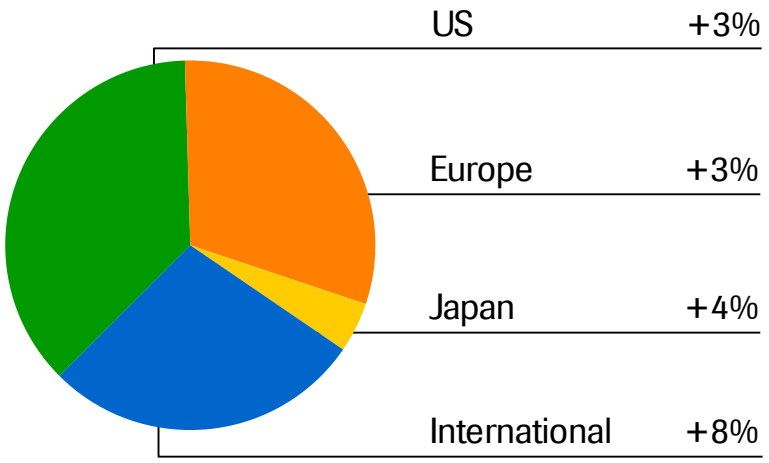
Global sales

CER growth +5%



Regional sales

CER growth



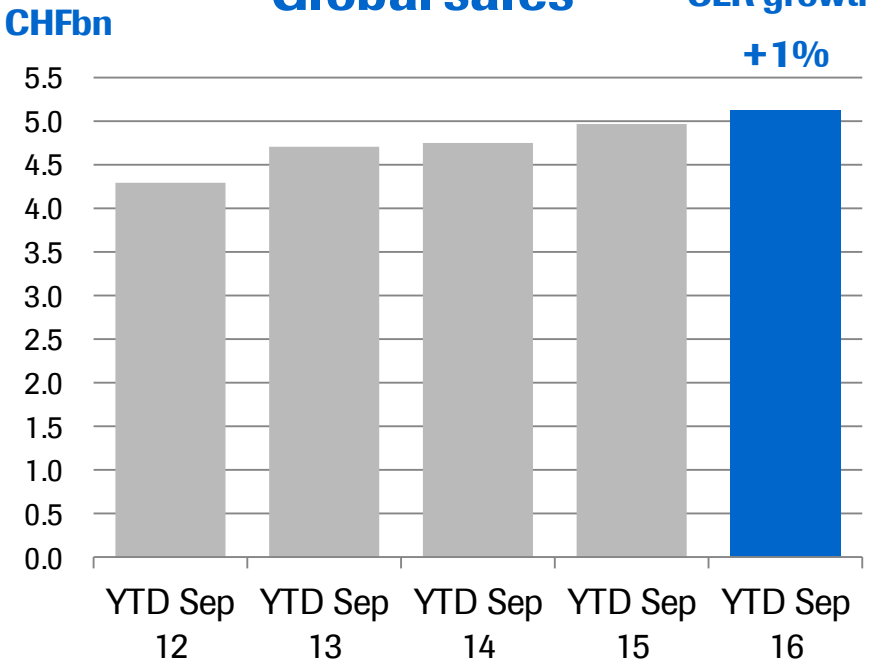
YTD Sep 2016 sales of CHF 5,125m

- US: Solid volume momentum in 1L mBC due to longer treatment times and eBC
- EU: Solid volume momentum with increasing conversion to the subcutaneous formulation
- International: Strong growth remains driven by APAC (China)

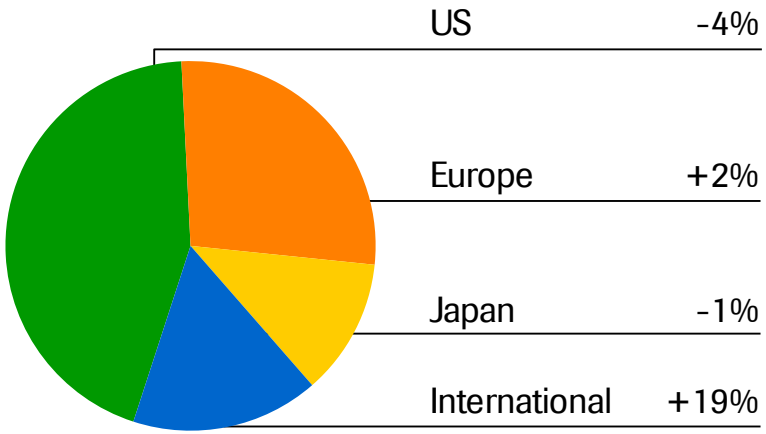
CER=Constant Exchange Rates

Avastin

Global sales



Regional sales



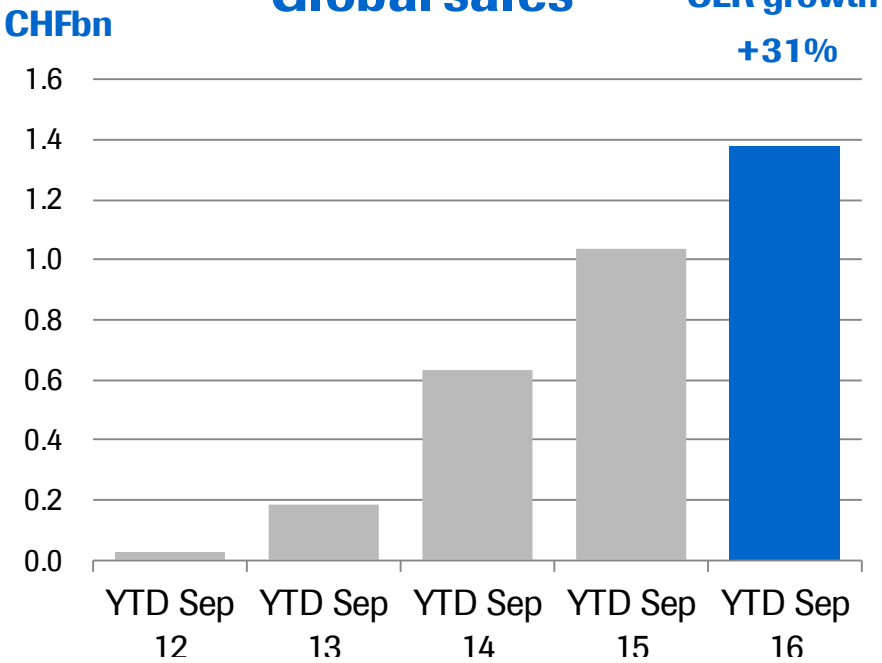
YTD Sep 2016 sales of CHF 5,114m

- US: Sales decline due to softness in niche indications and higher reserves
- EU: Growth driven by several indications, but impacted by UK delistings
- International: Growth driven by APAC (NSCLC launch in China) and LATAM
- Japan: Solid underlying growth; Negative impact from a one-time -11% price cut (April 1rst)

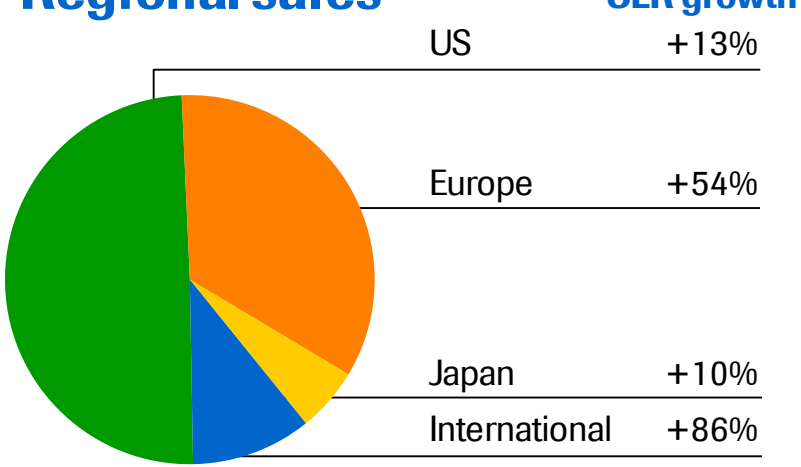
CER=Constant Exchange Rates

Perjeta

Global sales



Regional sales



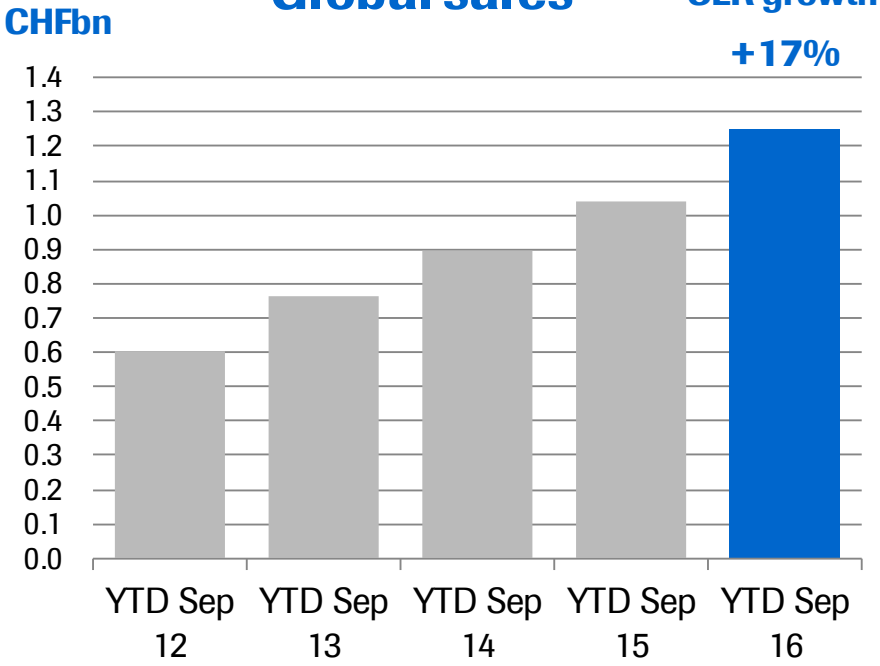
YTD Sep 2016 sales of CHF 1,379m

- US: Growth driven by further penetration in 1L mBC and neoadjuvant
- EU: Growth driven by momentum in neoadjuvant and 1L mBC, mainly Germany, France and Italy
- International: Strong growth in all region

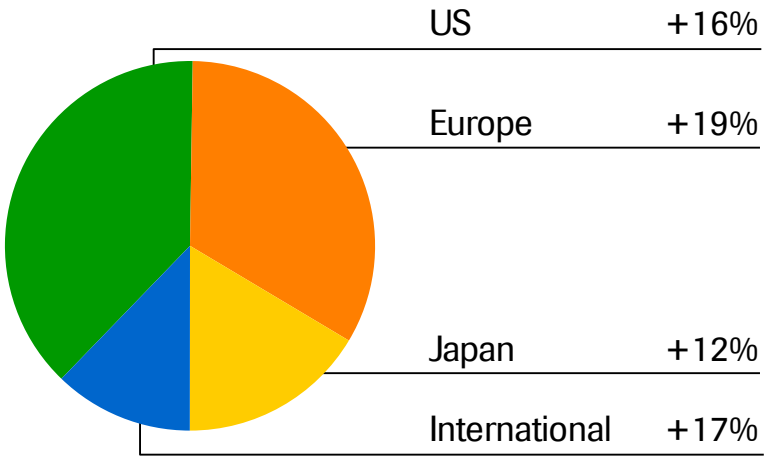
CER=Constant Exchange Rates

Actemra/RoActemra

Global sales



Regional sales



YTD Sep 2016 sales of CHF 1,247m

- US: Growth driven by continued SC uptake and increased monotherapy share
- EU: Growth driven by further strengthening market leadership in monotherapy
- Actemra SC represents 38% of sales
- Positive growth outlook following positive Ph3 results and BTD in giant cell arteritis

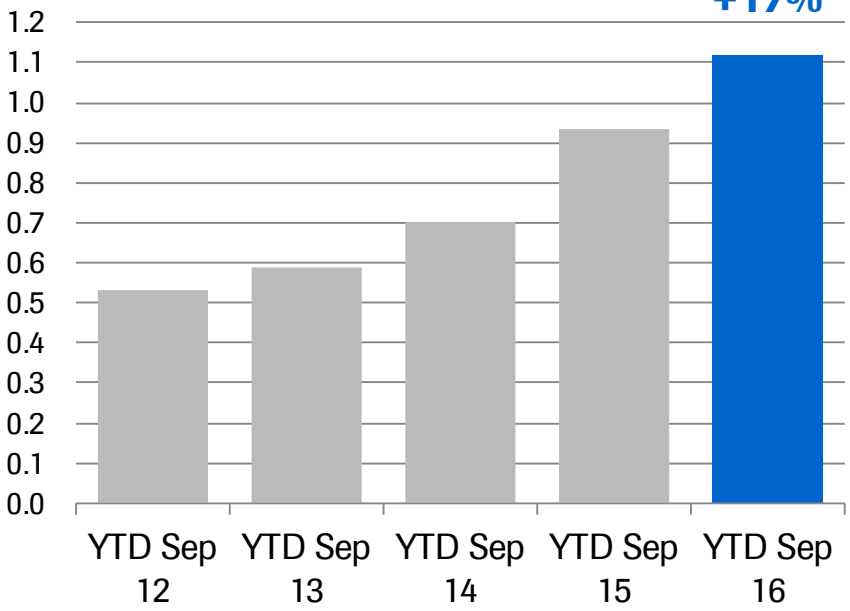
CER=Constant Exchange Rates

Xolair

Global sales

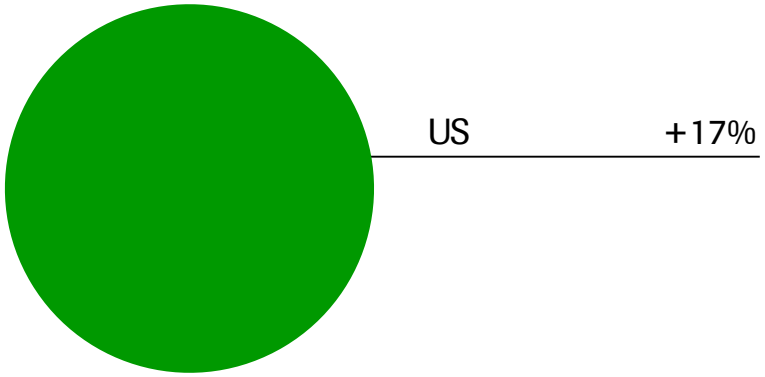
CHFbn

CER growth +17%



Regional sales

CER growth



YTD Sep 2016 sales of CHF 1,120m

- Growth driven by allergic asthma and chronic idiopathic urticaria (CIU)
- Positve growth outlook for 2016 supported by pediatric launch in H2

CER=Constant Exchange Rates

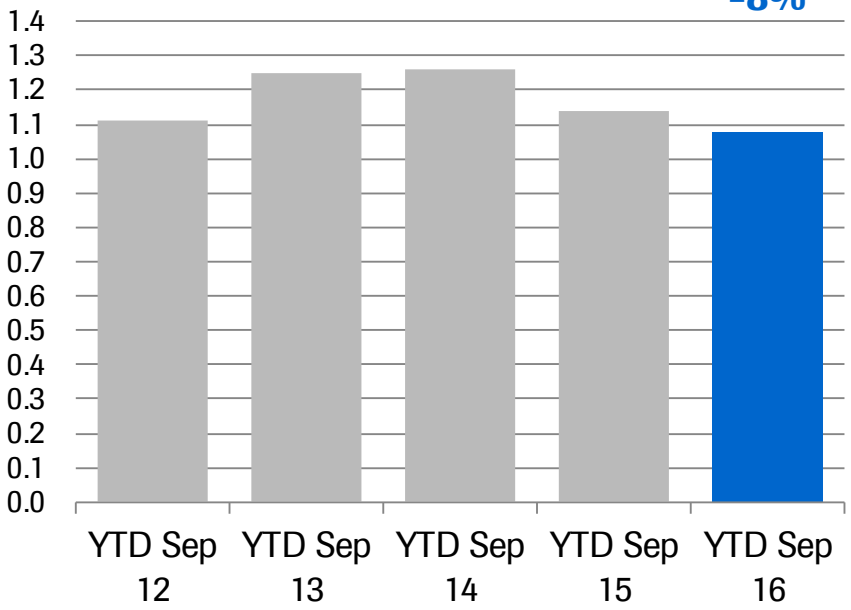
Lucentis

Global sales

CHFbn

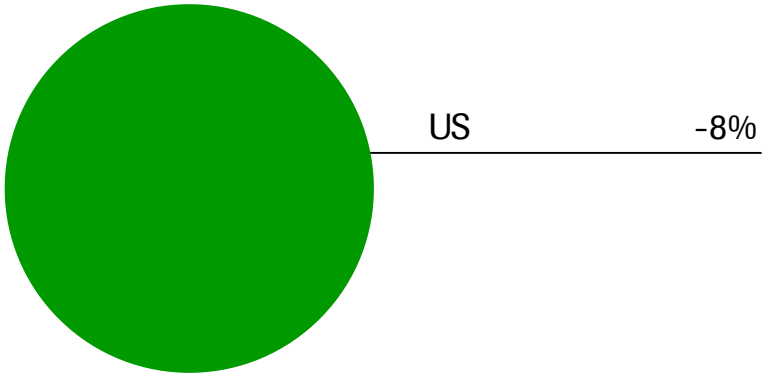
CER growth

-8%



Regional sales

CER growth



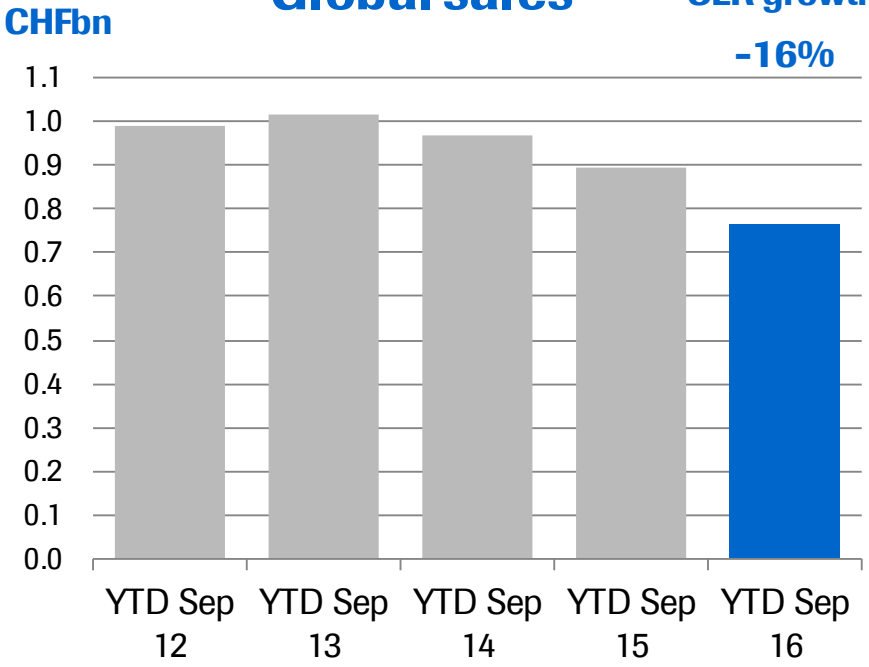
YTD Sep 2016 sales of CHF 1,077m

- In-class competition slows down significantly as patient shares stabilize in wAMD and DME
- First prefilled syringe approved to treat both wAMD and macular oedema after retinal vein occlusion; launch expected in H1 2017

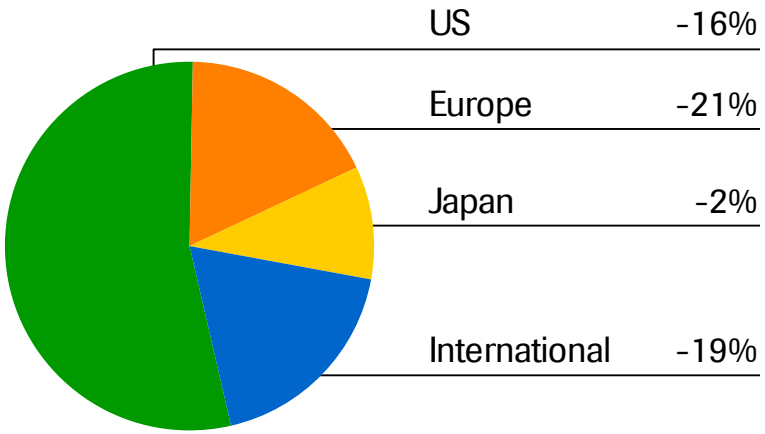
CER=Constant Exchange Rates

Tarceva

Global sales



Regional sales



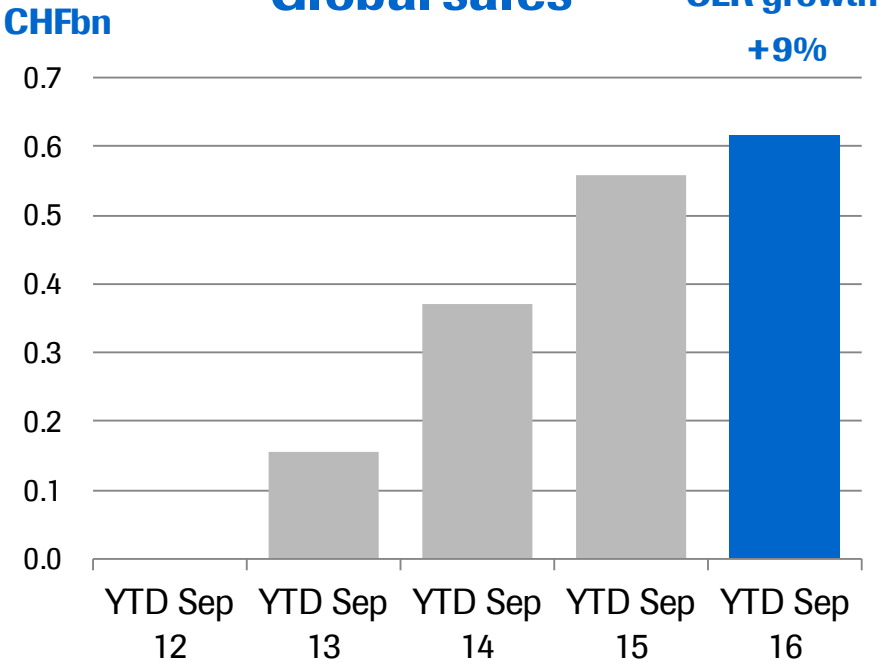
YTD Sep 2016 sales of CHF 765m

- Continued decline due to in-class competition (1L EGFR Mut+ NSCLC and 2/3L EGFR WT NSCLC) and out-of-class competition from immunotherapies (2L WT NSCLC)
- EU: Avastin + Tarceva approved in 1L EGFR+ NSCLC

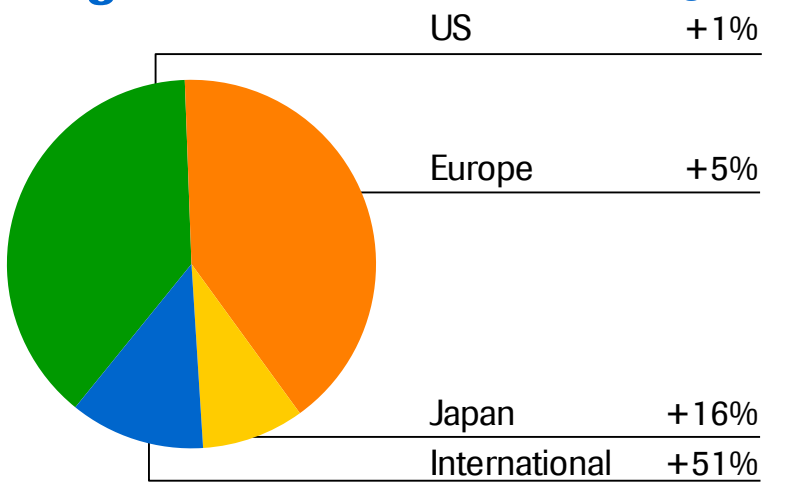
CER=Constant Exchange Rates

Kadcyla

Global sales



Regional sales



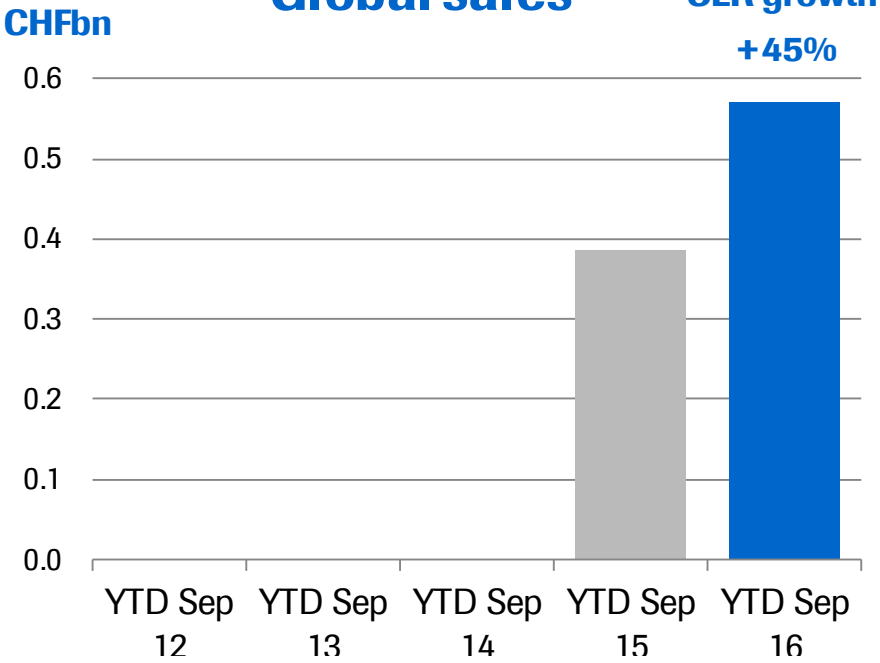
YTD Sep 2016 sales of CHF 616m

- Patient shares in 2L mBC above 60% in the US and EU, but growth slow-down expected
- Japan: Strong momentum due to updated guideline recommendations for 2L mBC
- International: Growth driven by all regions, especially Asia

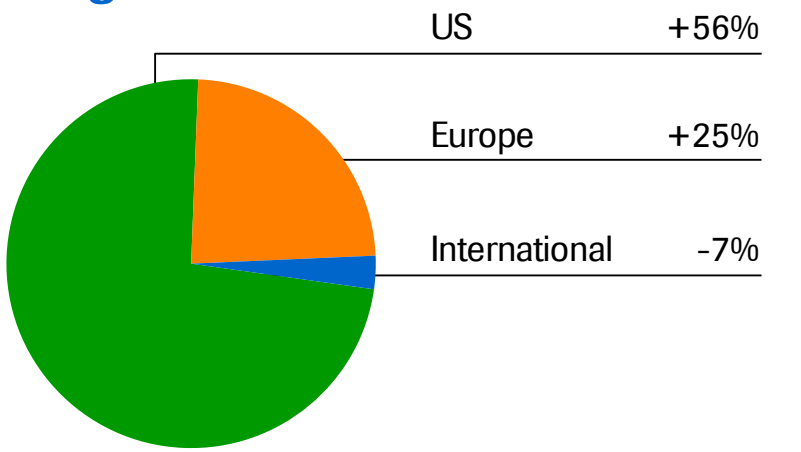
CER=Constant Exchange Rates

Esbriet

Global sales



Regional sales



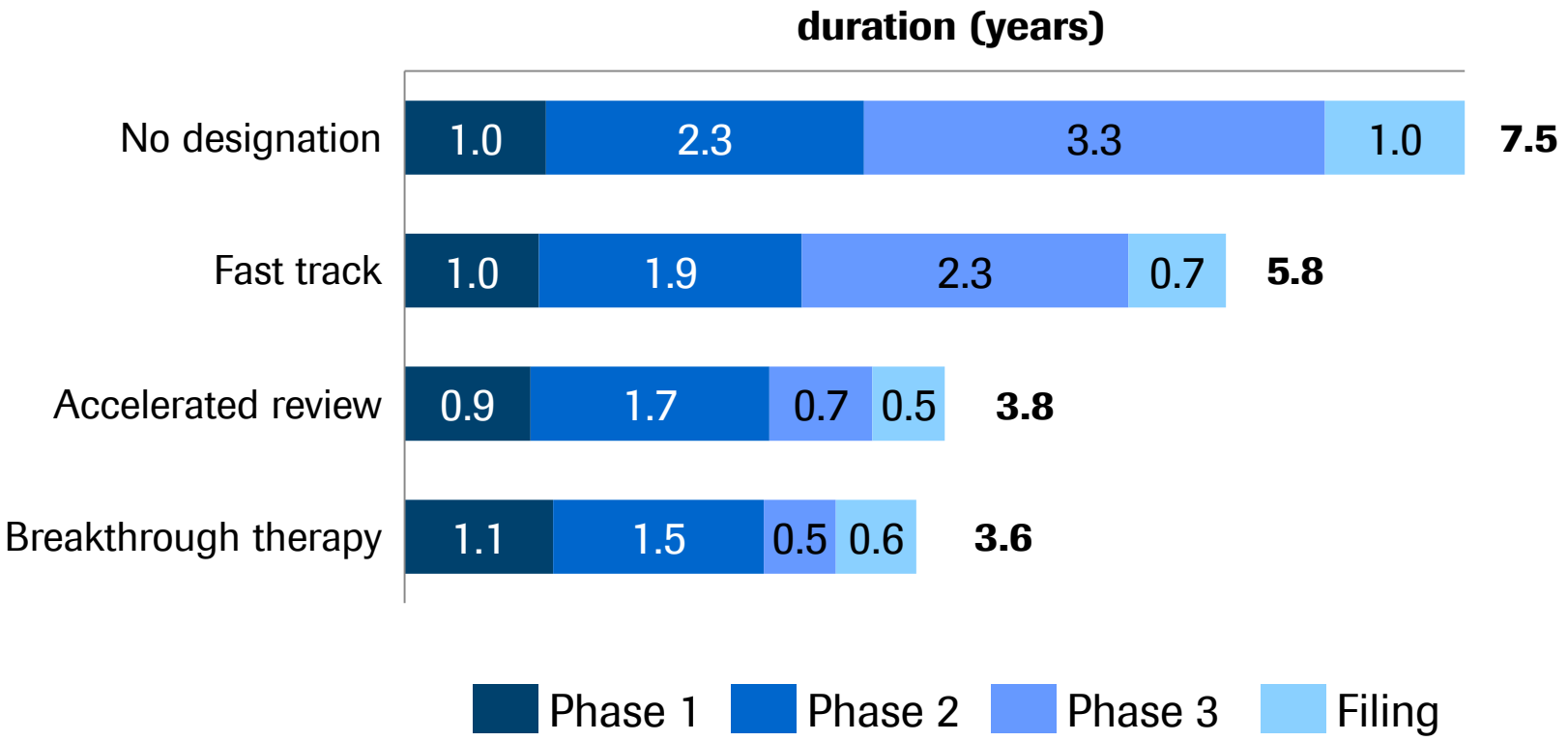
YTD Sep 2016 sales of CHF 571m

- Market leadership established in the US and all EU markets
- US: Growth driven by continued penetration in severe and moderate patients
- Steady growth expected going forward targeting mild and moderate patient segments

CER=Constant Exchange Rates

Breakthrough designation impacting cycle times

Shortest interval duration of all FDA designations



Source: Thomson Reuters Cortellis Competitive Intelligence for all a FDA approvals where milestone information is available 2012-2015. Phase 3 cycle time is defined from phase 3 FPI to submission; which may for the two latter designations happen before phase 3 finishes.

340B programs and trends

- **Content:**
  - Drug discount program created in 1992 by Congress, to allow safety-net providers with large shares of low-income, vulnerable patients to access discounted drug
  - Eligible providers include safety-net hospitals and clinics that receive federal grants, including community health centers, hemophilia treatment centers, and HIV/AIDS clinics. Eligible hospitals also include free-standing cancer hospitals.
- **Main trends:**
  - Shift in private oncology practices to hospital settings through acquisitions and mergers with community cancer clinics have caused 340B purchases to grow more quickly than total drug purchases
  - Recently, 340B hospitals have also increased efforts to claim drug discounts by investing in improved 340B billing software and provider referral arrangements*
- **Impact:**
  - As of Q2'16, 340B drug sales account for ~18% of volume for Genentech's products[1], a slight increase over 2015
  - These 340B trends and their impact are expected to continue at a moderate rate over the next few years

* In order to be an eligible 340B purchase, the prescribing referring physician must be contracted or employed by the 340B hospital. 340B hospitals are increasing the number of physicians that they contract with, which increases the portion of purchases which are eligible for 340B.

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

gRED (Genentech Research & Early Development)

Roche Group YTD Sept 2016 sales

Diagnostics

Foreign exchange rate information

YTD Sep 2016: Diagnostics Division CER growth

By Region and Business Area

	Global		North America		EMEA[1]		RoW	
	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth	CHFm	% CER growth
Professional Diagnostics	4,884	9	1,069	7	1,835	3	1,980	17
Diabetes Care	1,484	-2	212	-21	920	-2	352	12
Molecular Diagnostics	1,345	7	538	6	488	3	319	17
Tissue Diagnostics	652	13	392	13	163	10	97	15
Diagnostics Division	**8,365**	**7**	**2,211**	**4**	**3,406**	**2**	**2,748**	**16**

CER=Constant Exchange Rates

[1] Europe, Middle East and Africa

Diagnostics Division quarterly sales and CER growth[1]

	Q2 15		Q3 15		Q4 15		Q1 16		Q2 16		Q3 16	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Professional Diagnostics	1,547	8	1,515	7	1,688	9	1,519	7	1,714	11	1,651	9
Diabetes Care	550	0	476	-9	595	-3	443	-11	555	1	486	3
Molecular Diagnostics	431	14	416	8	471	9	446	11	457	5	442	6
Tissue Diagnostics	196	11	193	11	225	10	206	13	222	11	224	15
Dia Division	**2,724**	**7**	**2,600**	**4**	**2,979**	**7**	**2,614**	**5**	**2,948**	**8**	**2,803**	**8**

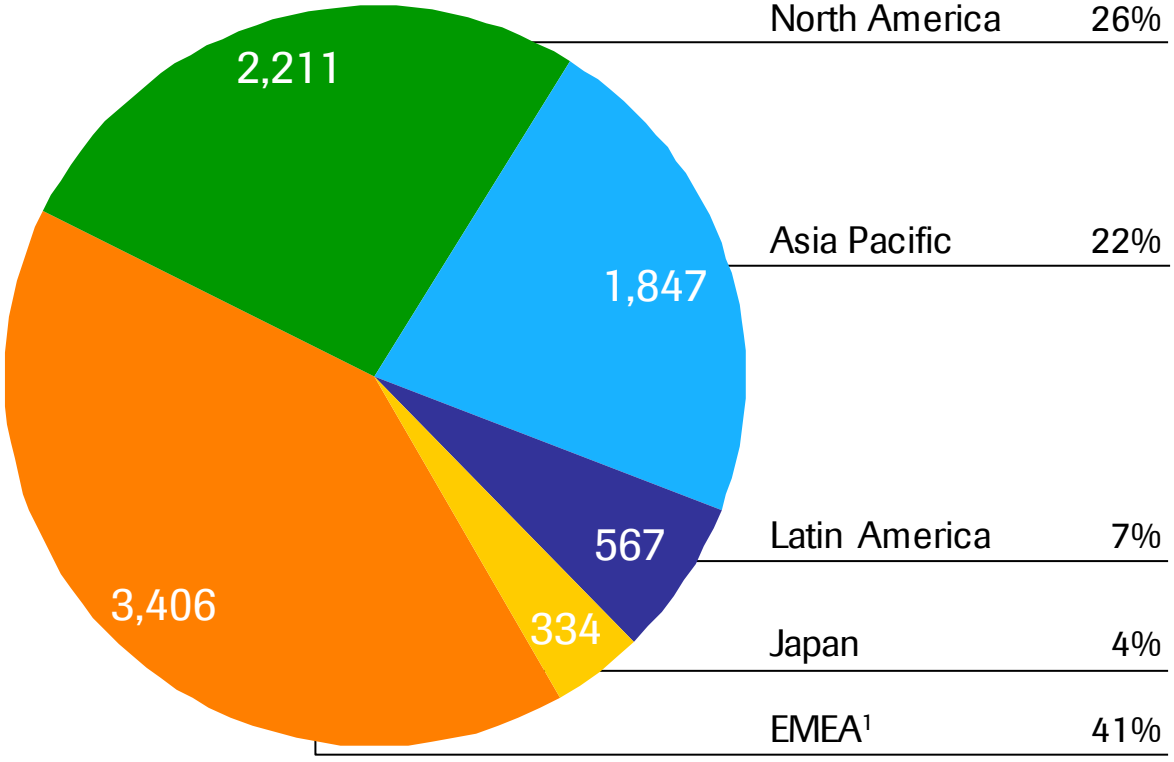
CER=Constant Exchange Rates

[1] versus same period of prior year

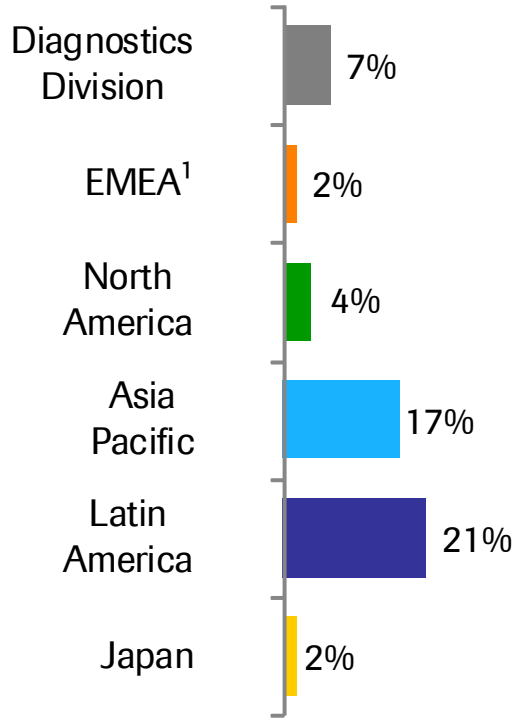
YTD Sep 2016: Diagnostics Division sales

Growth driven by Asia Pacific

CHF 8,365 m



CER sales growth



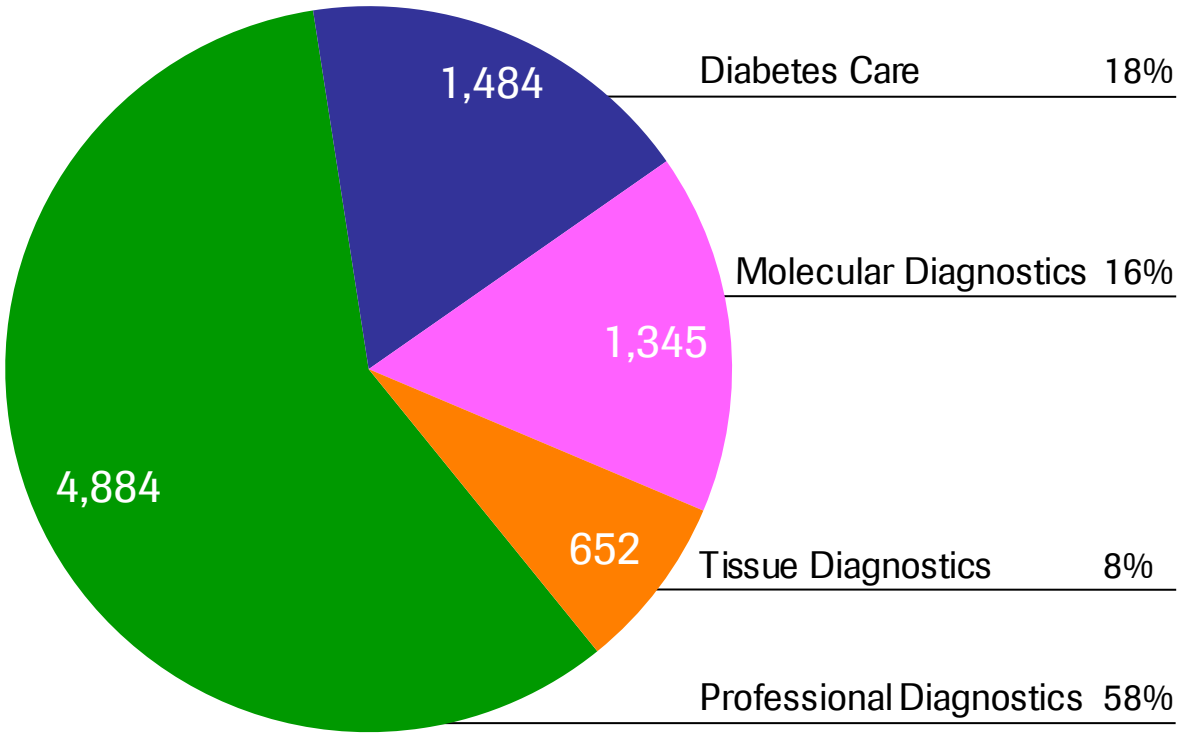
CER=Constant Exchange Rates

[1] Europe, Middle East and Africa

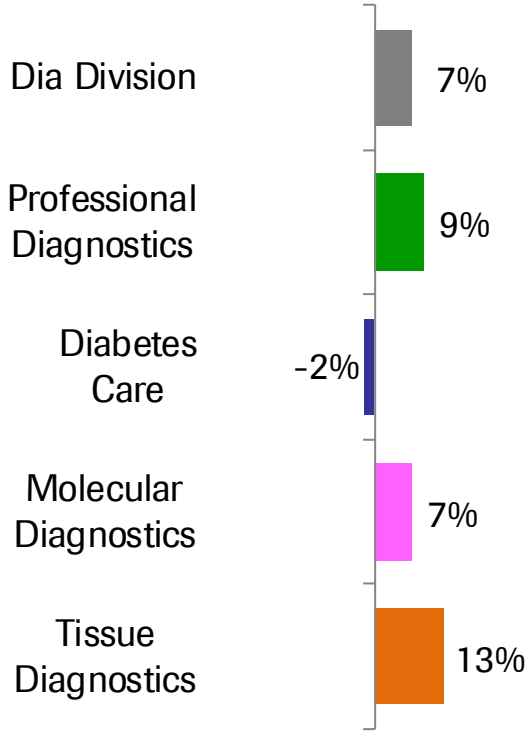
YTD Sep 2016: Diagnostics Division sales

Growth driven by Professional Diagnostics

CHF 8,365 m

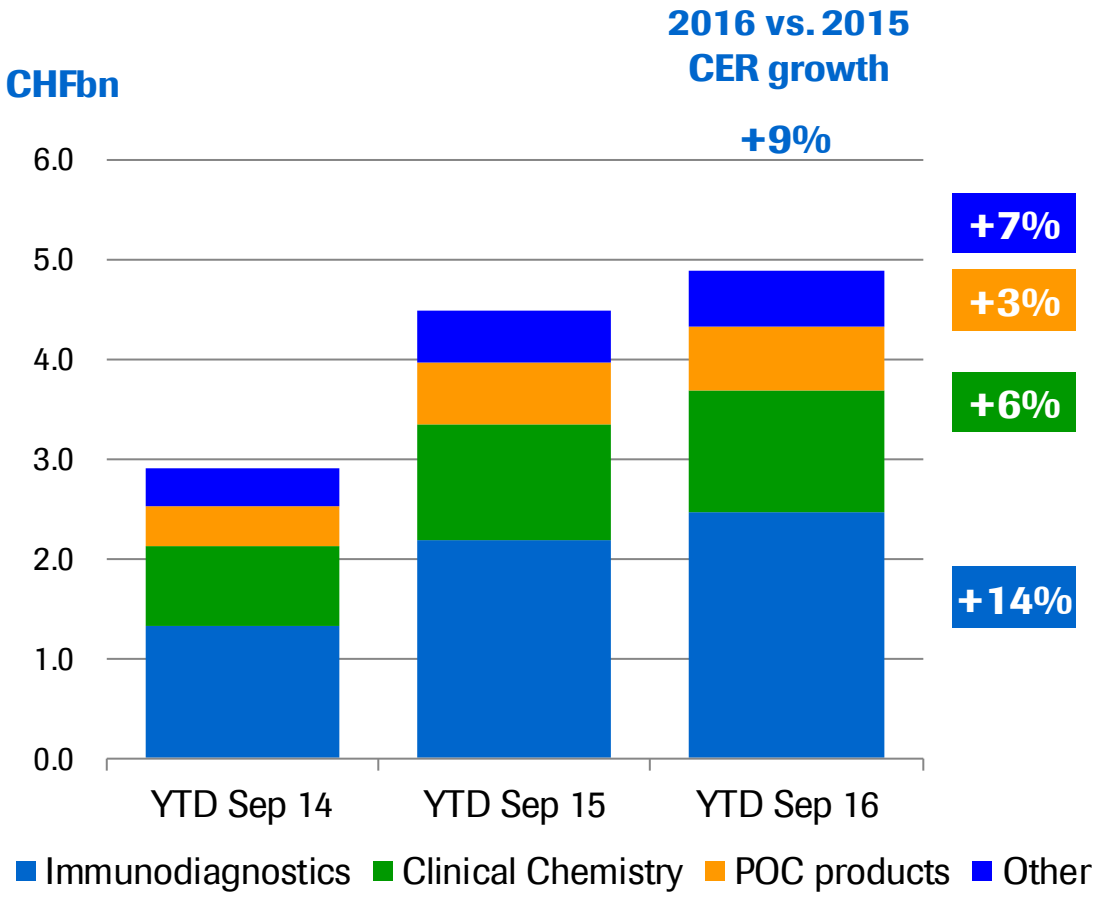


CER sales growth



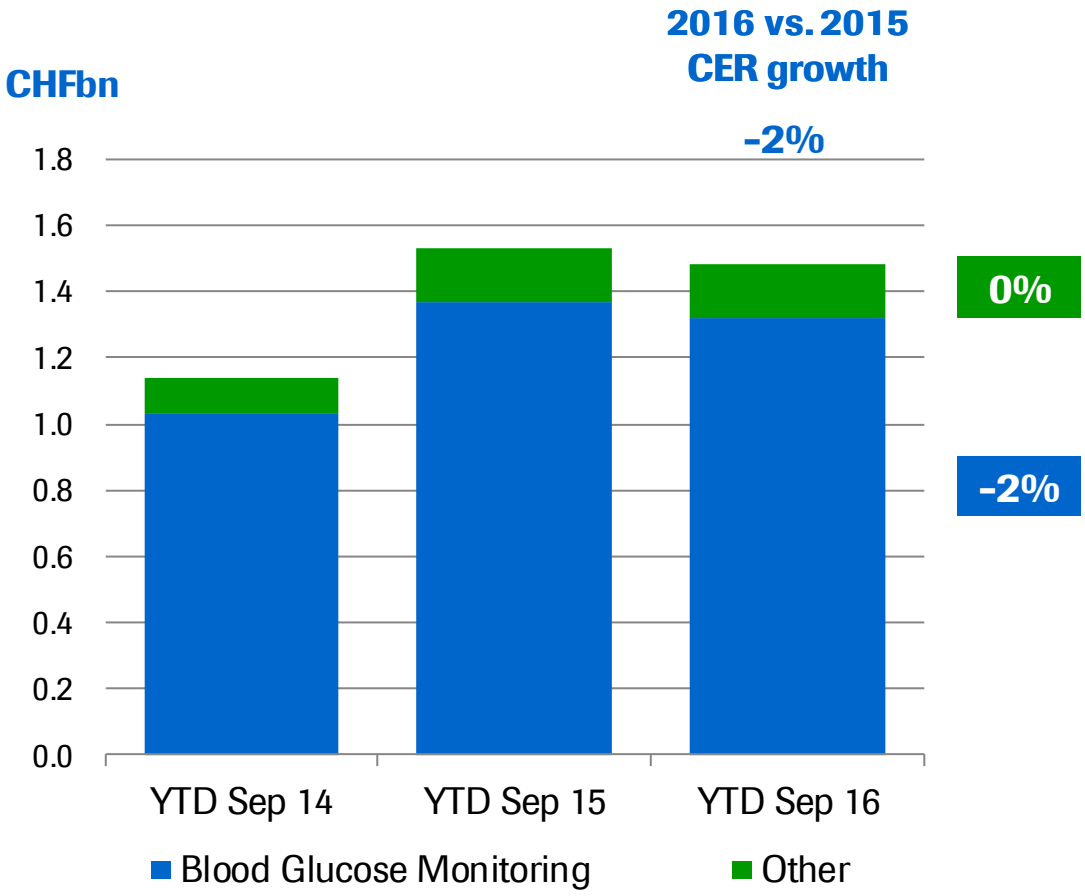
CER=Constant Exchange Rates

Professional Diagnostics



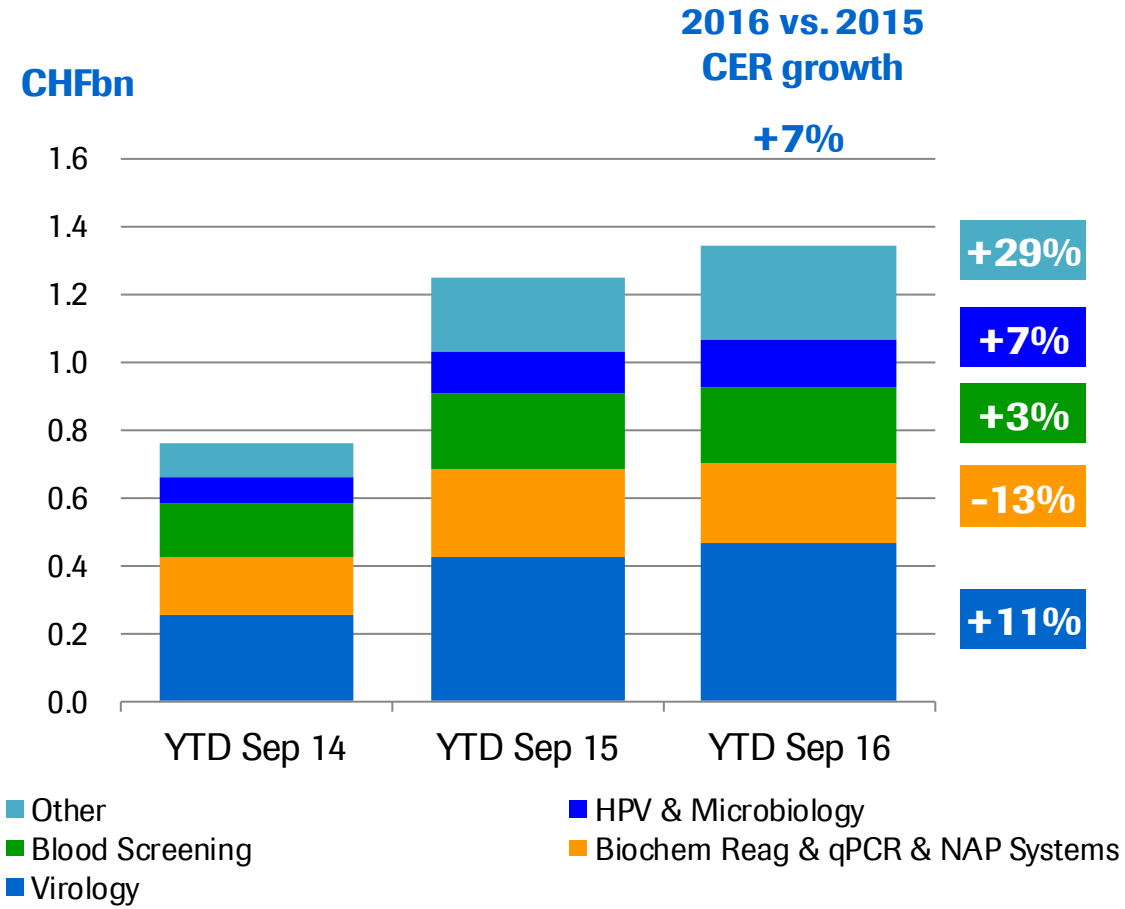
CER=Constant Exchange Rates

Diabetes Care



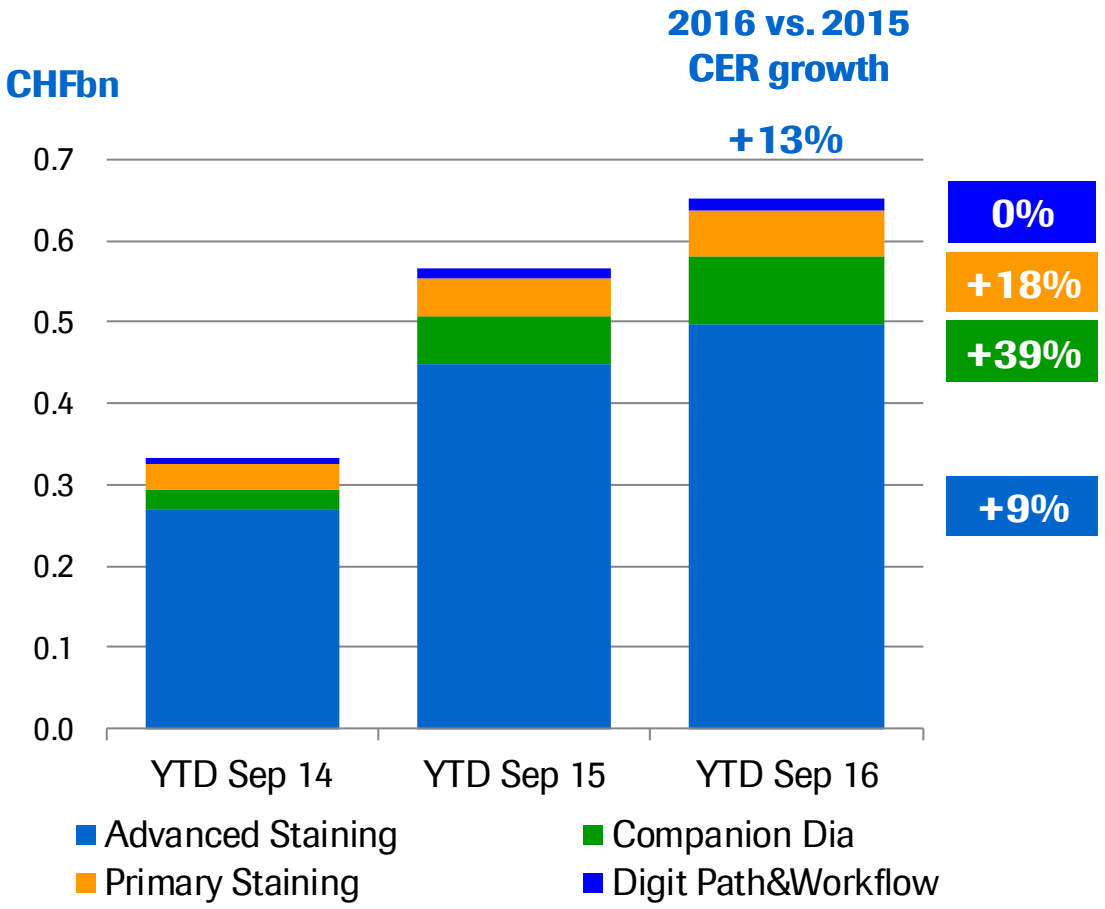
CER=Constant Exchange Rates

Molecular Diagnostics



CER=Constant Exchange Rates

Tissue Diagnostics



CER=Constant Exchange Rates

2016: Key planned product launches
Professional Diagnostics

Product	Description	Region
cobas c 513	dedicated HbA1C analyzer	US
cobas e 801	high throughput immunochemistry analyzer	EU ✓
CoaguChek INRange (Zenith)	Modified analyzer for intuitive self testing with full blue tooth connectivity	EU ✓

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2016: Key planned product launches
Molecular Diagnostics

Product	Description	Region
cobas® 6800/8800 HIV Qual	early infant diagnosis and confirmatory HIV test	EU
cobas® 6800/8800 CT/NG	fully automated solution for screening and diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae in symptomatic & asymptomatic patients*	EU
cobas® Liat Influenza A/B + RSV (CLIA)	automated multiplex real time RT-PCR assay for qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV)	US ✓

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2016: Key planned product launches
Tissue Diagnostics

Product	Description	Region
Companion Diagnostics	PD-L1 (SP142) for Bladder Cancer* – companion diagnostic for atezolizumab	US ✓
	PD-L1 (SP142) for NSCLC* – companion diagnostic for atezolizumab	US ✓

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2016: Key planned product launches
Sequencing

Product	Description	Region
Roche SMRT sequencer	single molecule sequencer for clinical research (in collaboration with Pacific Biosciences)	WW
ctDNA oncology panels	liquid biopsy for circulating tumor DNA for cancer therapy selection	US

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

2016: Key planned product launches
Diabetes Care

Product	Description	Region
Accu-Chek Guide	next-gen. bG monitoring system	EU ✓
Accu-Chek Insight CGM	new high-performance continuous glucose monitoring system	EU

Planned launches may be delayed or not occur as a result of adverse regulatory decisions or other factors

Pipeline summary

Marketed products additional indications

Global Development late-stage trials

pRED (Roche Pharma Research & Early Development)

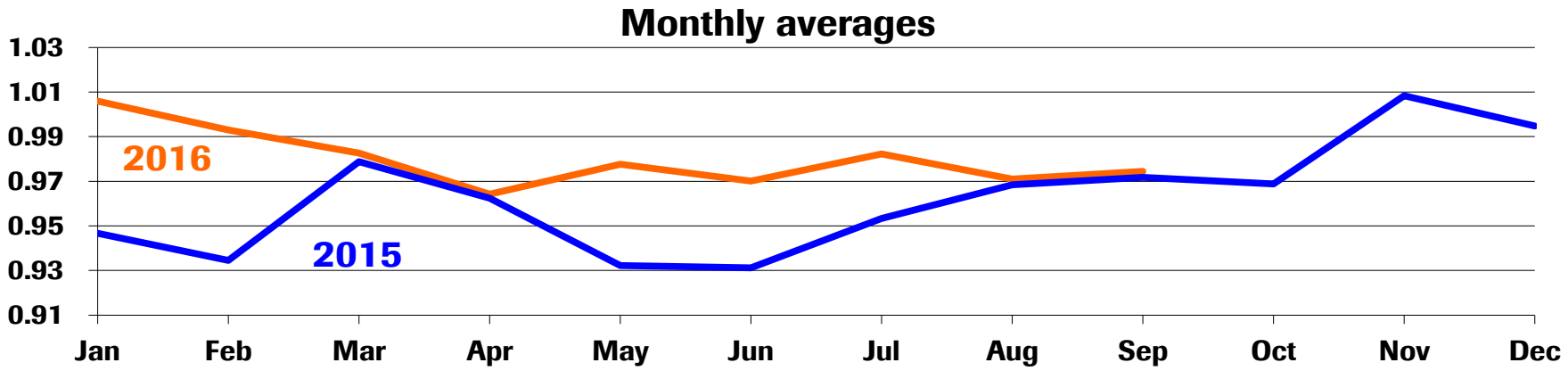
gRED (Genentech Research & Early Development)

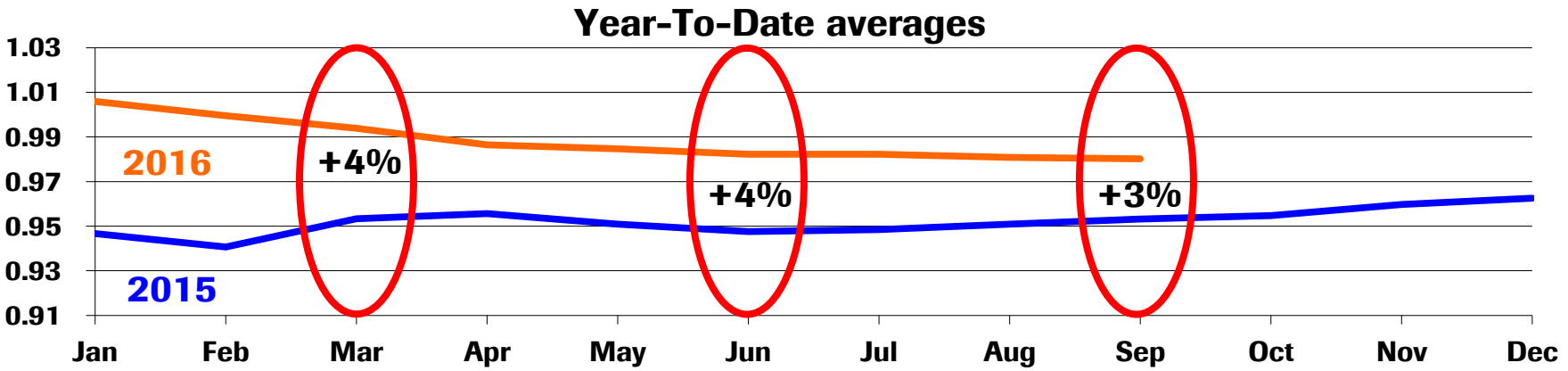
Roche Group YTD Sept 2016 sales

Diagnostics

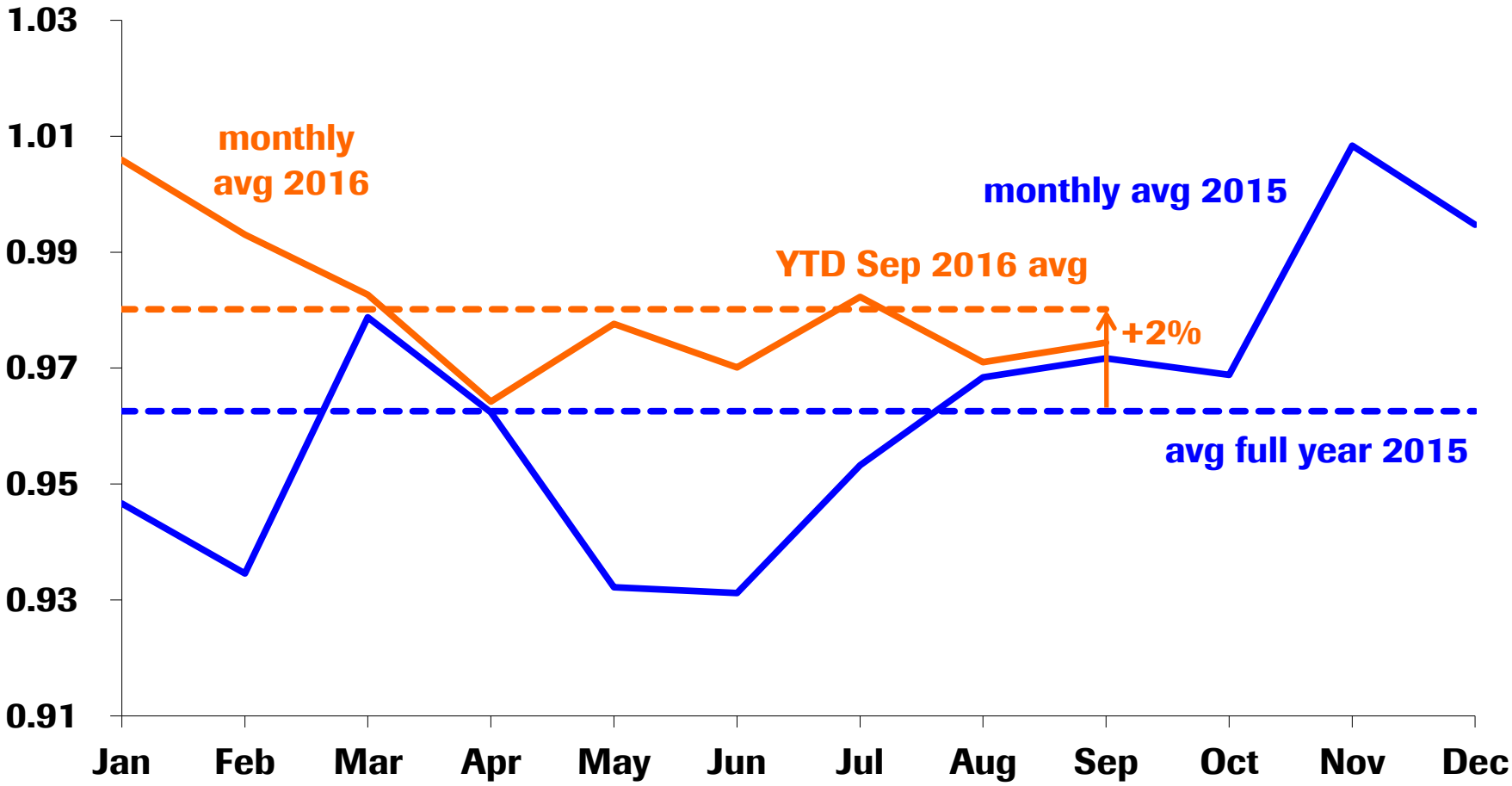
Foreign exchange rate information

CHF / USD


Monthly averages
1.03
1.01
0.99
0.97
0.95
0.93
0.91
2016
2015
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
2016
2015
+4%
+4%
+3%
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 2016
monthly avg 2015
YTD Sep 2016 avg
+2%
avg full year 2015
Jan
Feb
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Apr
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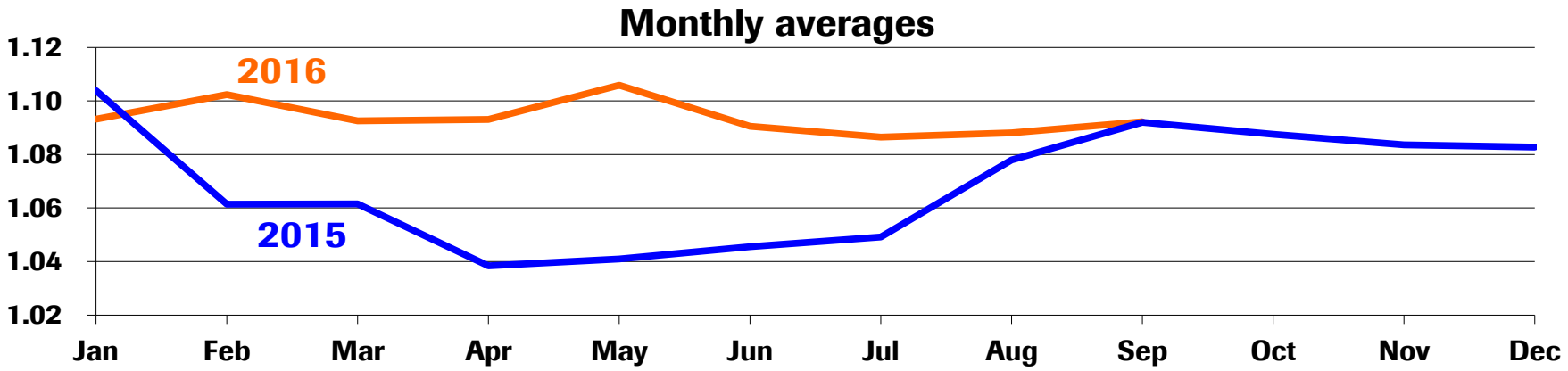
Nov
Dec

CHF / EUR


Monthly averages
1.12
1.10
1.08
1.06
1.04
1.02
2016
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Nov
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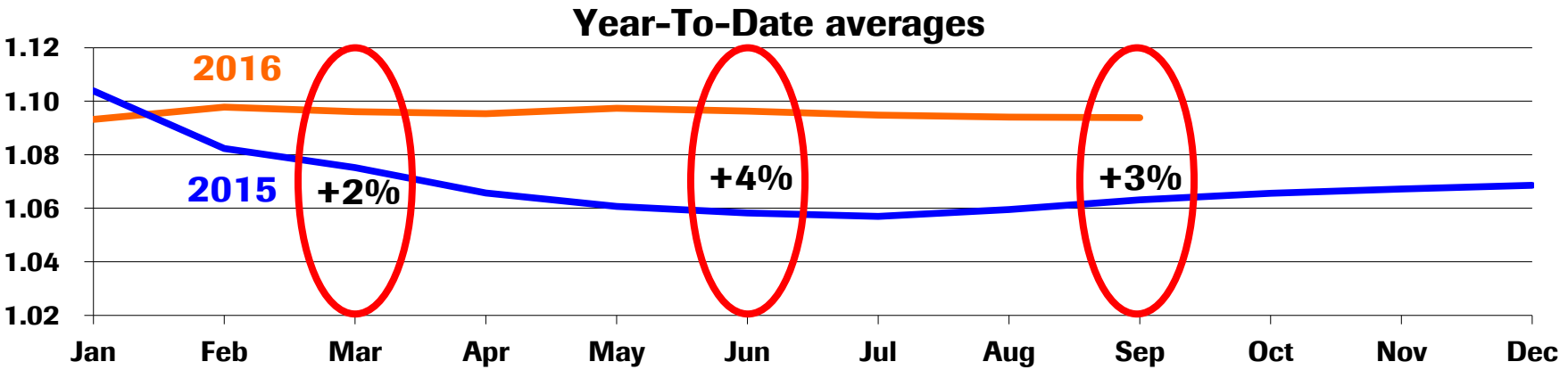
Year-To-Date averages
1.12
1.10
1.08
1.06
1.04
1.02
2016
2015
+2%
+4%
+3%
Jan
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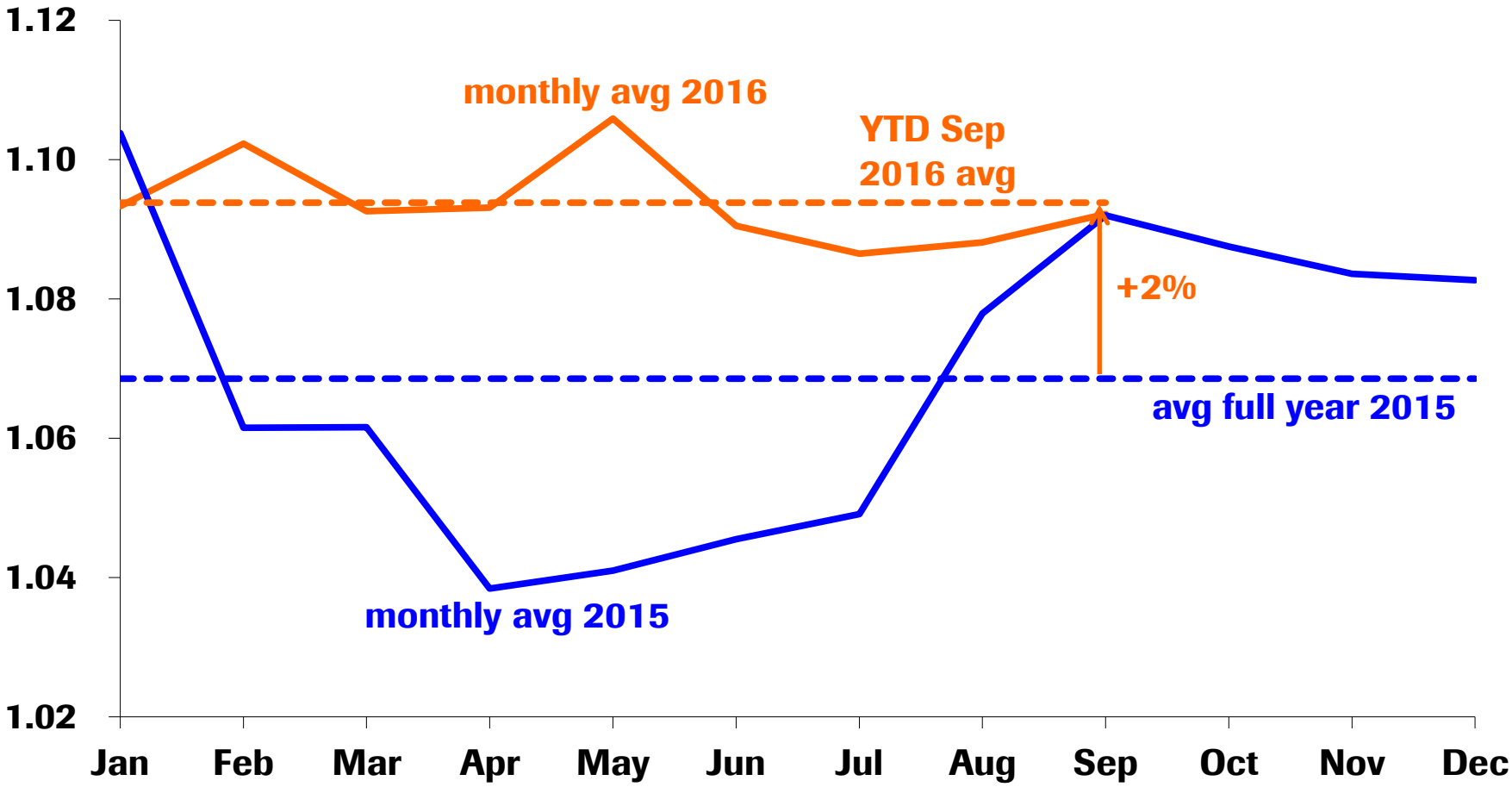
Nov
Dec

CHF / EUR


1.12
1.10
1.08
1.06
1.04
1.02
monthly avg 2016
YTD Sep
2016 avg
+2%
avg full year 2015
monthly avg 2015
Jan
Feb
Mar
Apr
May
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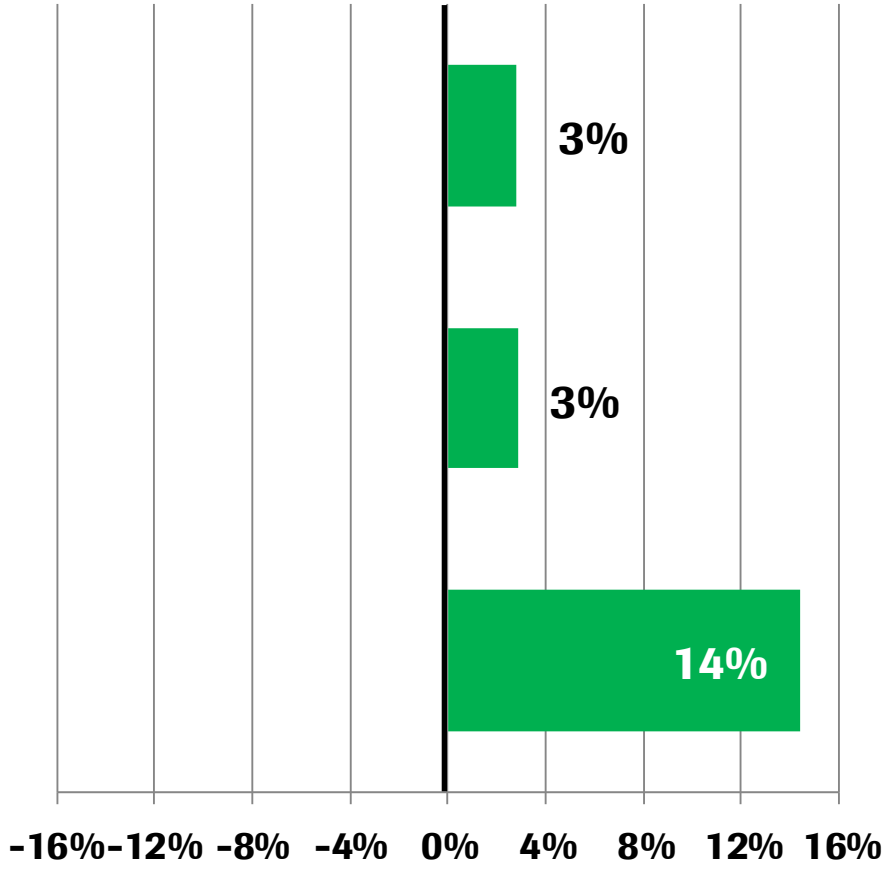
Jul
Aug
Sep
Oct
Nov
Dec

Average exchange rates

	YTD Sep 16	YTD Sep 15
USD	0.98	0.95
EUR	1.09	1.06
JPY	0.90	0.79

YTD Sep 16 vs. YTD Sep 15

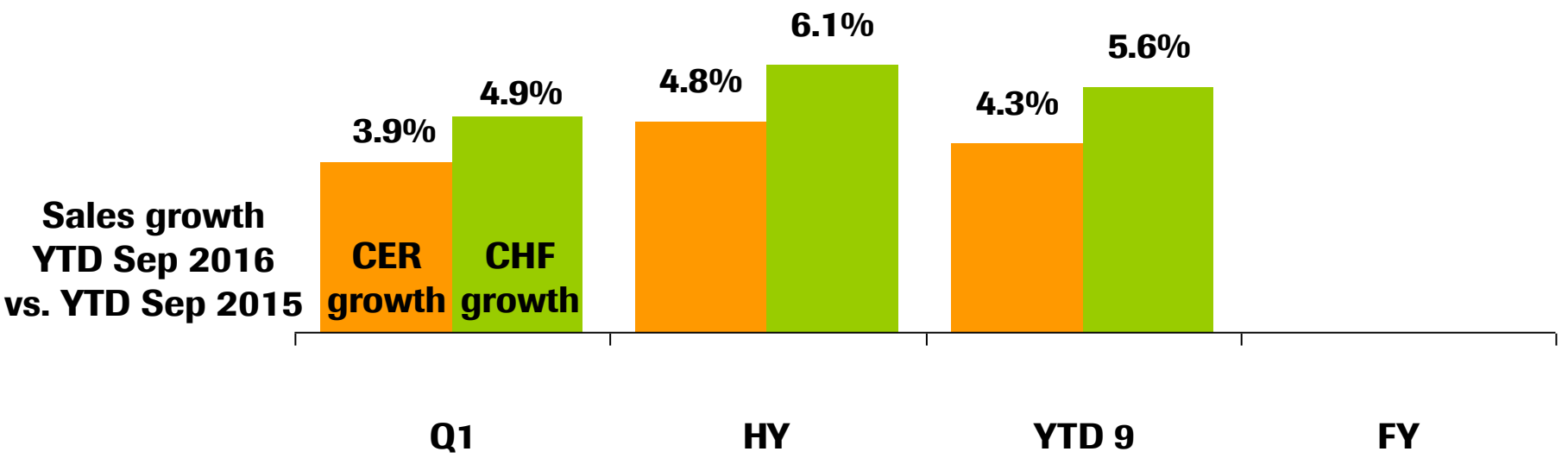


Exchange rate impact on sales growth

In YTD Sep 2016 positive impact of three main currencies

Development of average exchange rates versus prior year period

CHF / USD	+4.3%	+3.7%	+2.8%
CHF / EUR	+1.9%	+3.6%	+2.9%
CHF / JPY	+7.6%	+11.5%	+14.4%
Difference in CHF / CER growth	+1.0%p	+1.3%p	+1.3%p



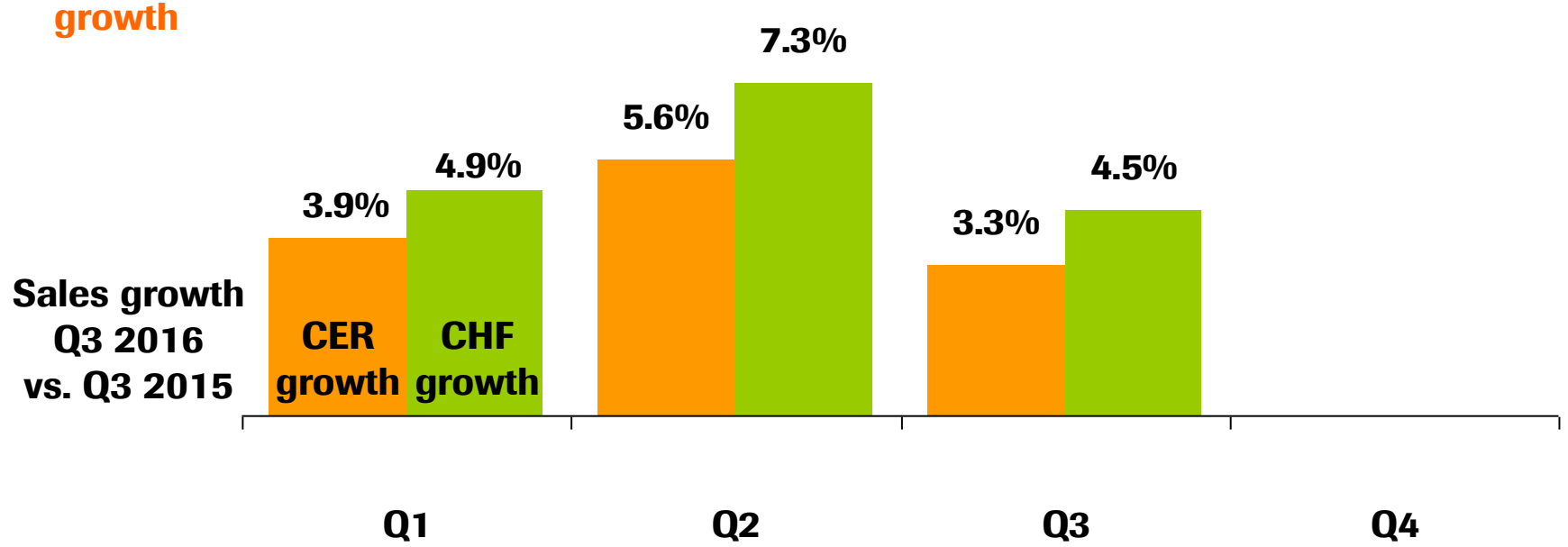
CER=Constant Exchange Rates

Exchange rate impact on sales growth

In Q3 2016 positive impact of three main currencies

Development of average exchange rates versus prior year period

	Q1	Q2	Q3
CHF / USD	+4.3%	+3.0%	+1.2%
CHF / EUR	+1.9%	+5.3%	+1.5%
CHF / JPY	+7.6%	+15.6%	+20.7%
Difference in CHF / CER growth	+1.0%p	+1.7%p	+1.2%p



CER=Constant Exchange Rates

Doing now what patients need next