



Roche

**2017** results

London, 01 February 2018



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## Group

Severin Schwan Chief Executive Officer





## **2017** performance

## **2017: Targets fully achieved**



Targets for 2017		FY 2017	
Group sales growth <sup>1</sup>	Mid-single digit (raised at HY)	+5%	<b>✓</b>
Core EPS growth <sup>1</sup>	Broadly in line with sales growth	+5%	<b>✓</b>
Dividend outlook	Further increase dividend in Swiss francs <sup>2</sup>	CHF 8.30	<b>~</b>

<sup>&</sup>lt;sup>1</sup> At constant exchange rates (CER); <sup>2</sup> 2017 dividend as proposed by the Board of Directors



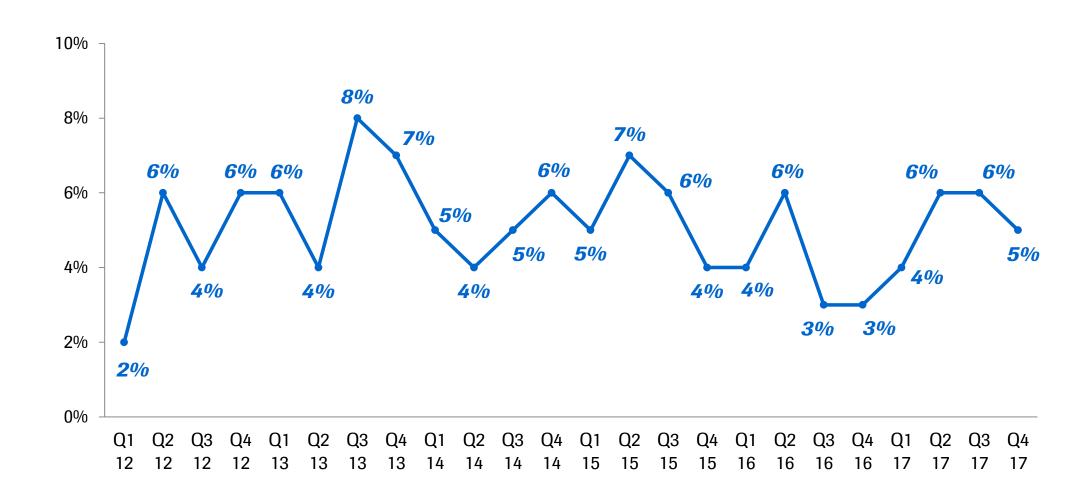


	2017	2016	Change	in %
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	41.2	39.1	5	5
<b>Diagnostics Division</b>	12.1	11.5	5	5
Roche Group	53.3	50.6	5	5

CER=Constant Exchange Rates 7

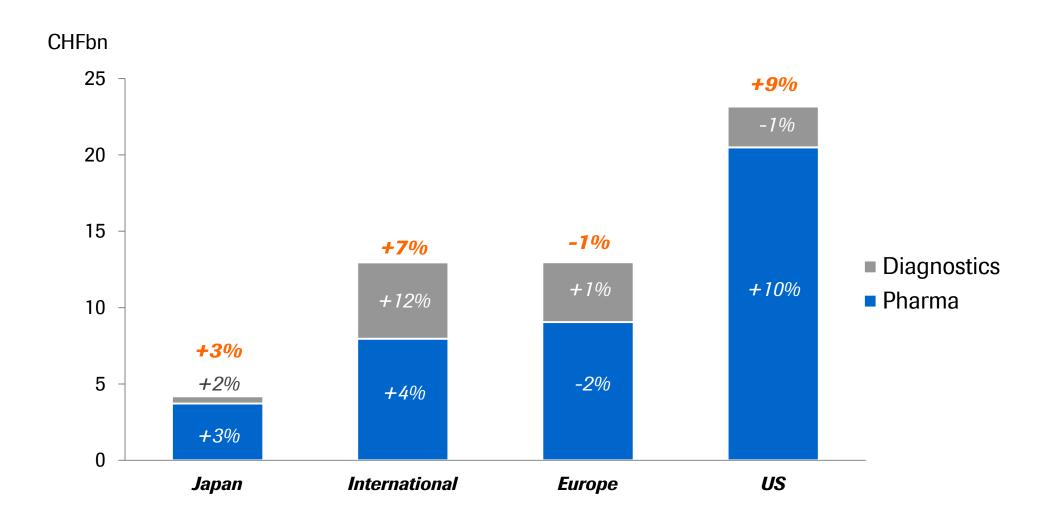








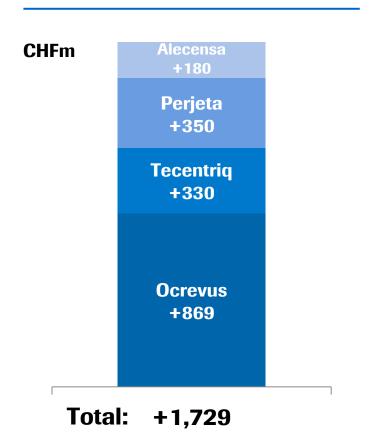






## 2017: Successful launch activities Differentiation driving growth

## Additional sales of new launches



- EU / US approval, NCCN guidelines category '1'
- US approval in Her2+ mBC, eBC & neoadjuvant
- US / EU approval in bladder (1/2L) & lung (2L)

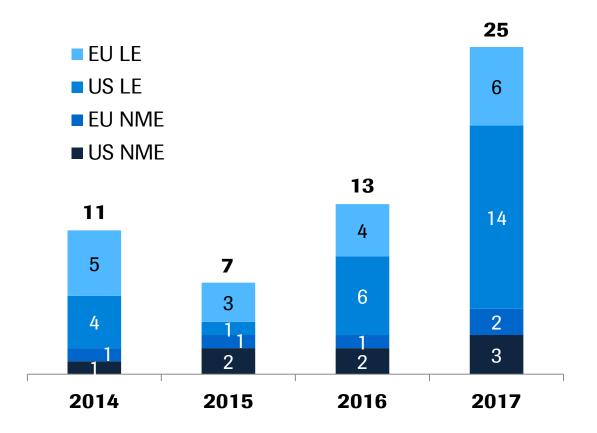
• US / EU / CH / Australia approval in RMS and PPMS

mBC=metastatic breast cancer; eBC=early breast cancer; PPMS=primary progressive multiple sclerosis; RMS=relapsing forms of multiple sclerosis; NCCN=National Comprehensive Cancer Network;





#### **Approvals (US & EU)**



#### **Major approvals:**

- **HER2:** Perjeta APHINITY (eBC) US
- CD20: Gazyva GALLIUM (1L iNHL) US
- Hemophilia: Hemlibra (Inh. patients) US / positive CHMP opinion
- Multiple Sclerosis: Ocrevus US / EU
- Lung Cancer: Alecensa US / EU

#### **Major trial read outs:**

- Hematology: Venclexta: MURANO (R/R CLL);
   Polatuzumab: (R/R aNHL)
- **Lung Cancer**: Tecentriq IMpower150,
- **Renal Cancer**: Tecentriq IMmotion151

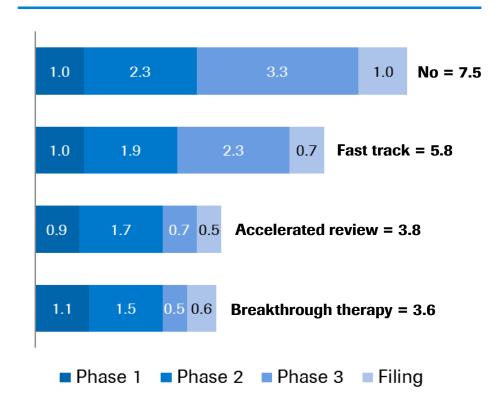


## Breakthrough designations: Accelerating cycle times and reflecting the quality of our research

## 19 Breakthrough Therapy Designations

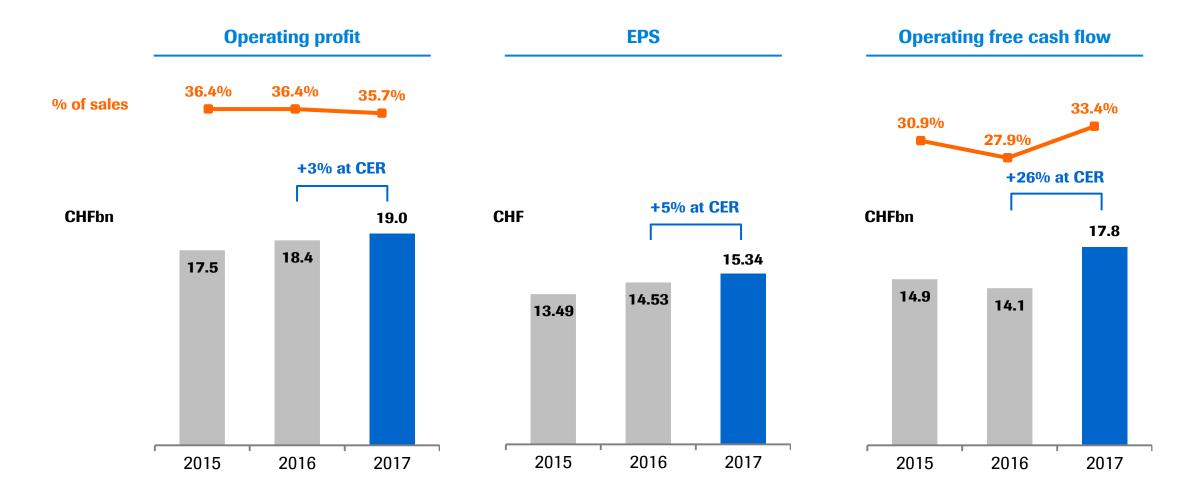
Year	Molecule			
2018	Balovaptan (autism spectrum disorders)			
	Polatuzumab vedotin + BR (R/R DLBCL)			
2017	Venclexta + LDAC (1L unfit AML)			
2017	<b>Zelboraf</b> (BRAF-mutated ECD)			
	Rituxan (Pemphigus vulgaris)			
	Actemra (Giant cell arteritis)			
	Alecensa (1L ALK+ NSCLC)			
2016	Ocrevus (PPMS)			
	Venclexta + HMA (1L unfit AML)			
	Venclexta + Rituxan (R/R CLL)			
	Actemra (Systemic sclerosis)			
2015	Tecentriq (NSCLC)			
2015	Venclexta (R/R CLL 17p del)			
	Hemlibra (Hemophilia A inhibitors)			
	Esbriet (IPF)			
2014	Lucentis (Diabetic retinopathy)			
	Tecentriq (Bladder)			
2013	<b>Alecensa</b> (2L ALK+ NSCLC)			
2013	Gazyva (1L CLL)			

#### **Phase duration (years)**







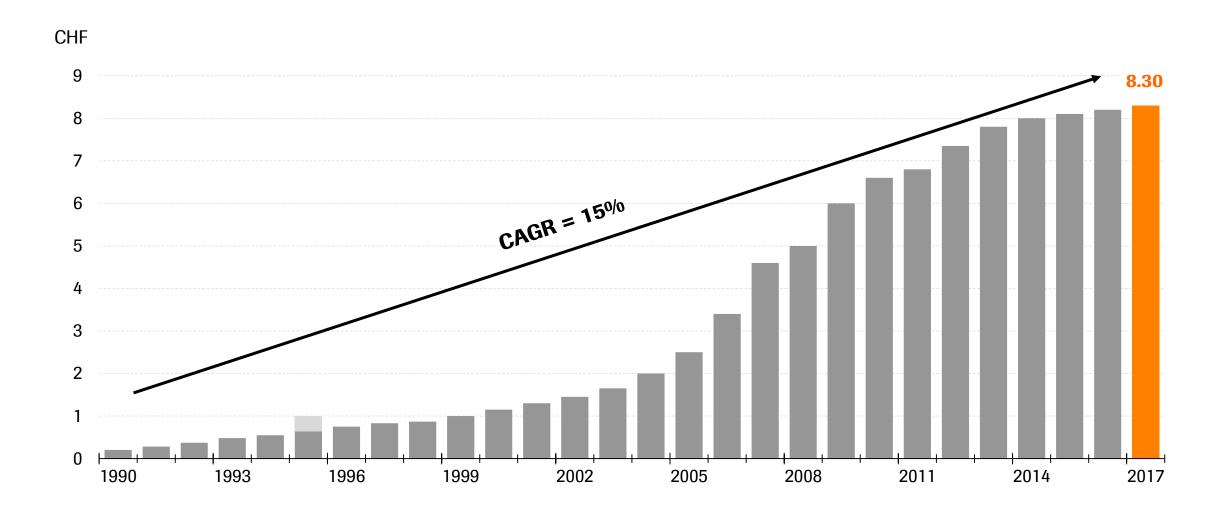


**CER=Constant Exchange Rates** 

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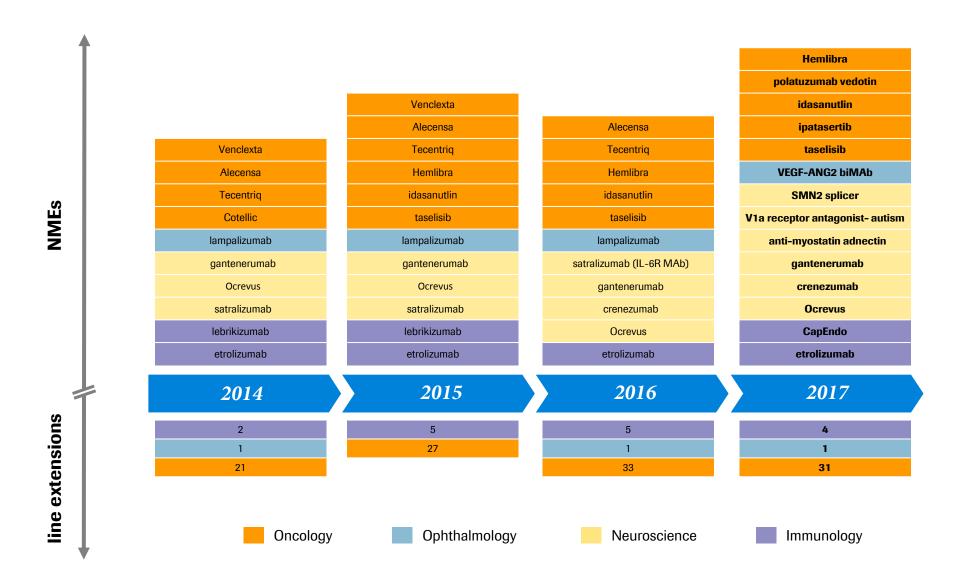




## performance







#### 2018 outlook



**Group sales growth**<sup>1</sup>

• Stable to low-single digit

Core EPS growth<sup>1</sup>

- Broadly in line with sales, excl. US tax reform benefit
- High-single digit, incl. US tax reform benefit

**Dividend outlook** 

Further increase dividend in Swiss francs

<sup>1</sup> At Constant Exchange Rates (CER)



## **Pharmaceuticals Division**

Daniel O'Day CEO Roche Pharmaceuticals





### 2017 results

**Innovation** 



# **2017: Pharma Division sales** *Strong growth in US due to ongoing launches*

	2017	2017 2016		Change in %		
	CHFm	CHFm	CHF	CER		
Pharmaceuticals Division	41,220	39,103	5	5		
United States	20,496	18,594	10	10		
Europe	9,051	9,159	-1	-2		
Japan	3,713	3,711	0	3		
International	7,960	7,639	4	4		

CER=Constant Exchange Rates 20



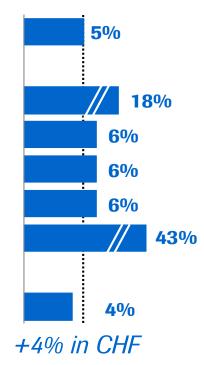
#### 2017: Pharma Division

# Core operating profit growth broadly in line with sales, supporting new launches

2017 CHFm % sales

Sales	41,220	100.0
Royalties & other op. inc.	2,284	5.5
Cost of sales	-8,707	-21.1
M & D	-6,720	-16.3
R & D	-9,036	-21.9
G & A	-1,440	-3.5
Core operating profit	17,601	42.7

**2017 vs. 2016 CER growth** 

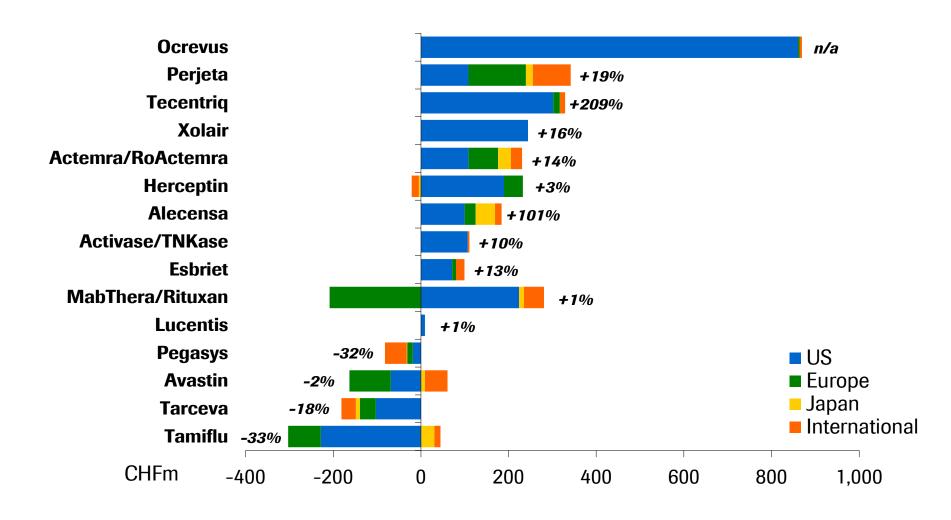


**CER=Constant Exchange Rates** 

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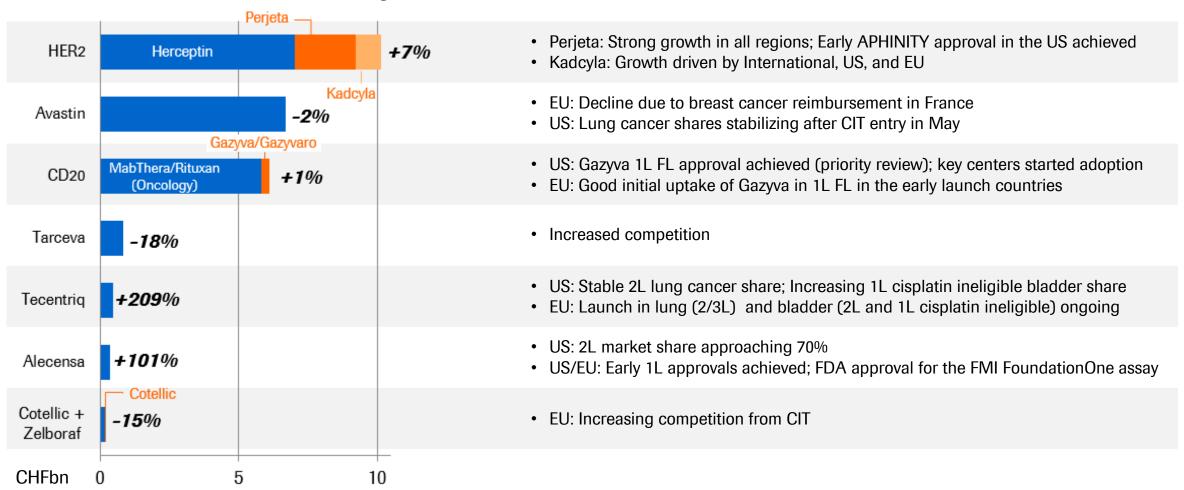
## 2017: Strong sales performance with increasing contribution from new launches



## 2017: Oncology portfolio rejuvenation ongoing

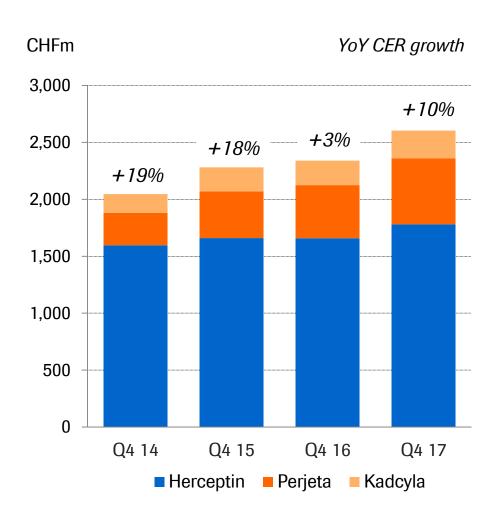


#### YoY CER growth



### **HER2** franchise: Growth driven by all products





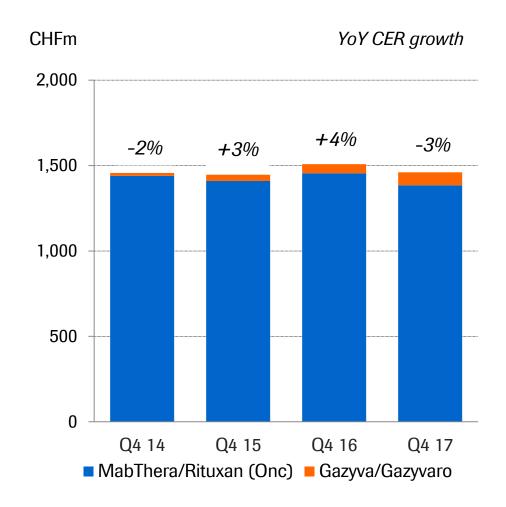
#### **HER2 franchise Q4 2017**

- Perjeta (+22%): Strong demand in neoadj. and 1L mBC driven by all regions; Accelerated growth in the US following approval in adjuvant BC (APHINITY)
- Kadcyla (+12%): Growth in International, US and EU

- US: Uptake of Perjeta + Herceptin in eBC following early APHINITY approval
- EU: Approval of APHINITY
- EU: Market entry of Herceptin biosimilars

## **CD20** franchise: Entering the transition phase in hematology





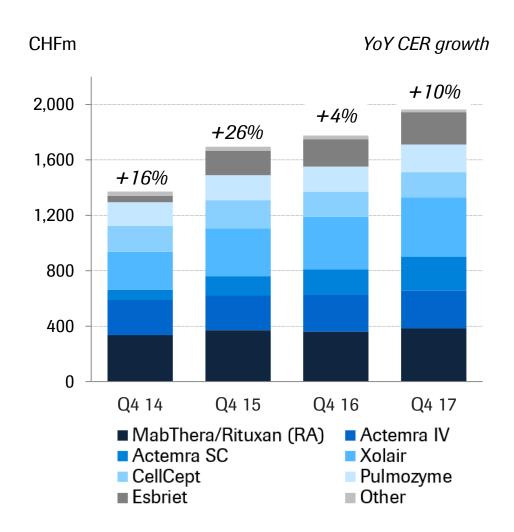
#### CD20 franchise Q4 2017

- MabThera/Rituxan (onc) US (+3%): Volume growth in all indications
- MabThera/Rituxan (onc) EU (-25%): Biosimilar launch in EU5 done; additional launches in smaller countries ongoing
- Gazyva/Gazyvaro (+42%): Positive early launch signals after
   1L FL approvals in EU and US

- Overall CD20 franchise decline due to biosimilar erosion.
- US/EU approval of Venclexta+Rituxan in R/R CLL (MURANO)

### Immunology: Annualized sales of around CHF 8bn





#### **Immunology Q4 2017**

#### **Esbriet** (+17%)

 Penetration in mild and moderate patient segment increasing, but slower than expected

#### **Xolair** (+15%)

Asthma: US pediatrics launch ongoing; only biologic approved for children

#### **Actemra** (+14%)

- · Launch in giant cell arteritis ongoing
- Further increase in SC uptake

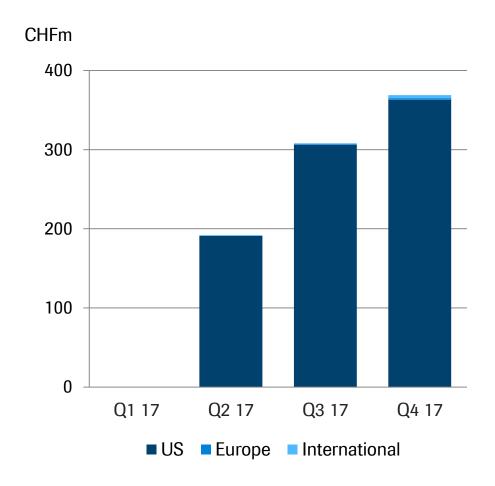
#### Outlook 2018

 Further strong growth expected with exception of MabThera/Rituxan

CER=Constant Exchange Rates; SC=subcutaneous 26

## Ocrevus: >5% US market share after three quarters





#### **Ocrevus Q4 2017**

- First patients returned for second treatment
- Continued strong uptake in RMS and PPMS (60/40)
- RMS: 30% treatment naive/previously discontinued vs. 70% switches from all other approved medications
- Broad base of prescribers and further increased level of US insurance coverage

- Further increasing US market share with earlier use across both indications
- EU approval achieved with label in RMS and PPMS



### 2017 results

### **Innovation**





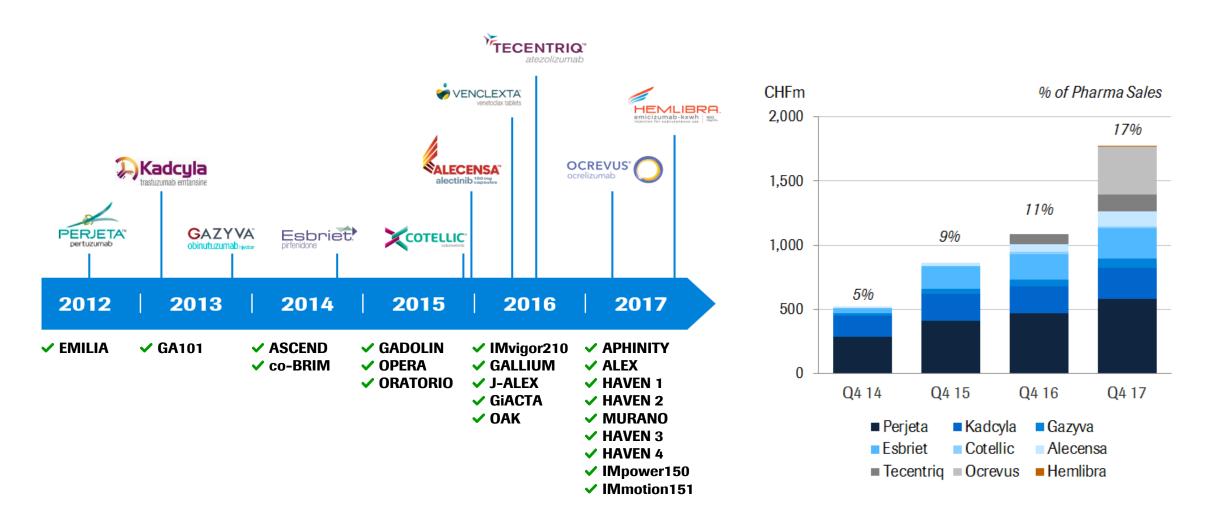
	Compound	Indication	Milestone	
	Alecensa	2L ALK+ NSCLC	EU approval	<b>✓</b>
	Ocrevus	RMS / PPMS	US/EU launch	<b>✓</b>
	Tecentriq	1L cisplatin ineligible mUBC	US approval	<b>✓</b>
Regulatory	Tecentriq	2/3L NSCLC and 1/2L mUBC	EU approval	<b>✓</b>
	Gazyva	1L FL (iNHL)	US/EU filing	<b>✓</b>
	Actemra	Giant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

#### **Additional 2017 news flow:**

- · Lucentis: US approval in mCNV and diabetic retinopathy
- Rituxan Hycela: US approval for blood cancers
- Hemlibra: Positive Ph III interim results in pediatric inhibitors (HAVEN 2) and positive Ph III interim results in inhibitors/non-inhibitors every 4 weeks dosing (HAVEN 4)
- Gazyva: EU/US approval in 1L FL
- Alecensa: US/EU approval in 1L ALK+ NSCLC
- Perjeta + Herceptin: Early US approval in adjuvant HER2+ eBC (APHINITY)
- Hemlibra: Early US approval in inhibitors
- **Tecentriq + Avastin**: Positive Ph III results in 1L RCC (IMmotion151)







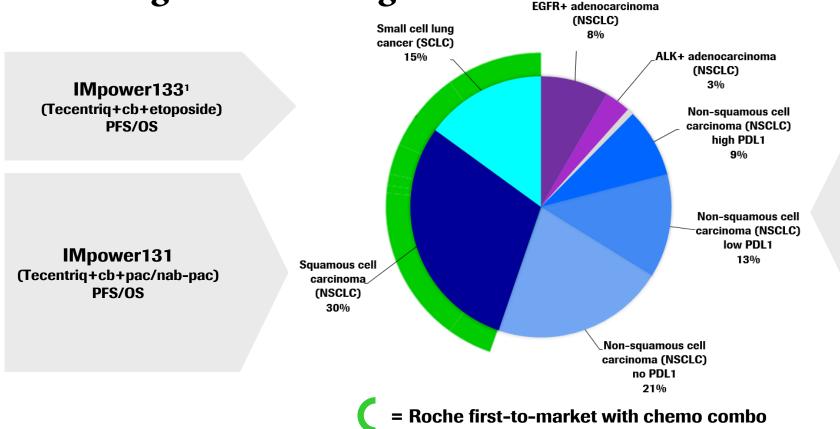
## **Update late-stage oncology pipeline**



BL	Tecentriq	OAK 🗸	TNBC Tecentriq+nab-pac IMpassion13
non-sq	Tecentriq+carbo/pac+/-Avastin	IMpower150	NBC Tecentriq+pac IMpassion13
L non-sq	Tecentriq+carbo+nab-pac	IMpower130	adj TNBC Tecentriq+nab-pac IMpassion03
Lsq	Tecentrig+carbo+pac/nab-pac	IMpower131	HER2+ Perjeta+Herceptin APHINITY
1L non-sq	Tecentriq+cis/carbo+pem	IMpower132	-/HER2- taselisib+fulvestrant <b>SANDPIPER</b>
IL Dx+	Tecentriq	IMpower110	0x+ TNBC ipatasertib+paclitaxel IPATunity130
Adj	Tecentriq	IMpower010	0x+ HR+ mBC ipatasertib+paclitaxel IPATunity130
1L SCLC	Tecentriq+carbo+etoposide	IMpower133	
1L ALK+	Alecensa	ALEX; J-ALEX	olorectal
Melano	ma		Tecentriq+Cotellic IMblaze370
1L BRAFwt	Tecentriq+Cotellic	IMspire170	
1L BRAFmut	Tecentriq+Cotellic+Zelboraf	IMspire150 TRILOGY	varian
			nt-line Avastin/carbo/pac+/-Tecentriq IMaGYN050
Renal			rostate
1L	Tecentriq+Avastin	IMmotion151	CRPC ipatasertib+abiraterone IPATENTIAL1
Adj	Tecentriq	IMmotion010	_ CRPC Tecentriq+enzalutamide IMbassador29
			ematology: CLL, MM, AML
Bladder		•	CLL Venclexta*+Gazyva CLL14
1L/2L+	Tecentriq	IMvigor210 C2	CLL Venclexta*+Rituxan MURANO
1L	Tecentriq	IMvigor210 C1	MM Venclexta*+bortezomib/dexa BELLINI
2L+	Tecentriq	IMvigor211	AML idasanutlin+cytarabine MIRROS
1L	Tecentriq+/-gem/plat	IMvigor130	ML Venclexta*+azacitidine Viale-A
Adj MIBC	Tecentriq	IMvigor010	DLBCL Polatuzumab+Rituxan-CHP POLARIX

CIT 1L lung cancer program reading out in H1 2018

Addressing all market segments





IMpower150

(Tecentriq+cb/pac+/-Avastin) PFS/OS (H1 2018)

i) **(PFS)** 

IMpower130

(Tecentriq+cb+nab-pac)
PFS/OS

IMpower132

(Tecentriq+cp/cb+pem)
PFS/OS

Tecentriq has the potential to be first-to-market chemo combo in 1L SCLC and 1L squamous NSCLC (45% of the total market)

### **Tecentriq in 1L NSCLC**

## Positive interim results presented at ESMO IO



#### Ph III interim results (IMpower150)

	E4599 <sup>1</sup>	IMpower150 <sup>2</sup> Tecentriq+Avastin+cb/pac vs Avastin+cb/pac (Arm B vs C)			
	Avastin+cb/pac vs cb/pac				
Patient population	1L AC	1L ITT-WT	1L T <sub>eff</sub> -high WT		
Patient number	N=878	N=692	N=284		
ORR	35% vs. 15%	64% vs 48%	69% vs 54%		
mOS (mos)	12.3 vs. 10.3 HR 0.79, p=0.003	19.2 vs 14.4 HR 0.775*, p=0.0262			
mPFS (mos)	6.2 vs. 4.5 HR 0.66, p<0.001	8.3 vs 6.8 HR 0.617, p<0.0001	11.3 vs 6.8 HR 0.505, p<0.0001		
Landmark PFS @ 1yr	18% vs 8.5%**	37% vs 18%	46% vs 18%		

- Statistically significant and clinically meaningful PFS improvement
- OS has numerical improvement in Arm B vs C, but data are not fully matured. Next interim analysis for all arms in 1H 2018.

#### **PFS Subgroup analysis**

						mPFS	s, mos
Subgroup (% of enrolled	d patient	s)			1.	Arm B	Arm C
ITT (incl EGFR/ALK mut+)	(100%)			0.61 ├──-	<b></b>	8.3	6.8
EGFR/ALK mut+ onlyb	(14%)		0.59 ⊢	<b></b>	1	9.7	6.1
ITT-WT	(87%)			0.62⊩	<b>—</b>	8.3	6.8
Teff-high WT	(43%)		0.51	<b></b>	1	11.3	6.8
Teff-low WT	(57%)			0.76	<b>→</b>	7.3	7.0
TC2/3 or IC2/3	(35%)		0.48	<b>-</b>		11.1	6.8
TC1/2/3 or IC1/2/3	(51%)		0.50 ⊢	<b>─</b>		11.0	6.8
TC0 and IC0	(49%)			0.77 ├──	<b></b> ♦	7.1	6.9
TC3 or IC3	(20%)	0.39	<b></b>			12.6	6.8
TC0/1/2 or IC0/1/2	(80%)			0.68	<b>•</b> ——	8.0	6.8
		0.25			1 Hazard	1.25 Ratio <sup>c</sup>	
					avor of Arm B:		

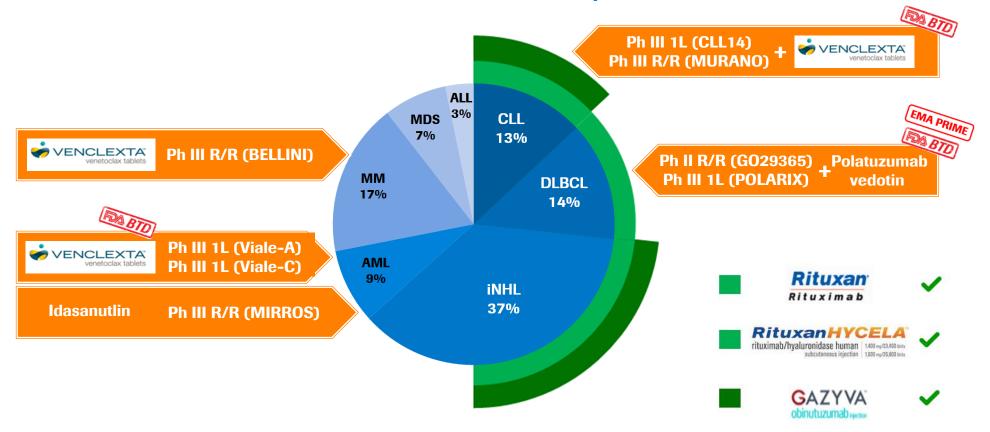
 PFS benefit (Arm B vs C) in key subgroups including patients with EGFR+ and ALK+ mutations, Teff low signatures, PDL1-negative tumors and liver metastases

<sup>&</sup>lt;sup>1</sup> Sandler A, et al., NEJM 2006; <sup>2</sup> Reck M, et al., ESMO IO 2017; \*OS data preliminary. Mature OS expected in H1 2018; \*\*taken from KM curve; cb=carboplatin; pac=paclitaxel; AC=all-comers; ITT=intent-to-treat; WT=wild type; ORR=overall response rate; mOS=median overall survival; mPFS=median progression free survival; TC=tumor cells; IC=immune cells

## Late-stage hematology: Improving the standard of care and extending into new indications



#### Incidence rates (330,000 pts<sup>1</sup>)

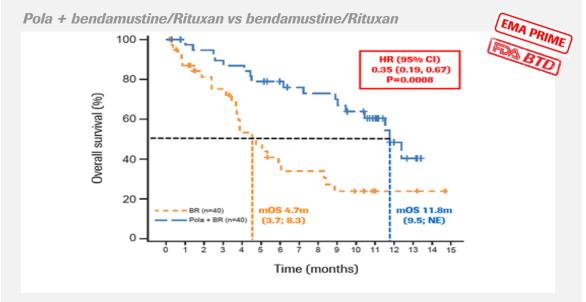


<sup>&</sup>lt;sup>1</sup> Datamonitor; incidence rates includes the 7 major markets (US, Japan, France, Germany, Italy, Spain, UK); CLL=chronic lymphoid leukemia; DLBCL (aNHL)=diffuse large B-cell lymphoma; iNHL=indolent non-hodgkin's lymphoma; AML=acute myeloid leukemia; MM=multiple myeloma; MDS=myelodysplastic syndrome; ALL=acute lymphoblastic leukemia; Venclexta in collaboration with AbbVie; Gazyva in collaboration with Biogen; Polatuzumab vedotin in collaboration with Seattle Genetics

## Polatuzumab vedotin and Venclexta Shifting the standard of care in DLBCL and CLL

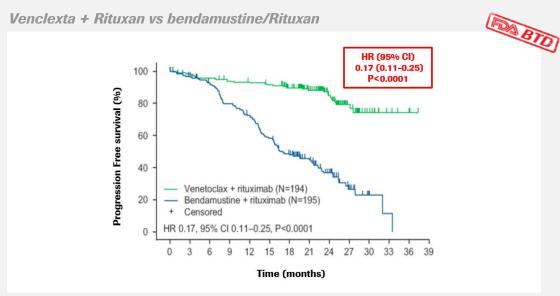


## Polatuzumab vedotin<sup>1</sup> Phase II (GO29365) update in R/R DLBCL



- Ph III study (POLARIX): Polatuzumab vedotin + Rituxan-CHP in 1L DLBCL achieved first-patient-in
- Polatuzumab vedotin could become potential foundational component in all regimes treating B-cell malignancies

## Venclexta<sup>2</sup> Phase III (MURANO) interim results in R/R CLL

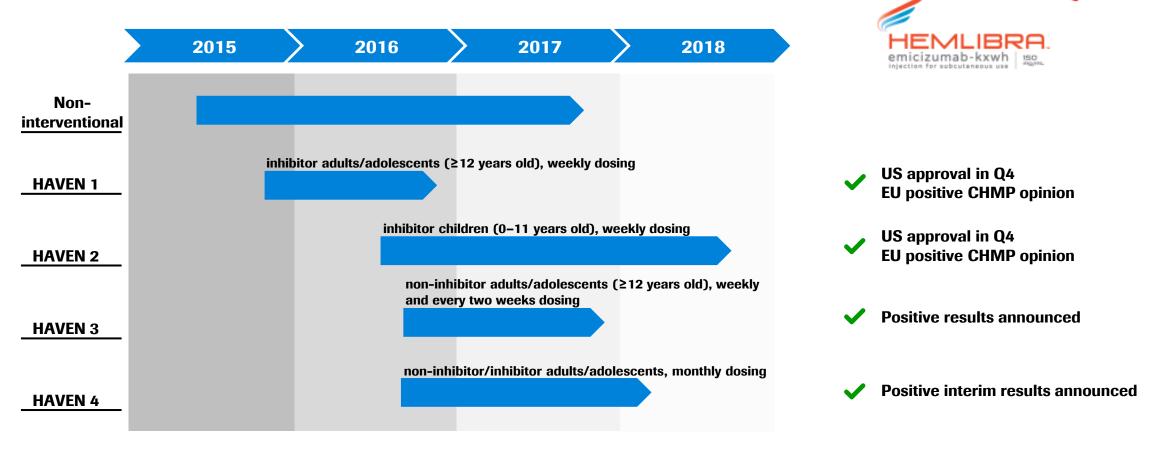


- MURANO data filed in US and EU
- Ongoing Ph III studies in 1L CLL (CLL14), 1L AML (Viale-A and Viale-C) and R/R MM (BELLINI)
- Potential early filing in 1L AML based on Ph1/2 results (with BTD)\*

<sup>&</sup>lt;sup>1</sup> Sehn L. H. *et al.*, ASH 2017; <sup>2</sup> Seymour J. *et al.*, ASH 2017; DLBCL=diffuse large B-cell lymphoma; CLL=chronic lymphoid leukemia; AML=acute myeloid leukemia; NHL=non-hodgkin's lymphoma; MM=multiple myeloma; \*as announced by partner AbbVie; Polatuzumab vedotin in collaboration with Seattle Genetics; Venclexta in collaboration with AbbVie

# Hemlibra's Ph III development nearing completion *HAVEN 1, 2 updates and HAVEN 4 run-in presented at ASH*

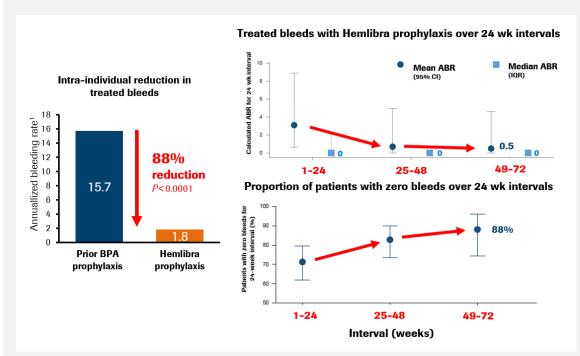




## Hemlibra for inhibitor patients Inhibitor results keep improving over time



### **Phase III update in adult inhibitors (HAVEN 1)**



- HAVEN 1 results improved further over time
- 88% treated bleed reduction in the intra-patient analysis
- Share of patients with zero bleeds increased to 88% in weeks 49-72

### **Phase III update in pediatric inhibitors (HAVEN 2)**

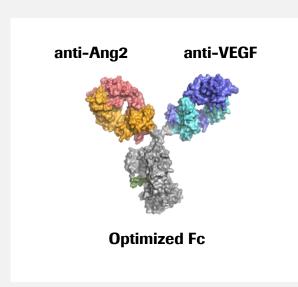
	% zero bleeds (95% CI) N=57*	% zero bleeds (95% CI) N=23**	ABR*** (95% CI) N=23**	Median ABR (IQR) N=23**
Treated bleeds	<b>94.7</b> (85.4; 98.9)	<b>87.0</b> (66.4; 97.2)	<b>0.2</b> (0.06; 0.62)	<b>0.0</b> (0.00; 0.00)
All bleeds	<b>64.9</b> (51.1; 77.1)	<b>34.8</b> (16.4; 57.3)	<b>2.9</b> (1.75; 4.94)	<b>1.5</b> (0.00; 4.53)
Treated spontaneous bleeds	<b>98.2</b> (90.6; 100.0)	<b>95.7</b> (78.1; 99.9)	<b>0.1</b> (0.01; 0.47)	<b>0.0</b> (0.00; 0.00)
Treated joint bleeds	<b>98.2</b> (90.6; 100.0)	<b>95.7</b> (78.1; 99.9)	<b>0.1</b> (0.01; 0.47)	<b>0.0</b> (0.00; 0.00)

- 40 additional patients and ~ 6 months of additional follow-up confirm earlier analysis
- 94.7% of children on Hemlibra prophylaxis with zero treated bleeds

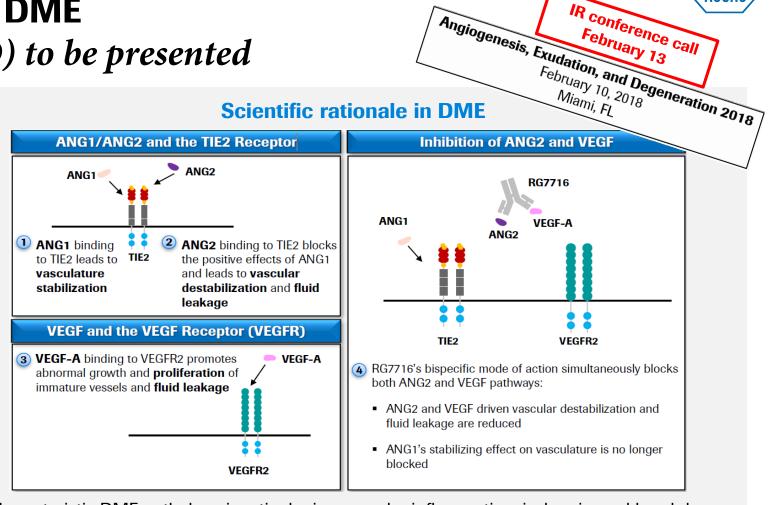
## Anti-VEGF/Ang2 biMAb in DME

Ph II results (BOULEVARD) to be presented





- First bispecific antibody in ophthalmology binding to VEGF and Angiopoetin2 (Ang2)
- Engineered Fc for improved pharmacokinetics and faster systemic clearance



- Characteristic DME pathology is retinal microvascular inflammation, ischemia, and breakdown of the blood-retinal barrier, resulting in leakage of fluid into the retina and vision loss
- Ang2 inhibition could improve blood-retinal barrier stability and reduce retinal vascular inflammation, contributing to an improved therapeutic benefit

IR conference call

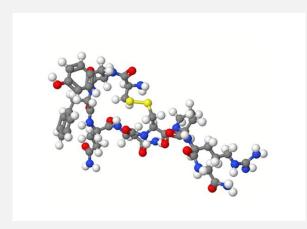
## Autism: V1a receptor antagonist (balovaptan)

## Roche

## Early data from first Ph II study in adults

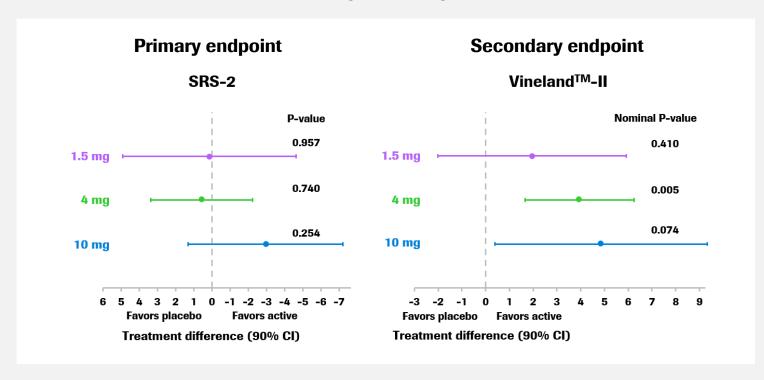


### **V1a receptor antagonist**



- Vasopressin (V)1a receptor modulates social behavior and is implicated in ASD
- Efficacy observed in environmental and genetic rodent models of autism
- Orally available, selective V1a receptor antagonist
- Good pharmacokinetic profile and well tolerated in Ph I and II studies

### **Phase II (VANILLA) results:**



- Primary EP (SRS-2) not met; however main secondary EP (Vineland<sup>™</sup>-II) met
- Vineland<sup>TM</sup>-II selected and agreed upon with health authorities as primary endpoint in future studies

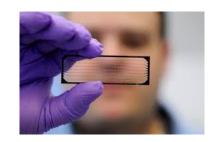
## Ignyta's entrectinib (pan-TRK/ROS1 inhibitor) fits our strategy\* Targeting mutations across different solid tumor types





### **Identify patients with targeted mutations**

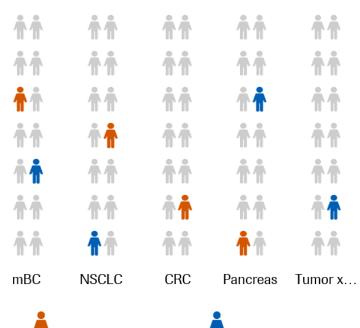
**Entrectinib: Treat selected patients across different tumors** 

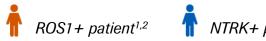












FoundationOne & Roche Diagnostics support identification of rare tumor mutations

<sup>&</sup>lt;sup>1</sup> NTRK 1,2,3=Neurotropic Tropomyosin Receptor Kinase 1, 2, 3; ROS1=c-ros oncogene 1

<sup>&</sup>lt;sup>2</sup> US+EU5 Prevalence: ROS1 in solid tumors ~6000 patients and NTRK in solid tumors ~8000 patients (both mutations have prevalence of 0.5 – 1.5% in most solid tumors; 80% in MASC)

<sup>\*</sup> The acquisition of Ignyta Inc. by Roche Holdings Inc. is pending and is subject to customary closing conditions. The closing of the transaction is expected to take place in the first half of 2018.



## **2017** results

### **Innovation**

## **Outlook**

## 2018: Key late-stage news flow\*



	Compound	Indication	Milestone
	Ocrevus	RMS / PPMS	EU approval
	Perjeta + Herceptin	Adjuvant HER2+ eBC	EU approval
	Tecentriq + cb/pac +/- Avastin	1L non-sq NSCLC	US/EU filing
	Tecentriq + Avastin	1L RCC	US/EU filing
Regulatory	Hemlibra	Hemophilia A inhibitors	EU approval
	Hemlibra	Hemophilia A non-inhibitors	US/EU filing
	Hemlibra	Every 4 weeks dosing inhibitors/non-inhibitors	US/EU filing
	baloxavir marboxil (CAP endonuclease inhibitor)	Influenza	US filing initiation
	Venclexta + Rituxan	R/R CLL	US/EU approval
	Tecentriq + chemo	1L lung program	Ph III IMpower130/131/132/133
Phase III readouts	Tecentriq + nab-pac	1L TNBC	Ph III IMpassion130
rnasc in reauduts	Tecentriq + Cotellic	2/3L CRC	Ph III IMblaze370 / COTEZO
	Actemra	Systemic sclerosis	Ph III focuSSced

<sup>\*</sup> Outcome studies are event-driven: timelines may change



## **Diagnostics Division**

Roland Diggelmann CEO Roche Diagnostics



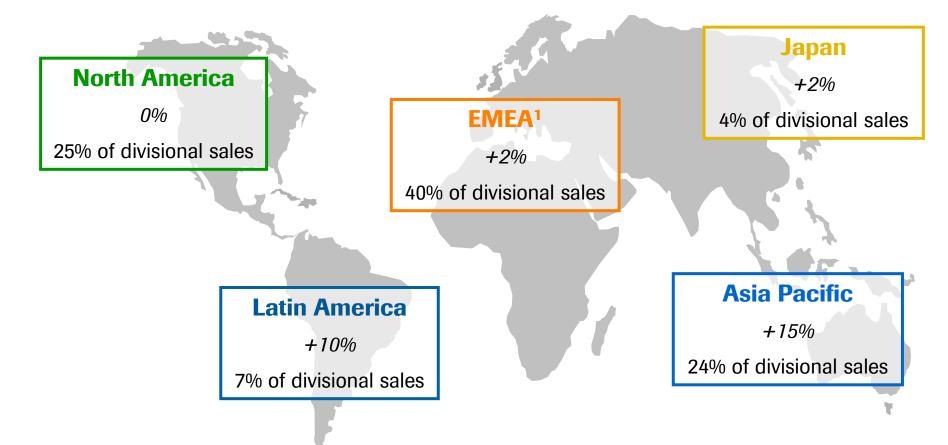


## 2017: Diagnostics Division sales Growth driven by CPS & Tissue Diagnostics

	2017	2016	Change	in %
	CHFm	CHFm	CHF	CER
Diagnostics Division	12,079	11,473	5	5
Centralised and Point of Care Solutions	7,179	6,698	7	7
Diabetes Care	1,965	2,016	-3	-4
Molecular Diagnostics	1,920	1,845	4	4
Tissue Diagnostics	1,015	914	11	11



## **2017: Diagnostics Division regional sales** *Strong growth in emerging markets*

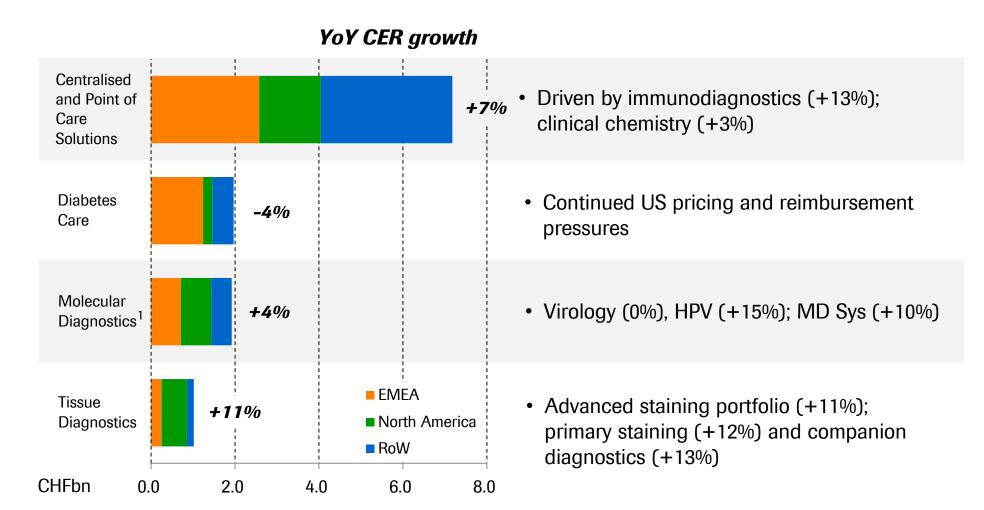


+17% growth in E7 countries<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Europe, Middle East and Africa; <sup>2</sup> Brazil, China, India, Mexico, Russia, South Korea, Turkey All growth rates at Constant Exchange Rates



## **2017: Diagnostics Division highlights** *Growth driven by Immunodiagnostics*



<sup>&</sup>lt;sup>1</sup> Underlying growth of Molecular Diagnostics excluding sequencing business: +4% CER=Constant Exchange Rates; EMEA=Europe, Middle East and Africa



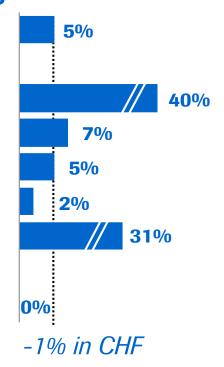
Roche

## Core operating profit growth excl. PSI +4%

2017
CHFm % sales

Sales	12,079	100.0
Royalties & other op. inc.	163	1.3
Cost of sales	-5,659	-46.8
M & D	-2,792	-23.1
R & D	-1,356	-11.2
G & A	-526	-4.4
Core operating profit	1,909	15.8

**2017 vs. 2016 CER growth** 

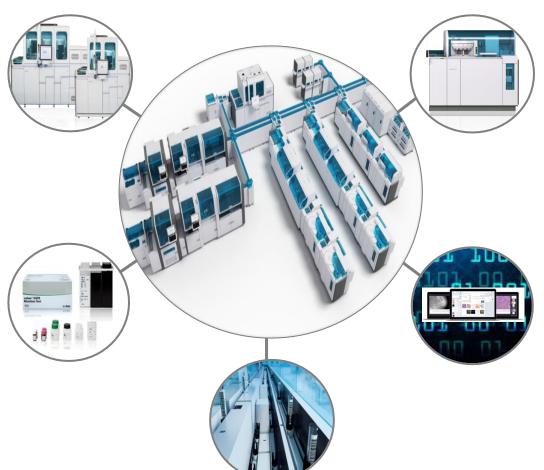


## Implementing the fully integrated core laboratory



### **Connecting disciplines**

(cobas 6800/8800, cobas 6500, cobas p 612)



Highest throughput analysers (cobas e 801, cobas c 702)

**Comprehensive menu** 

(Procalcitonin; Zika; MPX; Syphilis)

**Digitalised data management** (Navify tumor board)

Seamless workflow and laboratory IT (CCM High Speed)



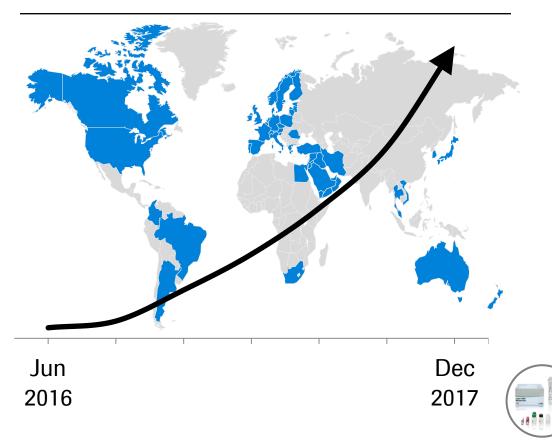


### **Launch Excellence**

- June 16: launch in CE mark countries
- Apr 17: US launch
- Complete menu of 96 parameters available in CE mark countries



### Units since launch ~900\*



### Launch of cobas t 511 / t 711

## Roche

## First cassette-based laboratory coagulation analysers



cobas t 711 analyser\*

- First customer monitoring with 10 assays
- Automatization reduces errors and increases walkaway capacity
- Maximized test capacity (up to 34200 tests on board)



## **Acquisition of Viewics, Inc.**



## Data-driven business analytics and digital capabilities for the laboratory



- Complements and expands our portfolio with business analytics
- Supports our customers in improving their lab performance and processes
- Proprietary big data extraction and cleansing integration technology
- HIPAA\* certified massively scalable platform



\*HIPPA: Health Insurance Portability and Accountability Act



## Bridging advanced analytics to provide clinical decision support solutions for patients and physicians

### **In-vitro data**

## Roche

Biomarkers
Tissue pathology
Genomics & sequencing

### **Digital platform & analytics**

Combined patient records
Real-time data
Best practices
Research outcomes

### **Workflow solutions + apps**

Speed, accuracy, confidence

### **Clinical decision support**

Speed, accuracy, confidence

### **Data driven patient care**

Early diagnosis
Early intervention
Individualised treatment

### In-vivo data



Medical imaging Patient monitoring

Combine in-vitro and in-vivo expertise - complementary strategic partnership



## **Key launches 2017: All targets achieved**



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

<sup>\* =</sup> Achieve commercial readiness, dependent on Pharma label and approval





	Area	Product	Market
	Central Laboratory	cobas pro integrated solution - Serum Work Area solution for medium throughput to lower high throughout labs	CE
	Specialty Testing	cobas m 511 - World's first fully digital morphology analyzer and cell counter	US
Instruments/	Workflow	CCM connectivity to cobas c513 - Connection of cobas c 513 to CCM Automation System for high volume HbA1c testing	WW
Devices	Tissue Dx	BenchMark ULTRA Plus - New and differentiated Advanced Staining System	CE
	Digital Pathology	VENTANA DP200 - Reliable low-volume scanner with superior image quality	CE
	Diabetes Care	Solo Patch Pump - Small and tubeless insulin delivery device operated through a remote control which includes a blood glucose meter	CE
	Endocrinology	IGFBP3 - Completion of the existing growth hormone menu of hGH and IGF-1	CE
	Infectious Diseases	Zika IgG - Highly specific immunoassay for the in vitro qualitative detection of IgG antibodies to Zika virus in human serum and plasma	CE
Tests/ Assays		cobas CT/NG - Highest throughput CT/NG test on the market with workflow efficiency benefits	US
Noouyo	Microbiology	cobas 6800/8800 MTB/MAI – High volume solution for MTB/MAI testing; efficient approach to disease management (mixed testing) for infectious disease	CE
	Virology	Plasma Separation Card - Card-like sample collection device; separates plasma from whole blood; for use with CAP/CTM HIV-1 & cobas HIV-1 (6800/8800)	CE 🗸
	Sequencing	AVENIO FFPET RUO oncology kits - 3 separate tissue based assay kits for solid tumors	WW
Software	Decision Support	NAVIFY Tumor Board v 1.x - EMR integration	WW



## **Finance**

Alan Hippe Chief Financial Officer





## 2017 results

**Focus on Cash** 

**Outlook** 

### **FY 2017: Highlights**



### **Business**

- Good sales growth of +5%1 and Core operating profit up +3%1
- Core EPS growth +5%<sup>1</sup>
- Dividend in Swiss francs further increased

### Cash flow

- Significant cash generation (Operating Free Cash Flow of CHF 17.8bn, +26%<sup>1</sup>)
- Net debt lower by CHF 6.3bn vs. YE 2016 as Free Cash Flow of CHF 13.4bn more than offsets dividends paid

### Net financial results

• Core net financial result improved by +25%¹ driven mainly by 15%¹ lower interest expenses² and lower losses on debt redemption

### **IFRS**

• Net income -9%¹ due to impairment of intangible assets

<sup>&</sup>lt;sup>1</sup> At Constant Exchange Rates (CER)

Roche

## **2017: Group performance**

## Core EPS growth +5%, in line with sales growth

	2017	2016	Change	e in %
	CHFm	CHFm	CHF	CER
Sales	53,299	50,576	5	5
Core operating profit as % of sales	<b>19,012</b> 35.7	<b>18,420</b> <i>36.4</i>	3	3
Core net income as % of sales	<b>13,404</b> <i>25.1</i>	<b>12,688</b> 25.1	6	6
Core EPS (CHF)	15.34	14.53	6	5
IFRS net income	8,825	9,733	-9	-9
Operating free cash flow as % of sales	<b>17,827</b> 33.4	<b>14,086</b> <i>27.9</i>	27	26
Free cash flow as % of sales	<b>13,420</b> 25.2	<b>9,130</b> <i>18.1</i>	47	47

CER=Constant Exchange Rates 58



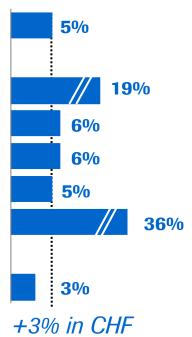
## **2017: Group operating performance**

## Core operating profit growth +3%, supporting new launches

2017 CHFm % sales

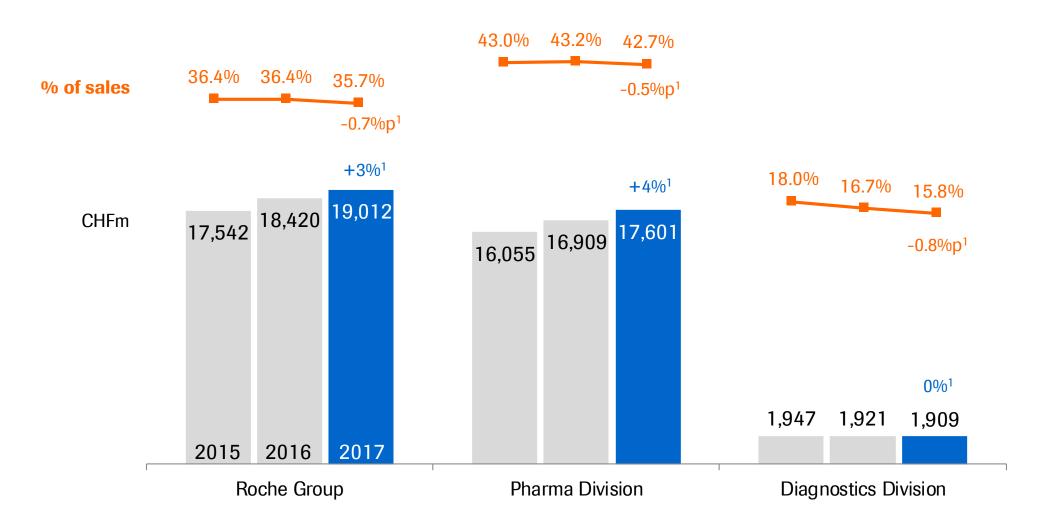
Sales	53,299	100.0
Royalties & other op. inc.	2,447	4.6
Cost of sales	-14,366	-27.0
M & D	-9,512	-17.8
R & D	-10,392	-19.5
G & A	-2,464	-4.6
Core operating profit	19,012	35.7

**2017 vs. 2016 CER growth** 







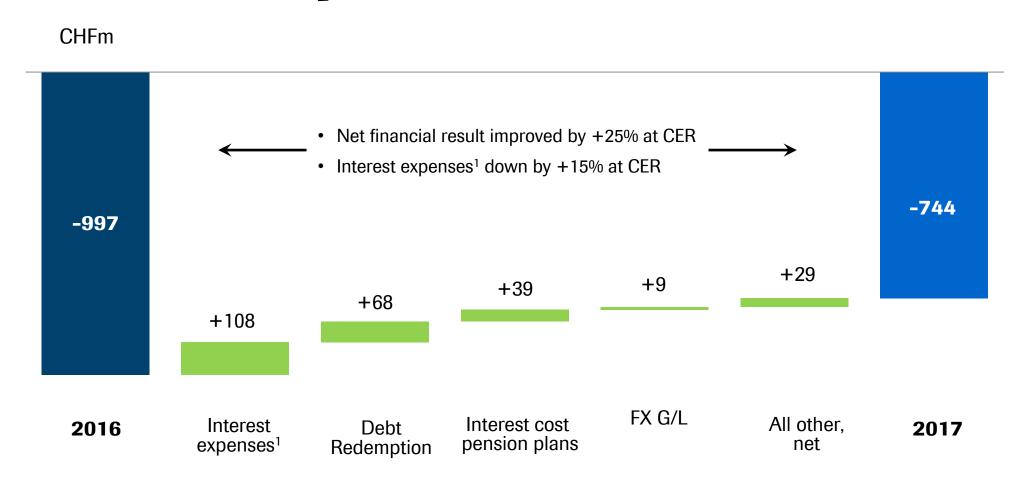


<sup>1</sup> At CER=Constant Exchange Rates



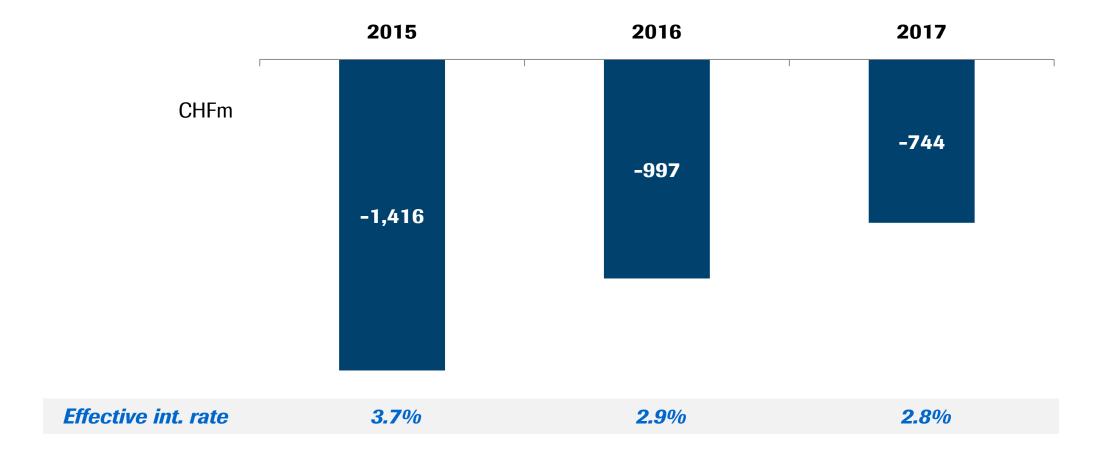
### 2017: Core net financial result

## +25% improvement mainly due to lower interest expenses and lower losses on debt redemption



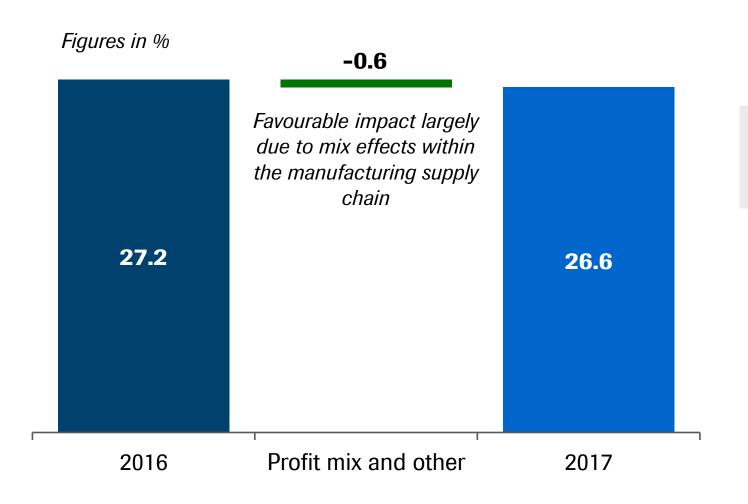






## 2017/18: Group Core tax rate





### 2018: Impact of US tax reform

 Corporate Core tax rate expected to be in the low twenties<sup>1</sup> vs mid to high-twenties range previously

63

<sup>&</sup>lt;sup>1</sup> barring any changes to tax legislation or other one-off items



## FY 2017: Non-core items; IFRS result impacted by impairments of goodwill & intangible assets

Full Year	2016	2017	CHFm	CHF	CER
Core operating profit	18,420	19,012	+592	+3%	+3%
Global restructuring plans	-1,233	-1,208	+25		
Amortisation of intangible assets	-1,783	-1,691	+92		
Impairment of intangible assets <sup>1</sup>	-1,508	-3,518	-2,010		
Alliances & Business Combinations	+234	+350	+116		
Legal & Environmental <sup>2</sup>	-61	+58	+119		
Total non-core operating items	-4,351	-6,009	-1,658		
IFRS operating profit	14,069	13,003	-1,066	-8%	-8%
Total financial result & taxes	-4,336	-4,178	+158		
IFRS net income	9,733	8,825	-908	-9%	-9%



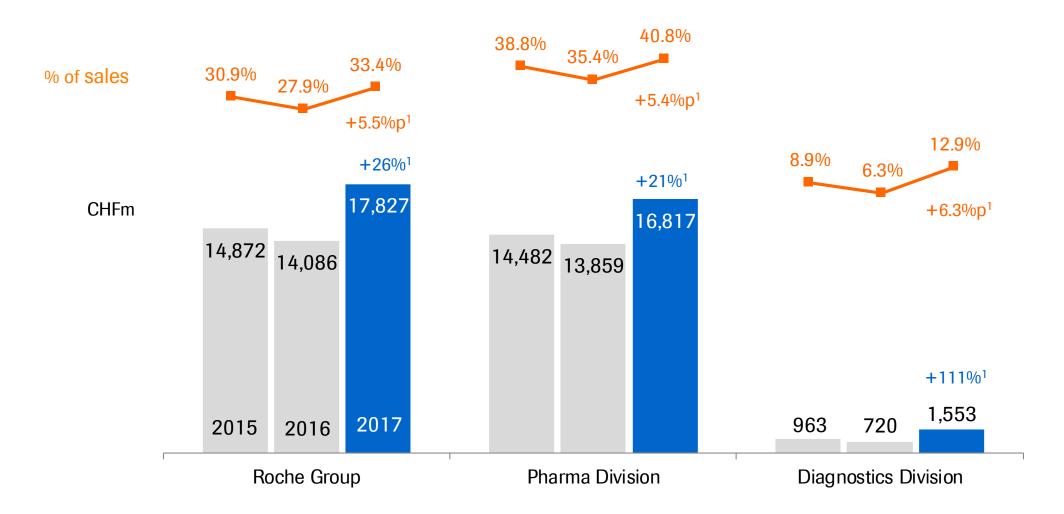
## **2017** results

### **Focus on Cash**

## **Outlook**





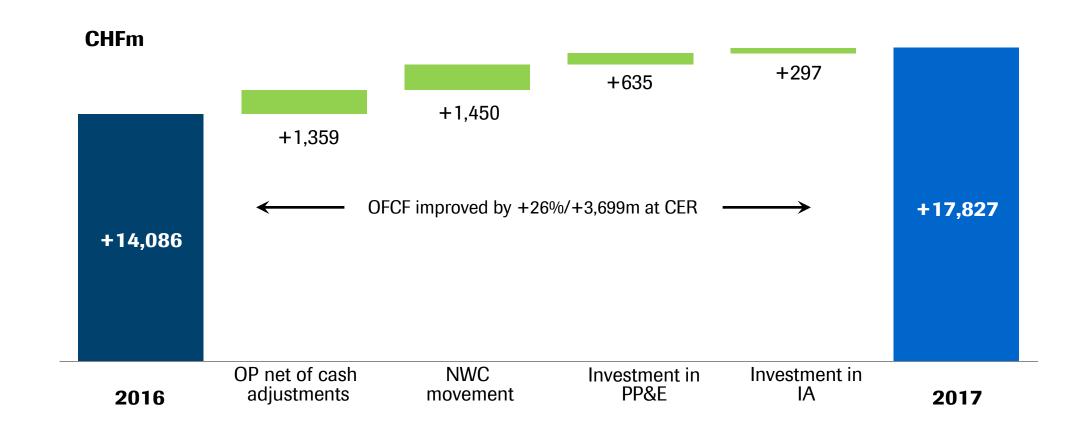


<sup>1</sup> At CER=Constant Exchange Rates





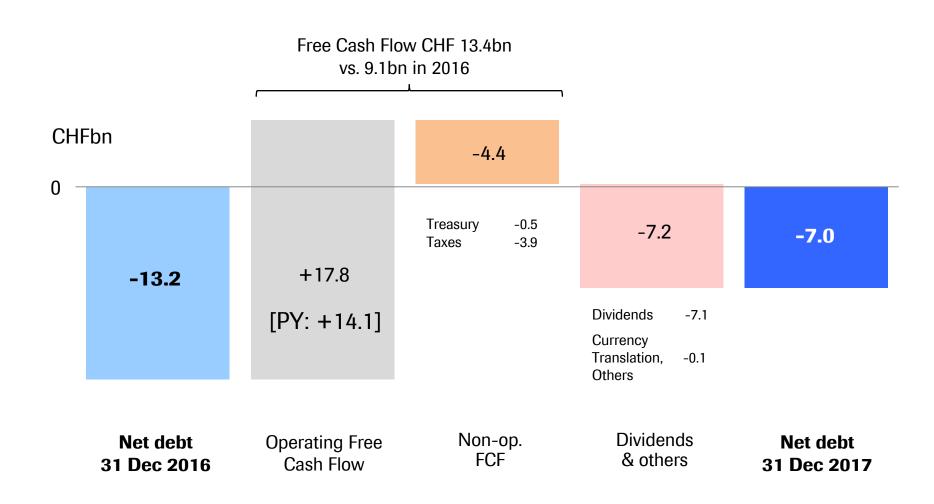
## CHF + 3.7bn/ + 26% higher than PY



67



## 2017: Group net debt significantly improved Lower net debt due to improved free cash flow

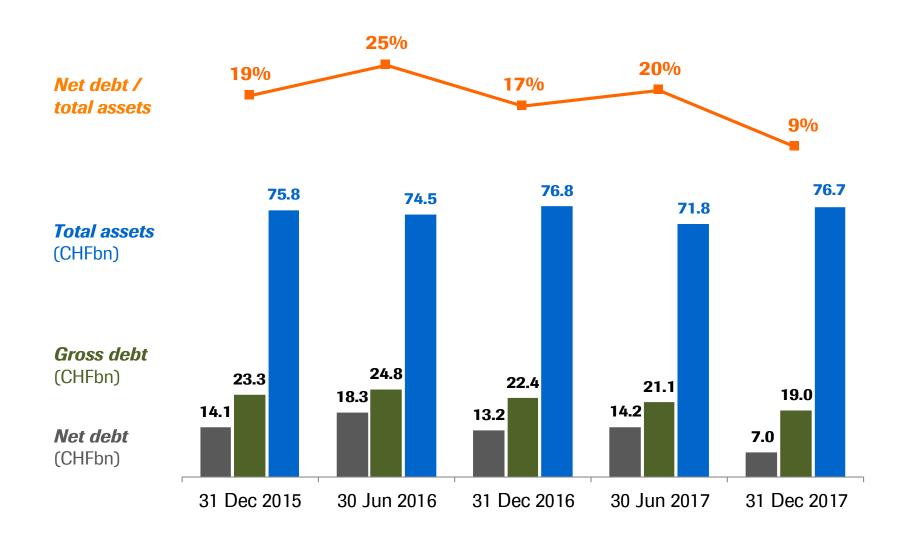


CER = Constant Exchange Rates (avg full year 2016)



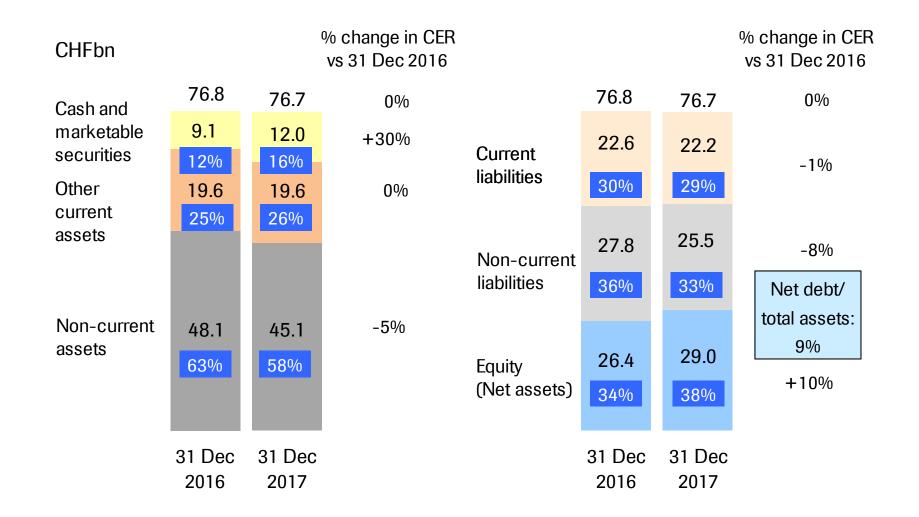
### **Balance sheet**

### Net debt to total assets now at 9% vs. 19% at YE 2015



### **Balance sheet 31 December 2017**







## **2017** results

### **Focus on Cash**

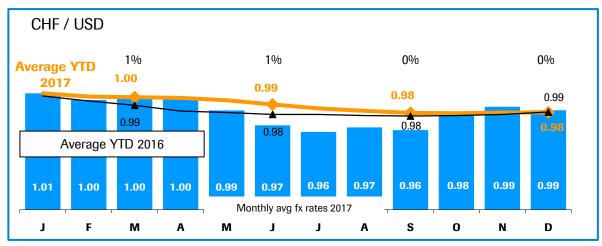
## **Outlook**

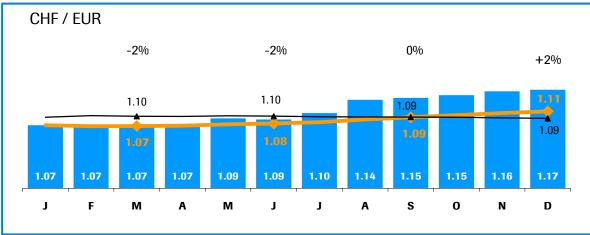
## **Low currency impact in 2017**



0

1





III 2017 IIIIpact is (%0p).					
	Q1	НҮ	Sep YTD	FY	
Sales	0	0	0	0	
Core operating		0			

0

0

In 2017 impact is (0/n).

**2018** currency impact<sup>1</sup> expected (based on **31 Dec 2017** FX rates):

• Up to +1%p FX impact on Sales, Core OP & Core EPS

<sup>1</sup> On Group growth rates 72

profit

Core EPS

### 2018 outlook



Group sales growth<sup>1</sup>

• Stable to low-single digit

Core EPS growth<sup>1</sup>

- Broadly in line with sales, excl. US tax reform benefit
- High-single digit, incl. US tax reform benefit

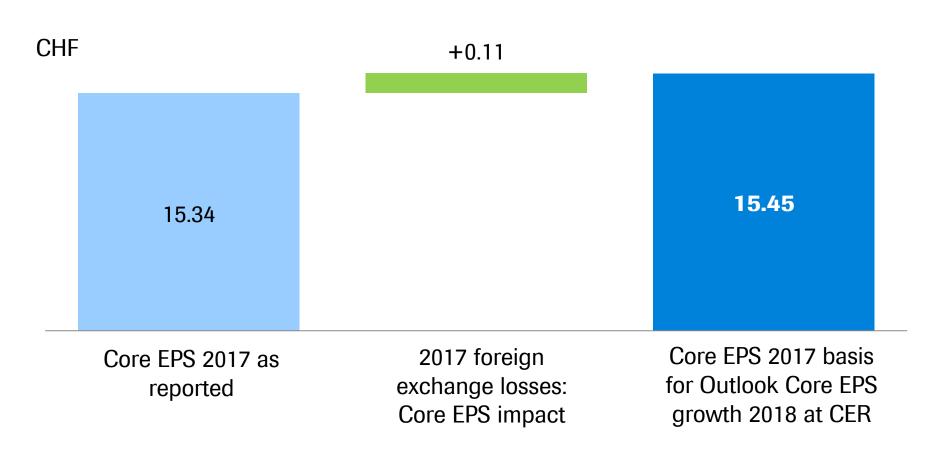
**Dividend outlook** 

Further increase dividend in Swiss francs

<sup>1</sup> At Constant Exchange Rates (CER)



# Full Year 2017: Core EPS Core EPS 2017 of CHF 15.45 is basis for outlook Core EPS growth 2018 at CER



CER=Constant Exchange Rates (avg full year 2017)



## **Pipeline summary**

## Changes to the development pipeline *FY 2017 update*



### **New to phase I**

#### 6 NMEs:

RG6109 NME - AML
RG6151 NME - asthma
RG6171 SERD (3) - ER+ (HER2neg) mBC
RG6174 NME - inflammatory diseases
RG6264 Perjeta + Herceptin FDC SC HER2+ eBC
RG7816 GABA-Aa5 PAM - autism

#### 1 Als:

**RG7446 Tecentriq + tazemetostat** – r/r DLBCL

### **Removed from phase I**

#### 3 NMEs:

RG6047 SERD (2) – ER+ (HER-neg) mBC RG7203 PDE10A inh – schizophrenia RG7986 ADC – r/r NHL

### **New to phase II**

#### 1 NME:

RG1678 bitopertin – beta thalassemia

### **Removed from phase II**

#### 1 AI:

RG3502 Kadcyla + Tecentriq - 2L Her2+ mBC

### **New to phase III**

#### 1 NMEs:

RG6152 baloxavir marboxil (CAP endonuclease inh) – influenza

#### 6 Als:

RG3648 Xolair – nasal polyps RG7421 Cotellic + Tecentriq – 1L BRAF WT melanoma

**RG7440** ipatasertib – 1L TNBC/HR+ BC **RG7446/RG7853 Tecentriq or Alecensa** - 1L NSCLC Dx+

RG7596 polatuzumab vedotin -1L DLBCL RG7601 Venclexta + LDAC - 1L AML

### New to registration

#### 1 Al following filing in US and EU:

RG7601 Venclexta + Rituxan - r/r CLL

#### 2 Als following filing in US:

RG435 Avastin - FL ovarian cancer RG3645 Lucentis 0.3mg PFS - DME/DR

#### 1 Al following filing in EU:

RG1569 Actemra auto injector - RA

### **Removed from phase III**

#### 1 NME:

RG7417 lampalizumab - geographic atrophy

### **Removed from registration**

#### 3 Als following US approval:

RG435 Avastin - GBM RG7159 Gazyva - 1L FL RG7204 Zelboraf - Erdheim-Chester disease

### 1 Al following US and EU approval:

RG7853 Alecensa – 1L ALK+ NSCLC

### 1 NME following EU approval:

RG1594 Ocrevus - PPMS + RMS

## **Roche Group development pipeline**



### **Phase I (43 NMEs + 23 Als)**

RG6264	Perjeta + Herceptin FDC SC	HER2+ BC
RG6026	CD20 TCB	heme tumors
RG6058	TIGIT ± Tecentriq	solid tumors
RG6109		AML
RG6114	mPl3K alpha inh	HR+ BC
RG6146	BET inh combos	solid + heme tumors
RG6160	-	multiple myeloma
RG6171	SERD (3)	ER+ (HER2neg) mBC
RG6180	personalized cancer vaccine ± T	oncology
RG6185	pan-RAF inh + Cotellic	solid tumors
RG7155	emactuzumab + Tecentriq	solid tumors
NG/100	emactuzumab + selicrelumab	solid tumors
RG7159	anti-CD20 combos	heme tumors
RG7386	FAP-DR5 biMAb	solid tumors
DC7401	Cotellic + Zelboraf + T	melanoma
RG7421	Cotellic + T	2L BRAF WT mM
	Tecentriq	solid tumors
	Tecentriq	NMIBC
	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chemo	HCC, GC, PaC
	T + Cotellic	solid tumors
	T + ipi/IFN	solid tumors
DO7440	T + Tarceva/Alecensa	NSCLC
RG7446	T + anti-CD20 combos	heme tumors
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T + HMA	MDS
	T + radium 223	mCRPC
	T + guadecitabine	AML
	T + rucaparib	ovarian ca
	T + Gazyva/tazemetostat	r/r DLBCL + FL
RG7461	FAP IL2v FP combos	solid tumors
D07001	Venclexta + Cotellic/idasanutlin	AML
RG7601	Venclexta ± azacitadine	r/r MDS
	ChK1 inh	solid tumors

RG7802	CEA TCB ± Tecentriq	solid tumors
RG7813	CEA IL2v FP* + Tecentriq	solid tumors
RG7828	CD20 TDB ± Tecentriq	heme tumors
D07070	selicrelumab (CD40) + T	solid tumors
RG7876	selicrelumab + vanucizumal	b solid tumors
RG7882	MUC16 ADC	ovarian ca
CHU	Raf/MEK dual inh	solid tumors
CHU	glypican-3/CD3 biMAb	solid tumors
RG6069	anti-fibrotic agent	fibrosis
RG6107	C5 inh MAb	PNH
RG6151	-	asthma
RG6174	-	inflammatory diseases
RG7835	IgG-IL2 FP	autoimmune diseases
RG7880	IL-22Fc	inflammatory diseases
RG7990	-	asthma
RG6004	HBV LNA	HBV
RG6080	nacubactam	bact. infections
RG7854	TLR7 agonist (3)	HBV
RG7861	anti-S. <i>aureus</i> TAC	infectious diseases
RG7907	HBV Capsid (2)	HBV
RG7992	FGFR1/KLB MAb	metabolic diseases
RG6000	-	ALS
RG6029	Nav1.7 inh (2)	pain
RG6042	ASO	Huntington's
RG7816	GABA Aa5 PAM	autism
RG7906	-	psychiatric disorders
RG6147	-	geographic atrophy
RG7945	-	glaucoma
CHU	PTH1 recep. ago	hypoparathyroidism
CHU	-	hyperphosphatemia
New Molecular	Entity (NME) <b>RG-No</b> Roche	e/Genentech

New Molecular Entity (NM Additional Indication (AI) Oncology Immunology Infectious Diseases CardioMetabolism Neuroscience Ophthalmology RG-No Roche/Genentech
CHU Chugai managed
PRO Proximagen managed
NOV Novimmune managed
\*INN: cergutuzumab amunaleukin

\*\*out-licensed to Galderma and Maruho for atopic dermatitis

\*\*\* Ph2 Pivotal § FPI expected Q1 2018

T=Tecentriq; TCB=T cell bispecific; TDB=T cell dependent bispecific

### Phase II (19 NMEs + 9 Als)

RG7388	idasanutlin §	polycythemia vera
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7440	ipatasertib	TNBC neoadj
RG7596	polatuzumab vedotin	r/r DLBCL + FL
	Venclexta + Rituxan	DLBCL
RG7601	Venclexta + Rituxan	r/r FL
	Venclexta + azacitadine	1L MDS
RG7604	taselisib + letrozole	(HER2-neg) BC neoadj
RG7686	codrituzumab	liver cancer
RG3637	lebrikizumab ± Esbriet	IPF
RG6125	Cadherin-11 MAb	RA
RG6149	ST2 MAb	asthma
RG7159	obinutuzumab	lupus
RG7625	Cat-S antag	autoimmune diseases
RG7845	BTK inh	RA, lupus, CSU
CHU	nemolizumab** p	ruritus in dialysis patients
PRO	VAP-1 inh	inflammatory disease
NOV	TLR4 MAb	autoimmune diseases
CHU	URAT1 inh	gout
RG1662	basmisanil	CIAS
RG1678	bitopertin	beta thalassemia
RG6083	olesoxime	SMA
RG6100	Tau MAb	Alzheimer's
RG7314	balovaptan (V1a receptor antag	) autism
RG7916	SMN2 splicer(2)***	SMA
RG7935	a-synuclein MAb	Parkinson's
RG3645	ranibizumab PDS	wAMD
RG7716	VEGF-ANG2 biMAb	wAMD, DME

## **Roche Group development pipeline**



### Phase III (9 NMEs + 34 Als)

RG3502	Kadcyla	HER2+ BC adj
RG3502	Kadcyla + Perjeta	HER2+ BC adj
RG6013	Hemlibra	hemophilia A w/o FVIII inh
RG0013	Hemlibra	Q4W hemophilia A
RG7388	idasanutlin + chemo	AML
RG7440	ipatasertib + chemo	1L CRPC
NG/440	ipatasertib	1L TNBC/HR+ BC
RG7421	Cotellic + Zelboraf + T	1L BRAFm melanoma
NG/421	Cotellic + T	1L BRAF WT melanoma
RG7596	polatuzumab vedotin	1L DLBCL
	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq Dx+	1L sq + non-sq SCLC
	Tecentriq	RCC adj
	T + nab-paclitaxel	1L non-sq NSCLC
	T + chemo+ Avastin	1L ovarian cancer
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
RG7446	T + nab-paclitaxel	1L sq NSCLC
	T + paclitaxel	1L TNBC
	T + nab-paclitaxel	1L TNBC
	T + nab-paclitaxel	TNBC neoadj
	T + Avastin	RCC
	T + Cotellic	3L CRC
	T ± chemo	1L mUC
	T + chemo	1L extensive stage SCLC
	T + enzalutamide	CRPC
RG7446/RG7853	Tecentriq or Alecensa	1L NSCLC Dx+

IIVILS T 34 AIS)		
	Venclexta + Gazyva	1L CLL
D07001	Venclexta + bortezomib	MM
RG7601	Venclexta + azacitidine	1L AML
	Venclexta + LDAC	1L AML
RG7604	taselisib + fulvestrant ER+(F	HER2-neg) mBC
RG105	MabThera pen	nphigus vulgaris
RG1569	Actemra sys	stemic sclerosis
RG3648	Xolair	nasal polyps
RG7413	etrolizumab	ulcerative colitis
NG/413	etrolizumab	Crohn's
RG6152	baloxavir marboxil (CAP endonuclease in	h) influenza
RG1450	gantenerumab	Alzheimer's
RG6168	satralizumab (IL-6R Mab)	NMO
RG6206	anti-myostatin adnectin	DMD
RG7412	crenezumab	Alzheimer's

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

RG-No Roche/Genentech
CHU Chugai managed
RG1569 Branded as RoActemra (EU)

T=Tecentriq

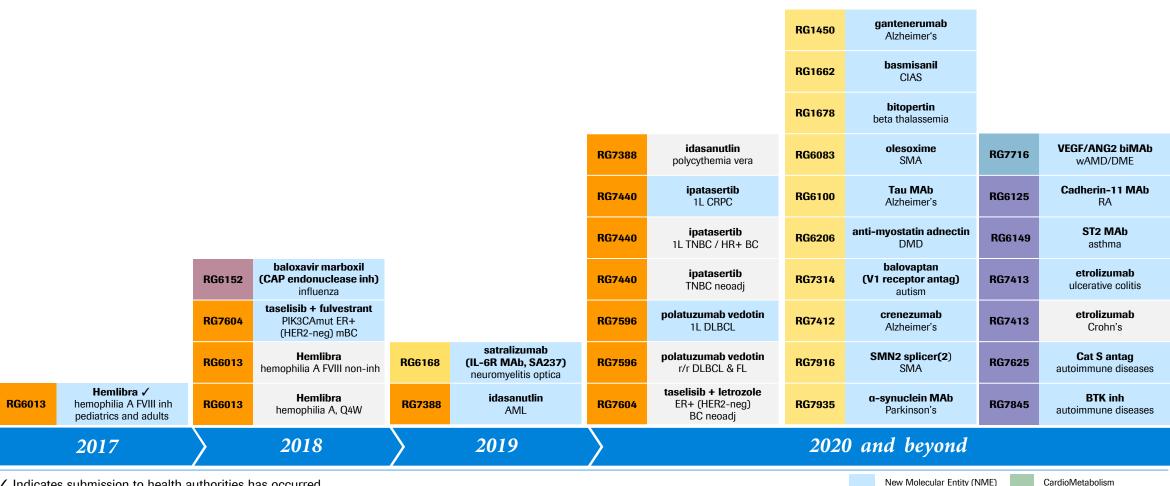
### Registration (1 NME + 5 Als)

RG435	Avastin <sup>1</sup>	ovarian FL
RG1273	Perjeta + Herceptin <sup>2</sup>	HER2+ BC adj
RG6013	Hemlibra <sup>3</sup>	hemophilia A FVIII inh
RG7601	Venclexta + Rituxan	r/r CLL
RG1569	Actemra auto injector <sup>4</sup>	RA
RG3645	Lucentis 0.3mg PFS <sup>1</sup>	DME/DR

- 1 US only
- 2 Approved in US
- 3 Approved in US; positive CHMP opinion
- 4 EU only

## Roche

## NME submissions and their additional indications Projects currently in phase II and III



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

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

Neuroscience

Ophthalmology

## Al submissions for existing products Projects currently in phase II and III



	2017		2018		2019		2020 an	d beyon	d
RG7853	<b>Alecensa ✓</b> 1L ALK+ NSCLC	RG7446	<b>Tecentriq + nab-paclitaxel</b> TNBC	RG7601	<b>Venclexta + bortezomib</b> MM	RG7421	Cotellic + Tecentriq ± taxane TNBC	RG7446	<b>Tecentriq + chemo + Avastin</b> 1L ovarian cancer
RG7601	Venclexta + Rituxan (US) ✓ r/r CLL	RG7446	<b>Tecentriq + Avastin</b> RCC	RG7601	<b>Venclexta + Gazyva</b> 1L CLL	RG7601	<b>Venclexta + aza</b> 1L MDS	RG7446	<b>Tecentriq</b> RCC adj
RG7204	<b>Zelboraf (US) ✓</b> Erdheim-Chester disease	RG7446	Tecentriq + chemo 1L extens. stage SCLC	RG7446	<b>Tecentriq + paclitaxel</b> 1L TNBC	RG7601	<b>Venclexta + Rituxan</b> DLBCL	RG7446	<b>Tecentriq + enzalutamide</b> CRPC
RG7159	<b>Gazyva (US) √</b> 1L FL	RG7446	Tecentriq + chemo + pemetrexed 1L non-sq NSCLC	RG7446	Tecentriq + nab-paclitaxel TNBC neoadj	RG7601	<b>Venclexta + Rituxan</b> r/r FL	RG7446	<b>Tecentriq</b> MIBC adj
RG1273	Perjeta + Herceptin ✓ HER2+ BC adj.	RG7446	Tecentriq + nab-paclitaxel 1L non-sq NSCLC	RG7446	<b>Tecentriq</b> 1L non-sq + sq NSCLC (Dx+)	RG3502	<b>Kadcyla</b> HER2+ BC adj.	RG7446	<b>Tecentriq</b> NSCLC adj
RG435	ovarian FL	RG7446	Tecentriq + nab-paclitaxel 1L sq NSCLC	RG7421	1L BRAFmut melanoma	RG3502	HER2+ BC adj.	RG7446	1L mUC
	GBM Avastin (US) ✓	RG7446	Tecentriq + chemo + Avastin 1L non-sq NSCLC		1L BRAF WT melanoma  Cotellic + Tecentriq + Zelboraf		Kadcyla + Perjeta	RG7853	1L NSCLC Dx+  Tecentriq ± chemo
RG435	Avastin (US) ✓	RG7446	<b>Tecentriq + Cotellic</b> 3L CRC	RG7421	Cotellic + Tecentriq			RG7446/	Tecentriq or Alecensa
RG1569	Actemra auto injector (EU) ✓	RG7601	Venclexta + azacitidine/LDAC 1L AML					RG7159	<b>obinutuzumab</b> Iupus nephritis
RG36452	Lucentis 0.3mg PFS (US)   DME/DR	RG7601	Venclexta + Rituxan (EU) ✓ r/r CLL					RG3648	<b>Xolair</b> nasal polyps
		RG1569	Actemra auto injector (US) RA/GCA					RG3645	<b>ranibizumab PDS</b> wAMD
		RG1569	Actemra systemic sclerosis						
		RG105	<b>MabThera</b> pemphigus vulgaris						

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

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

Neuroscience

Ophthalmology

## **Major granted and pending approvals 2017**



		US		EU		Japan-Chugai
Approved	RG105	<b>Rituxan Hycela™</b> (SC) NHL/CLL, Jun 2017	RG435	Avastin chemo backbone extension rel. OC Pt-sensitive, Jun 2017	RG7446	<b>Tecentriq</b> 2L+ NSCLC, Jan 2017
<b>F</b> F. C. C.	RG435	<b>Avastin</b> GBM, Dec 2017	RG7159	<b>Gazyva</b> 1L follicular lymphoma, Sep 2017	СНИ	<b>Actemra</b> Takayasu arteritis and giant cell arteritis, Aug 2017
	RG1273	<b>Perjeta + Herceptin</b> HER2+ BC adj, Dec 2017	RG7446	<b>Tecentriq</b> mUC 2L, Sep 2017		
	RG6013	<b>Hemlibra (emicizumab)</b> hemophilia A FVIII inh (ped + adults), Nov 2017	RG7446	<b>Tecentriq</b> 2L+ NSCLC, Sep 2017		
	RG7159	<b>Gazyva</b> 1L follicular lymphoma , Nov 2017	RG7853	<b>Alecensa</b> 2L ALK+ NSCLC, Feb 2017 1L ALK+ NSCLC, Dec 2017		
	RG7204	<b>Zelboraf</b> Erdheim-Chester disease, Nov 2017	RG1569	Actemra giant cell arteritis, Sep 2017		
	RG7446	<b>Tecentriq</b> 1L bladder cancer, cis-ineligible, Apr 2017	RG1594	<b>Ocrevus</b> PPMS & RMS, Jan 2018		
	RG7853	<b>Alecensa</b> 1L ALK+ NSCLC, Nov 2017				
	RG1569	<b>Actemra</b> giant cell arteritis, May 2017 CRS, Aug 2017				0.500.000
	RG1594	<b>Ocrevus</b> PPMS & RMS, Mar 2017				cular Entity (NME)  Indication (Al)  CardioMetabolism  Neuroscience  Ophthalmology
	RG3645	<b>Lucentis</b> mCNV, Jan 2017 DR w/o DME, Apr 2017			Immunolo Infectious	gy Other
Pending	RG435	<b>Avastin</b> Ovarian FL, Filed Aug 2017	RG1273	Perjeta + Herceptin HER2+ BC adj, Filed Aug 2017	RG6013	<b>emicizumab</b> hemophilia A FVIII inh (ped + adults), Filed Jul 2017
Pending Approval	RG7601	<b>Venclexta + Rituxan</b> r/r CLL, Filed Dec 2017	RG6013	<b>Hemlibra (emicizumab)</b> hemophilia A FVIII inh (ped + adults), Filed Jun 2017		
	RG3645	<b>Lucentis</b> 0.3 mg PFS DME/DR, Filed Dec 2017	RG7601	<b>Venclexta + Rituxan</b> r/r CLL, Filed Jan 2018		
			RG1569	Actemra auto injector RA, Filed Jan 2018		





### **Phase I (10 NMEs + 28 Als)**

RG6026	CD20 TCB	hematopoietic tumors
RG6058	TIGIT ± Tecentriq	solid tumors
RG6160	-	multiple myeloma
RG6180	personalized cancer vaccine ± T	oncology
RG7155	emactuzumab + Tecentriq	solid tumors
NG/100	emactuzumab + selicrezumab	solid tumors
RG7421	Cotellic + Zelboraf + T	melanoma
NG/421	Cotellic + T	BRAF WT mM2L
	Tecentriq	solid tumors
	Tecentriq	NMIBC
	T-based Morpheus platform	pancreatic ca
	T + Cotellic ± Avastin	2/3L CRC
	T ± Avastin ± chemo	HCC, GC, PaC
	T + Cotellic	solid tumors
	T + ipi/IFN	solid tumors
RG7446	T + Tarceva/Alecensa	NSCLC
NG/440	T + anti-CD20 multiple combos	lymphoma
	T ± lenalidomide ± daratumumab	MM
	T + K/HP	HER2+ BC
	T + HMA	MDS
	T + radium 223	mCRPC
	T + guadecitabine	AML
	T + rucaparib	ovarian ca
	T + Gazyva/tazemetostat	r/r DLBCL + FL
RG7461	FAP IL2v FP + Tecentriq ± Avastin	RCC
RG7802	CEA TCB ± Tecentriq	solid tumors
RG7813	CEA IL2v FP* + Tecentriq	solid tumors
RG7828	CD20 TDB ± Tecentriq	solid tumors
RG7876	selicrelumab (CD40) + T	solid tumors
RG/8/6	selicrelumab + vanucizumab	solid tumors

AMGN**	Tecentriq + talimogene laherp	TNBC, CRC
BLRX**	Tecentriq + BL-8040	AML, solid tumors
CRVS**	Tecentriq + CPI-444	solid tumors
EXEL**	Tecentriq + cabozantinib	solid tumors
HALO**	Tecentriq + PEGPH20	CCC, GBC
INO**	Tecentriq + INO5401+INO9012	bladder ca
JNJ**	Tecentriq ± daratumumab	solid tumors
KITE**	Tecentriq + KTE-C19	r/r DLBCL

### **MORPHEUS Platform - Phase lb/II (4 Als)**

RG7446	T-based Morpheus	pancreatic cancer
	T-based Morpheus	gastric cancer
	T-based Morpheus	HR+ BC
	T-based Morpheus	NSCLC

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

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

RG-No Roche/Genentech
\*INN: cergutuzumab amunaleukin
T=Tecentriq; TCB=T cell bispecific
TDB=T cell dependent bispecific

### Phase II (5 Als)

RG7421	Cotellic + Tecentriq ± taxane	TNBC
Gradalis**	Tecentriq + Vigil	ovarian ca
GTHX**	Tecentriq + trilaciclib	SCLC
IMDZ**	Tecentriq + NY-ESO-1	soft tissue sarcoma
SNDX**	Tecentriq + entinostat	TNBC

### Phase III (20 Als)

RG7421	Cotellic + Zelboraf + T	1L BRAFm melanoma
	Cotellic + Tecentriq	1L BRAF WT melanoma
	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq Dx+	1L sq + non-sq SCLC
	Tecentriq	RCC adj
	T + nab-paclitaxel	1L non-sq NSCLC
	T + chemo + Avastin	1L ovarian cancer
	T + chemo + Avastin	1L non-sq NSCLC
	T + chemo + pemetrexed	1L non-sq NSCLC
RG7446	T + nab-paclitaxel	1L sq NSCLC
	T + nab-paclitaxel	1L TNBC
	T + nab-paclitaxel	TNBC neoadj
	T + Avastin	RCC
	T + Cotellic	3L CRC
	T ± chemo	1L mUC
	T + chemo	1L extensive stage SCLC
	T + enzalutamide	CRPC
	T + paclitaxel	1L TNBC
RG7446/RG7853	Tecentriq or Alecensa	1L NSCLC Dx+



## Doing now what patients need next