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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;
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**Roche**

**HY 2019 results**

*Basel, 25 July 2019*

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**Group**

*Severin Schwan*  
*Chief Executive Officer*



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## **HY 2019 performance**

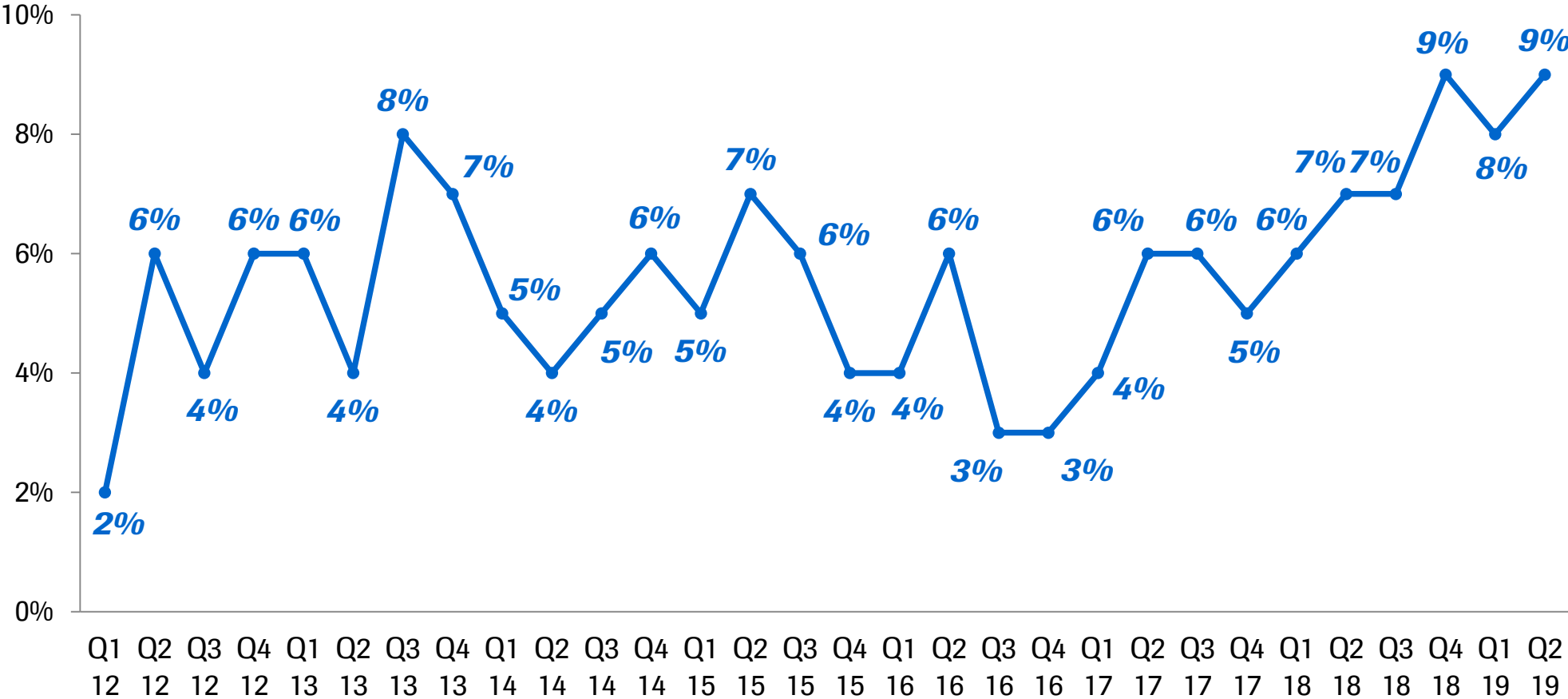
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## **Outlook**

# HY 2019: Strong sales growth

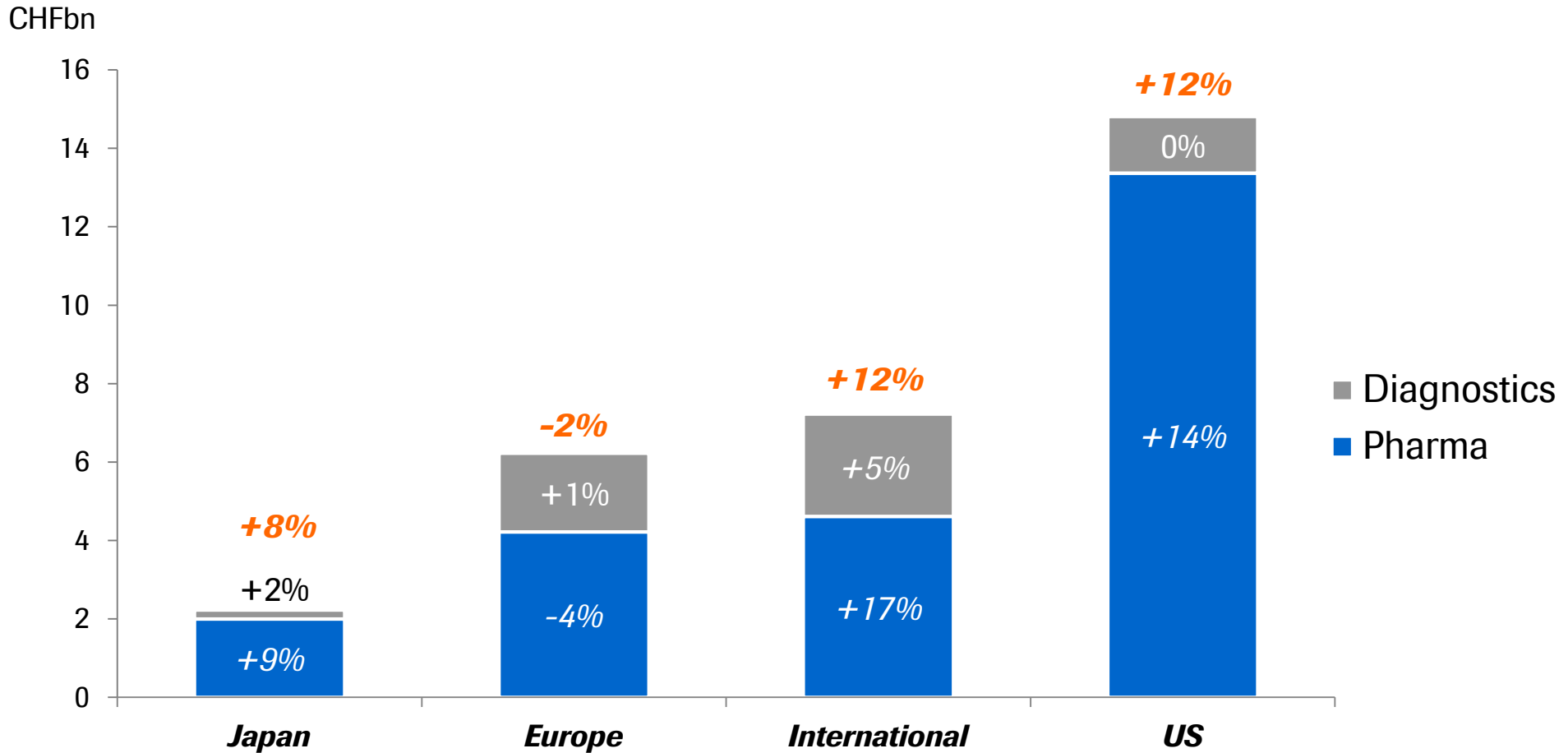
	<b>HY 2019</b>	<b>HY 2018</b>	<b>Change in %</b>	
	<b>CHFbn</b>	<b>CHFbn</b>	<b>CHF</b>	<b>CER</b>
<b>Pharmaceuticals Division</b>	<b>24.2</b>	21.8	<b>11</b>	<b>10</b>
<b>Diagnostics Division</b>	<b>6.3</b>	6.3	<b>0</b>	<b>2</b>
<b>Roche Group</b>	<b>30.5</b>	28.1	<b>8</b>	<b>9</b>

# Q2 2019: Group sales growth for the eighth consecutive year



All growth rates at Constant Exchange Rates (CER)

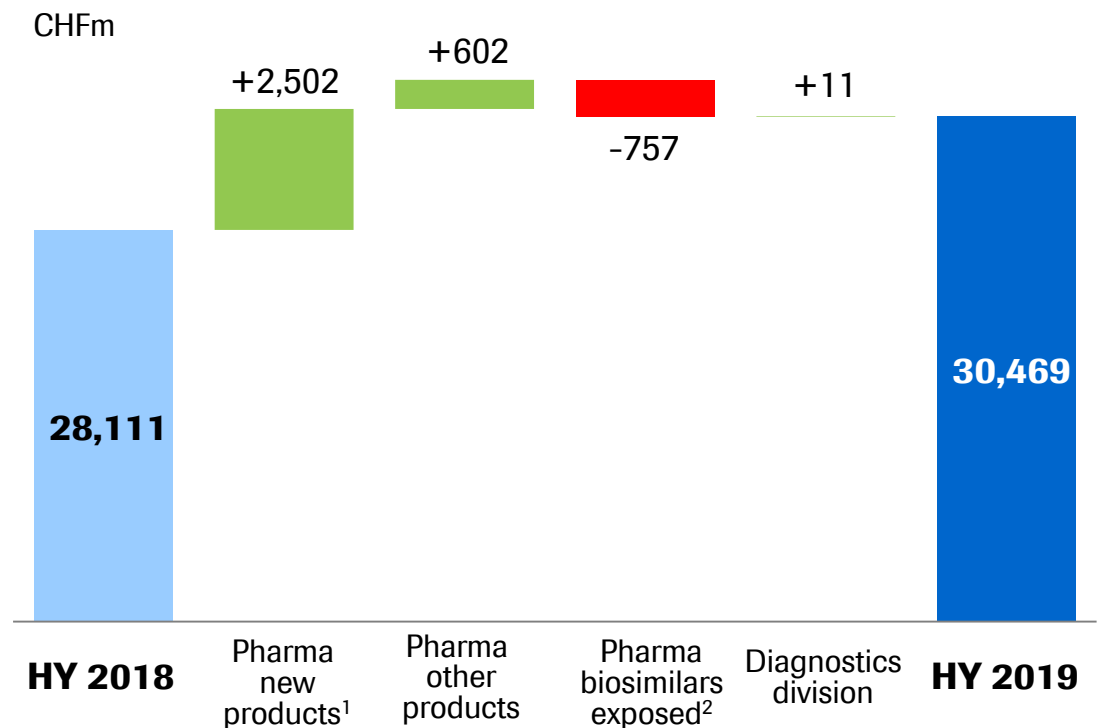
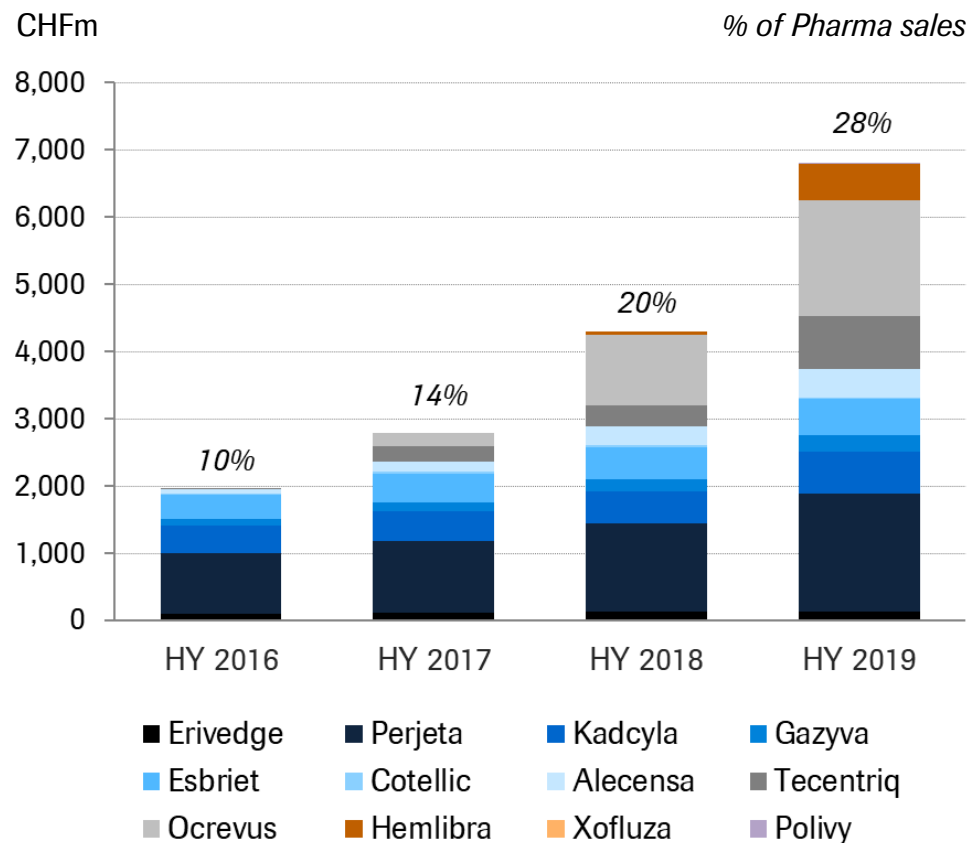
# HY 2019: Strong sales growth in US, International and Japan



All growth rates at Constant Exchange Rates (CER)

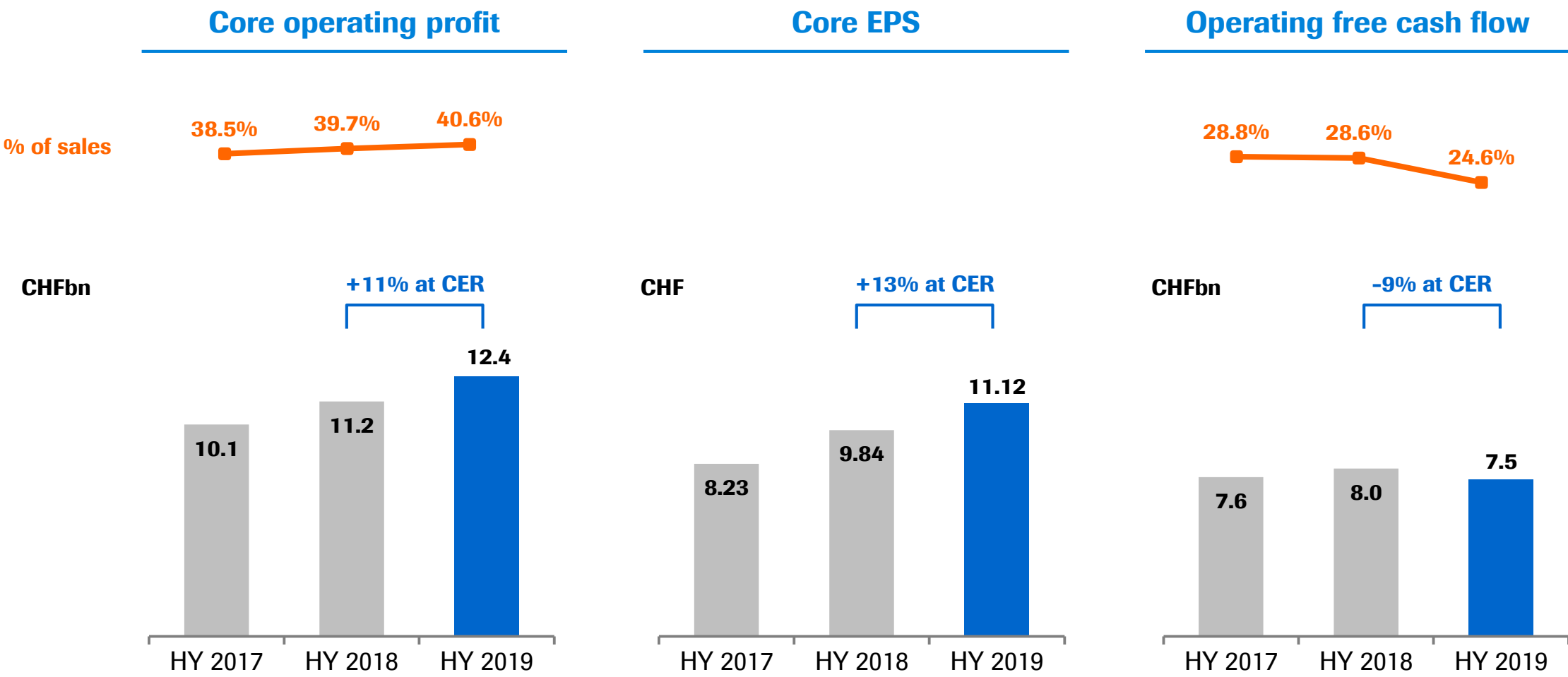


# New products with strong momentum



All absolute values are presented in CHFm reported; <sup>1</sup> Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, and Polivy; <sup>2</sup> MabThera and Herceptin in Europe and Japan

# HY 2019: Strong profitability growth



CER=Constant Exchange Rates

# Roche significantly advancing patient care

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

### 26 Breakthrough Therapy Designations (BTD)

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

### 7 Breakthrough Device Designations (BDD)

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

# Replace and extend the business: Excellent start into the year

## Replace/extend existing businesses

MabThera/Rituxan	Gazyva, Venclexta, Polivy, mosunetuzumab, CD20 x CD3
Herceptin	Perjeta, Kadcyla, Herceptin + Perjeta FDC-SC
Avastin	Tecentriq, Alecensa, Rozlytrek
Lucentis	faricimab Port delivery system (PDS)
Tamiflu	Xofluza

## Entering new franchises

<b>MS:</b> Ocrevus
<b>Hemophilia A:</b> Hemlibra
<b>CNS:</b> NMOSD, SMA, Huntington's, Autism, Alzheimer's

## Achievements HY 2019

### Entering new franchises

<b>Ocrevus:</b>	Treat early and with full dose to max benefit, good safety sustained (Data at AAN)
<b>satralizumab:</b>	Ph III mono & combo data – filing on-going
<b>risdiplam:</b>	1 year data in types 1/2/3 SMA
<b>Gazyva:</b>	Ph II positive headline in lupus nephritis
<b>Hemlibra:</b>	EU approval in Hemophilia A (non-inhibitors)

### Replace/extend existing businesses

<b>Gazyva+Ven:</b>	US approval in 1L CLL
<b>Polivy:</b>	US approval in R/R DLBCL
<b>Kadcyla:</b>	US approval in adj. HER2+ BC
<b>Tecentriq:</b>	EU approval in 1L NSCLC with Avastin US approval in 1L SCLC & 1L TNBC
<b>Herceptin:</b>	US approval Hylecta (SC formulation)
<b>Rozlytrek:</b>	JP approval in NTRK+ solid tumors
<b>Xofluza:</b>	US filing acceptance in high risk patients positive Ph IIIs in prevention and children

## **HY 2019 performance**

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## **Outlook**

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# Roche: Strong news flow over next 18 months

## *Diversifying the late stage pipeline and setting new SOC*

Product	Status
<b>risdiplam in SMA</b>	Phase II/III types 1/2/3
<b>HTT-ASO in Huntington's</b>	Phase II/III
<b>satralizumab in NMOSD</b>	Phase III (broad label)
<b>Gazyva in lupus nephritis</b>	Phase II
<b>etrolizumab in UC and Crohn's</b>	Phase III (induction and maintenance)
<b>PDS in nAMD</b>	Phase III
<b>faricimab in DME/nAMD</b>	Phase III

Neuroscience  
 Immunology  
 Ophthalmology  
 Oncology

Product	Status
<b>Tecentriq in 1L HCC</b>	Phase III
<b>Tecentriq in FL ovarian cancer</b>	Phase III
<b>Tecentriq in adj bladder cancer</b>	Phase III
<b>Tecentriq in neoadj TNBC</b>	Phase III
<b>Tecentriq in (neo)adj NSCLC</b>	Phase III
<b>Tecentriq in 1L melanoma</b>	Phase III (Dx+)
<b>Perjeta + Herceptin FDC-SC</b>	Phase III
<b>ipatasertib 1/2L TNBC</b>	Phase III (Dx+)
<b>ipatasertib 1L+ HR+</b>	Phase III (Dx+)
<b>ipatasertib in 1L mCRPC</b>	Phase III (all comers and Dx+)
<b>idasanutlin in R/R AML</b>	Phase III
<b>Polivy in 1L DLBCL</b>	Phase III

## 2019 outlook further raised

*Sales growth to “mid- to high-single digit” from “mid-single digit”*

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

- Mid- to high-single digit (from mid-single digit)

### Core EPS growth<sup>1</sup>

- Broadly in line with sales

### Dividend outlook

- Further increase dividend in Swiss francs

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

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## **Pharmaceuticals Division**

***Bill Anderson***  
***CEO Roche Pharmaceuticals***





# HY 2019: Pharmaceuticals Division sales

## *Strong growth in US, International and Japan*

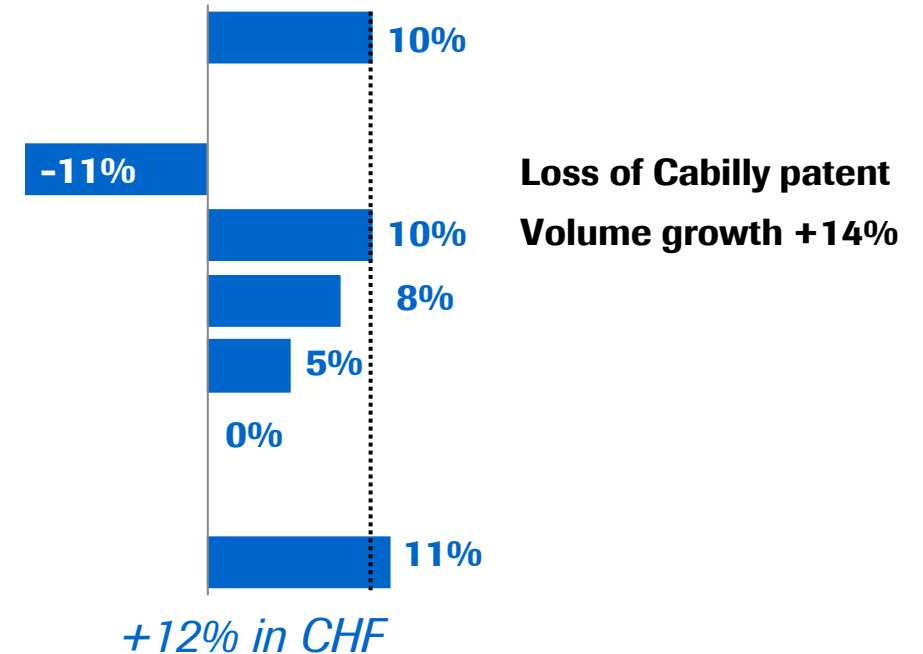
	HY 2019 CHFm	HY 2018 CHFm	Change in % CHF	CER
<b>Pharmaceuticals Division</b>	<b>24,194</b>	<b>21,847</b>	<b>11</b>	<b>10</b>
United States	13,370	11,378	18	14
Europe	4,221	4,528	-7	-4
Japan	1,988	1,781	12	9
International	4,615	4,160	11	17

# HY 2019: Pharma Division

*Strong Core operating profit grows ahead of sales*

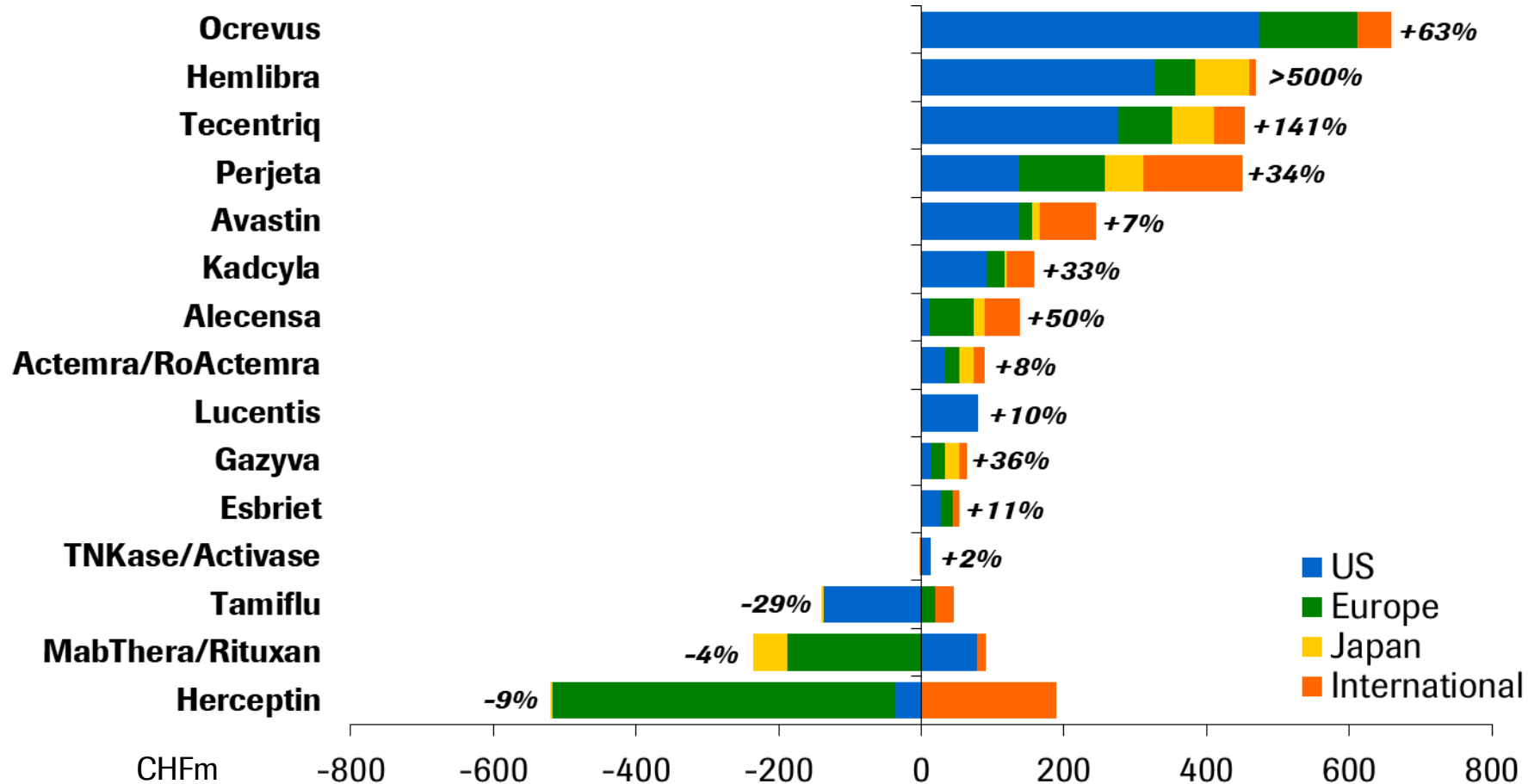
	HY 2019	
	CHFm	% sales
<b>Sales</b>	<b>24,194</b>	<b>100.0</b>
Royalties & other op. inc.	1,249	5.2
Cost of sales	-4,939	-20.6
M & D	-3,395	-14.0
R & D	-4,873	-20.1
G & A	-736	-3.0
<b>Core operating profit</b>	<b>11,500</b>	<b>47.5</b>

## 2019 vs. 2018 CER growth

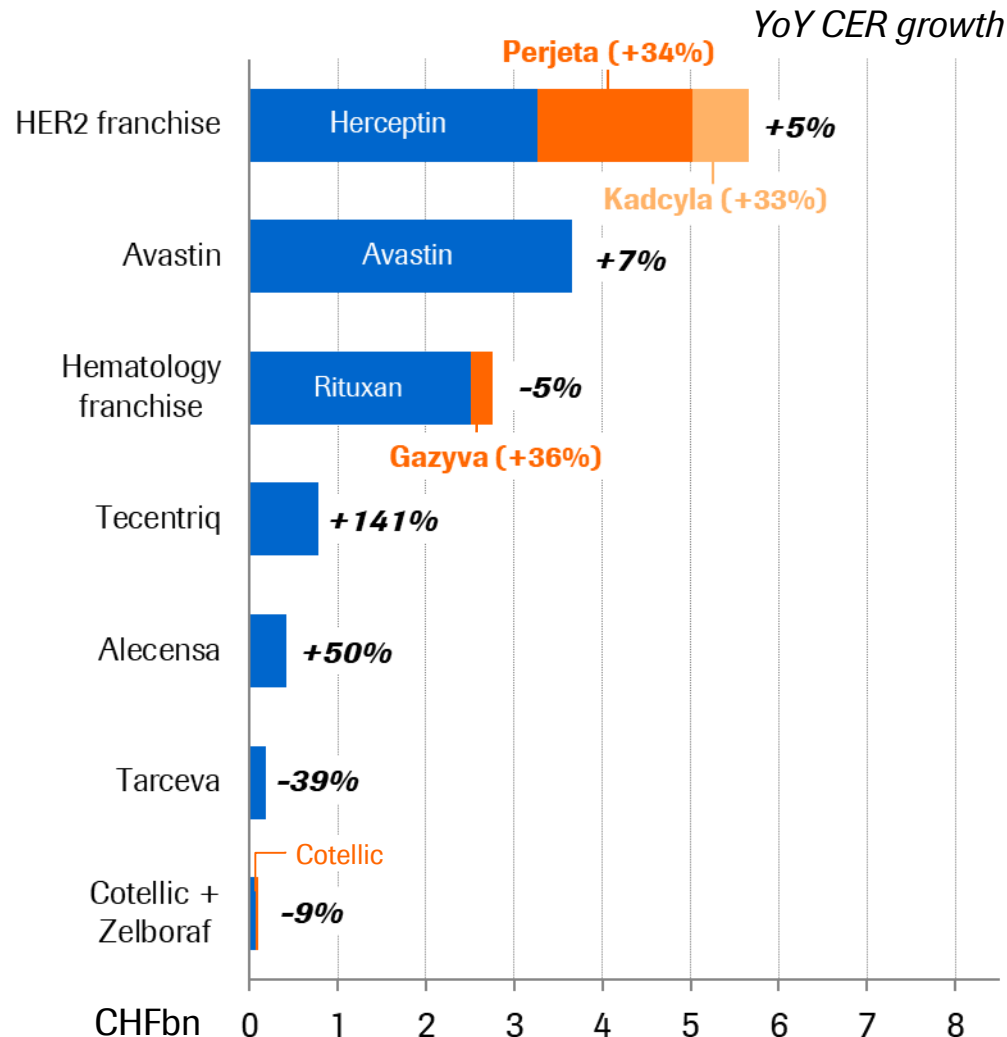


# HY 2019: Portfolio rejuvenation on-going

## *Strong growth from new products*



# HY 2019: Oncology sales +6% driven by recent approvals



## Oncology Q2 update

### HER2 franchise

- Perjeta: Growth driven by eBC
- Kadcylla: Strong uptake in adj BC and growth in 2L mBC

### Avastin franchise

- Stable growth in CRC and OC; strong uptake in China

### Hematology franchise

- Venclexta\*: Strong growth in 1L AML & 1L and R/R CLL
- Gazyva: Growth driven by approved indications

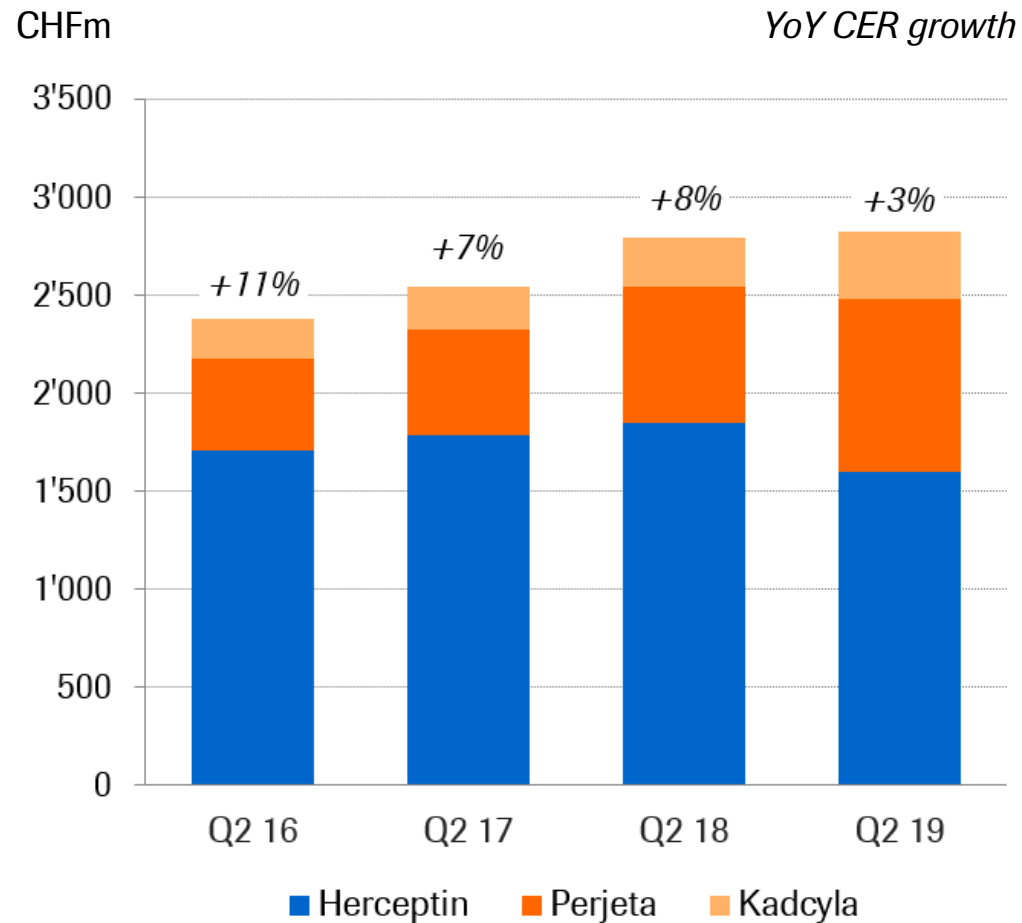
### Tecentriq

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

### Alecensa

- Further market share gains in 1L ALK+ NSCLC

# HER2 franchise: Growth due to Perjeta and Kadcylla



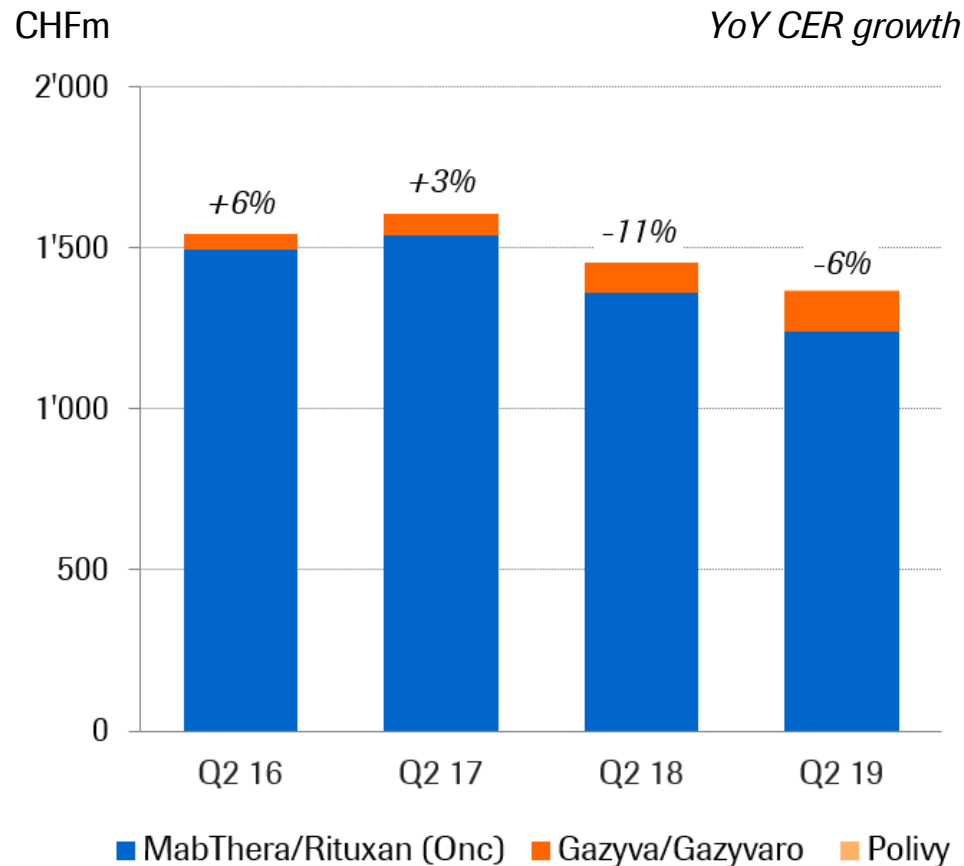
## HER2 franchise Q2 update

- Perjeta US (+9%): Growth driven by eBC (APHINITY); QoQ switching of eligible new patients to Kadcylla as planned
- Perjeta EU (+28%): Strong eBC uptake
- Kadcylla US (+62%): Growth in adjuvant setting for patients with residual disease (KATHERINE)

## Outlook 2019

- US/EU: Continued Perjeta and Kadcylla uptake in eBC
- US: Market entry of Herceptin biosimilars
- APHINITY 2<sup>nd</sup> OS interim analysis (5 years) and longer term iDFS results to be presented
- Ph III (FEDERICA) for Herceptin + Perjeta FDC-SC

# Hematology franchise: Increasing contribution from Gazyva, Venclexta, Polivy



## Hematology franchise Q2 update

### CD20 franchise

- MabThera (onc) EU (-33%): Erosion rate slows
- Gazyva (+38%): Growth driven by 1L FL

### Venclexta\*

- US: Strong growth driven by 1L and R/R CLL and 1L unfit AML
- US: Early approval for Venclexta + Gazyva in 1L CLL

### Polivy

- US: First sales following early approval in R/R DLBCL

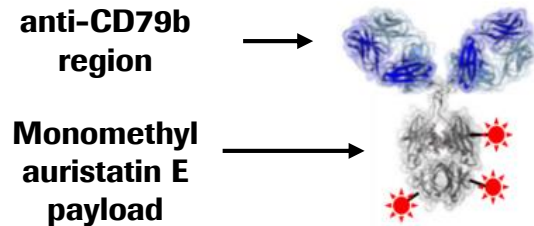
### Outlook 2019

- US: Market entry of Rituxan biosimilars expected in November
- EU: Polivy approval in R/R DLBCL

# Hematology franchise:

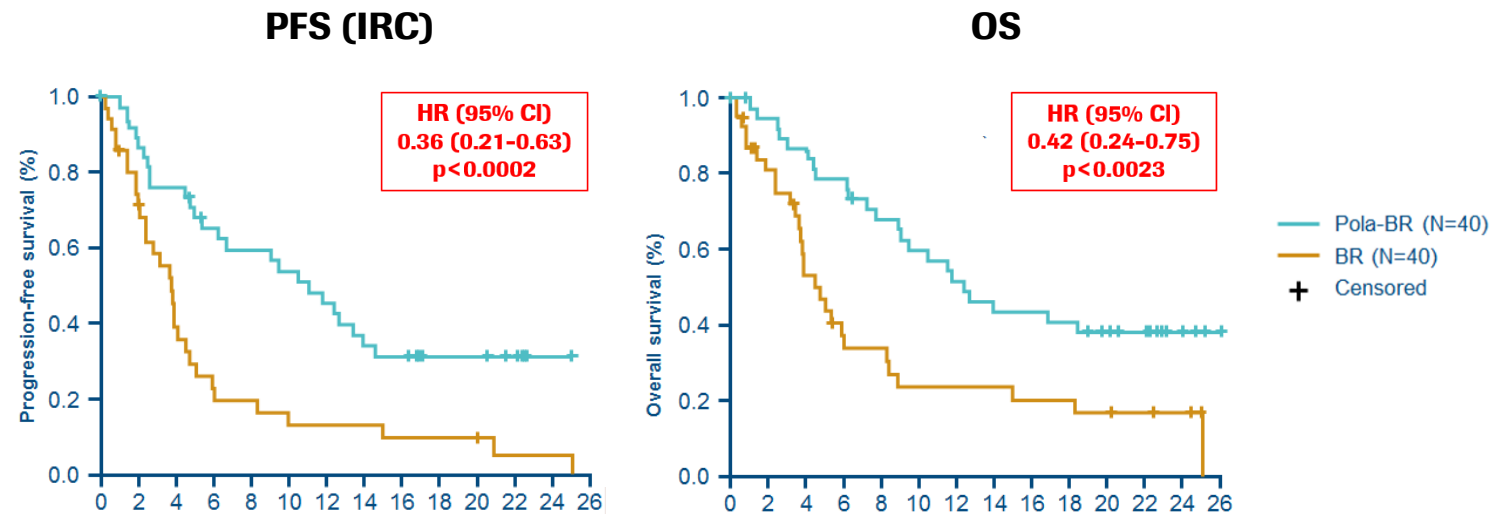
## *First approval for Polivy in R/R DLBCL*

### Polivy (polatuzumab vedotin)



- ADC targeting toxic payload to cells expressing CD79b
- Immediately accessible and economic off-the-shelf solution

### First and only pivotal randomized Ph II study with survival benefit <sup>1</sup>



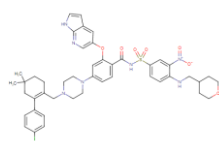
- Rapid uptake in R/R DLBCL following early US approval; EU approval expected in 2H
- Safely administered in combination with BR; potentially used as a bridge to consolidative therapies
- Ph III trials in 1L DLBCL (POLARIX) ongoing

# Hematology franchise:

## Fast approval for Venclexta + Gazyva in 1L CLL achieved

### Venclexta program

#### Bcl-2 inhibitor



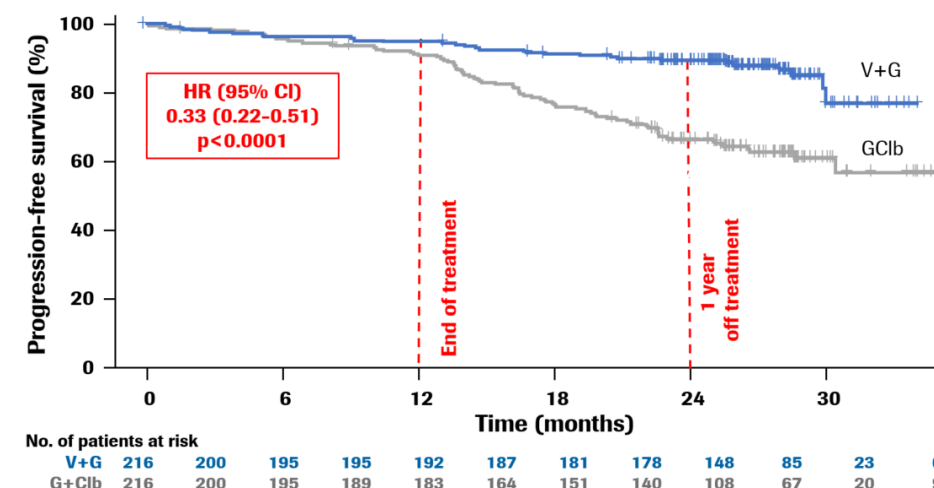
	Combination	Indication	Ph1	Ph2	Ph3
NHL	V+R/G+CHOP	1L DLBCL (aNHL)			
	V+R	DLBCL			
	V+polo+G/R	R/R DLBCL/FL			
CLL	V+G	1L CLL			✓
	V+R	R/R CLL			✓
	V	R/R CLL 17p			✓
	V	R/R CLL after ibru/idel			
	V+G	1L and R/R CLL			
MM	V+dex	t(11;14) R/R MM			
	V+bor+dex	R/R MM			
	V+Cotellic+/-T	R/R MM			
AML	V+aza	1L AML			✓
	V+LDAC	1L AML			✓
	V+idasanutlin	R/R AML unfit			
MDS	V+gilteritinib	R/R AML			
	V+aza	1L MDS			
	V+/-aza	R/R MDS			

### Minimal residual disease

	V+G	G+Clb
MRD-negative, %, bone marrow (95%CI)	57 (50-64)	17 (12-23)
p-value	<0.0001	
MRD-negative, %, peripheral blood (95%CI)	76 (69-81)	35 (29-42)
p-value	<0.0001	

### Ph III (CLL14) results:

#### IRC assessed PFS

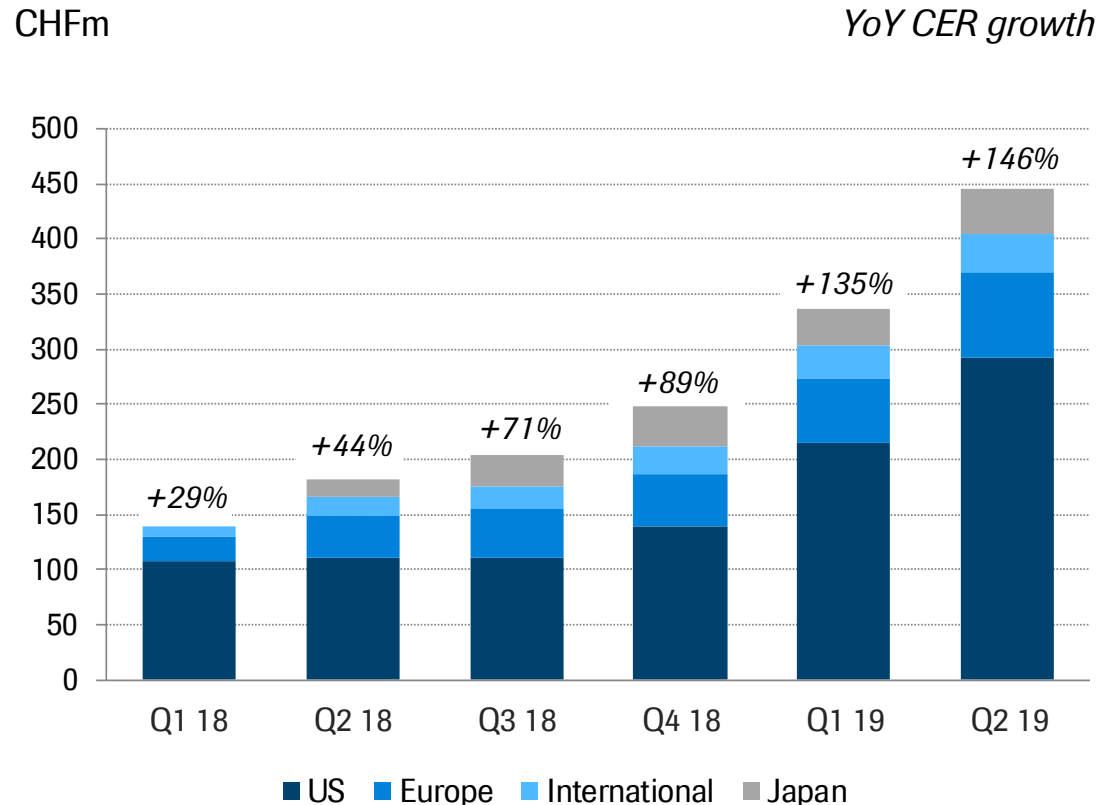


- PFS HR of 0.33 versus Gazyva + chlorambucil; mPFS not yet reached
- First fixed 12-month treatment, chemotherapy-free option
- Approval following 10 weeks after submission via the RTOR pilot program



# Tecentriq Q2 update

## *Global growth driven by lung and breast franchises*



### Lung franchise (NSCLC, SCLC)

- US: Growth driven by 1L NSCLC and first-in-class 1L SCLC
- EU: Increasing shares in 2L NSCLC; 1L NSCLC launches
- Japan: Strong launch in 1L NSCLC

### GU franchise (bladder cancer)

- US/EU: Stable shares in approved indications

### Breast franchise (TNBC)

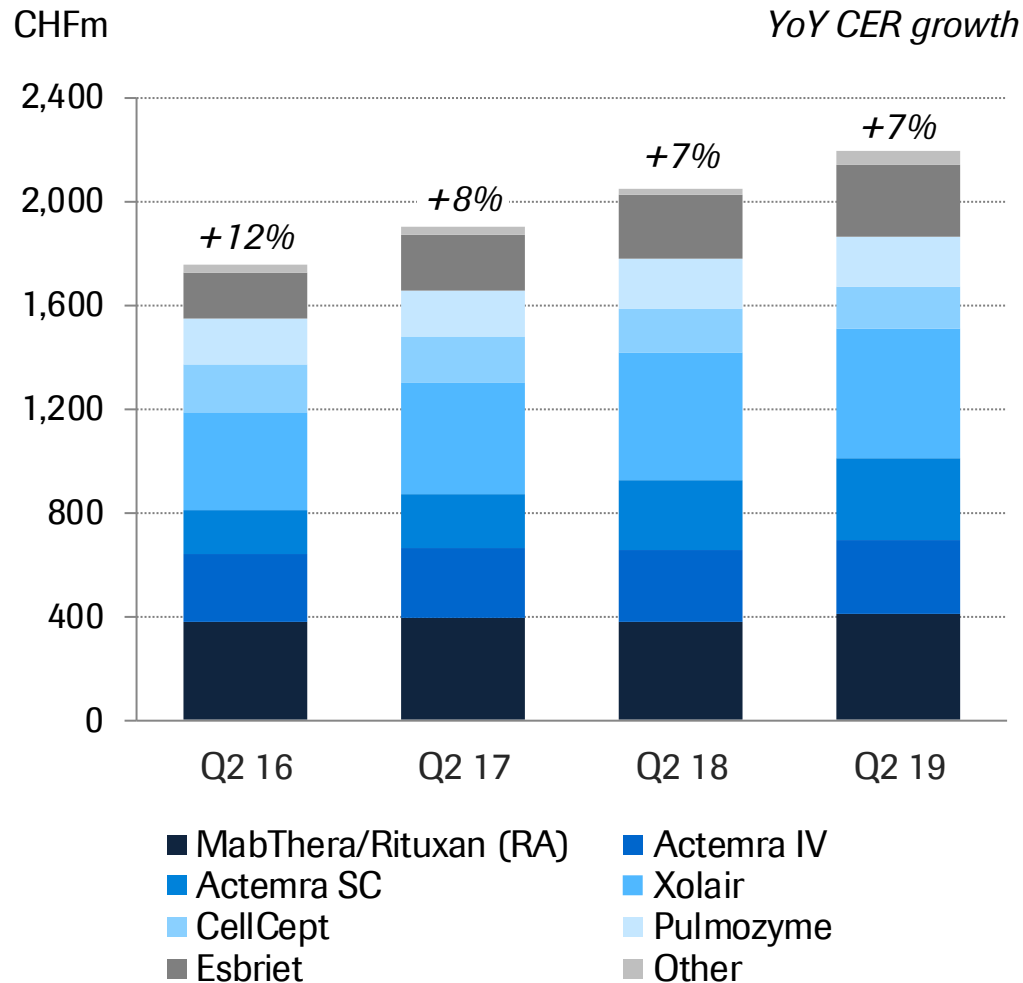
- US: Growth driven by first-in-class launch in PDL1+ 1L TNBC

### Outlook 2019

- EU approval in 1L SCLC and 1L TNBC
- 5 Ph III read-outs including HCC and BRAF+ melanoma

# Immunology franchise

## *Annualized sales approaching CHF 9bn*



### Immunology Q2 update

#### Esbriet (+13%)

- Growth in mild to moderate segments

#### Actemra (+10%)

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

#### Xolair (+2%)

- Growth driven by CIU
- Positive Ph III (POLYP I/II) results in nasal polyps

# Immunology franchise

## *Gazyva in immunology: Positive Ph II results in lupus nephritis*

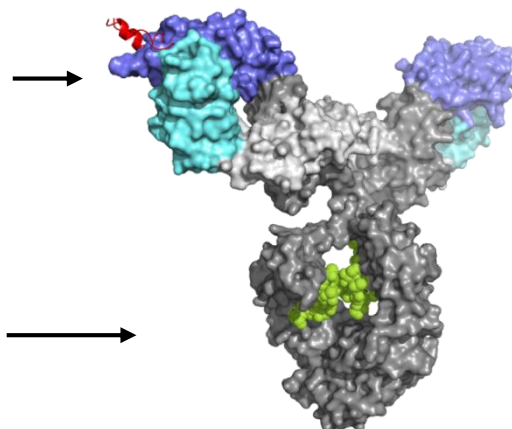
### Gazyva (glycoengineered anti-CD20 Mab)

#### Type II anti-CD20 region:

- Increased direct cell death
- Decreased CDC
- Reduced CD20 internalization

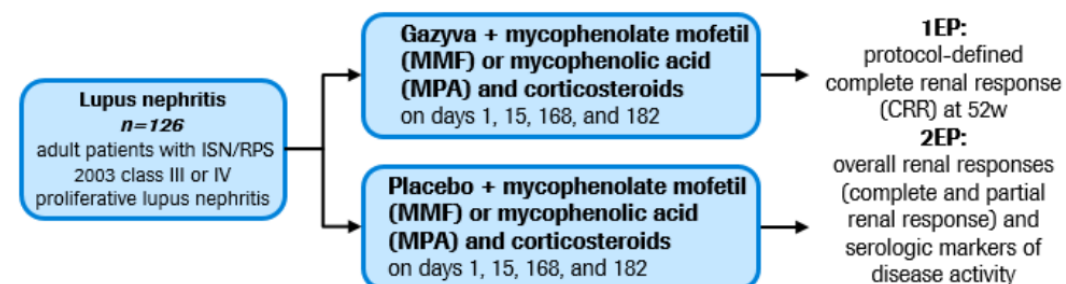
#### Glycoengineered Fc region:

- Higher FcγR affinity
- Enhanced ADCC/ADCP



- Gazyva's MOA shows greater potency than Rituxan in depleting peripheral and tissue-based B cell populations
- Recent studies suggest that tissue-based B cells play a role in lupus nephritis and that their complete depletion is needed

### Ph II (NOBILITY) results:

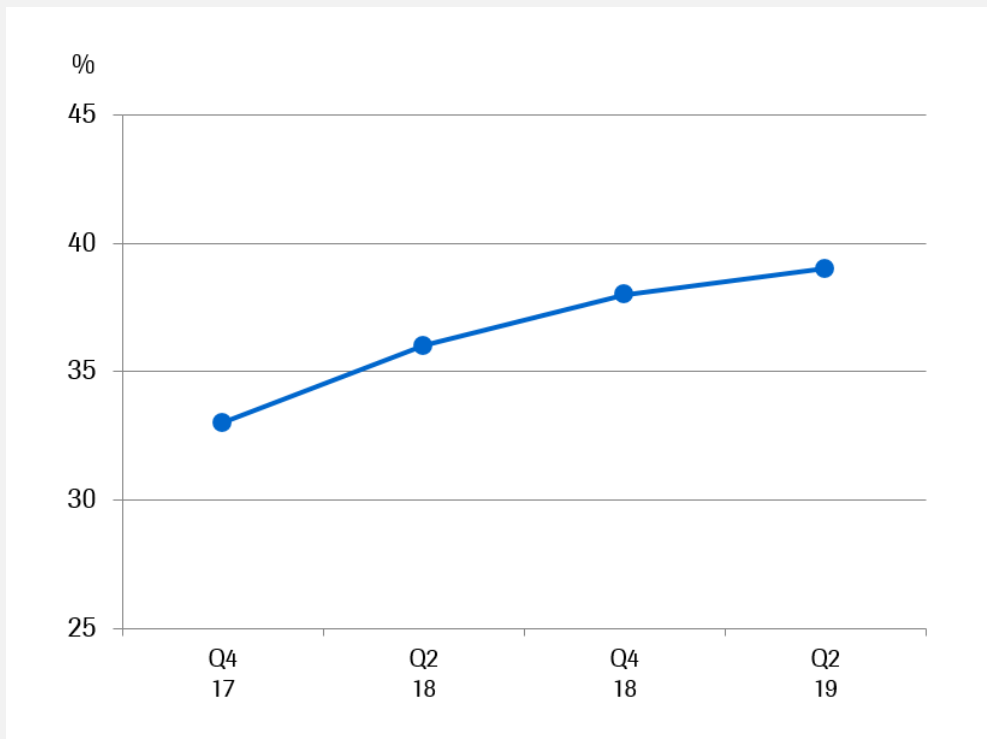


- Ph II (NOBILITY) met both primary and key secondary endpoints
- High unmet medical need; no treatment approved
- Data to be presented; Ph III program to be initiated

# Neuroscience franchise

*Close to 4 out of 10 MS patients in the US start a new therapy on Ocrevus*

New to brand patient share (US) <sup>1</sup>

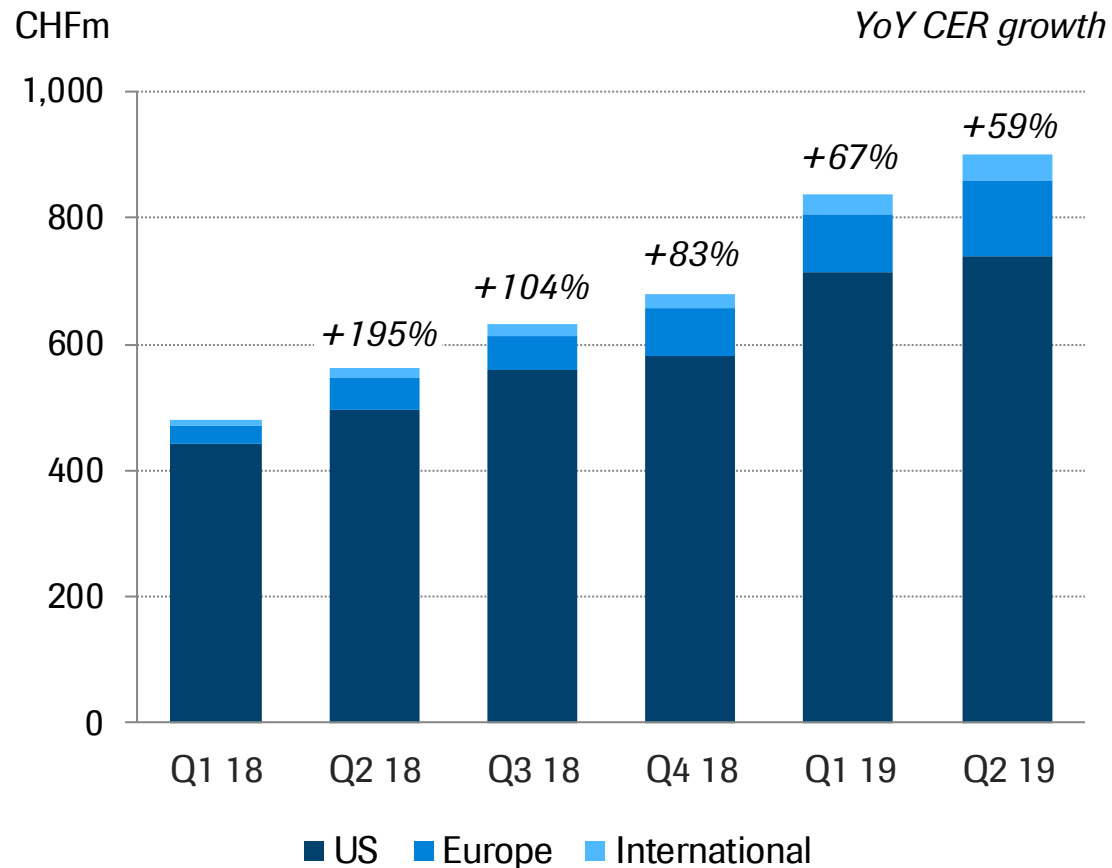


## Key milestones achieved

- No.1 prescribed DMT in the US for MS patients starting a new therapy<sup>1</sup>
- >100,000 patients have been treated globally
- >5,000 US neurologists have prescribed Ocrevus
- Safety profile remains in-line with benefit/risk from pivotal studies
- 5.5 years of long term safety data

# Neuroscience franchise

## *Ocrevus reaches 17% total US market share <sup>1</sup>*



### Ocrevus Q2 update

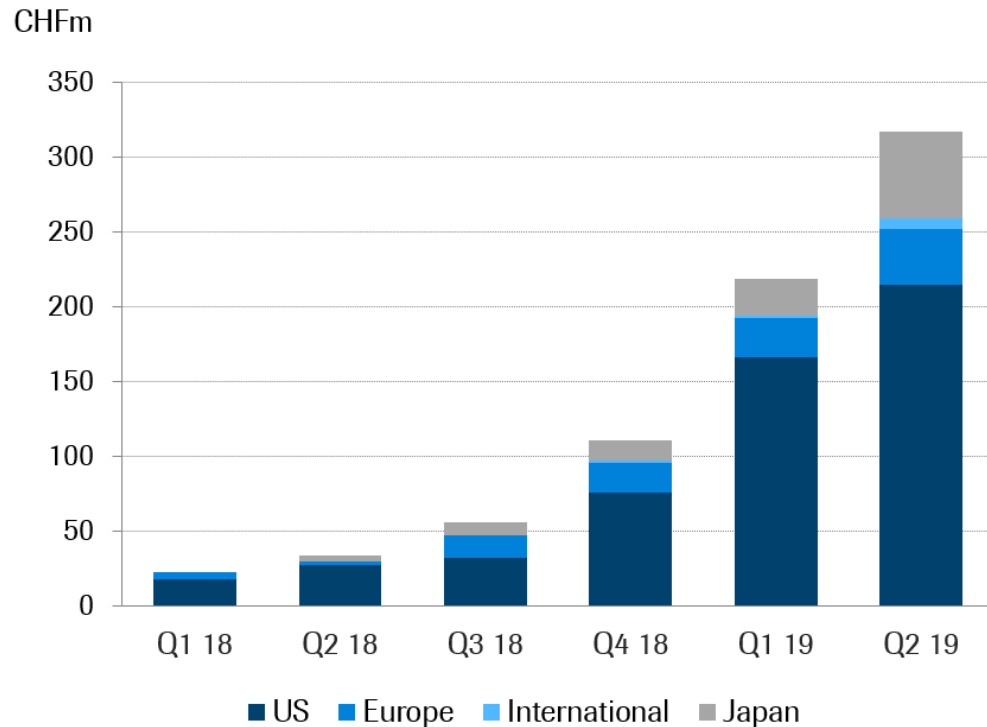
- US driven by continued growth in earlier lines and strong demand from returning patients
- Strong launches in EU and International
- Updated US label includes active SPMS and CIS

### Outlook 2019

- Moving into earlier lines displacing orals
- Ongoing launches in EU and International
- 13 on-going and new Ph III/IV studies

# Hemophilia A franchise

*Hemlibra with 14% total US market share after 20 months*



## Hemlibra Q2 update

- US: Strong uptake in non-inhibitors driven by large centers and patient requests
- Japan: Strong uptake in non-inhibitors and inhibitors
- Overall >3,500 patients treated globally
- ISTH: Pooled HAVEN data analysis shows 87.3% of patients without treated joint bleeds at weeks 25-48

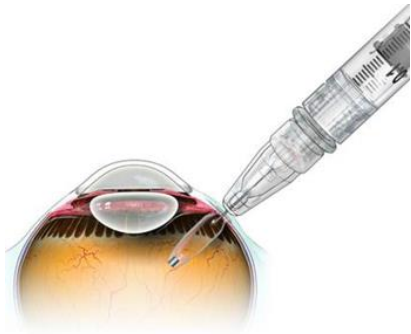
## Outlook 2019

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

# Ophthalmology franchise

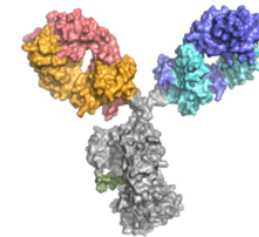
*Pivotal studies enrolling rapidly; worldwide rights to PDS secured*

## Port delivery system (PDS) with ranibizumab



- Ph III (ARCHWAY) in nAMD at fixed Q6M dosing fully recruited, data expected in 2020
- Ex-US rights to PDS with ranibizumab acquired from Novartis
- New indications, new MOAs in PDS planned to leverage platform technology

## Faricimab (anti-VEGF/Ang-2 biMab)



### anti-Ang-2

- Enhanced vessel stabilisation through Ang-2 inhibition

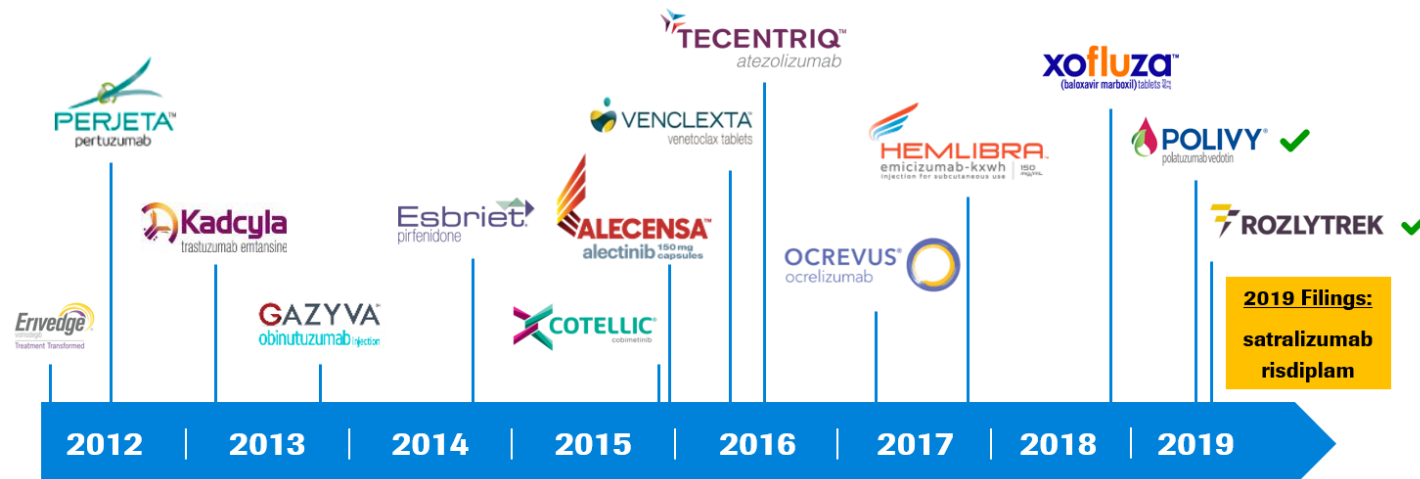
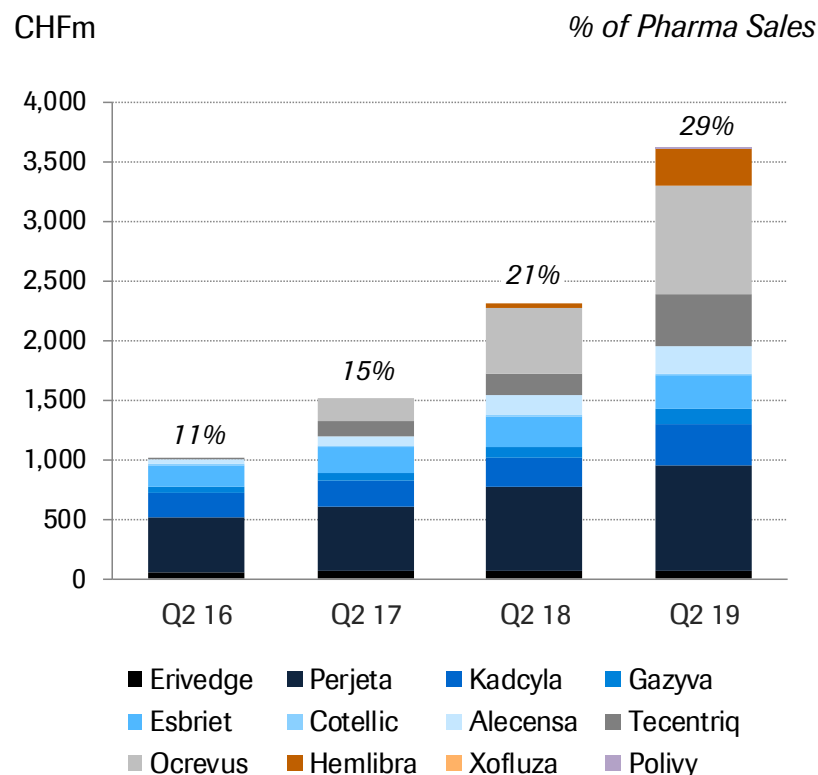
### anti-VEGF-A

- Proven efficacy through VEGF-A inhibition

- First bi-specific antibody in ophthalmology
- Robust Ph II data in DME and nAMD
- Rapid enrollment in the global Ph III studies in DME (YOSEMITE, RHINE) and nAMD (TENAYA, LUCERNE)

# New products exceed annualized sales of CHF 14bn\*

## *First approval for Polivy and Rozlytrek achieved*



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



# Strong short term news flow

*Diversifying the late stage pipeline and setting new standards of care*

Product	Filing date	Population
<b>risdiplam in SMA</b>	2019 in type 1/2/3	~ <b>18k</b> (rare disease)
<b>satralizumab in NMOSD</b>	2019	~ <b>21k</b> (rare disease)
<b>HTT-ASO in Huntington's</b>	Ph II & III ongoing; filing latest 2022	~ <b>83k</b> (rare disease)
<b>Gazyva in lupus nephritis</b>	initiating Ph III	~ <b>190k</b>
<b>etrolizumab in UC and Crohn's Disease</b>	filing in UC in 2020	<b>UC ~700k</b> <b>CD ~640k</b> (moderate to severe)
<b>PDS in nAMD</b>	fully recruited; filing in 2020	<b>nAMD ~4,090k</b> <b>DME ~4,400k</b>
<b>faricimab in DME/nAMD</b>	recruitment ahead of plan; filing in 2021/22	

Neuroscience
  Ophthalmology  
 Immunology
  Oncology

Product	Filing date	Population
<b>Tecentriq in 1L HCC</b>	2019	~ <b>300k<sup>1</sup></b>
<b>Tecentriq in neoadj TNBC</b>	2020	~ <b>19k</b>
<b>Tecentriq in adj bladder cancer</b>	2020	~ <b>50k</b>
<b>Tecentriq in 1L melanoma</b>	2020	~ <b>11k</b> (Dx+)
<b>Tecentriq in FL ovarian cancer</b>	2020	~ <b>41k</b>
<b>idasanutlin in R/R AML</b>	2020	~ <b>22k</b>
<b>Perjeta + Herceptin FDC-SC</b>	2020	~ <b>75k</b>
<b>ipatasertib 1/2L TNBC</b>	2020	~ <b>11k</b> (Dx+)
<b>ipatasertib 1L+ HR+ (chemo treated only)</b>	2020	~ <b>83k</b> (Dx+) ~ <b>15k</b> (Dx+/chemo only)
<b>ipatasertib in 1L mCRPC</b>	2020	~ <b>200k</b> (AC) <b>100k</b> (Dx+)
<b>Polivy in 1L DLBCL</b>	2020/21	~ <b>52k</b>
<b>Tecentriq in (neo)adj NSCLC</b>	2021/22	~ <b>75k</b>

Source: Roche/Genentech, incidence/prevalence in the major markets (US, FR, DE, IT, ES, GB); <sup>1</sup> including China; SOC=standard of care; SMA=spinal muscular atrophy; NMOSD=neuromyelitis optica spectrum disorder; UC=ulcerative colitis; CD=Crohn's disease; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; HCC=hepatocellular carcinoma; TNBC=triple-negative breast cancer; FL=front line; R/R AML=relapsed/refractory acute myeloid leukemia; FDC=fixed dose combination; HR=hormone receptor; mCRPC=metastatic castration resistant prostate cancer; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer; AC=all comers

# Roche Pharma Day 2019

## *Strategic business outlook and late stage pipeline update*



### **Roche Pharma Day 2019**

#### ***London***

**Monday, 16 September 2019, 9:00am-2:45pm BST**

#### **Meeting information:**

09:00am Registration  
09:30am Event starts  
2:45pm Event ends  
followed by a buffet reception

#### **Venue:**

Hilton London Tower Bridge  
5 More London Place  
Tooley Street, London  
SE1 2BY

#### **Senior management present:**

- Bill Anderson, CEO Pharma
- Sandra Horning, Chief Medical Officer and Head Global Product Development
- Teresa Graham, Head of Global Product Strategy
- Paulo Fontoura, Global Head Neuroscience and Rare Diseases Clinical Development
- Elena Bernedo-Arzac, Head Oncology Global Product Strategy
- Cristin Hubbard, Head I2O Global Product Strategy
- Zafar Hakim, I2O Global Product Strategy
- Atul Dandekar, Global Head of Ophthalmology, I2O Global Product Strategy
- Sascha Fauser, Global Head of Ophthalmology pRED
- Bryn Roberts, Global Head of Operations pRED

# 2019: Key late-stage news flow\*

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

## Additional 2019 news flow:

- **MabThera/Rituxan**: EU approval of pemphigus vulgaris
- **Herceptin Hylecta**: US approval SC formulation
- **Venclexta + Gazyva**: US approval in 1L unfit CLL; EU filed

- **Rozlytrek**: Japan early approval for NTRK+ solid tumors
- **Gazyva**: Positive Ph II results in lupus nephritis
- **Xolair**: Positive Ph III results in nasal polyps

\*Outcome studies are event-driven: timelines may change; \*\* Study met its primary endpoint of PFS: 22.4m vs. 11.5m with a HR of 0.63; Higher proportion of deaths in Venclexta arm; IA=interim analysis

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## **Diagnostics Division**

***Michael Heuer***  
***CEO Roche Diagnostics***



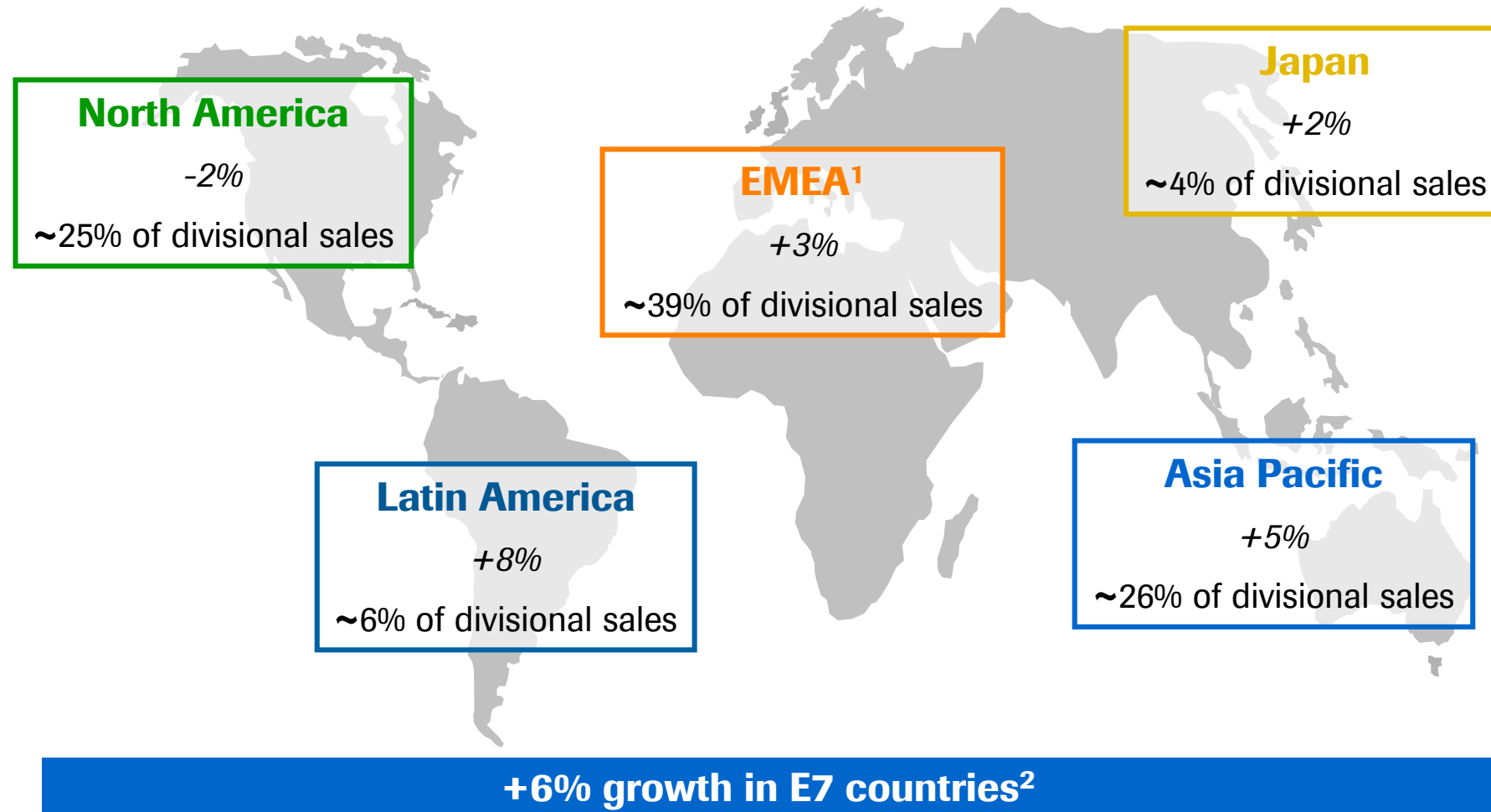
# HY 2019: Diagnostics Division sales

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

	HY 2019 CHFm	HY 2018 CHFm	Change in %	
			CHF	CER
<b>Diagnostics Division</b>	<b>6,275</b>	<b>6,264</b>	<b>0</b>	<b>2</b>
Centralised and Point of Care Solutions	3,762	3,755	0	3
Molecular Diagnostics	1,029	979	5	6
Diabetes Care	958	991	-3	1
Tissue Diagnostics	526	539	-2	-3

# HY 2019: Diagnostics Division regional sales

## *Growth driven by Asia Pacific and EMEA*

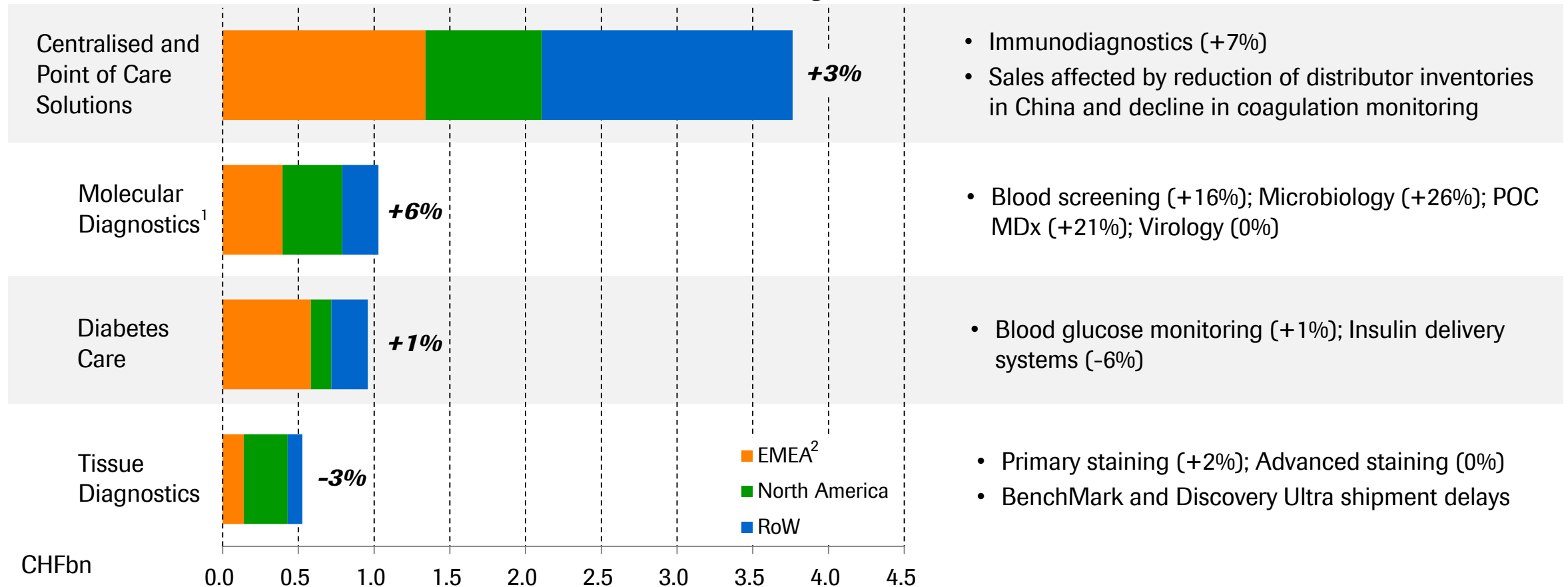


<sup>1</sup> Europe, Middle East and Africa; <sup>2</sup> Brazil, China, India, Mexico, Russia, South Korea and Turkey; all growth rates at Constant Exchange Rates (CER)

# HY 2019: Diagnostics Division highlights

## *Growth driven by Immunodiagnostics*

### YoY CER growth



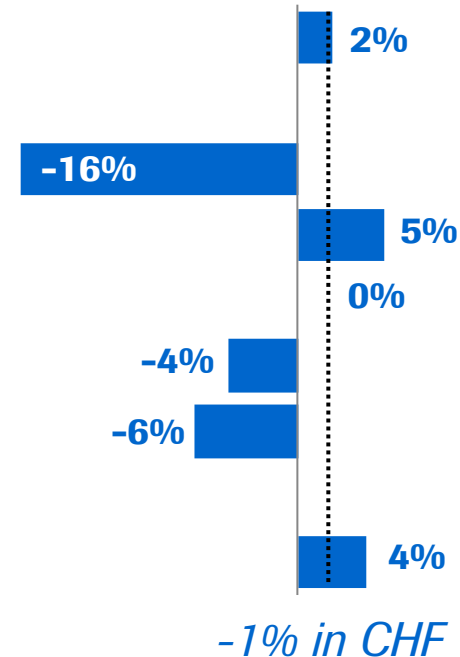
<sup>1</sup> Underlying growth of Molecular Diagnostics excluding sequencing business: +5%; <sup>2</sup> EMEA=Europe, Middle East and Africa; CER=Constant Exchange Rates

# HY 2019: Diagnostics Division

*Core operating profit growing at +4%*

	HY 2019	
	CHFm	% sales
<b>Sales</b>	<b>6,275</b>	<b>100.0</b>
Royalties & other op. inc.	33	0.5
Cost of sales	-2,929	-46.6
M & D	-1,405	-22.4
R & D	-688	-11.0
G & A	-222	-3.5
<b>Core operating profit</b>	<b>1,064</b>	<b>17.0</b>

## 2019 vs. 2018 CER growth

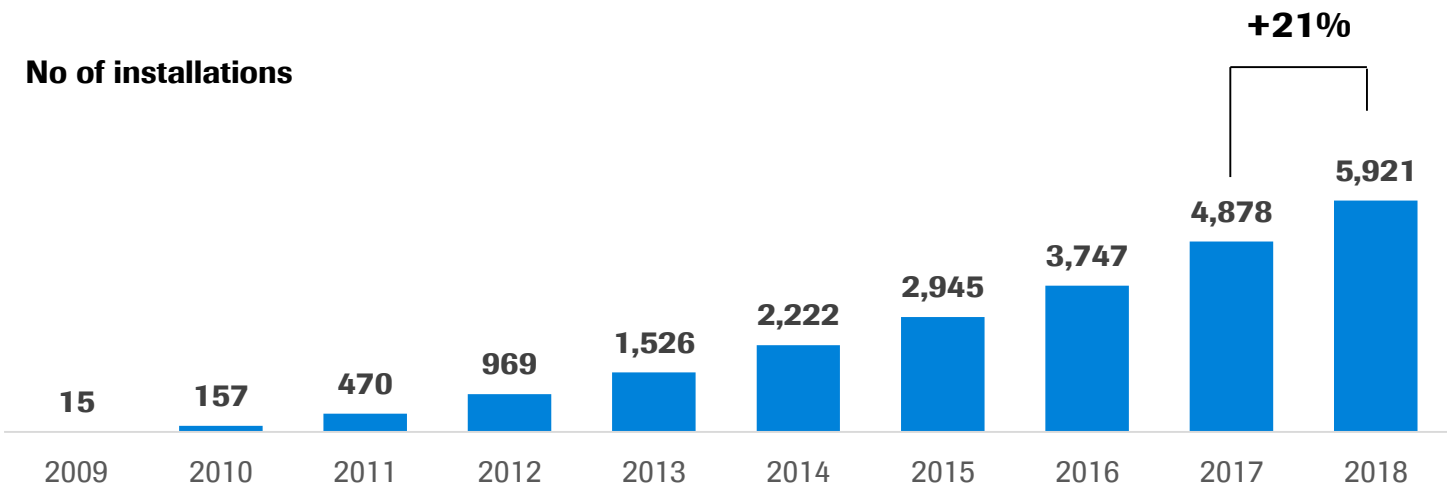




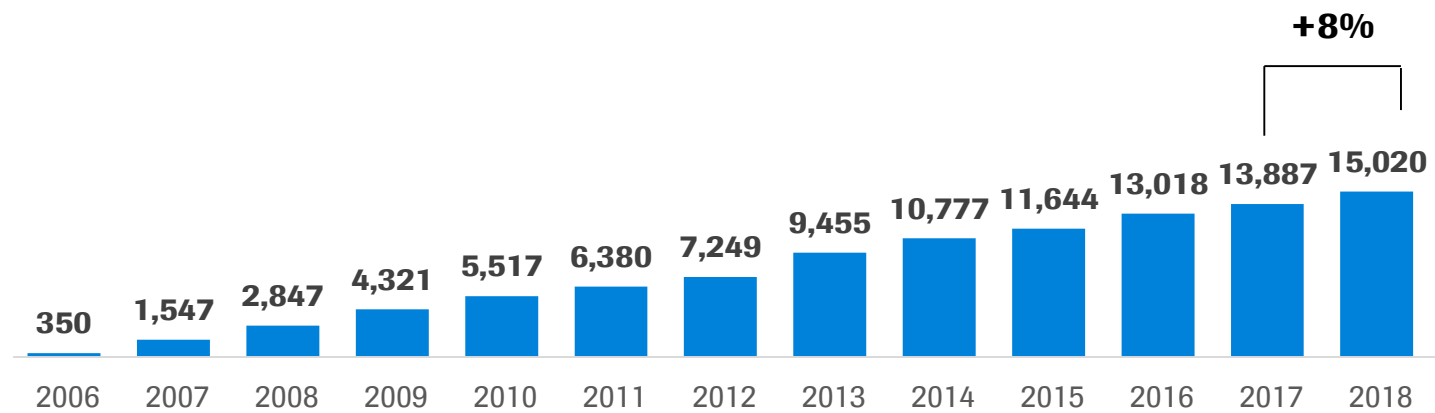
# Increasing our installed base to ensure future growth



**cobas 8000 modular analyzer series**



**cobas 6000 modular analyzer series**



# FDA clearance of cobas<sup>®</sup> TV/MG

## *Menu expansion of high volume STI testing on cobas 6800/8800*



- Better diagnosis and screening of STIs and improved patient care
- Ability to test four STIs from a single patient sample
- Highest throughput testing solution on the market today for combination CT/NG and TV/MG testing

**Installed instrument base: >700\***

\*June 2019

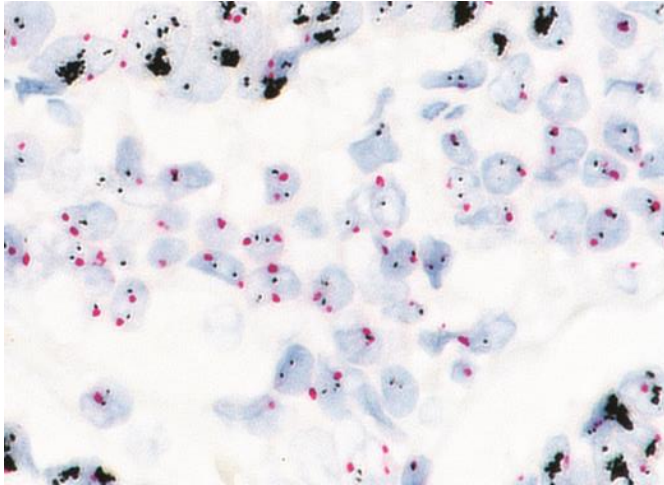
# cobas<sup>®</sup> 6800/8800 systems driving growth in molecular

## *Continued menu expansion of our high medical value assays*

Donor Screening		Infectious Disease		Sexual Health		Transplant		Respiratory		Antimicrobial Stewardship	
MPX	✓	HIV-1	✓	HPV	✓	CMV	✓	MTB	✓	MTB-RIF/INH	✓
WNV	✓	HBV	✓	CT/NG	✓	EBV	<b>Launch 2019</b> (CE-IVD in 2019, US-IVD in 2020)	MAI	✓		
DPX	✓	HCV	✓	TV/MG	✓	BKV	<b>Launch 2019</b> (CE-IVD in 2019, US-IVD in 2020)	MPLX Respiratory			
HEV (Not available in the US)	✓	HIV-1/2 Qual (CE-IVD, <b>US-IVD in 2020</b> )	✓	HPV Self Sampling (CE-IVD in 2020)				(CE-IVD in 2020, US-IVD in 2021)			
CHIKV/DENV (Not available in the US)	✓										
Zika (US-IVD, <b>CE-IVD in 2019</b> )	✓										
Babesia (US-IND, US-IVD & CE-IVD in 2019)											

# VENTANA HER2 dual ISH DNA probe cocktail

## *Brightfield microscopy as an alternative to FISH testing*



← HER2+ receptor



**Increased performance**, with oligo probes and new detection kits; highly concordant with FISH



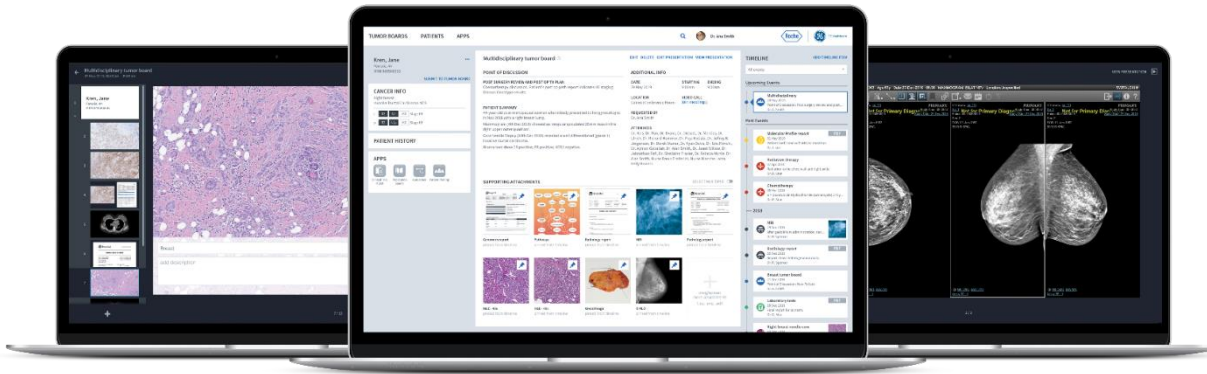
**Brightfield** assay that allows for interpretation within the context of tissue morphology



**CE IVD** assay, indicated for patients for whom Herceptin treatment is considered

# NAVIFY Tumor Board 2.0 in collaboration with GE Healthcare

## *Clinical decision support with medical imaging capabilities*



### NAVIFY Tumor Board 2.0:

- Integration of GE Healthcare's medical image viewer\* into NAVIFY Tumor Board 2.0
- Enables radiologists to upload patient records to same dashboard as patient files from other disciplines

# Key launches 2019



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

<sup>1</sup> CE: European Conformity, US: FDA approval, WW: Worldwide; GEHC DICOM: GE Healthcare Digital Imaging and Communications in Medicine; T2: Type II Diabetes; PwDs: People with Diabetes

<sup>2</sup> NAVIFY Mutation Profiler and Therapy Matcher received CE mark; US approval expected by end of 2019.

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## Finance

*Alan Hippe*  
*Chief Financial Officer*



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## **HY 2019 results**

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**Focus on Cash**

**Outlook**



# HY 2019: Highlights

## *Business*

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- Sales growth of +9%<sup>1</sup> and Core operating profit up +11%<sup>1</sup>
- Core EPS growth +13%<sup>1</sup>

## *Cash flow*

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- Operating Free Cash Flow of CHF 7.5bn, -9%<sup>1</sup> lower due to higher net working capital and higher investments in intangible assets
- Net debt lower by CHF 3.3bn vs. Jun 30<sup>th</sup> 2018; higher by CHF 2.7bn vs. Dec 31<sup>st</sup> 2018 due to dividend payments

## *Net financial results*

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- Net financial result decreased by -55%<sup>1</sup> driven by lower income from Equity securities

## *IFRS*

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- Net income +19%<sup>1</sup> driven by business growth and lower income tax expenses

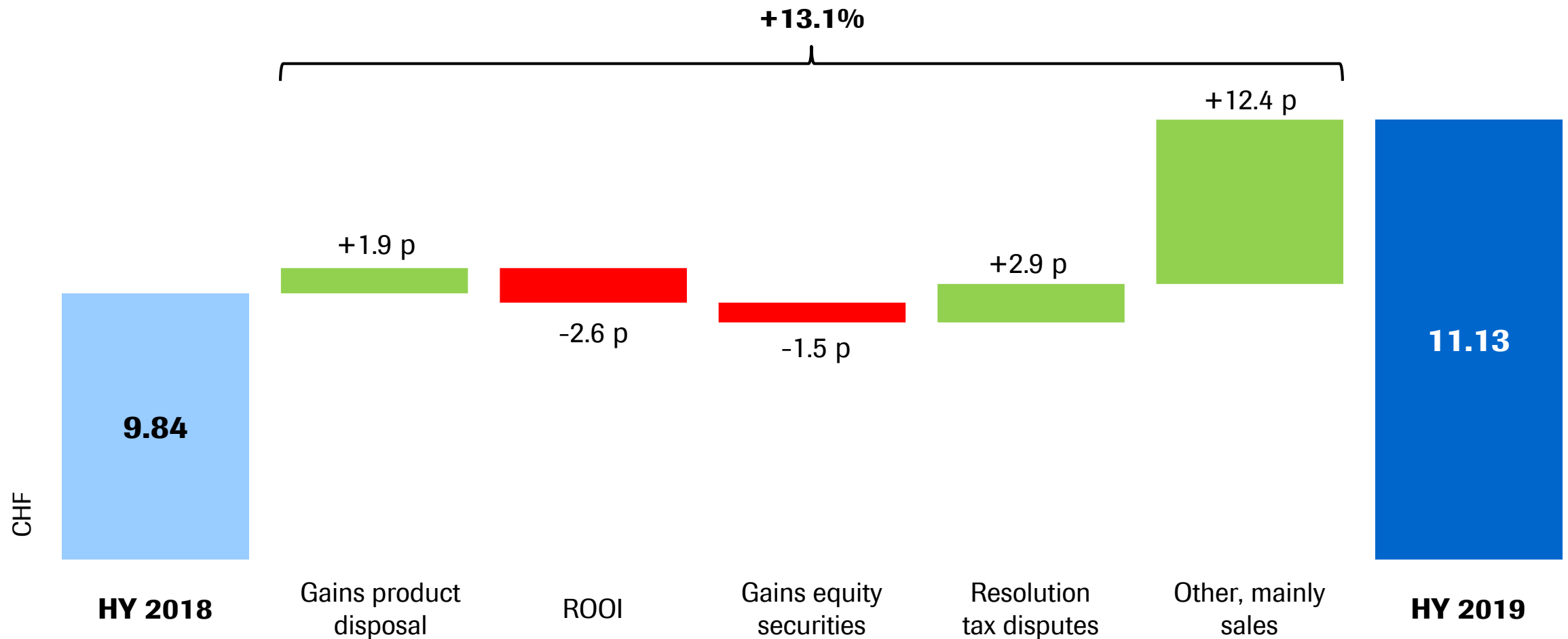
<sup>1</sup> At Constant Exchange Rates (CER)

# HY 2019: Group performance

*Core Operating profit up +11%; Core EPS growth of +13%*

	HY 2019 CHFm	HY 2018 CHFm	Change in % CHF	CER
<b>Sales</b>	<b>30,469</b>	<b>28,111</b>	<b>8</b>	<b>9</b>
<b>Core operating profit</b> <i>as % of sales</i>	<b>12,363</b> 40.6	<b>11,162</b> 39.7	<b>11</b>	<b>11</b>
<b>Core net income</b> <i>as % of sales</i>	<b>9,896</b> 32.5	<b>8,679</b> 30.9	<b>14</b>	<b>14</b>
<b>Core EPS (CHF)</b>	<b>11.12</b>	<b>9.84</b>	<b>13</b>	<b>13</b>
<b>IFRS net income</b>	<b>8,904</b>	<b>7,516</b>	<b>18</b>	<b>19</b>
<b>Operating free cash flow</b> <i>as % of sales</i>	<b>7,508</b> 24.6	<b>8,042</b> 28.6	<b>-7</b>	<b>-9</b>
<b>Free cash flow</b> <i>as % of sales</i>	<b>5,277</b> 17.3	<b>5,966</b> 21.2	<b>-12</b>	<b>-13</b>

# HY 2019: Core EPS development



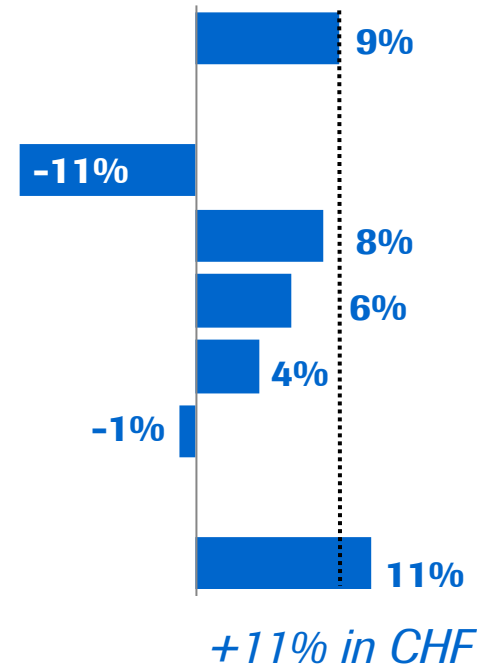
All at CER (Constant Exchange Rates, average FY 2018); <sup>1</sup> ROOI = Royalties and other operating income excl. Gains on product disposals

# HY 2019: Group operating performance

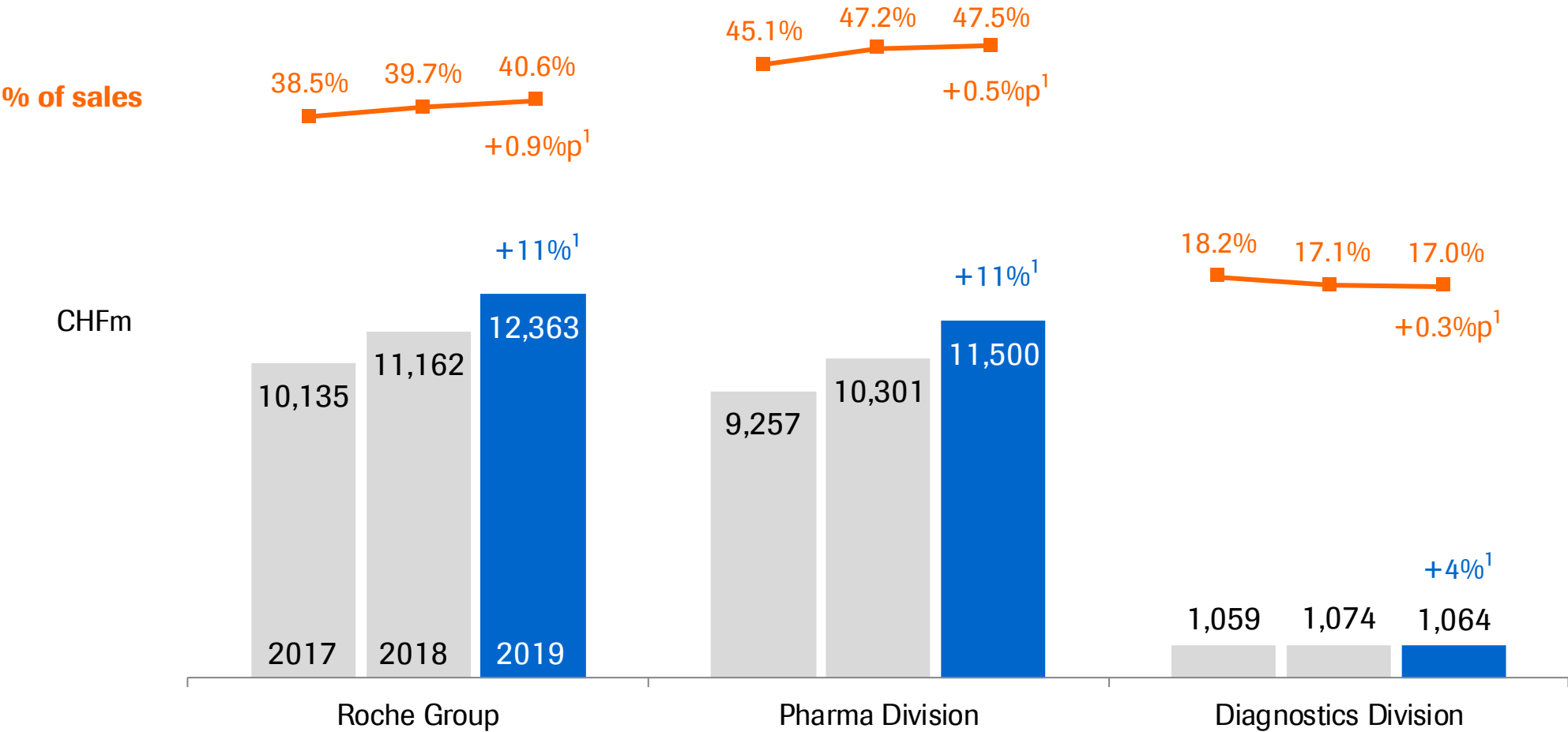
*Core operating profit growth ahead of sales growth*

	HY 2019	
	CHFm	abs. CER
<b>Sales</b>	<b>30,469</b>	<b>2,385</b>
Royalties & other op. inc.	1,282	-159
Cost of sales	-7,868	-591
M & D	-4,800	-250
R & D	-5,561	-200
G & A	-1,159	17
<b>Core operating profit</b>	<b>12,363</b>	<b>1,202</b>

2019 vs. 2018  
CER growth



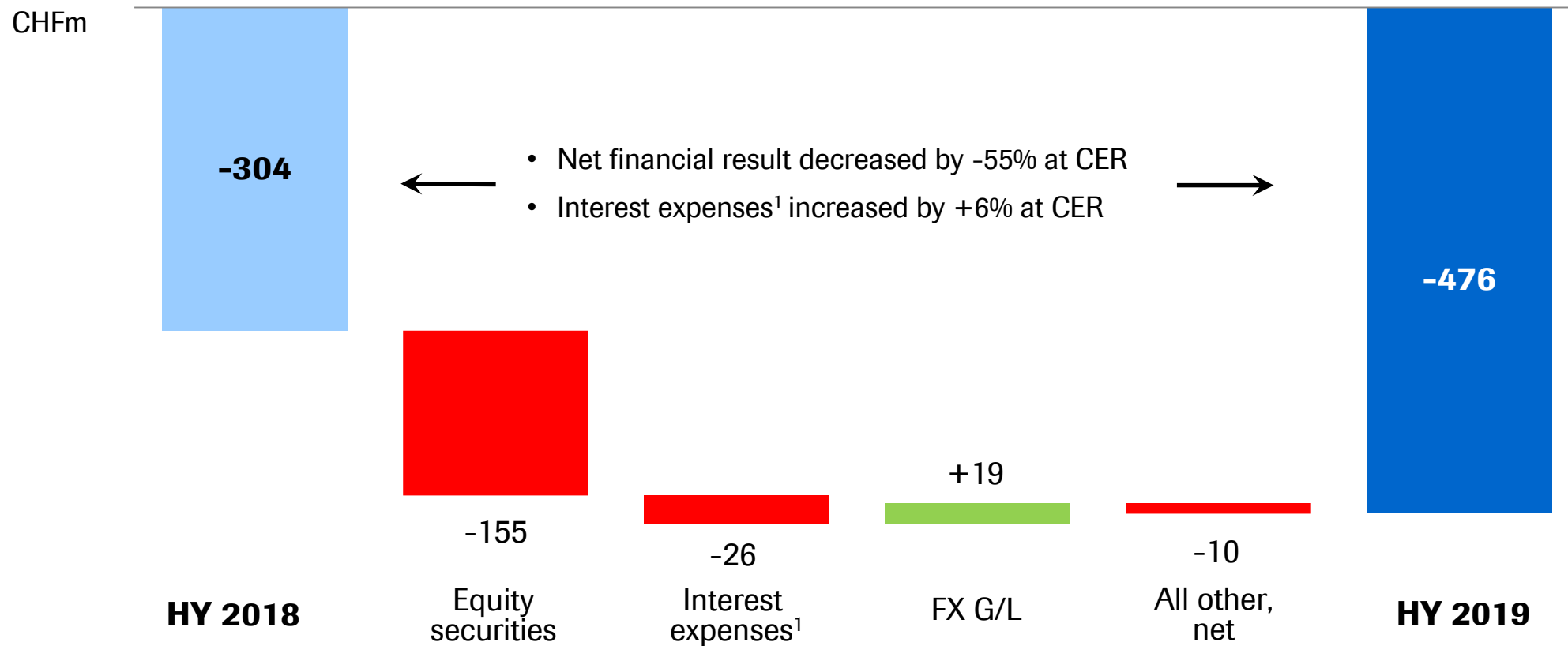
# HY 2019: Core operating profit and margin further improved



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

# HY 2019: Core net financial result

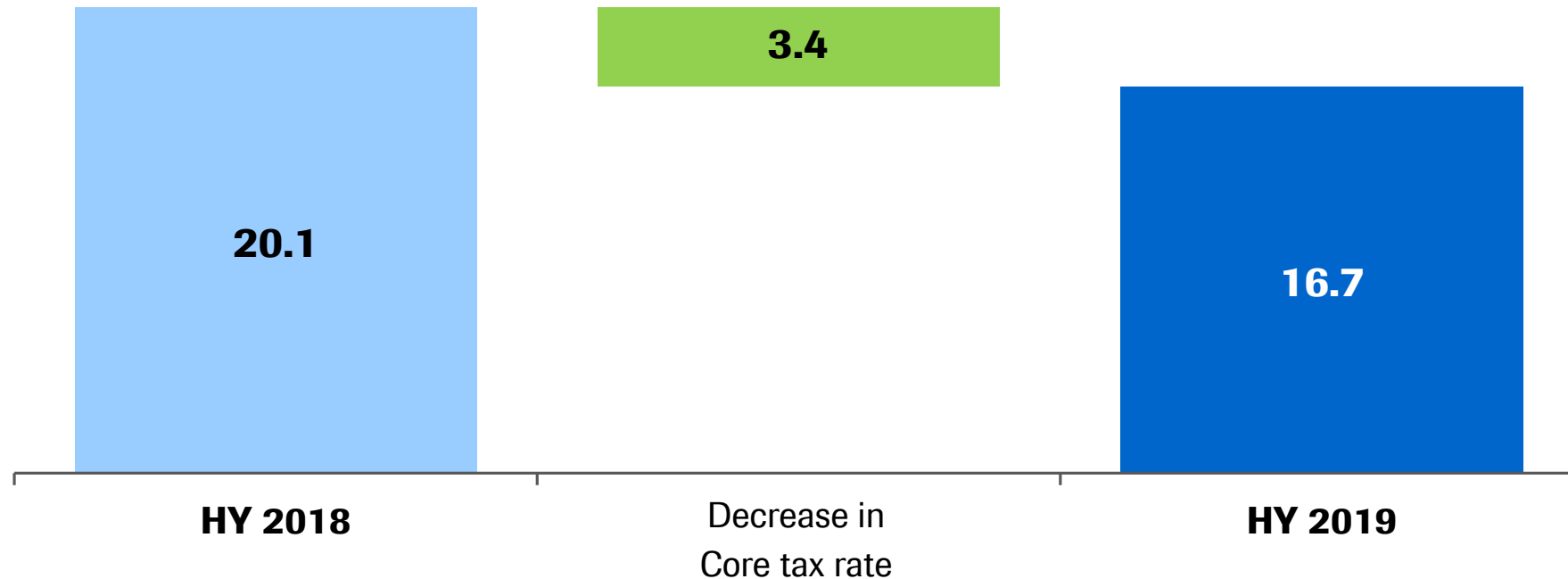
*Decline due to lower income from Equity securities*



## **HY 2019: Group Core tax rate**

*Decrease mainly due to the impacts from the resolution of tax disputes*

Figures in %



## HY 2019: Non-core items

*Slight increase of total non-core operating items due to amortisation and impairment of IA and Global restructuring plans*

	2018	2019		Change in %	
	CHFm	CHFm	CHFm	CHF	CER
<b>Core operating profit</b>	<b>11,162</b>	<b>12,363</b>	<b>1,201</b>	<b>+11</b>	<b>+11</b>
Global restructuring plans	-427	-477	-50		
Amortisation of intangible assets	-628	-737	-109		
Impairment of intangible assets <sup>1</sup>	-273	-324	-51		
M&A and alliance transactions	46	84	38		
Legal & Environmental	-68	-68	0		
<i>Total non-core operating items</i>	<i>-1,350</i>	<i>-1,522</i>	<i>-172</i>		
<b>IFRS Operating profit</b>	<b>9,812</b>	<b>10,841</b>	<b>1,029</b>	<b>+10</b>	<b>+11</b>
<i>Total financial result &amp; taxes</i>	<i>-2,296</i>	<i>-1,937</i>	<i>359</i>		
<b>IFRS net income</b>	<b>7,516</b>	<b>8,904</b>	<b>1,388</b>	<b>+18</b>	<b>+19</b>



## **HY 2019 results**

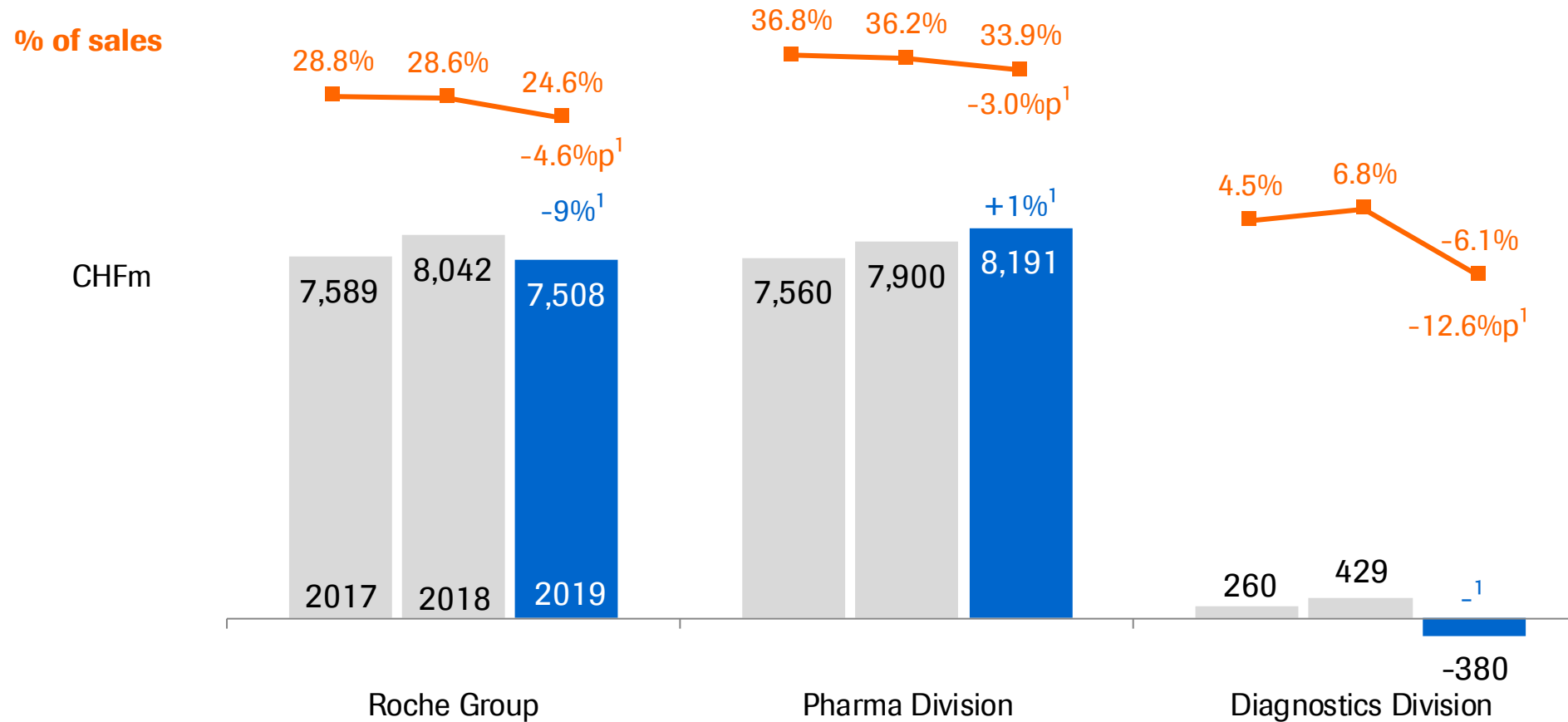
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### **Focus on Cash**

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## **Outlook**

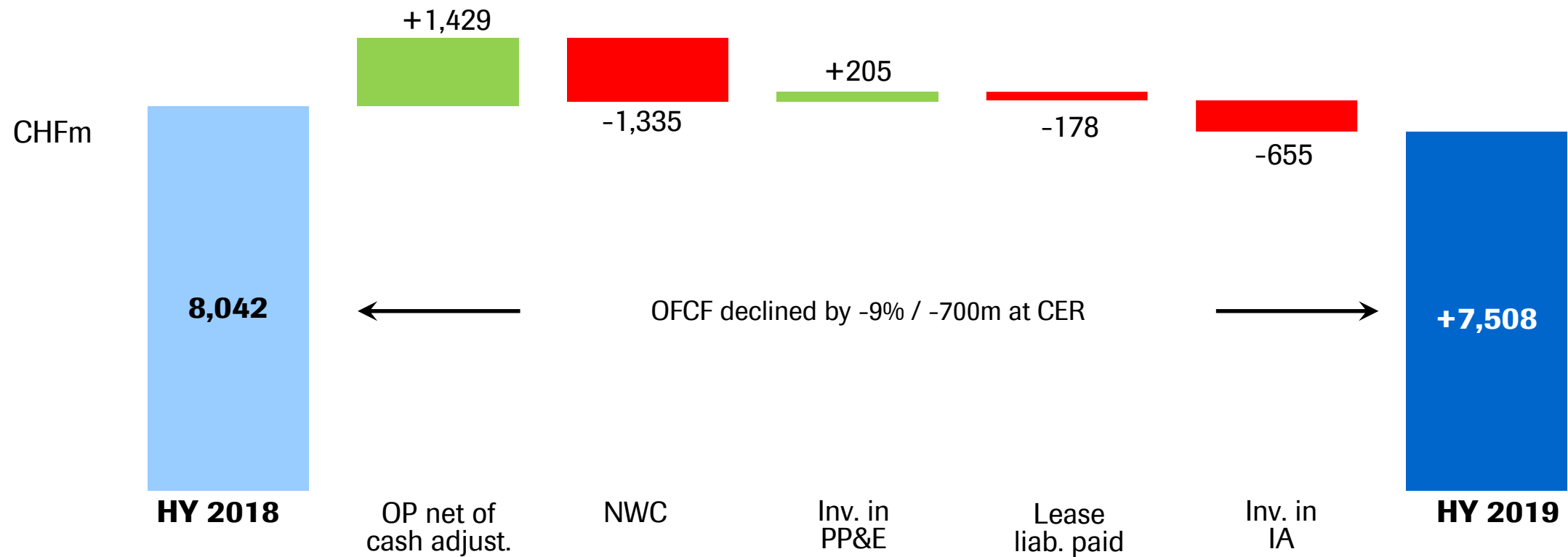
# HY 2019: Operating free cash flow and margin



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

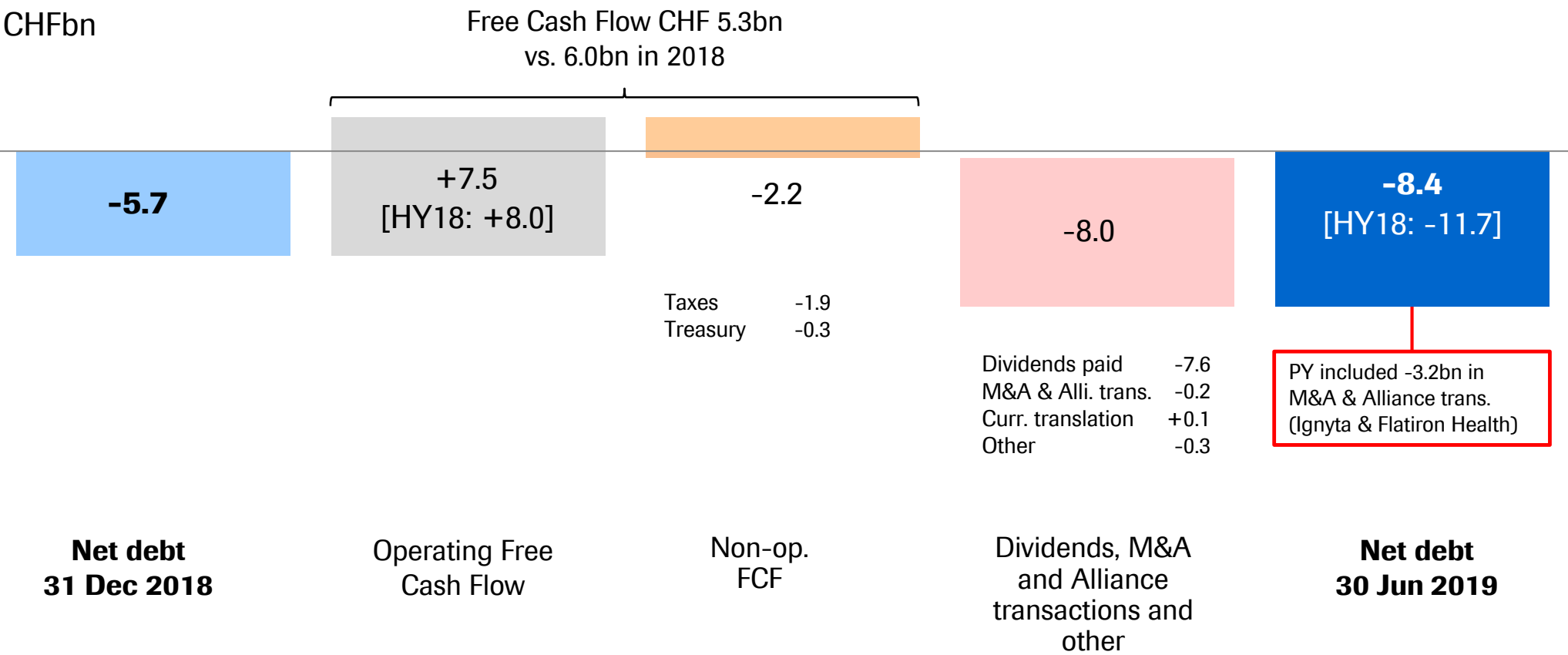
# HY 2019: Operating Free Cash Flow

*Lower than PY (-9%) driven by higher NWC and higher IA investments*



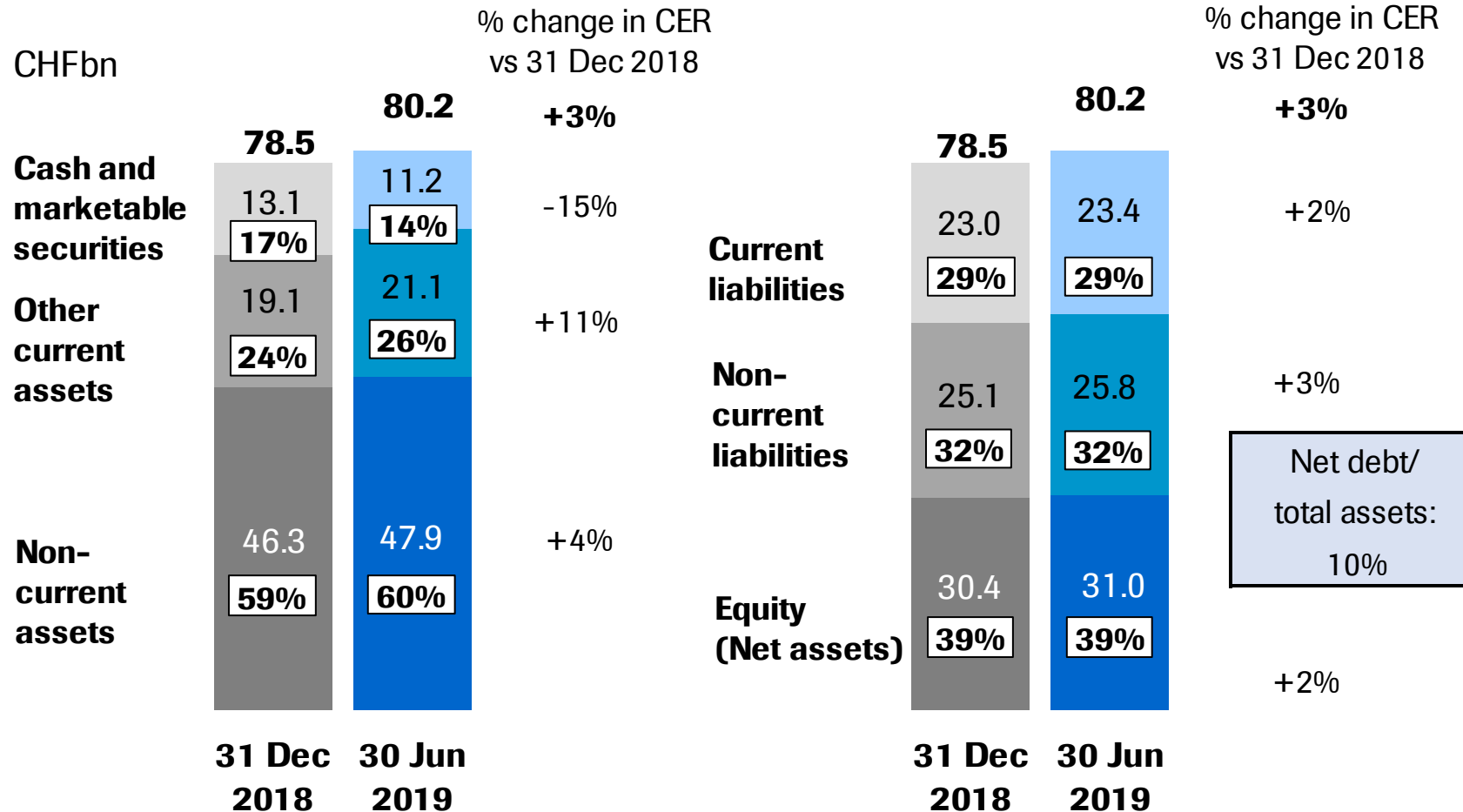
# HY 2019: Group net debt slightly up

## *Driven by dividends paid*



# Balance sheet 30 June 2019

*Equity ratio at 39% (30 Jun 2018: 39%; 31 Dec 2018: 39%)*



**HY 2019 results**

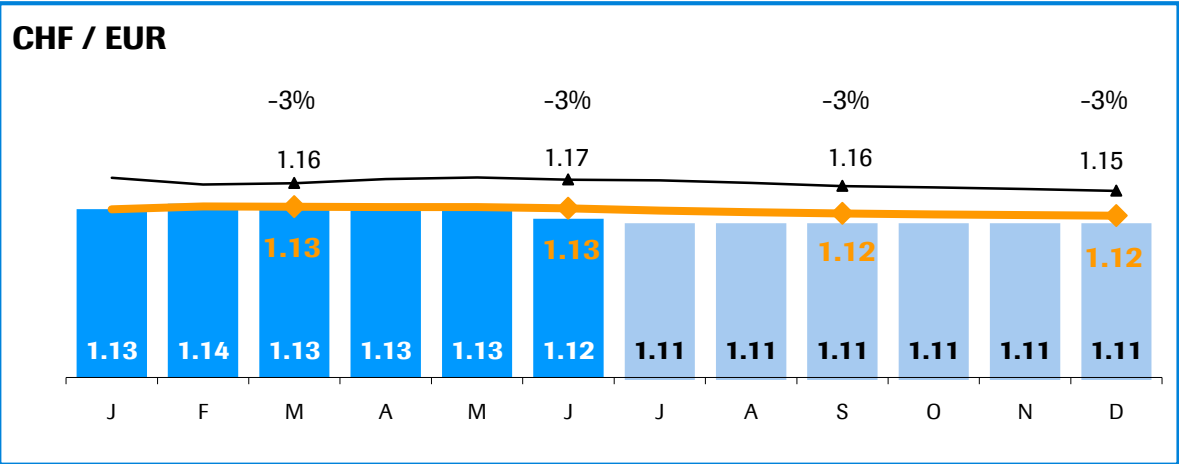
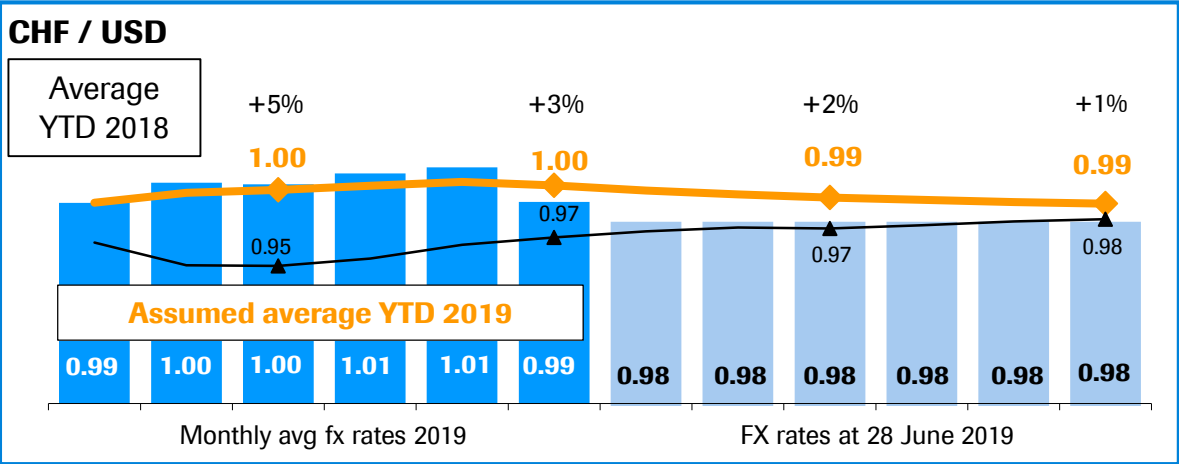
**Focus on Cash**

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**Outlook**

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# Low currency impact expected in 2019



**Assuming the 28 June 2019 exchange rates remain stable until end of 2019, 2019 impact<sup>1</sup> is expected to be (%p):**

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

<sup>1</sup> On group growth rates

## 2019 outlook further raised

*Sales growth to “mid- to high-single digit” from “mid-single digit”*

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

- Mid- to high-single digit (from mid-single digit)

### Core EPS growth<sup>1</sup>

- Broadly in line with sales

### Dividend outlook

- Further increase dividend in Swiss francs

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



# Changes to the development pipeline

## *Q2 2019 update*

New to phase I	New to phase II	New to phase III	New to registration
<b>3 NMEs:</b> <b>RG7921</b> - wAMD <b>RG6244</b> - asthma <b>RG6179</b> - DME  <b>2 AIs:</b> <b>RG7440 ipatasertib + rucaparib</b> - mCRPC, solid tumors <b>RG7601 Venclexta + AMG176</b> - AML	<b>1 NME :</b> <b>IONIS ASO factor B</b> - geographic atrophy  <b>1NME transitioned from Ph1:</b> <b>RG6147</b> - geographic atrophy		
Removed from phase I	Removed from phase II	Removed from phase III	Removed from registration
<b>1 NME:</b> <b>RG6174</b> - inflammatory diseases  <b>1 AI:</b> <b>RG7446 Tecentriq + radium 223</b> - mCRPC		<b>2 AIs:</b> <b>RG7421 Cotellic + Tecentriq</b> - 1L BRAF WT melanoma <b>RG7446 Tecentriq + enzalutamide</b> - mCRPC	

# Roche Group development pipeline



## Phase I (41 NMEs + 20 AIs)

RG6026	CD20 x CD3 / combos	heme tumors	RG7769	PD1-TIM3 biMAb	solid tumors
RG6107	crovalimab (C5 inh MAb)	PNH	RG7802	cibisatamab ± T	solid tumors
RG6109	-	AML	RG7827	FAP-4-1BBL FP	solid tumors
RG6114	mPI3K alpha inh	HR+ BC	RG7828	mosunetuzumab / combos	heme tumors
RG6123	-	solid tumors	RG7876	selicrelumab + Avastin	solid tumors
RG6146	BET inh combos	solid & heme tumors	CHU	Raf/MEK dual inh	solid tumors
RG6148	-	HER2 expressing BC	CHU	glypican-3 x CD3	solid tumors
RG6160	-	multiple myeloma	CHU	codrituzumab	HCC
RG6171	SERD (3)	ER+ (HER2-) mBC	RG6151	-	asthma
RG6180	iNeST*± T	solid tumors	RG6173	-	asthma
RG6185	pan-RAF inh + Cotellic	solid tumors	RG6244	-	asthma
RG6194	HER2 x CD3	BC	RG7835	-	autoimmune diseases
RG7159	anti-CD20 combos	heme tumors	RG7880	IL-22Fc	inflammatory diseases
RG7421	Cotellic + Zelboraf + T	melanoma	RG6004	HBV LNA	HBV
	Cotellic + T	2L BRAF WT mM	RG6084	-	HBV
	Cotellic + T	RCC, bladder, head & neck ca	RG6217	-	HBV
RG7440	ipatasertib + Taxane + T	TNBC	RG7854	TLR7 agonist (3)	HBV
	ipatasertib + rucaparib	mCRPC, solid tumors	RG7861	anti-S. aureus TAC	infectious diseases
RG7446	Tecentriq (T)	solid tumors	RG7907	HBV CpAM (2) (Capsid)	HBV
	T-based Morpheus platform	solid tumors	RG7992	FGFR1/KLB MAb	metabolic diseases
	T + Avastin + Cotellic	2/3L CRC	RG6000	-	ALS
	T ± Avastin ± chemo	HCC, GC, PaC	RG6237	-	neuromuscular disorders
	T + Tarceva/Alecensa	NSCLC	RG7816	GABA Aa5 PAM	autism
	T + anti-CD20 combos	heme tumors	RG6179	-	DME
	T + K/HP	HER2+ BC	RG7774	-	retinal disease
	T + rucaparib	ovarian ca	RG7921	-	wAMD
	FAP IL2v FP combos	solid tumors	CHU	PTH1 recep. ago	hypoparathyroidism
RG7601	Venclexta + idasanutlin	AML	CHU	-	hyperphosphatemia
	Venclexta + AMG176	AML	CHU	-	endometriosis
	Venclexta ± azacitidine	r/r MDS			
	Venclexta + gilteritinib	r/r AML			
	Venclexta + Cotellic + T	MM			

RG-No - Roche/Genentech

NOV- Novimmune managed

CHU- Chugai managed

\*Individualized NeoAntigen Specific Immunotherapy

## Phase II (15 NMEs + 10 AIs)

RG6180	iNeST* + pembrolizumab	malignant melanoma
RG6058	tiragolumab ± T	NSCLC
RG7388	idasanutlin	polycythemia vera
	idasanutlin	AML fit 1L
RG7421	Cotellic + Tecentriq ± taxane	TNBC
RG7440	ipatasertib	TNBC neoadj
RG7446	Tecentriq	SC NSCLC
RG7596	Polivy (polatuzumab vedotin)	r/r FL
RG7601	Venclexta + Rituxan	DLBCL
	Venclexta + azacitidine	1L MDS
	Venclexta + fulvestrant	2L HR+BC
RG6149	ST2 MAb	asthma
RG7159	Gazyva	lupus
RG7625	petesicatib	autoimmune diseases
RG7845	fenebrutinib	RA, lupus, CSU
CHU	nemolizumab*	pruritus in dialysis patients
NOV	TLR4 MAb	autoimmune diseases
RG1662	basimisanil	CIAS
RG6100	Tau MAb	Alzheimer's
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7916	risdiplam§	SMA
RG7906	-	psychiatric disorders
RG7935	prasinezumab	Parkinson's
RG6147	-	geographic atrophy
IONIS	ASO factor B	geographic atrophy

  NMEs  
  Additional Indication (AI)  
  Oncology / Hematology  
  Immunology  
  Infectious Diseases

  CardioMetabolism  
  Neuroscience  
  Ophthalmology  
  Other

§ Ph2 pivotal

# out-licensed to Galderma and Maruho AD

T=Tecentriq

# Roche Group development pipeline

## Phase III (11 NMEs + 32 AIs)

RG3502	Kadcyla + Perjeta	HER2+ eBC
RG6264	Perjeta + Herceptin FDC SC	HER2+ BC
RG7388	idasanutlin + chemo	AML
RG7440	ipatasertib + abiraterone	1L CRPC
	ipatasertib + chemo	1L TNBC/HR+ BC
RG7421	Cotellic + Zelboraf + T	1L BRAFm melanoma
RG7596	Polivy (polatuzumab vedotin)	1L DLBCL
RG7446	Tecentriq	NSCLC adj
	Tecentriq	MIBC adj
	Tecentriq	NMIBC, high risk
	Tecentriq Dx+	1L sq + non-sq NSCLC
	Tecentriq	RCC adj
	T + chemo + Avastin	1L ovarian cancer
	T + pemetrexed	1L non-sq NSCLC
	T + nab-paclitaxel	1L sq NSCLC
	T ± chemo	SCCHN adj
	Tecentriq	HER2+ BC neoadj
	T + paclitaxel	1L TNBC
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + nab-paclitaxel	TNBC neoadj
	T + Avastin	1L HCC
	T + Avastin	1L RCC
	T ± chemo	1L mUC

RG7446/RG7853/R G6268	Tecentriq or Alecensa or entrectinib	1LNSCLC Dx+
RG7601	Venclexta + bortezomib	MM
	Venclexta	r/r MM t(11:14)
	Venclexta + HMA	1L AML
RG7853	Alecensa	NSCLC adj
RG3648	Xolair	nasal polyps
RG7413	etrolizumab	ulcerative colitis
	etrolizumab	Crohn's
RG6152	Xofluza	influenza, hospitalized pts
	Xofluza	influenza, pediatric
	Xofluza	influenza post exposure prophylaxis
RG1450	gantenerumab	Alzheimer's
RG6042	HTT ASO	Huntington's
RG6168	satralizumab	NMOSD
RG6206	anti-myostatin adnectin	DMD
RG7314	balovaptan	autism
RG6321	port delivery system with ranibizumab	wAMD
RG7716	faricimab	DME
	faricimab	wAMD

## Registration (3 NMEs + 7 AIs)

RG3502	Kadcyla <sup>1</sup>	HER2+ eBC
RG6268	Rozlytrek (entrectinib)	NSCLC ROS1+
	Rozlytrek (entrectinib)	NTRK1 tumor agnostic
RG7446	T + nab-paclitaxel	1L non-sq NSCLC
	T + nab-paclitaxel <sup>1</sup>	1L TNBC
	T + chemo <sup>1</sup>	1L extensive stage SCLC
RG7596	Polivy (polatuzumab vedotin) <sup>1</sup>	r/r DLBCL
RG7601	Venclexta + Gazyva <sup>1</sup>	1L CLL
RG6152	Xofluza <sup>1</sup>	influenza
	Xofluza <sup>2</sup>	influenza, high risk

<sup>1</sup> Approved in US

<sup>2</sup> Filed in US

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

CardioMetabolism  
 Neuroscience  
 Ophthalmology  
 Other

# NME submissions and their additional indications

## *Projects currently in phase II and III*

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

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

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

	CardioMetabolism
	Neuroscience
	Ophthalmology
	Other
FDC =fixed-dose combination	
*Individualized NeoAntigen Specific Immunotherapy	

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

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

Immunology  
Infectious Diseases  
CardioMetabolism

Topic	Percentage
Neuroscience	35%
Ophthalmology	35%
Other	30%

# Cancer immunotherapy pipeline overview

## Phase I (11 NMEs + 21 AIs)

RG6026	CD20 x CD3 / combos	heme tumors
RG6123	-	solid tumors
RG6160	-	multiple myeloma
RG6180	iNeST* ± T	solid tumors
RG6194	HER2 x CD3	BC
RG7421	Cotellic + Zelboraf + T	melanoma
	Cotellic + T	2L BRAF WT mM
	Cotellic + T	RCC, bladder, head & neck ca
RG7440	ipatasertib + Taxane + T	TNBC
RG7446	Tecentriq (T)	solid tumors
	T-based Morpheus platform	solid tumors
	T + Avastin + Cotellic	2/3L CRC
	T ± Avastin ± chem	HCC, GC, PaC
	T + Tarceva/Alecensa	NSCLC
	T + anti-CD20 combos	heme tumors
	T + K/HP	HER2+ BC
	T + rucaparib	ovarian ca
RG7461	FAP IL2v FP combos	solid tumors
RG7601	Venclexta + Cotellic + T	MM
RG7769	PD1-TIM3 biMAb	solid tumors
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL FP	solid tumors
RG7828	mosunetuzumab / combos	heme tumors
RG7876	selicrelumab + Avastin	solid tumors
CHU	glypican-3 x CD3	solid tumors

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

## MORPHEUS Platform - Phase Ib/II (7 AIs)

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

## Phase II (2 NMEs + 5 AIs)

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

## Phase III (20 AIs)

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

## Registration (3 AIs)

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

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

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

RG-No Roche/Genentech  
 \*Individualized NeoAntigen Specific Immunotherapy  
 T=Tecentriq

# Major pending approvals 2019

US		EU		China		Japan-Chugai	
<b>RG7446</b>	<b>Tecentriq + nab-paclitaxel</b> 1L non sq NSCLC Filed Nov 2018	<b>RG7596</b>	<b>Polivy (polatuzumab vedotin)</b> r/r DLBCL Filed Dec 2018	<b>RG99</b>	<b>CellCept</b> lupus nephritis Filed Aug 2018	<b>RG7446</b>	<b>Tecentriq + nab-paclitaxel</b> 1L TNBC Filed Dec 2018
<b>RG6268</b>	<b>Rozlytrek (entrectinib)</b> NSCLC ROS1+ Filed Dec 2018	<b>RG7446</b>	<b>Tecentriq + nab-paclitaxel</b> 1L non sq NSCLC Filed Oct 2018	<b>RG6264</b>	<b>Perjeta</b> HER2+ eBC neoadj Filed Aug 2018	<b>RG7446</b>	<b>Tecentriq + chemo</b> 1L extensive stage SCLC Filed Dec 2018
<b>RG6268</b>	<b>Rozlytrek (entrectinib)</b> NTRK+ solid tumors Filed Dec 2018	<b>RG7446</b>	<b>Tecentriq + nab-paclitaxel</b> 1L TNBC* Filed Sep.2018	<b>RG105</b>	<b>MabThera</b> CLL Filed Apr 2019	<b>RG6268</b>	<b>Rozlytrek (entrectinib)</b> NSCLC ROS1+ Filed Mar 2019
<b>RG6152</b>	<b>Xofluza</b> Influenza, high risk pts Filed Dec. 2018	<b>RG7446</b>	<b>Tecentriq + chemo</b> 1L extensive stage SCLC Filed Sep. 2018	<b>RG6264</b>	<b>Perjeta + Herceptin</b> 1L HER2+ mBC Filed Dec 2018	<b>RG7853</b>	<b>Alecensa</b> r/r ALK+ ALCL Filed Jun 2019
		<b>RG6268</b>	<b>Rozlytrek (entrectinib)</b> NSCLC ROS1+ Filed Jan 2019	<b>RG405</b>	<b>Avastin</b> 1L/2L glioblastoma Filed Jan 2019		
		<b>RG6268</b>	<b>Rozlytrek (entrectinib)</b> NTRK1 tumor agnostic Filed Jan 2019	<b>RG3502</b>	<b>Kadcyla</b> HER2+ eBC Filed Feb 2019		
		<b>RG3502</b>	<b>Kadcyla</b> HER2+EBC Filed Feb 2019	<b>RG7159</b>	<b>Gazyva</b> 1L FL Filed Feb 2019		
		<b>RG7601</b>	<b>Venclexta+Gazyva</b> 1L CLL Filed Jul 2019	<b>RG7159</b>	<b>Gazyva</b> r/r FL Filed Feb 2019		
				<b>RG105</b>	<b>MabThera</b> FL Filed Apr 2019		

New Molecular Entity (NME)

Additional Indication (AI)

Oncology / Hematology

Immunology

Infectious Diseases

CardioMetabolism

Neuroscience

Ophthalmology

Other

\*CHMP positive opinion

# Major granted approvals 2019

US		EU		China		Japan-Chugai	
<b>RG597</b>	<b>Herceptin SC Hylecta</b> Feb 2019	<b>RG105</b>	<b>MabThera</b> pemphigus vulgaris Mar 2019	<b>RG1569</b>	<b>Herceptin</b> BC neoadj Jan 2019	<b>RG105</b>	<b>Rituxan</b> CD20 + CLL Mar 2019
<b>RG7446</b>	<b>Tecentriq + nab-paclitaxel</b> 1L TNBC Mar 2019	<b>RG6013</b>	<b>Hemlibra</b> hemophilia A FVIII non-inh Mar 2019			<b>RG6268</b>	<b>Rozlytrek (entrectinib)</b> NTRK+ solid tumors June 2019
<b>RG7446</b>	<b>Tecentriq + chemo</b> 1L extensive stage SCLC Mar 2019	<b>RG6013</b>	<b>Hemlibra</b> Q4W hemophilia A Mar 2019			<b>RG1569</b>	<b>Actemra</b> CRS Mar 2019
<b>RG7601</b>	<b>Venclexta + Gazyva</b> 1L CLL May 2019	<b>RG7446</b>	<b>Tecentriq + chemo + Avastin</b> 1L non-sq NSCLC Mar 2019			<b>RG1569</b>	<b>Actemra</b> Adult Onset Still's disease Mar 2019
<b>RG3502</b>	<b>Kadcyla</b> HER2+ eBC May 2019						
<b>RG7596</b>	<b>Polivy (polatuzumab vedotin)</b> r/r DLBCL June 2019						

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



*Doing now what patients need next*