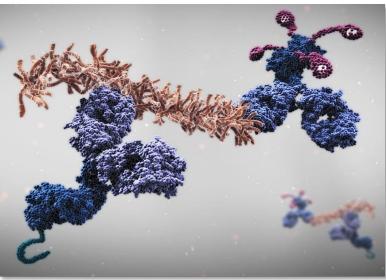


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# **Committed to innovation and growth**

*Roland Diggelmann, CEO Roche Diagnostics* 

Interlaken, 8 June 2016





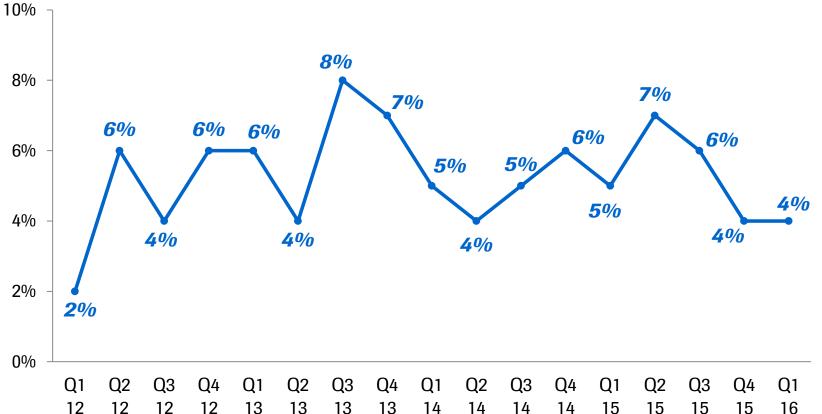
#### **Q1 2016 Group results**

Diagnostics Business model & strategy Q1 2016 overview Outlook

#### 0% Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 12 12 12 12 13 13 13 13 14 14 14 14

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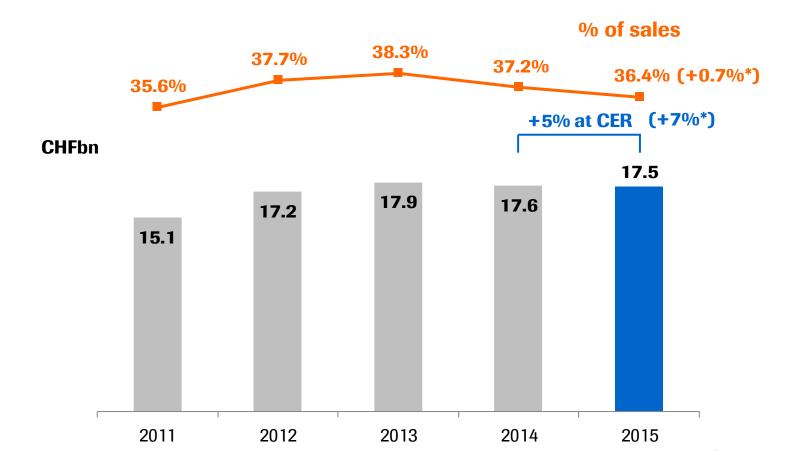
#### Q1 2016: Sales growth for fifth consecutive year



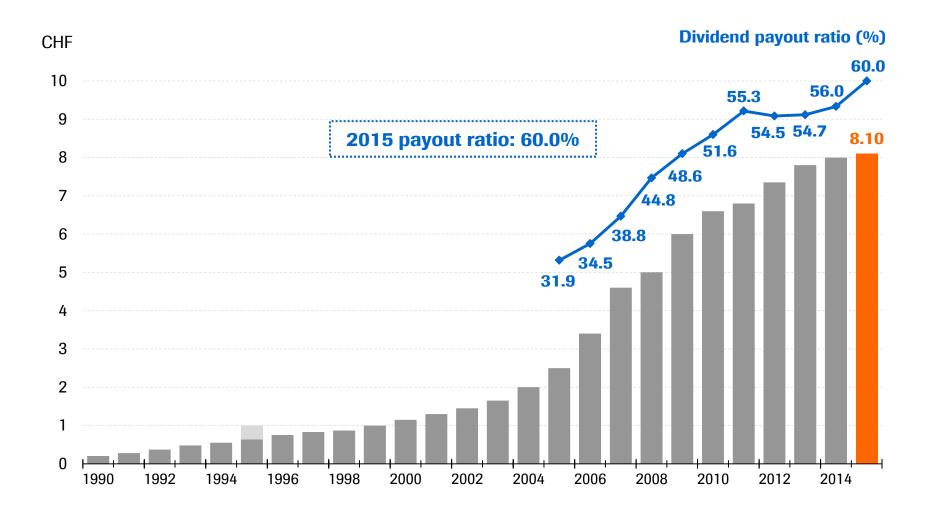




# **2015: Strong underlying Group Core operating profit & margin**



## 2015: Dividend and payout ratio further increased



Payout ratio calculated as dividend per share divided by Core earnings per share (diluted); 2015 dividend as proposed by the Board of Directors; Note: For 1995, a special dividend was paid out to mark F. Hoffmann-La Roche's 100th anniversary in 1996

#### **Q1 2016: Solid sales growth continues**



	<b>2016</b>	2015	Change in %	
	CHFbn	CHFbn	CHF	CER
Pharmaceuticals Division	9.8	9.3	5	4
<b>Diagnostics Division</b>	2.6	2.5	4	5
Roche Group	12.4	11.8	5	4



#### **Roche significantly advancing patient care** *Recognition for innovation 2013-present*

## **12** Breakthrough Therapy Designations

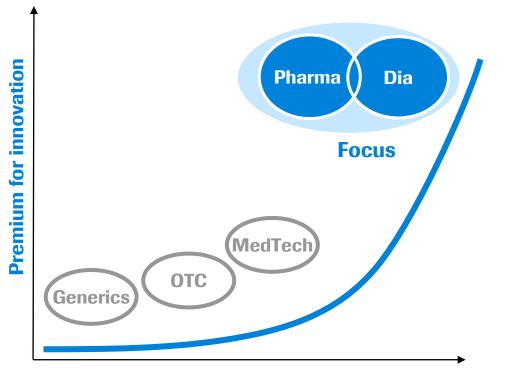
Rank	Company	#
1	Roche	12
2	BMS	8
3	Novartis	7
3	Merck	6
3	Pfizer	6
4	GSK	5

Year	Molecule
2016	<b>Ocrelizumab</b> (PPMS)
	Venclexta (AML)
	Venclexta + Rituxan (R/R CLL)
2015	Actemra (Systemic sclerosis)
	Atezolizumab (NSCLC)
	Venclexta (R/R CLL 17p del)
	Emicizumab/ACE 910 (Hemophilia A)
2014	<b>Esbriet</b> (IPF)
	Lucentis (DR)
	Atezolizumab (Bladder)
2013	Alectinib (2L ALK+ NSCLC)
	Gazyva (1L CLL)

Source: <u>http://www.focr.org/breakthrough-therapies</u> as at 22 March 2016; PPMS=Primary Progressive Multiple Sclerosis; CLL=Chronic Zymphocytic Leukemia; NSCLC=Non-Small Cell Lung Cancer; IPF=Idiopathic Pulmonary Hypertension; DR=Diabetic Retinopathy



#### **Roche strategy: Focused on medically differentiated therapies**



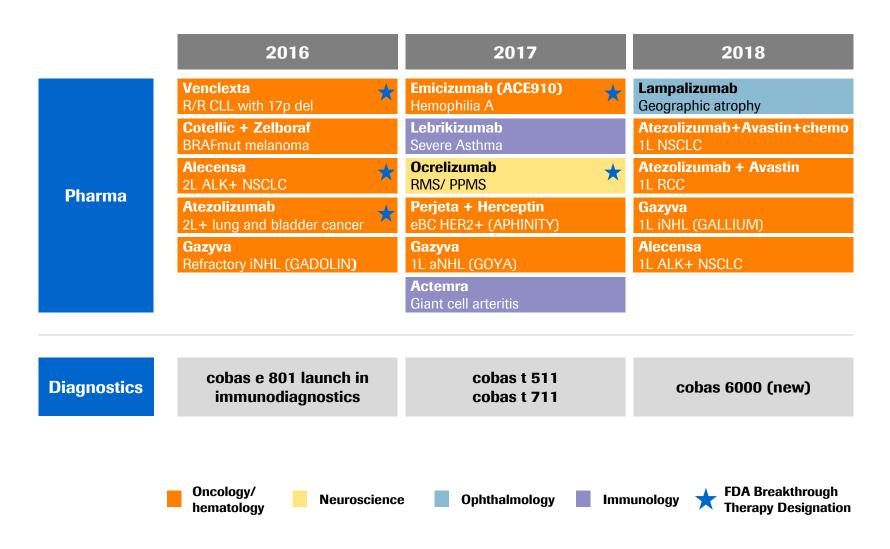
#### **Regulators:**

Optimised benefit / risk ratio Payors: Optimised benefit / cost ratio

Differentiation

#### **Significant launch activities ahead**





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

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

Core EPS growth<sup>1</sup>

Ahead of sales growth

Low to mid-single digit

#### **Dividend outlook**

Further increase dividend in Swiss francs



#### 2016 outlook



#### **Q1 2016 Group results**

Diagnostics Business model & strategy Q1 2016 overview Outlook

#### In-Vitro Diagnostics market overview Large and growing market; Roche is market leader **Market size** Market share USD 55 bn Roche **Professional Diagnostics** 20% **Molecular Diagnostics** Others 45% Abbott **Tissue Diagnostics** 9% Siemens **Diabetes Monitoring**

Danaher

Biomerieux

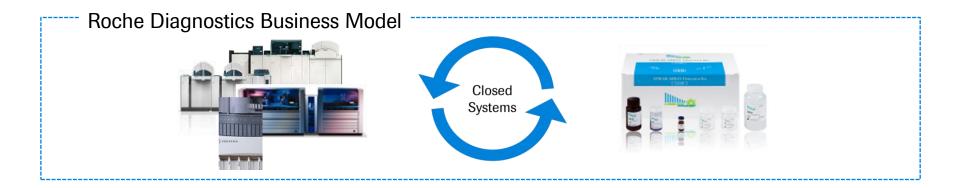
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Roche



## **Our business model** *Customer focus and place instruments to generate recurring revenues through reagent usage*



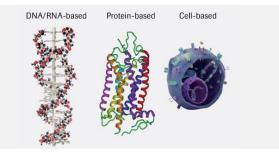




## **Roche Diagnostics** *Our competitive advantage*

#### **Total solution offering**

Breadth of technologies



#### Comprehensive menu



#### IT and workflow connectivity



#### **Strong commercial presence**

Active in all diagnostics segments

Large installed base worldwide

Millions of patients each day





#### **Q1 2016 Group results**

## **Diagnostics**

Business model & strategy Q1 2016 overview Outlook

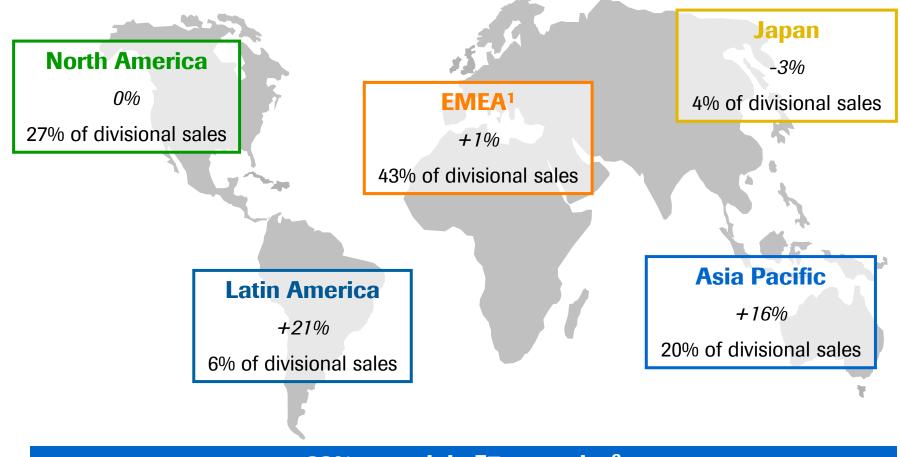


## **Q1 2016: Diagnostics Division sales** *Strong sales growth in laboratory businesses*

	2016	2015	Change in %	
	CHFm	CHFm	CHF	CER
<b>Diagnostics Division</b>	2,614	2,511	4	5
Professional Diagnostics	1,519	1,425	7	7
Molecular Diagnostics	446	401	11	11
Diabetes Care	443	507	-13	-11
Tissue Diagnostics	206	178	16	13



#### **Q1 2016: Diagnostics regional sales** *Growth driven by Asia Pacific and Latin America*

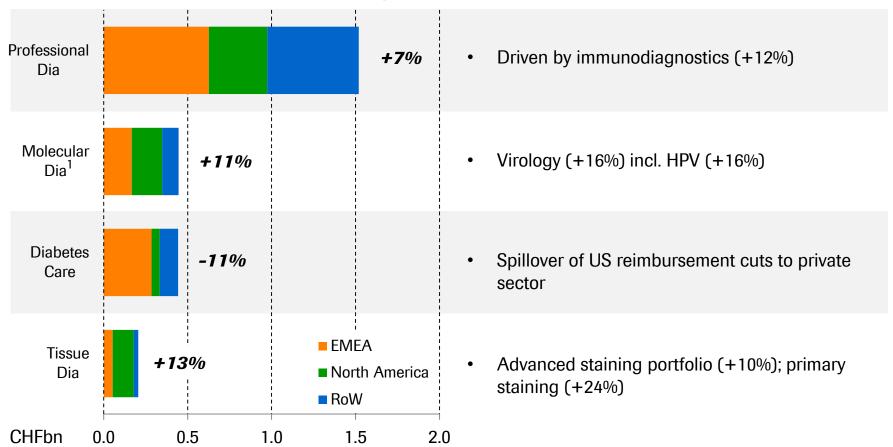


#### 23% growth in E7 countries<sup>2</sup>

<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



## **Q1 2016: Diagnostics highlights** *Growth driven by Professional Diagnostics*



#### YoY CER growth

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



## **Strategic Focus of Roche Diagnostics** *Medical Value and Testing Efficiency*











Menu Breadth

**System Innovation** 

**Workflow & IT** 

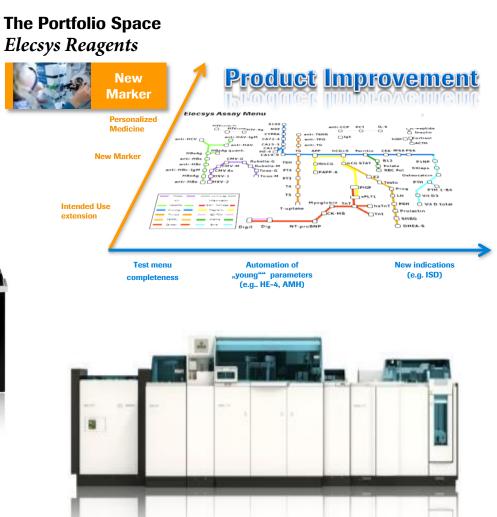


# ELECSYS: The Roche platform for antibody-based diagnostics

World class reagents & customer oriented system concept



Principle of antibody-based Elecsys assays



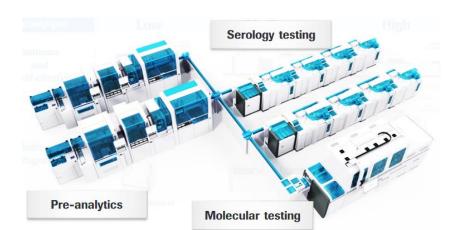
## **Providing the full solution in hepatitis testing** *Comprehensive menu in serology & molecular*

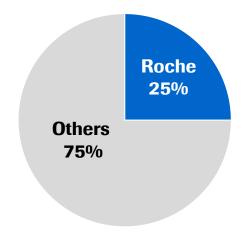
#### **Complete platform and test portfolio**

- Hepatitis contributes ~60% of Roche's Infectious Disease/Virology portfolio
- Serology hepatitis: (+5%<sup>1</sup>)
- Molecular/NAT\* hepatitis: (+11%<sup>1</sup>)

#### Leader in a CHF 4.3bn market

- 5yr CAGR: ~6% projected
- Strong growth potential in serology





Roch

## **FDA approves IND for cobas Zika assay** *Screening initiated at Puerto Rico blood centers*

- Currently testing in Puerto Rico, expect to expand to additional centers in southern US
- Operating under an IND\* costrecovery model, no commercial sales
- LightMix Zika Virus rRT-PCR Test (CE mark pending); available worldwide (ex-US)



Kochi

\*Investigational New Drug Application (IND)

## **Tissue Diagnostics: Launch of VENTANA HE 600** *Potential to change standard of care in H&E\* staining*



- Latest platform with individual slide staining technology, avoids sample cross contamination
- Platform features:
  - Highest result quality and reproducibility
  - Highest test capacity and most efficient workflow
  - Easy and safe to operate



# First FDA approval of EGFR liquid biopsy test v2 as companion diagnostic for Tarceva

#### **Patient example** SQI\* 25 20 15 →\_\_\_L858R T790M 10 📥 cfDNA WT 5 0 40 145 187 230 272 357 532 390 574 Time (days) Treatment Clinical **Re-appearance** of tumor initiation Progression mutations

#### **Detection of tumor mutations may aid in the management of NSCLC patients**

\*SQI (semi-quantitative index) reflects a trend in the cell free tumor DNA quantity. Upon TKI treatment, we see a decline in tumor mutations (L858R and T790M), in a background of non-tumor DNA (cfDNA\_WT); Sorenson et al Cancer 2014;120:3896-901



#### **Q1 2016 Group results**

#### **Diagnostics**

Business model & strategy Q1 2016 overview Outlook

## **Key launches 2016**



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



## Doing now what patients need next