

## Strategy, Culture, and Rejuvenation

**Severin Schwan** | CEO

The Octavian Seminar, January 2021



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### **COVID-19: Roche's contributions**

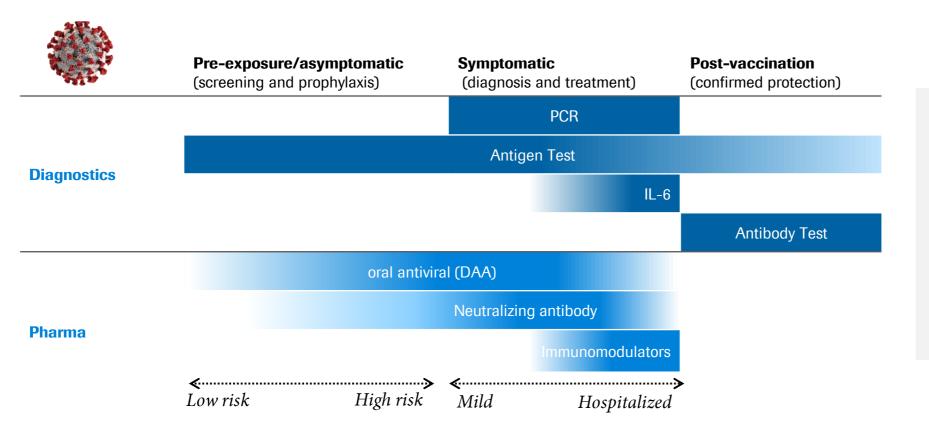
**Priorities to maintain leadership position** 

**Environment, Governance, and Social Responsibility** 

**Outlook** 

# Roche's response to the pandemic *Potential use cases for Dia/Pharma COVID-19 portfolio*



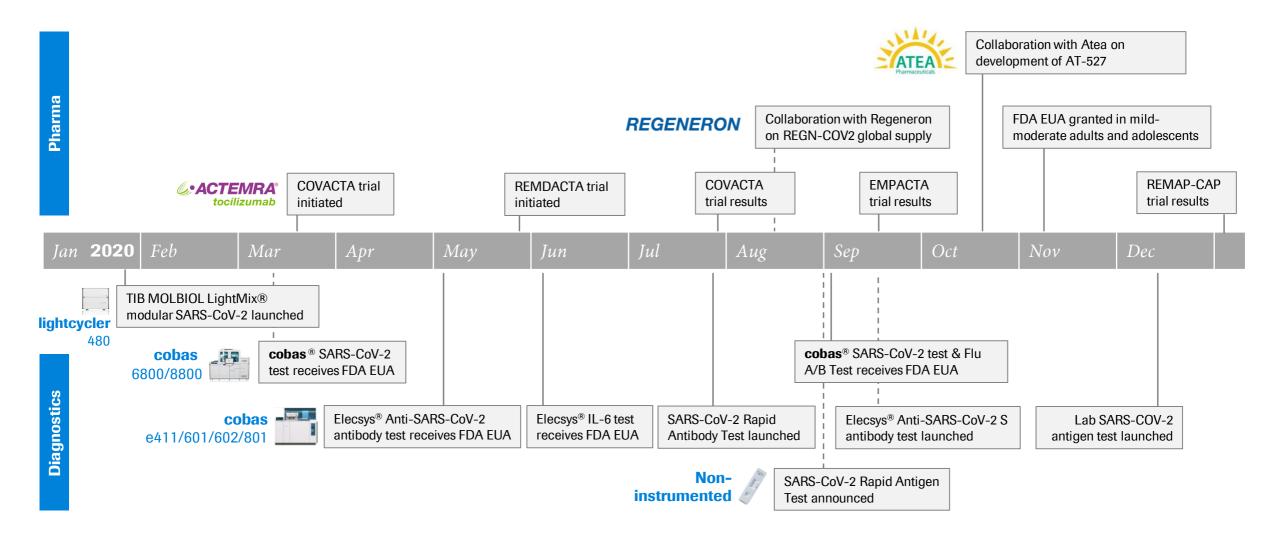


## Use cases will continue to persist with vaccine rollout

- People not yet vaccinated
- Vaccine ineffective/wore off
- Antibody testing
- Population surveillance
- Screening
- Flu/COVID diagnosis

## Responding quickly and broadly to the pandemic





## **Increasing testing capacity and installed base**



				Installed base	Test capacity
High throughput		<b>cobas 6800/8800</b> ~1,500-4,000 tests in 24h	<ul> <li>cobas<sup>®</sup> SARS-CoV-2</li> <li>cobas<sup>®</sup> SARS-CoV-2 &amp; Influenza A/B</li> </ul>	>1,000	>20m per month
	beet a	<b>cobas e411/601/602/801</b> ~300 tests / hour	<ul> <li>Elecsys® Anti-SARS-CoV-2</li> <li>Elecsys® Anti-SARS-CoV-2 S</li> <li>SARS-CoV-2 rapid antibody</li> <li>Elecsys® Anti-SARS-CoV-2 antigen</li> </ul>	~40,000	~100m per month
Point of care	9	<b>cobas Liat</b> ~1 test in 20 minutes	cobas® SARS-CoV-2 & Influenza A/B (POC)	>5,000	~1m per month
		Rapid Antigen ~1 test in 20 minutes	<ul> <li>SARS-CoV-2 rapid antigen</li> <li>SARS-CoV-2 rapid antigen (nasal)*</li> <li>SARS-CoV-2 &amp; Influenza A/B rapid antigen*</li> </ul>	Non-instrumented	~80m per month



<sup>\*</sup> In development; 1. Unique set of circumstances e.g. EUA FDA has allowed; 2. cobas® SARS-CoV-2 test based on first regulatory approval; 3. Elecsys® Anti-SARS-CoV-2 test based on first regulatory approval; 4. Based on internal calculated averages



### **COVID-19: Roche's contributions**

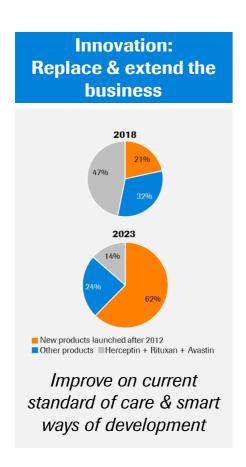
### **Priorities to maintain leadership position**

**Environment, Governance, and Social Responsibility** 

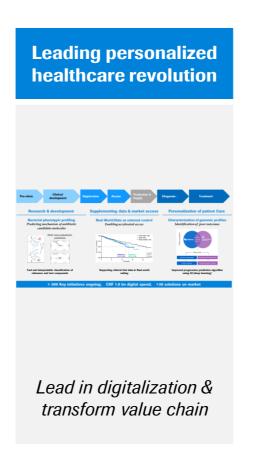
**Outlook** 

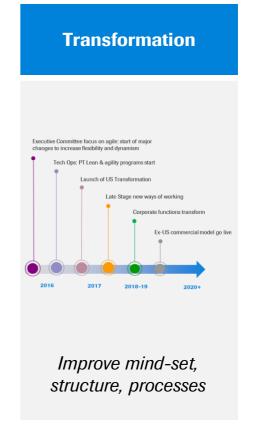
## 4 Priorities to maintain leadership position





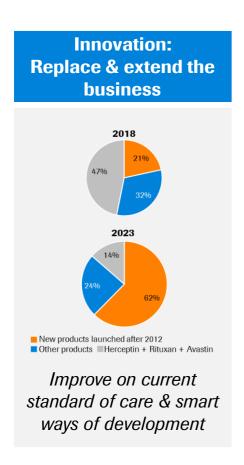




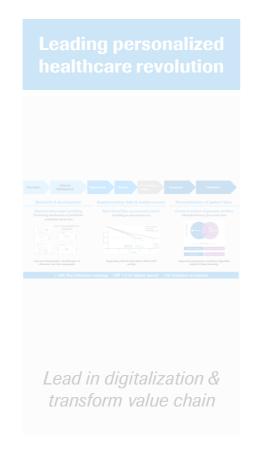


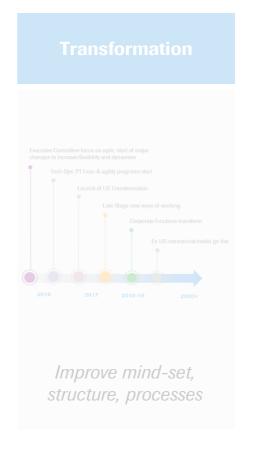
## 4 Priorities to maintain leadership position











## New medicines: Replace and extend the business



#### Replace/extend existing businesses

#### **Entering new franchises**

MabThera/Rituxan	Gazyva, Venclexta, Polivy, mosunetuzumab, glofitamab
Herceptin	Perjeta, Kadcyla, Phesgo
Avastin	Tecentriq, Alecensa, Rozlytrek, Gavreto
Lucentis	faricimab Port delivery system (PDS)
Tamiflu	Xofluza

#### **Oncology:**

Tecentriq (mUC, HCC, Mel), tiragolumab, giredestrant (HR+ BC) inavolisib (HR+BC) ipatasertib (mCRPC)

#### **Hematology:**

Hemlibra, crovalimab (PNH), cevostamab (MM)

#### MS:

Ocrevus, fenebrutinib

#### CNS:

Enspryng (NMOSD), Evrysdi (SMA), tominersen (HTT), gantenerumab (Alzh.), SRP-9001 (DMD)

#### **Immunology:**

etrolizumab (CD), Gazyva (LN), rhPTX-2 (IPF)

#### **Infectious Disease:**

casirivimab & imdevimab, AT-527



## Strong short- and mid-term news flow Diversifying the late stage pipeline and setting new standards of care

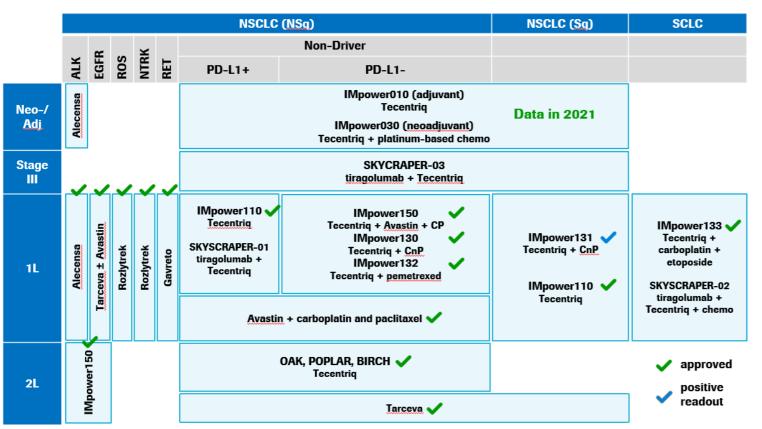
Product	Indication	Filing	Population	Product	Indication	Filing	Population	
tominersen	Huntington's	2022	~83k	Courate	RET+ NSCLC	filed	~2k (Dx+)	
gantenerumab	Alzheimer's	2022	~9,300k (prodromal) ~3,600k (mild) ~21k	Gavreto	thyroid cancer	filed	<b>∼6k</b> (Dx+)	
				Tecentriq*	NeoAdj TNBC	2020	~23k	
SRP-9001	DMD	2023 /24			Adj SCCHN	2021	~8k	
etrolizumab	Crohn's	2022	~570k (moderate/severe)		Adj RCC	2021/22	~20k	
					(Neo)Adj NSCLC	2021/22	~100k	
PDS	nAMD DME	2020	nAMD ~3,600k DME ~4,700k		Adj HCC	2022	tbd	
		2022		Tecentriq + P+H	NeoAdj HER2+ BC	2021	~40k	
faricimab	DME nAMD	2021		ipatasertib	1L mCRPC	2021**	~100 (Dx+)	
Actemra +		2021	n/a	Polivy	1L DLBCL	2021	~51k	
remdesivir	COVID-19			tiragolumab + T	1L SCLC	2022	~57k	
casirivimab &	COVID-19	2021	n/a	mosunetuzumab	R/R FL	2021	~3k	
imdevimab				glofitamab	R/R DLBCL	2022	~24k	
crovalimab	PNH	2022	~14k	Venclexta	R/R MM t(11;14)	2022	~6k (Dx+)	
Neuro	oscience Ophtha	almology	Infectious diseases	giredestrant	2L/3L mBC	2022	~74k	
Immunology Oncology/Hematology								

Source: Roche/Genentech, incidence/prevalence in the major markets (US, FR, DE, IT, ES, GB); DMD=duchenne muscular dystrophy; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; NSCLC=non-small cell lung cancer; TNBC=triple-negative breast cancer; SCCHN=squamous cell carcinoma of the head and neck; RCC=renal cell carcinoma; HCC=hepatocellular carcinoma; mCRPC=metastatic castration resistant prostate cancer; DLBCL=diffuse large B-cell lymphoma; SCLC=small cell lung cancer; FL=follicular lymphoma; PNH=paroxysmal nocturnal hemoglobinuria; \*all adjuvant studies are event driven, timelines / readout depending on events; \*\*met primary endpoint, data further maturing

## Strong replacement power of franchises - example of Lung Cancer



Early disease, novel combinations, targeted agents



<sup>\*</sup> IMpower132 approved in Japan

Tiragolumab granted

Breakthrough Therapy Designation (BTD)

#### **Cancer immunotherapy**

Tecentriq neoadjuvant and adjuvant data in 2021; Tiragolumab BTD in PD-L1 high NSCLC



#### **Driver mutations**

Rare mutations ( $\leq$ 2%) add up to  $\sim$ 10% of the lung cancer market:  $\sim$ 4bn opportunity





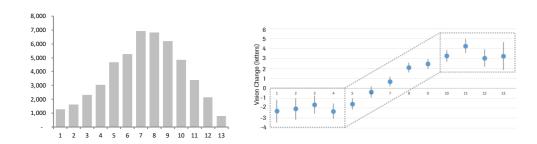


GDC-6036



## Replace and extend current business – example Ophthalmology Improve on durability, extend geographical outreach

## Adherence to IVT therapies is low and infrequent dosing in the real world correlates with vision loss



Only 50% of patients can be extended to Q3M dosing with current IVT therapies

## PDS and faricimab have the potential to improve real world outcomes with longer durability



 Port Delivery System (PDS): permanent, refillable intraocular implant. One-time ~30 min outpatient surgical procedure. Refill twice yearly in-office



**Faricimab:** in DME met primary endpoint, strong durability across all studies (>50% for 16 weeks); nAMD phase 3 to read out in 2021

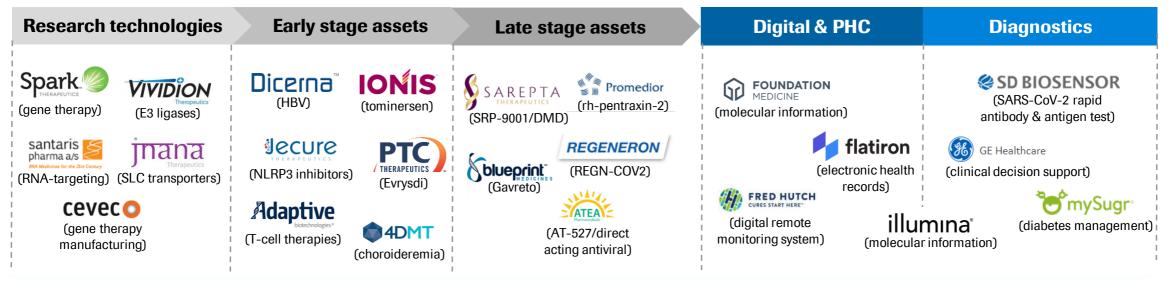
<sup>1.</sup> Source: Evaluate Pharma; DME=diabetic macular edema; nAMD=neovascular AMD; IVT=intravitreal

## Investing in external innovations<sup>1</sup>



## Accelerate drug discovery and diagnostic technologies

Technology stage at the time of licensing



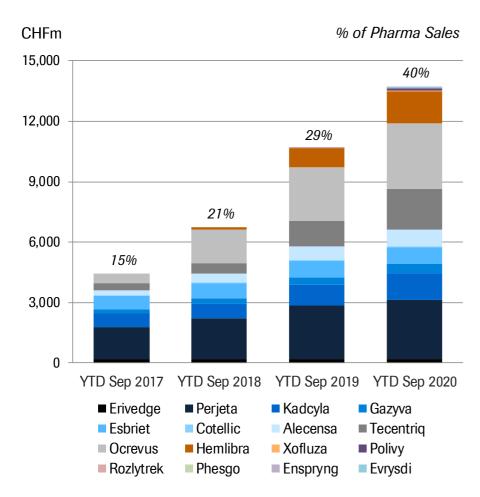
132 new agreements in 2020 focused on

High disease burden / Promising targets / Novel enabling techologies / Decision support

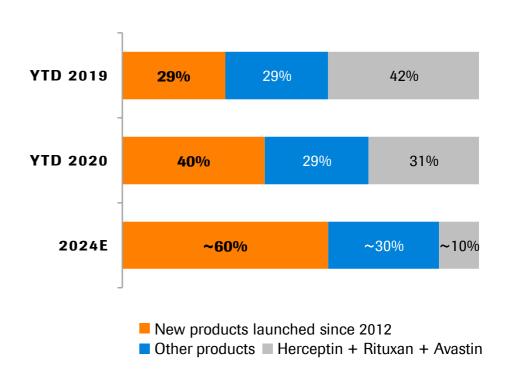




## Increasing share of sales coming from recent launches



### Pharma sales mix





## Launching new medicines in virtual environment; example Evrysdi US launch





#### **SMA Patients:**

Evrysdi shipped to patient's home through contactless delivery



#### **Health Care Professionals:**

Digital tools and resources to educate HCPs and their staff



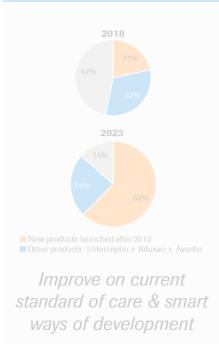
### **SMA Community:**

Virtual webinars and social media events in partnership with patient advocacy groups

Strong launch and initial uptake: Evrysdi projected to become treatment of choice in the US for the majority of patients in 2021

## 4 Priorities to maintain leadership position





#### **Diagnostics: Growing installed base** & expanding menu



Expansion with additional solutions and entering new disciplines

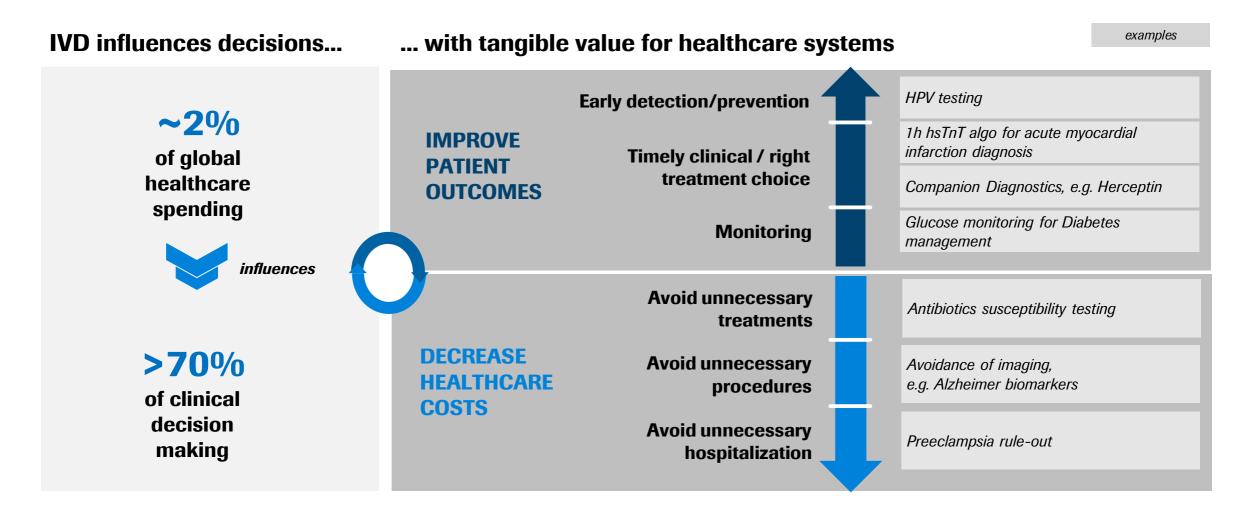




competitive fitness

## Roche

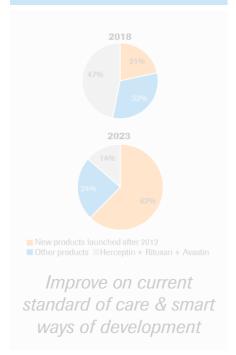
## Role of in-vitro diagnostics Playing a foundational role to improve outcomes & lower costs



## 4 Priorities to maintain leadership position



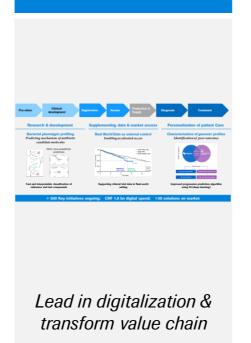
## Innovation: Replace & extend the business



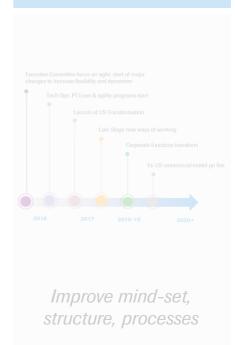
## Diagnostics: Growing installed base & expanding menu



## Leading personalized healthcare revolution



#### Transformation



## Pharma digital strategic priorities



**Pre-clinic** 

Examples:

Clinical development

Registration

**Access** 

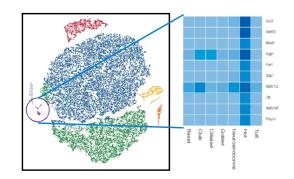
Production & Supply

**Diagnosis** 

**Treatment** 

**Research & development** 

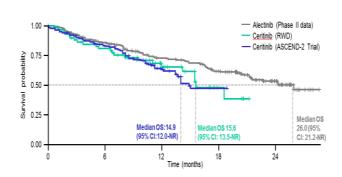
Single cell and spatial genomics
Discovering previously unknown cell types



Using massively parallel methods to profile millions of cells per day

#### **Supplementing data & market access**

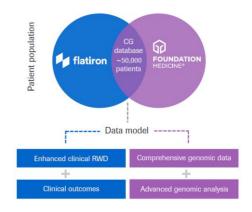
#### Real World Data as external control Enabling accelerated access



Supporting clinical trial data in Real world setting

#### **Personalization of patient care**

## Characterization of genomic profiles Identification of poor outcomes



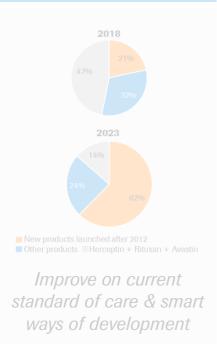
Improved progression prediction algorithm using AI (deep learning)

> 300 Key initiatives ongoing and >30 solutions on market

## 4 Priorities to maintain leadership position



## Innovation: Replace & extend the business



### Diagnostics: Growing installed base & expanding menu

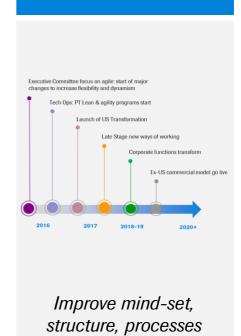


solutions and entering new

## Leading personalized healthcare revolution



#### **Transformation**



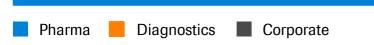


# Adjusting to a changing environment Initiatives across the entire company/value chain

**Improve processes & Optimization manufacturing Improving structures &** simplify decision taking & logistics processes Clinical **Pre-clinic Production & Supply Sales & Marketing** Registration development **Manufacturing strategic alignment Resourcing flexibility & digital R&D** interfaces & governance & lean production go-to-market models Diagnostics division transformation across the value chain

Finance / Procurement / IT / HR (end-2-end enterprise planning & centers of excellence)

**New ways of working: mindset and processes** 







#### Pharma cost structure

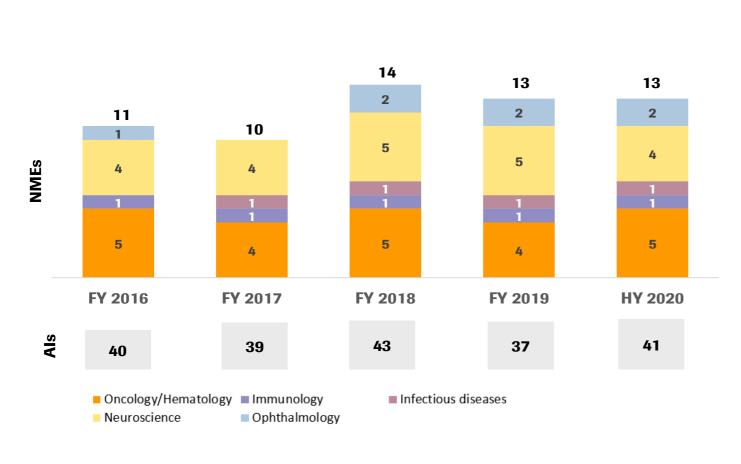
## **Cost of sales** Cost of sales M&D M&D G&A G&A illustrative R&D R&D Outlook **HY 2020**

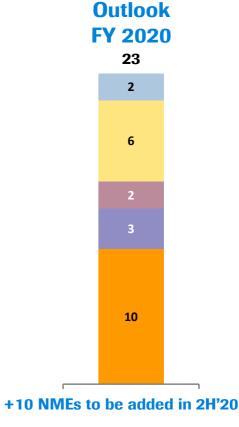
#### **Principles for resource allocation**

- Re-allocate resources into R&D while working on and protecting profitability
- Optimizing costs and efforts by
  - More targeted and often virtual stakeholder engagement
  - Personalized, digital content & services
- Improve performance by dynamic resource allocation



## Invest in innovation: Assets in Ph III & registration Strong momentum in the second half 2020





Gavreto in RET+ NSCLC & thyroid cancer

REGN-COV2 Ph III in COVID-19 (run by Regeneron)

giredestrant Ph III in 1L HR+ mBC glofitamab Ph III in r/r DLBCL mosunetuzumab Ph III in r/r FL crovalimab Ph III in PNH

rhPentraxin-2 Ph III in IPF
Gazyva Ph III in Lupus nephritis
fenebrutinib Ph III in RMS & PPMS
SRP-9001 Ph III in DMD (run by
Sarepta)

NME=new molecular entity; Al=additional indication



### **COVID-19: Roche's contributions**

**Priorities to maintain leadership position** 

### **Environment, Governance, and Social Responsibility**

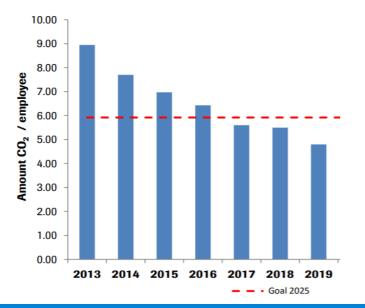
**Outlook** 

### Our impact on society



## Roche ranked most sustainable healthcare company by DJSI for the 11th time

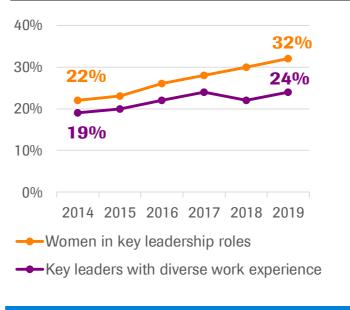




Goal: scope 1&2 greenhouse gas emissions to real zero by 2050<sup>1</sup>



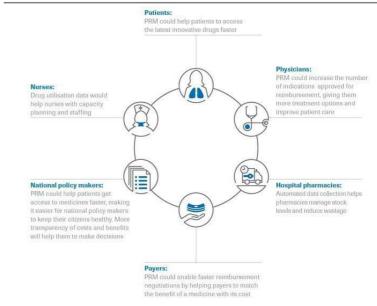
#### **Providing a great workplace**



32% of key leadership roles held by women



#### **Access to our products**



Personalized Reimbursement Models deliver benefits to multiple stakeholders

<sup>1.</sup> Without buying CO2 certificates 2. Genentech's annual average net price increase in the U.S., weighted by sales; 3. for inflation CPI-U Medical Care is used for all medical care expenditures (incl. prescription and non-prescription drugs, medical supplies, physicians' services, hospital services, and health insurance) – source: U.S. Bureau of Labor Statistics (US BLS);



### **COVID-19: Roche's contributions**

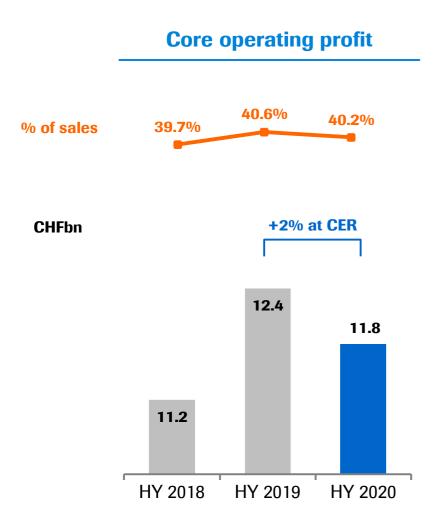
**Priorities to maintain leadership position** 

**Environment, Governance, and Social Responsibility** 

### **Outlook**

## Defending margins despite headwinds and investment in innovation





#### **Sales**



New Product Growth: 40% of sales YTD Sep 20 (up from 29% YTD Sep 19)

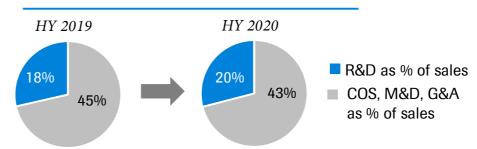
**Diagnostics:** COVID-19 testing



**Biosimilars / COVID-19:** contraction in AHR in 2020

**Diagnostics:** routine business

### **Expenses**



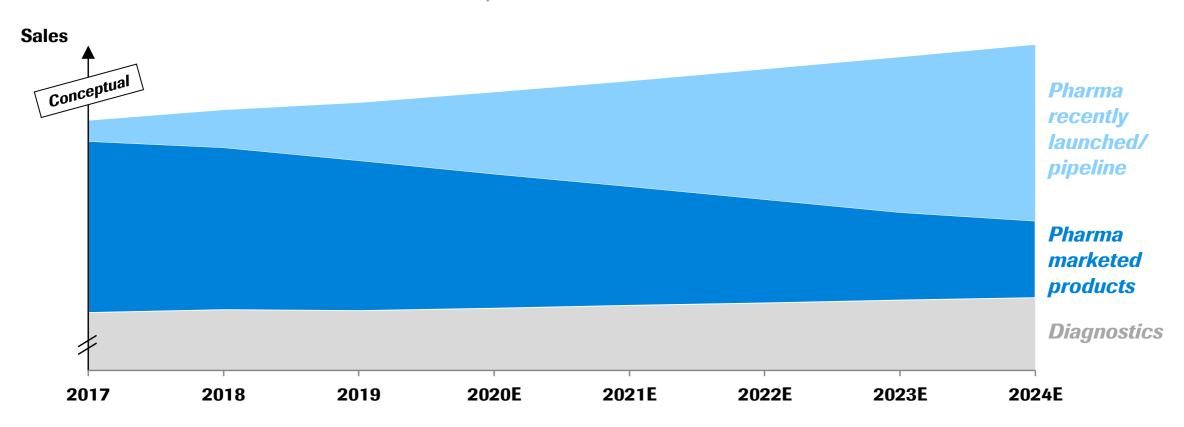
CER=Constant Exchange Rates 28

## **Growing through biosimilar transition**



#### Pharma NME and Dia launches

Ocrevus, Perjeta, Hemlibra, Tecentriq, Venclexta, Gazyva, Alecensa, Xofluza, Polivy, Rozlytrek, Evrysdi, Enspryng, Gavreto, ipatasertib, tiragolumab, etrolizumab, PDS, faricimab, tominersen, gantenerumab, etc. cobas 6800/8800, cobas 5800, cobas Mass Spec, cobas Liat, etc.

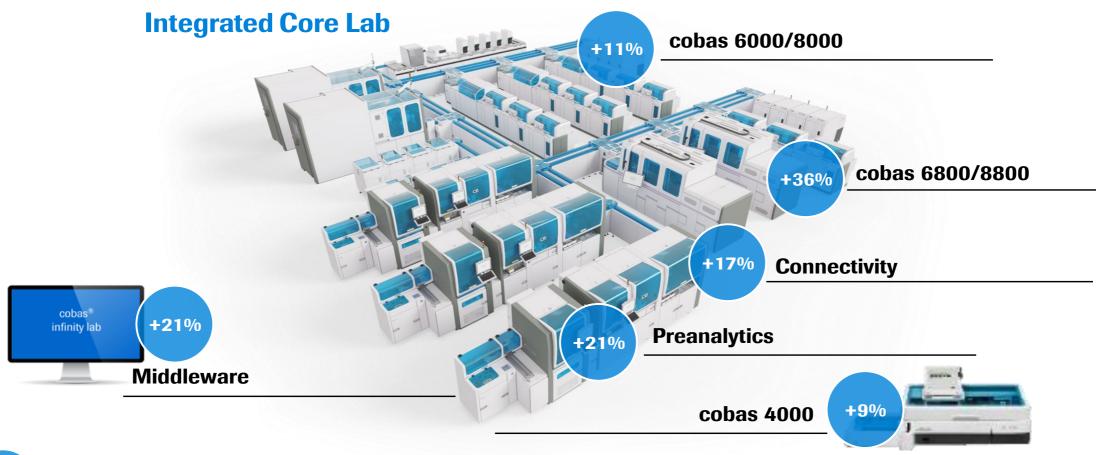




## Doing now what patients need next

## Growing installed base worldwide driving reagents consumption

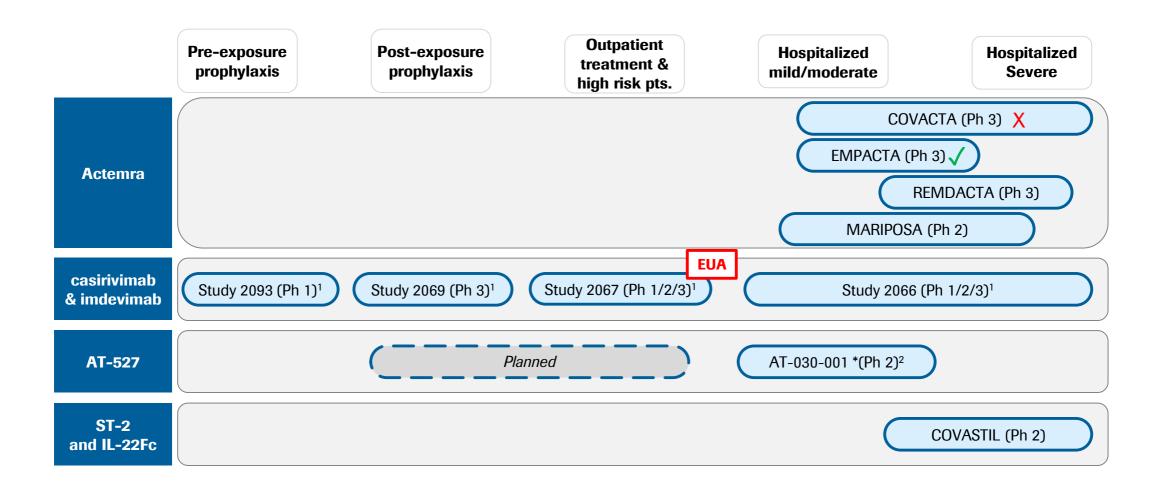






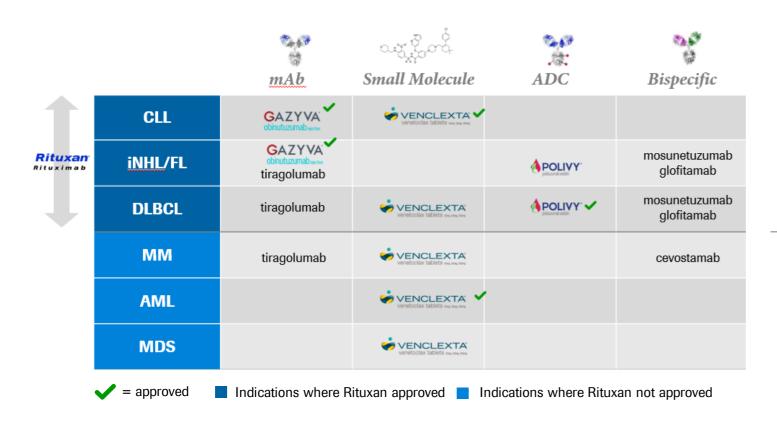


# Roche-sponsored/partnered trials for COVID-19 Pursuing multiple options to maximize public health impact





## Hematology: continuing to redefine the standard of care in B-cell malignancies and expanding into new diseases



#### **B-cell malignancies**

Polivy 1L DLBCL data in 2021; mosun/glofit advanced to randomized Ph 3 trials in NHL

#### **New hematologic diseases**

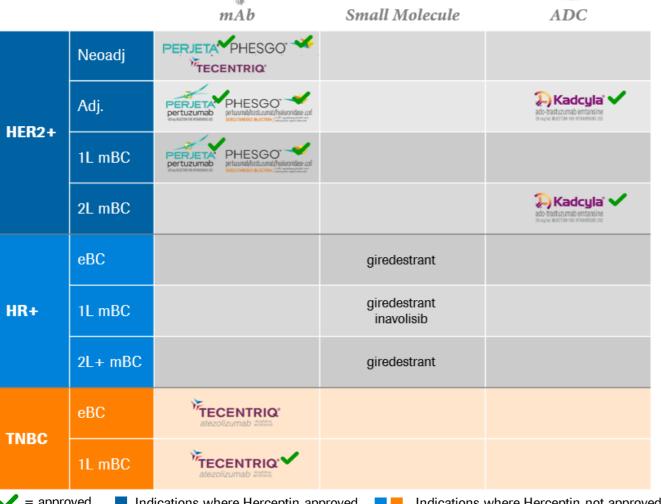
Venclexta >40% US market share in AML; ongoing Ph 3 trials in MM and MDS



## Replace and extend franchises: the example of Breast Cancer: **Expanding into TNBC and HR+ BC**

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#### HER2+ BC

Phesgo approved in US and EU in 2020 (SC fixed dose combination of Hercptin + Perjeta)

#### HR+/HER2-BC

SERD and Pi3K programs advanced to Ph 3 in HR+ BC with large addressable population

#### **TNBC**

Tecentriq positive Ph III results in neoadjuvant TNBC



## Doing now what patients need next