Roche

This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as ‘believes’, ‘expects’, ‘anticipates’, ‘projects’, ‘intends’, ‘should’, ‘seeks’, ‘estimates’, ‘future’ or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

1 pricing and product initiatives of competitors;
2 legislative and regulatory developments and economic conditions;
3 delay or inability in obtaining regulatory approvals or bringing products to market;
4 fluctuations in currency exchange rates and general financial market conditions;
5 uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
6 increased government pricing pressures;
7 interruptions in production;
8 loss of or inability to obtain adequate protection for intellectual property rights;
9 litigation;
10 loss of key executives or other employees; and
11 adverse publicity and news coverage.

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# Roche

# 2020 results

*Basel, 4 February 2021*

# Group

*Severin Schwan*
*Chief Executive Officer*

## 2020 performance

# Outlook

# 2020: Targets fully achieved despite COVID-19 pandemic

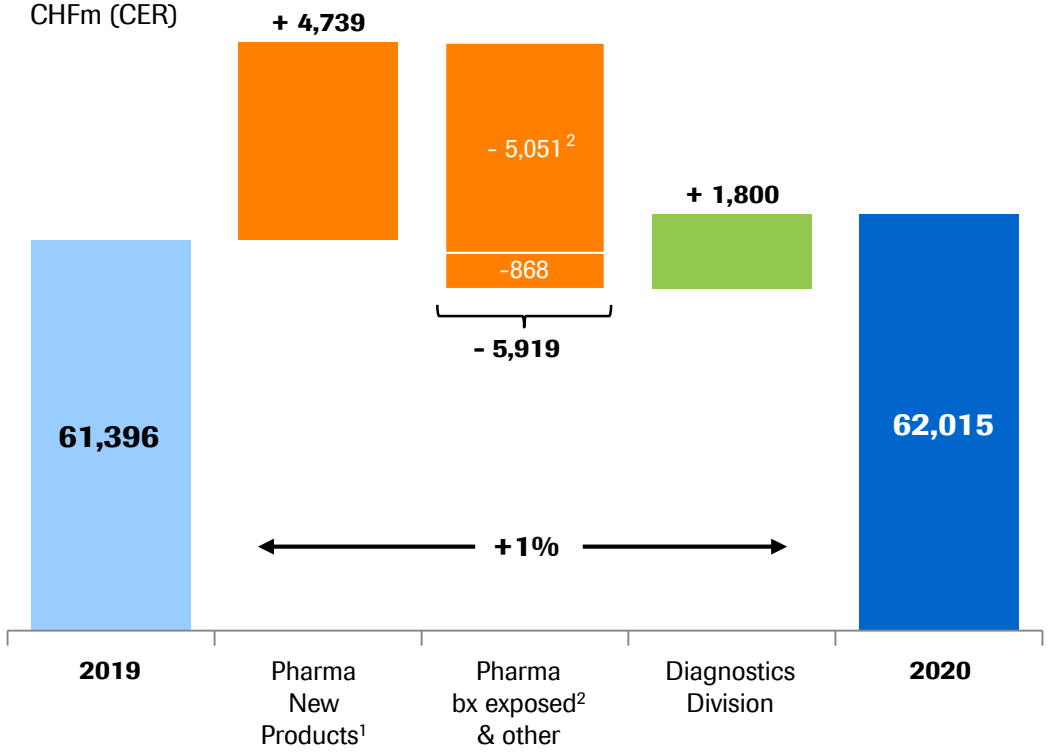
| *Targets for 2020* | | *FY 2020* | |
|---|---|---|---|
| **Group sales growth[1]** | Low- to mid-single digit | **+1%** | ✔ |
| **Core EPS growth[1]** | Broadly in line with sales growth | **+4%** | ✔ |
| **Dividend outlook** | Further increase dividend in Swiss francs[2] | **CHF 9.10** | ✔ |

[1] At constant exchange rates (CER); [2] 2020 dividend as proposed by the Board of Directors

# 2020: Successfully managing the transition in volatile environment

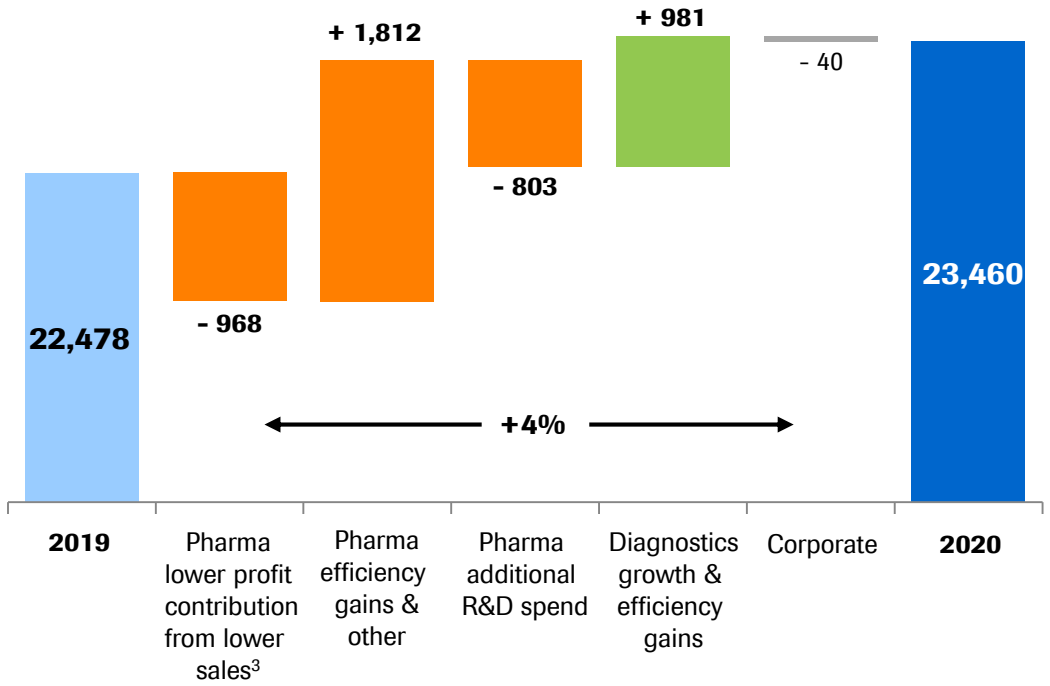
## Compensated for biosimilar & COVID-19

**Group Sales**
CHFm (CER)




## Efficiency gains & investment into future

**Group Core OP**
CHFm (CER)




At constant exchange rates (CER); [1] Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi; [2] MabThera, Herceptin & Avastin in Europe (Avastin: as of Jul 20) and MabThera, Herceptin & Avastin in U.S. and Japan; [3] Pharma sales decline minus proportional cost of sales 2020

# Responding quickly and broadly to the pandemic

Roche

**Pharma**

**AT-527**

Collaboration with Atea on development of AT-527

**casirivimab/imdevimab**

**Collaboration with Regeneron on casirivimab/imdevimab global supply**

**FDA EUA granted in mild-moderate adults and adolescents**

ACTEMRA® tocilizumab

COVACTA trial initiated

REMDACTA trial initiated

COVACTA trial results

EMPACTA trial results

**REMAP-CAP trial results**

Jan 20 | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan 21 | Feb

**Diagnostics**

**LightCycler® 480**

TIB MOLBIOL LightMix® modular SARS-CoV-2 launched

**cobas® 6800/8800**

**cobas® SARS-CoV-2 test receives FDA EUA**

**cobas® SARS-CoV-2 test & Flu A/B Test receives FDA EUA**

**cobas® e411/601/602/801**

**Elecsys® Anti-SARS-CoV-2 antibody test receives FDA EUA**

Elecsys® IL-6 test receives FDA EUA

Elecsys® Anti-SARS-CoV-2 S antibody test launched

Lab SARS-COV-2 antigen test launched

**Non-instrumented**

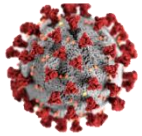
SARS-CoV-2 Rapid Antibody Test launched

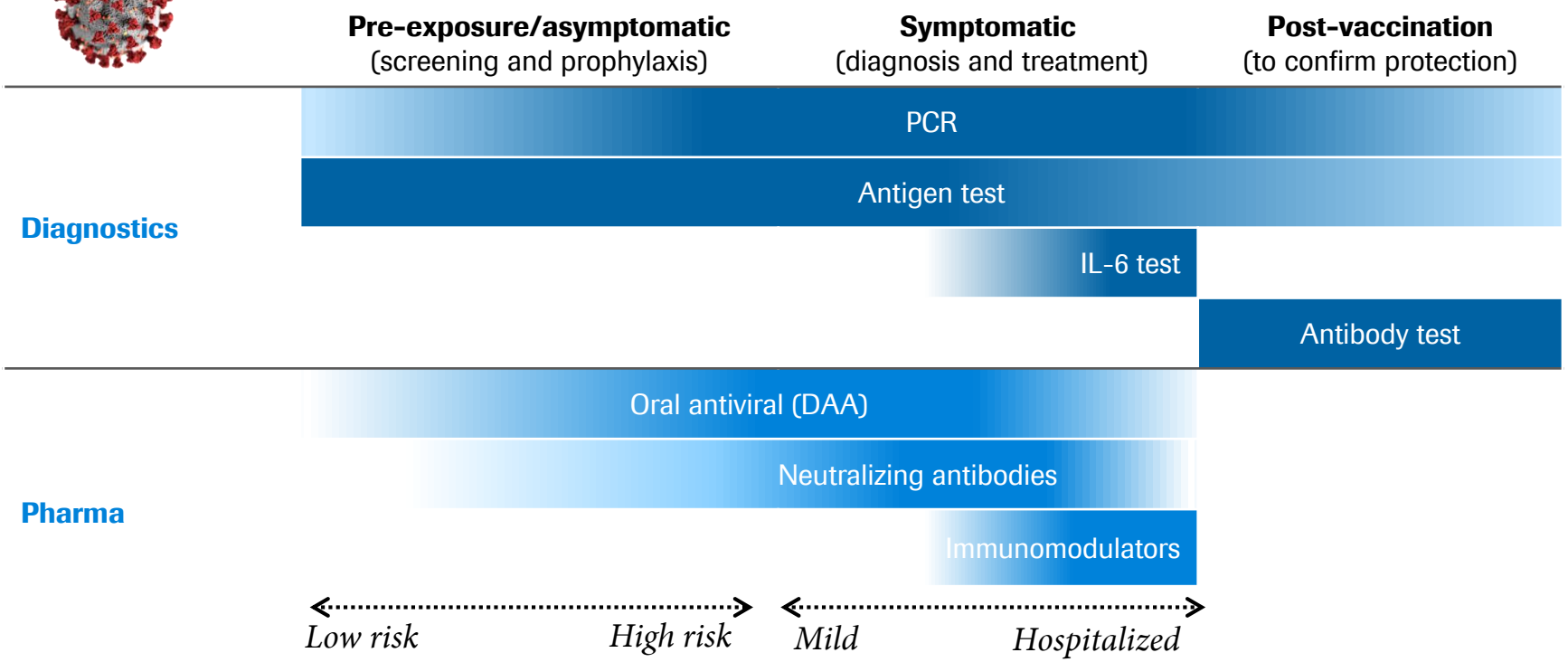
**SARS-CoV-2 Rapid Antigen Test launched**

**SARS-CoV-2 Rapid Antigen Test Nasal launched**

Overview - not all COVID-19 related developments captured; EUA=emergency use authorization

# Potential use cases for 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-19 diagnosis

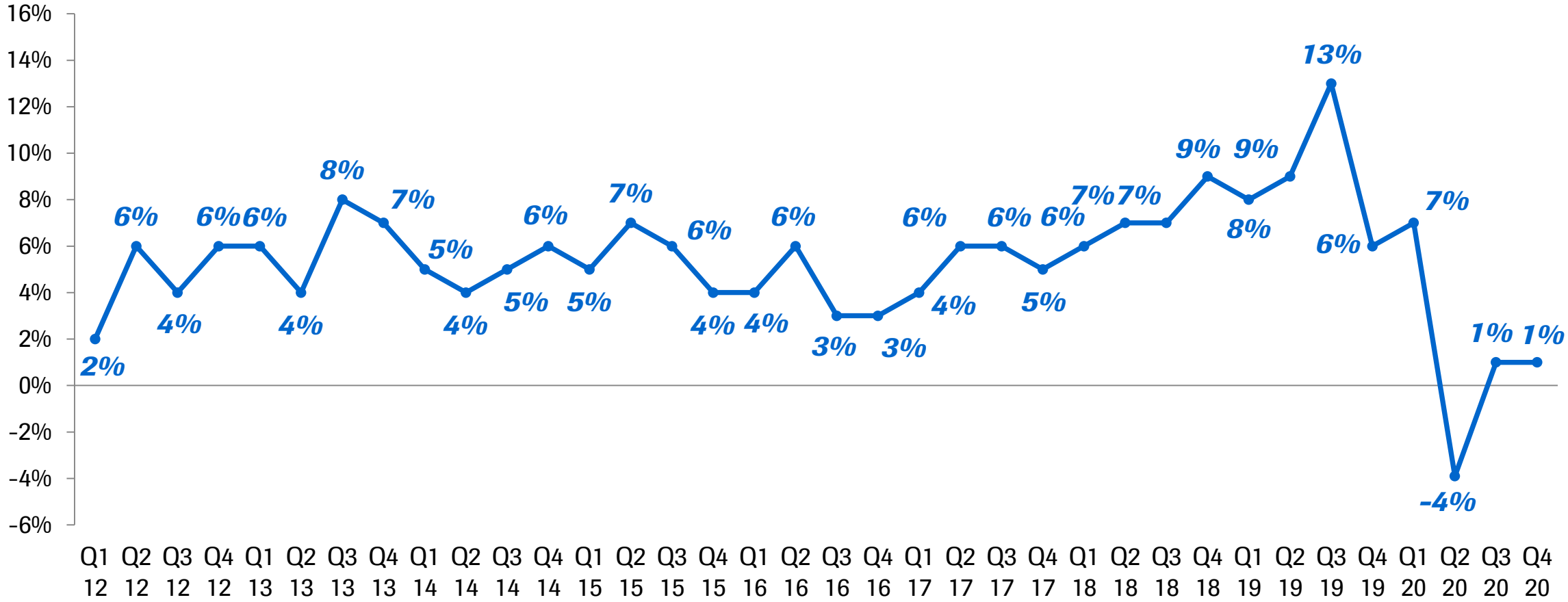
PCR=polymerase chain reaction test

# 2020: Sales growth due to Diagnostics Division

| | 2020 CHFbn | 2019 CHFbn | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Pharmaceuticals Division** | **44.5** | 48.5 | **-8** | **-2** |
| **Diagnostics Division** | **13.8** | 12.9 | **6** | **14** |
| **Roche Group** | **58.3** | 61.5 | **-5** | **1** |

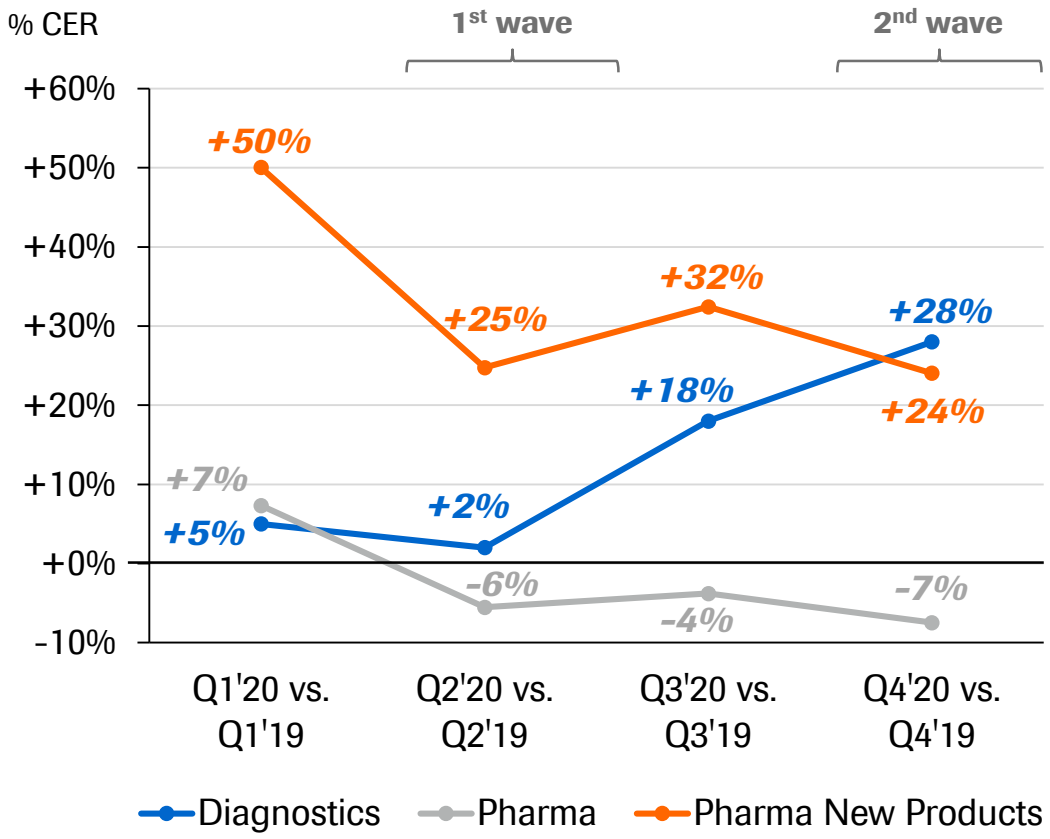
CER=Constant Exchange Rates

# 2020: Group sales growth impacted by COVID-19




At constant exchange rates (CER)

# 2020: Pandemic heavily impacting business dynamics




## Pharmaceuticals

- Severe impact from biosimilars and COVID-19
- Q4 carry over effect (Ocrevus administration)

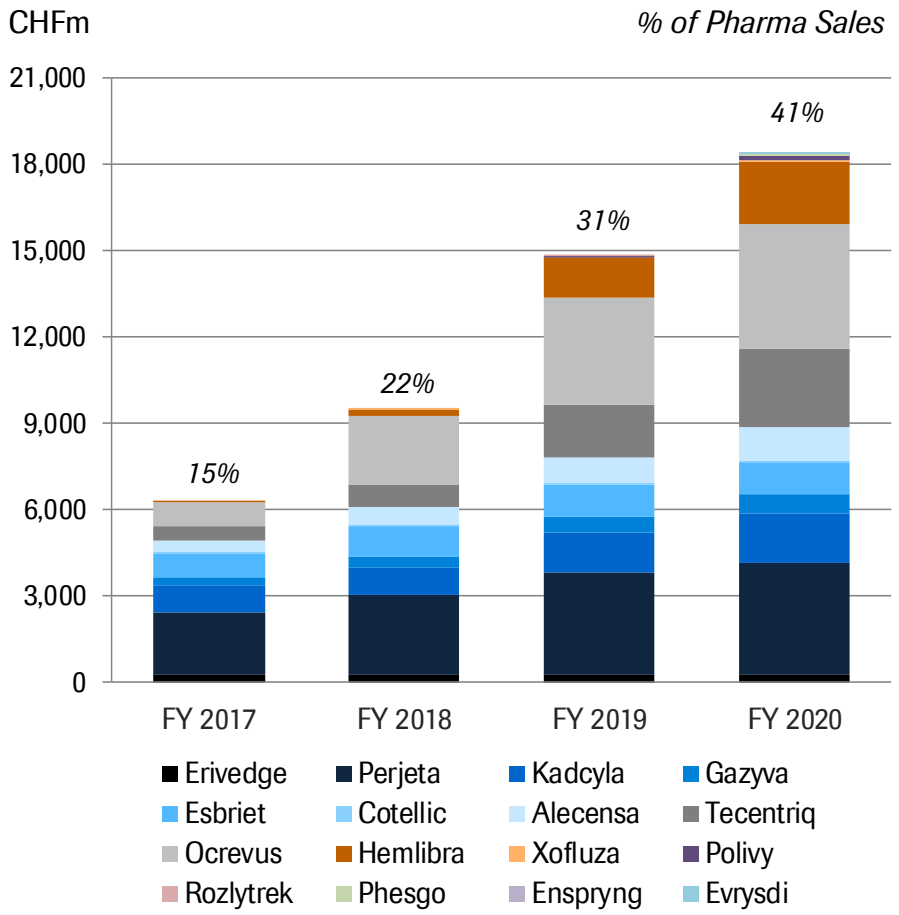
## Diagnostics

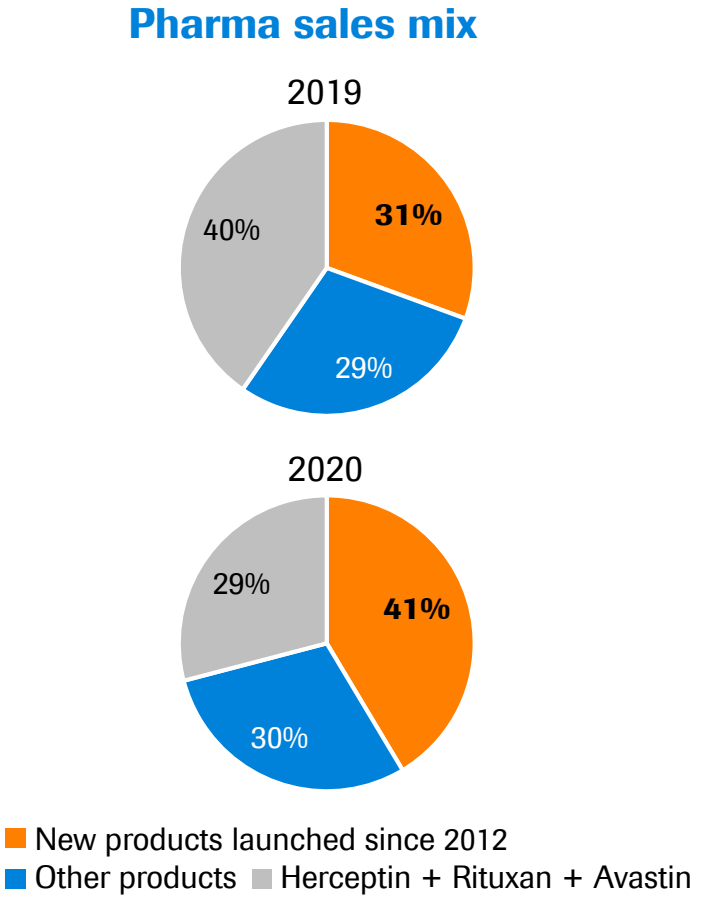
- Routine diagnostics impacted by COVID-19, gradual recovery since June 2020
- COVID-19 testing overcompensating negative impact on routine testing since June 2020

Growth rates at CER (Constant Exchange Rates)

# Pharma: New products with strong momentum

## *Accelerated portfolio rejuvenation in Q4 2020*

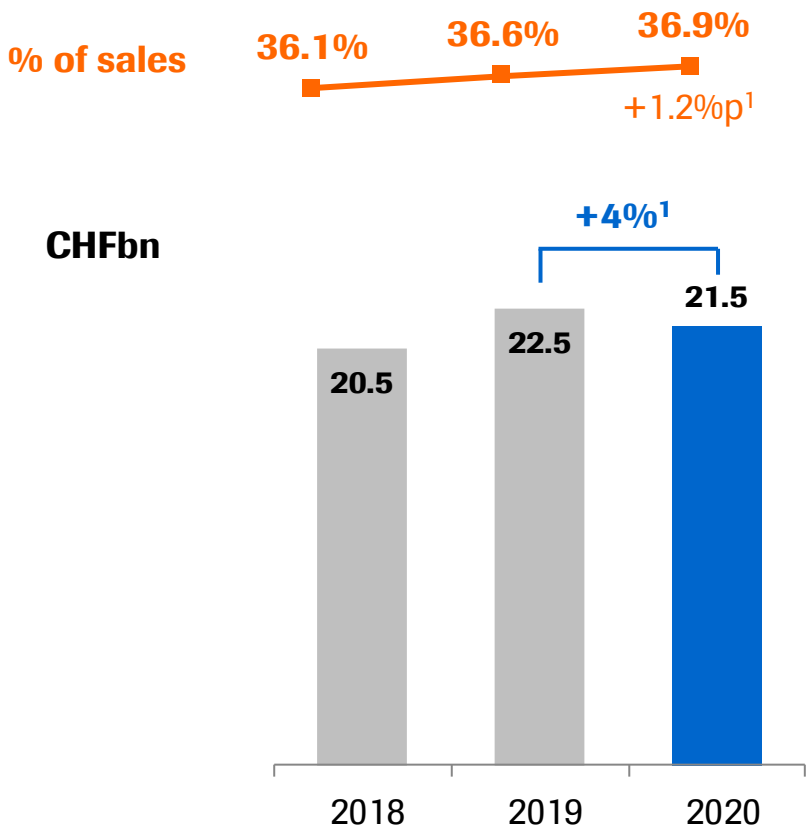


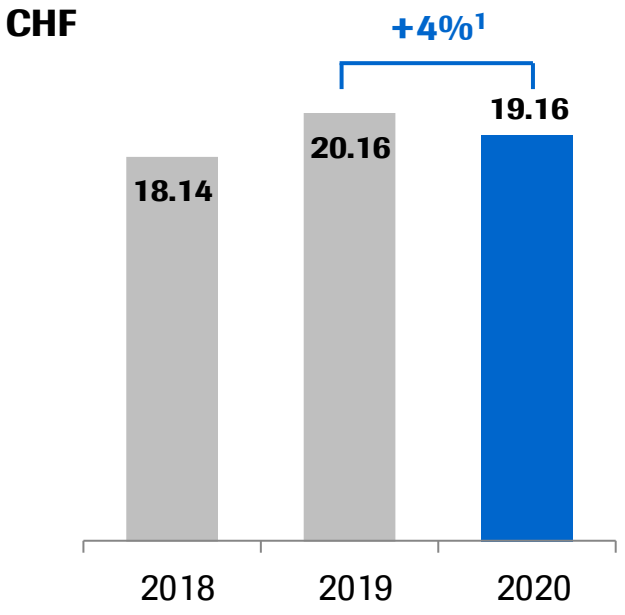

All absolute values are presented in CHFm reported

# 2020: Growth of profitability and Core EPS

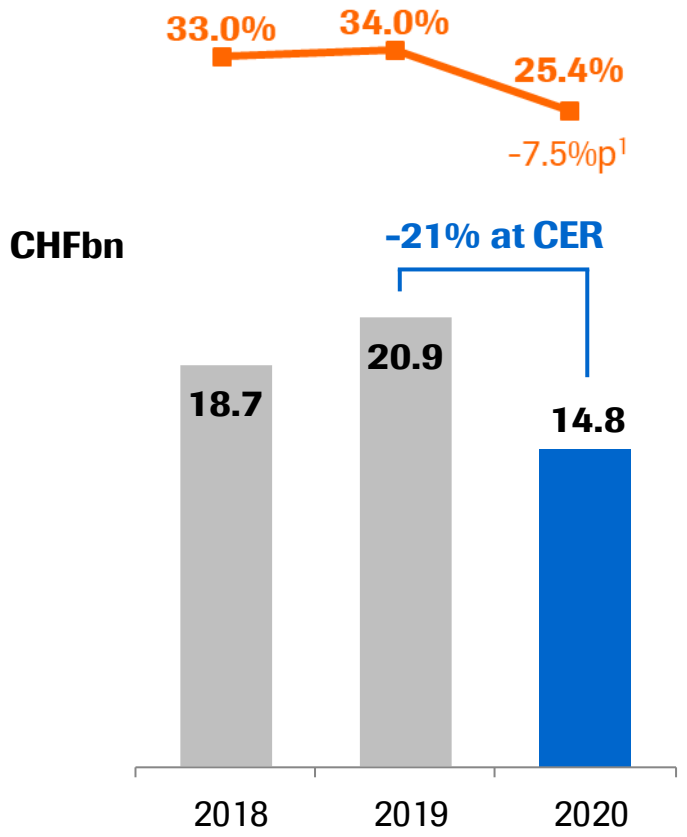
## Core operating profit




## Core EPS




## Operating free cash flow



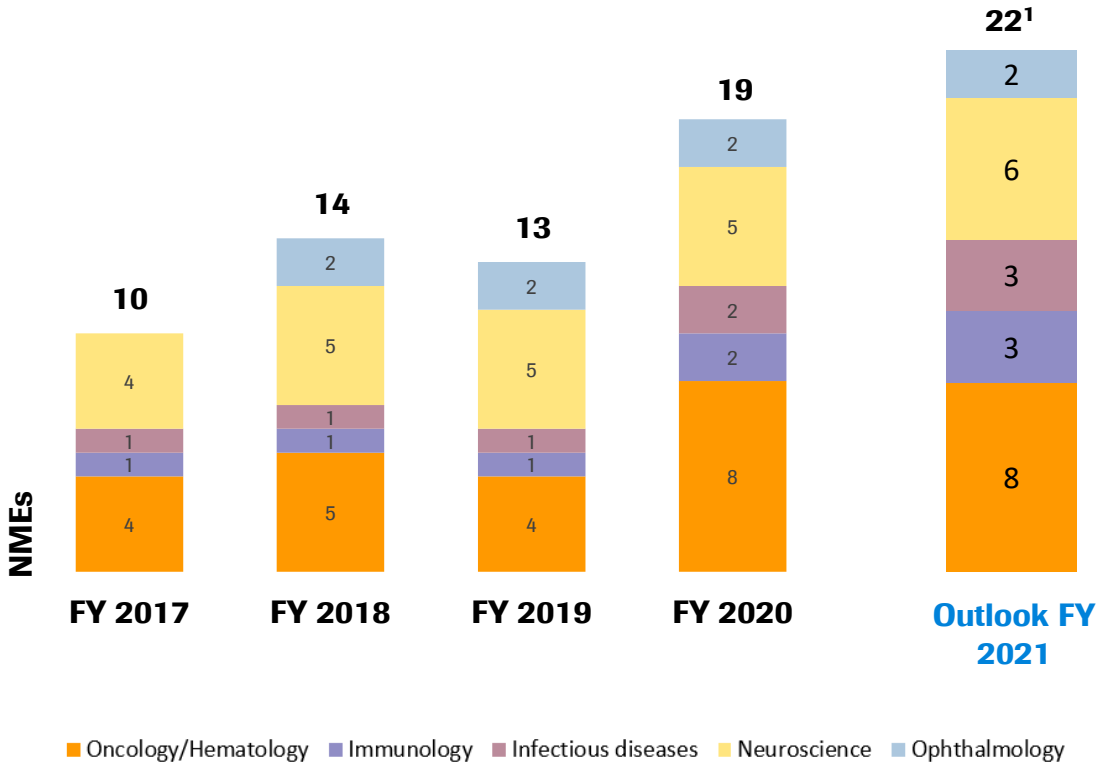

[1] at CER=Constant Exchange Rates

## 2020 performance

# Outlook

# Continuing to invest in innovation

## Assets in Ph III & registration at all time high




## Diagnostics major systems launches ahead

**cobas®** 5800[2]

**cobas®** pure[2]

**cobas®** pro (high throughput)

NME=new molecular entity; [1] Ph III in SRP-9001 DMD, Ph III in AT-527 COVID-19, Ph III in rh-PTX-2 in IPF; [2] currently in development and not commercially available

# Strong short- and mid-term news flow

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

| Product | Indication | Filing/Data | |
|---|---|---|---|
| **tominersen** | Huntington's | 2022 | |
| **gantenerumab** | Alzheimer's | 2022 | |
| **SRP-9001** | DMD | latest 2023 | |
| **etrolizumab** | Crohn's | 2022 | |
| **PDS** | nAMD<br>DME | 2020/21<br>2022 | ✓ |
| **faricimab** | DME<br>nAMD | 2021 | ✓<br>✓ |
| **Actemra +/- remdesivir** | COVID-19 related pneumonia | 2021 | |
| **casirivimab/ imdevimab** | SARS-CoV-2 | 2021 | |
| **AT-527** | SARS-CoV-2 | 2021/22 | |
| **crovalimab** | PNH | 2022 | |

| Product | Indication | Filing/Data |
|---|---|---|
| **Tecentriq** | Adj SCCHN | 2021 |
| | (Neo)Adj NSCLC | 2021/22 |
| | Adj RCC | 2022 |
| | Adj HCC | 2022 |
| **ipatasertib** | 1L mCRPC | 2022 |
| **Polivy** | 1L DLBCL | 2021 |
| **tiragolumab + T** | 1L SCLC | 2022 |
| **mosunetuzumab** | R/R FL | 2021 |
| **glofitamab** | R/R DLBCL | 2022 |
| **Venclexta** | R/R MM t(11;14) | 2022 |
| **giredestrant** | 2L/3L mBC | 2022 |
| **inavolisib** | 1L HR+ BC | 2022/23 |

✓ Positive top-line announced  Neuroscience  Immunology  Ophthalmology  Infectious diseases  Oncology/Hematology

Source: DMD=duchenne muscular dystrophy; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; PNH=paroxysmal nocturnal hemoglobinuria; SCCHN=squamous cell carcinoma of the head and neck; RCC=renal cell carcinoma; NSCLC=non-small cell lung cancer; HCC=hepatocellular carcinoma; mCRPC=metastatic castration resistant prostate cancer; DLBCL=diffuse large B-cell lymphoma; SCLC=small cell lung cancer; FL=follicular lymphoma; MM=multiple myeloma

# Outlook 2021: Growing sales & profit and investing in the future

*Aim to defend margins despite headwinds*

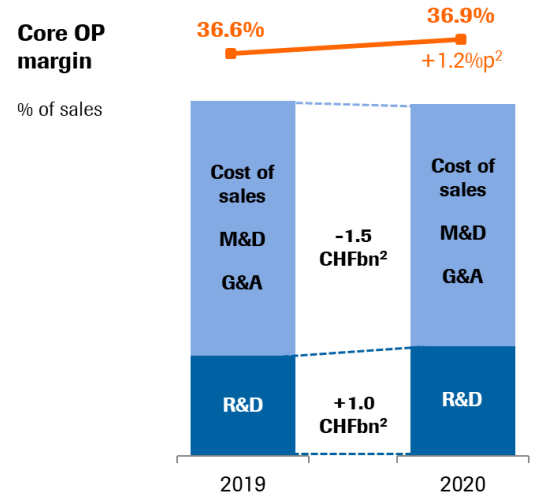
## Sales[1]

**Pharma:** New Products growth to continue overcompensating for the biosimilar impact

**Diagnostics:** Strong sales growth expected in particular in H1 21

**Pharma:** AHR erosion additional impact of roughly CHF –4.6 bn

## Expenses




**Trends expected to continue:**
Investing into the future while protecting the margin

[1] based on assumption of general normalization in 2H '21; [2] at CER=Constant Exchange Rates; AHR=Avastin, Herceptin, MabThera/Rituxan

# 2021 outlook
## *Further growing top and bottom line*

| | |
|---|---|
| **Group sales growth[1]** | • Low- to mid-single digit |
| **Core EPS growth[1]** | • Broadly in line with sales growth |
| **Dividend outlook** | • Further increase dividend in Swiss francs |

[1] At Constant Exchange Rates (CER); based on the current assessment of the COVID-19 impact

# Pharmaceuticals Division

*Bill Anderson*
*CEO Roche Pharmaceuticals*

# 2020: Pharmaceuticals Division sales

*New products growing strongly – sales impacted by COVID-19 pandemic*

| | 2020 CHFm | 2019 CHFm | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Pharmaceuticals Division** | **44,532** | **48,516** | **-8** | **-2** |
| United States | 23,647 | 26,711 | -11 | -6 |
| Europe | 8,198 | 8,453 | -3 | 1 |
| Japan | 3,765 | 4,143 | -9 | -6 |
| International | 8,922 | 9,209 | -3 | 7 |

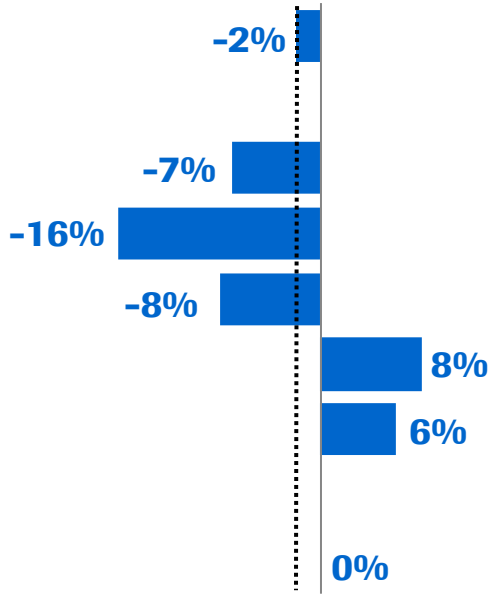
CER=Constant Exchange Rates

# 2020: Pharma Division

## *Core operating profit stable vs. prior year and significant reallocation of resources into R&D*

| | 2020 CHFm | 2020 % sales |
|---|---|---|
| **Sales** | **44,532** | **100** |
| Royalties & other op. inc. | 1,959 | 4.4 |
| Cost of sales | -8,070 | -18.2 |
| M & D | -6,633 | -14.9 |
| R & D | -10,597 | -23.8 |
| G & A | -1,714 | -3.8 |
| **Core operating profit** | **19,477** | **43.7** |

**2020 vs. 2019 CER growth**




*-7% in CHF*

CER=Constant Exchange Rates

# Reallocating resources into R&D

## *Providing more patient benefit at less cost to society*

**1** **Doubling of medical advances[1]**

- Re-allocation of resources into R&D, while working on and protecting profitability
- R&D Mission Support

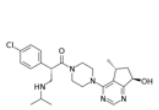
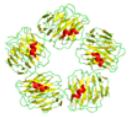
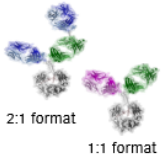
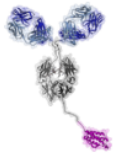
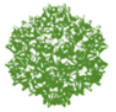
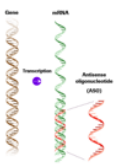
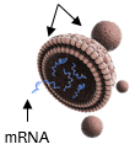
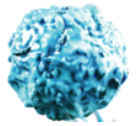
**2** **Significantly progress other patient benefits**

| Research technologies | Early stage assets | Late stage assets | Digital & PHC |
|---|---|---|---|

cevec (gene therapy manufacturing) · Adaptive (T-cell therapies) · Jecure (NLRP3 inhibitors) · SAREPTA (SRP-9001) · blueprint (Gavreto) · PTC (Evrysdi) · FOUNDATION MEDICINE · flatiron

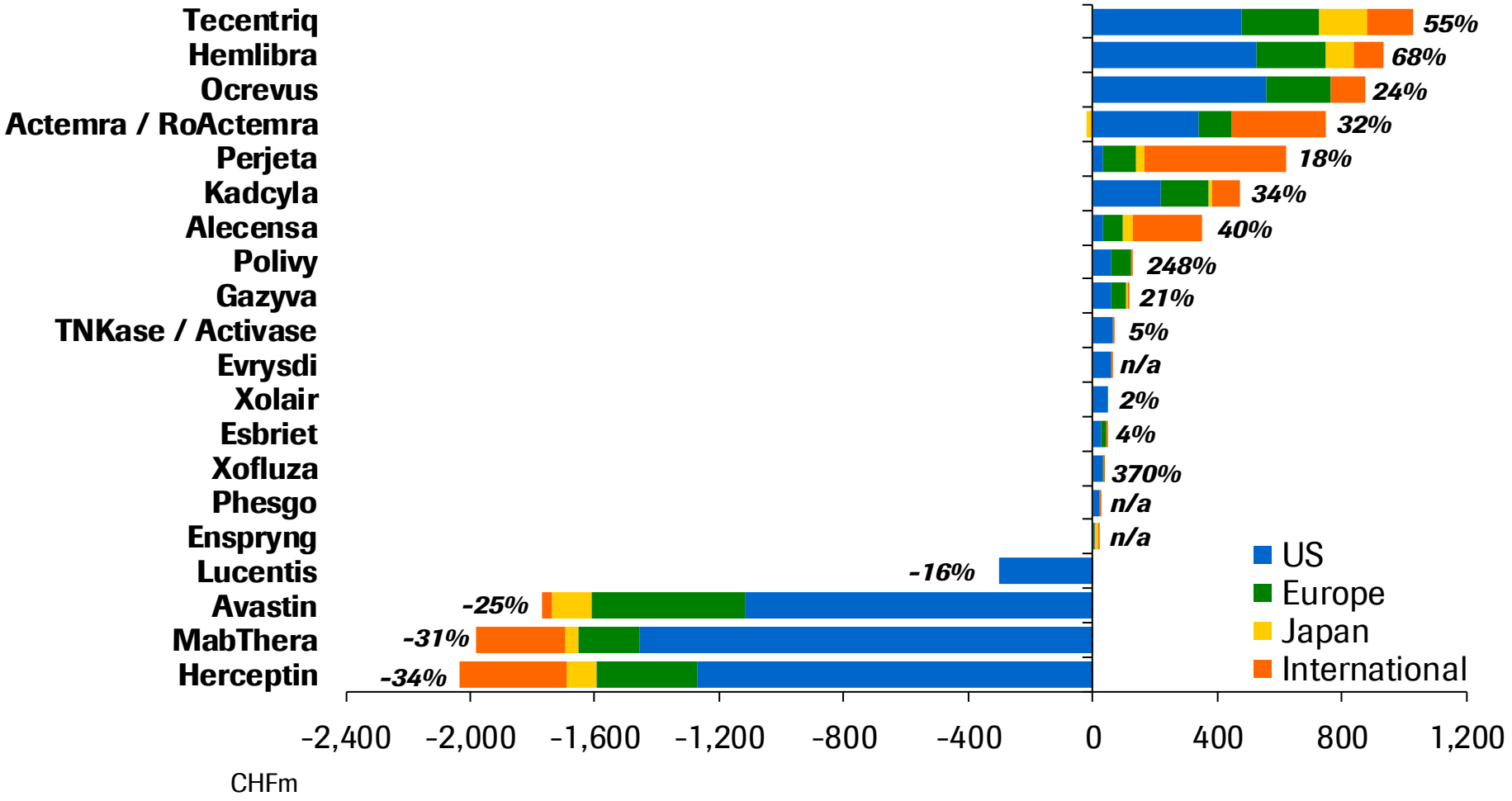
santaris pharma a/s (RNA therapy) · Spark (gene therapy) · ATEA (AT-527) · IONIS (tominersen) · Promedior (rh-pentraxin-2) · REGENERON (casirivimab/ imdevimab) · illumina

**92 new agreements in 2020**

| | Small molecules | Recombinant proteins | Antibodies | Antibody drug conjugates | Bi-specifics | Fusion proteins | Gene therapy | RNA technologies | Personalized mRNA vaccine | Personalized T cells |
|---|---|---|---|---|---|---|---|---|---|---|
| |  |  | | |  |  | AVV Adeno associated virus  |  | iNeST platform: mRNA-LPX Liposome  | Activated T cell with neoantigen specificity  |
| **launched** | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | | |
| **NMEs in clinical development *** | **#12** | **#1** | **#19** | **undisclosed** | **#15** | **#8** | **#7** | **#6** | **#2** | **#1** |

[1] First approval of a new molecule in a new indication; * Molecule classification for NMEs in clinical development where details have been disclosed - there are 20 additional undisclosed NMEs in clinical development; PHC=personalized healthcare; NME=new molecular entity.

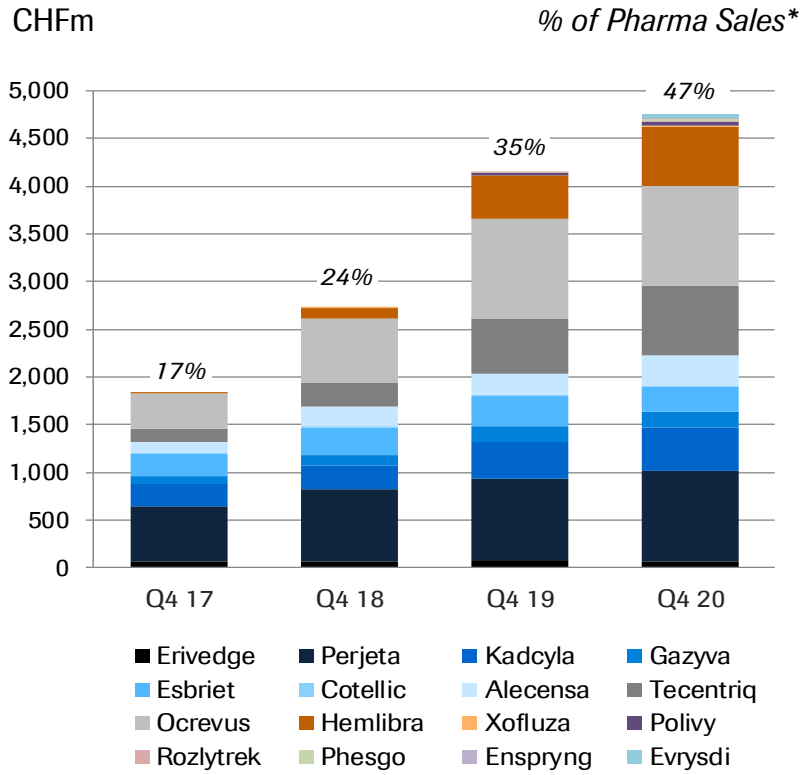
# 2020: Strong growth for new products leading to a more diversified portfolio

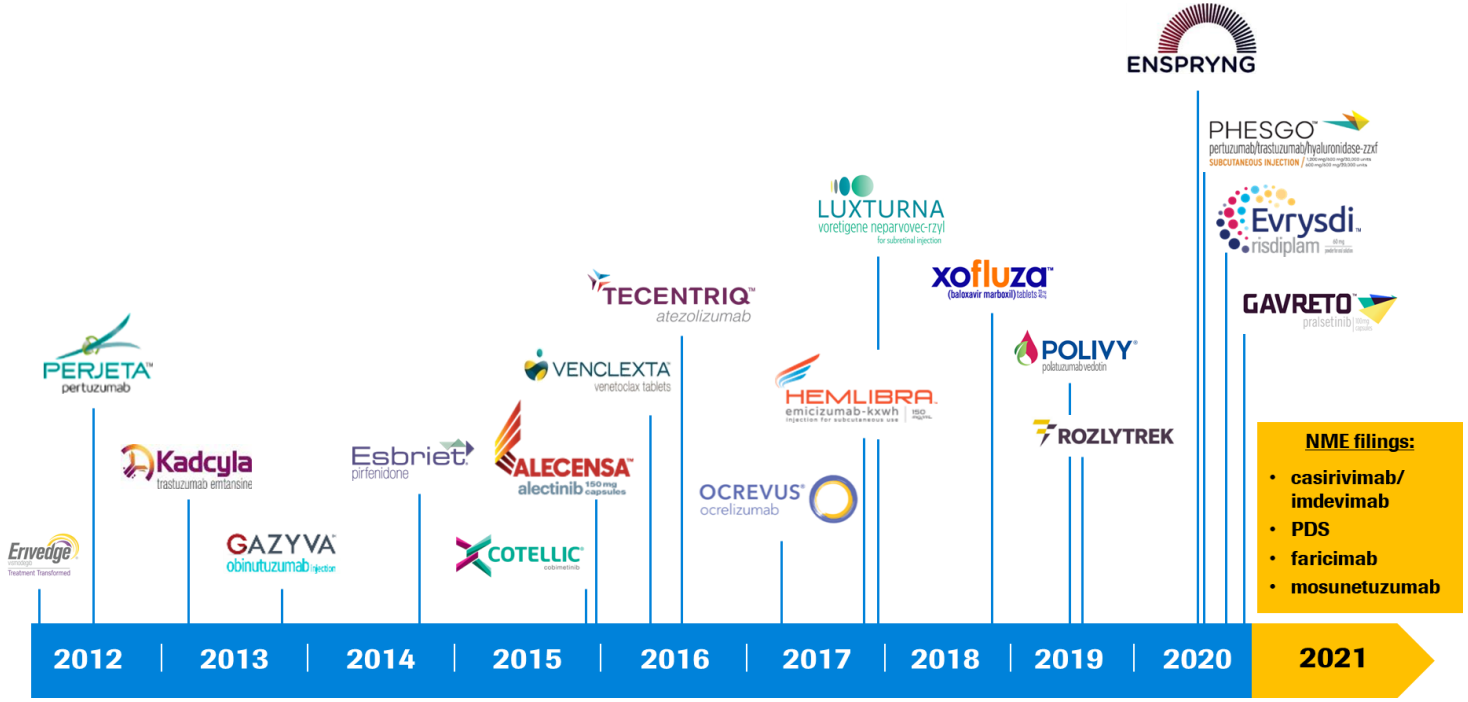



Absolute values and growth rates at Constant Exchange Rates (CER)

# New products account for >47% of Pharma sales*

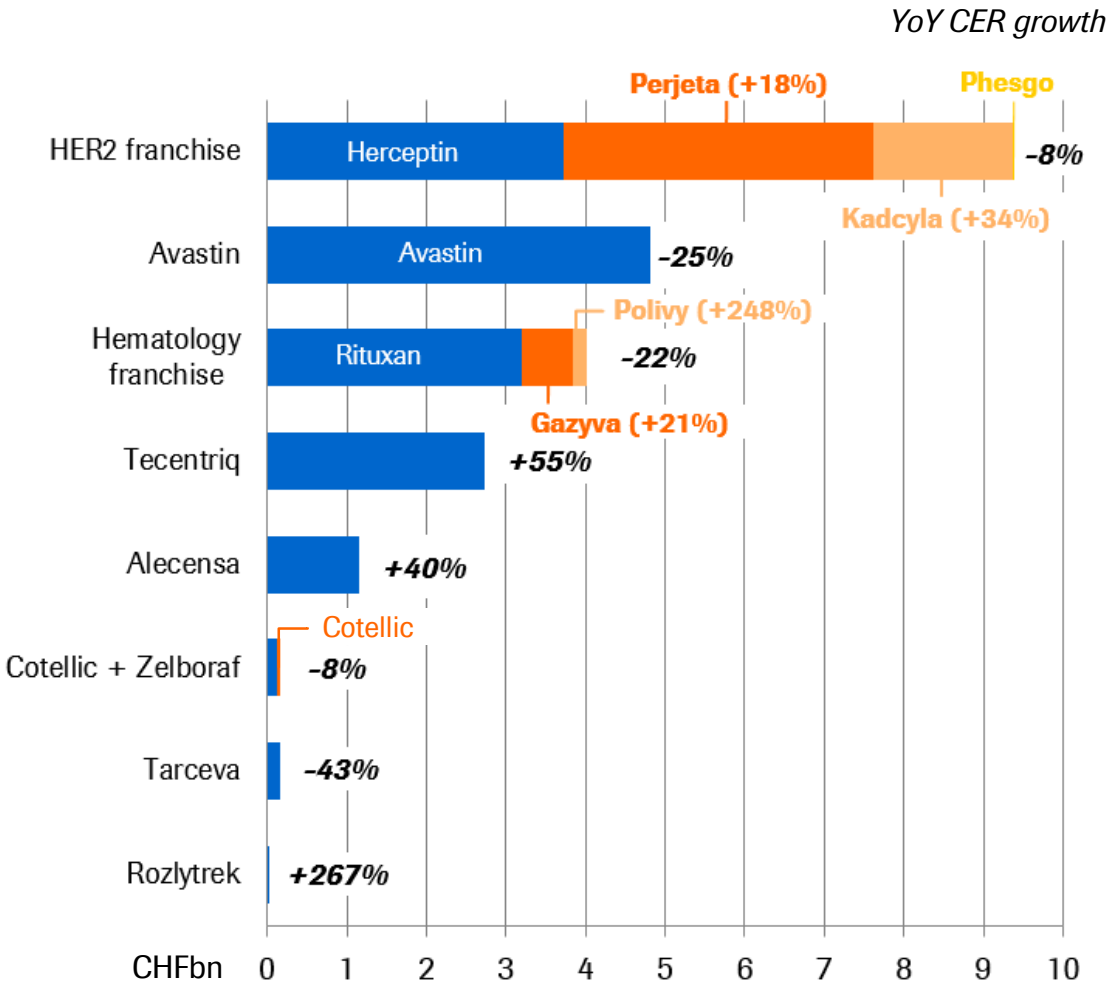
## *4 NMEs launched in 2020: ENSPRYNG, PHESGO, GAVRETO & EVRYSDI*




* Venclexta sales are booked by partner AbbVie and therefore not included (Q4: USDm 365); Gavreto sales are initially booked by partner Blueprint Medicines and therefore not included, Gavreto discovered by Blueprint Medicines; NME=new molecular entity

# 2020: Oncology -10% due to biosimilars & COVID-19




## HER2 franchise

- Kadcyla and Perjeta with strong global uptake in adjuvant BC
- Phesgo launched in US and EU

## Avastin franchise

- Biosimilar erosion in all regions

## Hematology franchise*

- Venclexta: Strong growth in 1L CLL and 1L AML
- Gazyva: Growth in 1L CLL and 1L FL
- Polivy: Strong US/EU launch in R/R DLBCL

## Tecentriq

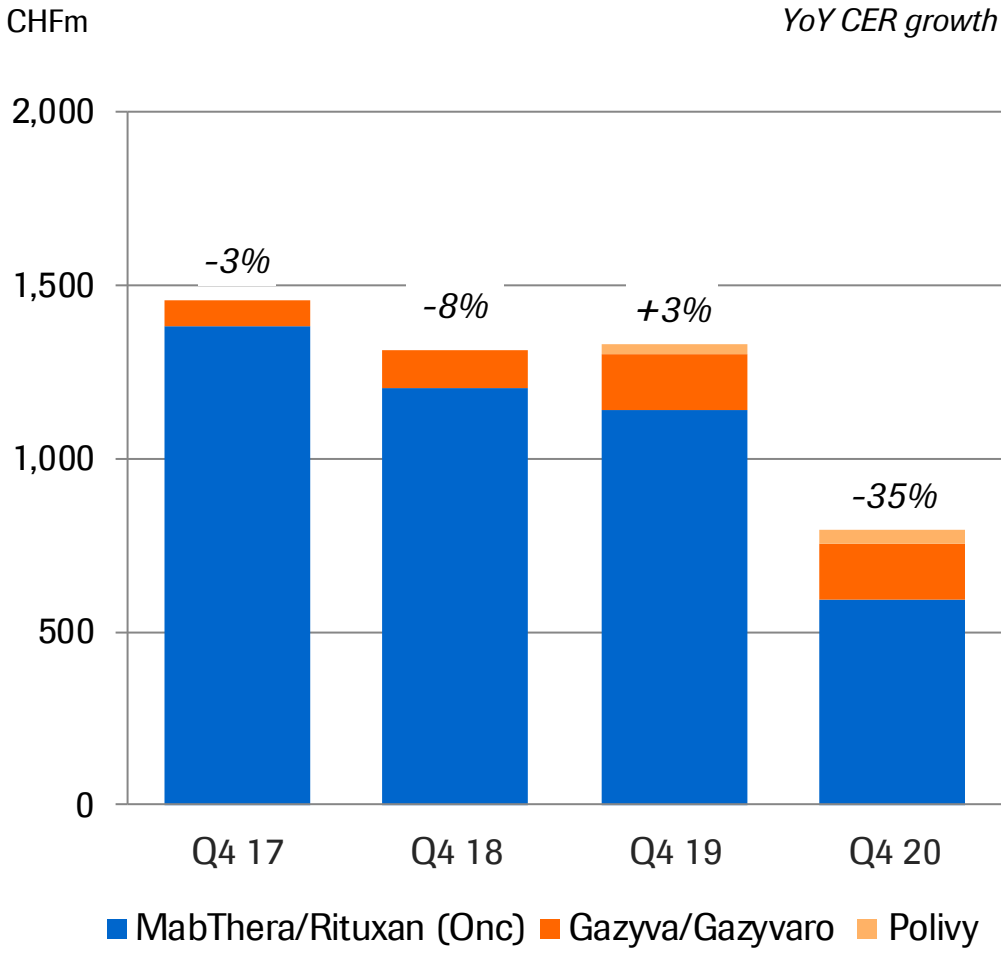
- Growth driven by 1L SCLC, 1L TNBC and 1L HCC

## Alecensa

- Strong performance in all regions

CER=Constant Exchange Rates; 2020 Oncology sales: CHF 23.3bn; CER growth -10%; * Venclexta sales booked by AbbVie and therefore not included (FY-2020 sales of USD 1,337m); Polivy in collaboration with Seagen; BC=breast cancer; AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; R/R DLBCL=relapsed/refractory diffuse large B cell lymphoma; SCLC=small cell lung cancer; TNBC=triple negative breast cancer; HCC=hepatocellular carcinoma

# Hematology franchise: Growth from Venclexta, Gazyva, and Polivy




## Hematology franchise Q4 update

### CD20 franchise

- MabThera/Rituxan onc (-43%): Biosimilar and COVID-19 impact
- Gazyva (+6%): Growth in 1L CLL and 1L FL; some COVID-19 impact

### Venclexta*

- Strong growth driven by 1L CLL and 1L unfit AML
- Ph III (Viale-A) in 1L unfit AML approved in US; filed in EU
- Updated NCCN guidelines in CLL & AML to «category 1»

### Polivy

- US/EU: strong uptake in R/R DLBCL

### Outlook 2021

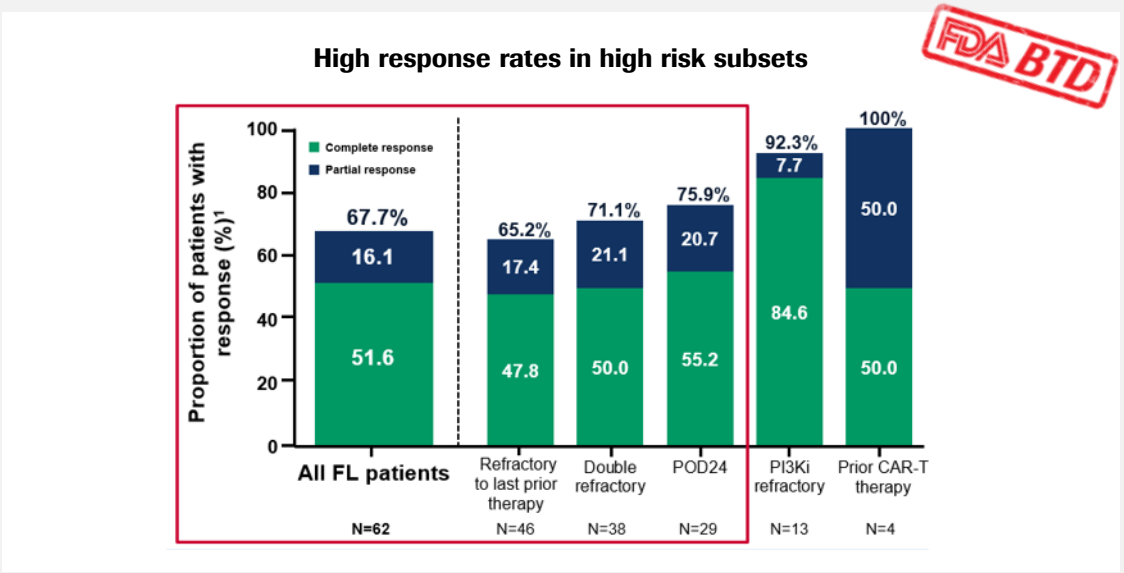
- Ph III (POLARIX) results for Polivy in 1L DLBCL expected
- CD20xCD3 program updates; Early filing potential in 3L+ FL/DLBCL

CER=Constant Exchange Rates; * Venclexta sales are booked by AbbVie (FY-2020 sales of USDm 1,337); Gazyva in collaboration with Biogen; Polivy in collaboration with Seagen; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; AML=acute myeloid leukemia; NCCN=national comprehensive cancer network; R/R DLBCL=relapsed/refractory diffuse large B cell lymphoma; SC=subcutaneous

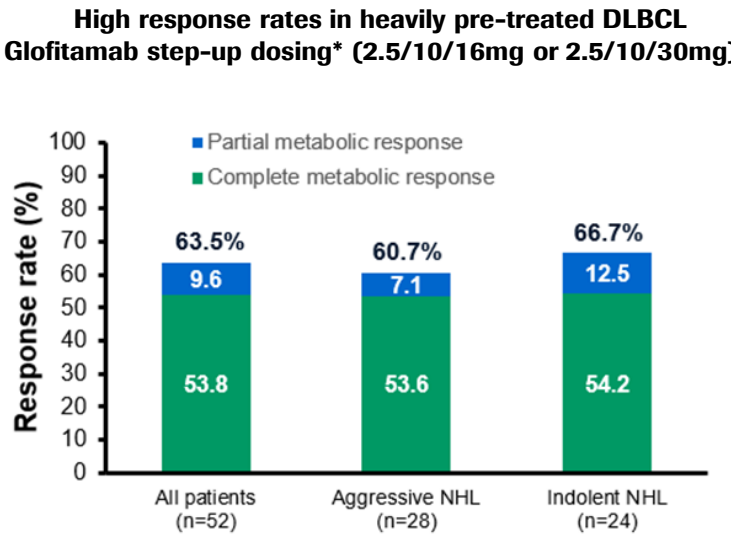
# Hematology franchise: CD20 x CD3 program update

## *Potential for early filings in 3L+ FL and 3L+ DLBCL*

### Ph I (GO29781): Mosunetuzumab in R/R FL




### Ph I (NP30179): Glofitamab in R/R DLBCL

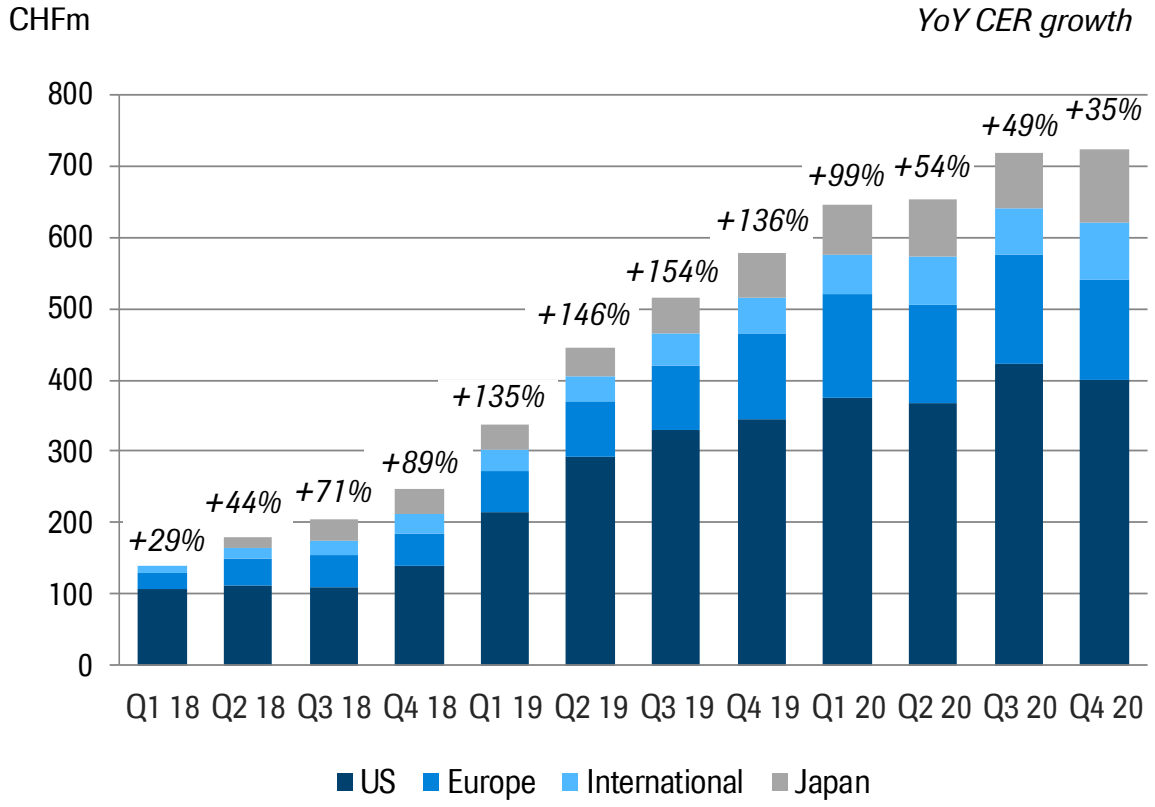



- Mosunetuzumab in R/R FL: High and durable responses with low grade 2 and no grade ≥3 CRS (no protocol-required hospitalization)
- Glofitamab in R/R DLBCL: Off-the-shelf option with high CR rates in heavily pre-treated patients and manageable CRS (mostly grade 1-2)
- Ph I mosunetuzumab SC: Less frequent grade 2 CRS than IV at 7-fold higher dose; SC step up dosing to be further explored
- Ph III safety run-in for mosunetuzumab + lenalidomide in 2L+ FL ongoing
- Ph III safety run-in for glofitamab + GemOx in 2L+ DLBCL ongoing

Assouline et al, ASH 2020; FL = follicular lymphoma; R/R = relapsed/refractory; CR=complete response; CRS=cytokine release syndrome; Hutchings et al, ASH 2020; *Patients with missing or no response assessment are included as non-responders. Two aNHL and six iNHL patients did not have a response assessment reported at time of CCOD; DLBCL=Diffuse large B-cell lymphoma; GemOx=gemcitabine+oxaliplatin

# Tecentriq overview: Growth driven by first-in-class indications

## *First adjuvant trials to read out in 2021*




### Tecentriq Q4 update

### Lung franchise (NSCLC, SCLC)

- US/EU/Japan: Growth driven by 1L SCLC and 1L NSCLC
- BTD for tiragolumab + Tecentriq in PDL1+ NSCLC

### Breast franchise (TNBC)

- US/EU: Growth driven by 1L PDL1+ TNBC

### GI franchise (HCC)

- US: 1L HCC reaching 50% market share after 7 months
- EU/China: 1L HCC first-in-class approvals achieved

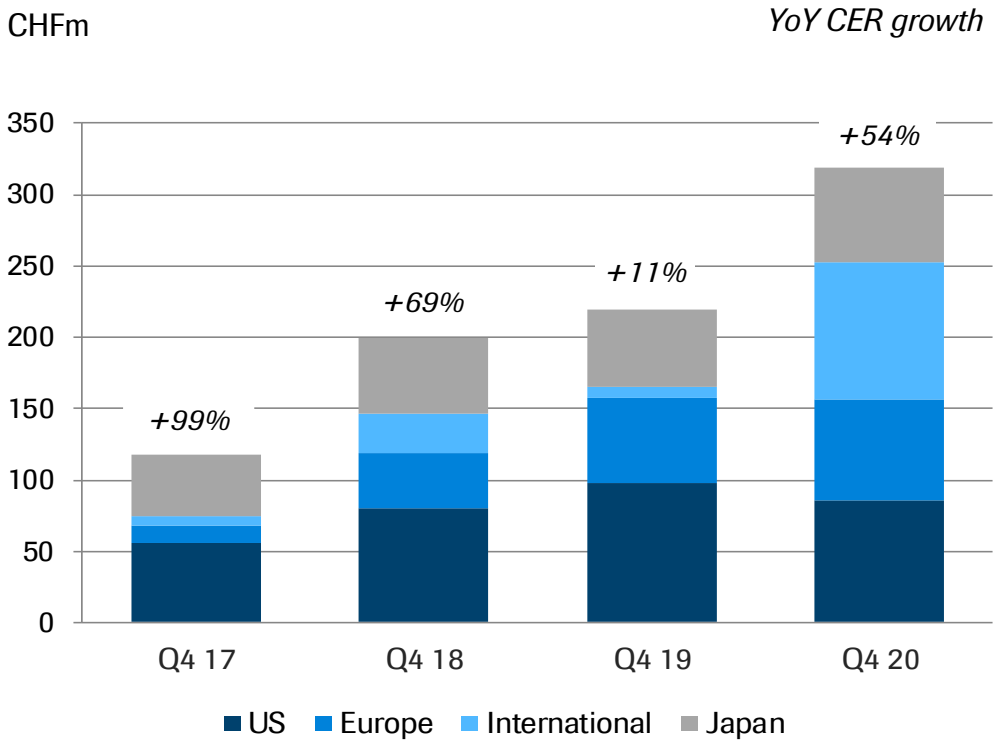
### Outlook 2021

- Ph III (IMpower010) Tecentriq in adj NSCLC
- Ph III (IMvoke010) Tecentriq in adj SCCHN

CER=Constant Exchange Rates; HCC=hepatocellular cancer; NSCLC=non small cell lung cancer; SCLC=small cell lung cancer; TNBC=triple negative breast cancer

# Lung cancer franchise: Alecensa in ALK+ NSCLC

## *Strong 1L momentum continues in all markets*




### Alecensa Q4 update

- US (-4%): 1L New patient share > 70%
- EU (+22%): 1L New patient share EU-5 >80%
- Japan (+29%): 1L New patient share > 70%
- International (>500%): Driven by China NRDL listing
- FoundationOne Liquid CDx (FMI's blood-based NGS test) approved as companion diagnostic for Alecensa

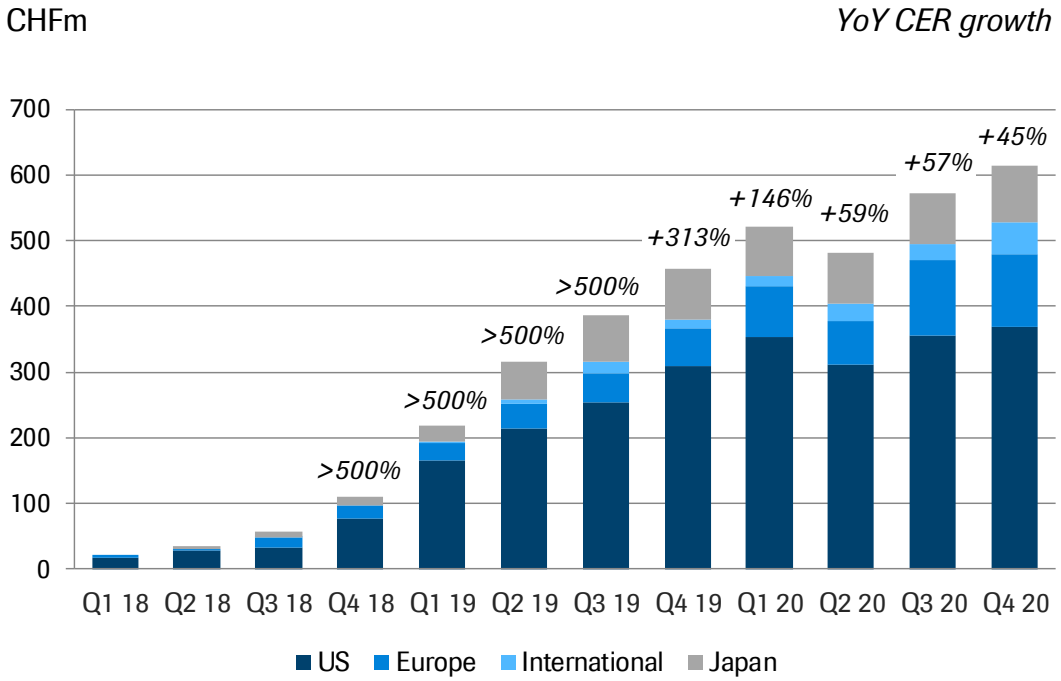
### Outlook 2021

- Strong growth, especially in International to continue

CER=Constant Exchange Rates; NSCLCL=non-small cell lung cancer; NRDL=national drug reimbursement list; FMI=Foundation medicine; NGS=next generation sequencing

# Hemophilia A franchise: Hemlibra growing strongly

## *28% total US patient share and 22% total EU-5 patient share reached*




### Hemophilia Q4 update

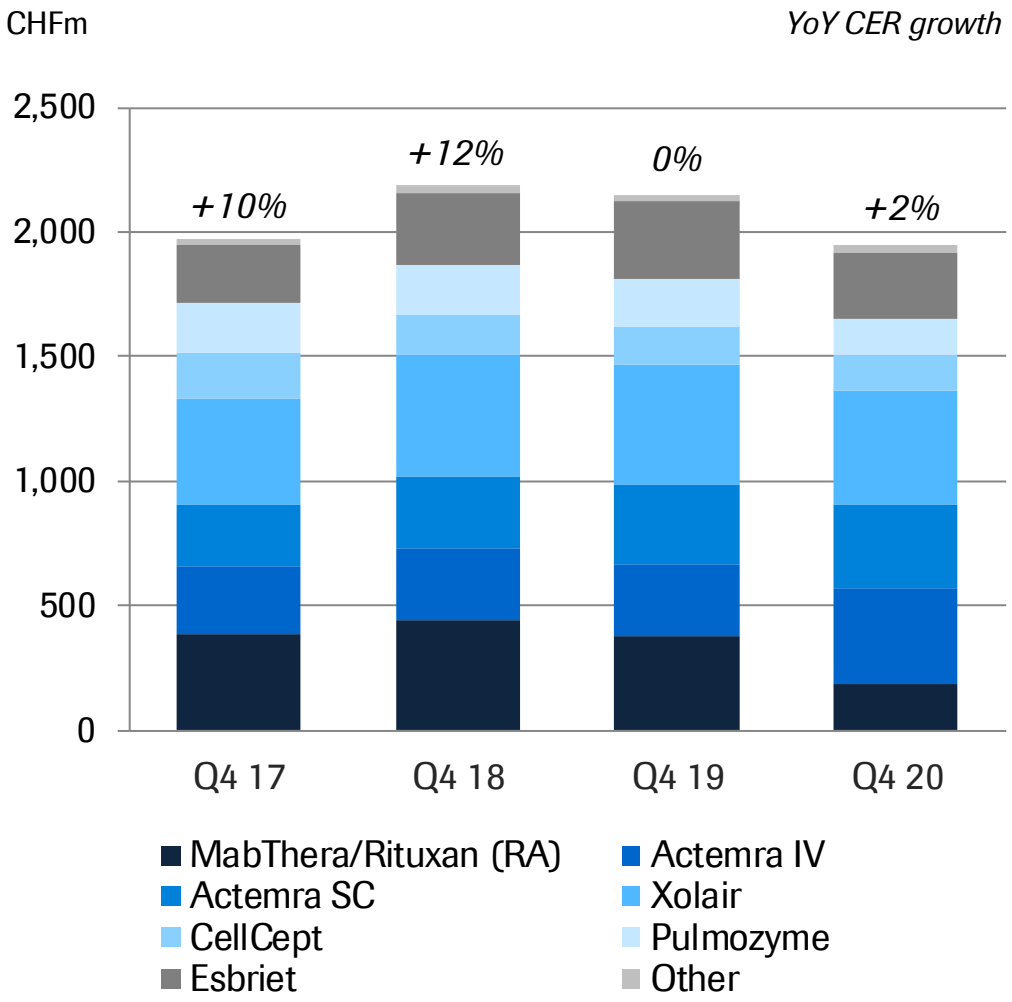
- US/EU: Gaining market share in non-inhibitors
- Minor COVID-19 impact leading to delayed patient starts
- Around 9,500 patients treated globally, thereof 5,000 in the US
- Hemlibra continues to penetrate across all patient types

### Outlook 2021

- Further growth expected
- US/EU: Further patient share gains in non-inhibitors expected

CER=Constant Exchange Rates

# Immunology franchise: Stable sales driven by Actemra




## Immunology Q4 update

### Esbriet (-9%)

- Growth in mild/moderate segments
- BTD in unclassifiable interstitial lung disease (uILD)

### Actemra (+29%)

- Remains leading RA monotherapy in EU-5
- Sales driven by COVID-19; Positive study results (REMAP-CAP)

### Xolair (+3%)

- Remains leader in biologics asthma market; growth in CIU
- Self-injection (home use) approval in the US expected in H1

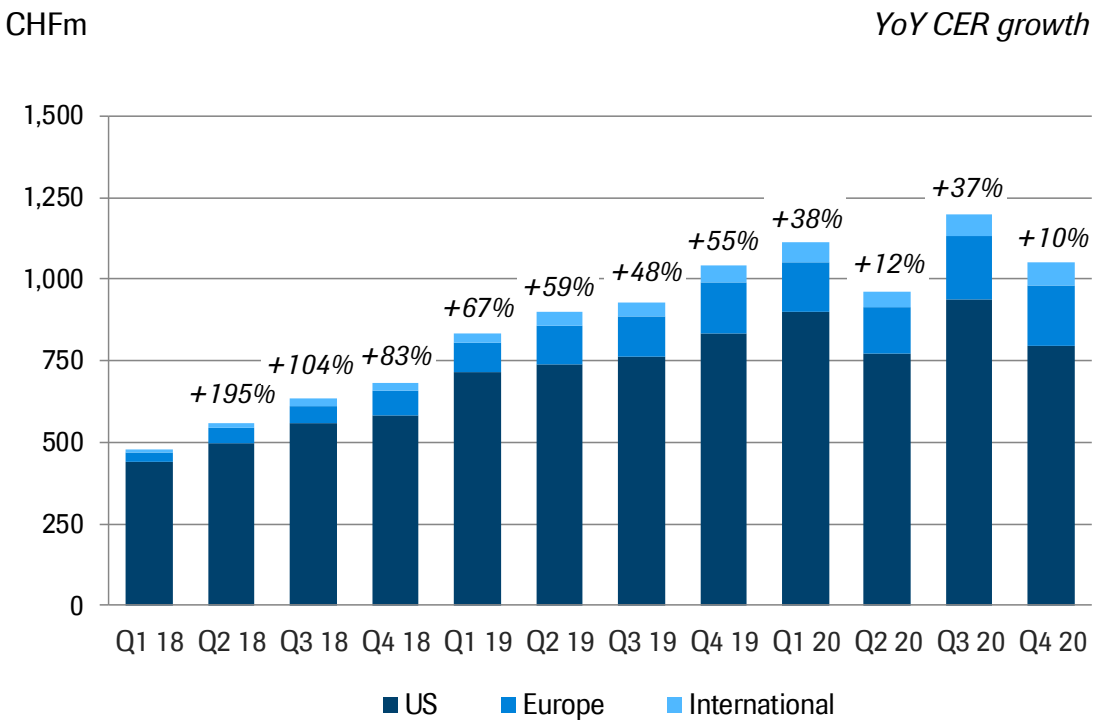
### Outlook 2021

- Ph III (REMDACTA) results for Actemra+remdesivir in COVID-19
- Ph III (STARSCAPE) rhPTX-2+SOC in IPF first-patient-in in Q1
- Ph III (MAJESTY) Gazyva in MN first-patient-in in Q1

CER=Constant Exchange Rates; RA=rheumatoid arthritis; CIU=chronic idiopathic urticaria; SOC=standard of care; IPF=idiopathic pulmonary fibrosis; MN=membranous nephropathy

# MS franchise: Ocrevus with 25% total US market share

## *Market leadership momentum continues*




### Ocrevus Q4 update

- US new patient share remains ~40%
- Q4 growth despite COVID-19 and carry over from Q2 (1st wave)
- Shorter infusion approved in US
- Higher dose Ocrevus: Ph III (MUSETTE) in RMS and Ph III (GAVOTTE) in PPMS first-patient-in
- Fenebrutinib (BTKi): Ph III program PPMS (FENtrepid) first-patient-in

### Outlook 2021

- Continued growth expected
- Ongoing launches in EU and International
- Fenebrutinib (BTKi): Ph III program in RMS (FENhance)

CER=Constant Exchange Rates; MS=multiple sclerosis; RMS=relapsing MS; PPMS=primary progressive MS

# SMA franchise: Successful virtual US launch of Evrysdi

## *>1,000 US patients treated (>10% total share) after less than 5 months*

### Broad uptake across all patient types

**Patients treated with all SMA types**
Pattern mirrors disease prevalence:
25% type 1, 50% type 2, 25% type 3

**Naive (~1/3) and previously treated (~2/3)**
Pts switching from both Spinraza & Zolgensma

**Broad range of ages**
2 month old infants to 70+ year old adults
~50% of patients are adults

**>350 HCPs have prescribed Evrysdi**

**~2,500 patients treated worldwide between clinical trials, commercial, and compassionate use program**

### Access enabled by compelling value proposition

- ~55% of lives covered due to active payer engagement
- Rapid payer coverage by Commercial and Medicaid plans
- Most payer policies fully aligned to the FDA label

### H1 2021 Outlook

- Anticipated approvals in EMA, China, and Japan
- Primary analysis from Ph II (JEWELFISH) study in previously treated patients
- 2-year data from pivotal Ph III trials SUNFISH and FIREFISH

* SMA=spinal muscular atrophy; HCP=health care professional

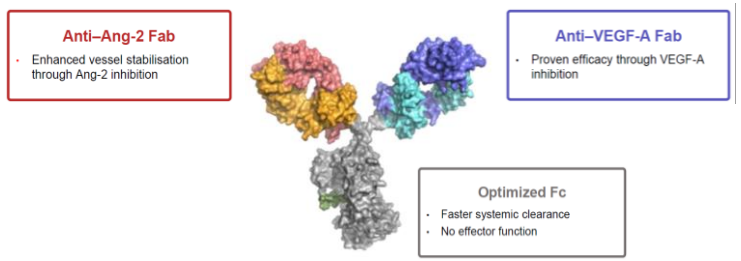
# Ophthalmology franchise: Benefitting patients globally

## *Faricimab: Positive results in DME & nAMD; PDS: launch on track*

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

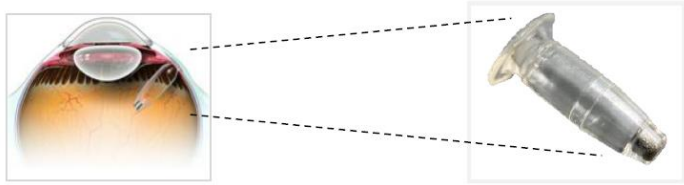
Bascom Palmer Eye Institute
UNIVERSITY OF MIAMI HEALTH SYSTEM

IR event 16 Feb




- Ph III (YOSEMITE & RHINE) results in DME positive with >50% of patients being able to extend time between treatments to 16 weeks
- Ph III (LUCERNE & TENAYA) results in nAMD positive with nearly half (45%) of patients being treated every 16 weeks
- First time this level of durability has been achieved in Ph III
- Filing on track for 2021; Data to be presented at Angiogenesis

### Port delivery system (PDS)

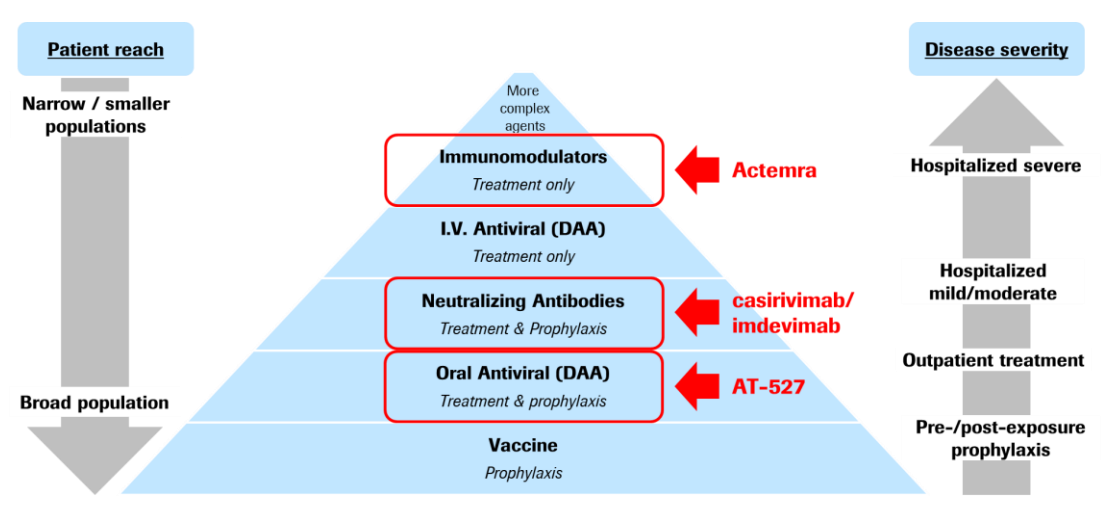


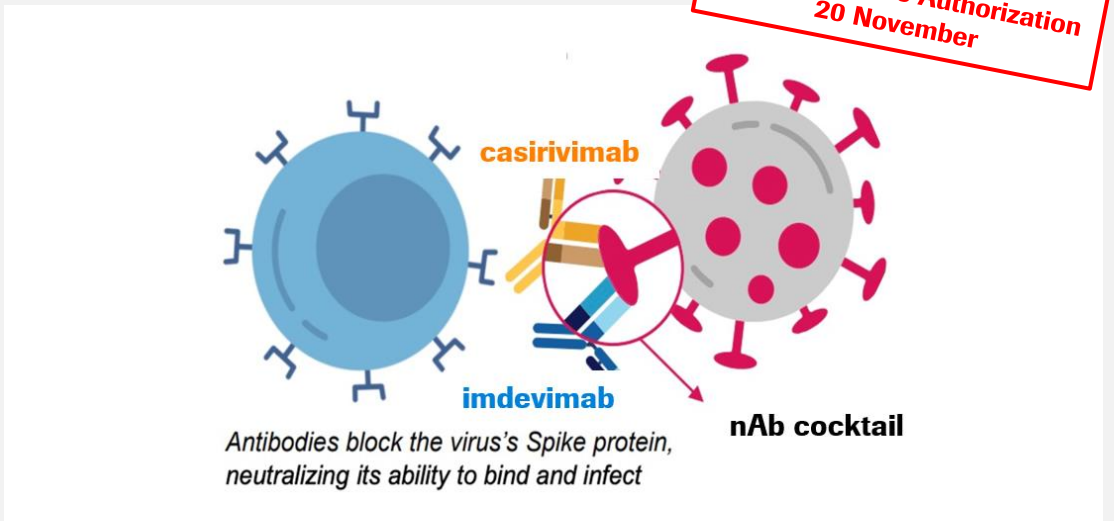
- Ph III (ARCHWAY) data in nAMD show more than 98% of patients were able to go six months between treatments
- Generally well tolerated with favorable benefit-risk profile
- Ph III trials in DME (PAGODA) and DR (PAVILION) enrolling rapidly; Ex-US studies to be initiated
- Additional Ph III (ARCHWAY) data to be presented at Angiogenesis
- US approval expected in 2021

nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; DR=diabetic retinopathy

# Infectious diseases: SARS-CoV-2 development program

## *Positive read-outs for nAb cocktail – first shipments*




**Casirivimab + imdevimab (nAb cocktail):**

- Ph II (Study 2067) in outpatient setting: Primary endpoint of viral load reduction met; FDA EUA granted on Nov 20; First governmental orders from US and Europe received
- Ph II (Study 2066) in hospitalized patients: Futility analysis passed in sero-negative patients for lower risk of mechanical ventilation and/or death, supporting additional investigation in this population
- Ph III (Study 2069) post-exposure prophylaxis: Positive interim results showing reduction in overall infections within the first week and 100% prevention of symptomatic infections

**Actemra for COVID-19 pneumonia:**

- REMAP-CAP study with positive data release by the Imperial College London

nAb=neutralizing antibodies; DAA=direct acting antiviral; EUA=emegency use authorization

# 2020: Key late-stage news flow*

| | Compound | Indication | Milestone | |
|---|---|---|---|---|
| Regulatory | **Rozlytrek** | NTRK pan tumor; ROS1+ NSCLC | EU approval | ✓ |
| | **Venclexta + Gazyva** | 1L unfit CLL | EU approval | ✓ |
| | **Polivy + Rituxan +chemo** | R/R DLBCL | EU approval | ✓ |
| | **Evrysdi (risdiplam)** | SMA type 1/2/3 | US approval | ✓ |
| | **Enspryng (satralizumab)** | NMOSD | US/EU approval | ✓ |
| | **Xolair** | Nasal polyps | US approval | ✓ |
| | **Zelboraf + Cotellic + Tecentriq** | 1L BRAF+ Melanoma | US approval | ✓ |
| | **Tecentriq + Avastin** | 1L HCC | US approval; EU filing | ✓ |
| | **Tecentriq** | 1L PDL1+ NSCLC | US approval | ✓ |
| | **Phesgo (PH FDC SC)** | HER2+ breast cancer | US/EU approval | ✓ |
| Phase III / pivotal readouts | **idasanutlin + chemo** | R/R AML | Ph III MIRROS | ✗ |
| | **risdiplam** | SMA type 1 | Ph II/III FIREFISH (part 2) | ✓ |
| | **Tecentriq + Avastin** | 1L OC | Ph III IMagyn050 | ✗ |
| | **Tecentriq + chemo** | Neoadjuvant TNBC | Ph III IMpassion031 | ✓ |
| | **Venclexta + azacitidine** | 1L unfit AML | Ph III Viale A | ✓ |
| | **ipatasertib + chemo** | Dx+ HR+ BC / Dx+ 1L TNBC | Ph III IPATunity130 | ✗ |
| | **ipatasertib + abiraterone** | 1L mCRPC | Ph III IPATential150 | ✓ |
| | **PDS** | nAMD | Ph III Archway | ✓ |
| | **faricimab** | DME | Ph III YOSEMITE/RHINE | ✓ |
| | **etrolizumab** | Ulcerative Colitis | Ph III HIBISCUS/LAUREL/HICKORY/GARDENIA | ✗ |
| | **balovaptan** | Autism spectrum disorders | Ph II aV1ation | ✗ |

## Additional 2020 news flow:

- **casirivimab/imdevimab:** Positive Ph II results in outpatients; US EUA granted
- **Actemra**: Positive Ph III (EMPACTA) in severe COVID-19 related pneumonia
- **Actemra**: Ph III (COVACTA) did not meet primary endpoint; potentially clinically meaningful benefits in time to hospital discharge and duration of ICU stay
- **Gavreto**: US approval in RET fusion-positive mNSCLC
- **Gavreto**: US approval in metastatic RET+ thyroid cancer
- **Xolair**: US filing of prefilled syringe for self-administration across all indications
- **Evrysdi**: Positive Ph III (FIREFISH part 2) results in type 1 SMA
- **Esbriet**: US priority review granted in unclassifiable interstitial lung disease (UILD)

* Outcome studies are event-driven: timelines may change; EUA=emergency use authorization; ICU=intensive care unit

# 2021: Key late-stage news flow*

| | Compound | Indication | Milestone |
|---|---|---|---|
| Regulatory | **Evrysdi** | SMA type 1/2/3 | EU approval |
| | **PDS ranibizumab** | nAMD (continuous delivery) | US/EU filing; US approval |
| | **faricimab** | DME/nAMD | US/EU joint filing (DME+AMD) |
| | **casirivimab/imdevimab** | SARS-CoV-2 | EU approval |
| | **Venclexta + azacitidine** | 1L unfit AML | EU approval |
| | **Tecentriq** | 1L PDL1+ NSCLC | EU approval |
| | **Xofluza** | Healthy patients; High risk patients; Post exposure | EU approval ✔ |
| Phase III / pivotal readouts | **faricimab** | nAMD | Ph III TENAYA/LUCERNE ✔ |
| | **casirivimab/imdevimab** | SARS-CoV-2 Outpatient | Ph III Study 2067 |
| | **casirivimab/imdevimab** | SARS-CoV-2 Post-exposure prophylaxis | Ph III Study 2069 |
| | **Tecentriq** | Adjuvant NSCLC | Ph III IMpower010 |
| | **Evrysdi** | SMA type 1/2/3 switching study | Ph II JEWELFISH |
| | **Polivy + R-CHP** | 1L DLBCL | Ph III POLARIX |
| | **Tecentriq + chemo** | Adjuvant SCCHN | Ph III IMvoke010 |
| | **mosunetuzumab** | 3L+ FL | Ph Ib GO29781 |
| | **glofitamab** | 3L+ DLBCL | Ph Ib NP30179 |

* Outcome studies are event-driven: timelines may change

# Diagnostics Division

*Thomas Schinecker*
*CEO Roche Diagnostics*

# 2020: Diagnostics Division sales

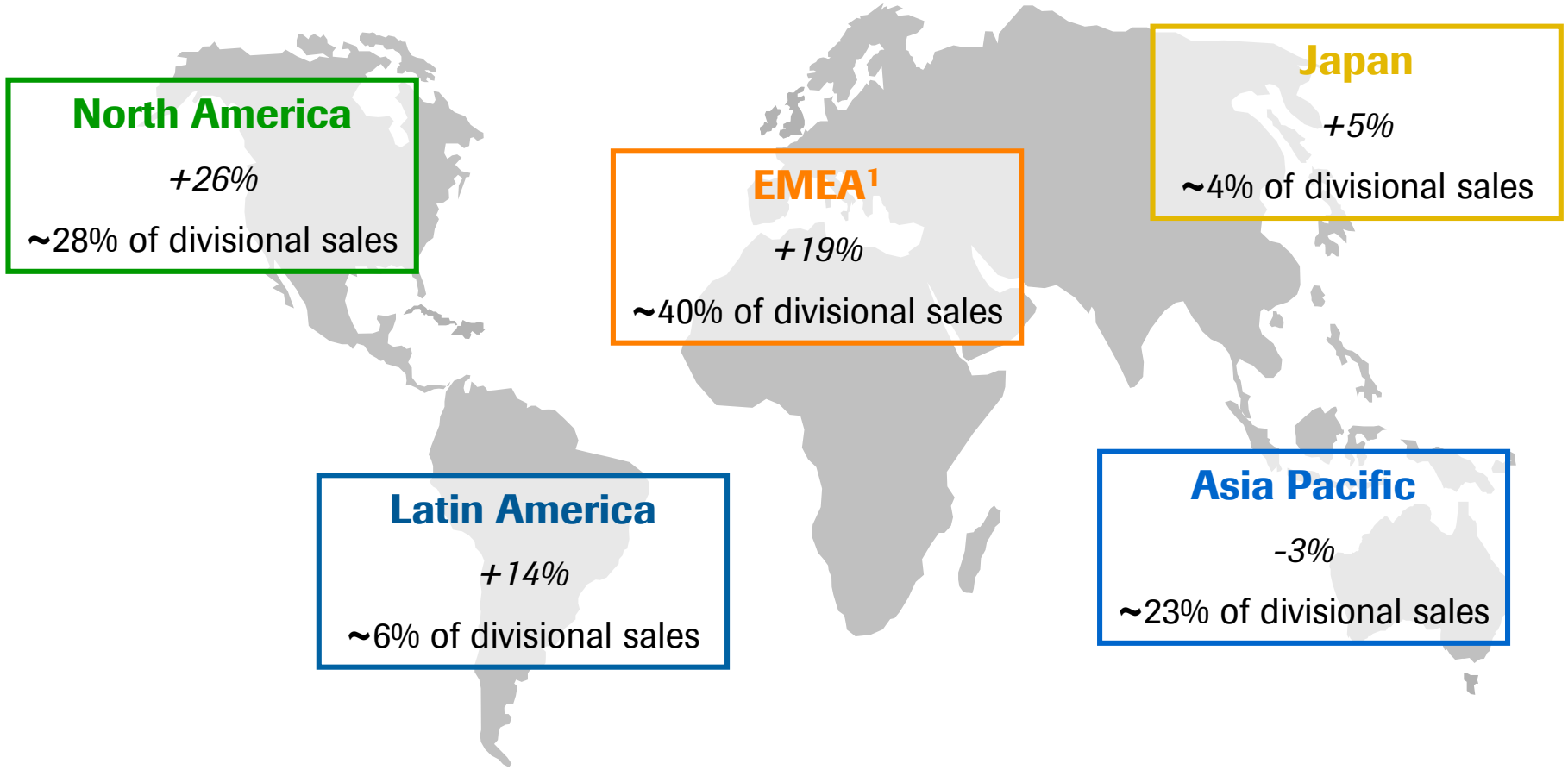
## *Strong growth driven by Molecular Diagnostics*

| | 2020 CHFm | 2019 CHFm | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Diagnostics Division** | **13,791** | **12,950** | **6** | **14** |
| Centralised and Point of Care Solutions | 7,273 | 7,819 | -7 | -1 |
| Molecular Diagnostics | 3,760 | 2,109 | 78 | 90 |
| Diabetes Care | 1,670 | 1,918 | -13 | -5 |
| Tissue Diagnostics | 1,088 | 1,104 | -1 | 5 |

CER=Constant Exchange Rates; Underlying growth of Molecular Diagnostics excluding sequencing business: +102%

# 2020: Diagnostics Division regional sales

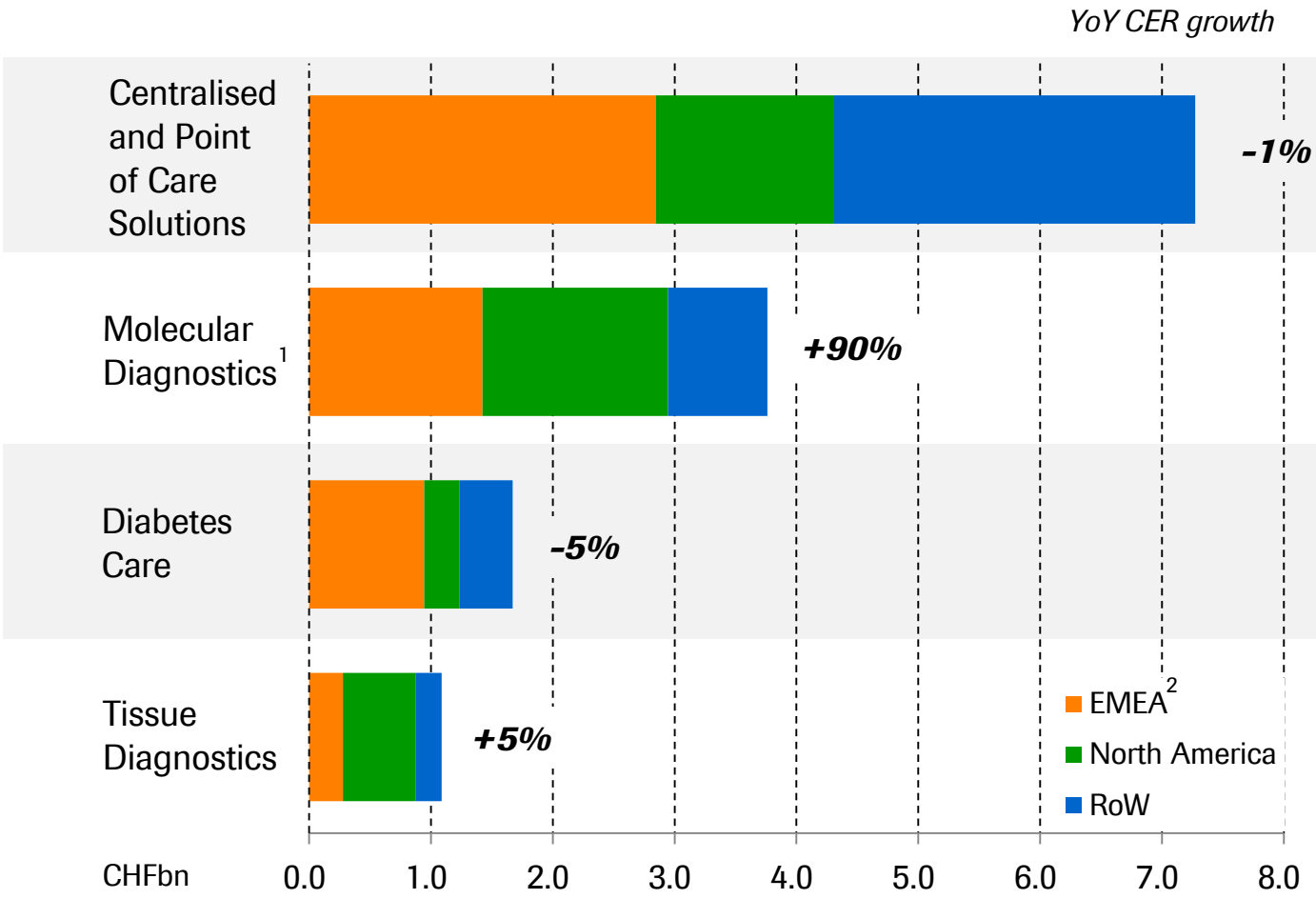
## *Growth driven by COVID-19 testing*




All growth rates at Constant Exchange Rates (CER); [1] Europe, Middle East and Africa

# 2020: Diagnostics Division highlights

## *Strong growth driven by COVID-19 testing*




- Immunodiagnostics (-6%)
- Clinical Chemistry (-11%)
- POC[3] Immunodiagnostics (+667%)

- Virology (+180%)
- LightMix Systems (+189%)
- POC[3] Molecular (+152%)

- Blood glucose monitoring (-4%)
- Insulin delivery systems (-15%)

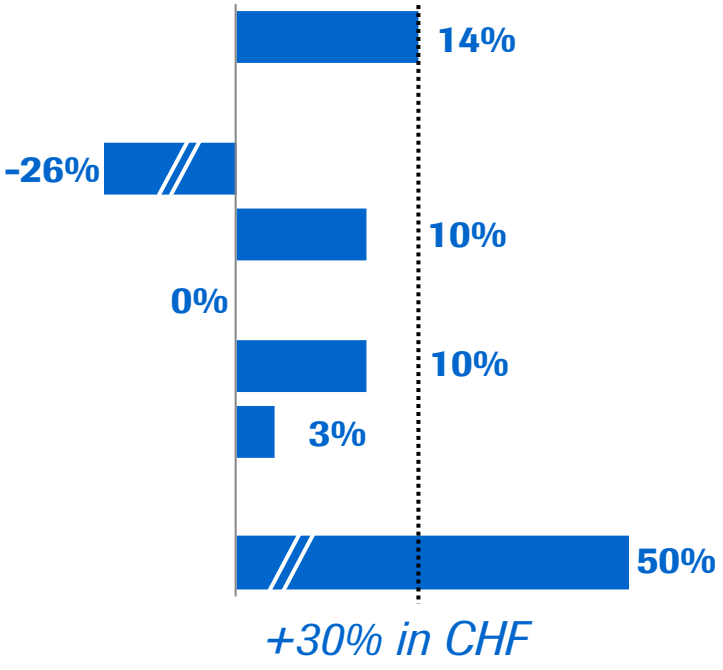
- Advanced staining (+5%)
- Companion diagnostics (+8%)

CER=Constant Exchange Rates; [1] Underlying growth of Molecular Diagnostics excluding sequencing business: +102%; [2] EMEA=Europe, Middle East and Africa; [3] POC=point of care

# 2020: Diagnostics Division

*Very strong core operating profit growth of +50%*

| | 2020 CHFm | 2020 % sales |
|---|---|---|
| **Sales** | **13,791** | **100** |
| Royalties & other op. inc. | 61 | 0.4 |
| Cost of sales | -6,497 | -47.0 |
| M & D | -2,728 | -19.8 |
| R & D | -1,556 | -11.3 |
| G & A | -507 | -3.7 |
| **Core operating profit** | **2,564** | **18.6** |




CER=Constant Exchange Rates

# SARS-CoV-2 diagnostics portfolio[1]

## *Comprehensive portfolio of tests and digital solutions*

| | Clinical Labs | | Near Patient | |
|---|---|---|---|---|
| **Molecular solutions** | • TIB MOLBIOL LightMix® Modular SARS-CoV-2 | *Launched* | • **cobas**® SARS-CoV-2 & Influenza A/B | *Launched* |
| | • **cobas**® SARS-CoV-2 | *Launched* | | |
| | • **cobas**® SARS-CoV-2 & Influenza A/B | *Launched* | | |
| **Immunology solutions** | • Elecsys® Anti-SARS-CoV-2 | *Launched* | • SARS-CoV-2 Rapid Antibody | *Launched*[3] |
| | • Elecsys® Anti-SARS-CoV-2 S[2] | *Launched* | • SARS-CoV-2 Rapid Antigen | *Launched*[3,4] |
| | • Elecsys® SARS-CoV-2 antigen | *Launched*[4] | • SARS-CoV-2 Rapid Antigen Test Nasal | *Launched*[3,4] |
| | • Elecsys® IL-6 Test to diagnose cytokine release syndrome | *Launched* | • SARS-CoV-2 & Influenza A/B Rapid Antigen | *In-development*[3] |
| **Digital solutions** | • Viewics LabOps COVID-19 for efficiency improvements | *Launched* | • NAVIFY Remote Monitor[5] | *Launched* |
| | | | • v-TAC[6] digital algorithm for blood-gas | *Launched* |
| | | | • iThemba Life COVID-19 | *Launched* |
| | | | • **cobas**® infinity POC COVID-19 Portal | *Launched* |

*Recently launched*

[1] Not all products are available in all countries; [2] S=spike protein; [3] external distribution partnership; [4] not yet approved in the U.S.; [5] US only; [6] v-TAC=venous to arterial conversion

# Investing CHFm >600 to increase supply chain capacities

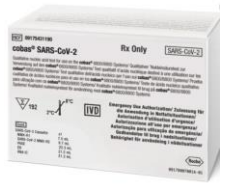
*Driving to unprecedented volume in record time!*

## CONSUMABLES

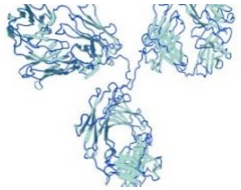
- **60** new manufacturing lines
- **17** locations with 5 new partners

## REAGENTS

- **20** new manufacturing lines
- **4** major facility expansions



- **CHFm >600** investment
- **>1200** new employees



- **8** new manufacturing lines
- **1** new biotech facility

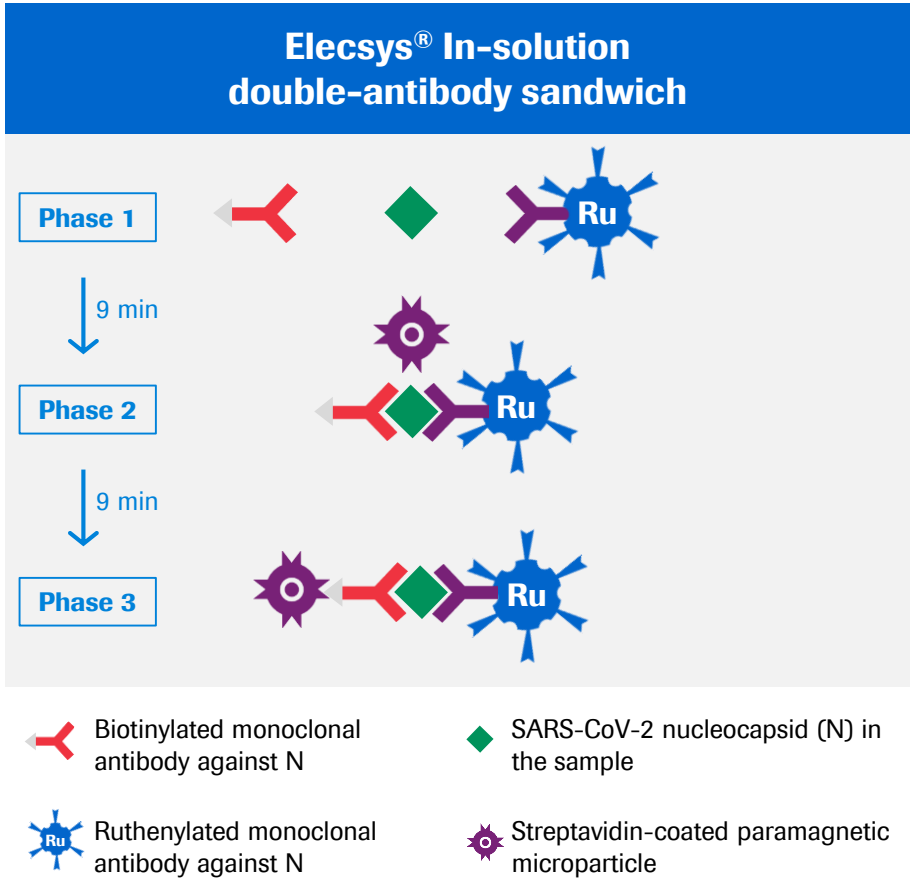
- **1** new manufacturing space

## RAW MATERIALS

## INSTRUMENTS

# Launch of Elecsys® SARS-CoV-2 Antigen Test in CE mark countries

## *High performing test to detect SARS-CoV-2*

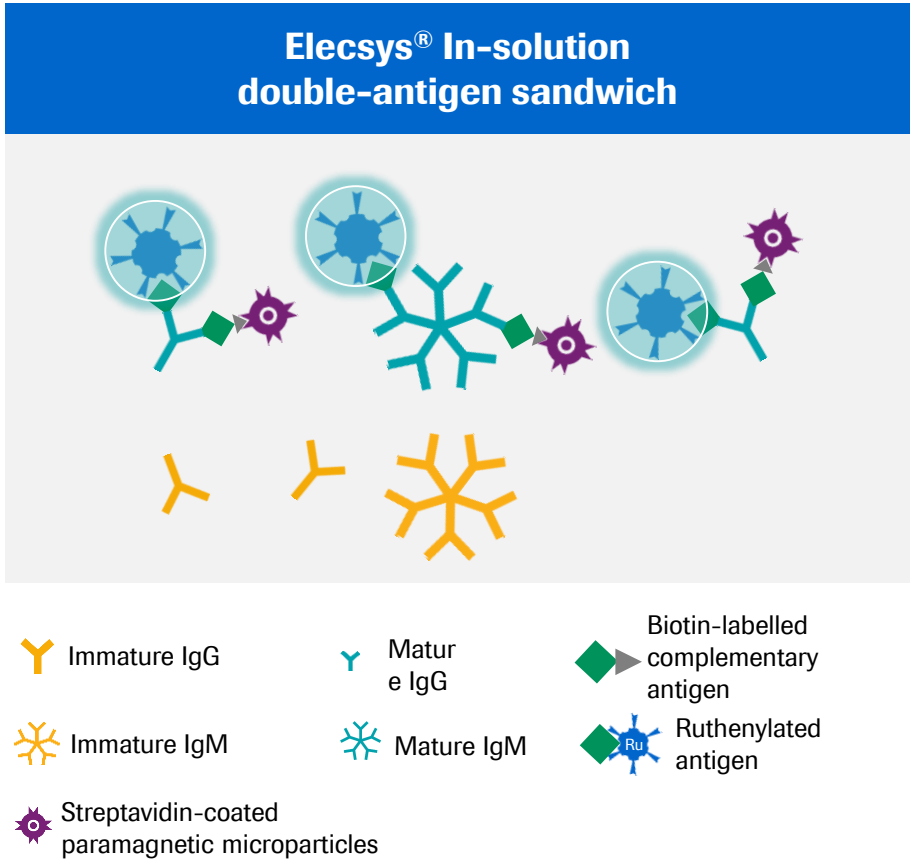



- Test to detect active SARS-CoV-2 infections
- Excellent performance:
  - Sensitivity 94.5% (n=200 positive samples[1])
  - Specificity 99.9% (n=2,747 negative samples[2])
- Potential to scale up to double-digit million tests/month
- Available for all **cobas**® e[3] immunoanalyzers (installed base > 40,000)
- SARS-CoV-2 Extraction Solution: virus inactivation time of 2 minutes

[1] Based on samples from 200 symptomatic individuals and **cobas**® SARS-CoV-2 Target 2 Ct value < 30; [2] Based on samples from 548 symptomatic individuals and 2199 known/suspected exposure/screening individuals; [3] **cobas**® e: cobas e 801, **cobas**® e 602, **cobas**® e 601, **cobas**® e 411

# FDA grants EUA for Elecsys® Anti-SARS-CoV-2 S immunoassay

## *In clinical studies with major vaccine developers*

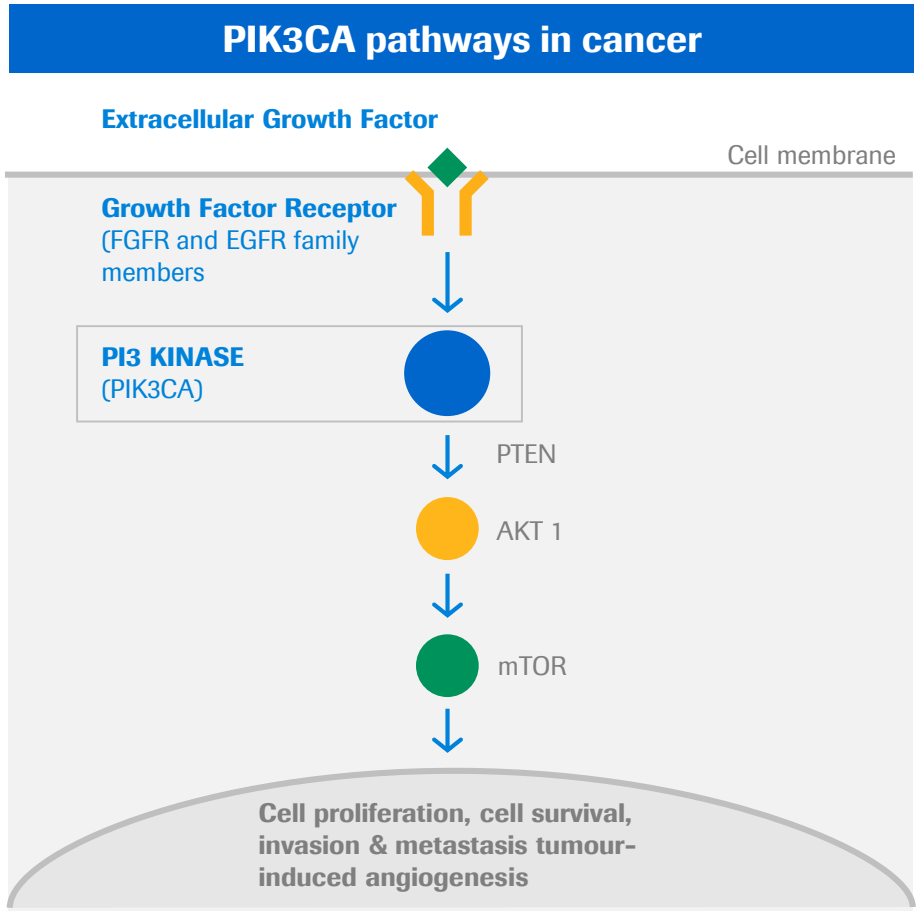



- FDA Emergency use authorization[1] on December 2nd
- Quantitative immunoassay detecting antibodies to the receptor binding domain (RBD) of the spike protein (anti-S)
- Excellent performance:
  - Sensitivity 98.8% (n=1423 positive samples[2])
  - Specificity 99.98% (n=5991negative samples)
- Excellent correlation of the Elecsys® Anti-SARS-CoV-2 S units with the new WHO International Standard
- Potential to scale up to double-digit million tests/month
- Available on all **cobas**® e[3] immunoanalyzers (installed base >40,000)

[1] Includes: CE-IVD FDA-EUA, India, Indonesia, Singapore, Thailand, Taiwan, Philippines, Vietnam, Argentina; [2] n=1423 positive samples, 14 days or later after diagnosis with PCR;
[3] **cobas**® e: **cobas**® e 801, **cobas**® e 602, **cobas**® e 601, **cobas**® e 411

# Launch of cobas® PIK3CA Mutation Test (CE-IVD)

## *Enables clinicians to make fast targeted treatment decisions*




- PCR test for detection of 17 PIK3CA mutations in advanced or metastatic breast cancer
- Up to 40% of patients with HR+/HER2- harbor a PIK3CA mutation [1]
- High analytical sensitivity for 0.7 to 3.5% mutation level (variant dependent)
- Clinical reproducibility > 99%; 100% concordance vs NGS
- Runs on **cobas® z** 4800 (installed base>2000)

[1] **cobas®** PIK3CA Mutation Test CE-IVD package insert 1. Vasan N et al., Annals of Onco 2019

# End-to-end Digital Pathology solution with IVD image analysis

## *Powerful pipeline utilising latest advances in AI technology*

**SCANNING**

*VENTANA DP 200*

**PATHOLOGIST WORKFLOW**

*NAVIFY Digital Pathology*

**IMAGE ANALYSIS**

*uPath Image Analysis Algorithms*

PD-L1

HER2 Dual ISH

HER2 (4B5)

*NAVIFY Tumor Board*

- Three next-generation CE-IVD algorithms launched in 2020 utilizing whole slide analysis for medical decision support to critical cancer diagnosis
- Cloud based clinical workflow software and algorithms on the NAVIFY platform

# Outlook on 2021 new systems launches

*Enabling comparable results in different size laboratories*

| Throughput | Low | Medium | High |
|---|---|---|---|
| SWA** solutions | cobas® pure* 2021 | cobas® pro | cobas® pro (high throughput) 2021 |
| Molecular solutions | cobas® 5800* 2021 | cobas® 6800 | cobas® 8800 |

* Currently in development and not commercially available; ** Serum Work Area

# Roche Diagnostics Investors Day 2021

*Innovating Diagnostics, Shaping Healthcare, Changing lives*

**23rd March 2021, 14:00–16:00 CEST (virtual set up)**

**Presenters:**

**Thomas Schinecker,** *CEO Diagnostics*
**Ann Costello,** *Global Head Roche Diagnostics Solutions*
**Palani Kumaresan,** *Head of Research & Development*
**Benjamin Lilienfield,** *Life Cycle Leader Systems*
**Andre Ziegler,** *Global Clinical Leader Cardiology*
**Michael Hombach,** *Global Clinical Leader Infectious disease*
**Jill German,** *Global Head of Pathology Lab*

# Key launches 2020

| | Area | Product | Description | Market[1] | |
|---|---|---|---|---|---|
| Instruments/ Devices | **Workflow** | cobas® prime | Next generation pre-analytical platform to support cobas® 6800/8800 Systems | CE | ✓ |
| | **Diabetes Care** | Accu-Chek Solo Diabetes Manager | Integration of the Accu-Chek Guide test strip technology into the Accu-Chek Solo Diabetes Manager (remote control) | CE | ✓ |
| Tests/ Assays | **Infectious Diseases** | Elecsys® EBV EBNA IgG | EBV panel offering 3 different assays (EBV IgM, EBV VCA IgG, and EBV EBNA IgG) for the qualitative detection of antibodies to Epstein-Barr Virus (EBV) | CE | ✓ |
| | | Elecsys® EBV VCA IgG | | | ✓ |
| | | Elecsys® EBV IgM | | | ✓ |
| | | cobas® HIV-1&2 Qual | Qualitative detection and confirmation of HIV-1 & HIV-2 | US | ✓ |
| | | cobas® EBV | Monitoring tests for transplant patients to aid in the management of EBV and BKV infections | US | ✓ |
| | | cobas® BKV | | | ✓ |
| | **Cervical Cancer** | cobas® HPV (6800/8800) | The world's leading cobas® HPV assay for use on the fully automated cobas® 6800/8800 Systems | US | ✓ |
| | | CINtec *PLUS* Cytology | Next generation "Pap" test which leverages p16/Ki-67 dual-stain biomarker technology on cervical cytology samples | US | ✓ |
| | **Tissue Dx** | VENTANA HER2 Dual ISH | Fully automated, brightfield ISH assay to determine eligibility for HER2 targeted therapy | US | ✓ |
| | | Algorithm - HER2 (4B5) | Whole slide image analysis algorithm for HER2 (4B5) | CE | ✓ |
| Software | **Sequencing** | NAVIFY Mutation Profiler | Software as a medical device for annotating, variant classification, clinical interpretation and reporting from comprehensive genomic profile testing | US | |
| | **Diabetes Care** | RocheDiabetes InsulinStart | A messaging service designed for people with type 2 diabetes to ease the transition from oral antidiabetics to a complimentary insulin therapy | CE | ✓ |
| | | mySugr app | Enabling control of the Accu-Chek Insight insulin pump from the mySugr app | WW | |
| | | RocheDiabetes Care Platform | New releases with improved features focusing on device connectivity, integration of 3rd parties, and healthcare professionals' workflow optimisation | WW | ✓ |

[1]CE: European Conformity, US: FDA approval, WW: Worldwide; EBV=Epstein-Barr virus; BKV=BK virus

# Key launches 2021

| | Area | Product | Description | Market[1] |
|---|---|---|---|---|
| Instruments | Core Lab | cobas® pure integrated solutions | Low-to-medium volume SWA | CE |
| | | cobas® pro integrated solutions | New high throughput configurations of the cobas pro instrument | CE |
| | Point of Care | cobas® pulse | Successor of Accu-Chek® Inform II | CE |
| | Molecular Lab | cobas® 5800 | Fully automated low throughput PCR system | CE |
| | | AVENIO Edge System | Automated sequencing library preparation and target enrichment instrument | WW |
| | Diabetes Care | Accu-Chek Instant Forward | New features for the Instant meter to increase performance and user experience | WW |
| Tests | Core Lab | Elecsys® SARS-CoV-2 Antigen | Automated laboratory assay intended as an aid in the diagnosis of SARS-CoV-2 infection | US |
| | | Elecsys® NT-proBNP IU<br>• extensions in Heart Failure<br>• extension for Atrial Fibrillation<br>Elecsys® TnT–hs 3 claim extensions in Coronary Arterial Disease | A set of 5 intended use extensions in the Coronary Arterial Disease, Atrial Fibrillation and Heart Failure Space | CE |
| | Molecular Lab | AVENIO FoundationOne kit (RUO) | Decentralized kit of the FoundationOne test | WW |
| | | KAPA HyperPETE kit | New targeted sequencing portfolio using primer extension for small targets | WW |
| Digital Solutions | Pathology Lab | uPath 2.0 | First IVD release and version of Open API of the clinical pathologist workflow module for NAVIFY Digital Pathology & on-premise uPath | WW |
| | | RUO Algorithms | Whole slide image analysis algorithms (ER (SP1), Ki-67 (30-9), and PR (1E2)) | WW |
| | Insights | NAVIFY Oncology 1.0 | Modular Oncology decision support solution | WW[3] |
| | | NAVIFY Pass 1.0 | Solution for providers to communicate SARS-CoV-2 rapid antigen test results to a mobile app | US & CE[3] |
| | Core Lab | Elecsys® GAAD Algorithm | Algorithm for early detection of HCC in patients with chronic liver disease. | CE |
| | Diabetes Care | Remote Patient Monitoring | Module within RDCP that enables remote Health Care Professional - Patient with Diabetes interaction, including a patient dashboard, check-in and chat functionality | WW[3] |
| | | Accu-Chek SugarView | Meter-free blood glucose testing using a smartphone and app | OUS[3] |

RDCP: Roche Diabetes Care Platform; [1] CE: European Conformity, US: FDA approval, WW: Worldwide, OUS: Outside the US; [2] Reasearch Use Only; [3] Only a few selected countries

# Finance

*Alan Hippe*
*Chief Financial Officer*

## 2020 results

## Focus on Cash

## Outlook

# 2020: Highlights

## *Business*

- Sales growth of +1%[1] despite biosimilars impact of CHF -5.1bn[2]
- Core operating profit up +4%[1] and Core EPS growth of +4%[1]
- Dividend[3] in Swiss francs further increased

## *Cash flow*

- Operating Free Cash Flow of CHF 14.8bn despite higher investments in in-licensing and higher inventories
- Net debt lower by CHF 0.6bn vs. YE 2019, now at CHF -1.9bn, as FCF of CHF 10.9bn offsets dividends paid (CHF -8.0bn)

## *Net financial result*

- Core net financial expenses decreased by +34%[1] due to lower interest expenses (CHFm 182) mainly driven by early debt redemption in 2019 (loss of CHFm 202)

## *IFRS*

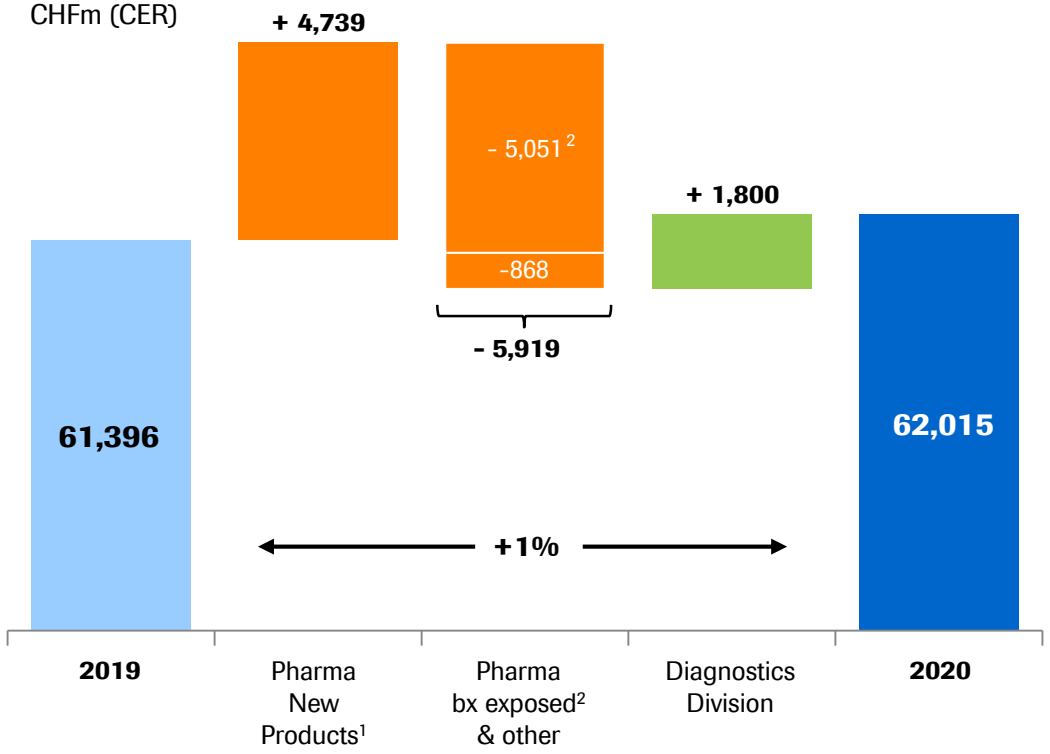
- Net income increased by +17%[1] driven by lower impairments of intangible assets and goodwill and the release of the Accutane US litigation provision

[1] At Constant Exchange Rates (CER); [2] MabThera, Herceptin & Avastin in Europe (Avastin: as of Jul 20) and US & Japan Herceptin, Avastin & MabThera; [3] based on 2020 dividend as proposed by the Board of Directors; FCF=free cash flow

# 2020: Successfully managing the transition in volatile environment

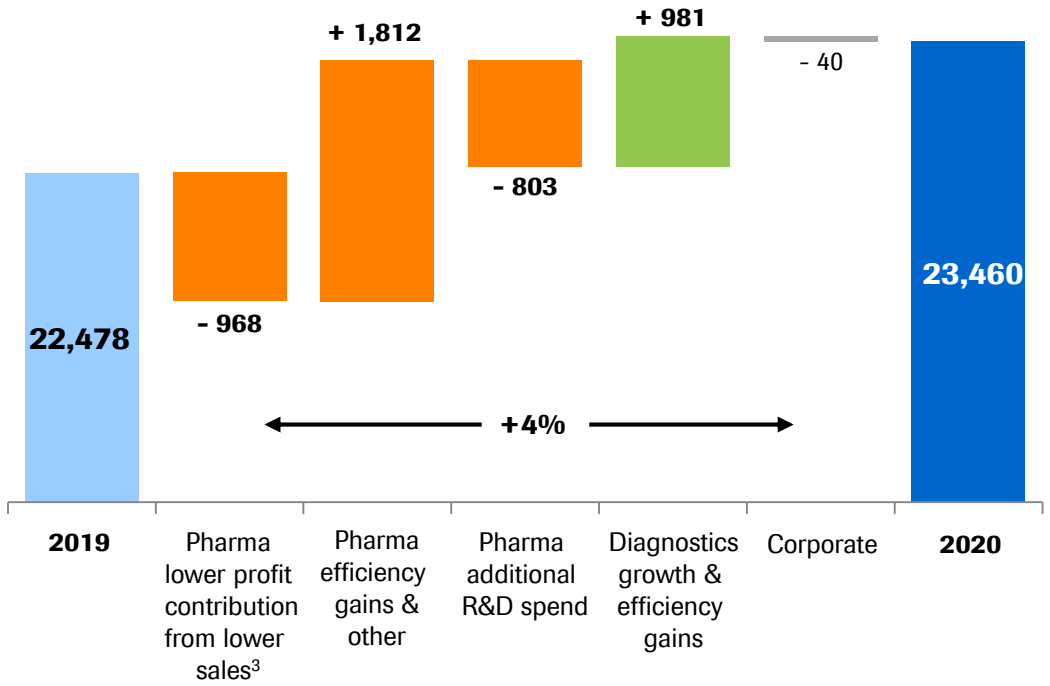
## Compensated for biosimilar & COVID-19

**Group Sales**
CHFm (CER)




## Efficiency gains & investment into future

**Group Core OP**
CHFm (CER)




At constant exchange rates (CER); [1] Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi; [2] MabThera, Herceptin & Avastin in Europe (Avastin: as of Jul 20) and MabThera, Herceptin & Avastin in U.S. and Japan; [3] Pharma sales decline minus proportional cost of sales 2020

# 2020: Group performance

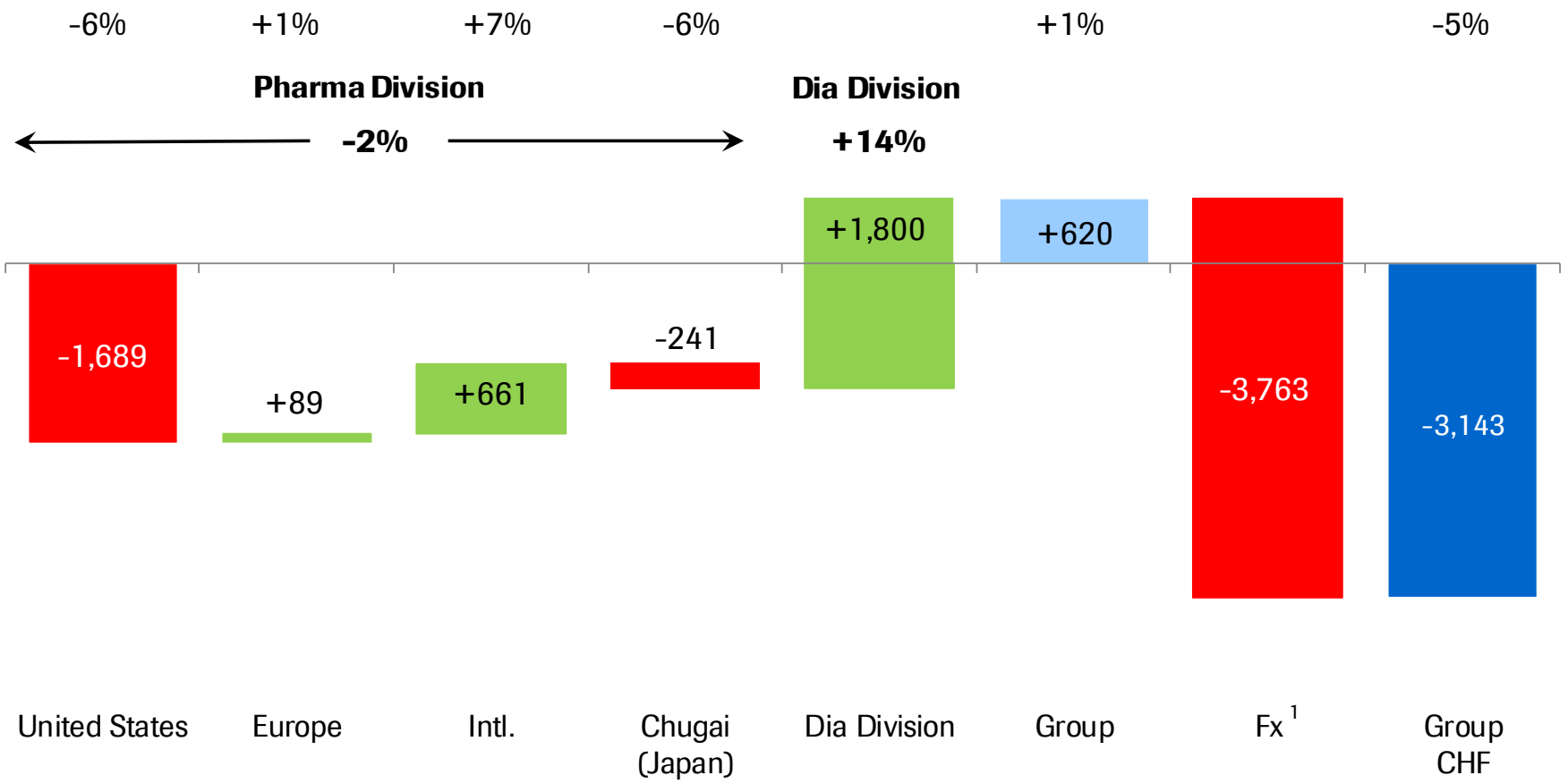
## *Core operating profit up +4 & Core EPS growth of +4%*

| | 2020 CHFm | 2019 CHFm | Change in % CHF | Change in % CER |
|---|---|---|---|---|
| **Sales** | **58,323** | **61,466** | **-5** | **1** |
| **Core operating profit** | **21,536** | **22,479** | **-4** | **4** |
| *as % of sales* | *36.9* | *36.6* | | |
| **Core net income** | **17,378** | **18,062** | **-4** | **5** |
| *as % of sales* | *29.8* | *29.4* | | |
| **Core EPS (CHF)** | **19.16** | **20.16** | **-5** | **4** |
| **IFRS net income** | **15,068** | **14,108** | **7** | **17** |
| **Operating free cash flow** | **14,815** | **20,921** | **-29** | **-21** |
| *as % of sales* | *25.4* | *34.0* | | |
| **Free cash flow** | **10,943** | **16,764** | **-35** | **-26** |
| *as % of sales* | *18.8* | *27.3* | | |

CER=Constant Exchange Rates

# 2020: Group sales

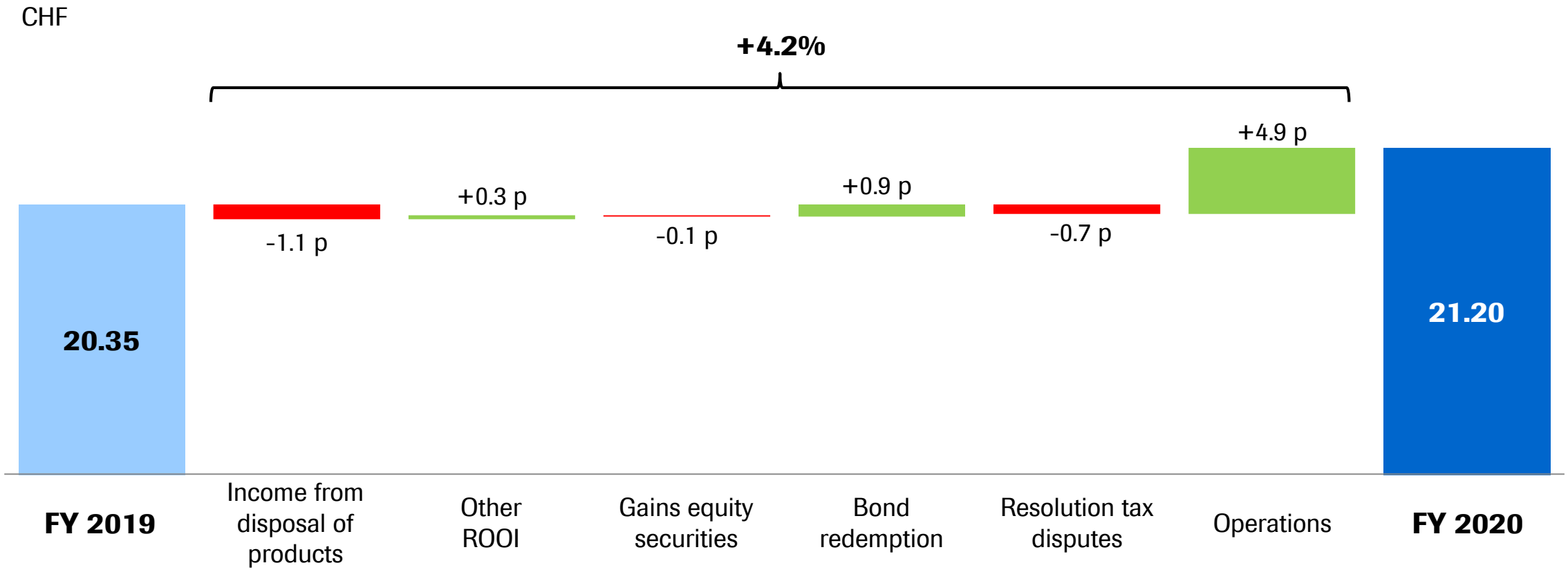
***CER sales increase of +1%, driven by Diagnostics and International, partly offset by a decrease in the US; Fx impact of -6%p***




Absolute values in CHFm at Constant Exchange Rates (avg full year 2019); [1] avg full year 2019 to avg full year 2020 fx

# 2020: Core EPS development

## *Operations growth is main driver for Core EPS growth*

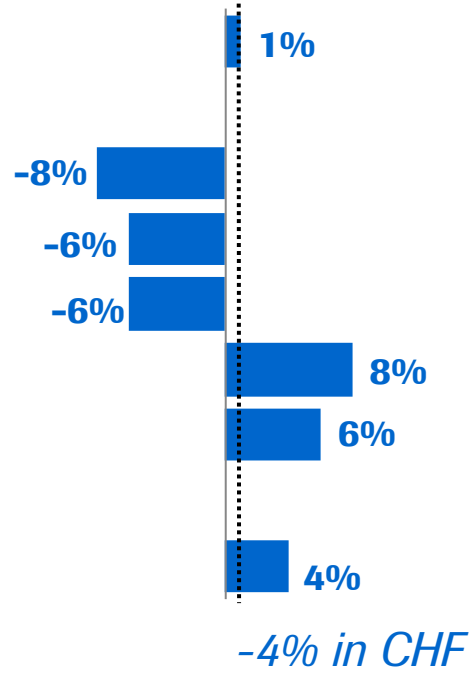



All at CER (Constant Exchange Rates, average FY 2019); ROOI=Royalties and other operating income excl. Gains on product disposals

# 2020: Group operating performance

## *Core operating profit growth ahead of sales growth*

| | 2020 CHFm | 2020 abs. CER |
|---|---|---|
| **Sales** | **58,323** | **620** |
| Royalties & other op. inc. | 2,020 | -175 |
| Cost of sales | -14,567 | 1,015 |
| M & D | -9,361 | 631 |
| R & D | -12,153 | -953 |
| G & A | -2,726 | -157 |
| **Core operating profit** | **21,536** | **981** |

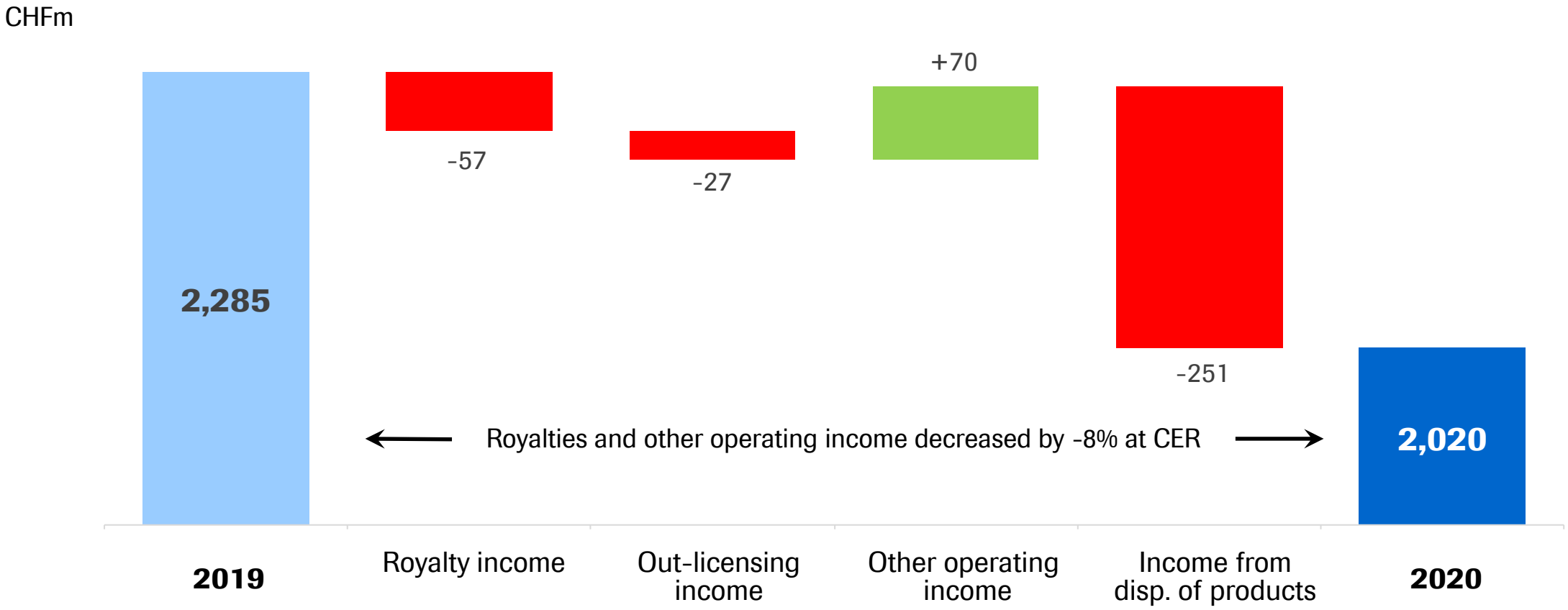



*-4% in CHF*

CER=Constant Exchange Rates

# 2020: Royalties and other operating income

***Lower income on product disposals, partially offset by higher other operating income from Venclexta profit share***




CER = Constant Exchange Rates

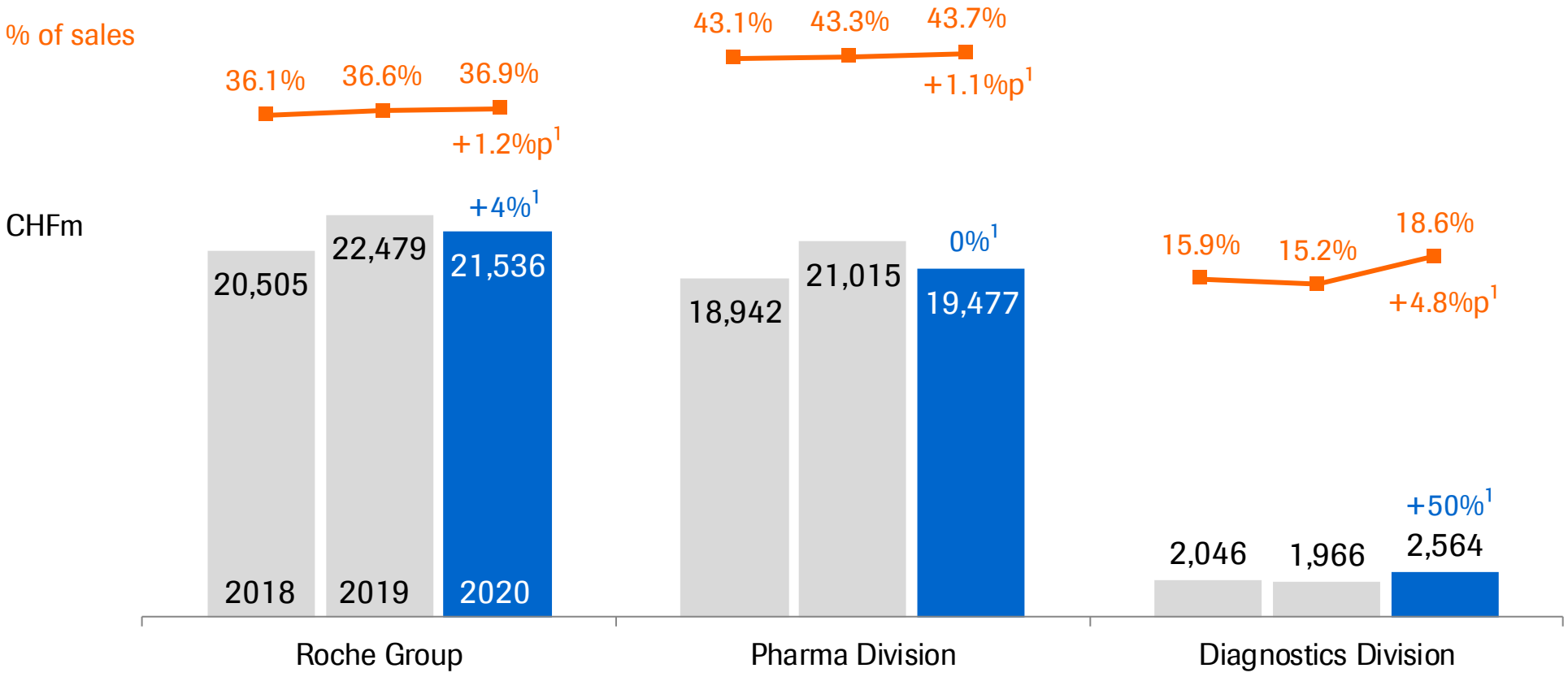
# Major transformation ongoing across the Group
## *Example: Cost of Sales*

| Cost of Sales | 2019 | 2020 | abs. CER | % CER |
|---|---|---|---|---|
| Pharma Division | 10,180 | 8,070 | +1,652 | -16% |
| Manufacturing cost | 6,086 | 5,021 | +787 | -13% |
| Dia Division | 6,183 | 6,497 | -637 | +10% |
| Manufacturing cost | 6,079 | 6,395 | -638 | +11% |
| **Group** | **16,363** | **14,567** | **+1,015** | **-6%** |
| **Manufacturing Cost** | **12,165** | **11,416** | **+149** | **-1%** |

- Manufacturing cost of goods sold and period costs: Product mix, productivity improvements, and lower inventory write-offs
- Collaboration and profit sharing agreements: Decrease driven by lower MabThera/Rituxan sales (US)
- Royalty expenses: Decrease related to expired Cabilly patent, partially offset by increased sales for certain royalty-bearing products (Ocrevus, etc.)

Variances at constant exchange rates (CER)

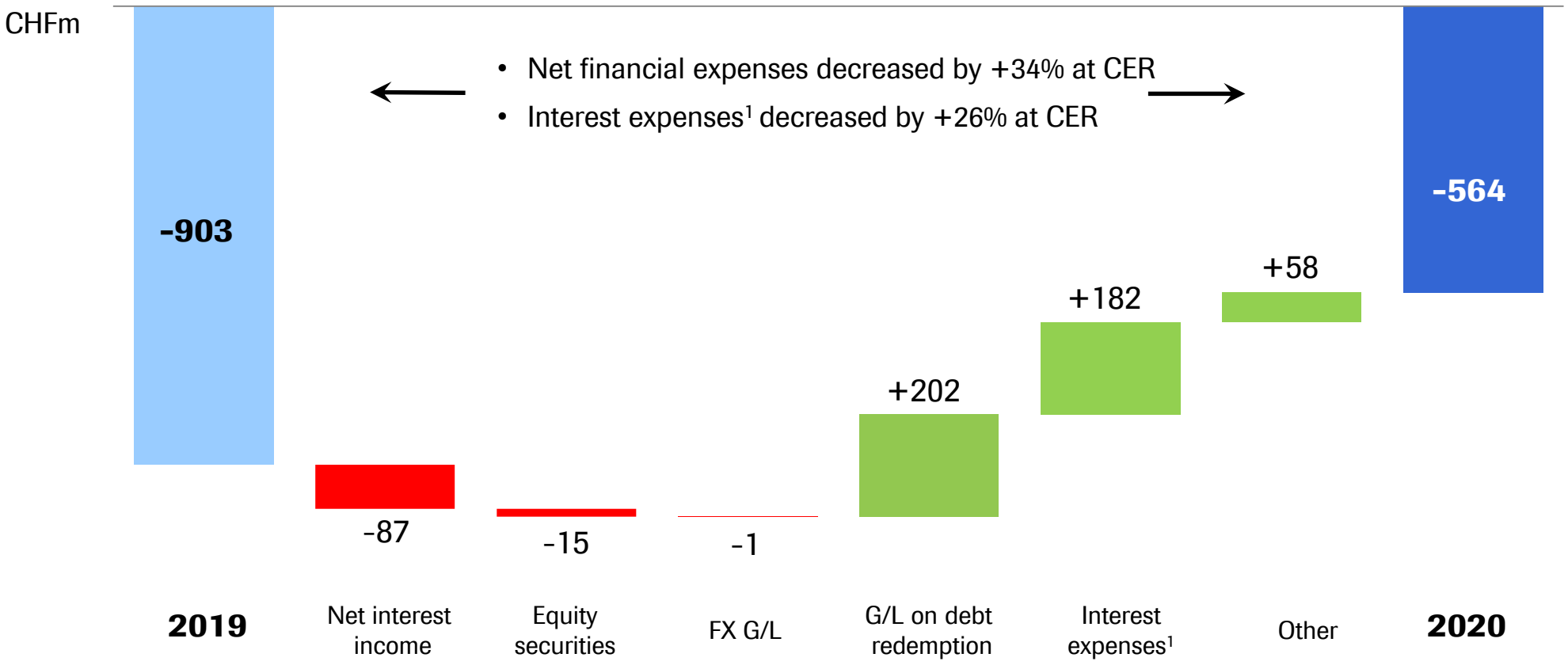
# 2020: Core operating profit and margin




[1] At CER=Constant Exchange Rates

# 2020: Core net financial result

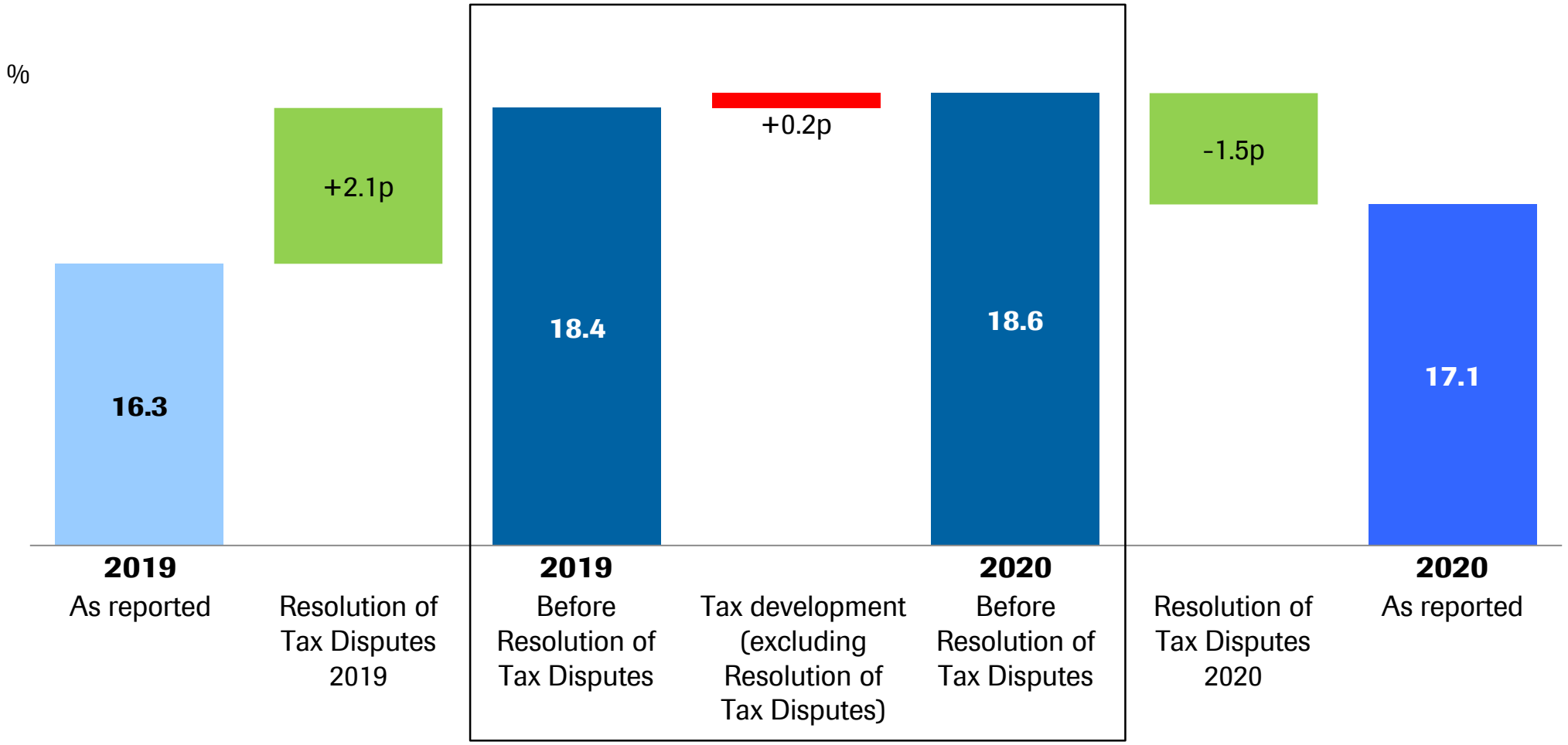
## *Improvement driven by net loss on debt redemption in 2019 and lower interest expenses*




CER=Constant Exchange Rates; [1] incl. amortisation of debt discount and net gains on interest rate derivatives

# 2020: Group Core tax rate

*Tax rate relatively stable excluding resolution of several tax disputes*



# 2020: Non-core and IFRS income

## *Total non-core operating items decreasing due to lower IA impairments and Legal & Environmental income*

| | 2019 | 2020 | | Change in % | |
|---|---|---|---|---|---|
| | CHFm | CHFm | CHFm | CHF | CER |
| **Core operating profit** | **22,479** | **21,536** | **-943** | **-4** | **+4** |
| Global restructuring plans | -1,206 | -909 | 297 | | |
| Amortisation of intangible assets | -1,532 | -1,750 | -218 | | |
| Impairment of intangible assets[1] | -1,756 | -672 | 1,084 | | |
| M&A and alliance transactions | 43 | -9 | -52 | | |
| Legal & Environmental[2] | -480 | 347 | 827 | | |
| *Total non-core operating items* | -4,931 | -2,993 | 1,938 | | |
| **IFRS Operating profit** | **17,548** | **18,543** | **995** | **+6** | **+16** |
| *Total financial result & taxes* | -3,440 | -3,475 | -35 | | |
| **IFRS net income** | **14,108** | **15,068** | **960** | **+7** | **+17** |

CER=Constant Exchange Rates; IA=intangible assets; [1] incl. goodwill; [2] incl. pension plan settlements

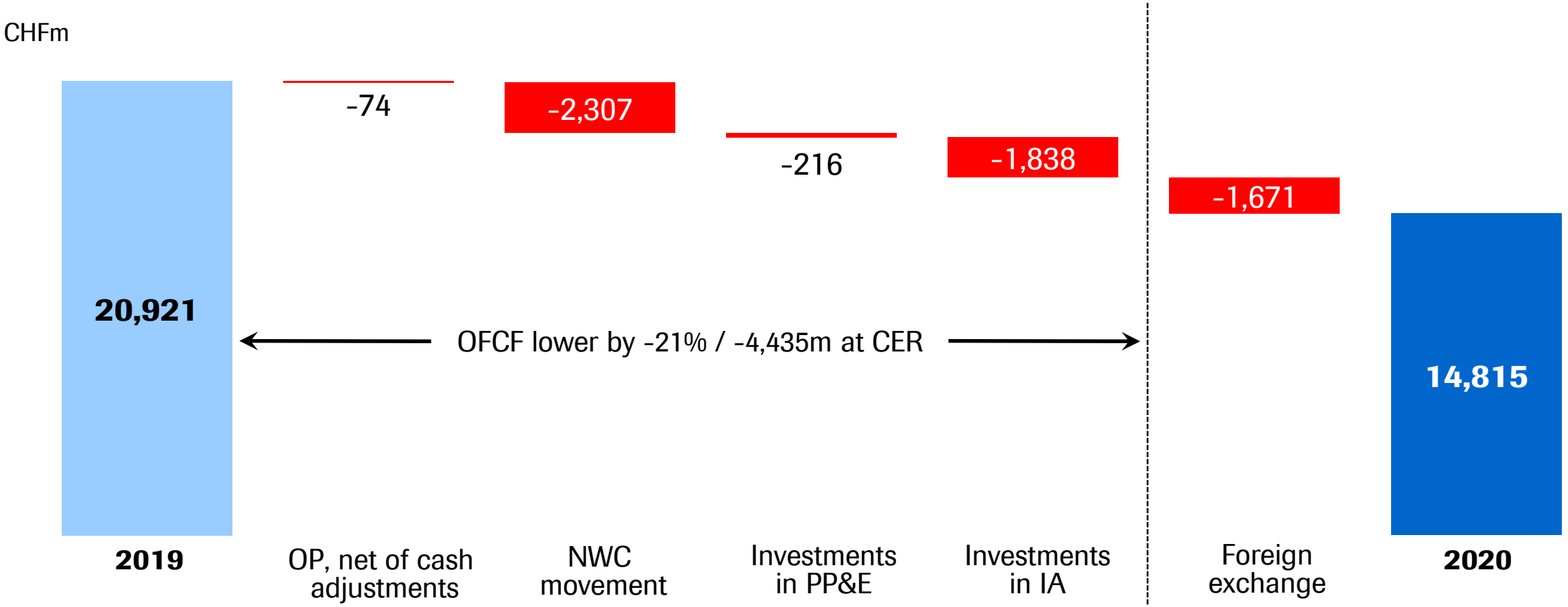
2020 results

Focus on Cash

Outlook

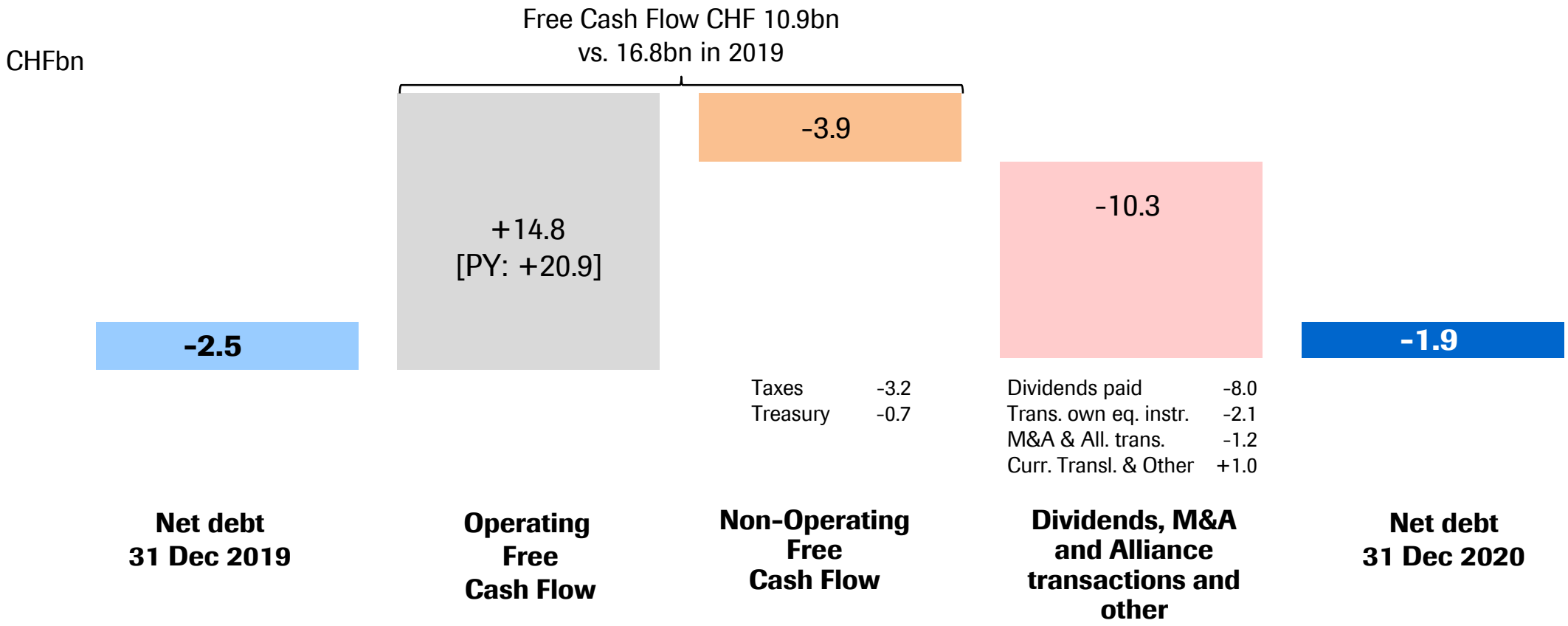
# 2020: Operating Free Cash Flow

## *OFCF down by -21% driven by Net Working Capital movement and higher investments in Intangible Assets*




CER=Constant Exchange Rates; OP=Operating Profit; NWC=Net Working Capital; PP&E=Property, Plant & Equipment incl. change of lease liability paid; IA=Intangible Assets

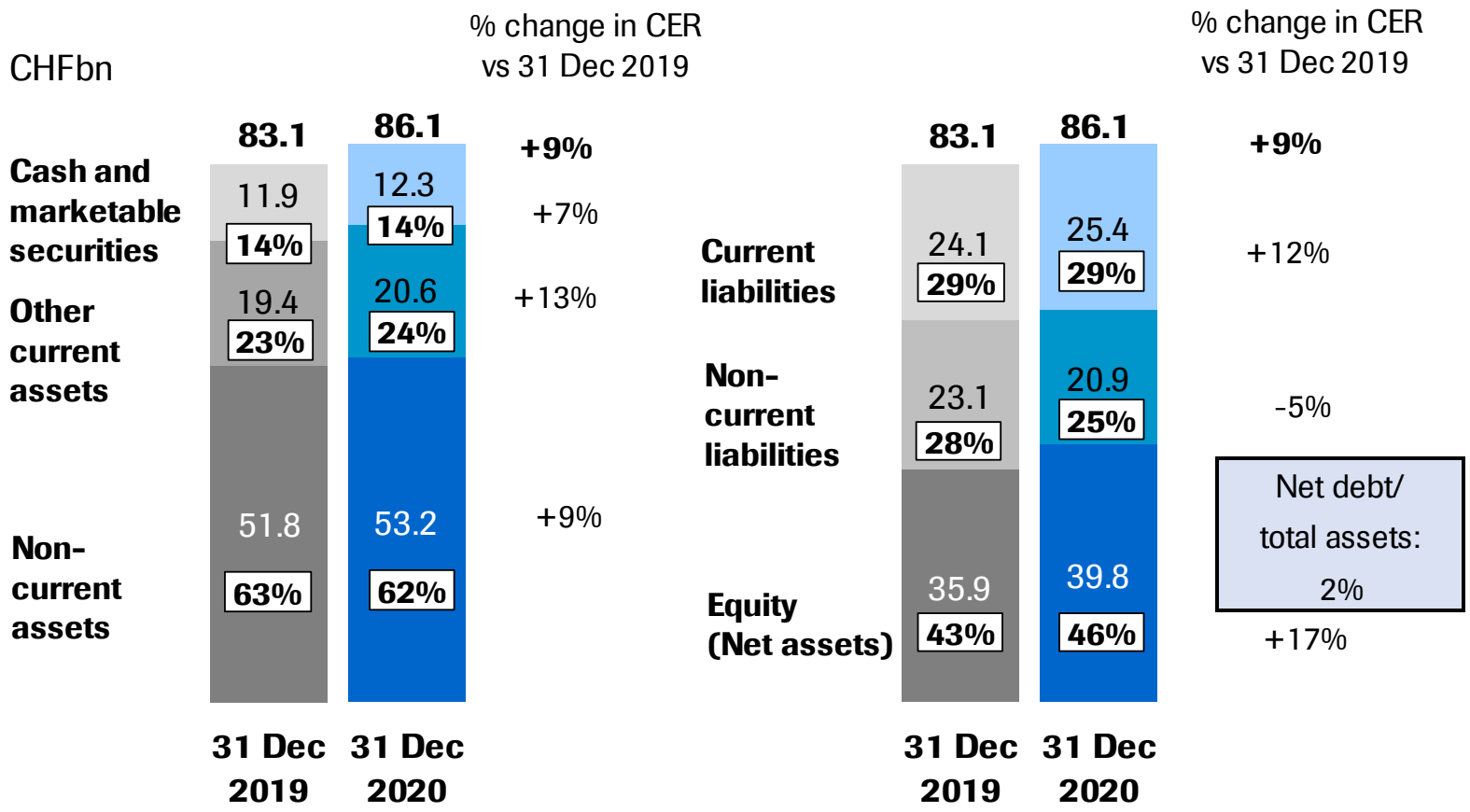
# 2020: Group net debt lower vs. YE 2019




| | | Intangible Asset | Equity | M&A | Total |
|---|---|---|---|---|---|
| Thereof investments in Innovation | 2020: | -3.2 | -0.4 | -1.2 | -4.8 |
| | 2019: | -1.4 | 0.0 | -4.8 | -6.2 |

# Balance sheet 31 December 2020

*Equity ratio at 46% (31 Dec 2019: 43%)*



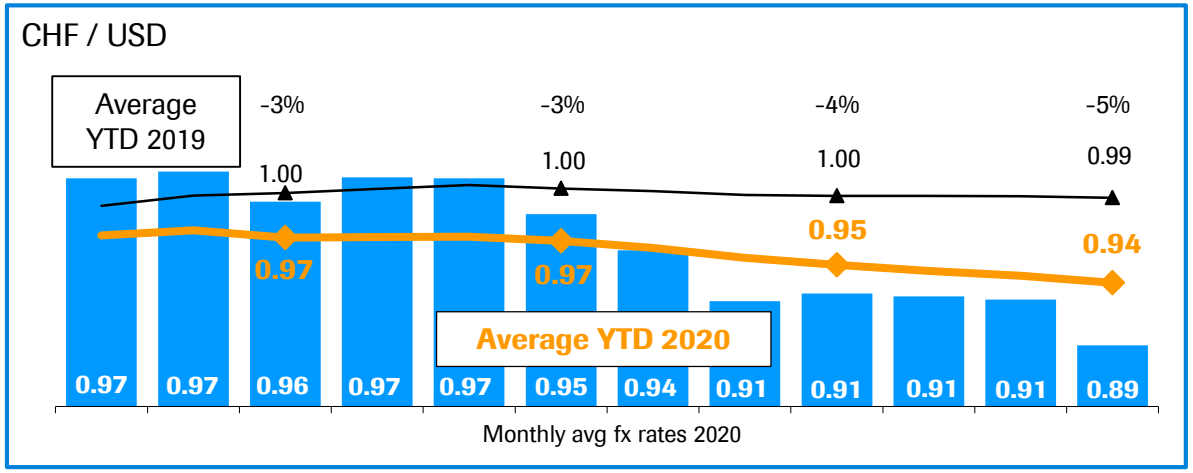

CER = Constant Exchange Rates

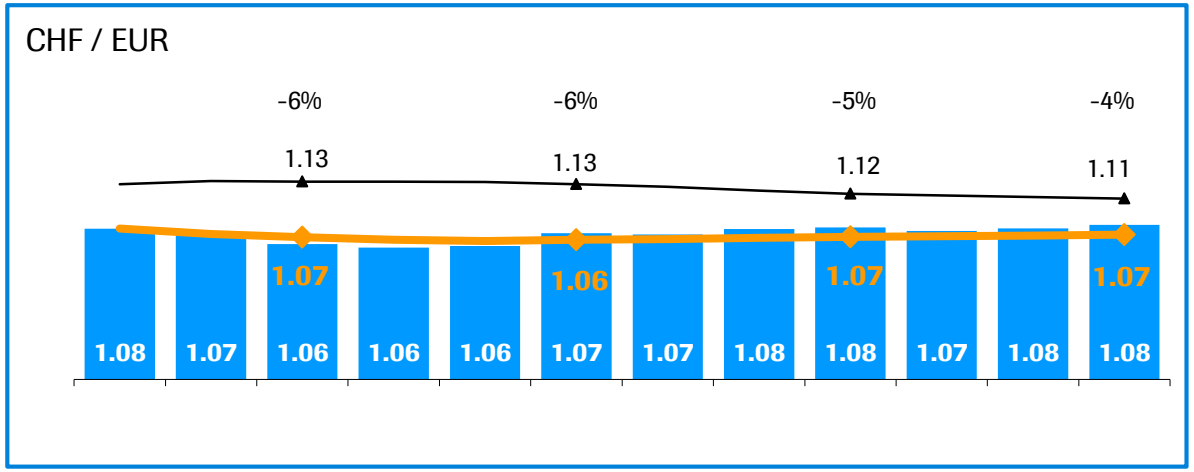
2020 results

Focus on Cash

**Outlook**

# High currency impact in 2020




[1] On group growth rates

***In 2020 impact[1] is (%p):***

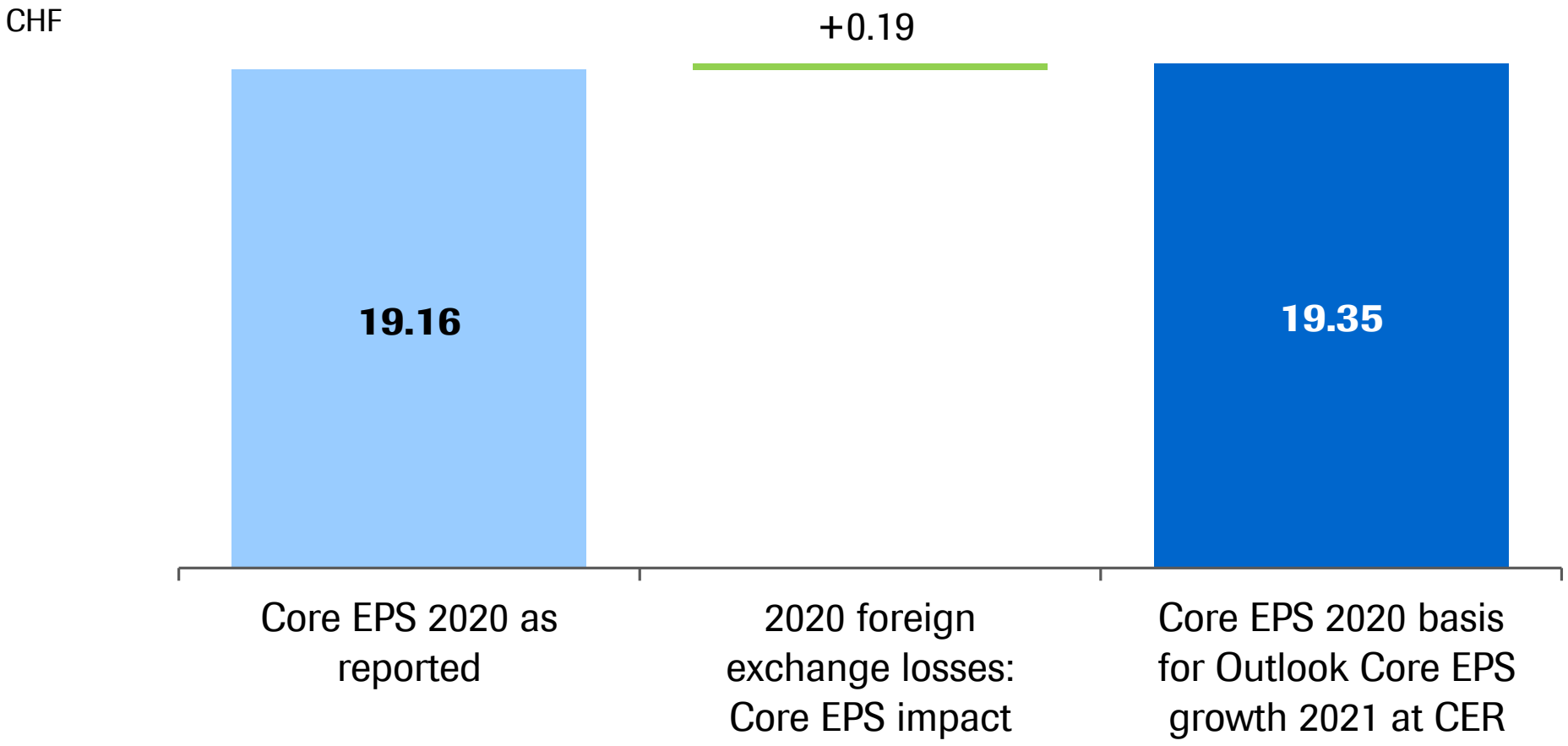
| | Q1 | HY | Sep YTD | FY |
|---|---|---|---|---|
| Sales | **-5** | **-5** | **-6** | **-6** |
| Core operating profit | | **-7** | | **-8** |
| Core EPS | | **-8** | | **-9** |

***2021** currency impact[1] expected (based on **31 Dec 2020** FX rates):*

- For FY around -3%p to -5%p FX impact on Sales, Core OP & Core EPS

# 2020: Core EPS

***Core EPS 2020 of CHF 19.35 is basis for Core EPS outlook 2021 at CER***




CER = Constant Exchange Rates

# 2021 outlook
## *Further growing top and bottom line*

| | |
|---|---|
| **Group sales growth[1]** | • Low- to mid-single digit |
| **Core EPS growth[1]** | • Broadly in line with sales growth |
| **Dividend outlook** | • Further increase dividend in Swiss francs |

[1] At Constant Exchange Rates (CER); based on the current assessment of the COVID-19 impact

Roche

# Changes to the development pipeline
## *Q4 2020 update*

### New to phase I

**7 NMEs:**
**RG6006** Abx MCP - bacterial infections
**RG6007** HLA-A2-WT1 x CD3 - AML
**RG6120** VEGF-Ang2 DutaFab - nAMD
**RG6182** NME - neurodegenerative diseases
**RG6232** TYRP1 x CD3 - metastatic melanoma
**RG6234** NME - multiple myeloma
**RG6312** NME - geographic atrophy

### New to phase II

**2 NMEs:**
**RG6359** SPK-3006 - Pompe disease
**RG6422** AT-527 - adult non-hospitalised SARS-CoV-2

**2 AIs:**
**RG6058** tiragolumab+T+chemo - 1L non-squamous NSCLC
**RG6171** giredestrant - ER+/HER2- 2/3L mBC

### New to phase III

**3 NMEs:**
**RG7845** fenebrutinib – PPMS
**RG6026** glofitamab – 2L+ DLBCL*
**RG7828** mosunetuzumab – 2L+ FL*

**4 AIs:**
**RG1594** Ocrevus high dose - RMS & PPMS
**RG6413+RG6412** casivirimab+imdevimab – SARS-CoV-2 adult - ambulatory
**RG7446** Tecentriq - SC NSCLC

### New to registration

**1 NME:**
**RG6321** PDS with ranibizumab - wAMD

**2 AIs:**
**RG6062** Esbriet - UILD
**RG7446** Tecentriq+nab-paclitaxel - TNBC neoadjuvant

### Removed from phase I

**1 NME:**
**RG7461** simlukafusp alfa combos - solid tumors

**2 AIs:**
**RG7446** Tecentriq+Avastin+Cotellic - 2/3L CRC
**RG7446** Tecentriq + K/HP - HER2+ BC

### Removed from phase II

**2 NMEs:**
**RG6149** ST2 MAb - asthma
**RG7845** fenebrutinib - RA

### Removed from phase III

**3 AIs:**
**RG6152** Xofluza - influenza hospitalized patients
**RG7440** ipatasertib+chemo - 1L TNBC/HR+ BC
**RG7440** ipatasertib+Tecentriq+taxane - 1L TNBC

### Approvals

**2 NMEs approved in EU:**
**RG6152** Xofluza - influenza
**RG6264** Phesgo - HER2+ BC
**5 AIs approved in US:**
**RG1594** Ocrevus short infusion - RMS & PPMS
**RG3648** Xolair - nasal polyps
**RG6152** Xofluza - post exposure prophylaxis
**RG6396** Gavreto – RET-mutant thyroid cancer
**RG7601** Venclexta+azacitdine - 1L AML
**3 AIs approved in EU:**
**RG6152** Xofluza - influenza high risk & post exposure prophylaxis
**RG7446** Tecentriq+Avastin - 1L HCC

* phI safety run-in ongoing



Status as of February 04, 2021

# Roche Group development pipeline

## Phase I (49 NMEs + 14 AIs)

| | | |
|---|---|---|
| RG6007 | HLA-A2-WT1 x CD3 | AML |
| RG6026 | glofitamab monotherapy and combos | heme tumors |
| RG6058 | tiragolumab combos | heme & solid tumors |
| RG6076 | CD19-4-1BBL | heme tumors |
| RG6115 | TLR7 agonist (4) | HCC |
| RG6139 | PD1 x LAG3 | solid tumors |
| RG6160 | cevostamab (FcRH5 x CD3) | r/r MM |
| RG6171 | giredestrant (SERD) | ER+/HER2- BC |
| RG6180 | autogene cevumeran±T (iNeST[1]) | solid tumors |
| RG6185 | belvarafenib (pan-RAF inh)+Cotellic | solid tumors |
| RG6194 | HER2 x CD3 | BC |
| RG6232 | TYRP1 x CD3 | metastatic melanoma |
| RG6234 | - | multiple myeloma |
| RG6279 | PD1-IL2v | solid tumors |
| RG6286 | - | colorectal cancer |
| RG6290 | MAGE-A4 ImmTAC | solid tumors |
| RG6292 | anti-CD25 MAb ± T | solid tumors |
| RG6296 | BCMA x CD16a | r/r MM |
| RG6323 | IL15/IL15Ra-Fc | solid tumors |
| RG6330 | KRAS G12C | solid tumors |
| RG7440 | ipatasertib + Taxane + T | TNBC |
| | ipatasertib + rucaparib | mCRPC, solid tumors |
| | ipatasertib | prostate cancer, pretreated |
| RG7446 | Morpheus platform | solid tumors |
| | T + CD47 MAb | r/r AML |
| | T + Venclexta | maintenance 1L ES-SCLC |
| RG7601 | Venclexta + AMG176 | AML |
| | Venclexta ± azacitidine | r/r MDS |
| | Venclexta + gilteritinib | r/r AML |
| RG7769 | PD1 x TIM3 | solid tumors |
| RG7802 | cibisatamab ± T | solid tumors |
| RG7827 | FAP-4-1BBL + T | solid tumors |
| RG7828 | mosunetuzumab monotherapy + combos | heme tumors |
| RG7876 | selicrelumab combos | solid tumors |
| CHU | FIXa x FX | hemophilia |
| CHU | glypican-3 x CD3 | solid tumors |
| CHU | codrituzumab | HCC |
| CHU | CD137 switch antibody | solid tumors |
| CHU | - | solid tumors & endometriosis |
| SQZ | PBMC vaccine | solid tumors |
| RG6151 | - | asthma |
| RG6244 | - | asthma |
| RG6287 | - | IBD |
| RG6418 | NLRP3 inh | inflammation |
| RG6315 | - | immunologic disorders |
| RG7835 | IgG–IL2 | autoimmune diseases |
| RG6006 | Abx MCP | bacterial infections |
| RG6084 | PD-L1 LNA | HBV |
| RG6346 | HBV siRNA | HBV |
| RG6091 | UBE3A LNA | Angelman syndrome |
| RG6102 | brain shuttle gantenerumab | Alzheimer's |
| RG6182 | - | neurodegenerative diseases |
| RG6237 | - | neuromuscular disorders |
| RG7637 | - | neurodevelopmental disorders |
| RG7816 | GABA Aa5 PAM | autism |
| RG6120 | VEGF-Ang2 DutaFab | nAMD |
| RG6179 | - | DME |
| RG6247 | 4D-110 | choroideremia |
| RG6312 | - | geographic atrophy |
| RG7921 | - | nAMD |
| 4DMT | 4D-125 | X-linked retinitis pigmentosa |
| CHU | PTH1 recep. ago | hypoparathyroidism |
| CHU | - | hyperphosphatemia |

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

[1]Individualized Neoantigen Specific Immunotherapy T=Tecentriq
[2]RG6149 NME status, RG7880 AI status
[3]combination contributing as two entities

## Phase II (22 NMEs + 12 AIs)

| | | |
|---|---|---|
| RG6171 | giredestrant (SERD) | neoadjuvant ER+ BC |
| | giredestrant (SERD) | 2/3L ER+/HER2- mBC |
| RG6180 | autogene cevumeran + pembrolizumab | 1L melanoma |
| RG6357 | SPK-8011 | hemophilia A |
| RG6358 | SPK-8016 | hemophilia A with inhibitors to factor VIII |
| RG6058 | tiragolumab + T | NSCLC |
| | tiragolumab + T + chemo | 1L non-squamous NSCLC |
| | tiragolumab + T | cervical cancer |
| RG7601 | Venclexta + fulvestrant | 2L HR+BC |
| | Venclexta + carfilzomib | r/r MM t(11:14) |
| CHU | Oncolytic Type 5 adenovirus | esophageal cancer |
| RG6173 | anti-tryptase | asthma |
| RG6354 | rhPTX-2 (PRM-151) | myelofibrosis |
| | rhPTX-2 (PRM-151) | idiopathic pulmonary fibrosis |
| RG7880 | efmarodocokin alfa (IL22-Fc) | inflammatory diseases |
| RG6149/RG7880[2] | ST2 MAb or efmarodocokin alfa | COVID-19 pneumonia |
| NOV | TLR4 MAb | autoimmune diseases |
| IONIS | ASO factor B | IgA nephropathy |
| RG6413+RG6412[3] | casivirimab+imdevimab | SARS-CoV-2 adult-hospitalised |
| RG6422 | AT-527 | SARS-CoV-2 |
| RG7854+RG7907[3] | TLR7 ago(3) + CpAM (2) | HBV |
| RG6359 | SPK-3006 | Pompe disease |
| RG7992 | FGFR1 x KLB MAb | NASH |
| RG6100 | semorinemab | Alzheimer's |
| RG6356 | microdystrophin (SRP-9001) | DMD |
| RG7412 | crenezumab | familial Alzheimer's healthy pts |
| RG7906 | ralmitaront | schizophrenia |
| RG7935 | prasinezumab | Parkinson's |
| RG6147 | - | geographic atrophy |
| RG6367 | SPK-7001 | choroideremia |
| RG7774 | - | retinal disease |
| IONIS | ASO factor B | geographic atrophy |

RG-No - Roche/Genentech
CHU - Chugai managed
IONIS – IONIS managed
SQZ - SQZ Biotechnology managed
NOV - Novimmune managed
4DMT - 4DMT managed

Status as of February 04, 2021

# Roche Group development pipeline

## Phase III (14 NMEs + 34 AIs)

| | | |
|---|---|---|
| RG6013 | Hemlibra | mild to moderate hemophilia A |
| RG6026** | glofitamab + chemo | 2L+ DLBCL |
| RG6058 | tiragolumab + T + chemo | 1L SCLC |
| | tiragolumab + T | 1L PD-L1+ NSCLC |
| | tiragolumab + T | locally advanced esophageal cancer |
| | tiragolumab + T | stage III unresectable 1L NSCLC |
| RG6107 | crovalimab | PNH |
| RG6114 | inavolisib (mPI3K alpha inh) | 1L HR+ mBC |
| RG6171 | giredestrant (SERD) | ER+/HER2- mBC |
| RG7440 | ipatasertib + abiraterone | 1L CRPC |
| | ipatasertib + fulvestrant + palbociclib | 1L HR+ mBC |
| RG7596 | Polivy | 1L DLBCL |
| RG7446 | Tecentriq | NSCLC adj |
| | Tecentriq | NMIBC, high risk |
| | Tecentriq | RCC adj |
| | Tecentriq + cabozantinib | advanced RCC |
| | Tecentriq + cabozantinib | 2L NSCLC |
| | T ± chemo | SCCHN adj |
| | Tecentriq | HER2+ BC neoadj |
| | T + capecitabine or carbo/gem | 1L TNBC |
| | T + paclitaxel | TNBC adj |
| | T + Avastin | HCC adj |
| | T ± chemo | 1L mUC |
| | Tecentriq | SC NSCLC |

| | | |
|---|---|---|
| RG6268 | Rozlytrek ROS1+ | 1L NSCLC |
| RG7601 | Venclexta | r/r MM t(11:14) |
| | Venclexta + azacitidine | 1L MDS |
| RG7828** | mosunetuzumab + lenalidomide | 2L+ FL |
| RG7853 | Alecensa | ALK+ NSCLC adj |
| RG1569 | Actemra ± remdesivir | COVID-19 pneumonia |
| RG3648 | Xolair | food allergy |
| RG7159 | Gazyva | lupus nephritis |
| RG7413 | etrolizumab | Crohn's |
| RG6152 | Xofluza | influenza, pediatric (0-1 year) |
| | Xofluza | influenza, pediatric (1-12 years) |
| | Xofluza | influenza direct transmission |
| RG6413+ RG6412* | casivirimab+imdevimab | SARS-CoV-2 adult prophylaxis |
| | casivirimab+imdevimab | SARS-CoV-2 adult ambulatory |
| RG1450 | gantenerumab | Alzheimer's |
| RG1594 | Ocrevus high dose | RMS & PPMS |
| RG6042 | tominersen | Huntington's |
| RG7845 | fenebrutinib | PPMS |
| RG6321 | port delivery system with ranibizumab | DME |
| | port delivery system with ranibizumab | DR |
| RG7716 | faricimab | DME |
| | faricimab | wAMD |

T=Tecentriq
*combination contributing as two entities
** phI safety run-in ongoing

## Registration (4 NMEs + 7 AIs)

| | | |
|---|---|---|
| RG6396 | Gavreto (pralsetinib) [1] | RET+ NSCLC |
| | Gavreto (pralsetinib) [3] | RET+ MTC |
| RG7446 | Tecentriq Dx+ [1] | 1L sq + non-sq NSCLC |
| | T + nab-paclitaxel [4] | TNBC neoadj |
| RG7601 | Venclexta + azacitidine [1] | 1L AML |
| RG7853 | Alecensa | 1LNSCLC Dx+ |
| RG3648 | Xolair [2] | asthma home use |
| RG6062 | Esbriet | UILD |
| RG6168 | Enspryng (satralizumab) [1] | NMOSD |
| RG7916 | Evrysdi (risdiplam) [1] | SMA |
| RG6321 | port delivery system with ranibizumab [5] | wAMD |

[1] Approved in US, filed in EU
[2] Filed in US
[3] Approved in US
[4] Filed in EU
[5] US rolling submission initiated

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

Status as of February 04, 2021

# NME submissions and their additional indications

## *Projects in phase II and III*

| 2020 | | 2021 | | 2022 | | 2023 and beyond | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| RG6321 | **Port Delivery System with ranibizumab** wAMD✓[1] | RG6413+ RG6412 | **casivirimab+imdevimab** SARS-CoV-2 adult-prophylaxis | RG6042 | **tominersen** Huntington's | RG6026 | **glofitamab + chemo** 2L DLBCL | RG7907+ RG7854 | **TLR7 ago (3) + CpAM (2)** HBV | | |
| RG7916 | **Evrysdi (risdiplam)** SMA (EU) ✓ | RG6413+ RG6412 | **casivirimab+imdevimab** SARS-CoV-2 adult-ambulatory | RG1450 | **gantenerumab** Alzheimer's | RG6058 | **tiragolumab + Tecentriq (T)** 1L PD-L1+ cervical ca | RG7906 | **ralmitaront** schizophrenia | RG7992 | **FGFR1 x KLB MAb** NASH |
| RG6396 | **Gavreto (pralsetinib)** ✓ RET+ NSCLC | RG6413+ RG6412 | **casivirimab+imdevimab** SARS-CoV-2 adult-hospitalised | RG7413 | **etrolizumab** Crohn's | RG6058 | **tiragolumab + T** 1L PD-L1+ NSCLC | RG6356 | **microdystrophin SRP-9001** DMD | RG6354 | **rhPTX-2 (PRM-151)** IPF |
| RG6396 | **Gavreto (pralsetinib)** ✓[2] RET+ MTC | RG6321 | **Port Delivery System with ranibizumab** wAMD (EU) | RG6058 | **tiragolumab + Tecentriq** 1L SCLC | RG6058 | **tiragolumab + T** locally adv esophageal cancer | RG6100 | **semorinemab (Tau MAb )** Alzheimer's | RG6354 | **rhPTX-2 (PRM-151)** myelofibrosis |
| | | RG7716 | **faricimab** DME | RG6107 | **crovalimab** PNH | RG6058 | **tiragolumab + T** Stage III unresectable 1L NSCLC | RG7845 | **fenebrutinib** PPMS | RG6149 | **ST2 MAb** COVID-19 pneumonia |
| | | RG7716 | **faricimab** wAMD | RG7440 | **ipatasertib + abiraterone** 1L CRPC | RG6058 | **tiragolumab + T** 1L non-sq NSCLC | RG7935 | **prasinezumab** Parkinson's | RG6173 | **Anti-tryptase** asthma |
| | | | | | | RG6114 | **inavolisib** (mPI3K alpha inh) 1L HR+ BC | RG6180 | **autogene cevumeran** (iNeST[3]) 1L melanoma | RG7880 | **efmarodocokin alfa** (IL22-Fc) inflammatory diseases |
| | | | | | | RG6171 | **giredestrant (SERD)** ER+/HER2- mBC | RG7440 | **ipatasertib + fulv + palbociclib** 1L HR+ mBC | RG6321 | **Port Delivery System with ranibizumab** DME |
| | | | | | | RG6171 | **giredestrant (SERD)** 2L/3L ER+/HER2- mBC | RG7828 | **mosunetuzumab + lenalidomide** 2L FL | RG6321 | **Port Delivery System with ranibizumab** DR |

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
[1] US rolling submission initiated
[2] US only
[3] Individualized Neoantigen Specific Immunotherapy

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

Status as of February 04, 2021

# AI submissions for existing products

## *Projects in phase II and III*

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

### 2020

| | |
|---|---|
| RG3648 | **Xolair** ✓<br>Asthma home use |
| RG6062 | **Esbriet** ✓<br>UILD (US) |
| RG7421 | **Cotellic + Tecentriq + Zelboraf** ✓<br>1L+ BRAFm melanoma |
| RG7446 | **Tecentriq + nab-paclitaxel**<br>TNBC neoadj ✓ EU |
| RG7446 | **Tecentriq + Avastin** ✓<br>1L HCC |
| RG7601 | **Venclexta +azacitidine** ✓<br>1L AML |
| RG7853 | **Alecensa (BFAST)** ✓<br>1L NSCLC ALK+ |

### 2021

| | |
|---|---|
| RG6152 | **Xofluza**<br>influenza, pediatric (1-12 yrs) |
| RG1569 | **Actemra +/- remdesivir**<br>COVID-19 pneumonia |
| RG6062 | **Esbriet** ✓<br>UILD (EU) |
| RG6013 | **Hemlibra**<br>Mild to moderate hemophilia A (EU) |
| RG6268 | **Rozlytrek (BFAST)**<br>1L NSCLC ROS1+ |
| RG7596 | **Polivy**<br>1L DLBCL |

### 2022

| | |
|---|---|
| RG6152 | **Xofluza**<br>direct transmission |
| RG6152 | **Xofluza**<br>influenza, pediatric (0-1 year) |
| RG3648 | **Xolair**<br>Food allergy |
| RG7446 | **Tecentriq**<br>NSCLC adj |
| RG7446 | **Tecentriq**<br>RCC adj |
| RG7446 | **Tecentriq ± chemo**<br>1L mUC |

### 2023 and beyond

| | |
|---|---|
| RG7446 | **Tecentriq + Avastin**<br>HCC adj |
| RG7446 | **Tecentriq**<br>SC NSCLC |
| RG7446 | **Tecentriq**<br>HER2+ BC neoadj |
| RG7446 | **Tecentriq + paclitaxel**<br>TNBC adj |
| RG7446 | **Tecentriq**<br>High risk NMIBC |
| RG7446 | **Tecentriq + chemo**<br>SCCHN adj |
| RG7446 | **Tecentriq + capecitabine or carbo/gem**<br>TNBC |
| RG7446 | **Tecentriq + cabozantinib**<br>adv RCC |
| RG7446 | **Tecentriq + cabozantinib**<br>2L NSCLC |
| RG7159 | **Gazyva**<br>lupus nephritis |
| RG1594 | **Ocrevus**<br>high dose RMS & PPMS |
| RG7601 | **Venclexta**<br>r/r MM t(11:14) |
| RG7601 | **Venclexta + azacitidine**<br>1L MDS |
| RG7601 | **Venclexta + fulvestrant**<br>2L HR+BC |
| RG7853 | **Alecensa**<br>ALK+ NSCLC adj |

Status as of February 04, 2021

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

# Major pending approvals 2020–YTD 2021

| US | | EU | | China | | Japan-Chugai | |
|---|---|---|---|---|---|---|---|
| **RG6062** | **Esbriet**<br>UILD<br>Filed Nov 2020 | **RG6168** | **Enspryng (satralizumab)**<br>NMOSD<br>Filed Aug 2019 | **RG7916** | **Evrysdi (risdiplam)**<br>SMA<br>Filed March 2020 | **RG7596** | **Polivy**<br>r/r DLBCL<br>Filed June 2020 |
| **RG7853** | **Alecensa (BFAST)**<br>1L NSCLC ALK+<br>Filed Jan 2020 | **RG7446** | **Tecentriq**<br>1L non-sq + sq NSCLC Dx+<br>Filed Nov 2019 | **RG6168** | **Enspryng (satralizumab)**<br>NMOSD<br>Filed April 2020 | **RG7916** | **Evrysdi (risdiplam)**<br>SMA<br>Filed Oct 2020 |
| | | **RG7916** | **Evrysdi (risdiplam)**<br>SMA<br>Filed July 2020 | **RG6152** | **Xofluza**<br>influenza<br>Filed May 2020 | | |
| | | **RG7601** | **Venclexta+ azacitidine**<br>1L AML<br>Filed May 2020 | **RG6152** | **Xofluza**<br>influenza, high risk<br>Filed May 2020 | | |
| | | **RG6396** | **Gavreto (pralsetinib)**<br>**RET+ NSCLC**<br>Filed May 2020 | **RG6013** | **Hemlibra**<br>Hemophilia A<br>Filed June 2020 | | |
| | | **RG7446** | **Tecentriq + nab-paclitaxel**<br>TNBC neoadj<br>Filed Dec 2020 | **RG7159** | **Gazyva**<br>1L FL and r/r FL<br>Sept 2020 | | |
| | | **RG6062** | **Esbriet**<br>UILD<br>Filed Jan 2021 | **RG7446** | **Tecentriq**<br>1L non-sq + sq NSCLC Dx+<br>Filed Sept 2020 | | |
| | | | | **RG7446** | **Tecentriq + pemetrexed**<br>1L non-sq NSCLC<br>Filed Sept 2020 | | |

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

Status as of February 04, 2021

# Major granted approvals 2020 and YTD 2021

## US

| | |
|---|---|
| RG7601 | **Venclexta+Gazyva**<br>1L CLL<br>Mar 2020 |
| RG7446 | **Tecentriq+Avastin**<br>1L HCC<br>May 2020 |
| RG7446 | **Tecentriq**<br>1L non-sq + sq NSCLC Dx+<br>May 2020 |
| RG7421 | **Cotellic+Zelboraf+Tecentriq**<br>1L+ BRAFm melanoma<br>May 2020 |
| RG6264 | **Phesgo (Perjeta+Herceptin) FDC SC**<br>Her2+BC June 2020 |
| RG7916 | **Evrysdi (risdiplam)**<br>SMA<br>Aug 2020 |
| RG6168 | **Enspryng (satralizumab)**<br>NMOSD<br>Aug 2020 |
| RG6396 | **Gavreto (pralsetinib)**<br>**RET+ NSCLC**<br>Sept 2020 |
| RG7601 | **Venclexta+azacitidine**<br>1L AML<br>Oct 2020 |
| RG6152 | **Xofluza**<br>post exposure prophylaxis<br>Nov 2020 |
| RG6413+ RG6412 | **casivirimab+imdevimab**<br>SARS-CoV-2 (EUA*)<br>Nov 2020 |
| RG6396 | **Gavreto (pralsetinib)**<br>RET+ MTC<br>Dec 2020 |
| RG1594 | **Ocrevus**<br>Short infusion RMS & PPMS<br>Dec 2020 |
| RG3648 | **Xolair**<br>nasal polyps<br>Dec 2020 |

*Emergency Use Authorisation

## EU

| | |
|---|---|
| RG7596 | **Polivy**<br>r/r DLBCL<br>January 2020 |
| RG7601 | **Venclexta+Gazyva**<br>1L CLL<br>Mar 2020 |
| RG1594 | **Ocrevus**<br>Short infusion RMS & PPMS<br>May 2020 |
| RG6268 | **Rozlytrek (entrectinib)**<br>ROS1+ NSCLC<br>Aug 2020 |
| RG6268 | **Rozlytrek (entrectinib)**<br>NTRK+ tumor-agnostic<br>Aug 2020 |
| RG7446 | **Tecentriq +Avastin**<br>1L HCC<br>Nov 2020 |
| RG6264 | **Phesgo FDC SC**<br>Her2+BC<br>Dec 2020 |
| RG6152 | **Xofluza**<br>influenza<br>Jan 2021 |
| RG6152 | **Xofluza**<br>influenza, high risk<br>Jan 2021 |
| RG6152 | **Xofluza**<br>post exposure prophylaxis<br>Jan 2021 |

## China

| | |
|---|---|
| RG3502 | **Kadcyla**<br>HER2+ eBC<br>Jan 2020 |
| RG7446 | **Tecentriq+chemo**<br>1L extensive stage SCLC<br>Feb 2020 |
| RG405 | **Avastin**<br>1L/2L glioblastoma<br>Sept 2020 |
| RG7446 | **Tecentriq +Avastin**<br>1L HCC<br>Oct 2020 |

## Japan-Chugai

| | |
|---|---|
| RG6268 | **Rozlytrek (entrectinib)**<br>ROS1+ NSCLC<br>Feb 2020 |
| RG7853 | **Alecensa**<br>r/r ALK+ ALCL<br>Feb 2020 |
| RG105 | **Rituxan**<br>thrombocytopenic purpura<br>Feb 2020 |
| RG6168 | **Enspryng (satralizumab)**<br>NMOSD<br>June 2020 |
| RG3502 | **Kadcyla**<br>HER2+ eBC adj<br>Aug 2020 |
| RG7446 | **Tecentriq+Avastin**<br>HCC<br>Sept 2020 |
| RG7446 | **Tecentriq +Avastin**<br>1L non-sq NSCLC Dx+<br>Dec 2020 |

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

FDC = fixed-dose combination

Status as of February 04, 2021

*Doing now what patients need next*