Media Release

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Roche reports solid results in 2020

- **Group sales** increase 1%[1] at constant exchange rates (CER); 5% decline in Swiss francs, as a result of continued appreciation of the Swiss franc against most currencies
- **Pharmaceuticals Division** sales decline 2%; continued strong sales growth of newly launched medicines (+32%[2], including Tecentriq, Hemlibra, Ocrevus, Perjeta and Kadcyla) largely offsets the impact of competition from biosimilars (CHF -5.1 billion at CER[3]), but not the additional COVID-19-related impact from missed medical appointments
- **Diagnostics Division** sales grow 14% for the full year (+28% in the fourth quarter) due to COVID-19 diagnostics; more than offsetting a decline in routine testing due to COVID-19
- **Roche's contributions to the fight against the COVID-19 pandemic**:
  - Launch of 15 new diagnostic solutions for COVID-19
  - Key tests launched in the fourth quarter:
    - USA: Elecsys Anti-SARS-CoV-2 S antibody test, which can play a critical role in measuring a person's vaccine-induced immune response
    - Europe: Elecsys SARS-CoV-2 Antigen test to support high-volume testing of suspected COVID-19 patients
  - Production capacity for SARS-CoV-2 tests and COVID-19-related medicines ramped up significantly at unprecedented speed; substantial funds committed to further expand supply chain capacities (>CHF 800 million)
  - Major partnerships: With Regeneron to increase global supply of investigational antiviral antibody combination (August), with Atea to develop a potential oral COVID-19 treatment (October), and with Moderna to include our recently launched antibody test in their ongoing vaccine trials (December)
- **Approvals for medicines** in the fourth quarter:
  - USA: Gavreto (thyroid cancer); Xofluza (influenza); Xolair (nasal polyps)
  - Europe: Tecentriq plus Avastin (liver cancer), Phesgo (breast cancer), Xofluza (influenza)[4]
- **Strong pipeline**: record number of 19 new compounds in phase III trials or filed for approval; investment in research and development further increased by 8% to CHF 12.2 billion
- **Core earnings per share** (EPS) grow ahead of sales at 4% (-5% in CHF)
- **IFRS net income** of CHF 15.1 billion, increasing 17% (7% in CHF), mainly due to the lower goodwill write-offs compared to the previous year
- Board proposes **dividend** to increase to CHF 9.10. Subject to shareholder approval, this would be the 34th consecutive dividend increase)

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

Outlook for 2021: Despite the continued strong impact of biosimilars, sales are expected to grow in the low- to mid-single digit range, at constant exchange rates. Core earnings per share are targeted to grow broadly in line with sales, at constant exchange rates. Roche expects to increase its dividend in Swiss francs further.

Key figures 2020	CHF millions		% change	
	2020	2019	At CER	In CHF
Group sales	58,323	61,466	1	-5
Pharmaceuticals Division	44,532	48,516	-2	-8
Diagnostics Division	13,791	12,950	14	6
Core operating profit	21,536	22,479	4	-4
Core EPS - diluted (CHF)	19.16	20.16	4	-5
IFRS net income	15,068	14,108	17	7

Commenting on the Group's results, Roche CEO Severin Schwan said: "Roche continues to make important contributions to fighting the COVID-19 pandemic. We developed in record time a comprehensive portfolio of diagnostic solutions and entered new partnerships to develop and produce effective COVID-19 medicines. The demand for our new medicines which benefit people living with serious conditions, such as cancer, multiple sclerosis, haemophilia and spinal muscular atrophy, remains high. Based on our rejuvenated portfolio and the significant progress made in developing our product pipeline, Roche is strongly positioned for future growth."

Group results

In 2020, **Group** sales rose 1% (-5% in CHF) to CHF 58.3 billion. The core operating profit increased 4% (-4% in CHF), reflecting the underlying business performance, and core EPS grew 4% (-5% in CHF), ahead of sales. The appreciation of the Swiss franc against almost all currencies had a significant adverse net impact on the results expressed in Swiss francs compared to constant exchange rates.

The IFRS net income increased 17% (7% in CHF). This increase is mainly due to the lower goodwill write-offs compared to the previous year.

Sales in the **Pharmaceuticals Division** decreased 2% to CHF 44.5 billion, mainly due to stronger than expected biosimilars competition and the COVID-19 pandemic. The new medicines (launched since 2012) continued their strong growth (+32%, or +CHF 4.7 billion). In 2020, they generated sales of CHF 18.4 billion, thus already contributing more than 40% to the division's total sales.

While sales of the new medicines grew strongly, the impact of the competition from biosimilars for the established medicines Herceptin, Avastin and MabThera/Rituxan was significant, with an estimated combined CHF 5.1 billion of sales reduction in the US, Europe and Japan.

The COVID-19 pandemic also had an overall negative impact on the division's sales in 2020, especially for medicines where regular visits to health practices or hospitals are needed (ie, for infusions), as many people continue to avoid visits to doctors. This was partly compensated by additional sales of Actemra/RoActemra (+32%) mostly due to treatment of patients with severe COVID-19-associated pneumonia.

In the **United States**, sales decreased by 6%, as a result of the increasing competition from biosimilars for MabThera/Rituxan, Herceptin and Avastin (combined: -38%). This was partially offset by sales of Ocrevus, Hemlibra, Tecentriq and Actemra/RoActemra. Ocrevus sales were driven by both new and returning patient demand, partly dampened by COVID-19 effects. Tecentriq sales increased mainly due to growth in the new indications (certain forms of lung, breast and liver cancer).

In **Europe**, sales grew by 1% with new product sales more than compensating for the biosimilar competition to Herceptin, MabThera/Rituxan and Avastin (combined: -37%) and impacts of the COVID-19 pandemic. Tecentriq sales continued to grow strongly following successful launches. Hemlibra and Ocrevus also showed strong uptake.

In **Japan**, sales decreased by 6%, as a result of the considerable competition from biosimilars and government price cuts. This decline was partially compensated for by recently launched products including Tecentriq and Hemlibra. Perjeta sales grew due to the launch of an additional indication for early breast cancer.

In the **International region**, sales growth (+7%) was mostly driven by China and Russia. China saw a strong uptake of Perjeta and Alecensa; this was partially offset by the impact of the National Reimbursement Drug List update and the COVID-19 impacts.

The **Diagnostics Division** reported strong sales growth of 14% to CHF 13.8 billion. This growth is primarily due to our world-leading portfolio of new COVID-19 tests. Molecular Diagnostics was the main growth contributor (+90%), driven by molecular COVID-19 tests.

Sales of diagnostics for SARS-CoV-2, developed only this year, and emergency testing clearly exceeded COVID-19-related declines in routine diagnostics sales.

Additional product launches in the fourth quarter, such as the spike antibody test, which is used in several COVID-19 vaccine trials, further underlines Roche's speed and innovation power.

Growth was reported in **EMEA**[5] (+19%), **North America** (+26%), **Latin America** (+14%) and **Japan** (+5%). The sales decrease in **Asia-Pacific** (-3%) was driven by China (-11%) due to the decrease in routine testing following severe COVID-19 pandemic restrictions.

COVID-19: Roche's response to the pandemic

Roche is at the forefront of the fight against COVID-19 with a growing portfolio of diagnostics solutions, the development of new medicines and a number of partnerships across the industry, and committed significant funds (more than CHF 800 million for 2020/2021) to further expand production capacity across the entire supply chains.

Diagnostics:

- In 2020, Roche developed **15 solutions for SARS-CoV-2 diagnosis** in record time, including both molecular and immunodiagnostic tests for clinical laboratory and point of care. This new portfolio as well as the existing diagnostics menu for critical care will continue to make a significant contribution to the fight against the pandemic – as long as large parts of the population are not vaccinated or COVID-19 medicines are not widely available, tests are one of the few effective means in the fight against the pandemic.
- To support the high demand for SARS-CoV-2 testing, Roche created more than 1,000 new jobs worldwide and significantly increased total production capacity: By the end of 2020, more than 1,000 of the high-throughput cobas 6800/8800 instruments were in place; almost twice the number projected for the year were installed in 2020. These expansions will help laboratories meet the rapidly growing global demand for COVID-19 testing.

COVID-19: Diagnostic solutions developed in 2020

Solution	Usage	Availability	Launch date
TIB MOLBIOL LightMix Modular SARS-CoV-2 test	PCR detection of active infection, testing on on LightCycler instruments and cobas z 480 analyser	CE Mark; US research use only	Jan
cobas SARS-CoV-2 test (PCR)	Detection of SARS-CoV-2, testing on our high-throughput cobas 6800/8800 systems	FDA EUA and CE mark	March
Elecsys Anti-SARS-CoV-2 antibody test	Detection of antibodies against SARS-CoV-2 in patients, testing on established cobas e analysers	FDA EUA and CE mark	May
Viewics LabOPS COVID-19	Efficiency improvements in laboratories	USA	May
Roche v-TAC	Digital tool to simplify blood gas value conversion from patients	CE mark	May
Elecsys IL-6 test	IL-6 testing to help identify severe inflammatory response	FDA EUA and CE mark	June
SARS-CoV-2 Rapid Antibody test	For use in point-of-care settings to help identify patients that have developed antibodies against SARS-CoV-2	CE mark	July
iThemba Life COVID-19 App	Mobile health application; delivers COVID-19 testing results directly to user's smartphone	Sub-Saharan Africa	July
Navify Remote Monitor	Guidance for individuals returning to work or school during COVID-19	USA	Aug
cobas SARS-CoV-2 & Influenza A/B test	For cobas 6800/8800 systems: Detect/differentiate SARS-CoV-2, influenza A and/or B virus with a single sample	FDA EUA and CE mark	Sept
cobas SARS-CoV-2 & Influenza A/B test	For cobas Liat system: Detect/differentiate SARS-CoV-2, influenza A and/or B virus with a single sample in 20 minutes	FDA EUA and CE mark	Sept
Elecsys Anti-SARS-CoV-2 S antibody test	Quantitatively measure antibodies in people who have been exposed to SARS-CoV-2. Can play a critical role in measuring a person's vaccine-induced immune response	CE mark FDA EUA	Sept Dec
SARS-CoV-2 Rapid Antigen test	Triage people suspected of SARS-CoV-2, for use on symptomatic people in point-of-care settings; results available in 15 minutes	CE Mark	Sept

Elecsys SARS-CoV-2 Antigen test	High-volume laboratory antigen test for the testing and triage of suspected COVID-19 patients	CE Mark FDA EUA filed	Dec
cobas infinity POC COVID-19 connectivity portal	For use in point-of-care settings: Digital solution supporting the roll-out of the SARS-CoV-2 Rapid Antigen test	Globally	Dec

Pharmaceuticals:

- In 2020, Roche entered into a number of new partnerships, including with Gilead, Regeneron and Atea, to develop, manufacture and/or distribute molecules that potentially can both treat and prevent COVID-19.
- In addition, Roche is exploring the potential of its investigational molecules and existing portfolio: For example, Roche has initiated three global phase III clinical trials investigating the safety and efficacy of Actemra/RoActemra in COVID-19-associated pneumonia. Results of the COVACTA and EMPACTA studies have been submitted for publication and/or published in a peer-reviewed journal and have been uploaded on data-sharing platforms. Following initial interactions with health authorities, Roche will continue to monitor the evolving clinical evidence for Actemra/RoActemra in this setting, including in combination with an antiviral (remdesivir), in the ongoing phase III REMDACTA study.
- Overall, Roche has four different medicines in six clinical trials for COVID-19 infections.

COVID-19: Roche's contributions in the fourth quarter

Diagnostics:

In December, our **Elecsys Anti-SARS-CoV-2 S antibody test** received the Emergency Use Authorisation (EUA) from the FDA. This immunology test (already launched for markets accepting the CE mark) detects antibodies against the spike protein. This protein is the target of many COVID-19 vaccines in development. The test can be used to quantitatively measure antibodies in people who have been exposed to SARS-CoV-2 and can play an important part in characterising a vaccine-induced immune response.

Roche is working together with leading vaccine developers, such as Moderna, to include our antibody tests in their ongoing COVID-19 vaccine trials.

Also in December, Roche launched a high-volume **Elecsys SARS-CoV-2 Antigen test** as an aid in the diagnosis of an active SARS-CoV-2 infection. It is available in markets accepting the CE mark, and Roche has filed for an FDA EUA. Performed by healthcare professionals, this test uses swab samples from patients with symptoms suggestive of COVID-19 or from people with either known or suspected exposure to the virus.

Pharmaceuticals:

In October, Roche announced a partnership with **Atea Pharmaceuticals** to jointly develop, manufacture and distribute **AT-527** to people around the globe. Atea's compound has the potential to be the first novel oral antiviral to treat COVID-19 patients outside the hospital setting as well as in the hospital. Its formulation (pill) could allow for large-scale manufacturing and may help to facilitate access to a broad patient population.

In November, Roche's partner **Regeneron** received FDA EUA for their antiviral antibody combination (casirivimab and imdevimab) for the treatment of recently diagnosed high-risk patients with mild to

moderate COVID-19. As part of the global partnership with Regeneron, Roche is committing a significant amount of manufacturing capacity and is working to expand supply of this antibody combination beyond the US to as many people as possible.

Pharmaceuticals: Pipeline development in 2020

Despite the massive disruption of the global pandemic, Roche's commitment to developing new treatment options remained unchanged in 2020. The strong flow of positive study results and approvals form the basis for Roche's future growth.

Thanks to a range of innovative new approaches, Roche moved **nine new molecules** to late-stage development, compared to approx. three p.a. over the last four years. At the end of 2020, Roche had **19 new molecular entities (NMEs)** in late-stage development – more than ever before. Moreover, Roche launched **four new medicines** in 2020.

Pharmaceuticals: Key approvals in the fourth quarter 2020

Pharmaceuticals	Indication	Key markets
Tecentriq + Avastin	Unresectable hepatocellular carcinoma, the most common form of liver cancer. First and only cancer immunotherapy regimen approved for this indication	EU and China
Ocrevus	Shorter 2-hour infusion time for relapsing and primary progressive multiple sclerosis: The only approved B-cell therapy with a twice-yearly dosing schedule; shorter infusion time will further improve treatment experience	US
Phesgo	HER2-positive breast cancer; fixed-dose combination of Perjeta and Herceptin with hyaluronidase: Faster and less invasive delivery of this standard-of-care treatment.	EU
Gavreto	Advanced or metastatic RET-mutant and RET fusion-positive medullary thyroid cancers; approved across multiple RET-altered tumour types	US *(BTDs)*
Xofluza	Prevention of influenza following contact with infected person: First single-dose, post-exposure preventive treatment for influenza. Reducing the burden of influenza may help to mitigate strain on healthcare systems amid COVID-19	US
Xofluza	Influenza and as preventive treatment. First antiviral influenza drug with a novel mechanism of action to be approved in the EU in almost 20 years.	EU (Jan. 2021)
Xolair	Nasal polyps	US
Venclexta/Venclyxto combination	Acute myeloid leukaemia	US (full FDA approval)

BTD: Breakthrough Therapy Designation

Pharmaceuticals: Key approvals January – September 2020

Pharmaceuticals	Indication	Key markets
Rozlytrek	Solid tumours expressing a neurotrophic tyrosine receptor kinase gene fusion	EU
Rozlytrek	ROS1-positive, advanced non-small cell lung cancer	EU
Venclexta/Venclyxto +Gazyva/Gazyvaro	Previously untreated chronic lymphocytic leukaemia	EU
Polivy + MabThera/Rituxan	Relapsed or refractory diffuse large B-cell lymphoma	EU

Evrysdi	Oral medication, spinal muscular atrophy type 1, 2, 3	US
Enspryng	Neuromyelitis optica spectrum disorder, a rare autoimmune disease of the central nervous system	US
Zelboraf + Cotellic +Tecentriq	BRAF V600 mutation-positive advanced melanoma	US
Tecentriq + Avastin	Unresectable or metastatic hepatocellular carcinoma	US
Tecentriq	First-line (initial) monotherapy for certain people with metastatic non-small cell lung cancer	US
Phesgo	HER2-positive breast cancer; fixed-dose combination of Perjeta and Herceptin with hyaluronidase, administered by subcutaneous injection	US

Pharmaceuticals: Key development milestones in the fourth quarter of 2020

In December, Roche announced three year follow-up phase III data results reinforcing the long-term benefit of **Hemlibra** for people with haemophilia A. Hemlibra maintained low treated bleed rates and was well tolerated in people with haemophilia A of all ages (with and without factor VIII inhibitors). The proportion of participants who experienced zero treated bleeds increased over the course of the study period.

Also in December, Roche presented exploratory data from our phase III study (IMvigor010) in early bladder cancer. It showed that people with muscle-invasive urothelial cancer who had detectable circulating tumour DNA (ctDNA), a biomarker that can be used to identify minimal residual disease, were more likely to benefit from treatment with adjuvant **Tecentriq** monotherapy compared with those without ctDNA.

Faricimab is the first investigational bispecific antibody designed for the eye and targets two distinct pathways – via angiopoietin-2 and vascular endothelial growth factor-A – that drive a number of retinal conditions. Roche recently announced positive topline results from four global phase III studies**:**

- YOSEMITE and RHINE in people living with diabetic macular oedema, a leading cause of blindness. Both studies met their primary endpoint and showed that faricimab demonstrated non-inferior visual acuity gains. More than half of participants in the personalised dosing arms had extended time between treatments to 16 weeks at year one.
- TENAYA and LUCERNE in neovascular age-related macular degeneration, the leading cause of blindness in people over 60: The time between treatments could be extended to 16 weeks for almost half of participants.

Roche plans to file for approval in both indications in the first quarter of 2021.

Furthermore, the FDA granted Fast Track Designation (FTD) to Roche's investigational next generation oral selective oestrogen receptor degrader (SERD) **giredestrant** for a certain type of breast cancer, and Breakthrough Therapy Designation (BTD) to **tiragolumab** for a certain type of lung cancer. Tiragolumab is a novel cancer immunotherapy designed to bind to TIGIT; this marks the 37th BTD for Roche's portfolio of medicines.

BTDs and FTDs are processes designed to expedite the development and review of medicines intended to treat serious diseases – thus enabling them to be approved and made available to patients more quickly. These recognitions reflect the high degree of innovation of Roche's research and development.

Pharmaceuticals: Key development milestones in the fourth quarter 2020

Study: compound	Indication	Outcome
Phase III MURANO and CLL14: Venclexta/Venclyxto combo	Relapsed or refractory chronic lymphocytic leukaemia	Reinforcing long-term benefit
GO29365: Polivy + MabThera/Rituxan	Relapsed or refractory diffuse large B-cell lymphoma	Reinforcing benefit/risk profile; showing continued survival benefit
HAVEN: Hemlibra	Haemophilia A	Reinforcing long-term benefit; proportion of participants who experienced zero treated bleeds increased
GO29781, GO40554, NP30179, GO39775: Mosunetuzumab, glofitamab, cevostamab	Blood cancers (non-Hodgkin lymphoma, multiple myeloma)	Bispecific antibodies: Showing encouraging activity across multiple types of blood cancer
Phase III IMvigor010: Tecentriq (exploratory analysis)	Early bladder cancer	People with muscle-invasive urothelial cancer who had detectable ctDNA more likely to benefit from adjuvant treatment with Tecentriq, compared with those w/o ctDNA
Phase III YOSEMITE and RHINE: Faricimab	Diabetic macular oedema	Demonstrated non-inferior visual acuity gains; given at intervals of up to every 16 weeks
Phase III TENAYA and LUCERNE: Faricimab	Neovascular age-related macular degeneration	Demonstrated non-inferior visual acuity gains; given at intervals of up to every 16 weeks
Giredestrant	Oestrogen receptor positive, HER2-negative metastatic breast cancer	FTD
Phase II CITYSCAPE: Tiragolumab + Tecentriq	PD-L1-high non-small cell lung cancer	BTD; further evidence that targeting both immune inhibitory receptors, TIGIT and PD-L1, may potentially amplify immune response

Diagnostics: Key launches in 2020 (apart from COVID-19)

In addition to its broad new COVID-19 testing portfolio, Roche introduced several other important diagnostic advancements for customers and patients.

These include the **cobas prime** (the first fully automatic, pre-analytical system to prepare the variety and volume of samples labs receive for molecular testing) and three next-generation **uPath image analysis algorithms** for rapid and accurate test results in oncology (digital pathology: automated analysis of scans generated from tissue samples).

Other Roche market firsts include the **cobas Epstein-Barr virus (EBV) and BK virus (BKV) tests**, which were approved by the FDA mid-year. Both tests had previously received breakthrough device status. These fast, reliable tools (both performed on our high-throughput cobas 6800/8800 systems) enable healthcare professionals to monitor and treat patients at risk for the common, but life-threatening, consequences of EBV and BKV infections after transplantation of solid organs and/or stem cells.

Pharmaceuticals sales

Pharmaceuticals Division Sales in 2020	CHF millions		As % of sales		% change	
	2020	2019	2020	2019	At CER	In CHF
Pharmaceuticals Division	44,532	48,516	100.0	100.0	-2	-8
United States	23,647	26,711	53.1	55.1	-6	-11
Europe	8,198	8,453	18.4	17.4	1	-3
Japan	3,765	4,143	8.5	8.5	-6	-9
International*	8,922	9,209	20.0	19.0	7	-3

*Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

Pharmaceuticals: Established products

Avastin (CHF 5.0 billion, -25%). Advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, relapsed glioblastoma (a type of brain tumour) and liver cancer in combination with Tecentriq. Sales were impacted by the biosimilar competition in the US, Europe and Japan.

MabThera/Rituxan (CHF 4.2 billion, -31%). Forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. The sales decline was driven by all regions, due to the biosimilar erosion as well as market contraction from the COVID-19 pandemic restrictions.

Herceptin (CHF 3.7 billion, -34%). HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales were impacted by biosimilars in the US, Japan and Europe. In the US, the switch to Kadcyla as the new standard of treatment (notably in early breast cancer) also impacted sales.

Actemra/RoActemra (CHF 2.9 billion, +32%). Rheumatoid arthritis, forms of juvenile idiopathic arthritis and giant cell arteritis as well as CAR T cell-induced severe or life-threatening cytokine release syndrome. A number of countries included this medicine in their treatment guidelines for severe COVID-19-associated pneumonia. Actemra/RoActemra is not currently approved for this use; various clinical studies have been carried out and the results made available to healthcare authorities. The US was the major contributor to the sales increase, along with Russia, India and Spain.

Xolair (CHF 1.9 billion, +2%, US only). Chronic idiopathic urticaria and allergic asthma. The sales increase was driven by the demand in both indications. Xolair remains the market leader in the larger allergic asthma indication.

Lucentis (CHF 1.4 billion, -16%, US only). Eye conditions, including 'wet' age-related macular degeneration. The COVID-19 pandemic caused some disruption in hospitals and ophthalmology practices and many patients delayed treatment during the restrictions.

Pharmaceuticals: Medicines launched since 2012

Ocrevus (first approved in 2017; CHF 4.3 billion, +24%). Relapsing and primary progressive forms of multiple sclerosis; shorter 2-hour infusion. The strong demand for this treatment in both indications has continued, while the COVID-19 pandemic has had a certain negative impact. In the US, growth was driven both by new and returning patients.

Perjeta (first approved in 2012; CHF 3.9 billion, +18%). HER2-positive breast cancer. The increased patient demand for this medicine was mostly driven by the International region, mainly China (in both early breast cancer and metastatic breast cancer settings).

Tecentriq (first approved in 2016; CHF 2.7 billion, +55%). Cancer immunotherapy for various types of cancer (either alone or in combinations), ie, certain types of lung, bladder, breast and liver cancer. Strong sales growth reported by all regions, notably in the US, where higher sales were driven by the new indications for extensive-stage small cell lung cancer, PD-L1-positive triple-negative breast cancer and unresectable or metastatic hepatocellular carcinoma.

Hemlibra (first approved in 2017; CHF 2.2 billion, +68%). Haemophilia A with and without factor VIII inhibitors; only prophylactic treatment that can be administered subcutaneously once weekly, once every two weeks or once every four weeks. Sales continued to show a strong uptake, especially in the US and Europe, despite COVID-19 restrictions having some impact on potential new patients.

Kadcyla (first approved in 2013; CHF 1.7 billion, +34%). HER2-positive breast cancer. The increased demand for Kadcyla was driven by its usage in the early breast cancer setting. Sales benefited from the positive read-out from the KATHERINE study and patients switching to the new standard of treatment.

Alecensa (first approved in 2015; CHF 1.2 billion, +40%). ALK-positive non-small cell lung cancer. The global uptake continued across all regions.

Esbriet (first approved in 2014; CHF 1.1 billion, +4%). Idiopathic pulmonary fibrosis (IPF). Sales continued to expand, driven by increased use in indications other than IPF in the US.

Gazyva/Gazyvaro (first approved in 2013; CHF 632 million, +21%). Chronic lymphocytic leukaemia, rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma.

Polivy (first approved in 2019; CHF 169 million, +248%). Relapsed or refractory diffuse large B-cell lymphoma; part of combination therapy. The dynamics in the market suggest that Polivy represents a new much-needed fixed-duration treatment option for people with this aggressive form of lymphoma.

Evrysdi (first approved in 2020; CHF 55 million*). Spinal muscular atrophy (SMA) in adults and children two months of age and older. Evrysdi helps infants to survive without permanent ventilation and to achieve the ability to sit without support, a key motor milestone not normally seen in the natural course of the disease; first and only medicine for SMA that can be taken at home.

Xofluza (first approved in 2018; CHF 43 million, +370%). Acute, uncomplicated influenza, for people with high risk of developing flu-related complications; prevention of influenza following contact with infected person.

Rozlytrek (first approved in 2019; CHF 24 million, +267%). Specific form of non-small cell lung cancer (NSCLC); solid tumours expressing a specific gene fusion; ROS1-positive, advanced NSCLC.

Phesgo (first approved in 2020; CHF 23 million*). Early and metastatic HER2-positive breast cancer (fixed-dose combination of Perjeta and Herceptin for subcutaneous injection). Offers faster administration in just minutes, compared to hours with standard intravenous administration.

Enspryng (first approved in 2020; CHF 18 million*). Rare autoimmune disease of the central nervous system (neuromyelitis optica spectrum disorder; NMOSD). Using novel recycling antibody technology, Enspryng is the first subcutaneous NMOSD treatment that can be self-administered at home. Currently approved in 14 countries with multiple additional country approvals anticipated in the near-term.

* recently launched, no growth figures available

Top-selling pharmaceuticals Sales in 2020	**Total**		**United States**		**Europe**		**Japan**		**International***	
	CHF m	**%**	**CHF m**	**%**	**CHF m**	**%**	**CHF m**	**%**	**CHF m**	**%**
Avastin	4,992	-25	1,795	-37	1,252	-27	717	-15	1,228	-2
Ocrevus	4,326	24	3,408	18	674	41	-	-	244	68
MabThera/Rituxan	4,223	-31	2,864	-32	379	-33	64	-39	916	-22
Perjeta	3,883	18	1,476	2	1,150	10	294	9	963	75
Herceptin	3,732	-34	1,356	-47	665	-32	140	-40	1,571	-17
Actemra/RoActemra	2,858	32	1,212	36	783	16	366	-5	497	116
Tecentriq	2,738	55	1,566	40	576	72	330	82	266	93
Hemlibra	2,190	68	1,388	56	373	135	313	40	116	233
Xolair	1,904	2	1,904	2	-	-	-	-	-	-
Kadcyla	1,745	34	807	34	560	35	90	13	288	37

* Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

Diagnostics sales

Diagnostics Division	CHF millions		As % of sales		% change	
Sales in 2020	2020	2019	2020	2019	At CER	In CHF
Diagnostics Division	13,791	12,950	100.0	100.0	14	6
Business Areas						
Centralised and Point of Care Solutions	7,273	7,819	52.7	60.4	-1	-7
Molecular Diagnostics	3,760	2,109	27.3	16.3	90	78
Diabetes Care	1,670	1,918	12.1	14.8	-5	-13
Tissue Diagnostics	1,088	1,104	7.9	8.5	5	-1
Regions						
Europe, Middle East, Africa	5,491	4,897	39.5	37.9	19	12
North America	3,867	3,253	28.4	25.1	26	19
Asia-Pacific	3,128	3,437	22.7	26.5	-3	-9
Latin America	788	854	5.7	6.6	14	-8
Japan	517	509	3.7	3.9	5	2

Centralised and Point of Care Solutions sales declined by 1%; its immunodiagnostics business was strongly impacted by the decline in routine testing worldwide, but particularly in China, due to the COVID-19 pandemic. In EMEA, the decline of the routine testing has been more than compensated by the sales growth of the point-of-care COVID-19 testing products (such as our SARS-CoV-2 Rapid Antigen test), while in North America, this decline was offset by the Roche CustomBiotech business (products and solutions for diagnostics and biotech manufacturers).

Sales in **Molecular Diagnostics** increased 90%. The strong sales growth was driven by the segments virology (predominantly SARS-CoV-2, such as the first high-throughput PCR test launched in March), LightMix systems (pathogen detection panel) as well as point-of-care molecular diagnostics.
Diabetes Care sales decreased 5% due to patients switching to continuous glucose monitoring systems. The COVID-19 pandemic also had a negative impact. The decrease was reflected mainly in the EMEA region. Demand for digital diabetes management solutions (RocheDiabetes Care Platform, mySugr and Accu-Chek SugarView) continued to be strong.

Tissue Diagnostics sales increased 5%, due to growth in advanced staining instruments sales and recovery from manufacturing delays in the prior year, as well as increased sales in companion diagnostics. This was partially offset by lower testing volume due to the COVID-19 pandemic.

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

References

[1] Unless otherwise stated, all growth rates in this document are at constant exchange rates (CER: average 2019)
[2] Launched since 2012: Erivedge, Perjeta, Kadcyla, Gazyva/Gazyvaro, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi
[3] Biosimilar competition for MabThera/Rituxan, Herceptin and Avastin in the US, Europe and Japan
[4] Approval in January 2021
[5] EMEA = Europe, Middle East and Africa

Cautionary statement regarding forward-looking statements
This Annual Report 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 Annual Report, such as: (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.

The statement regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche's earnings or earnings per share for 2020 or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Dr. Daniel Grotzky
Phone: +41 61 688 31 10

Nina Mählitz
Phone: +41 79 327 54 74

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Patrick Barth
Phone: +41 61 688 44 86

Karsten Kleine
Phone: +41 61 682 28 31

Nathalie Meetz
Phone: +41 61 687 43 05