

Basel, 15 October 2020

First nine months of the year with 1% sales growth at constant exchange rates, significant impact of COVID-19 pandemic

- Group sales increase 1%¹ at constant exchange rates and decline 5% in Swiss francs as a result of continued appreciation of the Swiss franc against most currencies
- Impact of COVID-19 pandemic: Following strong sales growth in the first quarter (+7%) and COVID-19 related decline in the second quarter (-4%) sales stabilise in the third quarter (+1%) supported by continued strong sales of new medicines and COVID-19 tests
- Outlook for 2020 confirmed
- Pharmaceuticals Division sales decrease 1%, newly launched medicines (+35%)², including Tecentriq, Ocrevus, Hemlibra and Perjeta, largely compensating for the impact of COVID-19 and competition from biosimilars
- Diagnostics Division sales grow 9%, with COVID-19 testing as the main contributor
- Approvals for medicines in the third quarter:
 - In the US: Enspryng for the treatment of a rare autoimmune disease of the CNS (neuromyelitis optica spectrum disorder); Evrysdi (risdiplam) for the treatment of spinal muscular atrophy; Gavreto (pralsetinib) for the treatment of a specific form of non-small cell lung cancer (NSCLC); Tecentriq plus Cotellic and Zelboraf for the treatment of a specific form of melanoma
 - In Europe: Rozlytrek for the treatment of adults with a specific form of NSCLC and for adults and paediatric patients 12 years of age and older with solid tumours expressing a specific gene fusion
- Initiation of 11 phase 3 studies in the third quarter
- Diagnostic launches in the third quarter in the US: Ventana HER2 Dual ISH DNA Probe Cocktail assay to aid in the assessment of Herceptin therapies; cobas EBV test for Epstein-Barr virus and cobas BKV test for BK virus in transplant patients; cobas HIV-1/HIV-2 qualitative test; Elecsys HIV Duo Immunoassay; expanded use for CINTec PLUS Cytology test to aid clinicians in cervical cancer screening

Sales	CHF millions		As % of sales		% change	
	2020	2019	2020	2019	At CER	In CHF
January - September 2020						
Group sales	43,979	46,066	100.0	100.0	+1	-5
Pharmaceuticals Division	34,317	36,559	78.0	79.4	-1	-6
United States	18,389	20,036	41.8	43.5	-4	-8
Europe	6,268	6,310	14.3	13.7	+4	-1

Japan	2,802	3,076	6.4	6.7	-6	-9
International*	6,858	7,137	15.5	15.5	+6	-4
Diagnostics Division	9,662	9,507	22.0	20.6	+9	+2

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

Commenting on the Group's sales in the first nine months, Roche CEO Severin Schwan said: "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. With the recent launch of the rapid antigen test, we further strengthened our position as a leading supplier of COVID-19 tests. At the same time, we continue to deliver solutions for patients suffering from other severe diseases. I am particularly pleased about the FDA approvals in the third quarter for three new medicines: Enspryng and Evrysdi for rare diseases, and the cancer medicine Gavreto. After the pandemic-related decline in the second quarter, sales stabilised in the third quarter due to continued strong demand for our new medicines and COVID-19 tests. Based on our current assessment, we confirm the outlook for the full-year."

Roche's contributions to the fight against the COVID-19 pandemic in the third quarter:

- Launch of new diagnostic products for COVID-19: SARS-CoV-2 rapid antigen test in the EU; cobas SARS-CoV-2 & influenza A/B test for use on the cobas 6800/8800 System; cobas SARS-CoV-2 & influenza A/B test on the cobas Liat System in urgent and emergency care settings; Elecsys Anti-SARS-CoV-2 S antibody test for markets accepting the CE Mark; adding up to a total of 13 new diagnostic solutions developed in 2020
- Production capacity for SARS-CoV-2 tests ramped up significantly
- Results phase III Empacta study: Actemra/RoActemra reduced the likelihood of needing mechanical ventilation in hospitalised patients with COVID-19-associated pneumonia
- Partnership of Roche and Regeneron on new antiviral antibody cocktail: Initial data showed REGN-COV2 antibody cocktail reduced viral levels and improved symptoms in non-hospitalised COVID-19 patients. Regeneron has submitted request to the US FDA for an Emergency Use Authorization (EUA) for REGN-COV2

Outlook confirmed for 2020

Based on the current assessment of the COVID-19 impact, 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.

Group sales

In the first nine months of 2020, Group sales increased 1% to CHF 44.0 billion.

Sales in the Pharmaceuticals Division decreased 1% to CHF 34.3 billion. Sales grew strongly in the first quarter (+7%). As a result of COVID-19, they decreased in the second quarter (-6%) and since summer first signals of recovery are seen (-4% in the third quarter). Key growth drivers were the cancer medicine

Tecentriq, the multiple sclerosis medicine Ocrevus, the haemophilia medicine Hemlibra, Actemra/RoActemra in immunology and Perjeta in breast cancer.

With a strong growth of 35% the new medicines generated sales of CHF 13.7 billion and grew by CHF 3.7 billion at constant exchange rates over 2019, more than offsetting the impact of the competition from biosimilars (sales reduction CHF 3.5 billion at constant exchange rates).

In the US, overall sales decreased 4%. While sales of Ocrevus, Hemlibra, Tecentriq, Actemra/RoActemra and Kadcylla increased, the competition from biosimilars for Herceptin, MabThera/Rituxan and Avastin affected total growth as expected. Ocrevus sales increased by 23% and were driven by both new and returning patient demand but partly impacted by COVID-19 effects. Hemlibra sales increased 68%, resulting from the ongoing rollout in the US. Tecentriq sales increased by 46%, driven by the launch in unresectable hepatocellular carcinoma (HCC) as well as the growth in the new indications extensive stage small cell lung cancer (ES-SCLC) and metastatic triple-negative breast cancer.

In Europe, sales increased 4% as the strong demand for Tecentriq, Ocrevus, Hemlibra, Kadcylla and Perjeta was able to offset the impact of lower sales of Herceptin (-32%), Avastin (-16%) and MabThera/Rituxan (-32%). The first biosimilar versions of Avastin were introduced in Europe in the third quarter of 2020.

In the International region (+6%), growth was mostly driven by Perjeta, Actemra/RoActemra, Alecensa, Tecentriq and Ocrevus, partially offset by the impact of the National Reimbursement Drug List update in China and COVID-19.

Sales decreased in Japan (-6%) as a result of the considerable competition from biosimilars, generics, COVID-19 and government price cuts. This decline was partially compensated by recently launched products including Tecentriq and Hemlibra.

The Diagnostics Division recorded very strong sales growth of 9% to CHF 9.7 billion, with particularly strong growth of 18% in the third quarter. After a 5% increase in the first quarter, momentum slowed to 2% growth in the second quarter as a result of the pandemic. The overall very strong sales growth is primarily due to the industry-leading portfolio of new COVID-19 tests. The Molecular Diagnostics business made the largest contribution (+77%) with PCR tests for COVID-19. Sales of diagnostic solutions for SARS-CoV-2 developed only this year clearly exceeded COVID-19 related declines in routine diagnostics sales. Additional product launches in the third quarter, including the SARS-CoV-2 antigen rapid test, further strengthened Roche's position as the world's leading supplier of COVID-19 tests.

Growth was reported in North America (+22%), EMEA³ (+9%), Latin America (+12%) and Japan (+5%). In the Asia-Pacific region (-4%), sales were heavily impacted by the pandemic, especially in China. Overall, demand was impacted by COVID-19 in all regions since the second quarter. Routine testing decreased significantly due to a decline in regular health checks while emergency and SARS-CoV-2 testing increased significantly.

Roche's contributions to the fight against the COVID-19 pandemic

In September, the Elecsys Anti-SARS-CoV-2 S antibody test was launched for markets accepting the CE Mark. Roche has filed for Emergency Use Authorisation (EUA) from the FDA. The Elecsys Anti-SARS-CoV-2 S immunology test, which targets antibodies against the spike protein, 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. The majority of current candidate vaccines aim to induce an antibody response against the spike protein of the virus.

In the same month, Roche received an EUA from the FDA for its cobas SARS-CoV-2 & Influenza A/B test for use on the cobas 6800/8800 Systems. This test is intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A and influenza B in patients suspected by their healthcare provider of having a respiratory viral infection; it is also available in markets accepting the CE Mark.

For urgent and emergency care settings, Roche also received EUA from the FDA in September for the cobas SARS CoV-2 & Influenza A/B test on the cobas Liat System, which provides results in 20 minutes.

Roche also launched the SARS-CoV-2 rapid antigen test in markets accepting the CE Mark and plans to submit files for an EUA with the FDA. The SARS-CoV-2 rapid antigen test is for use in point of care settings for symptomatic people. This can help healthcare professionals identify a SARS-CoV-2 infection in people suspected of carrying the virus with results typically ready in 15 minutes. In addition, it serves as a valuable initial screening test for individuals who have been exposed to SARS-CoV-2-infected patients or in a high-risk environment.

Roche also announced that it intends to launch a high-volume SARS-CoV-2 Antigen test as an aid in the diagnosis of SARS-CoV-2 infection. The test is planned to be made available at the end of 2020 for markets accepting the CE Mark. Roche also intends to file for EUA from the FDA. The test is performed by healthcare professionals and uses swab samples from patients with signs and symptoms suggestive of COVID-19, or people with either known or suspected exposure to SARS-CoV-2.

The portfolio of our recently developed SARS-CoV-2 tests as well as our existing diagnostics menu for critical care have become a significant factor in supporting patient management during the COVID-19 pandemic. Roche has already increased its overall production of tests fourfold over the usual volumes and has committed significant funds to continue expanding production capacity for PCR tests over the coming year. Our investments are expected to result in more than 1,000 new jobs in the US and Europe.

The phase III Empacta study met its primary endpoint, showing that patients with COVID-19 associated pneumonia who received Actemra/RoActemra plus standard of care were 44% less likely to progress to mechanical ventilation or death compared to patients who received placebo plus standard of care. The cumulative proportion of patients who progressed to mechanical ventilation or death by day 28 was 12.2% in the Actemra/RoActemra arm versus 19.3% in the placebo arm. There was no statistical difference in mortality between patients who received Actemra/RoActemra or placebo by day 28. Approximately 85% of the 389 patients were from minority racial and ethnic groups. The trial was conducted in Brazil, Kenya, Mexico, Peru, South Africa and the USA.

In August, Roche and Regeneron joined forces in the fight against COVID-19 to develop, manufacture and distribute REGN-COV2, Regeneron’s investigational antiviral antibody cocktail. Regeneron has submitted a request to the FDA for an Emergency Use Authorization (EUA) for REGN-COV2. Initial data from the REGN-COV2 phase II portion of an ongoing study showed a reduction in viral load, an acceleration of symptom alleviation and a decrease in medical visits in non-hospitalised patients with COVID-19. Additional data from this study are expected by the end of 2020. We will be working with health authorities and global health institutions in a concerted, collective response, with the aim of achieving broad approvals.

Drug launches, filings, pivotal phase III trial readouts and pivotal trial starts planned by the Roche Group are largely on track.

The Covacta study of Actemra/RoActemra did not meet its primary endpoint of improved clinical status in hospitalised adult patients with severe COVID-19-associated pneumonia. In addition, the key secondary endpoints, which included the difference in patient mortality at week four, were not met; however, there was a positive trend in time to hospital discharge in patients treated with Actemra/RoActemra. This study generated robust information which will help physicians make decisions about the treatment of patients with this disease.

Overview of Roche Diagnostics’ COVID-19 diagnostic solutions developed in the first nine months of 2020

<i>Test</i>	<i>Usage</i>	<i>Availability</i>	<i>Launch date</i>
TIB MOLBIOL LightMix Modular SARS-CoV-2 tests (PCR)	Detection of active infection	CE Mark and research use only in US	24 January
cobas SARS-CoV-2 test (PCR)	Detection of active infection, testing on our high-throughput instruments	FDA EUA and CE Mark	12 March
Elecsys Anti-SARS-CoV-2 test	Detection of antibodies against SARS-CoV-2 in patients, testing on established cobas e analysers	FDA EUA and CE Mark	3 May
Viewics LabOPS COVID-19	Efficiency improvements in laboratories	USA	7 May
Roche v-TAC	Digital tool to simplify blood gas value conversion from patients	CE Mark	15 May
Elecsys IL-6 test	IL-6 testing to help identify severe inflammatory response	FDA EUA and CE-Mark	4 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	28 July
Navify Remote Monitor	Collection of self-reported risk factors and display of recommendations based on official guidelines for individuals returning to work or school during COVID-19	USA	31 Aug
cobas SARS-CoV-2 & influenza A/B test for use on the cobas 6800/8800 Systems	Detect and differentiate SARS-CoV-2, influenza A virus and/or influenza B virus with a single sample	FDA EUA	4 September

cobas SARS-CoV-2 & influenza A/B for use on cobas Liat System	Detect and differentiate SARS-CoV-2, influenza A virus and/or influenza B virus with a single sample in 20 minutes	FDA EUA	14 September
Elecsys anti-SARS-CoV-2 S antibody test	Quantitatively measure antibodies in people who have been exposed to SARS-CoV-2	CE Mark FDA EUA filed	18 September
SARS-CoV-2 rapid antigen test	Triage people suspected of SARS-CoV-2, results available in 15 minutes	CE Mark	21 September
Elecsys SARS-CoV-2 antigen test	A high-volume laboratory antigen test for the testing and triage of suspected COVID-19 patients	Expecting CE Mark	December 2020

Regulatory achievements in the third quarter

Regulators around the globe granted approvals for new Roche medicines, line extensions of existing medicines and new tests.

The FDA approved Evrysdi (risdiplam), an oral medication for the treatment of spinal muscular atrophy (SMA) in adults and children 2 months of age and older. Evrysdi showed clinically meaningful improvements in motor function across two clinical trials in people with varying ages and levels of disease severity, including types 1, 2, and 3 SMA. Evrysdi also improved survival without permanent ventilation at 12 and 23 months of treatment, compared to natural history.

FDA approval was granted for Enspryng (satralizumab-mwge) as the first and only subcutaneous treatment for adults living with anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD). NMOSD is a rare, lifelong and debilitating autoimmune disorder of the central nervous system, often misdiagnosed as multiple sclerosis, that primarily damages the optic nerve(s) and spinal cord, causing blindness, muscle weakness and paralysis. Enspryng demonstrated significant reduction in the risk of relapse compared with placebo as a monotherapy and when used concurrently with baseline immunosuppressant therapy.

The FDA also approved Gavreto (pralsetinib) for the treatment of adults with metastatic RET fusion-positive non-small cell lung cancer as detected by an FDA approved test. This indication was approved under the FDA's Accelerated Approval programme, based on data from the phase I/II ARROW study. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

The European Commission granted conditional marketing authorisation for Rozlytrek for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have not received a prior NTRK inhibitor and who have no satisfactory treatment options. The European Commission has also approved Rozlytrek for the treatment of adults with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.

The FDA also granted approval for Tecentriq plus Cotellic and Zelboraf for the treatment of BRAF V600 mutation-positive advanced melanoma patients.

In Japan, Tecentriq in combination with Avastin, was approved by the Ministry of Health, Labour and Welfare for the treatment of unresectable hepatocellular carcinoma.

The FoundationOne Liquid companion diagnostic test (F1L CDx) received FDA approval. Furthermore, the comprehensive liquid biopsy service received the CE Mark in May. Both regulatory milestones allow for the new test to be commercialised in all markets that recognise the CE Mark and/or the FDA approval. F1L CDx is the most comprehensive pan-tumour liquid biopsy test for all solid tumours, incorporating multiple companion diagnostics. This test supports efforts to improve treatment results by helping oncologists optimise and personalise treatment for their patients with advanced cancer during all lines of therapy, and particularly for those where tissue-based testing is not possible.

Additional regulatory achievements in the third quarter of 2020:

<i>Pharmaceuticals</i>	<i>Status</i>	<i>Indication</i>
SRP-9001 Micro-Dystrophin Gene Therapy (Sarepta Therapeutics)	US FDA Fast Track Designation	Treatment of Duchenne muscular dystrophy
Tecentriq in combination with Avastin	European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommendation for approval	Treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy
Gavreto	FDA Priority Review, decision on approval expected by 28 February 2021	Treatment of people with advanced or metastatic RET-mutant MTC and RET fusion-positive thyroid cancer. This New Drug Application was accepted for review under the FDA's Real-Time Oncology Review (RTOR) pilot programme.
Xolair	FDA acceptance of filing	Self-administration (home use) for the treatment of asthma

Diagnostics – key launches in the third quarter

In addition to the new COVID-19 portfolio, Roche received FDA approval for the Ventana HER2 Dual ISH DNA Probe Cocktail assay for the detection of the HER2 biomarker in breast cancer and as a companion diagnostic for Herceptin therapy. HER2 - human epidermal growth factor receptor 2 - is an important biomarker sometimes found in breast cancers. Its detection and inhibition can help healthcare professionals manage this aggressive cancer more effectively. This new assay is designed to be completed within the same day, enabling clinicians to get results back faster than with other common methods of confirmatory testing

for HER2. Results can be read using light microscopy, eliminating the need for a specialised fluorescence microscope.

The FDA also authorised the cobas EBV test, the first quantitative in vitro diagnostic test for Epstein-Barr virus (EBV) DNA in the US. The test meets World Health Organization standards for consistent result reporting among laboratories across the US, allowing for results to be easily comparable across hospitals and laboratories. Monitoring of Epstein-Barr virus DNA can help prevent the progression of life-threatening diseases such as cancer in transplant patients.

Roche also received FDA clearance for the BK virus quantitative test on cobas 6800/8800 Systems to support better care for transplant patients. The test provides standardised, high-quality results that can help healthcare professionals better assess the risk of complications caused by the BK virus in transplant patients and identify effective treatment options.

In August, the FDA approved the cobas HIV-1/HIV-2 qualitative test for use on the fully automated cobas 6800/8800 Systems in the US. The test provides healthcare professionals with a single result to confirm HIV diagnosis and differentiate HIV-1 and HIV-2, an important distinction needed to identify appropriate treatment options.

In September, Roche launched the Elecsys HIV Duo immunoassay in the US, following FDA approval in April 2020. Through separate measurement of the HIV p24 antigen (the virus) and anti-HIV antibodies (caused by immune reaction), this test can detect an acute HIV infection earlier than current methods. This approval enables a robust, comprehensive infectious diseases menu on the cobas e 801 system and a significant step towards bringing holistic value to the US market within the area of infectious diseases.

Roche announced FDA approval in September for the expanded use of CINTec PLUS Cytology, the first triage test based on biomarker technology for women whose cervical cancer screening results are positive for high-risk types of human papillomavirus (HPV). Additional information from this test supports clinical decisions on which women will benefit most from immediate follow-up. Laboratories can now use CINTec PLUS Cytology to triage positive results from the cobas HPV Test run on the fully integrated, automated and high-throughput cobas 6800/8800 Systems.

Key development milestones in the third quarter of 2020

Regulatory filings and product launches for 2020 as well as pivotal trial read-outs and pivotal starts in 2020 are largely on track. We are making significant efforts to protect all studies with continued support from health authorities, but the ultimate outcome will depend on the length and severity of the pandemic.

Results from the phase III IMpassion031 study, evaluating Tecentriq in combination with chemotherapy (Abraxane, albumin-bound paclitaxel; nab-paclitaxel; followed by doxorubicin and cyclophosphamide) in comparison with placebo plus chemotherapy (including nab-paclitaxel), demonstrated a statistically significant and clinically meaningful improvement in pathological complete response (pCR) for the treatment of people with early TNBC, regardless of PD-L1 expression. The IMpassion031 study is the second positive phase III study from Roche to demonstrate the benefit of Tecentriq in TNBC and the first Tecentriq

study to demonstrate a benefit in early TNBC.

The final overall survival (OS) analysis of the phase III IMpassion130 study, evaluating Tecentriq in combination with nab-paclitaxel, compared with placebo plus nab-paclitaxel, as a first-line treatment for patients with metastatic TNBC, was consistent with the first and second interim analyses. There was no significant difference in OS between the treatment groups in the ITT population. Clinically meaningful improvements of 7.5 months in median OS were seen with Tecentriq plus nab-paclitaxel in PD-L1-positive patients.

Detailed results from the phase III Archway study showed that 98.4% of Port Delivery Systems (PDS) patients were able to go six months without needing additional treatment and achieved vision outcomes equivalent to patients receiving monthly ranibizumab eye injections, a current standard of care. This study evaluates the investigational Port Delivery System with ranibizumab for the treatment of neovascular or “wet” age-related macular degeneration (nAMD), a leading cause of blindness globally.

New two-year data from part 1 of the pivotal Firefish study of Evrysdi in infants aged two to seven months with symptomatic Type 1 SMA showed that infants treated with the therapeutic dose of Evrysdi (17/21) continued to improve and achieve motor milestones.

Pharmaceuticals Division

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Avastin	4,023	-22	1,489	-34	1,082	-16	534	-17	918	-6
MabThera/Rituxan	3,443	-27	2,365	-27	304	-32	48	-41	726	-21
Ocrevus	3,274	29	2,610	23	490	51	-	-	174	75
Herceptin	3,079	-31	1,161	-44	522	-32	109	-40	1,287	-13
Perjeta	2,929	17	1,138	3	858	12	219	12	714	60
Actemra/RoActemra	2,134	33	942	42	568	13	267	-7	357	117
Tecentriq	2,015	64	1,166	46	437	102	225	86	187	96
Hemlibra	1,575	79	1,020	68	261	155	227	53	67	183
Xolair	1,451	2	1,451	2	-	-	-	-	-	-
Kadcyla	1,295	37	617	44	404	36	63	5	211	33

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

Key pharmaceutical products

Avastin (-22%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales were impacted by the biosimilar competition in the US, Europe and Japan.

MabThera/Rituxan (-27%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. The sales decline was driven by all regions, due to the launch of biosimilars in the US and most EU markets and in Japan.

Herceptin (-31%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales were impacted by biosimilars in the US, Europe and Japan. In the US, the switch to Kadcyła in the adjuvant setting also impacted sales.

Actemra/RoActemra (+33%). For 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 Actemra/RoActemra in their treatment guidelines for severe COVID-19 pneumonia. Actemra/RoActemra is not currently approved for this use; Roche is conducting several phase III clinical studies. The US and the International region were the major contributors to the sales increase.

Xolair (+2%, US only). For 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 (-14%, US only). For eye conditions, including neovascular ('wet') age-related macular degeneration, macular oedema following retinal vein occlusion, diabetic macular oedema, and diabetic retinopathy. Sales decreased in all approved indications and were especially affected by the COVID-19 pandemic due to disruptions in hospitals and ophthalmology practices and many patients delaying treatment during restrictions.

Highlights for medicines launched since 2012

Ocrevus (first approved in 2017; CHF 3.3 billion, +29%). For the treatment of both the relapsing (RMS) and primary progressive (PPMS) forms of multiple sclerosis (MS). 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, with a higher proportion of sales coming from returning patients. In Europe and the International region, Ocrevus continues to show strong initial uptake where launched.

Perjeta (first approved in 2012; CHF 2.9 billion, +17%). As therapy for HER2-positive breast cancer. Sales grew strongly in the International region. The increased patient demand for Perjeta for adjuvant early breast cancer therapy supports its continued strong growth.

Tecentriq (first approved in 2016; CHF 2.0 billion, +64%). Approved either alone or in combination with targeted therapies and/or chemotherapies in various forms of NSCLC, in small cell lung cancer (SCLC), certain types of metastatic urothelial cancer, and in PD-L1-positive metastatic TNBC. In the US and several other countries, Tecentriq in combination with Avastin is approved for people with unresectable or metastatic HCC and in the US and two other countries Tecentriq is approved in combination with Cotellic and Zelboraf for the treatment of people with BRAF V600 mutation-positive advanced melanoma. Strong sales growth was reported by all regions, driven mainly by the indications in ES-SCLC and TNBC. Sales in Japan increased due to robust uptake in first-line NSCLC and first-line ES-SCLC.

Hemlibra (first approved in 2017; CHF 1.6 billion, +79%). For treating people with haemophilia A with factor VIII inhibitors. It is also approved to treat people with haemophilia A without factor VIII inhibitors. Hemlibra is the only prophylactic treatment that can be administered subcutaneously and with multiple dosing options (once weekly, once every two weeks or once every four weeks). Sales continued to show a strong uptake in all regions, despite COVID-19 restrictions having some impact on potential new patients.

Kadcyla (first approved in 2013; CHF 1.3 billion, +37%). For treating 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.

Esbriet (first approved in 2014; CHF 844 million, +9%). For idiopathic pulmonary fibrosis. Sales continued to expand, driven by growth in the US and Europe.

Alecensa (first approved in 2015; CHF 841 million, +35%). To treat ALK-positive lung cancer. Alecensa showed continued sales growth across all regions.

Gazyva/Gazyvaro (first approved in 2013; CHF 472 million, +27%). For chronic lymphocytic leukaemia (CLL), rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Sales increased in all regions.

Polivy (first approved in 2019; CHF 126 million, +>500%). Part of combination therapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma.

Xofluza (first approved in 2018; CHF 28 million, +286%). For the treatment of acute, uncomplicated influenza, or flu, in people 12 years of age and older and people with high risk of developing flu-related complications.

Rozlytrek (first approved in 2019; CHF 15 million, +319%). For a specific form of NSCLC and for solid tumours expressing a specific gene fusion. In Japan, Rozlytrek was approved for treatment of ROS1 fusion-positive NSCLC.

Evryzdi (risdiplam, first approved in 2020; CHF 8 million^{*4}). For the treatment of spinal muscular atrophy (SMA) in adults and children two months of age and older.

Phesgo (fixed-dose combination of Perjeta and Herceptin with hyaluronidase, first approved in 2020; CHF 7 million^{*}). For the treatment of early and metastatic HER2-positive breast cancer by subcutaneous injection (SC) administered in combination with intravenous chemotherapy.

Enspryng (satralizumab, first approved in 2020; CHF 7 million^{*}). For a rare neurodegenerative disease (neuromyelitis optica spectrum disorder).

Diagnosics Division

Sales	CHF millions		As % of sales		% change	
	2020	2019	2020	2019	At CER	In CHF
January - September 2020						
Diagnosics Division	9,662	9,507	100.0	100.0	+9	+2
Business Areas						
Centralised and Point of Care Solutions	5,028	5,766	52.0	60.6	-7	-13
Molecular Diagnostics	2,578	1,547	26.7	16.3	+77	+67
Diabetes Care	1,261	1,395	13.1	14.7	-2	-10
Tissue Diagnostics	795	799	8.2	8.4	+5	-1
Regions						
Europe, Middle East, Africa	3,686	3,617	38.4	38.0	+9	+2
North America	2,768	2,366	28.4	24.9	+22	+17
Asia-Pacific	2,287	2,550	23.7	26.8	-4	-10
Latin America	554	615	5.7	6.5	+12	-10
Japan	367	359	3.8	3.8	+5	+2

In the first nine months 2020, COVID-19 and emergency testing strongly increased while routine testing decreased as a result of continued declining or delayed regular health checks and medical appointments. Nevertheless, Roche's broad, diversified test portfolio and its large number of instruments installed worldwide provided for a strong sales growth.

During 2020, Roche has increased its production capacity (reagents and consumables) for COVID-19 testing massively. This includes all our products used in fighting COVID-19 infections.

Centralised and Point of Care Solutions sales declined by 7%, its immunodiagnosics business (-8%) was strongly impacted by the COVID-19 impact on routine testing worldwide. COVID-19 related products such as the Elecsys Anti-SARS-CoV-2 test, Custom Biotech, Elecsys IL-6 test and the SARS-CoV-2 rapid antigen test partly offset the COVID-19 impact.

Sales in **Molecular Diagnostics** increased 77%, with 88% growth in the underlying molecular business. Growth was driven by virology (predominantly SARS-CoV-2), Quantitative PCR (to detect molecular/genetic targets) and Nucleic Acid Purification (to isolate and purify genetic material), Molecular Diagnostics systems, Molecular Point-of-Care (influenza viruses).

Diabetes Care sales decreased 2%, with the continued contraction of the Blood Glucose Monitoring (BGM) market due to patients switching to Continuous Glucose Monitoring (CGM) systems. The COVID-19 pandemic also had an impact. The decrease was reflected mainly in the EMEA region, notably in Germany, UK and Italy. The positive uptake of digital diabetes management solutions continued: AccuChek

SugarView, RocheDiabetes Care Platform and mySugr.

Tissue Diagnostics sales increased 5%, supported by advanced staining, instrument sales and companion diagnostics business. However, overall sales were impacted by 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 eleventh 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

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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, Kadcyła, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi
- [3] EMEA = Europe, Middle East and Africa
- [4] recently launched, no growth figures available

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.

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