Media Release

Basel, 22 April 2020

First quarter with 2% growth in Swiss francs, 7%[1] at constant exchange rates

- **Group sales increase 2% in Swiss francs and 7% at constant exchange rates, driven by new products, more than compensating for impact of competition from biosimilars**
- **Pharmaceuticals Division sales up 7%, led by Tecentriq, Hemlibra, Ocrevus and Perjeta**
- **Diagnostics Division sales grow 5%, with molecular testing as main contributor**
- **Important approvals in the first quarter:**
  - **in China: Tecentriq for first-line combination therapy of extensive-stage small cell lung cancer**
  - **in the US: CINtec Plus Cytology test and cobas HPV test for use on cobas 6800/8800 Systems for cervical cancer screening**
  - **in the EU: Polivy in combination with bendamustine and MabThera/Rituxan, for the treatment of adult patients with a special form of B-cell lymphoma**
  - **in the EU: Venclexta/Venclyxto in combination with Gazyva/Gazyvaro for adults with previously untreated chronic lymphocytic leukaemia**
- **Based on the current assessment of the COVID-19 impact the outlook for 2020 is confirmed**

Impact of the COVID-19 pandemic

- Volatility in some markets has limited impact on business performance in the first quarter
- Global supply chain for medicines and tests remain intact
- FDA issued Emergency Use Authorization for the cobas SARS-CoV-2 test (coronavirus) for detection of infection with the virus; test also available in markets accepting the CE mark
- Production capacity for cobas SARS-CoV-2 test ramped up massively
- Clinical phase III study to evaluate the safety and efficacy of Actemra/RoActemra in severe COVID-19 pneumonia ongoing in several countries. Results are expected in early summer. Rapid increase of production capacity for Actemra/RoActemra
- Anti-SARS-CoV-2 serology test to detect antibodies in people exposed to SARS-CoV-2 in late stage development with availability aimed for early May. Monthly production is ramped up to high double-digit million tests by June with further scale up as fast as possible.

Commenting on the Group's performance in the first quarter, Roche CEO Severin Schwan said: "The global coronavirus pandemic outbreak during the first quarter poses an unprecedented challenge in particular for healthcare systems worldwide. Roche made important contributions to the fight against COVID-19. In close collaboration with authorities we were able to make our cobas SARS-CoV-2 test available and to initiate a global phase III study of Actemra/RoActemra in COVID-19 pneumonia in record time. With healthcare needs remaining high, Roche's business has so far proved to be resilient in this difficult environment. The uptake of our recently introduced medicines continues to be strong. Based on our current assessment, we confirm the outlook for the full-year."

1 Unless otherwise stated, all growth rates in this document are at constant exchange rates (CER: average 2019).

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Sales	CHF millions		As % of sales		% change	
January - March 2020	2020	2019	2020	2019	At CER	In CHF
Group sales	15,143	14,826	100.0	100.0	+7	+2
Pharmaceuticals Division	12,262	11,927	81.0	80.4	+7	+3
United States	6,616	6,623	43.7	44.7	+3	0
Europe	2,264	2,101	15.0	14.2	+14	+8
Japan	948	941	6.3	6.3	+3	+1
International*	2,434	2,262	16.0	15.2	+16	+8
Diagnostics Division	2,881	2,899	19.0	19.6	+5	-1

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

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 three months of the year, Group sales rose 7% to CHF 15.1 billion. Sales in the Pharmaceuticals Division increased 7% to CHF 12.3 billion. Key growth drivers were the cancer medicine Tecentriq, the haemophilia medicine Hemlibra, the multiple sclerosis medicine Ocrevus and the breast cancer medicine Perjeta. The strong uptake of newly introduced medicines generated sales of CHF 4.6 billion, including a growth of CHF 1.6 billion at constant exchange rates over 2019, more than offsetting the impact of the competition from biosimilars (CHF 857 million at constant exchange rates).[2]

In the US, the sales growth (+3%) was predominantly generated by recently launched medicines such as Ocrevus, Hemlibra and Tecentriq, partially offset by the competition from biosimilars.

In Europe, sales increased (+14%) as the strong demand for Tecentriq, Ocrevus, Perjeta, Hemlibra, Actemra/RoActemra and Kadcyla, was able to offset the impact of lower sales of Herceptin (-32%) and MabThera/Rituxan (-24%). The first biosimilar versions of Avastin are expected later this year.

In the International region, sales increased 16%, the main contributors were Perjeta, Ocrevus, Tamiflu and Alecensa. In China, the strong uptake of recently launched medicines Perjeta and Alecensa and higher sales of established products including Tamiflu and Rocephin offset the National Reimbursement Drug List price cut and COVID-19 impact for Herceptin, Avastin and MabThera/Rituxan.

2 In Europe: MabThera/Rituxan and Herceptin; in Japan: MabThera/Rituxan, Herceptin and Avastin; in the US: Herceptin, Avastin and MabThera/Rituxan

Growth in Japan (+3%) was also driven by recently launched products Hemlibra, Tecentriq and Perjeta, despite considerable competition from biosimilars.

Diagnostics Division sales increased 5% to CHF 2.9 billion. The business area Molecular Diagnostics (+29%) was the main growth contributor, driven by molecular testing. Growth was reported in North America (+12%), EMEA[3] (+7%), Latin America (+20%) and Japan (+14%). In the Asia-Pacific region (-11%) sales were strongly impacted by the COVID-19 pandemic shutdown in China. Overall, demand in North America, Europe and Latin America was less affected by COVID-19 in the first quarter due to the later onset of the pandemic in these regions. Routine testing decreased due to a decline in regular health checks while emergency and COVID-19 testing strongly increased.

Regulatory achievements in the first quarter
Regulators around the globe granted approvals for new Roche medicines, line extensions of existing medicines and new tests.

In China the National Medical Products Administration (NMPA) approved Tecentriq in combination with chemotherapy (carboplatin and etoposide) for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

The European Commission approved Polivy in combination with bendamustine and MabThera/Rituxan, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for a haematopoietic stem cell transplant.

The Commission also approved Venclexta/Venclyxto in combination with Gazyva/Gazyvaro for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia.

3 EMEA = Europe, Middle East and Africa

Additional regulatory achievements in the first quarter of 2020:

Pharmaceuticals	*Status*	*Indication*
Tecentriq	USA, Priority review	Tecentriq for first-line (initial) monotherapy for people with advanced non-squamous and squamous non-small cell lung cancer (NSCLC) without EGFR or ALK mutations with high PD-L1 expression (TC3/IC3 wild-type), as determined by PD-L1 biomarker testing.
Tecentriq	USA, submission of sBLA under the Real-Time Oncology Review pilot programme	Roche completed the submission of a sBLA to the FDA for Tecentriq in combination with Avastin for the treatment of people with unresectable HCC, the most common form of liver cancer, who have not received prior systemic therapy. The FDA is reviewing the application under the Real-Time Oncology Review pilot programme, which aims to explore a more efficient review process to ensure safe and effective treatments are available to pts as early as possible
Tecentriq	China, sBLA acceptance and Priority Review	In January the NMPA accepted the sBLA for the combination in HCC and granted priority review in February 2020.
Perjeta, Herceptin	US Food and Drug Administration (FDA) - Biologics License Application	The FDA accepted Roche's Biologics License Application for the fixed-dose combination of Perjeta and Herceptin with hyaluronidase, administered by subcutaneous injection in combination with intravenous chemotherapy, for the treatment of eligible patients with HER2-positive breast cancer.
Esbriet	US FDA Breakthrough Therapy Designation (BTD)	FDA grants BTD for Roche's Esbriet in unclassifiable interstitial lung disease.
Xofluza	US FDA New Drug Application (NDA)	FDA accepts Roche's NDA for Xofluza for the treatment of influenza in children. The application seeks approval of a new, additional formulation of Xofluza as granules for oral suspension for people one year of age and older with influenza. The FDA also accepts a supplemental NDA to expand the indication of Xofluza for post-exposure prophylaxis, potentially offering Xofluza as a preventive treatment for influenza after exposure to an infected individual.

Diagnostics – key launches in the first quarter of 2020
The cobas SARS-CoV-2 test, for the detection of coronavirus, was developed in just six weeks and launched following Emergency Use Authorization from the FDA, and is available in markets accepting the CE mark. The test is for use on Roche's fully automated cobas 6800 and 8800 Systems, which are widely available around the world. Hospitals and laboratories can now run the test on these high-volume systems that deliver the fastest time-to-results, with the cobas 6800 and 8800 Systems providing 1,440 results and 4,128 results in 24 hours, respectively. This means that more tests can be completed faster, bringing certainty to patients, healthcare providers, and communities around the globe.

The FDA approved the CINtec Plus Cytology test as the first biomarker-based triage test for women whose primary cervical cancer screening results are positive for the human papillomavirus using the cobas 4800 HPV test. This biomarker technology simplifies clinical decision making by providing easy to understand results so that clinicians and women are clear on next steps.

The cobas HPV test was FDA-approved for use on the cobas 6800/8800 Systems for cervical cancer screening. The test identifies women at risk of cervical cancer, with the goal of finding and treating precancerous lesions early to help stop the progression of disease.

Key development milestones in the first quarter of 2020
Regulatory filings and product launches for 2020 are largely on track. Pivotal trial read outs and pivotal starts in 2020 are also largely on track. While in general clinical studies in cancer seem to continue without major delays, there could potentially be some impact of COVID-19 on chronic diseases studies. We are taking significant efforts to protect all studies with continued support by health authorities, but the ultimate outcome will depend on the length and severity of the pandemic.

In cooperation with the FDA Roche initiated a randomised, double-blind, placebo-controlled phase III clinical trial in collaboration with the Biomedical Advanced Research and Development Authority (BARDA) to evaluate the safety and efficacy of Actemra/RoActemra plus standard of care in hospitalised adult patients with severe COVID-19 pneumonia compared to placebo plus standard of care.

An anti-SARS-CoV-2 serology test to detect antibodies in people who have been exposed to SARS-CoV-2 that causes the COVID-19 disease is in late stage development. Antibody testing is central to help identify people who have been infected by the virus, especially those who may have been infected but did not display symptoms. Roche is collaborating closely with health authorities and aims to have the antibody test available by early May in countries accepting the CE mark and is actively working with the FDA for an Emergency Use Authorization. Roche is planning on an accelerated ramp up of monthly production to high double-digit million tests by June and will further scale up production as fast as possible.

One-year data from the pivotal part 2 of Sunfish, a global placebo-controlled study evaluating risdiplam in people aged 2-25 with type 2 or 3 spinal muscular atrophy (SMA), showed that the change from baseline in the primary endpoint of the Motor Function Measure scale (MFM-32) was significantly greater in people treated with risdiplam, compared to placebo.

The phase III VIALE-A study met its dual primary endpoints of overall survival and composite complete remission rate. Venclexta/Venclyxto in combination with azacitidine, a hypomethylating agent, showed a statistically significant improvement in overall survival in people with previously untreated acute myeloid leukaemia who were ineligible for intensive induction chemotherapy, compared to azacitidine alone. Venclexta/Venclyxto is being developed by AbbVie and Roche.

The FDA granted Breakthrough Device Designation to the Elecsys GALAD score. This algorithmic score combines gender and age with the biomarker results of the Elecsys AFP, AFP-L3 and PIVKA-II and is intended to aid the diagnosis of early stage hepatocellular carcinoma.

Pharmaceuticals Division

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Avastin	1,497	-13	586	-27	423	-3	181	-5	307	5
MabThera/Rituxan	1,389	-15	973	-14	123	-24	17	-39	276	-9
Herceptin	1,207	-24	475	-38	193	-32	40	-26	499	4
Ocrevus	1,112	38	898	29	156	79	-	-	58	119
Perjeta	1,011	22	395	-1	307	21	74	49	235	83
Actemra/RoActemra	666	30	296	44	209	27	89	6	72	27
Tecentriq	644	99	376	79	145	169	69	111	54	101
Hemlibra	521	146	353	119	78	216	74	207	16	**
Xolair	468	3	468	3	-	-	-	-	-	-
Kadcyla	428	55	204	68	132	43	18	3	74	63

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

** over 500%

Key pharmaceutical products

Avastin (-13%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales were impacted by biosimilar competition in the US and Japan.

MabThera/Rituxan (-15%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. In the US, Europe and Japan sales were affected by biosimilar competition.

Herceptin (-24%). 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 Kadcyla in the adjuvant setting also impacted sales. Growth was reported in the International region.

Actemra/RoActemra (+30%). 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. Sales growth was reported in all regions, driven by the constant uptake of the subcutaneous formulation. A global phase III study of Actemra/RoActemra in COVID-19 pneumonia was initiated in several countries, including the US and Japan.

Xolair (+3%, US only). For chronic idiopathic urticaria and allergic asthma.

Lucentis (-13%, US only). For eye conditions, including neovascular ('wet') age-related macular degeneration, macular oedema following retinal vein occlusion, diabetic macular oedema, and diabetic retinopathy. Due to the COVID-19 pandemic patients delayed their visits to physicians and thus postponed therapy.

Highlights for medicines launched since 2012
Ocrevus (first approved in 2017; CHF 1.1 billion, +38%). For the treatment of both the relapsing (RMS) and primary progressive (PPMS) forms of multiple sclerosis (MS). More than 150,000 people with MS have been treated with Ocrevus globally, in clinical-trial and real-world settings; data continue to show a consistent and favourable benefit-risk profile. The strong demand for this treatment in both indications has continued.

Perjeta (first approved in 2012; CHF 1.0 billion, +22%). 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 644 million, +99%). Approved either alone or in combination with targeted therapies and/or chemotherapies in various forms of non-small cell and small cell lung cancer, certain types of metastatic urothelial cancer, and in PD-L1-positive metastatic triple-negative breast cancer. Strong sales growth was reported by all regions, driven mainly by the indications ES-SCLC and triple-negative breast cancer.

Hemlibra (first approved in 2017; CHF 521 million, +146%). 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). The uptake is very strong in the US, Japan and Europe.

Kadcyla (first approved in 2013; CHF 428 million, +55%). For treating HER2-positive breast cancer. The increased demand for Kadcyla was driven by the US, Europe and the International region, supported by its adjuvant use in treating patients with residual in invasive disease.

Esbriet (first approved in 2014; CHF 292 million, +22%). For idiopathic pulmonary fibrosis. Sales continued to expand, driven by growth in the US and Europe.

Alecensa (first approved in 2015; CHF 268 million, +43%). To treat ALK-positive lung cancer. Alecensa showed continued sales growth across all regions, with the International region and Europe as main drivers.

Gazyva/Gazyvaro (first approved in 2013; CHF 165 million, +49%). 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 38 million). 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, +371%). 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 3 million). For lung cancer with a specific gene mutation and solid tumours carrying a certain gene fusion. In Japan, Rozlytrek was approved for treatment of RSO1 fusion positive NSCLC.

Diagnostics Division

Sales	CHF millions		As % of sales		% change	
January - March 2020	2020	2019	2020	2019	At CER	In CHF
Diagnostics Division	2,881	2,899	100.0	100.0	+5	-1
Business Areas						
Centralised and Point of Care Solutions	1,572	1,681	54.5	58.0	-1	-6
Molecular Diagnostics	614	502	21.3	17.3	+29	+22
Diabetes Care	425	465	14.8	16.0	-2	-9
Tissue Diagnostics	270	251	9.4	8.7	+12	+8
Regions						
Europe, Middle East, Africa	1,215	1,210	42.2	41.7	+7	0
North America	835	764	29.0	26.4	+12	+9
Asia–Pacific	545	652	18.9	22.5	-11	-16
Latin America	181	179	6.3	6.2	+20	+1
Japan	105	94	3.6	3.2	+14	+12

In the first quarter 2020, sales of individual business segments were volatile, partly due to the impact of the COVID-19 pandemic. In general terms, emergency and COVID-19 testing strongly increased while routine testing decreased as a result of declining regular health checks. However, Roche's broad, diversified test portfolio and its large number of instruments installed worldwide could balance out these effects.

Centralised and Point of Care Solutions sales declined by 1%, its immunodiagnostics business (-4%) was strongly impacted by the COVID-19 shutdown in China. This was partially offset by strong increases in Point-of-care testing (+8%) driven by emergency testing, including blood gas analysis.

Sales in **Molecular Diagnostics** increased by 29%, with 32% growth in the underlying molecular business. Growth was driven by Quantitative PCR (to detect molecular/genetic targets) and Nucleic Acid Purification (to isolate and purify genetic material), virology (predominantly corona- and influenza viruses), cervical cancer diagnosis, blood screening and the sequencing business. From January 2020 to late March 2020 Roche increased its production capacity (reagents and consumables) for SARS-CoV-2 testing almost 10-fold. This includes the product portfolio running on MagNA Pure and LightCycler instruments that have been supporting multiple SARS-CoV-2 coronavirus solutions in the market since January, as well as developing and offering the first high-throughput cobas SARS-CoV-2 Test to be run on the fully automated cobas 6800/8800 Systems. In virology, routine testing, including HBV and HCV, decreased as a result from the shift of resources to SARS-CoV-2 testing.

Diabetes Care sales decreased by 2%, mainly due to price pressure for blood glucose monitoring products in the EMEA region, especially in Germany, Italy and the UK, and the impact of COVID-19 particularly in China. Sales growth partially offsetting this development mainly came from the Accu-Chek Guide and Accu-Check Instant product lines. A positive market uptake was seen for the digital diabetes management solutions: Accu-Chek SugarView, RocheDiabetes Care Platform and mySugr.

Tissue Diagnostics sales increased 12%. Sales growth was driven by advanced staining and supported by instrument sales, which returned to growth after shipment delays were resolved in the second half of 2019. Regionally, the increase of sales was led by North America (+12%) and EMEA (+9%).

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.

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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