Media Release

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Roche reports very strong results in 2019

- Group sales increase 9%[1] at constant exchange rates and 8% in Swiss francs, driven by new products, more than compensating for impact of competition from biosimilars
- Pharmaceuticals Division sales up 11%, resulting from high demand for recently launched medicines, led by Ocrevus, Hemlibra, Tecentriq and Perjeta
- Diagnostics Division sales grow by 3%, primarily due to its immunodiagnostics business
- New treatment options approved in the fourth quarter:
    - in the US: Tecentriq combination therapy for the initial treatment of a form of lung cancer; Xofluza for people at high risk of developing flu-related complications
    - in the EU: Kadcyla treatment after surgery of HER2-positive early breast cancer
- Core earnings per share grow ahead of sales at 13%
- On IFRS basis, net income increases 32% to CHF 14.1 billion, due to strong underlying operating results and the base effect of high goodwill impairments in 2018
- Board proposes dividend to increase to CHF 9.00. Subject to shareholder approval, this would be the 33rd consecutive dividend increase

Outlook for 2020: 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 further increase its dividend in Swiss francs.

Key figures	**CHF millions**		**% change**	
January - December 2019	**2019**	**2018**	**At CER[1]**	**In CHF**
Group sales	61,466	56,846	+9	+8
Pharmaceuticals Division	48,516	43,967	+11	+10
Diagnostics Division	12,950	12,879	+3	+1
Core operating profit	22,479	20,505	+11	+10
Core EPS - diluted (CHF)	20.16	18.14	+13	+11
IFRS net income	14,108	10,865	+32	+30

1 Unless otherwise stated, all growth rates in this document are at constant exchange rates (CER: average 2018).

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Commenting on the Group's results, Roche CEO Severin Schwan said: "In 2019, Roche achieved excellent operating results. I am delighted about the launches of our new cancer medicines Polivy and Rozlytrek, additional indications for Tecentriq and Kadcyla and priority review of risdiplam, our new medicine for a neurological disorder. Based on the progress made in rejuvenating our portfolio, Roche is very well positioned to grow going forward. For 2020 we expect sales growth in the low- to mid-single digit range in spite of the even greater impact of the competition from biosimilars."

Group results

In 2019, Group sales rose 9% to CHF 61.5 billion and core EPS grew 13%, ahead of sales. The core operating profit increased 11%, reflecting the strong underlying business performance. The IFRS net income increased 32%, due to strong underlying operating results and the base effect of high goodwill impairments in 2018.

Sales in the Pharmaceuticals Division increased 11% to CHF 48.5 billion. Key growth drivers were the multiple sclerosis medicine Ocrevus, the new haemophilia medicine Hemlibra and cancer medicines Tecentriq and Perjeta. The strong uptake of newly introduced medicines generated CHF 5.4 billion in growth, more than offsetting the impact of the competition from biosimilars for MabThera/Rituxan and Herceptin in Europe and Japan (decline combined CHF 1.2 billion) and MabThera/Rituxan, Herceptin and Avastin in the US (estimated decline CHF 0.3 billion).

In the US, sales increased 13%, led by Ocrevus, Hemlibra and Tecentriq. Ocrevus sales were driven by the demand from both new and returning patients. The first biosimilar versions of MabThera/Rituxan, Herceptin and Avastin were launched in the market later in the year.

In Europe, sales stabilised as the strong demand for new medicines, including Ocrevus, Perjeta, Tecentriq, Alecensa and Hemlibra was able to offset the impact of lower sales of Herceptin (-43%) and MabThera/Rituxan (-33%).

Growth in Japan (+9%), was also driven by recently launched products, despite considerable competition from biosimilars. The launches of first biosimilar versions of Avastin in late 2019 had a limited impact on sales in the reporting period.

In the International region, sales grew 15%, mainly driven by a significant increase in the number of patients benefiting from Roche cancer drugs in China with strong sales of Herceptin, Avastin and MabThera/Rituxan.

Diagnostics Division sales increased 3% to CHF 12.9 billion. The business area Centralised and Point of Care Solutions (+3%) was the main contributor, with growth driven by the immunodiagnostics business. Growth was reported in Asia-Pacific (+6%), Latin America (+12%) and EMEA[2] (+2%). In North America, sales were stable.

2 EMEA = Europe, Middle East and Africa

In December, Roche completed the acquisition of Spark Therapeutics, Inc. (Spark Therapeutics), based in Philadelphia, USA. Spark Therapeutics's investigational gene therapies have the potential to provide long-lasting effects, dramatically and positively changing the lives of patients with conditions where no, or only palliative, therapies exist. Greater understanding of the human genome and genetic abnormalities have allowed Spark Therapeutics's scientists to tailor investigational therapies to patients suffering from very specific genetic diseases. This approach holds great promise in developing effective treatments for a host of inherited diseases, including blindness, haemophilia, lysosomal storage disorders and neurodegenerative diseases.

Also in December, Roche signed a licensing agreement with Sarepta Therapeutics, Inc., providing Roche with exclusive commercial rights to SRP-9001, Sarepta's investigational gene therapy for Duchenne muscular dystrophy (DMD), outside the US. DMD is an X-linked rare degenerative neuromuscular disorder causing severe progressive muscle loss and premature death. SRP-9001 is currently in clinical development for DMD.

Regulatory achievements
In 2019, regulators around the globe granted approvals for new Roche medicines, line extensions of existing medicines and new tests or recommended the approval of our products. These decisions are important milestones in our efforts to rejuvenate our portfolio.

Achievements in the fourth quarter of 2019

Pharmaceuticals	*Status*	*Product*	*Indication*
US FDA	Approved	Tecentriq combination	First-line metastatic non-squamous non-small cell lung cancer (NSCLC)
US FDA	Approved	Xofluza	For people with high risk of developing flu-related complications
European Commission	Approved	Kadcyla	Adjuvant (after surgery) treatment of HER2-positive early breast cancer
US FDA	Priority review	Risdiplam	Spinal muscular atrophy (SMA)
US FDA	FDA filing acceptance	Satralizumab	Neuromyelitis optica spectrum disorder (NMOSD)
EU CHMP	Approval recommended	Polivy	Adults with relapsed or refractory diffuse large B-cell lymphoma who are not candidates for a haematopoietic stem cell transplant
Diagnostics			
EU	CE-mark	Accu-Chek SugarView app	Therapy-relevant information for non-insulin dependent type 2 diabetes or pre-diabetes

Key approvals of medicines January – September 2019

Product	*Indication*	*Key markets*
Tecentriq (in combination with chemotherapy)	Metastatic PD-L1 positive triple-negative breast cancer (TNBC)	US, EU
Tecentriq (in combination with chemotherapy)	extensive-stage small cell lung cancer (ES-SCLC)	US, EU
Tecentriq (in combination with chemotherapy)	metastatic non-squamous NSCLC that is not EGFR-mutant or ALK-positive	EU
Tecentriq (in combination with Avastin and chemotherapy)	metastatic non-squamous NSCLC	EU
Hemlibra	severe haemophilia A without factor VIII inhibitors	EU
Rozlytrek	ROS1/NTRK-positive tumours	Japan (NTRK), US (ROS1 & NTRK)
Polivy	relapsed or refractory diffuse large B-cell lymphoma after at least two prior therapies	US

Key development milestones
Our pipeline delivered a strong, constant flow of positive study results – the basis for Roche's future growth.

Achievements in the fourth quarter of 2019
Positive results from the phase III IMbrave150 study evaluating Tecentriq in combination with Avastin show statistically significant and clinically meaningful improvements in overall survival (OS) and progression-free survival (PFS), compared with sorafenib, in people with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

The phase II Nobility study of Gazyva/Gazyvaro for adults with proliferative lupus nephritis met the primary endpoint with Gazyva/Gazyvaro, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrating superiority compared to placebo plus standard of care.

Further study results announced in the fourth quarter

Study, compound	*Indication*	*Outcome*
Aphinity study, Perjeta-based treatment regimen	HER2-positive early breast cancer	Clinical benefit further strengthened by evidence of six-year results
Phase III IMspire150 study, Tecentriq in combination with Cotellic and Zelboraf	previously untreated BRAF V600 mutation-positive advanced melanoma	Primary endpoint of PFS met
Pivotal part 2 of the Sunfish study, risdiplam	People aged 2-25 with type 2 or 3 SMA	Primary endpoint met: change from baseline in the Motor Function Measure 32 scale after one year of treatment
CLL14 study, Venclexta/Venclyxto plus Gazyva/Gazyvaro	Previously untreated chronic lymphocytic leukaemia	Remissions achieved were sustained over time

Diagnostics – key launches in the fourth quarter of 2019

In November, Roche announced the launch of the cobas mobile solution, an innovative tablet application, making it possible for laboratory personnel to stay connected at all times. Enabling faster decision-making and enhancing the walk away time, the cobas mobile solution allows laboratory personnel to interact directly with their analysers from anywhere in the lab, thereby improving efficiency and convenience.[3]

In December, the Accu-Chek SugarView app received the CE Mark, allowing the launch of this innovative diabetes management solution in Europe and countries around the world accepting the CE Mark. Now officially classified as in-vitro diagnostics (IVD) software, the app will be made widely accessible by Roche initially for certain smartphone models via the Google Play Store, thus enabling broader access to therapy-relevant information for non-insulin dependent people with type 2 diabetes or pre-diabetes.

3 Available for up to eight cobas 8000 modular analyser series or cobas pro integrated solutions

Diagnostics – key launches January – September 2019

Ventana PD-L1 (SP142) Assay	Triple-negative breast cancer	US, countries accepting the CE-mark
Navify Tumor Board 2.0	Decision support system	US, Canada
Ventana HER2 Dual ISH DNA Probe Cocktail assay	Breast and gastric cancer	Europe, the Middle East and Africa, Latin America and Asia-Pacific; to be submitted for FDA approval
cobas MTB-RIF/INH test	Antibiotics-resistant tuberculosis	Countries accepting the CE-mark
cobas pro integrated solutions	Serum Work Area (clinical chemistry and immunochemistry) laboratory solution	US – FDA clearance
cobas Babesia whole blood test	Whole blood screening for Babesia (a blood parasite)	US – FDA approval

Pharmaceuticals Division

Sales	CHF millions		As % of sales		% change	
January - December 2019	2019	2018	2019	2018	At CER	In CHF
Pharmaceuticals Division	48,516	43,967	100.0	100.0	+11	+10
United States	26,711	23,233	55.1	52.8	+13	+15
Europe	8,453	8,693	17.4	19.8	+1	-3
Japan	4,143	3,701	8.5	8.4	+9	+12
International*	9,209	8,340	19.0	19.0	+15	+10

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

Key pharmaceutical products in 2019

Avastin (+4%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). The sales growth was driven by the International region (+13%), in particular in China due to increased numbers of patients treated. In the US (+2%), continued sales growth was seen in all approved indications, with sales growing at 9% through the first six months of 2019 but impacted by the first biosimilar launch in July 2019.

MabThera/Rituxan (-4%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. In Europe (-33%) and in Japan (-44%), sales were affected by biosimilars. In the US, sales increased 3%, with growth in both the immunology and oncology segments and also driven by the subcutaneous formulation. In the US, the first biosimilar version of MabThera/Rituxan was launched in November 2019, which has had

only a limited impact on sales so far. In China, growth resulted from increased numbers of patients treated.

Herceptin (-12%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales were impacted by biosimilar launches in Europe and Japan from mid-2018 and in the US (-8%) in part by the switch to Kadcyla in the adjuvant setting and in part due to the launch of the first biosimilars in July 2019. This development was partially offset by increased sales in China.

Actemra/RoActemra (+8%). 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 and strong sales in the US and Japan.

Xolair (+1%, US only). For chronic idiopathic urticaria and allergic asthma. Growth was reported in both indications.

Lucentis (+8%, US only). For eye conditions, including neovascular ('wet') age-related macular degeneration, macular oedema following retinal vein occlusion, diabetic macular oedema, and diabetic retinopathy. Growth was driven by sales increases in all approved indications and the ongoing rollout of prefilled syringes.

Highlights for medicines launched since 2012
Ocrevus (first approved in 2017; CHF 3.7 billion, +57%). 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. In addition to sales increases in the US, it continues to show strong initial uptake in international markets, including Germany, Italy, Spain and UK.

Perjeta (first approved in 2012; CHF 3.5 billion, +29%). As therapy for HER2-positive breast cancer. Sales grew strongly in all regions. The increased patient demand for Perjeta for adjuvant early breast cancer therapy supports its continued strong growth.

Tecentriq (first approved in 2016; CHF 1.9 billion, +143%). 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 TNBC. Strong sales growth was reported by all regions. In the US, the new indications for ES-SCLC and triple-negative breast cancer drove sales growth.

Kadcyla (first approved in 2013; CHF 1.4 billion, +45%). For treating HER2-positive breast cancer. The increased demand for Kadcyla was driven by the US (+74%) and the International region, supported by its use in treating patients with residual disease after surgery.

Hemlibra (first approved in 2017; CHF 1.4 billion, >500%). 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.

Esbriet (first approved in 2014; CHF 1.1 billion, +9%). For idiopathic pulmonary fibrosis. Sales continued to expand, driven by growth in Europe and the US.

Alecensa (first approved in 2015; CHF 876 million, +38%). To treat ALK-positive lung cancer. Alecensa showed continued sales growth across all regions, with Europe and the International region being the main drivers.

Gazyva/Gazyvaro (first approved in 2013; CHF 552 million, +43%). For chronic lymphocytic leukaemia (CLL), rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Sales expanded in all regions.

Polivy (first approved in 2019; CHF 51 million). Part of combination therapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma who have received at least two prior therapies. FDA granted accelerated approval.

Rozlytrek (first approved in 2019; CHF 7 million). For lung cancer with a specific gene mutation and solid tumours carrying a certain gene fusion. Rozlytrek received approvals in the US and in Japan.

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Avastin	7,073	4	3,019	2	1,794	2	871	0	1,389	13
MabThera/Rituxan	6,477	-4	4,488	3	590	-33	109	-44	1,290	-1
Herceptin	6,039	-12	2,707	-8	1,013	-43	243	-5	2,076	10
Ocrevus	3,708	57	3,049	44	495	148	-	-	164	161
Perjeta	3,522	29	1,528	13	1,092	24	280	90	622	71
Actemra/RoActemra	2,311	8	944	8	705	4	398	9	264	14
Xolair	1,969	1	1,969	1	-	-	-	-	-	-
Tecentriq	1,875	143	1,180	148	349	138	188	126	158	138
Lucentis	1,826	8	1,826	8	-	-	-	-	-	-
Kadcyla	1,393	45	635	74	432	19	82	7	244	56

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

Diagnostics Division

Sales	CHF millions		As % of sales		% change	
January - December 2019	2019	2018	2019	2018	At CER	In CHF
Diagnostics Division	12,950	12,879	100.0	100.0	+3	+1
Business Areas						
Centralised and Point of Care Solutions	7,819	7,768	60.4	60.3	+3	+1
Molecular Diagnostics	2,109	2,019	16.3	15.7	+6	+4
Diabetes Care	1,918	1,980	14.8	15.4	+1	-3
Tissue Diagnostics	1,104	1,112	8.5	8.6	0	-1
Regions						
Europe, Middle East, Africa	4,897	4,986	37.9	38.7	+2	-2
Asia–Pacific	3,437	3,334	26.5	25.9	+6	+3
North America	3,253	3,213	25.1	24.9	0	+1
Latin America	854	844	6.6	6.6	+12	+1
Japan	509	502	3.9	3.9	-2	+1

Centralised and Point of Care Solutions sales were up by 3%. The immunodiagnostics business grew 6%, again making this unit the largest contributor to the division's sales growth. The positive impact of instrument launches and the ongoing rollouts, mainly in China, the US and South Korea, was partially offset by the decline in the coagulation monitoring business in North America.

Sales in **Molecular Diagnostics** increased by 6%, with 6% growth in the underlying molecular business. Growth was driven by blood screening as well as by the sequencing business. Regional growth was led by Asia-Pacific (+16%) mainly in China, and EMEA (+6%).

Diabetes Care sales increased by 1%, driven by North America (+15%). The sales growth mainly came from the Accu-Chek Guide product line. This was partially offset by price pressure in Germany, UK and Italy.

Tissue Diagnostics sales were stable. Sales growth for advanced staining reagents was offset by lower instruments sales due to shipment delays. Regionally, the decline in sales was led by North America (-6%). In the Asia-Pacific region sales increased by 14%, with China being the main growth market.

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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