Media Release

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Roche reports very strong results in 2018

- Group sales increase 7%[1] at constant exchange rates and in Swiss francs
- Pharmaceuticals Division sales up 7%, driven mainly by Ocrevus, Perjeta, Tecentriq, Alecensa and Hemlibra
- Diagnostics Division sales grow 7%, primarily due to demand for immunodiagnostic solutions
- In the fourth quarter, the US FDA approves Tecentriq in combination with Avastin for a specific form of lung cancer; Venclexta for a form of leukaemia; and Xofluza for influenza
- Core earnings per share grow ahead of sales at 19%, or 8% excluding the effect of the US tax reform
- On IFRS basis, net income increases 24%
- Board proposes dividend to increase to CHF 8.70
- Outlook for 2019: 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 2018	**2018**	**2017**	**At CER[1]**	**In CHF**
Group sales	56,846	53,299	+7	+7
Pharmaceuticals Division	43,967	41,220	+7	+7
Diagnostics Division	12,879	12,079	+7	+7
Core operating profit	20,505	19,012	+9	+8
Core EPS - diluted (CHF)	18.14	15.34	+19	+18
excl. US tax reform			+8	+7
IFRS net income	10,865	8,825	+24	+23

[1] Unless otherwise stated, all growth rates in this document are at constant exchange rates (CER: average 2017).

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Commenting on the Group's results, Roche CEO Severin Schwan said: "In 2018, Roche achieved very good growth in both divisions. I am particularly pleased with the very strong demand for our new medicines, delivering significant benefit for patients fighting serious diseases like cancer, multiple sclerosis and haemophilia. Roche is also making major progress in driving digitalisation, and in leveraging real-world healthcare data and analytics to support product development and advance personalised healthcare. Based on the successful launches and our strong product pipeline Roche is well positioned for continued growth."

Group results

In 2018, Group sales rose 7% to CHF 56.8 billion. Core operating profit increased 9%, reflecting the strong underlying business performance. Core EPS grew 19% and IFRS net income increased 24%, including the benefits from the US tax reform and higher net financial income.

Sales in the Pharmaceuticals Division increased 7% to CHF 44.0 billion. Key growth drivers were the new multiple sclerosis medicine Ocrevus and cancer medicines Perjeta, Tecentriq, Alecensa as well as the new haemophilia medicine Hemlibra. With sales of CHF 2.4 billion in its first full year on key markets, Ocrevus is the most successful new product launch in the history of Roche. As expected, the strong uptake of newly introduced medicines was partially offset by lower sales of MabThera/Rituxan and of Tarceva.

In the US, sales increased 14%, led by Ocrevus, Perjeta and Lucentis. Ocrevus sales were supported by continued strong new patient demand as well as follow-up treatments. The 32% sales increase of Perjeta was driven by its use for adjuvant (after surgery) treatment of patients with HER2-positive early breast cancer at high risk of recurrence.[2]

In Europe (-7%), sales were affected by competition from biosimilars for MabThera/Rituxan (-47%) and Herceptin (-16%), offset by the strong launches of our new medicines Ocrevus, Tecentriq, Alecensa, and of Perjeta in metastatic HER2-positive breast cancer and adjuvant therapy.

In the International region, sales grew 10%, led by the Asia–Pacific and Latin America subregions. In Japan, sales declined 1% due to government price cuts and biosimilar competition for MabThera/Rituxan (-36%) and Herceptin (-16%).

Diagnostics Division sales increased 7% to CHF 12.9 billion. Centralised and Point of Care Solutions (+8%) was the main contributor, led by the growth of its immunodiagnostics business (+11%). All business areas reported sales increases. In regional terms, growth was driven by Asia-Pacific (+13%) and North America (+7%). Sales increased 3% in EMEA[3], 9% in Latin America, and 6% in Japan.

[2] US Food and Drug Administration prescribing information for Perjeta

[3] EMEA = Europe, Middle East and Africa

Important milestones for Roche medicines

Roche medicines passed important regulatory milestones in recent months, including the following key achievements: In December 2018, the US Food and Drug Administration (FDA) approved Tecentriq in combination with Avastin, paclitaxel and carboplatin for the initial treatment of people with metastatic non-squamous non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumour aberrations.

The FDA granted accelerated approval to Venclexta in combination with azacitidine or decitabine, or low dose cytarabine, for the treatment of people with newly-diagnosed acute myeloid leukaemia (AML), aged 75 years and older, or for those ineligible for intensive induction chemotherapy due to coexisting medical conditions.[4] AML is the most common type of aggressive leukaemia in adults and has the lowest survival rate of all types of leukaemia.

In October, FDA approved Xofluza (baloxavir marboxil) for the treatment of acute, uncomplicated influenza in people aged 12 years and older. Xofluza is a first-in-class, single-dose oral medicine with a novel proposed mechanism of action that inhibits polymerase acidic endonuclease, an enzyme essential for viral replication.[5] It has demonstrated efficacy against a wide range of influenza viruses, including oseltamivir-resistant strains and avian strains (H7N9, H5N1) in non-clinical studies.[6]

Based on the IMpower133 study, the FDA granted priority review for Tecentriq, in combination with carboplatin and etoposide (chemotherapy), for the initial treatment of people with extensive-stage small cell lung cancer (ES-SCLC). The IMpower133 results represent the first clinically meaningful advance in the disease in over 20 years.[7]

Priority review was granted for Tecentriq plus Abraxane (albumin-bound paclitaxel; *nab*-paclitaxel) for the initial treatment of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) in people whose disease expresses the PD-L1 protein, as determined by PD-L1 biomarker testing. The priority review was based on the IMpassion 130 study, the first positive phase III immunotherapy study in TNBC, an aggressive disease with limited treatment options.

Polatuzumab vedotin in combination with MabThera/Rituxan plus bendamustine has been granted breakthrough therapy designation and orphan drug designation by the FDA, as well as PRIME designation and orphan drug designation by the European Medical Agency (EMA), for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma who are not candidates for haematopoietic stem cell transplantation. Files for regulatory review and approval of polatuzumab have been submitted to FDA.

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[4] Venclexta/Venclyxto sales are booked by partner AbbVie.

[5] Shi F, et al. Viral RNA polymerase: a promising antiviral target for influenza A virus. Curr Med Chem. 2013;20(31):3923–34

[6] Taniguchi K, et al. Inhibitory Effect of S-033188, a novel inhibitor of influenza virus cap-dependent endonuclease, against avian influenza A/H7N9 virus in vitro and in vivo. Poster presentation at ESWI, September 2017.

[7] Evans WK, et al. J Clin Oncol, 1985

Entrectinib, in development for the treatment of neurotrophic tropomyosin receptor kinase (NTRK) fusion-positive solid tumours, was granted breakthrough therapy designation by the FDA, PRIME designation by the EMA, and Sakigake and orphan drug designations by the health authorities in Japan. Files for regulatory review and approval of entrectinib have been submitted to FDA.

Advancing personalised healthcare

In 2018, Roche concluded several transactions to further advance its personalised healthcare strategy. This includes three US-based companies: Foundation Medicine, with its comprehensive genomic profiling assays to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies and clinical trials; Flatiron Health, a market leader in the curation and development of real-world evidence for cancer research; Ignyta, with entrectinib as its lead drug candidate. Entrectinib is an example of highly targeted novel treatment approaches based on genetic profiling**.**

In early 2018, Roche Diagnostics and GE Healthcare announced their agreement to enter into a strategic partnership, combining Roche's *in vitro* diagnostics Know-how with GE Healthcare's *in vivo* expertise. The aim is to co-develop and co-market decision support software solutions, anchored by a shared digital platform designed to also allow third parties to potentially place their product and company-agnostic applications. The initial focus is on oncology and acute care.

Outlook for 2019

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.

Dividend proposal

The Board of Directors proposes a dividend increase to CHF 8.70 per share and non-voting equity security. Subject to approval by the Annual General Meeting of Shareholders on 5 March 2019, this will be Roche's 32nd consecutive annual dividend increase.

Pharmaceuticals Division

Sales	CHF millions		As % of sales		% change	
January - December 2018	2018	2017	2018	2017	At CER	In CHF
Pharmaceuticals Division	43,967	41,220	100.0	100.0	+7	+7
United States	23,233	20,496	52.8	49.7	+14	+13
Europe	8,693	9,051	19.8	22.0	-7	-4
Japan	3,701	3,713	8.4	9.0	-1	0
International*	8,340	7,960	19.0	19.3	+10	+5

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

Clinical trial results on Roche medicines
Roche announced results from a number of late-stage studies during the fourth quarter, including the following studies: The phase III Katherine study met its primary endpoint, showing that Kadcyla as a single agent reduced the risk of disease recurrence or death (invasive disease-free survival; iDFS) by half compared to Herceptin as an adjuvant (after surgery) treatment in people with HER2-positive early breast cancer (eBC) who have residual disease present following neoadjuvant (before surgery) treatment.

Data from the primary analysis of the phase III Haven 2 study evaluating Hemlibra prophylaxis in children younger than 12 years of age with haemophilia A with factor VIII inhibitors showed that nearly 77% of children receiving Hemlibra once weekly experienced zero treated bleeds. Hemlibra once weekly reduced treated bleeds by 99% compared to prior bypassing agents in a prospective intra-patient comparison. Hemlibra every two weeks and every four weeks also showed clinically meaningful control of bleeding.

Results of the head-to-head phase III study of Alecensa versus crizotinib in an Asian patient population with ALK-positive advanced or metastatic NSCLC showed a reduction in the risk of disease worsening or death by 78%. Alecensa lowered the risk of tumour spread or growth in the brain or central nervous system by 86%.

An integrated analysis of the pivotal entrectinib phase II Startrk-2, phase I Startrk -1 and phase I Alka-372-001 trials showed that entrectinib shrank tumours (objective response rate; ORR) in more than half (57.4%) of people with neurotrophic tropomyosin receptor kinase (NTRK) fusion-positive solid tumours. The study data also demonstrate the potential of entrectinib to treat a range of difficult-to-treat and rare cancers regardless of their site of origin.

Based on the positive phase III results, Roche will be moving forward with satralizumab for neuromyelitis optica spectrum disorder (NMOSD). Roche will be solely responsible for the global regulatory filings and commercialisation except in Japan, Taiwan and Korea. The programme transition from Chugai to Roche was initiated in January 2019.

Key pharmaceutical products

HER2-franchise (Herceptin, Perjeta and Kadcyla, +7%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer (Herceptin only).

Herceptin (+1%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales increases were mainly driven by growth in the US and in China. This growth was partially offset by the sales decline in Europe (-16%) due to the first biosimilar launches from mid-2018.

Avastin (+3%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales increased in the International region (+12%), in particular in China due to broader market penetration, in the US (+1%) and in Japan (+3%), but declined in Europe (-1%).

MabThera/Rituxan (-8%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales development was impacted by Europe (-47%) as a result of the market entry of biosimilars. In the US, sales increased 4%, with growth in both the immunology and oncology segments, also driven by the subcutaneous formulation. Sales were also higher in the International region (+11%), particularly in China due to broader market penetration.

Actemra/RoActemra (+12%). 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 continued uptake of the subcutaneous formulation.

Xolair (+11%, US only). For chronic idiopathic urticaria and allergic asthma. Growth was driven by demand in both indications.

Lucentis (+18%, 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 the ongoing rollout of prefilled syringes and sales increases in all approved indications.

Highlights on medicines launched since 2012

Perjeta. For HER2-positive breast cancer. Sales (CHF 2.8 billion, +27%) grew in all regions. As of December 2018, Perjeta was registered in 73 countries including the US, the EU and recent approvals in Japan and China for adjuvant treatment. This indication strongly supports its continued growth, which is also driven by increased demand in adjuvant early breast cancer therapy in the US and in neoadjuvant metastatic usage in Europe.

Ocrevus (CHF 2.4 billion, +172%). For both the relapsing and primary progressive forms of multiple sclerosis (MS). Ocrevus has now been approved in 74 countries, with more than 80,000 people treated globally as of December 2018. Strong demand in both indications has continued.

Esbriet (CHF 1.0 billion, +19%). For idiopathic pulmonary fibrosis (IPF). Sales continued to expand, driven by growth in the US (+19%) and Europe (+17%).

Tecentriq (CHF 772 million, +59%). For advanced bladder cancer, advanced lung cancer and initial therapy of non-squamous NSCLC. Sales growth was reported by all regions, mainly driven by Europe, notably in Germany, and by the launch in Japan in 2018.

Alecensa (CHF 637 million, +76%). For ALK-positve lung cancer. Alecensa showed continued strong sales growth across all regions, with the US and Europe as the main drivers.

Gazyva/Gazyvaro (CHF 390 million, +40%). For chronic lymphocytic leukaemia (CLL), rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Sales expanded, especially in Europe and in the US.

Hemlibra (CHF 224 million). For people with haemophilia A with inhibitors to factor VIII. Hemlibra is approved in more than 50 countries, including the US, the EU and Japan. In several countries, including the US, Hemlibra is also approved for people with haemophilia A without factor VIII inhibitors. Hemlibra is the only prophylactic treatment that can be administered subcutaneously and at multiple dosing options (once weekly, every two weeks or every four weeks).

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Herceptin	6,982	1	2,908	9	1,849	-16	249	-16	1,976	10
Avastin	6,849	3	2,904	1	1,820	-1	847	3	1,278	12
MabThera/Rituxan	6,752	-8	4,290	4	916	-47	188	-36	1,358	11
Perjeta	2,773	27	1,325	32	915	15	143	18	390	45
Ocrevus	2,353	172	2,080	144	206	**	-	-	67	**
Actemra/RoActemra	2,160	12	857	14	701	7	354	15	248	15
Xolair	1,912	11	1,912	11	-	-	-	-	-	-
Lucentis	1,659	18	1,659	18	-	-	-	-	-	-
Activase/TNKase	1,284	6	1,231	6	-	-	-	-	53	5
Esbriet	1,031	19	754	19	230	17	-	-	47	29

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

** over 500%

Diagnostics Division

Sales	CHF millions		As % of sales		% change	
January - December 2018	2018	2017	2018	2017	At CER	In CHF
Diagnostics Division	12,879	12,079	100.0	100.0	+7	+7
Business Areas						
Centralised and Point of Care Solutions	7,768	7,179	60.3	59.4	+8	+8
Molecular Diagnostics	2,019	1,920	15.7	15.9	+5	+5
Diabetes Care	1,980	1,965	15.4	16.3	+2	+1
Tissue Diagnostics	1,112	1,015	8.6	8.4	+10	+10
Regions						
Europe, Middle East, Africa	4,986	4,773	38.7	39.5	+3	+4
Asia–Pacific	3,334	2,939	25.9	24.4	+13	+13
North America	3,213	3,011	24.9	24.9	+7	+7
Latin America	844	884	6.6	7.3	+9	-5
Japan	502	472	3.9	3.9	+6	+6

In October, Roche officially opened a new manufacturing site and R&D centre in Suzhou, China, to support the future diagnostic needs within China and the region. With its regional headquarters in Singapore and eight existing branches across China, Roche is already a major healthcare provider in Asia-Pacific.

Centralised and Point of Care Solutions (+8%) was the largest contributor to the division's sales growth. Serum Work Area solutions, comprising the immunodiagnostics (+11%) and clinical chemistry (+7%) businesses, were the main growth drivers.

cobas pro integrated solution, a Serum Work Area solution for medium throughput to lower high throughput laboratories was launched in countries accepting the CE mark. This new generation of SWA solutions provides a high level of efficiency and continuous loading of supplies. Furthermore, it offers simplicity through automated maintenance and calibration. It also features the broadest SWA assay menu consolidated on a single platform, short assay incubation times and low sample volume requirements.

Sales in **Molecular Diagnostics** increased 5%. In virology, sales were up 4%, with strong growth in HIV monitoring. Sales in the blood screening and human papillomavirus (HPV) screening businesses grew 9% and 8% respectively. Continued high demand was reported for cobas Liat tests, the new system for molecular point of care testing.

The Navify Tumor Board, a cloud-based software solution that fundamentally changes the way oncology care teams prepare for, conduct and document clinical treatment decisions, was further extended by the launch of the Navify Clinical Trial Match and Navify Publication Search apps in 2018. These apps scan globally renowned resources and are fully integrated with the Navify Tumor Board and represent the start of the Navify apps ecosystem, with more apps from Roche, partners and third parties to follow.

Tissue Diagnostics sales increased 10%. The advanced staining business continued its strong growth (+10%); demand for the primary staining portfolio was high (+13%).

The Ventana DP 200 slide scanner was launched in March 2018, creating high-quality tissue slide images that offer pathologists a digital image that accurately reproduces what would be seen under the microscope. These images serve as the basis for a full menu of image analysis algorithms currently under development. Roche also launched uPath enterprise software, a universal digital pathology software for lab administrators, histotechnicians and pathologists. This software allows for improved case management, including case sharing among colleagues to seek second opinions. More importantly, uPath software enables pathologists with patient-centric case viewing for quick diagnosis, and will provide a platform for a full menu of image analysis algorithms currently under development.

Diabetes Care sales increased 2%, mainly driven by the new Accu-Chek Guide and Accu-Chek Instant blood glucose monitoring systems. Launched in pilot markets, the new Accu-Chek Solo micropump received encouraging customer feedback. An enhanced positive acceptance is visible for the integrated diabetes management solutions including mySugr.

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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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