Media Release

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Roche reports a strong start in 2018

- Group sales increase 6%[1] at constant exchange rates and 5% in Swiss francs
- Pharmaceuticals Division sales up 7%, driven mainly by Ocrevus and Perjeta
- Diagnostics Division sales grow 5%, with increases in all business areas
- Approvals: Ocrevus for relapsing forms of multiple sclerosis and primary progressive multiple sclerosis, and Hemlibra for people with haemophilia A with inhibitors to factor VIII in the EU
- Positive phase III study results for cancer immunotherapy medicine Tecentriq in renal cell cancer and certain forms of lung cancer
- Outlook raised for 2018 to low single-digit sales growth

Sales	**CHF millions**		**As % of sales**		**% change**	
January - March 2018	**2018**	**2017**	**2018**	**2017**	**At CER**	**In CHF**
Group sales	13,583	12,942	100.0	100.0	+6	+5
Pharmaceuticals Division	10,672	10,177	78.6	78.6	+7	+5
United States	5,516	5,070	40.6	39.2	+15	+9
Europe	2,287	2,273	16.8	17.6	-7	+1
Japan	851	856	6.3	6.6	0	-1
International*	2,018	1,978	14.9	15.2	+5	+2
Diagnostics Division	2,911	2,765	21.4	21.4	+5	+5

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

Commenting on the Group's sales, Roche CEO Severin Schwan said: "We have started the year with strong sales growth in both our Pharmaceuticals and Diagnostics Divisions. I am particularly pleased with the strong demand for our new medicines, which contributed significantly to our growth. Based on our performance in the first quarter, we raise the outlook for the full-year."

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

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Group sales

In the first three months of 2018, Group sales rose 6% to CHF 13.6 billion. Sales in the Pharmaceuticals Division increased 7% to CHF 10.7 billion. A key growth driver was Ocrevus, used to treat two forms of multiple sclerosis. It continued its strong growth in the US and was launched in Europe and additional countries worldwide during the first quarter. The continued strong sales increase of Perjeta was supported by the US approval for its use for adjuvant (after surgery) treatment of patients with HER2-positive early breast cancer at high risk of recurrence.[2] By the end of the first quarter, 10 countries had granted approval for Perjeta in this additional indication. The growth reported for the Pharmaceuticals Division was partially offset by lower sales of MabThera/Rituxan, Tarceva and Avastin.

In the US, sales increased 15%, led by Ocrevus, Herceptin and Perjeta. In Europe, sales declined 7%, mainly due to lower MabThera/Rituxan sales as a result of competition from biosimilars. The new launches Ocrevus, Tecentriq and Hemlibra had good early uptake. In the International region, sales grew 5%, led by the Asia–Pacific and Latin America subregions. In Japan, sales were stable.

Diagnostics Division sales increased 5% to CHF 2.9 billion. Centralised and Point of Care Solutions (+4%) was a key contributor, led by the growth of its immunodiagnostics business (+5%). Sales increased in all business areas. In regional terms, growth was driven by Asia-Pacific (+10%) and North America (+7%). Sales increased 2% in EMEA[3], and 1% in Latin America. In Japan, sales declined 8%, predominantly resulting from lower sales for hepatitis tests due to a base effect of strong test sales in 2017.

Important approvals in Pharmaceuticals

In January 2018, the European Medicines Agency (EMA) approved Ocrevus for the treatment of relapsing and primary progressive forms of multiple sclerosis. It is the first and only approved disease-modifying medicine for people in the EU with early primary progressive multiple sclerosis. In February, the EMA granted approval for Hemlibra for people with haemophilia A with inhibitors to factor VIII. This is the first new medicine in over 20 years to treat people with haemophilia A with inhibitors to factor VIII. Hemlibra demonstrated superior efficacy compared to prior treatment with bypassing agents in two phase III studies in adults, adolescents and children.

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

[3] EMEA = Europe, Middle East and Africa

In March, the US Food and Drug Administration (FDA) approved the Lucentis 0.3 mg prefilled syringe as a new method of administering the medicine to treat all forms of diabetic retinopathy.

Milestones for Roche medicines

In the first quarter, Roche announced positive results from several Tecentriq studies. Data of the phase III IMmotion151 study were presented at the Genitourinary Cancers Symposium in February 2018, following the announcement of positive results for progression-free survival (PFS) in December 2017. The study investigated Tecentriq and Avastin as a first-line treatment for advanced or metastatic renal cell carcinoma (mRCC) and met its co-primary endpoint of investigator-assessed progression-free survival (PFS) in people whose disease expressed the PD-L1 (programmed death-ligand 1) protein.

The phase III IMpower131 study met its co-primary endpoint of PFS and demonstrated that the combination of Tecentriq plus chemotherapy (carboplatin and paclitaxel) reduced the risk of disease worsening or death (PFS) compared with chemotherapy alone in the initial (first-line) treatment of people with advanced squamous non-small cell lung cancer (NSCLC).

The phase III IMpower150 study met its co-primary endpoint of overall survival (OS) at an interim analysis and showed that initial (first-line) treatment with the combination of Tecentriq and Avastin plus carboplatin and paclitaxel (chemotherapy) helped people with advanced non-squamous NSCLC live significantly longer compared with Avastin plus carboplatin and paclitaxel. A survival benefit was observed across key subgroups, including those with varying levels of PD-L1 expression.

In April, the FDA granted Hemlibra a Breakthrough Therapy Designation (BTD) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A without inhibitors to factor VIII.

In the first quarter, Roche closed two acquisitions: Flatiron Health and Ignyta, Inc.
Roche acquired Flatiron Health to accelerate development and delivery of breakthrough medicines for patients with cancer. Flatiron Health will continue its operations as a separate legal entity.
Ignyta, Inc., now part of Roche's Pharmaceuticals Division, develops potentially life-saving, precisely targeted therapeutics guided by diagnostic tests. Its lead molecule entrectinib targets tumours with one of two genetically defined gene rearrangements: ROS1 fusions in NSCLC, and NTRK fusions across a broad range of solid tumours.

Roche Diagnostics – increasing access to HIV testing for patients living in remote areas

In January 2018, the cobas Plasma Separation Card was launched. This new solution is a stable and easy-to-use sample collection device for HIV plasma viral load testing. Traditionally, plasma viral load analyses required blood samples to be cooled during transport to the lab. The card allows for simple and reliable quantitative testing of patients with HIV living in remote areas - even areas of extreme heat and humidity - while meeting WHO requirements for determining HIV viral load prior to initiating treatment.

Outlook raised for 2018

Sales are now expected to grow low single-digit, at constant exchange rates. Core earnings per share are targeted to grow high single-digit, at constant exchange rates. Excluding the US tax reform impact, core earnings per share are targeted to grow broadly in line with sales. Roche expects to further increase its dividend in Swiss francs.

Pharmaceuticals Division

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Herceptin	1,774	2	728	13	551	-3	59	-10	436	-8
MabThera/Rituxan	1,713	-8	1,023	4	282	-44	54	-11	354	11
Avastin	1,640	-2	699	-3	469	-3	184	2	288	2
Perjeta	613	18	287	18	215	13	28	11	83	34
Actemra/RoActemra	499	13	192	15	172	9	73	14	62	15
Ocrevus	479	-	443	-	28	-	-	-	8	-
Xolair	442	7	442	7	-	-	-	-	-	-
Lucentis	393	6	393	6	-	-	-	-	-	-
Activase/TNKase	323	8	311	8	-	-	-	-	12	14
Tamiflu	292	11	161	10	21	45	74	14	36	2

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

Key pharmaceutical products in 2018

HER2-franchise (Herceptin, Perjeta and Kadcyla) +6%

Herceptin (+2%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales increases were mainly driven by growth in the US.

MabThera/Rituxan (-8%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales increases were recorded in the US and in the International region. Sales in Europe (-44%) were affected by the market entry of biosimilars.

Avastin (-2%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales declined in the US and in Europe (-3% each) but increased in the International region and in Japan (+2% each).

Actemra/RoActemra (+13%). 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 (US only). Sales growth was reported in all regions, supported by steady growth in demand for the subcutaneous formulation.

Xolair (+7%, US only). For chronic idiopathic urticaria and allergic asthma. Growth was mainly driven by increasing demand across indications.

Lucentis (+6%, US only). For eye conditions including wet age-related macular degeneration, macular oedema following retinal vein occlusion, diabetic macular oedema, and diabetic retinopathy. Growth was driven by increased demand for 0.5 mg prefilled syringes in wet age-related macular degeneration and continued growth in diabetic retinopathy.

Highlights on certain medicines launched since 2012

Perjeta. For HER2-positive breast cancer. Sales (CHF 613 million, +18%) grew in all regions. In late 2017, the US FDA approved Perjeta for use in combination with Herceptin and chemotherapy for adjuvant (after surgery) treatment of HER2-positive early breast cancer at high risk of recurrence. The approval in this new indication strongly supports Perjeta's continued growth, which is also driven by increased demand in the neoadjuvant and metastatic settings across the regions.

Ocrevus (CHF 479 million). For both the relapsing and primary progressive forms of multiple sclerosis. Ocrevus has now been approved in over 55 countries and strong demand in both indications has continued. More than 40,000 people had been treated globally as at the end of March 2018.

Tecentriq (CHF 139 million, +29%). For advanced bladder cancer and advanced lung cancer. Tecentriq is approved in 70 countries. Roche is conducting a large number of studies of Tecentriq in combination with medicines from Roche's marketed and investigational portfolios as well as those with our external partners.

Alecensa (CHF 119 million, +81%). For a specific form of lung cancer. Alecensa is approved in 56 countries; it showed continued strong sales growth in the US, Europe and in Japan.

Gazyva/Gazyvaro (CHF 84 million, +27%). For chronic lymphocytic leukaemia (CLL), rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Sales expanded in Europe and in the US.

Hemlibra (CHF 23 million). For people with haemophilia A with inhibitors to factor VIII. Hemlibra is approved in the US, the EU, Australia and in Japan. Early signs of demand are promising.

Diagnostics Division

Sales	CHF millions		As % of sales		% change	
January - March 2018	2018	2017	2018	2017	At CER	In CHF
Diagnostics Division	2,911	2,765	100.0	100.0	+5	+5
Business Areas						
Centralised and Point of Care Solutions	1,716	1,641	58.9	59.4	+4	+5
Diabetes Care	478	447	16.4	16.2	+5	+7
Molecular Diagnostics	468	441	16.1	15.9	+6	+6
Tissue Diagnostics	249	236	8.6	8.5	+7	+6
Regions						
Europe, Middle East, Africa	1,221	1,126	41.9	40.7	+2	+8
North America	753	740	25.9	26.8	+7	+2
Asia–Pacific	656	594	22.5	21.5	+10	+10
Latin America	188	203	6.5	7.3	+1	-7
Japan	93	102	3.2	3.7	-8	-9

Centralised and Point of Care Solutions (+4%) was the largest contributor to the division's sales growth. Integrated Serum Work Area solutions, comprising the immunodiagnostics (+5%) and clinical chemistry (+3%) segments, were the main growth drivers. The new cobas t 511 and t 711 coagulation analysers are being well received by customers. These fully automated systems are designed for qualitative and quantitative in vitro blood coagulation determinations.

Sales in **Molecular Diagnostics** increased 6%. In virology, sales are up 5%, with strong growth in HIV monitoring. Strong demand in cobas Liat tests was driven by a severe flu season. Sales in the blood screening and human papillomavirus (HPV) screening businesses grew 5% each.

Tissue Diagnostics sales increased 7%, driven by the advanced staining and primary staining portfolios, which grew 8% and 20% respectively. The Ventana DP 200 high-speed slide scanner with unique no-touch slide processing was launched in countries accepting the CE mark, and for research use only (RUO) in the US. It reduces slide handling errors and produces excellent image quality and reliability.

Diabetes Care sales increased 5%, supported by sales growth in the blood glucose monitoring business. While market conditions continue to be challenging, all regions showed sales growth in the first quarter. The Accu-Chek Guide and Accu-Chek Instant systems, which make up Roche's new blood glucose monitoring platform, have been launched in additional markets.

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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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