Media Release

Basel, 17 April 2019

Roche reports a strong start in 2019 and raises the outlook for the full-year

- Group sales increase 8%[1] at constant exchange rates and 9% in Swiss francs
- Pharmaceuticals Division sales up 10%, driven mainly by Ocrevus, Perjeta, Hemlibra and Tecentriq
- Diagnostics Division sales grow 1%, with Molecular Diagnostics as main contributor
- Important approvals in the first quarter. In the US: Tecentriq combination therapy for extensive-stage small cell lung cancer; Tecentriq combination therapy for triple-negative breast cancer and companion diagnostic test; Herceptin Hylecta for subcutaneous injection for breast cancer; in the EU: Hemlibra for people with severe haemophilia A without factor VIII inhibitors; Tecentriq plus Avastin combination therapy for initial treatment of a form of lung cancer
- Outlook raised for 2019 to mid-single digit sales growth

Sales	**CHF millions**		**As % of sales**		**% change**	
January - March 2019	**2019**	**2018**	**2019**	**2018**	**At CER**	**In CHF**
Group sales	14,826	13,583	100.0	100.0	+8	+9
Pharmaceuticals Division	11,927	10,672	80.4	78.6	+10	+12
United States	6,623	5,516	44.7	40.6	+14	+20
Europe	2,101	2,287	14.2	16.8	-6	-8
Japan	941	851	6.3	6.3	+7	+11
International*	2,262	2,018	15.2	14.9	+17	+12
Diagnostics Division	2,899	2,911	19.6	21.4	+1	0

*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, driven by the newly launched products in our Pharmaceuticals Division. Demand for our new medicines remains high. Health authorities granted a number of important approvals for our medicines in the first quarter. These include the first cancer immunotherapies for triple-negative breast cancer and small

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

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cell lung cancer, two diseases with high unmet patient need. Based on our performance in the first quarter, we raise the outlook for the full-year."

Outlook raised for 2019

Sales are now expected to grow in the 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.

Group sales

In the first three months of 2019, Group sales rose 8% to CHF 14.8 billion. Sales in the Pharmaceuticals Division increased 10% to CHF 11.9 billion. Key growth drivers were the multiple sclerosis medicine Ocrevus and cancer medicines Perjeta and Tecentriq as well as the new haemophilia medicine Hemlibra. As expected, the strong uptake of newly introduced medicines was partially offset by lower sales of Herceptin and of MabThera/Rituxan.

In the US, sales increased 14%, led by Ocrevus, Hemlibra, Perjeta and Tecentriq. Ocrevus sales were driven by both new and continuing patient demand.

In Europe (-6%), sales were affected by competition from biosimilars for Herceptin (-44%) and MabThera/Rituxan (-38%). This decline was partially offset by the strong growth of Ocrevus, Perjeta, Tecentriq, Alecensa and Hemlibra.

In the International region sales grew 17%, mainly driven by China. In Japan, sales increased 7%, driven by recently launched products, including Tecentriq, Hemlibra and Perjeta. This growth was partially offset by biosimilar competition for MabThera/Rituxan (-50%) and Herceptin (-9%).

Diagnostics Division sales increased 1% to CHF 2.9 billion. Molecular Diagnostics (+7%) was the main contributor, led by the growth of its cervical cancer business. In regional terms, growth was reported in EMEA[2] (+3%) and Latin America (+8%). Sales were impacted by one-time supply chain effects in Centralised and Point of Care Solutions in Asia-Pacific and in coagulation monitoring systems in North America.

Important milestones for Roche medicines

In the first quarter, regulatory authorities approved new indications for a number of Roche medicines, granted priority review procedures for and recommended approvals of several Roche drug candidates.

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[2] EMEA = Europe, Middle East and Africa

The US Food and Drug Administration (FDA) approved Tecentriq in combination with carboplatin and etoposide (chemotherapy) for the initial (first-line) treatment of adults with extensive-stage small cell lung cancer. This approval is based on results from the phase III IMpower133 study.

The FDA granted accelerated approval to Tecentriq plus chemotherapy (paclitaxel protein-bound particles for injectable suspension) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer in people whose tumours express PD-L1, as determined by an FDA-approved test. This decision is based on progression-free survival (PFS) data from the phase III IMpassion130 study.

The European Commission approved Tecentriq in combination with Avastin, paclitaxel and carboplatin for the first-line treatment of adults with metastatic non-squamous non-small cell lung cancer (NSCLC), including EGFR mutant or ALK-positive NSCLC after failure of appropriate targeted therapies.

Furthermore, the European Commission approved Hemlibra for routine prophylaxis of bleeding episodes in people with severe haemophilia A without factor VIII inhibitors. Hemlibra can be used in all age groups, and now also at multiple dosing options (once weekly, every two weeks, or every four weeks) for all indicated people with haemophilia A, including those with factor VIII inhibitors.

The FDA approved Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) for subcutaneous (under the skin) injection for the treatment of certain people with HER2-positive early breast cancer in combination with chemotherapy and HER2-positive metastatic breast cancer in combination with paclitaxel or alone in people who have received one or more chemotherapy regimens for metastatic disease. This new treatment includes the same monoclonal antibody as intravenous Herceptin in combination with recombinant human hyaluronidase PH20, an enzyme that helps to deliver trastuzumab under the skin.

The European Commission approved MabThera for the treatment of adults with moderate to severe pemphigus vulgaris, a rare condition characterised by progressive painful blistering of the skin and/or mucous membranes. Extensive blistering can lead to serious, life-threatening fluid loss, infection and/or death.

Progress in the product pipeline

The FDA granted priority review for entrectinib for the treatment of adult and paediatric patients with neurotrophic tropomyosin receptor kinase (NTRK) fusion-positive, locally advanced or metastatic solid tumours who have either progressed following prior therapies or as an initial therapy when there are no acceptable standard therapies, and for the treatment of people with metastatic, ROS1-positive NSCLC.

The FDA also granted priority review for polatuzumab vedotin in combination with bendamustine plus MabThera/Rituxan (BR) for the treatment of people with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL).

Roche completed the submission of a supplemental Biologics License Application to the FDA for Kadcyla for adjuvant treatment of people with HER2-positive early breast cancer (eBC) with residual disease after neoadjuvant treatment. The FDA is reviewing the application under the Real-Time Oncology Review and Assessment Aid pilot programmes, which aim to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible.[3]

Roche and Spark Therapeutics, Inc. announced that they have entered into a definitive merger agreement for Roche to acquire Spark Therapeutics in full. Spark Therapeutics, based in Philadelphia, Pennsylvania, USA, is a fully integrated company committed to discovering, developing and delivering gene therapies for genetic diseases, including blindness, haemophilia, lysosomal storage disorders and neurodegenerative diseases.

Roche Diagnostics: companion test for triple-negative breast cancer

The FDA approved the Ventana PD-L1 (SP142) Assay[4] as the first companion diagnostic to help identify triple-negative breast cancer (TNBC) patients eligible for treatment with Tecentriq plus chemotherapy (paclitaxel protein-bound particles for injectable suspension). The assessment of PD-L1 biomarker status on tumour-infiltrating immune cells with the assay is essential for identifying the patients most likely to benefit from the treatment.

A diagnosis of triple-negative breast cancer means that the three most common proteins associated with breast cancer growth – oestrogen receptor, progesterone receptor and HER2/neu – are not expressed on the tumour.

[3] https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OCE/ucm612927.htm.

[4] This product is intended for in vitro diagnostic (IVD) use.

Pharmaceuticals Division

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Avastin	1,798	9	824	12	461	1	194	2	319	16
MabThera/Rituxan	1,694	-3	1,168	9	171	-38	28	-50	327	-4
Herceptin	1,666	-6	791	3	300	-44	56	-9	519	26
Perjeta	868	41	412	36	267	27	51	74	138	83
Ocrevus	836	67	715	54	92	232	-	-	29	261
Actemra/RoActemra	534	6	212	5	174	4	86	13	62	10
Xolair	469	1	469	1	-	-	-	-	-	-
Lucentis	457	11	457	11	-	-	-	-	-	-
Activase/TNKase	362	7	351	7	-	-	-	-	11	-10
Tecentriq	336	135	216	91	57	158	33	-	30	262

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

Key pharmaceutical products

Avastin (+9%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales growth was driven by the US (+12%) and the International region (+16%), in particular in China due to broader market penetration.

MabThera/Rituxan (-3%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. In Europe (-38%) and in Japan (-50%) sales were affected by biosimilars. In the US, sales increased 9%, with growth in both the immunology and oncology segments, also driven by the subcutaneous formulation.

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

Herceptin (-6%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales were impacted by biosimilar launches from mid-2018, partially offset by increased sales in China and the US.

Actemra/RoActemra (+6%). 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.

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

Lucentis (+11%, 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.

Highlights on medicines launched since 2012
Perjeta (CHF 868 million, +41%). For HER2-positive breast cancer. Sales grew in all regions. The increased demand for Perjeta for adjuvant early breast cancer therapy supports its continued strong growth. The regimen has been approved in 81 countries including the US, EU, Japan and China.

Ocrevus (CHF 836 million, +67%). For both the relapsing and primary progressive forms of multiple sclerosis (MS). Ocrevus has now been approved in 85 countries. The strong demand in both indications has continued, in addition to strong sales increases in the US growth was supported by launches in Europe and the International region.

Tecentriq (CHF 336 million, +135%). For advanced bladder cancer, advanced lung cancer, initial therapy of non-squamous NSCLC, extensive-stage small cell lung cancer and PD-L1-positive triple-negative breast cancer. Sales growth was reported by all regions, mainly driven by the US, Europe and Japan. In the US growth was driven by the new indications extensive-stage small cell lung cancer and triple-negative breast cancer.

Esbriet (CHF 250 million, +10%). For idiopathic pulmonary fibrosis (IPF). Sales continued to expand, driven by growth in the US (+7%) and Europe (+14%).

Hemlibra (CHF 219 million). For people with haemophilia A with inhibitors to factor VIII. Hemlibra is approved in this indication in more than 60 countries. It is the only approved medicine for all people with haemophilia A, with or without factor VIII inhibitors, in the US, Australia, Singapore, the UAE, Chile, Brazil and Japan. In Europe, Hemlibra is approved for inhibitor patients and those with severe haemophilia A without 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). The uptake is very strong in the US, Japan and Europe.

Alecensa (CHF 196 million, +61%). For ALK-positive lung cancer. Alecensa showed continued strong sales growth across all regions, with the Europe and the International region as the main drivers.

Gazyva/Gazyvaro (CHF 115 million, +35%). For chronic lymphocytic leukaemia (CLL), rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Sales expanded, especially in the US and in Europe.

Diagnostics Division

Sales	CHF millions		As % of sales		% change	
January - March 2019	2019	2018	2019	2018	At CER	In CHF
Diagnostics Division	2,899	2,911	100.0	100.0	+1	0
Business Areas						
Centralised and Point of Care Solutions	1,681	1,716	58.0	58.9	-1	-2
Molecular Diagnostics	502	468	17.3	16.1	+7	+7
Diabetes Care	465	478	16.0	16.4	+1	-3
Tissue Diagnostics	251	249	8.7	8.6	-1	+1
Regions						
Europe, Middle East, Africa	1,210	1,221	41.7	41.9	+3	-1
North America	764	753	26.4	25.9	-3	+1
Asia–Pacific	652	656	22.5	22.5	0	-1
Latin America	179	188	6.2	6.5	+8	-5
Japan	94	93	3.2	3.2	-3	+1

Centralised and Point of Care Solutions sales declined 1%. While the immunodiagnostics business grew 3%, clinical chemistry was down 2%. In China, sales were affected by reduced distributor inventory levels. Sales in the US were impacted by free-of-charge deliveries following the recall of CoaguChek test strips in the fourth quarter 2018.

Sales in **Molecular Diagnostics** increased 7%, making this unit the largest contributor to the division's sales growth. Sales in cervical cancer diagnosis and blood screening grew strongly.

Tissue Diagnostics sales were down 1%. Sales were impacted by BenchMark and Discovery Ultra instrument shipment delays during the first quarter resulting in lower instrument placements in the North America and the Asia-Pacific regions.

Diabetes Care sales increased 1%, mainly driven by the new Accu-Chek Guide and Accu-Chek Instant blood glucose monitoring systems. Roche expanded the collaboration agreement with Senseonics for the distribution of the Eversense XL insertable continuous glucose monitoring sensor in 17 additional markets in Europe, Latin America and the Asia Pacific region.

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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