Media Release

Basel, 25 July 2019

Roche reports very strong performance in the first half of 2019 – Outlook raised

- Group sales increase 9%[1] at constant exchange rates and 8% in Swiss francs
- Pharmaceuticals Division sales up 10%, driven mainly by Ocrevus, Hemlibra, Tecentriq and Perjeta
- Diagnostics Division sales grow 2%, primarily due to its immunodiagnostics business and overall stronger growth in the second quarter
- Approvals in the second quarter, in the US Polivy for previously treated aggressive lymphoma; Kadcyla for adjuvant treatment of HER2-positive early breast cancer; Venclexta in combination with Gazyva for previously untreated chronic lymphocytic leukaemia; in Japan Rozlytrek for the treatment of NTRK-positive tumours
- Core earnings per share grow ahead of sales at 13%
- On IFRS basis, net income increases 19%
- Outlook raised for 2019 to mid- to high-single digit sales growth, at constant exchange rates.

Key figures	**CHF millions**		**% change**	
January - June 2019	**2019**	**2018**	**At CER[1]**	**In CHF**
Group sales	30,469	28,111	+9	+8
Pharmaceuticals Division	24,194	21,847	+10	+11
Diagnostics Division	6,275	6,264	+2	0
Core operating profit	12,363	11,162	+11	+11
Core EPS - diluted (CHF)	11.12	9.84	+13	+13
IFRS net income	8,904	7,516	+19	+18

Commenting on the Group's results, Roche CEO Severin Schwan said: "In the first half of the year, we achieved very strong results, driven by high demand for our new medicines. I am very pleased with the expedited approvals health authorities granted for Polivy and Rozlytrek. These medicines represent important treatment options for patients fighting cancer. Based on the performance in the first half of the year, we are increasing the outlook for the full-year 2019."

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

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Outlook raised for 2019
Sales are now expected to grow in the mid- to high-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 results
In the first half of 2019, Group sales rose 9% to CHF 30.5 billion and core EPS grew 13%, ahead of sales. Core operating profit increased 11%, reflecting the strong underlying business performance. IFRS net income increased 19%, due to the strong underlying core results and one-time effects resulting from a remeasurement of deferred tax positions as well as the release of acquisition related provisions.

Sales in the Pharmaceuticals Division increased 10% to CHF 24.2 billion. Key growth drivers were the multiple sclerosis medicine Ocrevus, the new haemophilia medicine Hemlibra and cancer medicines Tecentriq, Perjeta and Avastin. The strong uptake of newly introduced medicines more than offset lower sales of Herceptin and of MabThera/Rituxan.

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

In Europe (-4%), sales were affected by the competition from biosimilars for Herceptin (-45%) and MabThera/Rituxan (-36%). This decline was increasingly offset by the strong growth of Ocrevus, Perjeta, Tecentriq, Alecensa and Hemlibra.

In Japan, sales increased 9%, driven by recently launched products, including Hemlibra, Tecentriq and Perjeta. The growth in Japan was partially offset by biosimilar competition for MabThera/Rituxan (-46%).

In the International region sales grew 17%, mainly driven by China with strong sales of Herceptin, Avastin and MabThera/Rituxan as well as launches of Alecensa and Perjeta.

Diagnostics Division sales increased 2% to CHF 6.3 billion. The business area Centralised and Point of Care Solutions (+3%) was the main contributor, led by the growth of the immunodiagnostics business. In regional terms, growth was reported in Asia-Pacific (+5%) and EMEA[2] (+3%). Sales declined in North America (-2%).

Core operating profit increased 11% in the Pharmaceuticals Division and 4% in the Diagnostics Division.

[2] EMEA = Europe, Middle East and Africa

Important milestones for Roche medicines
In the second quarter, health authorities granted several approvals for Roche medicines. The US Food and Drug Administration (FDA) granted accelerated approval for Polivy (polatuzumab vedotin-piiq) in combination with bendamustine plus Rituxan for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma who have received at least two prior therapies. The FDA's Accelerated Approval Program allows the conditional approval of a medicine that fulfils an unmet medical need for a serious condition.

In Japan, the Ministry of Health, Labour and Welfare (MHLW) approved Rozlytrek (entrectinib) for the treatment of adult and paediatric patients with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive, advanced recurrent solid tumours. Rozlytrek is the first tumour-agnostic medicine to be approved in Japan that targets NTRK gene fusions, which have been identified in a range of hard-to-treat solid tumour types, including pancreatic, thyroid, salivary gland, breast, colorectal, and lung.[3] Separately, the MHLW approved the FoundationOne CDx Cancer Genomic Profile as a companion diagnostic for Rozlytrek.

Kadcyla received FDA approval for adjuvant (after surgery) treatment of people with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant (before surgery) taxane and Herceptin-based treatment. Kadcyla was reviewed and approved under the FDA's Real-Time Oncology Review (RTOR) and Assessment Aid pilot programmes, leading to an approval in just over 12 weeks after completing the submission. Kadcyla is the first Roche medicine approved under the RTOR pilot programme, which is exploring a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible.

The FDA also approved Venclexta/Venclyxto in combination with Gazyva/Gazyvaro for the treatment of people with previously untreated chronic lymphocytic leukaemia or small lymphocytic lymphoma, also under the FDA's new RTOR and Assessment Aid pilot programme. The approval is based on the results of the randomised phase III CLL14 study, which evaluated 12-month, fixed-duration treatment with Venclexta plus Gazyva compared to Gazyva plus chlorambucil. The results showed that the combination of Venclexta plus Gazyva produced a durable and significant reduction in the risk of disease worsening or death (progression-free survival [PFS], as assessed by Independent Review Committee) by 67% compared to Gazyva plus chlorambucil, a current standard-of-care.

The European Medicines Agency's Committee for Medicinal Products for Human Use recommended the approval of Tecentriq plus chemotherapy (Abraxane; nab-paclitaxel) for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer whose tumours have PD-L1 expression (≥ 1%) and who have not received prior chemotherapy for metastatic disease.

[3] Demetri GD et al. Efficacy and Safety of Entrectinib in Patients with NTRK Fusion-Positive (NTRK-fp) Tumors: Pooled Analysis of Startrk-2, Startrk-1 and Alka-372-001. Presented at ESMO 2018; October 19-23, 2018; Munich, Germany. Abstract LBA17.

Progress in the product pipeline
New data from the Ocrevus studies showed higher exposure to the medicine correlated with a lower risk of disability progression and lower B-cell levels in patients with MS. Importantly, safety findings remained consistent across all exposure levels.

Long-term data from the phase III Opera and Oratorio open-label extension (OLE) trials in RMS and PPMS show that earlier treatment with Ocrevus significantly reduced the risk of permanent disability progression and this effect was sustained over time

With more than 100,000 patients now treated globally, real-world and study experience with Ocrevus is rapidly growing. Ocrevus safety remains in line with the benefit-risk profile assessed in pivotal studies and assigned in the label.

Positive additional results of a prespecified exploratory analysis from the phase III IMpower150 study demonstrated that the combination of Tecentriq, Avastin, carboplatin and paclitaxel (chemotherapy) gave patients with chemotherapy-naïve, metastatic non-squamous non-small cell lung cancer (NSCLC), with baseline liver metastases an overall survival (OS) advantage compared with the combination of Avastin and chemotherapy. In addition, Tecentriq, Avastin and chemotherapy reduced the risk of disease worsening or death (PFS) by 59% in patients with baseline liver metastases, compared with Avastin and chemotherapy.

Results from the pivotal phase III CLL14 study in previously untreated chronic lymphocytic leukaemia (CLL) show that Venclexta/Venclyxto plus Gazyva/Gazyvaro met the primary endpoint of investigator-assessed PFS. The 12-month, fixed-duration, chemotherapy-free combination reduced the risk of disease worsening or death by 65% compared to Gazyva/Gazyvaro plus chlorambucil, when given to people with previously untreated CLL who have co-existing medical conditions.

The phase I/II Startrk-NG study showed entrectinib shrank tumours (objective response rate; ORR) in all children and adolescents who had NTRK, ROS1 or ALK fusion-positive solid tumours (11 of 11 patients), including two patients achieving a complete response. The study evaluates the investigational medicine entrectinib in children and adolescents with recurrent or refractory solid tumours with and without NTRK, ROS1 or anaplastic lymphoma kinase (ALK) gene fusions.

In spinal muscular atrophy (SMA) data from the dose-finding part 1 of the pivotal Firefish trial showing infants with type 1 SMA achieved key motor milestones after one year of treatment with investigational risdiplam. Furthermore, data from part 1 of the pivotal Sunfish trial in people aged 2 -25 years with type 2 or 3 SMA were presented at the AAN meeting.[4] A sustained median increase from baseline in SMN protein of greater than two-fold, as measured in blood, was seen after 12 months of treatment with risdiplam. Roche is planning to include these new data in regulatory filing with the FDA.

The Xofluza phase III Ministone-2 study met its primary endpoint, demonstrating that Xofluza was well tolerated in children with flu. The study also showed that Xofluza is comparable to oseltamivir – a proven

[4] 71st American Academy of Neurology (AAN) Annual Meeting from 4-10 May in Philadelphia, Pennsylvania

effective treatment for children with flu – at reducing the duration of flu symptoms, including fever. The study assessed Xofluza versus an active comparator (oseltamivir) in children aged between one and less than 12 years old with flu. Additionally, the phase III Blockstone study showed Xofluza is effective at preventing influenza infection in healthy people compared with placebo after exposure to an infected household member.

In February 2019, Roche announced that it had entered into a definitive merger agreement to fully acquire Spark Therapeutics, Inc. ('Spark Therapeutics'). Regulatory review of the transaction is ongoing, and the parties are actively working with the US and UK authorities to facilitate that process. The closing of the transaction is currently expected to take place in 2019. 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 – next generation solutions for individualised treatments
The Navify Tumor Board 2.0, the first collaboration product with GE Healthcare, was released for the markets. Incorporating medical image viewing and storage capabilities with other patient data, the product enables tumour boards - multi-disciplinary teams who determine treatment plans for cancer patients - to have a more comprehensive view of each patient in one place. The integration of GE Healthcare's medical image viewer into Navify Tumor Board 2.0 enables radiologists to upload their patient records to the same dashboard where patient files from other disciplines in the cancer care team are stored. Having complete patient diagnostic information in one location helps specialists use the limited time they have during tumour boards to review all relevant files quickly and agree on the best possible treatment plan for each cancer patient.

Roche launched the Ventana HER2 Dual ISH DNA Probe Cocktail companion diagnostic test for breast and gastric cancer patients eligible for targeted therapy. HER2 - human epidermal growth factor receptor 2 - is an important biomarker in breast and gastric cancers, and its detection and inhibition can help manage these aggressive diseases more effectively. This test is designed to be completed within the same day, enabling clinicians to get results back quicker than with the most common methods of confirmatory testing for HER2. Results can be read using light transmission microscopy, eliminating the need for a specialised fluorescence microscope.

The cobas MTB-RIF/INH test to detect resistance to antibiotics within tuberculosis DNA was launched in countries accepting the CE-mark. This assay is part of the mycobacteria test menu that includes the cobas MTB and cobas MAI tests for use on the cobas 6800/8800 Systems. This continues the expansion of the testing menu on the cobas 6800/8800 Systems, supporting true consolidation and efficient testing. Tuberculosis is the leading cause of infectious disease deaths worldwide.[5] The rising challenge of drug resistance compounds the global tuberculosis health crisis. The high sensitivity of the cobas MTB test enables the increased detection of tuberculosis in challenging smear-negative samples.

[5] World Health Organization. Global tuberculosis report 2018. Geneva, Switzerland; WHO, 2018.

Pharmaceuticals Division

Sales January - June 2019	CHF millions		As % of sales		% change	
	2019	2018	2019	2018	At CER	In CHF
Pharmaceuticals Division	24,194	21,847	100.0	100.0	+10	+11
United States	13,370	11,378	55.3	52.1	+14	+18
Europe	4,221	4,528	17.5	20.7	-4	-7
Japan	1,988	1,781	8.2	8.2	+9	+12
International*	4,615	4,160	19.0	19.0	+17	+11

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

Key pharmaceutical products in 2019

Avastin (+7%). 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 (+9%) and the International region (+13%), in particular in China due to broader market penetration.

MabThera/Rituxan (-4%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. In Europe (-36%) and in Japan (-46%) sales were affected by biosimilars. In the US, sales increased 4%, with growth in both the immunology and oncology segments, also driven by the subcutaneous formulation. In China, growth resulted from a broader market penetration.

HER2-franchise (Herceptin, Perjeta and Kadcyla, +5%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer (Herceptin only).

Herceptin (-9%). 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 (-2%) by the switch to Kadcyla in the adjuvant setting. 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, Japan and Europe.

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

Lucentis (+10%, 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 1.8 billion, +34%). 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.

Ocrevus (CHF 1.7 billion, +63%). For both the relapsing (RMS) and primary progressive (PPMS) forms of multiple sclerosis (MS). 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 782 million, +141%). 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 triple-negative breast cancer and extensive-stage small cell lung cancer.

Hemlibra (CHF 535 million). Approved for people with haemophilia A with factor VIII inhibitors in over 70 countries and for people with haemophilia A without factor VIII inhibitors in over 40 countries worldwide. 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, Europe and Japan.

Esbriet (CHF 532 million, +11%). For idiopathic pulmonary fibrosis (IPF). Sales continued to expand, driven by growth in the US (+8%) and Europe (+16%).

Alecensa (CHF 421 million, +50%). For ALK-positive lung cancer. Alecensa showed continued strong sales growth across all regions, with Europe and the International region as the main drivers.

Gazyva/Gazyvaro (CHF 241 million, +36%). For chronic lymphocytic leukaemia (CLL), rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Sales expanded, especially in Japan, Europe and in the US.

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Avastin	3,659	7	1,630	9	920	2	424	3	685	13
MabThera/Rituxan	3,339	-4	2,281	4	323	-36	58	-46	677	2
Herceptin	3,264	-9	1,509	-2	568	-45	123	-2	1,064	21
Perjeta	1,755	34	788	22	541	28	120	87	306	77
Ocrevus	1,735	63	1,456	50	211	179	-	-	68	204
Actemra/RoActemra	1,135	8	460	8	355	6	188	12	132	13
Xolair	972	1	972	1	-	-	-	-	-	-
Lucentis	928	10	928	10	-	-	-	-	-	-
Tecentriq	782	141	508	124	134	129	75	386	65	173
Activase/TNKase	686	2	661	2	-	-	-	-	25	-2

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

Diagnostics Division

Sales	CHF millions		As % of sales		% change	
January - June 2019	2019	2018	2019	2018	At CER	In CHF
Diagnostics Division	6,275	6,264	100.0	100.0	+2	0
Business Areas						
Centralised and Point of Care Solutions	3,762	3,755	59.9	60.0	+3	0
Molecular Diagnostics	1,029	979	16.4	15.6	+6	+5
Diabetes Care	958	991	15.3	15.8	+1	-3
Tissue Diagnostics	526	539	8.4	8.6	-3	-2
Regions						
Europe, Middle East, Africa	2,456	2,492	39.2	39.8	+3	-1
Asia–Pacific	1,606	1,573	25.6	25.1	+5	+2
North America	1,589	1,570	25.3	25.1	-2	+1
Latin America	398	413	6.3	6.6	+8	-4
Japan	226	216	3.6	3.4	+2	+5

Centralised and Point of Care Solutions sales were up 3%. The immunodiagnostics business grew 7%, making this unit again the largest contributor to the division's sales growth. Recent instrument launches and respective ongoing rollouts, expansion of the test menu, increases in access to healthcare as well as increased focus on chronic disease care contribute to growth.

Sales in **Molecular Diagnostics** increased 6%, driven by blood screening as well as by continued strong demand for the cobas 6800/8800 Systems.

Tissue Diagnostics sales were down 3%. Sales were mainly impacted by BenchMark and Discovery Ultra instrument shipment delays.

Diabetes Care sales grew 1%, mainly driven by good uptake of the new Accu-Chek Guide and increasing sales of Accu-Chek Instant blood glucose monitoring systems. The Accu-Chek Guide Me, an accurate, easy-to-use, low-cost meter with connectivity, was launched in the US.

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 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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