Media Release

Basel, 16 October 2019

Roche reports very strong sales growth in the first nine months of 2019 – outlook raised

- Group sales increase 10%[1] at constant exchange rates and 9% in Swiss francs, due to new products
- Pharmaceuticals Division sales up 12%, driven by high demand for recently launched medicines, mainly Ocrevus, Hemlibra, Tecentriq and Perjeta
- Diagnostics Division sales grow 4%, primarily due to its immunodiagnostic testing portfolio
- New treatment options and diagnostic test approved in the third quarter:
  - in the US Rozlytrek for lung cancer with a specific gene mutation and solid tumours carrying a certain gene fusion
  - in the EU three new indications for Tecentriq: for a certain type of breast cancer; for the initial treatment of non-small cell as well as small cell lung cancer
  - in the US cobas Babesia test for individual blood donation testing to reduce transmission of this parasite through transfusions
- Outlook raised again: Roche now expects sales to grow in the high-single digit range, at constant exchange rates, for 2019

Sales	**CHF millions**		**As % of sales**		**% change**	
January - September 2019	**2019**	**2018**	**2019**	**2018**	**At CER**	**In CHF**
Group sales	46,066	42,080	100.0	100.0	+10	+9
Pharmaceuticals Division	36,559	32,702	79.4	77.7	+12	+12
United States	20,036	17,192	43.5	40.9	+14	+17
Europe	6,310	6,607	13.7	15.7	-1	-4
Japan	3,076	2,700	6.7	6.4	+11	+14
International*	7,137	6,203	15.5	14.7	+20	+15
Diagnostics Division	9,507	9,378	20.6	22.3	+4	+1

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

[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: "The uptake of our newly introduced medicines is very strong. We are successfully entering new disease areas and providing important new treatment options to serve more patients with severe conditions. Based on the strong demand for our new medicines and continued progress of our product pipeline we have raised the outlook for 2019 and I am confident that we will continue to grow beyond this year."

Outlook raised
Sales are now expected to grow in the 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 nine months of 2019, Group sales rose 10% to CHF 46.1 billion. Sales in the Pharmaceuticals Division increased 12% to CHF 36.6 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, Kadcyla, Perjeta and Avastin. Ocrevus sales were driven by both new and returning patient demand.

In Europe (-1%), sales were affected by the competition from biosimilars for Herceptin (-44%) and MabThera/Rituxan (-33%). This decline was almost offset by the strong growth of Ocrevus, Perjeta, Tecentriq, Alecensa and Hemlibra.

In Japan, sales increased 11%, driven by recently launched products, including Hemlibra, Perjeta and Tecentriq. The growth in Japan was partially offset by lower sales of MabThera/Rituxan (-46%) driven by biosimilar competition.

In the International region sales grew 20%, mainly driven by significantly increased numbers of patients benefitting from Roche cancer drugs in China with strong sales of Herceptin, Avastin and MabThera/Rituxan as well as the uptake of Perjeta and Alecensa.

Diagnostics Division sales increased 4% to CHF 9.5 billion. The business area Centralised and Point of Care Solutions (+5%) was the main contributor, with growth driven by the immunodiagnostics business. Growth was reported in Asia-Pacific (+9%), EMEA[2] (+3%) and Latin America (+9%). In North America sales declined 1%.

[2] EMEA = Europe, Middle East and Africa

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. Closing of the transaction is expected until the end of this year.

Important milestones for Roche medicines
In the third quarter, health authorities granted approvals for several Roche medicines which represent important new treatment options for patients with severe diseases.

The European Commission approved Tecentriq plus chemotherapy (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.

Furthermore, the European Commission also granted one-year extension of the Market Exclusivity for Tecentriq on the basis that the new indication with the combination brings significant benefit over existing therapies.

The Commission also approved Tecentriq in combination with chemotherapy (carboplatin and etoposide) for the initial (first-line) treatment of adults with extensive-stage small cell lung cancer.

Further, the Commission approved Tecentriq in combination with chemotherapy (nab-paclitaxel), for the initial treatment of adults with metastatic non-squamous non-small cell lung cancer (NSCLC) who do not have EGFR mutant or ALK-positive NSCLC.

The US Food and Drug Administration (FDA) approved Rozlytrek for the treatment of adults with ROS1-positive, metastatic NSCLC. The FDA has also granted accelerated approval to Rozlytrek for the treatment of adult and paediatric patients 12 years of age and older with solid tumours that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy.

Furthermore, FDA approved MabThera/Rituxan, in combination with glucocorticoids, for the treatment of granulomatosis with polyangiitis and microscopic polyangiitis in paediatric patients 2 years of age and older. Both are rare, potentially life-threatening diseases affecting small and medium sized blood vessels.

The FDA granted Breakthrough Therapy Designation to Gazyva for adults with lupus nephritis. This designation was granted based on data from the phase II Nobility study in adult patients with proliferative lupus nephritis which showed Gazyva, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrated enhanced efficacy compared to placebo plus standard of care alone in achieving complete renal response at one year.

The FDA also granted Breakthrough Therapy Designation for Cotellic in histiocytic neoplasms, who do not harbor the BRAF V600 mutation. This was based on a phase II study in adults with histiocytosis of any mutational status demonstrating a high overall response rate of 89%.

Progress in the product pipeline
The phase III FeDeriCa study met its primary endpoint and showed a new investigational fixed-dose combination of Perjeta and Herceptin, administered by subcutaneous injection in combination with intravenous chemotherapy, demonstrated non-inferior levels of Perjeta in the blood (pharmacokinetics) compared to standard IV infusion of Perjeta plus Herceptin and chemotherapy in people with HER2-positive early breast cancer. This way of drug administration is typically preferred by patients and significantly reduces the time spent receiving treatment**.**

Longer-term data from the phase III open-label extension studies (Opera I, Opera II and Oratorio) showed that patients who were treated with Ocrevus continuously for six years or more had reduced risk of disability progression in relapsing MS and primary progressive MS. These results suggest earlier treatment with Ocrevus, administered twice yearly, reduced the risk of disability progression and this effect was sustained over time. More than 130,000 people 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 phase III IMpower110 study evaluating Tecentriq as a first-line (initial) monotherapy compared with chemotherapy (cisplatin or carboplatin and pemetrexed or gemcitabine) in advanced non-squamous and squamous NSCLC without ALK or EGFR mutations met its primary endpoint at an interim analysis. The study showed that Tecentriq monotherapy demonstrated a statistically significant overall survival benefit of 7.1 months in people with high PD-L1 expression, compared with chemotherapy alone.

The phase III IMvigor130 study with Tecentriq plus platinum-based chemotherapy met its co-primary endpoint of investigator-assessed progression-free survival. The study showed a statistically significant reduction in the risk of disease worsening or death in people with previously untreated locally advanced or metastatic urothelial carcinoma compared with chemotherapy alone.

The phase III Ministone-2 study showed that one-dose Xofluza was a well-tolerated and effective potential treatment for flu in otherwise healthy children aged one to less than 12 years old. The study met its primary endpoint, which evaluated the proportion of patients with adverse events (AEs) or severe AEs up to study day 29, demonstrating results consistent with the safety profile of Xofluza.

Separately, the phase III Blockstone study showed preventive treatment with Xofluza after exposure to an infected household member significantly reduced the risk of people developing flu by 86% versus placebo. The results showed just 1.9% of Xofluza-treated household members had flu compared with 13.6% in the placebo-treated group.

Roche presented full pivotal phase III study results for satralizumab, which targets the interleukin-6 (IL-6) receptor, for neuromyelitis optica spectrum disorder (NMOSD), a rare, debilitating central nervous system

disease.[3] Results from the SAkuraStar study show that satralizumab monotherapy achieved a 55% reduction in the risk of relapses compared to placebo in the overall group of people with NMOSD, reflective of the real-world population. A 74% reduction in the risk of relapse for satralizumab monotherapy versus placebo was shown in people with aquaporin-4 antibodies (AQP4-IgG seropositive patients).

Roche Diagnostics – new tests and increased access

The FDA cleared the cobas pro integrated solutions, a new generation of Serum Work Area (clinical chemistry and immunochemistry) laboratory solution, designed to optimise laboratory operations. With the cobas pro integrated solutions, laboratories are now able to run tests faster on less equipment, automate manual tasks and deliver results more quickly to aid in treatment decisions. **This** in-turn is helping physicians to provide evidence-based diagnostic and treatment decisions more cost-effectively and quickly for all patients.

The FDA approved the cobas Babesia whole blood test for use on the cobas 6800/8800 Systems for individual blood donation testing. This is Roche's first commercially available whole blood test to screen donations and follows May 2019's FDA-updated industry guidance recommending screening and testing for Babesia, to reduce the risk of transmitting this parasite through transfusions.

Roche launched the cobas EBV and BKV Tests for use on the cobas 6800/8800 Systems for transplant patients in countries accepting the CE mark. Immunocompromised transplant recipients are at risk of major complications when infected with Epstein-Barr or BK viruses (BKV is member of the human polyomavirus family). With the new tests, healthcare professionals can now determine which transplant patients are at risk of further complications caused by reactivation of these viruses.

The Global Access Program was expanded beyond HIV, to include Mycobacterium tuberculosis (MTB), Hepatitis B and C (HBV and HCV), and Human Papillomavirus (HPV) for low and middle-income country programmes where the disease burden is the highest. The expansion of the Global Access Program highlights Roche's commitment to make cost-effective resources more easily available for many people, implement scale-up programs, and contribute to the elimination of diseases in the regions with the greatest need.

[3] 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)

Pharmaceuticals Division

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Avastin	5,465	8	2,372	7	1,355	3	665	5	1,073	18
MabThera/Rituxan	4,959	-3	3,389	4	470	-33	84	-46	1,016	2
Herceptin	4,799	-9	2,174	-4	801	-44	185	-1	1,639	21
Perjeta	2,665	34	1,158	17	805	24	201	101	501	93
Ocrevus	2,664	57	2,216	44	338	169	-	-	110	164
Actemra/RoActemra	1,706	9	696	9	527	5	295	12	188	14
Xolair	1,485	2	1,485	2	-	-	-	-	-	-
Lucentis	1,370	9	1,370	9	-	-	-	-	-	-
Tecentriq	1,297	146	837	149	227	122	125	174	108	155
Activase/TNKase	1,020	3	981	3	-	-	-	-	39	0

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

Key pharmaceutical products in 2019

Avastin (+8%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales growth was driven by the International region (+18%), in particular in China due to increased numbers of patients treated, and the US (+7%).

MabThera/Rituxan (-3%). For forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. In Europe (-33%) 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 increased numbers of patients treated.

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 (-4%) by the switch to Kadcyla in the adjuvant setting. This development was partially offset by increased sales in China.

Actemra/RoActemra (+9%). 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 (+2%, US only). For chronic idiopathic urticaria and allergic asthma. Growth was reported in both indications.

Lucentis (+9%, 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 2.7 billion, +34%). 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.

Ocrevus (CHF 2.7 billion, +57%). For both the relapsing (RMS) and primary progressive (PPMS) forms of multiple sclerosis (MS). The strong patient demand in both indications has continued. In addition to sales increases in the US, growth was supported by launches in additional markets.

Tecentriq (CHF 1.3 billion, +146%). For advanced bladder cancer, advanced lung cancer, initial therapy of non-squamous NSCLC, extensive-stage small cell lung cancer and PD-L1-positive advanced triple-negative breast cancer. Sales growth was reported by all regions. In the US growth was driven by the new indications triple-negative breast cancer and extensive-stage small cell lung cancer.

Kadcyla (CHF 1.0 billion, +40%). For HER2-positive breast cancer. The increased demand for Kadcyla was driven by the US and the International region, supported by its usage in patients with residual disease after surgery.

Hemlibra (CHF 921 million). Approved for people with haemophilia A with factor VIII inhibitors in almost 90 countries and for people with haemophilia A without factor VIII inhibitors in almost 60 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, Japan and Europe.

Esbriet (CHF 813 million, +9%). For idiopathic pulmonary fibrosis (IPF). Sales continued to expand, driven by growth in Europe (+19%) and the US (+5%).

Alecensa (CHF 656 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 390 million, +40%). For chronic lymphocytic leukaemia (CLL), rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Sales expanded in all regions.

Diagnostics Division

Sales	CHF millions		As % of sales		% change	
January - September 2019	**2019**	**2018**	**2019**	**2018**	**At CER**	**In CHF**
Diagnostics Division	9,507	9,378	100.0	100.0	+4	+1
Business Areas						
Centralised and Point of Care Solutions	5,766	5,625	60.6	60.0	+5	+3
Molecular Diagnostics	1,547	1,468	16.3	15.7	+7	+5
Diabetes Care	1,395	1,484	14.7	15.8	-2	-6
Tissue Diagnostics	799	801	8.4	8.5	0	0
Regions						
Europe, Middle East, Africa	3,617	3,666	38.0	39.1	+3	-1
Asia–Pacific	2,550	2,406	26.8	25.7	+9	+6
North America	2,366	2,344	24.9	25.0	-1	+1
Latin America	615	623	6.5	6.6	+9	-1
Japan	359	339	3.8	3.6	+3	+6

Centralised and Point of Care Solutions sales were up 5%. The immunodiagnostics business grew 10%, making this unit again the largest contributor to the division's sales growth. As a general trend, customers are looking for ways to increase efficiency and improve turnaround time and patient outcomes. Automation and connectivity play a very important role as do novel biomarkers. Products like cobas pro, which just recently received FDA-clearance, serve these needs.

Sales in **Molecular Diagnostics** increased 7%, driven by blood screening as well as by Sequencing sample prep and microbiology.

Tissue Diagnostics sales were stable. Sales growth of advanced staining reagents was impacted by BenchMark and Discovery Ultra instrument shipment delays. Instruments are now being shipped again.

Diabetes Care sales declined (-2%), resulting from price pressure in some European and Asia-Pacific 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. 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 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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