Media Release

Ad hoc announcement pursuant to Art. 53 LR

Basel, 21 July 2022

Roche achieves good results in the first six months of 2022

- **Group sales** up 5%[1] at constant exchange rates (CER) and 5% in Swiss francs
- **Pharmaceuticals Division sales** increase 3%; continued strong demand for new medicines to treat severe diseases; as expected, the impact of biosimilars slows down further
- **Diagnostics Division sales** grow 11%; ongoing strong base business; demand for COVID-19 tests is expected to decline in the second half of the year
- **IFRS net income** increases by 12% (12% in Swiss francs), while **core earnings per share** are up 11%
- **Highlights** in the second quarter:
    - EU approvals of **Polivy** (first-line treatment for aggressive form of blood cancer), **Lunsumio** (follicular lymphoma) and **Tecentriq** (early-stage lung cancer); EU marketing authorisation application submitted for **glofitamab** (blood cancer)
    - US approval of **Evrysdi** (babies under two months of age with spinal muscular atrophy) and US priority review for **Lunsumio**
    - Launch of innovative platforms and systems for tissue-based cancer diagnostics, of HPV self-sampling solution and monkeypox virus test kits
- **Outlook for 2022 confirmed**

Roche CEO Severin Schwan: “We achieved good results in the first half of the year, thanks to the continued strong demand for our diagnostics base business and our new medicines to treat haemophilia, cancer and neurological disorders. Thanks to the ongoing renewal of our portfolio, we continue to grow despite biosimilars, whose impact declined further as expected. Based on our current assessment, we confirm the outlook for the full year.”

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Key figures January - June 2022	CHF millions		% change	
	2022	2021	CER	CHF
Group sales	32,295	30,713	5	5
Pharmaceuticals Division	22,347	21,671	3	3
Diagnostics Division	9,948	9,042	11	10
Core operating profit	12,668	11,652	9	9
Core EPS (in CHF) - diluted	11.76	10.56	11	11
IFRS net income	9,161	8,216	12	12

Outlook confirmed for 2022

Sales are expected to be stable or grow in the low-single digits (at constant exchange rates). Core earnings per share are targeted to grow in the low- to mid-single digit range (at constant exchange rates), including the accretive effect of the 2021 share repurchase. Roche expects to further increase its dividend in Swiss francs.

Roche anticipates sales of COVID-19 medicines and diagnostics to decrease by approximately CHF 2 billion to around CHF 5 billion, and sales losses due to biosimilars in the current year to be roughly CHF 2.5 billion. Excluding those effects, Group sales are expected to grow in the high-single digit range.

Group results

In the first half of the year, the Roche Group achieved sales growth of 5% (5% in CHF) to CHF 32.3 billion.

IFRS net income increased 12% (12% in CHF), while **core earnings per share (EPS)** were up 11%. This includes positive effects of the resolution of a patent dispute in Japan and the repurchase of Roche shares from Novartis. In the second half of the year, core EPS is expected to be impacted by the decline of COVID-19 sales and a base effect from the resolution of several tax disputes that were recognised in the second half of 2021 and will not recur in 2022.

Pharmaceuticals Division sales increased by 3% to CHF 22.3 billion. New medicines to treat severe diseases continued their strong growth.

Hemlibra (haemophilia), Ocrevus (multiple sclerosis), Evrysdi (spinal muscular atrophy), Phesgo (breast cancer) and Tecentriq (cancer) alone contributed an additional CHF 1.5 billion in new sales.

As expected, the impact of competition from biosimilars for the established cancer medicines Avastin, Herceptin and MabThera/Rituxan slowed down further (combined CHF 1.0 billion of sales reduction).

Sales in the **United States** grew by 1%. Sales growth of new medicines such as Hemlibra, Ocrevus and Tecentriq was partly offset by the biosimilar-related decline in sales of Avastin, MabThera/Rituxan and Herceptin and a sales decrease for the eye treatment Lucentis.

Sales in **Europe** decreased by 4%. The main reason for this were lower sales of Ronapreve (COVID-19) compared to the same period last year, during which various countries placed initial orders. Excluding this base effect, sales in Europe grew 6%.

Sales in **Japan** increased by 34% mainly due to the high demand for Ronapreve and other innovative medicines such as Evrysdi, Polivy, Hemlibra and Enspryng.

Sales in the **International** region grew by 2%. Sales in China declined by 7% due to the impacts of biosimilars and the country's COVID-19 restrictions. Excluding China, the region achieved a sales growth of 7%.

Diagnostics Division sales increased by 11% to CHF 9.9 billion. The division's base business recorded continued strong growth in all regions (+6%), with immunodiagnostics products, particularly cardiac tests, as the main contributors.

Roche's industry-leading COVID-19 portfolio generated sales of CHF 3.1 billion in the first six months of the year (compared to CHF 2.5 billion during the same period last year). The demand for COVID-19 tests is likely to decrease in the third quarter of 2022.

Sales in the **Asia-Pacific** and **North America** regions increased by 39% and 34%, respectively, while sales in the **Europe, Middle East and Africa (EMEA)** region fell by 14%. This is primarily due to an increase or decrease in sales of COVID-19 tests.

Access to healthcare

In May, Roche renewed its commitment to the World Federation of Hemophilia (WFH) Humanitarian Aid Program until the end of 2028: Roche will continue to provide its prophylactic medicine Hemlibra to treat people with haemophilia A in developing countries.

Also in May, Roche entered into a partnership with the Global Fund to support low- and middle-income countries in strengthening critical diagnostic infrastructure. This new partnership aims to help millions of previously undiagnosed people with tuberculosis and HIV get diagnosed and eventually treated.

Pharmaceuticals: key approvals and development milestones in the 2nd quarter of 2022

Oncology

Oncology remains Roche's primary area of research and development. The company has one of the industry's broadest and most comprehensive oncology pipelines and portfolios.

Blood cancers are challenging to treat at all stages. In the second quarter, Roche achieved a number of milestones in this area:

- The European Commission (EC) approved the **Polivy** combination therapy for people with previously untreated diffuse large B-cell lymphoma (DLBCL). This is the first therapy in more than 20 years to significantly improve outcomes in this aggressive form of blood cancer.
- In addition, the EC approved Roche's first-in-class bispecific antibody **Lunsumio** for people with relapsed or refractory follicular lymphoma (FL), and shortly after, the FDA granted priority review for this innovative medicine. Lunsumio represents a new type of immunotherapy that is a chemotherapy-free, fixed-duration treatment option.
- **Glofitamab** is a potential first-in-class bispecific antibody that may improve the lives of people with an aggressive form of blood cancer (diffuse large B-cell lymphoma; DLBCL). Roche submitted glofitamab for approval to the European Medicines Agency.

Approximately half of all people with early-stage non-small cell lung cancer (eNSCLC) develop recurrence after surgery, which in some cases is no longer curable. Treating this cancer at an earlier stage offers thus the best chance to prevent recurrence. In June, the EC approved **Tecentriq** in eNSCLC. It is currently the first and only cancer immunotherapy available for the adjuvant treatment of certain people with eNSCLC in Europe.

Roche reported initial results from the first interim analysis of the SKYSCRAPER-01 study in PD-L1-high metastatic non-small cell lung cancer. **Tiragolumab** plus Tecentriq did not meet its co-primary endpoint of progression-free survival. The study will continue for the co-primary endpoint of overall survival to mature, which is a decisive factor in this setting.

Neurosciences

Roche has approved medicines and investigational compounds for the treatment of multiple sclerosis, spinal muscular atrophy (SMA), neuromyelitis optica spectrum disorders, Myasthenia Gravis, Alzheimer's disease, Huntington's disease, Parkinson's disease and Duchenne muscular dystrophy.

SMA affects approximately one in 10,000 babies and is the leading genetic cause of infant mortality. In May, the FDA approved **Evrysdi** for use in babies under two months of age with SMA. This approval is particularly important, as early treatment of SMA, before symptoms start to appear, can help babies achieve motor milestones. In addition, Roche announced new three-year data, reinforcing the long-term efficacy and safety of Evrysdi in infants with symptomatic type 1 SMA.

In June, Roche announced study results of **crenezumab**. The study evaluated the potential of crenezumab to slow or prevent Alzheimer's disease in cognitively unimpaired people who carry a specific genetic mutation which causes early-onset Alzheimer's disease. While the treatment did not demonstrate a statistically significant clinical benefit, Roche is confident that the rich data collected will enhance the broader scientific community's knowledge of Alzheimer's disease as well as support future research efforts in the field.

Pharmaceuticals: key development milestones in the second quarter of 2022

	Compound	Indication	Milestone
Regulatory	Polivy combination	Previously untreated diffuse large B-cell lymphoma (DLBCL)	EU approval
	Lunsumio (mosunetuzumab)	Relapsed or refractory follicular lymphoma (FL)	EU approval
	Glofitamab	Relapsed or refractory (R/R) DLBCL	Submitted for EU approval
	Evrysdi	For babies under two months of age with spinal muscular atrophy (SMA)	FDA approval
Phase III, pivotal and other key readouts	Evrysdi	SMA type 1 (infants): long-term efficacy and safety	FIREFISH study (new three-year data)
	Giredestrant	ER-positive, HER2-negative untreated early breast cancer	Phase II coopERA study (final analysis)
	Venclexta/Venclyxto plus Gazyva/Gazyvaro	Previously untreated chronic lymphocytic leukaemia	Phase III CLL14 study (new five-year data)

	Gazyva/Gazyvaro plus chemotherapy	Previously untreated FL	Phase III GALLIUM study (final analysis)
	Crenezumab	Alzheimer's disease	Phase II API ADAD (Colombia) trial: co-primary endpoints not met
	Hemlibra	Mild to moderate haemophilia A	Phase III HAVEN 6 study
	Vabysmo	Neovascular age-related macular degeneration (AMD)	Phase III TENAYA and LUCERNE studies (new two-year data)
	Perjeta	HER2-positive breast cancer: invasive disease-free survival	Phase III APHINITY study (new eight-year data)

Diagnostics: key milestones in the second quarter of 2022

Diagnostic tools are crucial for responding to and ultimately controlling emerging public health challenges. In May, Roche and its subsidiary TIB Molbiol swiftly developed three unique PCR **LightMix Modular Virus** test kits that detect the monkeypox virus and aid in tracking its epidemiologic spread.

Furthermore, Roche received FDA Emergency Use Authorization (EUA) for its **cobas SARS-CoV-2 Duo**, the first PCR test to detect the COVID-19 virus and simultaneously measure the viral load in an individual. It helps healthcare providers with contact tracing, patient triage, therapy and monitoring.

Every year, over 600,000 women worldwide are diagnosed with cervical cancer, and more than half die from the disease. Cervical cancer is caused by infection with the human papillomavirus (HPV) and is preventable with timely diagnosis. In June, Roche launched a **self-sampling solution** for the **cobas HPV test** in countries accepting the CE mark. Enabling women to self-collect their own specimens for HPV testing is a critical step in the fight against cervical cancer.

Also in June, Roche announced the CE launch of the **VENTANA DP 600**. This high-capacity slide scanner produces high-resolution, digital images of stained tissue samples that help diagnose cancer. It also enables better and more personalised healthcare: in combination with our AI image analysis algorithms, this solution can help ensure that each patient receives the most effective treatment plan possible.

In addition, Roche launched the **BenchMark ULTRA PLUS**, an advanced tissue staining platform. This system enables pathologists to provide quick and accurate results that help inform patient treatment options.

Around 60 million people worldwide live with chronic hepatitis C (HCV) infection, but only one in five is aware of it. In July, Roche launched **Elecsys HCV Duo**, the first commercially available diagnostic test for the simultaneous and independent determination of the hepatitis C virus (HCV) antigen and antibody status.

Pharmaceuticals sales

Sales	CHF millions		As % of sales		% change	
January - June 2022	2022	2021	2022	2021	At CER	In CHF
Pharmaceuticals Division	22,347	21,671	100.0	100.0	3	3
United States	11,363	10,802	50.8	49.8	1	5
Europe	4,104	4,485	18.4	20.7	-4	-8
Japan	2,202	1,808	9.9	8.3	34	22
International*	4,678	4,576	20.9	21.2	2	2

*Asia-Pacific, CEETRIS (Central Eastern Europe, Turkey, Russia and Indian subcontinent), Latin America, Middle East, Africa, Canada, others

Top-selling pharmaceuticals	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Ocrevus	2,910	17	2,140	11	539	34	-	-	231	43
Perjeta	2,061	5	740	1	457	-17	120	-1	744	34
Hemlibra	1,826	30	1,098	26	360	30	180	19	188	89
Tecentriq	1,758	11	951	13	383	19	218	-7	206	9
Actemra/RoActemra	1,455	-10	664	-7	420	-3	174	4	197	-37
Herceptin	1,179	-16	263	-27	233	-11	28	-28	655	-11
Avastin	1,142	-29	342	-38	116	-53	263	-13	421	-20
MabThera/Rituxan	1,117	-21	691	-22	105	-17	17	-8	304	-19
Kadcyla	1,074	14	415	-1	350	10	68	23	241	52
Xolair	1,025	11	1,025	11	-	-	-	-	-	-

* Asia-Pacific, CEETRIS (Central Eastern Europe, Turkey, Russia and Indian subcontinent), Latin America, Middle East, Africa, Canada, others

Pharmaceuticals sales: selected top-selling and new medicines

Ocrevus (first approved in 2017; CHF 2.9 billion, +17%). Relapsing and primary progressive forms of multiple sclerosis; two-hour-only infusion. The demand for this treatment in both indications remained strong, mainly in the United States. In Europe and the International region, Ocrevus continued to show high uptake where launched, notably in Germany, Italy, Spain and Canada.

Perjeta (first approved in 2012; CHF 2.1 billion, +5%). HER2-positive breast cancer. Sales increased mostly due to continued high demand in the International region.

Hemlibra (first approved in 2017; CHF 1.8 billion, +30%). Haemophilia A with and without factor VIII inhibitors; only prophylactic treatment that can be administered subcutaneously once weekly, every two or every four weeks. Sales continued to show an impressive uptake, especially in the United States, the International region and in Europe.

Tecentriq (first approved in 2016; CHF 1.8 billion, +11%). Cancer immunotherapy (either alone or in combinations) for various types of cancer, e.g. lung, bladder, breast and liver cancer. Sales increased mostly due to higher demand in the United States and Europe. Sales in Japan decreased, primarily due to governmental price cuts.

Actemra/RoActemra[2] (CHF 1.5 billion, -10%). Rheumatoid arthritis, forms of juvenile idiopathic arthritis and giant cell arteritis, CAR T-cell-induced severe or life-threatening cytokine release syndrome and COVID-19 pneumonia. Sales decreased mainly in the International region and United States, driven by fewer hospitalised patients with severe COVID-19 pneumonia.

Herceptin[2] (CHF 1.2 billion, -16%). HER2-positive breast cancer and HER2-positive metastatic gastric cancer. Sales decreased mainly because of biosimilar uptake in various countries.

Avastin[2] (CHF 1.1 billion, -29%). Advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, relapsed glioblastoma (a type of brain tumour) and liver cancer in combination with Tecentriq. The sales decrease was due to biosimilar uptake in various countries.

MabThera/Rituxan[2] (CHF 1.1 billion, -21%). Forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales further decreased due to the biosimilar erosion across all regions.

Kadcyla (first approved in 2013; CHF 1.1 billion, +14%). HER2-positive breast cancer. Sales growth was driven by the usage of Kadcyla in the early breast cancer setting. Patients switching to this new standard care setting also drove sales.

Xolair[2] (CHF 1.0 billion, +11%, United States only). Chronic spontaneous urticaria and allergic asthma. Sales grew in the chronic spontaneous urticaria indication. Xolair remains the market leader in the larger allergic asthma indication.

Alecensa (first approved in 2015; CHF 745 million, +19%). ALK-positive non-small-cell lung cancer. The global uptake continued with sales growth across all regions. The International region and the United States were the main drivers.

Ronapreve (first approved in 2021; CHF 609 million, +11%). Antibody combination for the prevention and treatment of recently diagnosed high-risk patients with mild to moderate COVID-19. The sales growth in Japan was partly offset by the sales decline in Europe.

Lucentis[2] (CHF 572 million, -17%, United States only). Eye conditions, including 'wet' age-related macular degeneration. Sales decreased primarily due to competitive pressure. The first biosimilar version of Lucentis (with a restricted label) has come to market in the US at the beginning of the third quarter of 2022.

Evrysdi (first approved in 2020; CHF 500 million, +106%). Spinal muscular atrophy (SMA) in adults, children and babies. It is the first and only medicine for SMA that can be administered at home. Evrysdi continued to show a strong uptake across all regions, driven by Europe and the United States.

Esbriet (first approved in 2014; CHF 457 million, -14%). Idiopathic pulmonary fibrosis (IPF). Sales declined due to a reduced share of new patient prescriptions; the first generic versions were launched in the US in the second quarter of 2022.

Gazyva/Gazyvaro (first approved in 2013; CHF 349 million, +8%). Chronic lymphocytic leukaemia, rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma. Approved as a shorter infusion time of 90 minutes, compared to the standard infusion of 3–4 hours.

Phesgo (first approved in 2020; CHF 325 million, +241%). Early and metastatic HER2-positive breast cancer (fixed-dose combination of Perjeta and Herceptin for subcutaneous injection). Offers faster administration in just minutes, compared to hours with standard intravenous administration. Sales continued to show a considerable uptake, especially in Europe and the United States.

Polivy (first approved in 2019; CHF 177 million, +91%). Previously untreated and relapsed or refractory diffuse large B-cell lymphoma; part of combination therapy; a fixed-duration treatment option for people with this aggressive form of blood cancer.

Vabysmo (first approved in 2022; CHF 109 million[3]). Neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular oedema (DME), two leading causes of vision loss. Sales of this new eye medicine showed an excellent uptake.

Enspryng (first approved in 2020; CHF 84 million, +132%). Rare autoimmune disease of the central nervous system (neuromyelitis optica spectrum disorders; NMOSD); first subcutaneous NMOSD treatment that can be self- or carer-administered at home. Enspryng continued to show a very good uptake.

Rozlytrek (first approved in 2019; CHF 34 million, +54%). Specific form of non-small cell lung cancer (NSCLC); solid tumours expressing a specific gene fusion; ROS1-positive, advanced NSCLC.

Susvimo (first approved in 2021; CHF 2 million[3]). Eye implant with continuous drug delivery for neovascular or 'wet' age-related macular degeneration (nAMD) treatment.

Diagnostics sales

Sales	CHF millions		As % of sales		% change	
January - June 2022	2022	2021	2022	2021	At CER	In CHF
Diagnostics Division	9,948	9,042	100.0	100.0	11	10
Customer Areas						
Core Lab[4]	3,875	3,770	38.9	41.7	4	3
Point of Care[4]	2,609	1,798	26.2	19.9	46	45
Molecular Lab[4]	1,980	1,990	19.9	22.0	1	-1
Diabetes Care	832	894	8.4	9.9	-5	-7
Pathology Lab	652	590	6.6	6.5	10	11
Regions						
Europe, Middle East, Africa	3,350	4,144	33.4	45.8	-14	-19
North America	2,868	2,055	29.0	22.7	34	40
Asia–Pacific	3,171	2,293	32.0	25.4	39	38
Latin America	559	550	5.6	6.1	2	2

Core Lab. Focuses on central labs; provides diagnostics solutions in the areas of immunoassays, clinical chemistry and custom biotech. Sales increased by 4% due to the growth of routine testing mainly in the areas of immunoassays, with cardiac tests as main contributors, and clinical chemistry. Sales grew across all regions, with the largest contribution coming from EMEA and Asia-Pacific.

Point of Care. Focuses on diagnostics solutions in emergency rooms, medical practices or directly with patients; includes SARS-CoV-2 rapid tests, blood gas and electrolyte tests. Continued significant sales growth of 46%. The SARS-CoV-2 Rapid Antigen test was the main growth driver, especially in the Asia-Pacific and North America regions.

Molecular Lab. Focuses on molecular labs; provides diagnostics solutions for pathogen detection and monitoring, donor screening, sexual health and genomics. The sales growth was driven by growth in the base business across the portfolio and by the GenMark business, which was acquired in April 2021. This growth was largely offset by lower COVID-19-related sales in the EMEA and North America regions. The Asia-Pacific region was the main driver of growth.

Diabetes Care. Focuses on integrated personalised diabetes management for people with diabetes and healthcare professionals. Sales decreased by 5% due to the base effect of the resolution of a rebate dispute in the first quarter of 2021. Excluding this, sales decreased by 1% as a result of the continued contraction of the blood glucose monitoring market. This was partly offset by higher demand in emerging markets.

Pathology Lab. Focuses on pathology labs; provides diagnostics solutions for tissue biopsies and companion diagnostics. These targeted diagnostics support the specific therapy decisions for each patient. Sales increased by 10% due to growth in the advanced staining business and the companion diagnostics business.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

References

[1] Unless otherwise stated, all growth rates and comparisons to the previous year in this document are at constant exchange rates (CER: average rates 2021) and all total figures quoted are reported in CHF.
[2] Established products (launched before 2012), including Actemra/RoActemra, Avastin, Herceptin, MabThera/Rituxan, Xolair, Lucentis, Activase/TNKase, Pulmozyme and CellCept.
[3] Recently approved; no growth figures available.
[4] Sales in the Point of Care customer area include sales from the Liat business (POC molecular), and sales in the Core Lab customer area include sales from the Life Science Alliances business. These were both previously shown as part of the Molecular Lab customer area. The comparative information for 2021 has been restated accordingly.
POC molecular sales: Q1/21 = CHF 90m, Q2/21 = CHF 92m, Q3/21 = CHF 175m, Q4/21 = CHF 194m.
Life Science Alliances sales: Q1/21 = CHF 21m, Q2/21 = CHF 23m, Q3/21 = CHF 23m, Q4/21 = CHF 20m.

Cautionary statement regarding forward-looking statements

This document contains certain forward-looking statements. These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this document, such as: (1) pricing and product initiatives of competitors; (2) legislative and regulatory developments and economic conditions; (3) delay or inability in obtaining regulatory approvals or bringing products to market; (4) fluctuations in currency exchange rates and general financial market conditions; (5) uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side effects of pipeline or marketed products; (6) increased government pricing pressures; (7) interruptions in production; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity and news coverage. The statement regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche's earnings or earnings per share for this or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

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