Media Release

Ad hoc announcement pursuant to Art. 53 LR

Basel, 18 October 2022

Roche records solid results for the first nine months of 2022

- **Group sales** up 2%[1] at constant exchange rates (CER) and 1% in Swiss francs; as expected, significantly lower COVID-19-related sales in both divisions in the third quarter
- **Sales in the Pharmaceuticals Division** at the previous year's level with significantly lower sales of COVID-19-related products (Ronapreve and Actemra/RoActemra) and losses to biosimilars, offset by strong growth of newer medicines
- **Sales in the Diagnostics Division** rise 6%; base business remains strong; as expected, demand for COVID-19 tests sharply down in third quarter
- **Highlights** in the third quarter:
    - EU approval for **Vabysmo** (severe eye diseases)
    - US approvals for **Xofluza** (influenza in children)
    - Launch of a digital PCR diagnostic platform and of COVID-19, skin and breast cancer tests
    - "Breakthrough Device Designation" granted for Alzheimer's blood tests
- **Outlook for 2022 confirmed**

Severin Schwan, CEO of Roche: "Group sales grew 2% despite the expected sharp decline in COVID-19-related products in both divisions in the third quarter. The demand for our newer medicines for multiple sclerosis, haemophilia, spinal muscular atrophy and cancer remains high. I am particularly pleased that so many patients with severe eye disease have already accessed our new medicine Vabysmo and started treatment. Likewise, our Diagnostics Division base business continued to grow strongly. Based on our current assessment, we confirm the outlook for the full year."

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Sales	CHF millions		As % of sales		% change	
January–September 2022	2022	2021	2022	2021	At CER	In CHF
Group sales	47,037	46,684	100.0	100.0	2	1
Pharmaceuticals Division	33,189	33,379	70.6	71.5	0	-1
United States	17,199	16,707	36.6	35.8	-1	3
Europe	6,100	6,610	13.0	14.2	-1	-8
Japan	3,029	3,186	6.4	6.8	7	-5
International*	6,861	6,876	14.6	14.7	0	0
Diagnostics Division	13,848	13,305	29.4	28.5	6	4

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

Outlook for 2022 confirmed

Roche expects stable sales or sales growth in the low-single-digit range (at constant exchange rates). Core earnings per share are targeted to grow in the low- to mid-single-digit range (at constant exchange rates). Roche expects to increase its dividend in Swiss francs further.

Group sales

In the first nine months, the **Roche Group** generated sales growth of 2% (1% in CHF) to CHF 47 billion.

As expected, the third quarter of 2022 was particularly challenging due to base effects, as the demand for COVID-19 medicines and tests was exceptionally high in the same quarter of 2021.

Sales of the **Pharmaceuticals Division** were at the same level as in the previous year, at CHF 33.2 billion.

The newer medicines Ocrevus (multiple sclerosis), Hemlibra (haemophilia), Evrysdi (spinal muscular atrophy) and Phesgo (breast cancer) continued their strong growth. The eye medicine Vabysmo, which was only launched at the beginning of the year, is now also one of

the strongest growth drivers. These top-five medicines alone generated additional sales totalling CHF 2.2 billion.

As expected, sales growth was offset by the biosimilars-related decline in sales, especially for the established cancer medicines Avastin, MabThera/Rituxan and Herceptin. Sales of Actemra/RoActemra and Ronapreve (COVID-19) were also significantly lower than in the same period of 2021, with a decline of roughly CHF 1 billion, as the pandemic continued to weaken in many countries in 2022.

Sales in the **United States** decreased slightly with 1%. Growth of Ocrevus, Hemlibra, Vabysmo, Xolair and Tecentriq partially offset lower sales of Actemra/RoActemra, Avastin, Herceptin, MabThera/Rituxan, Lucentis and Esbriet.

In **Europe**, sales were also slightly down by 1%. The main reason for this was the decline in sales of the COVID-19 medicine Ronapreve compared to the previous year. Excluding this base effect, sales in Europe grew by 6%.

Sales were up in **Japan** (+7%), mainly due to supply of Ronapreve to the government, followed by sales growth of Evrysdi, Hemlibra, Polivy and Enspryng. This more than offset the impact of government price cuts and biosimilars.

Sales in the **International** region were stable. The impact of biosimilars and decline in sales of Actemra/RoActemra was compensated by Perjeta, Kadcyla, Hemlibra and Ocrevus sales.

The **Diagnostics Division** generated a 6% increase in sales to CHF 13.8 billion. The division's base business continued its strong sales growth across all regions (+6%), with the largest contributions coming from the Europe, Middle East and Africa (EMEA) and Asia-Pacific regions. Immunodiagnostic products were the main growth drivers.

As expected, the demand for COVID-19 tests declined sharply in the third quarter of 2022 (CHF 0.6 billion versus CHF 1.0 billion in the same period last year).

Sales in the **Asia-Pacific** and **North America** regions increased strongly, by 28% and 20%, respectively. The 13% decline in sales in the **EMEA region** is primarily due to the lower demand for COVID-19 tests.

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

Ophthalmology

In September, the European Commission (EC) approved **Vabysmo**, the first bispecific antibody for the eye. Vabysmo simultaneously targets and inhibits two disease pathways that drive neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular oedema (DME) – two of the leading causes of vision loss. With the potential to require fewer eye injections over time, while also improving and maintaining vision, Vabysmo could offer a less burdensome treatment schedule for individuals, their caregivers and healthcare systems.

Oncology

In August, the FDA accepted the supplemental Biologics License Application (sBLA) for the **Polivy** combination therapy for previously untreated diffuse large B-cell lymphoma (DLBCL), an aggressive form of blood cancer. In four out of ten people with DLBCL, the cancer returns after initial treatment, at which point treatment options are limited and survival is short. Later in August, the Japanese health authorities granted approval for this Polivy combination in previously untreated DLBCL.

Also in August, Roche announced that the IMscin001 study met its co-primary endpoints. The study evaluated a subcutaneous formulation of cancer immunotherapy **Tecentriq** in people with advanced non-small cell lung cancer. Administered under the skin, this new formulation reduces the time spent receiving treatment to a matter of minutes, compared with up to an hour for an infusion.

Neuroscience

In October, Roche presented new data from its expanding neuromuscular disease portfolio. New two-year **Evrysdi** data show improvement or maintenance of motor function in people with spinal muscular atrophy (SMA). SMA is a severe, progressive neuromuscular disease that can be fatal. It is the leading genetic cause of infant mortality.

In addition, data from ongoing clinical trials of gene therapy **delandistrogene moxeparvovec** for Duchenne muscular dystrophy (DMD) reinforce our confidence in the phase III EMBARK study. DMD is a rare, progressive neuromuscular disease, leading to a loss of muscle function and premature death.

Virology

In August, the FDA approved **Xofluza** for the treatment of acute uncomplicated influenza in otherwise healthy children aged five years and older. Historically, school-aged children have

played a significant role in the community transmission of influenza. This approval marks the first single-dose oral influenza medicine approved in the US for children. Additionally, the FDA approved Xofluza for the prevention of influenza in children following contact with someone with influenza.

Pharmaceuticals: key development milestones in the third quarter of 2022

	Compound	Indication	Milestone
Regulatory	Vabysmo	Neovascular or 'wet' age-related macular degeneration (nAMD) and visual impairment due to diabetic macular oedema (DME)	EU approval
	Xofluza	Acute uncomplicated influenza in otherwise healthy children aged five years and older	US approval
	Xofluza	Prevention of influenza in children following contact with someone with influenza	US approval
	Polivy combination	Previously untreated diffuse large B-cell lymphoma (DLBCL)	Submitted for US approval; Japan approval
Phase III, pivotal and other key readouts	Tecentriq	Subcutaneous formulation in people with advanced non-small cell lung cancer	IMscin001 study
	Evrysdi	Spinal muscular atrophy (SMA)	JEWELFISH, RAINBOWFISH and SUNFISH studies (updated data)

Diagnostics: key milestones in the third quarter of 2022

In July, the FDA granted Breakthrough Device Designation to the **Elecsys Amyloid Plasma Panel**, an innovative new solution that enables **Alzheimer's disease** to be detected earlier. This panel measures two blood-based biomarkers, called pTau 181 and ApoE4. It has the potential to streamline a patient's journey and increase the speed of diagnosis, giving people living with Alzheimer's disease and their caregivers more time to plan and prepare for the future.

In August, Roche launched the **Digital LightCycler System**. This next-generation digital PCR system helps clinical researchers better understand the nature of a patient's cancer, genetic disease or infection. It has the potential to find and quantify ultra-rare, hard-to-detect disease mutations, leading to early diagnosis and therapy decisions.

Every four minutes, one person dies from skin cancer. However, when detected early, localised melanoma is curable with a simple surgical excision. The newly launched **PRAME (EPR20330) Antibody** test evaluates PRAME protein expression from patients with suspected melanoma. Identifying this critical biomarker helps clinicians determine if their patient has melanoma.

Approximately half of all patients with metastatic breast cancer express low levels of HER2 receptor protein. The newly launched **PATHWAY anti-HER2 (4B5) test** is the only FDA-approved companion diagnostic indicated as an aid in the assessment of HER2 low status in these patients. Historically these patients have simply been classified as HER2-negative, leaving them with few treatment options. They may now be eligible for targeted therapy.

With the launch of additional COVID-19 tests, Roche also reinforced its position as a world-leading supplier of COVID-19 diagnostics:

- The **Elecsys IGRA SARS-CoV-2 test** can help provide a deeper understanding of a person's immune response to SARS-CoV-2 infection or vaccination. It will serve as an additional tool to make better-informed decisions around care, sanitary measures and treatment options – particularly important for at-risk patient groups.
  (The test was launched in countries that accept the CE Mark.)
- The next generation portfolio of **SARS-CoV-2 Rapid Antigen tests ("2.0")** for self-testing and professional use feature innovative updates and enhanced performance, building on insights gained throughout the pandemic.
  (These tests are used under the CE mark.)

Based on continuous analysis performed since the onset of the pandemic, all Roche molecular tests detect all SARS-CoV-2 variants.

Pharmaceuticals sales

Sales	CHF millions		As % of sales		% change	
January–September 2022	**2022**	**2021**	**2022**	**2021**	**At CER**	**In CHF**
Pharmaceuticals Division	33,189	33,379	100.0	100.0	0	-1
United States	17,199	16,707	51.8	50.1	-1	3
Europe	6,100	6,610	18.4	20.0	-1	-8
Japan	3,029	3,186	9.1	9.5	7	-5
International*	6,861	6,876	20.7	20.4	0	0

*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	4,427	17	3,283	13	808	25	-	-	336	37
Perjeta	3,090	5	1,135	1	661	-16	175	-1	1,119	33
Hemlibra	2,778	28	1,684	22	542	32	277	20	275	76
Tecentriq	2,692	10	1,451	9	573	19	326	-5	342	16
Actemra/RoActemra	2,039	-23	914	-33	602	-3	256	1	267	-39
Herceptin	1,672	-18	376	-28	329	-13	40	-28	927	-15
Avastin	1,652	-29	497	-36	158	-51	378	-15	619	-21
Xolair	1,625	10	1,625	10	-	-	-	-	-	-
MabThera/Rituxan	1,596	-20	1,002	-20	156	-18	24	-10	414	-23
Kadcyla	1,590	11	619	-3	508	8	101	21	362	50

* 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 4.4 billion, +17%). Relapsing and primary progressive forms of multiple sclerosis; two-hour-only infusion. The demand for this treatment in both indications remained strong. In Europe and the International region, Ocrevus continued to show a high uptake.

Perjeta (first approved in 2012; CHF 3.1 billion, +5%). HER2-positive breast cancer. Sales increased mostly due to the continuing high demand in the International region, mainly China.

Hemlibra (first approved in 2017; CHF 2.8 billion, +28%). 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 a significant uptake, especially in the United States, Europe and the International region.

Tecentriq (first approved in 2016; CHF 2.7 billion, +10%). 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 the higher demand in the United States and Europe. Sales in Japan decreased, primarily due to governmental price cuts.

Actemra/RoActemra[2] (CHF 2.0 billion, -23%). 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. COVID-19 related sales decreased, mainly in the United States and the International region.

Herceptin[2] (CHF 1.7 billion, -18%). HER2-positive breast cancer and HER2-positive metastatic gastric cancer. The sales decrease was due to the biosimilar uptake in various countries.

Avastin[2] (CHF 1.7 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. Sales decreased because of the biosimilar uptake in various countries.

Xolair[2] (CHF 1.6 billion, +10%, United States only). Chronic spontaneous urticaria and allergic asthma. Sales grew in the chronic spontaneous urticaria indication. Xolair remains the leading medicine in the larger allergic asthma indication.

MabThera/Rituxan[2] (CHF 1.6 billion, -20%). Forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales decreased due to biosimilar erosion across all regions.

Kadcyla (first approved in 2013; CHF 1.6 billion, +11%). HER2-positive breast cancer. Sales growth was driven by the usage of Kadcyla in the early breast cancer setting. Sales also increased due to patients switching to this new standard care.

Alecensa (first approved in 2015; CHF 1.1 billion, +16%). ALK-positive non-small-cell lung cancer. The global uptake continued with sales growth across all regions.

Lucentis[2] (CHF 800 million, -25%, 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) came to market in the US at the beginning of the third quarter of 2022.

Evrysdi (first approved in 2020; CHF 793 million, +101%). 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.

Ronapreve (first approved in 2021; CHF 631 million, -36%). Antibody combination for the prevention and treatment of recently diagnosed high-risk patients with mild to moderate COVID-19. The sales decline in Europe was partly compensated by the increase in Japan.

Esbriet (first approved in 2014; CHF 590 million, -25%). Idiopathic pulmonary fibrosis (IPF). Sales decreased mainly because of the generic uptake, mainly in the United States. The first generic versions were launched in May 2022.

Gazyva/Gazyvaro (first approved in 2013; CHF 539 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 526 million, +150%). 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 strong uptake, especially in Europe and the United States.

Polivy (first approved in 2019; CHF 290 million, +79%). 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 282 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. Only launched in January 2022, the eye medicine is already one of the division's strongest growth drivers.

Enspryng (first approved in 2020; CHF 133 million, +108%). 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 an impressive uptake.

Rozlytrek (first approved in 2019; CHF 53 million, +50%). Specific form of non-small cell lung cancer (NSCLC); solid tumours expressing a specific gene fusion; ROS1-positive, advanced NSCLC.

Xofluza (first approved in 2018; CHF 6 million[3]). Acute, uncomplicated influenza, for people (including children) with high risk of developing flu-related complications; prevention of influenza following contact with an infected person.

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

Lunsumio (first approved in 2022; CHF 1 million[3]). Adult patients with relapsed or refractory follicular lymphoma. Promising market launch in first European countries.

Diagnostics sales

Sales	CHF millions		As % of sales		% change	
January–September 2022	**2022**	**2021**	**2022**	**2021**	**At CER**	**In CHF**
Diagnostics Division	13,848	13,305	100.0	100.0	6	4
Customer areas						
Core Lab[4]	5,833	5,677	42.1	42.6	5	3
Point of Care[4]	3,086	2,415	22.3	18.2	30	28
Molecular Lab[4]	2,735	3,030	19.8	22.8	-8	-10
Diabetes Care	1,219	1,294	8.8	9.7	-3	-6
Pathology Lab	975	889	7.0	6.7	10	10
Regions						
Europe, Middle East, Africa	4,595	5,715	33.2	43.0	-13	-20
North America	3,923	3,139	28.3	23.6	20	25
Asia-Pacific	4,522	3,611	32.7	27.1	28	25
Latin America	808	840	5.8	6.3	-3	-4

Core Lab. Focuses on central labs; provides diagnostics solutions in the areas of immunoassays, clinical chemistry and custom biotech. Sales were up 5%, with immunodiagnostics products (such as cardiac and oncology tests) and clinical chemistry products as the main growth drivers. Sales grew across all regions, with the largest contribution coming from the Asia-Pacific and EMEA regions.

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. With a plus of 30%, the customer area again reported a significant sales growth. The SARS-CoV-2

Rapid Antigen test continued to be 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. Sales declined by 8%, mainly due to lower COVID-19-related sales in the North America and EMEA regions. This was partly offset by growth in the base business across the portfolio and by the GenMark and TIB Molbiol businesses, which were acquired in the previous year.

Diabetes Care. Focuses on integrated personalised diabetes management for people with diabetes and healthcare professionals. Sales decreased by 3% due to the base effect of the resolution of a rebate dispute in 2021. Excluding this effect, sales remained stable. The continued contraction of the blood glucose monitoring market, in particular in the US and in major European markets, 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 grew by 10% across all regions. The advanced staining and the companion diagnostics businesses were the main growth drivers.

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] No growth figures available (product recently approved or growth rate not meaningful).
[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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