Media Release

Ad hoc announcement pursuant to Art. 53 LR

Basel, 27 July 2023

Roche reports strong growth in both divisions' base business; Group sales and profit reflect declining demand for COVID-19 products

- Excluding COVID-19 products, **Group** sales increase strongly by 8%[1] at constant exchange rates (CER)
- In line with the expected declining demand for COVID-19 products, **Group** sales decrease 2% (-8% in Swiss francs)
- **Pharmaceuticals Division** sales grow strongly by 8% due to continued high demand for newer medicines; new eye medicine Vabysmo is the strongest growth driver
- **Diagnostics Division's base business** continues its good growth momentum with an increase of 6%, while **total divisional sales** are 23% lower due to exceptionally high demand for COVID-19 tests in the first half of 2022
- **Core earnings per share** decrease 5%, driven by lower demand for COVID-19 products and a base effect from a patent settlement in 2022; **IFRS net income** down 9% due to lower core operating profit and higher interest expenses
- **Highlights** in the second quarter of 2023:
    - US and EU approvals of **Columvi** (aggressive form of blood cancer)
    - US approval of **Elevidys** for Roche partner Sarepta (first gene therapy for children with Duchenne muscular dystrophy)
    - Positive phase III data for subcutaneous injection of **Ocrevus** (multiple sclerosis); positive long-term efficacy and safety data for **Evrysdi** (spinal muscular atrophy) and positive phase II data for **fenebrutinib** (multiple sclerosis)
    - Start of phase III study of **tiragolumab** in combination with Tecentriq and Avastin (liver cancer)
    - **Partnership with Alnylam** to co-develop phase II RNAi therapeutic **zilebesiran** (hypertension in patients with high cardiovascular risk)
    - WHO prequalification of **cobas HPV test** enables improved access to cervical cancer screening in low and lower-middle income countries
- **Outlook for 2023 confirmed**

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Roche CEO Thomas Schinecker: “In the first half of 2023, sales in the base business of both our divisions grew strongly, largely offsetting the impact of declining demand for COVID-19 products. Vabysmo continues its strong momentum – now providing treatment for patients with severe eye conditions in over 70 countries. We reached several important pipeline milestones, including the US and EU approvals of our blood cancer medicine Columvi. I am also excited about our partnership with Alnylam to develop a potentially transformative medicine for patients living with hypertension, which affects 1.2 billion adults worldwide and is the leading cause of death from cardiovascular disease. We confirm our outlook for 2023.”

Key figures	**CHF millions**		**% change**	
January–June 2023	**2023**	**2022**	**At CER[1]**	**In CHF**
Group sales	29,779	32,295	-2	-8
Pharmaceuticals Division sales	22,681	22,347	8	1
Diagnostics Division sales	7,098	9,948	-23	-29
Core operating profit	10,911	12,668	-6	-14
Core EPS – diluted (CHF)	10.10	11.76	-5	-14
IFRS net income	7,563	9,161	-9	-17

Outlook for 2023 confirmed

Due to the sharp decline in sales of COVID-19 products of roughly CHF 5 billion, Roche expects a decrease in Group sales in the low single digit range (at CER). Excluding this COVID-19 sales decline, Roche anticipates solid sales growth in both divisions’ base business.

Core earnings per share are targeted to develop broadly in line with the sales decline (at CER). Roche expects to further increase its dividend in Swiss francs.

Group results

In the first half of 2023, the **Roche Group's base business** achieved strong sales growth of 8%. This partially compensated for the expected decline of COVID-19 sales.

Overall, Roche reported a 2% decline in **Group sales** (-8% in CHF).

The appreciation of the Swiss franc against most currencies had a significant adverse impact on the results presented in Swiss francs compared to constant exchange rates.

Core operating profit was down 6% (-14% in CHF), reflecting the sales decline in COVID-19 products and the income from the patent settlement in Japan in the first half of 2022.

Core earnings per share decreased 5%, also driven by lower demand for COVID-19 products and the base effect from the above-mentioned patent settlement; **IFRS net income** declined 9% due to lower core operating profit and higher interest expenses.

Sales in the **Pharmaceuticals Division** increased by 8% to CHF 22.7 billion. Newer medicines to treat severe diseases continued their strong growth.

The eye medicine Vabysmo, launched only in early 2022, was again the major driver of growth, with sales of CHF 1.0 billion, mainly in the US.

The top five growth drivers – Vabysmo, Ocrevus (multiple sclerosis), Hemlibra (haemophilia), Evrysdi (spinal muscular atrophy) and Phesgo (breast cancer) – generated total sales of CHF 7.5 billion, representing an increase of CHF 2.2 billion from the first half of 2022.

In the **United States**, sales grew 7%. Vabysmo generated CHF 0.8 billion in sales. The positive impact of the growth of Vabysmo, Ocrevus, Hemlibra, Tecentriq (cancer immunotherapy) and Activase/TNKase (cardiac diseases) was partly offset by lower sales of medicines for which patent protection has expired.

In **Europe**, sales increased by 5%, driven by the launch of Vabysmo and the continued uptake of Evrysdi, Phesgo, Hemlibra and Ocrevus. This was partially offset by the biosimilars impact and lower sales of Ronapreve (COVID-19).

Sales in **Japan** rose 14%, mainly due to supplies of Ronapreve to the government and supported by sales growth of Polivy, Vabysmo and Hemlibra. These more than offset the impact of biosimilars and government price cuts.

Sales in the **International region** grew by 9%. This positive trend was observed across all major markets. Perjeta (breast cancer), Evrysdi, Ocrevus, Hemlibra and Kadcyla (breast cancer) were the main drivers. Sales in China increased by 3%, driven by Tamiflu (influenza), Perjeta, Xofluza (influenza), Actemra/RoActemra (COVID-19/rheumatoid arthritis) and Polivy. This more than offset the impact of biosimilars.

The **Diagnostics Division's base business** – up 6% – achieved strong results over the first six months across all regions.

The main contributors to growth were immunodiagnostics, particularly cardiac tests, and diagnostics solutions for clinical chemistry.

Overall, the **Diagnostics Division** reported sales of CHF 7.1 billion, a decline of 23% reflecting the expected tapering of demand for COVID-19 tests (CHF 0.4 billion in the first half of 2023, compared to CHF 3.1 billion in the first half of 2022).

The impact of COVID-19 was evident in most regions: The **North America, Asia-Pacific** and **Europe, Middle East and Africa (EMEA)** regions experienced a sales decline of 30%, 23% and 22%, respectively. Sales in **Latin America** remained stable.

Pharmaceuticals: key development milestones in the second quarter of 2023

Compound	Milestone
Regulatory	
Evrysdi Spinal muscular atrophy	**CHMP recommends Evrysdi for babies under two months old with spinal muscular atrophy (SMA)** • Positive recommendation is based on interim data from ongoing RAINBOWFISH trial which showed majority of Evrysdi-treated babies were able to stand and walk within timeframes typical of healthy babies by 12 months' treatment • If approved by the European Commission, Evrysdi will be available to treat people of all ages with SMA in the European Union, including babies from birth • Evrysdi is now approved in 100 countries with more than 8,500 patients treated globally More information: Media Release, 21 July 2023
Columvi Blood cancer	**European Commission approves fixed-duration Columvi (glofitamab) for people with relapsed or refractory diffuse large B-cell lymphoma** • Columvi is the first CD20xCD3 T-cell-engaging bispecific antibody available in Europe to treat the most common and aggressive form of lymphoma • Approval is based on results from the phase I/II NP30179 study, where Columvi given as a fixed course induced early and long-lasting complete responses in people with heavily pre-treated or refractory diffuse large B-cell lymphoma • Columvi is given for a fixed period of time and made readily available, providing patients with a treatment end date and treatment-free period More information: Media Release, 11 July 2023
Columvi Blood cancer	**FDA approves Columvi, the first and only bispecific antibody with a fixed-duration treatment for people with relapsed or refractory diffuse large B-cell lymphoma** • Pivotal study showed durable responses, with a 56% overall response rate, a 43% complete response (remission) rate and a median duration of response of 1.5 years • Given over a fixed period of time, Columvi provides patients with a treatment end date and potential time off treatment • Columvi is part of Roche's industry-leading portfolio of T-cell-engaging bispecific

	antibodies in non-Hodgkin lymphoma, which also includes Lunsumio, the recently approved medicine for the treatment of follicular lymphoma More information: Media Release, 16 June 2023
Vabysmo Severe eye diseases	**FDA accepts application for Vabysmo for treatment of retinal vein occlusion (RVO)** • Acceptance based on two phase III studies that demonstrated early and sustained vision improvement with Vabysmo, meeting primary endpoint of non-inferiority compared to aflibercept • Application was further supported by data showing Vabysmo achieved rapid and robust drying of retinal fluid • If approved, RVO would be the third indication for Vabysmo in addition to neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular edema (DME) More information: Media Release, 9 May 2023
Phase III, pivotal and other key readouts; data presentations	
Vabysmo Severe eye diseases	**American Society of Retina Specialists (ASRS) meeting: New clinical and real-world data for Vabysmo reveal improved outcomes for people with two leading causes of vision loss** • Late-breaking post-hoc data indicate Vabysmo leads to less fibrosis, which may negatively impact vision, than aflibercept in people with diabetic macular edema (DME) • Real-world data reinforce that first-line Vabysmo use improves outcomes and extends treatment intervals rapidly during the first four months for people with neovascular or 'wet' age-related macular degeneration (nAMD) and DME • Clinical data reiterate Vabysmo's positive anatomical outcomes, including reduced blood vessel leakage in the macula and greater and faster retinal fluid control • Vabysmo is currently approved in over 70 countries to treat nAMD and DME, with more than one million doses distributed globally More information: Media Release, 20 July 2023
Ocrevus Multiple sclerosis	**Positive phase III results for Ocrevus twice a year, 10-minute subcutaneous injection in patients with multiple sclerosis (MS)** • Phase III OCARINA II trial met primary and secondary endpoints • Ocrevus twice a year, 10-minute injection has the potential to further improve the treatment experience and expand Ocrevus usage in MS centres with intravenous infusion (IV) capacity limitations or without IV infrastructure • Ocrevus remains the first and only therapy approved for both relapsing forms of MS or primary progressive MS (RMS and PPMS), and more than 300,000 people have been treated globally More information: Media Release, 13 July 2023
Evrysdi Spinal muscular atrophy	**Four-year follow-up data on Evrysdi show continued increase in number of children with a severe form of spinal muscular atrophy (SMA) who are able to sit, stand and walk** • Data from ongoing FIREFISH study confirm long-term efficacy and safety profile of Evrysdi in children with type 1 SMA • At month 48, 91% of children were alive • More than 95% maintained the ability to swallow – without treatment they would have required feeding support and majority would have died within two years

	• Evrysdi is now approved in 99 countries with more than 8,500 patients treated globally More information: Media Release, 30 June 2023
Crovalimab Paroxysmal nocturnal haemoglobinuria (PNH)	**European Hematology Association (EHA) Congress: New data show subcutaneously administered crovalimab achieved disease control and was well-tolerated in people with paroxysmal nocturnal haemoglobinuria (PNH)** • The COMMODORE 2 study demonstrated that subcutaneous crovalimab every four weeks was non-inferior to intravenous eculizumab every two weeks, with comparable safety, in people new to C5 inhibitors • Monthly self-administration of subcutaneous crovalimab has the potential to address the high burden of a disease that requires lifelong treatment including in settings where access to current C5 inhibitors is limited • The COMMODORE 1 study in people switching from currently approved C5 inhibitors supported the consistent benefit-risk profile of crovalimab as seen in the COMMODORE 2 study More information: Media Release, 9 June 2023
Tiragolumab Liver cancer	**American Society of Clinical Oncology (ASCO) meeting: Roche to present new data in blood cancers and solid tumours from its broad portfolio** • Phase Ib/II study evaluated tiragolumab in combination with Tecentriq and Avastin in patients with unresectable, locally advanced or metastatic hepatocellular carcinoma (uHCC) shows encouraging data • Based on the promising results, Roche expanded its development programme with the new phase III IMbrave152/SKYSCRAPER-14 study More information: IR Update, 26 May 2023
Fenebrutinib Multiple sclerosis	**BTK inhibitor fenebrutinib significantly reduces brain lesions in people with relapsing forms of multiple sclerosis** • Fenebrutinib is an investigational, potent and highly selective oral Bruton's tyrosine kinase (BTK) inhibitor, the only reversible BTK inhibitor currently in phase III multiple sclerosis (MS) trials • Phase II study met its primary and secondary endpoints by reducing the total number of new gadolinium-enhancing T1 brain lesions and significantly reducing the total number of new or enlarging T2 brain lesions compared to placebo • The safety profile of fenebrutinib was consistent with previous and ongoing clinical trials across more than 2,400 people to date More information: Media Release, 17 May 2023

Others	
Partnership with Alnylam	**Roche enters partnership with Alnylam to co-develop and co-commercialise RNAi therapeutic zilebesiran to treat hypertension in patients with high cardiovascular risk** • Partnership combines Roche's proven track record of successfully developing and launching innovative medicines worldwide with Alnylam's leadership in RNAi therapeutics • Zilebesiran, a phase II RNAi therapeutic, has best-in-disease potential for patients with hypertension at high risk of cardiovascular morbidity and mortality, by robustly and durably lowering blood pressure

	• Hypertension, the leading cause of cardiovascular disease, affects more than 1.2 billion adults worldwide. While several therapies exist, a significant unmet need, especially for high risk patients, remains More information: Media Release, 24 July 2023
Institute of Human Biology	**Roche launches Institute of Human Biology (IHB) to accelerate breakthroughs in research and development by unlocking the potential of human model systems** • The IHB aims to better predict which drug candidates are safe and most effective in patients by evolving and increasing the use of human model systems • Human model systems are miniature living 'replicas' of human tissues and organs that also have the potential to reduce reliance on animal testing • The institute brings together scientists from academia and industry to lead the broad adoption of human model systems in pharmaceutical R&D as well as in clinical practice More information: Media Release, 4 May 2023

Pharmaceuticals sales

Sales	**CHF millions**		**As % of sales**		**% change**	
January–June 2023	**2023**	**2022**	**2023**	**2022**	**At CER**	**In CHF**
Pharmaceuticals Division	22,681	22,347	100.0	100.0	8	1
United States	11,743	11,363	51.8	50.8	7	3
Europe	4,105	4,104	18.1	18.4	5	0
Japan	2,210	2,202	9.7	9.9	14	0
International*	4,623	4,678	20.4	20.9	9	-1

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

Top-selling medicines	Total		United States		Europe		Japan		International	
	CHF m	%	CHF m	%	CHF m	%	CHF m	%	CHF m	%
Ocrevus Multiple sclerosis	3,200	15	2,346	13	584	13	-	-	270	28
Hemlibra Haemophilia A	2,087	20	1,247	18	419	22	192	21	229	34
Perjeta[2] Breast cancer	2,082	9	763	7	413	-5	109	3	797	20
Tecentriq Cancer immunotherapy	1,853	12	1,000	9	398	9	214	11	241	28
Actemra/RoActemra[2] RA, COVID-19	1,296	-6	574	-11	383	-4	157	3	182	1
Xolair[2] Asthma	1,031	4	1,031	4	-	-	-	-	-	-
Kadcyla[2] Breast cancer	1,001	0	386	-4	298	-10	52	-13	265	24
Vabysmo Eye diseases (nAMD, DME)	957	**	788	**	103	**	46	**	20	**
MabThera/Rituxan[2] Blood cancer, RA	882	-17	534	-20	96	-4	13	-14	239	-13
Herceptin[2] Breast and gastric cancer	878	-19	176	-31	183	-17	17	-32	502	-14
Avastin[2] Various cancer types	837	-21	256	-23	57	-48	177	-23	347	-10
Alecensa Lung cancer	758	10	221	11	148	4	107	6	282	14
Evrysdi Spinal muscular atrophy	705	48	255	16	241	66	45	34	164	105
Activase/TNKase Cardiac diseases	621	15	592	15	-	-	-	-	29	12
Ronapreve COVID-19	550	2	-	-	-	-100	549	33	1	-99
Phesgo Breast cancer	517	69	209	57	240	57	-	-	68	216
Gazyva/Gazyvaro[2] Blood cancer	402	22	194	25	111	24	20	-17	77	28
Polivy Blood cancer	353	114	124	65	80	84	108	182	41	339
Lucentis[2] Various eye diseases	299	-46	299	-46	-	-	-	-	-	-

** Over 500%

DME: diabetic macular oedema / nAMD: neovascular or 'wet' age-related macular degeneration / RA: rheumatoid arthritis

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Diagnostics: key milestones in the first half of 2023

Product	Milestone
Elecsys beta-Amyloid (1-42) CSF II and **Elecsys Total-Tau CSF assays** Alzheimer's disease	**Roche receives FDA clearance for additional Alzheimer's disease Cerebrospinal Fluid (CSF) assays, supporting timely diagnosis and treatment decision-making** ● The Elecsys tTau/Abeta42 ratio helps clinicians define Alzheimer's disease (AD) biologically and expands Roche's AD CSF portfolio to include biomarkers for all three main pathological processes of Alzheimer's: amyloid plaques, tau tangles and neurodegeneration ● Confirmation of amyloid pathology via CSF FDA-cleared Alzheimer's biomarker testing or amyloid positron emission tomography (PET) is recommended in the appropriate use recommendations for new and emerging disease-modifying therapies shown to slow down cognitive decline when administered in early-disease stages ● Scalable and economical, Elecsys AD CSF assays can be added to any of Roche's widely available cobas fully automated immunoassay analyzers, giving patients broad access to high-quality testing in a timely manner More information: local Media Release, 27 June 2023
cobas HPV test Human papillomavirus (HPV)	**Roche awarded WHO prequalification for the cobas HPV test, increasing access to cervical cancer screening tools in low and lower-middle income countries (LMICs)** ● Every year, over 600,000 women worldwide are diagnosed with cervical cancer and over 340,000 die from this preventable disease, caused by infection with human papillomavirus (HPV). Nine out of ten women who die from cervical cancer live in LMICs ● WHO prequalification enables LMICs to use the cobas HPV test in their national cervical cancer elimination programmes, increasing access to the patients who need it most ● Establishing screening programmes helps prevent and detect cervical cancer, which is especially important in areas with limited healthcare resources where patients are often diagnosed with the disease at late stages More information: Media Release, 13 June 2023

Diagnostics sales

Sales	CHF millions		As % of sales		% change	
January–June 2023	**2023**	**2022**	**2023**	**2022**	**At CER**	**In CHF**
Diagnostics Division	7,098	9,948	100.0	100.0	-23	-29
Customer Areas[3]						
Core Lab	3,935	3,875	55.4	38.9	10	2
Molecular Lab	1,118	1,980	15.8	19.9	-40	-44
Diabetes Care	723	832	10.2	8.4	-5	-13
Pathology Lab	687	652	9.7	6.6	12	5
Point of Care	635	2,609	8.9	26.2	-74	-76
Regions						
Europe, Middle East and Africa	2,456	3,350	34.6	33.4	-22	-27
North America	1,940	2,868	27.3	29.0	-30	-32
Asia–Pacific	2,205	3,171	31.1	32.0	-23	-30
Latin America	497	559	7.0	5.6	0	-11

More information on Roche performance in the first half of 2023:

- Half-Year 2023 Finance Report
- Half-Year 2023 Presentation
- Appendix with Tables

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

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 endeavour 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.

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For more information, please visit www.roche.com.

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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 2022) and all total figures quoted are reported in CHF.
[2] Products launched before 2015.
[3] Core Lab: diagnostics solutions in the areas of immunoassays, clinical chemistry and custom biotech.
Point of Care: diagnostics solutions in emergency rooms, medical practices or directly with patients.
Molecular Lab: diagnostics solutions for pathogen detection and monitoring, donor screening, sexual health and genomics.
Diabetes Care: integrated personalised diabetes management.
Pathology Lab: diagnostics solutions for tissue biopsies and companion diagnostics.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Cautionary statement regarding forward-looking statements

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Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Karsten Kleine
Phone: +41 79 461 86 83

Nina Mählitz
Phone: +41 79 327 54 74

Kirti Pandey
Phone: +49 172 636 72 62

Sileia Urech
Phone: +41 79 935 81 48