Media Release

Ad hoc announcement pursuant to Art. 53 LR

Basel, 26 April 2023

Roche reports strong sales growth in base business of both divisions in the first quarter; Group sales decline due to expected drop in demand for COVID-19 tests

- As expected, significantly lower demand for COVID-19 tests leads to a decrease in **Group sales** (-3%[1] at constant exchange rates [CER] and -7% in Swiss francs); excluding this effect, Group sales grow 8%
- **Pharmaceuticals Division sales** up 9%; strong demand for newer medicines; Vabysmo for severe eye diseases is already the strongest growth driver
- **Diagnostics Division base business** grows 4%, while **divisional sales** are 28% lower due to exceptionally high demand for COVID-19 tests in the first quarter of 2022
- **Highlights** in the first quarter:
    - US approval of **Polivy** (first-line treatment for an aggressive form of blood cancer)
    - EU approval of **Hemlibra** (moderate haemophilia A)
    - Positive phase III data for **Vabysmo** (retinal vein occlusion, a serious eye disease), **Tecentriq plus Avastin** (adjuvant therapy for certain forms of liver cancer) and **crovalimab** (paroxysmal nocturnal haemoglobinuria, a rare blood disease)
    - Positive four-year efficacy and safety data for **Evrysdi** (spinal muscular atrophy)
    - Launch of **new assays** to identify clinically relevant mutations in brain cancers
- **Outlook for 2023 confirmed**

Roche CEO Thomas Schinecker: “We saw strong growth in the first quarter in both divisions’ base business, which largely compensated for the expected drop in sales of COVID-19 tests. We made progress in our pipeline in the first quarter, especially in blood cancer. Besides our recent approvals for our bispecific antibody medicines, Lunsumio and Columvi, we have also just received US approval of Polivy as first-line treatment for an aggressive form of blood cancer. In ophthalmology, Vabysmo, a medicine for severe eye diseases, has shown positive phase III data in retinal vein occlusion. If approved, this would be the third indication for Vabysmo which has already become our strongest growth driver just a year after its launch. We confirm our outlook for 2023.”

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Sales	CHF millions		As % of sales		% change	
January–March 2023	2023	2022	2023	2022	At CER	In CHF
Group	15,322	16,445	100.0	100.0	-3	-7
Pharmaceuticals Division	11,699	11,159	76.4	67.9	9	5
United States	5,853	5,489	38.2	33.4	6	7
Europe	2,071	2,072	13.5	12.6	5	0
Japan	1,390	1,337	9.1	8.1	18	4
International*	2,385	2,261	15.6	13.8	13	5
Diagnostics Division	3,623	5,286	23.6	32.1	-28	-31

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

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 constant exchange rates). 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 constant exchange rates). Roche expects to further increase its **dividend** in Swiss francs.

Group results

In the first three months of the year, **Group** sales declined by 3% (-7% in CHF) to CHF 15.3 billion. The appreciation of the Swiss franc against most currencies had a negative impact on the results reported in Swiss francs compared to constant exchange rates.

As expected, the first quarter 2023 results reflected the exceptionally high demand for COVID-19 tests in the same quarter of 2022, when the Omicron wave was at its peak.

Pharmaceuticals Division sales increased markedly by 9% to CHF 11.7 billion, driven by strong global demand for newer medicines to treat severe diseases.

The eye medicine Vabysmo, which was only launched in early 2022, became the division's biggest growth driver. The top five contributors to growth – Vabysmo, Ocrevus (multiple sclerosis), Hemlibra (haemophilia), Evrysdi (spinal muscular atrophy) and Tecentriq (cancer immunotherapy) – generated additional sales of CHF 1.1 billion.

The impact of the competition from biosimilars for the established cancer medicines Avastin, Herceptin and MabThera/Rituxan slowed down further (combined approx. CHF 330 million of sales reduction).

In the **United States**, sales increased by 6%. Newer medicines, such as Vabysmo, Ocrevus, Hemlibra and the cancer medicines Tecentriq and Phesgo, were the main contributors. This contrasted with declining sales of Actemra/RoActemra (COVID-19) and of medicines for which patent protection has expired.

In **Europe**, sales were up by 5%. Growth of Evrysdi, Vabysmo, Hemlibra, Phesgo, Ocrevus and other innovative medicines was partially offset by lower Ronapreve (COVID-19) sales and the biosimilars impact.

Sales in **Japan** increased (+18%), mainly due to higher supply of Ronapreve to the government than in the previous year, followed by sales growth of Polivy, Tamiflu (influenza), Vabysmo and Hemlibra.

Sales in the **International region** increased by 13%. The key factors were sales growth of Perjeta, Evrysdi, Tamiflu, Kadcyla and Ocrevus. In China, sales were up 4% due to high demand for Tamiflu, Actemra/RoActemra and Xofluza (influenza), which more than offset the impact of biosimilars.

The **Diagnostics Division's base business** recorded continued good growth (+4%).

Divisional sales were CHF 3.6 billion, down by 28% as sales of COVID-19 tests dropped to CHF 0.3 billion in the first quarter of 2023 from CHF 1.9 billion in the same period last year, when demand was exceptionally high.

Immunodiagnostic products, particularly cardiac tests, were the main growth drivers (+9%). Additional growth impulses came from the virology base business (+12%), blood screening (+15%) and diagnostics solutions for the detection and monitoring of cervical cancer (+22%).

The decline in sales across all regions is primarily due to the lower demand for COVID-19 tests. The **Europe, Middle East and Africa** (EMEA) and **North America** regions decreased by 30% and 39%, respectively. **Asia-Pacific** fell by 15%; **Latin America** reported a minus of 8%.

Pharmaceuticals: key development milestones in the first quarter of 2023

The Pharmaceuticals Division achieved a number of important product development milestones in the first three months of the year, including the US approval of **Polivy** (aggressive form of blood cancer), the EU approval of **Hemlibra** (moderate haemophilia A) as well as positive study results on **Vabysmo** for a serious retinal vascular condition and on **crovalimab** in PNH, a rare, life-threatening blood condition.

Compound	Milestone
Regulatory	
Hemlibra Haemophilia A	**EU: label expansion to include moderate haemophilia A** ● Hemlibra, already approved for severe haemophilia A in the EU, will now also provide an effective and convenient prophylactic treatment option for people with moderate haemophilia A ● Moderate haemophilia A can have a significant impact on the lives of people affected, with only 15% living a bleed-free life ● The approval is based on the results of the HAVEN 6 study, where Hemlibra demonstrated effective bleed control and a favourable safety profile in people with moderate haemophilia A without inhibitors More information: Media Release, 1 February
Columvi Blood cancer	**Columvi (glofitamab) to receive approval in Canada for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)** ● Columvi (glofitamab for injection) is the first CD20xCD3 T-cell-engaging bispecific antibody with fixed treatment duration approved in Canada to treat DLBCL ● Authorisation is based on results from the phase I/II NP30179 study, which demonstrated Columvi induced durable response rates in people with heavily pre-treated DLBCL More information: local Media Release, 25 March
Polivy Blood cancer	**FDA approves Polivy in combination with R-CHP for people with certain types of previously untreated diffuse large B-cell lymphoma** ● Polivy combination is the first FDA-approved therapy in nearly 20 years for the first-line treatment of diffuse large B-cell lymphoma, an aggressive disease and the most common form of non-Hodgkin lymphoma in the US ● POLARIX trial showed the Polivy combination reduced the risk of disease progression, relapse or death by 27% compared to the standard of care, R-CHOP, with a comparable safety profile ● First-line treatment with Polivy plus R-CHP has the potential to reduce the burden on patients and healthcare systems, associated with disease progression More information: Media Release, 20 April
Phase III, pivotal and other key readouts	
Crovalimab Haematology	**Positive data from global phase III programme for crovalimab in paroxysmal nocturnal haemoglobinuria (PNH), a rare, life-threatening blood condition** ● The COMMODORE 2 study met its co-primary efficacy endpoints, showing that crovalimab achieved disease control in people with PNH who had not been previously treated with complement inhibitors

	• The results of the phase III COMMODORE 1 study in people with PNH switching from currently approved C5 inhibitors to crovalimab supported the favourable benefit-risk profile of crovalimab, as seen in the pivotal COMMODORE 2 study • Results from both studies will be submitted to regulatory authorities around the world and presented at an upcoming medical meeting More information: Media Release, 7 February
Vabysmo Severe eye diseases	**New phase III data show Vabysmo rapidly improved vision and reduced retinal fluid in people with retinal vein occlusion (RVO)** • Vabysmo met its primary endpoint in two clinical trials, BALATON and COMINO, showing non-inferior visual acuity gains compared to aflibercept • More Vabysmo patients displayed an absence of blood vessel leakage in the retina compared to aflibercept patients in a pre-specified exploratory endpoint • If approved, RVO would be the third indication for Vabysmo in addition to neovascular or 'wet' age-related macular degeneration and diabetic macular oedema More information: Media Release, 10 February
Evrysdi Spinal muscular atrophy	**New four-year data for Evrysdi reinforce long-term efficacy and safety profile in some of the most severely affected people with types 2 and 3 spinal muscular atrophy (SMA)** • Data from pivotal SUNFISH study showed that increases in motor function observed during the first year were maintained through the fourth year, while the overall rate of adverse events continued to decrease • Data confirm long-term efficacy and safety profile of Evrysdi in a broad range of people with type 2 and non-ambulant type 3 SMA • More than 8,500 people – from newborns to the over 60s – have been treated with Evrysdi, which is now approved in more than 90 countries worldwide More information: Media Release, 20 March
Vabysmo Severe eye diseases	**Roche data highlight strength of ophthalmology portfolio and commitment to advancing eye care at ARVO 2023** • Vabysmo data suggest rapid and robust drying of retinal fluid in patients with neovascular or 'wet' age-related macular degeneration and diabetic macular oedema • Real-world data of Vabysmo demonstrate its ability to extend treatment intervals in the first four months while maintaining visual acuity • Clinical data on an investigational anti-interleukin-6 treatment in uveitic macular oedema will be presented for the first time More information: Media Release, 13 April
Tecentriq plus Avastin Liver cancer	**Tecentriq plus Avastin reduce the risk of cancer returning in people with certain types of liver cancer in a phase III study** • In the first-ever positive phase III trial in the adjuvant hepatocellular carcinoma (HCC) setting, Tecentriq plus Avastin reduced the risk of disease recurrence by 28% • Up to 80% of people with this type of HCC experience disease recurrence, at which point they are faced with poorer prognosis and shorter survival • These data will be presented at the American Association for Cancer Research (AACR) Annual Meeting 2023 More information: Media Release, 16 April

Pharmaceuticals sales

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United States	5,853	5,489	50.0	49.2	6	7
Europe	2,071	2,072	17.7	18.7	5	0
Japan	1,390	1,337	11.9	12.0	18	4
International*	2,385	2,261	20.4	20.1	13	5

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

Selected top-selling and new medicines	Total		United States		Europe		Japan		International	
	CHF m	%	CHF m	%	CHF m	%	CHF m	%	CHF m	%
Ocrevus Multiple sclerosis	1,636	14	1,188	13	298	11	-	-	150	32
Perjeta[2] Breast cancer	1,049	11	392	8	220	1	53	2	384	22
Hemlibra Haemophilia A	1,034	24	631	21	206	27	92	24	105	38
Tecentriq Cancer immunotherapy	920	15	507	14	195	11	105	12	113	34
Actemra/RoActemra[2] RA, COVID-19	676	-12	296	-22	193	-8	77	-	110	10
Ronapreve COVID-19	567	9	-	-	-	-	567	33	-	-
Kadcyla[2] Breast cancer	509	5	198	-3	154	-6	26	-8	131	42
Xolair[2] Asthma	479	5	479	5	-	-	-	-	-	-
Herceptin[2] Breast and gastric cancer	477	-17	91	-37	97	-17	9	-30	280	-7
MabThera/Rituxan[2] Blood cancer, RA	459	-17	274	-21	51	-	6	-13	128	-12
Vabysmo Eye diseases (nAMD, DME)	432	**	360	**	44	-	21	-	7	-
Avastin[2] Various cancer types	416	-24	133	-25	30	-45	91	-21	162	-19
Alecensa Lung cancer	372	9	106	7	73	3	50	5	143	14
Evrysdi Spinal muscular atrophy	363	62	124	13	113	74	21	47	105	189
Phesgo Breast cancer	241	72	98	62	114	59	-	-	29	232
Gazyva/Gazyvaro[2] Blood cancer	197	24	99	32	55	25	8	-35	35	27

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Lucentis[2] Various eye diseases	167	-35	167	-35	-	-	-	-	-	-
Polivy Blood cancer	150	96	46	35	40	93	51	169	13	340
Enspryng NMOSD	54	42	15	16	4	96	33	44	2	246
Rozlytrek Lung cancer	19	21	10	0	4	80	2	5	3	144
Xofluza Influenza	18	**	1	-10	-	-	-	-	17	**
Lunsumio Blood cancer	14	-	13	-	2	-	-	-	-1	-
Susvimo Eye implant	1	-33	1	-33	-	-	-	-	-	-

** Over 500%
DME: diabetic macular oedema / nAMD: neovascular or 'wet' age-related macular degeneration / NMOSD: neuromyelitis optica spectrum disorders / RA: rheumatoid arthritis

Diagnostics: key milestones in the first quarter of 2023

In the first quarter of the year, the Diagnostics Division launched important products in the areas of oncology and virology.

Product	Milestone
Regulatory	
IDH1 R132H and ATRX antibodies Brain cancer	**Launch of two new antibodies to identify clinically relevant mutations in patients with brain cancer** ● Recent advances in cancer genomics have deepened the medical community's understanding of the molecular alterations in brain tumours, more precisely subclassifying patients into specific diagnoses ● Understanding a patient's brain tumour mutation status in the IDH1 and ATRX genes enables more informed clinical decisions and may improve patient outcomes ● The IDH1 R132H and ATRX antibodies are the latest additions to Roche's neuropathology portfolio, which contains 29 biomarkers More information: Media Release, 23 February
VirSNiP SARS-CoV-2 Spike F486P COVID-19	**Launch of COVID-19 PCR test to detect the fast-spreading XBB.1.5 Omicron sub-variant** ● This new test for researchers specifically targets the XBB.1.5 Omicron sub-variant and runs on the real-time PCR platforms LightCycler 480 II and cobas z 480 ● Results from the test will help track the virus' lineage closely and provide insights into the epidemiology and the impact it has on public health ● Concern from the World Health Organization centres around the high transmissibility and growth advantage of XBB.1.5 More information: Media Release, 26 January

Collaborations	
Elecsys Amyloid Plasma Panel Alzheimer's disease	**Collaboration with Lilly to enhance early diagnosis of Alzheimer's disease** • Roche and Lilly will collaborate on the development of the Elecsys Amyloid Plasma Panel • The panel has demonstrated clinical performance and is currently undergoing additional investigation to ensure clinical validation • Once approved, the panel could help healthcare professionals to streamline the journey to diagnosis for more patients More information: Media Release, 22 March

Diagnostics sales

Sales	CHF millions		As % of sales		% change	
January–March 2023	**2023**	**2022**	**2023**	**2022**	**At CER**	**In CHF**
Diagnostics Division	3,623	5,286	100.0	100.0	-28	-31
Customer Areas[3]						
Core Lab	1,928	1,896	53.1	35.9	7	2
Molecular Lab	593	1,189	16.4	22.5	-48	-50
Point of Care	397	1,466	11.0	27.7	-72	-73
Diabetes Care	376	417	10.4	7.9	-5	-10
Pathology Lab	329	318	9.1	6.0	7	3
Regions						
Europe, Middle East, Africa	1,253	1,902	34.6	35.9	-30	-34
North America	1,029	1,705	28.4	32.2	-39	-40
Asia-Pacific	1,098	1,395	30.3	26.5	-15	-21
Latin America	243	284	6.7	5.4	-8	-14

More information on Roche sales in the first quarter of 2023:

- Q1 2023 presentation
- Appendix with tables

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 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

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