# **Media & Investor Release**



## Ad hoc announcement pursuant to Art. 53 LR

Basel, 24 April 2024

# Roche sales increase by 2% (CER) in first quarter with both divisions growing in high single digit ex COVID-19

- **Group sales** grew by 2%<sup>1</sup> at constant exchange rates (CER) (-6% in CHF), driven by the strong growth of newer medicines and diagnostics. Excluding COVID-19-related products, sales increased by 7%. Going forward, there will be no further material impact of COVID-19 sales decline
- Due to the appreciation of the Swiss franc against most currencies, sales were 6% lower when reported in CHF
- Pharmaceuticals Division base business<sup>2</sup> grew by 7%, driven by strong sales of medicines to treat severe diseases, such as Vabysmo (eye diseases), Phesgo (breast cancer), Ocrevus (multiple sclerosis), Polivy (blood cancer) and Hemlibra (haemophilia A). Divisional sales growth was 2%, reflecting the impact of the expected decline in sales of the COVID-19 medicine Ronapreve
- **Diagnostics Division base business**<sup>2</sup> grew by 8%, supported by growth across all regions because of demand for immunodiagnostic products, clinical chemistry tests and advanced staining solutions. As this growth was partially offset by the lower demand for COVID-19 tests, **divisional sales** grew by 2%
- **Highlights** in the first quarter:
  - US approvals of **Xolair** (food allergies) and **Alecensa** (early-stage lung cancer)
  - Positive phase III data for Xolair (food allergies), Columvi (blood cancer) and Ocrevus subcutaneous injection (multiple sclerosis); positive phase II results for zilebesiran (hypertension in people with high cardiovascular risk)
  - New positive long-term data for Vabysmo (retinal vein occlusion, a severe eye disease)
  - US approval for the first molecular test to screen for malaria in blood donors
  - US Breakthrough Device Designation for **blood test** to support earlier Alzheimer's disease diagnosis
- Outlook for 2024 confirmed



Roche CEO **Thomas Schinecker**: "We had a strong start into the year, with both our divisions reporting high single digit growth in their base business – excluding COVID-19 sales. After this quarter, the COVID-19-related impact on sales is largely behind us. The appreciation of the Swiss franc versus most currencies impacted sales reported in Swiss francs compared to the same period last year. The uptake of our eye medicine Vabysmo continues its momentum. We are pleased about the US approval of Xolair as the first and only medicine for multiple food allergies. Further, we recently received the US approval for Alecensa in early-stage lung cancer. With an unprecedented 76% reduction in the risk of disease recurrence or death versus chemotherapy, Alecensa significantly improves upon the standard of care for this specific form of lung cancer.

We are confident of growing our Group sales in the mid single digit range this year (at constant exchange rates) and therefore we confirm our outlook for 2024."

Sales	CHF m	CHF millions As % of sales		f sales	% ch	ange
January- March	2024	2023	2024	2023	At CER	In CHF
Group	14,399	15,322	100.0	100.0	2	-6
Pharmaceuticals Division	10,921	11,608	75.8	75.8	2	-6
United States	5,692	5,763	39.5	37.6	5	-1
Europe	2,200	2,071	15.3	13.5	11	6
Japan	649	1,390	4.5	9.1	-45	-53
International*	2,380	2,384	16.5	15.6	12	0
Diagnostics Division	3,478	3,714	24.2	24.2	2	-6

All figures shown in the table were restated to reflect the shift of the Foundation Medicine (FMI) business from the Pharmaceuticals Division to the Diagnostics Division.

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



#### **Outlook for 2024 confirmed**

Roche expects an increase in Group sales in the mid single digit range (CER). Core earnings per share are targeted to develop broadly in line with sales growth (CER), excluding the impact from the resolution of tax disputes in 2023. Roche expects to further increase its dividend in Swiss francs.

#### **Group sales**

In the first three months of 2024, **Group sales** increased by 2% CER (-6% in CHF) to CHF 14.4 billion as strong demand for newer medicines as well as diagnostics products including immunodiagnostics, clinical chemistry tests and advanced staining solutions more than offset the anticipated decline in COVID-19-related sales and the impact of biosimilar/generic erosion.

After this quarter, the impact of the drop in COVID-19-related sales is largely over and there will be no further material impact on Group sales.

Excluding COVID-19-related products, sales increased by 7%.

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

**Pharmaceuticals Division base business** grew by 7%, while **divisional sales** increased by 2% to CHF 10.9 billion as the strong global demand for newer medicines to treat severe diseases was partially offset by the expected decline in COVID-19 Ronapreve sales.

The eye medicine Vabysmo was the biggest growth driver, with Phesgo (breast cancer), Ocrevus (multiple sclerosis), Polivy (blood cancer) and Hemlibra (haemophilia A) being other significant contributors. Together, these medicines generated sales of CHF 4.2 billion, an increase of CHF 0.9 billion (at CER) from the first quarter of 2023.

The negative impact of biosimilar/generic erosion on our medicines Lucentis (eye diseases, US commercialisation rights only), MabThera/Rituxan (blood cancer), Herceptin (breast and stomach cancer), Avastin (various types of cancer), Esbriet (lung disease) and Actemra/RoActemra (arthritis, COVID-19) totalled CHF 0.4 billion (at CER), in line with expectations.

In the **United States**, sales increased by 5%, driven by strong demand for newer medicines such as Vabysmo, Polivy, Ocrevus, Phesgo and Evrysdi (spinal muscular atrophy) as well as for Xolair (allergies). This contrasted with lower sales of Lucentis, MabThera/Rituxan, Tecentriq (cancer immunotherapy), Esbriet, Avastin and Perjeta.

In **Europe**, sales grew by 11%, with Vabysmo, Phesgo, Hemlibra, Evrysdi and Ocrevus being the key drivers.



Sales in **Japan** were down by 45%, reflecting the base effect of the supply of Ronapreve to the government in the first quarter of 2023.

Sales in the **International region** increased by 12%, driven by strong growth in Hemlibra, Perjeta, Phesgo, Ocrevus, Tecentriq and Vabysmo. In China, sales grew by 11% due to high demand for Xofluza (influenza), Perjeta, Avastin, Polivy and Tecentriq.

The **Diagnostics Division's base business** continued good growth (8%), boosted by demand for immunodiagnostic products, clinical chemistry tests and advanced staining solutions. This was partially offset by the expected sales decline of COVID-19-related products, leading to **divisional sales** growing at 2% to CHF 3.5 billion.

Immunodiagnostic products, which include cardiac, oncology and thyroid tests, were the main growth drivers (10%). Additional growth impetus came from clinical chemistry (8%), advanced staining techniques in oncology (12%) and companion diagnostics (47%).

As expected, the sales of COVID-19 tests further declined to CHF 0.1 billion in the first quarter of 2024 from CHF 0.3 billion in the corresponding period last year.

Sales growth was reported across regions, with **Europe, Middle East and Africa** (EMEA) growing by 2%, **Asia-Pacific** by 1% and **Latin America** by 14%. **North America** recorded a decline of 1%, reflecting the drop in demand for COVID-19-related tests.

#### Pharmaceuticals: key milestones in the first quarter of 2024

Compound	Milestone
Regulatory	
Alecensa Lung cancer	<ul> <li>FDA approves Alecensa as first adjuvant treatment for people with ALK-positive early-stage lung cancer</li> <li>Approval based on phase III ALINA study showing Alecensa reduced the risk of disease recurrence or death by an unprecedented 76% in people with ALK-positive early-stage resected non-small cell lung cancer (NSCLC)</li> <li>This approval helps address an urgent unmet need, with about half of people living with early-stage NSCLC experiencing disease recurrence following surgery, despite adjuvant chemotherapy</li> <li>The National Comprehensive Cancer Network (NCCN) Guidelines recommend routine testing for ALK, EGFR and PD-L1 biomarkers in people with early-stage NSCLC to inform adjuvant therapy selection</li> <li>More information: Media Release, 19 April 2024</li> </ul>



# **Piasky** Chugai obtains regulatory approval for Piasky 340 mg for paroxysmal nocturnal haemoglobinuria in Japan Rare blood disease • Providing convenience of once every 4 week subcutaneous administration for treatmentnaive patients, or for patients switching to this drug from other C5 inhibitors, with paroxysmal nocturnal haemoglobinuria (PNH), a designated intractable disease This approval for not only treatment-naive PNH but also including patients switching from previously approved C5 inhibitors, is the first in the world Second approved drug that applies Chugai's proprietary recycling antibody technology and also the fifth Chugai-originated global product More information: Investor Relations Update, 26 March 2024 Xolair FDA approves Xolair as first and only medicine for children and adults with one or more Food allergy food allergies Approval is based on data from the NIH-sponsored phase III OUtMATCH study, which showed a significantly higher proportion of food allergy patients as young as one year treated with Xolair could tolerate small amounts of peanut, milk, egg and cashew without an allergic reaction, compared to placebo • More than 40% of children and more than 50% of adults with food allergies have experienced a severe reaction at least once in their lifetime Detailed OUtMATCH results were featured in a late-breaking symposium at the 2024 American Academy of Allergy, Asthma & Immunology annual meeting More information: Media Release, 16 February 2024 Phase III, pivotal and other key readouts Ocrevus SC Subcutaneous Ocrevus one-year data demonstrates near-complete suppression of Multiple clinical relapses and brain lesions in patients with progressive and relapsing forms of sclerosis multiple sclerosis • Results from the phase III study showed that subcutaneous (SC) injection was consistent with IV infusion and demonstrated near-complete suppression of relapse activity (97%) and MRI lesions (97.2%) through 48 weeks • The twice-yearly, 10-minute SC injection has the potential to expand the usage of Ocrevus to treatment centres without IV infrastructure or with IV capacity limitations US FDA and EMA accepted filings based on the data from OCARINA II, with EU approval anticipated mid-2024 and US approval anticipated in September 2024 More information: Media Release, 17 April 2024



# Columvi Columvi meets primary endpoint of overall survival in people with relapsed or Blood cancer refractory diffuse large B-cell lymphoma in phase III STARGLO study • Columvi, in combination with chemotherapy, demonstrated a statistically significant improvement in overall survival for people with relapsed or refractory diffuse large Bcell lymphoma • Data from the STARGLO study will be submitted to health authorities and presented at an upcoming medical meeting More information: Media Release, 15 April 2024 Zilebesiran Roche and Alnylam present positive results from the phase II KARDIA-2 study of Cardiovascular zilebesiran added to standard-of-care antihypertensives in patients with inadequately diseases controlled hypertension • The KARDIA-2 study met its primary endpoint demonstrating additive, placebo-adjusted systolic blood pressure reductions of up to 12.1 mmHg at month three. These results were statistically significant and clinically meaningful • Zilebesiran demonstrated an encouraging safety and tolerability profile when added to standard of care antihypertensives Roche and Alnylam have initiated the phase II KARDIA-3 study in adults with uncontrolled hypertension at high cardiovascular risk. More information: Investor Relations Update, 7 March 2024 Xolair New England Journal of Medicine publishes phase III data showing Xolair significantly Food allergies reduced allergic reactions across multiple foods in people with food allergies • Detailed results from the NIH-sponsored phase III OUtMATCH study showed treatment with Xolair increased the amount of peanuts, tree nuts, egg, milk and wheat that people as young as one year consumed without an allergic reaction • The US FDA recently approved Xolair as the first and only medicine for children and adults with one or more food allergies Allergic reactions can be life-threatening and it is estimated that food-related anaphylaxis results in 30,000 medical events treated in emergency rooms in the US each More information: Media Release, 25 February 2024 Vabysmo New long-term data for Vabysmo show sustained retinal drying and vision Severe eye improvements in retinal vein occlusion (RVO) diseases • Vabysmo sustained robust drying of retinal fluid, often associated with distorted or blurry vision Up to 60% of people receiving Vabysmo were able to extend treatment intervals to three or four months apart • Detailed results from two global phase III RVO studies were presented at Angiogenesis, Exudation, and Degeneration 2024 More information: Media Release, 1 February 2024



# Pharmaceuticals sales

Sales	CHF mi	illions	As % c	of sales	% change		
January-March	2024	2023	2024	2023	At CER	In CHF	
Pharmaceuticals Division	10,921	11,608	100.0	100.0	2	-6	
United States	5,692	5,763	52.1	49.4	5	-1	
Europe	2,200	2,071	20.1	17.8	11	6	
Japan	649	1,390	5.9	12.0	-45	-53	
International*	2,380	2,384	21.9	20.8	12	0	

All figures shown in the table were restated to reflect the shift of the Foundation Medicine (FMI) business from the Pharmaceuticals Division to the Diagnostics Division.

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

Top 20 best-selling	Tota	al	United States Europe		Japan		International			
pharmaceuticals	CHF m	%	CHF m	%	CHF m	%	CHF m	%	CHF m	%
Ocrevus Multiple sclerosis	1,658	8	1,180	5	310	8	-	-	168	28
<b>Hemlibra</b> Haemophilia A	1,040	8	592	-1	231	17	79	2	138	51
<b>Perjeta</b> <sup>3</sup> Breast cancer	936	-3	343	-7	171	-19	36	-19	386	14
<b>Tecentriq</b> Cancer immunotherapy	865	1	436	-9	210	12	86	-4	133	34
<b>Vabysmo</b> Eye diseases (nAMD, DME, RVO)	847	108	650	91	138	224	23	33	36	397
Actemra/RoActemra <sup>3</sup> RA, COVID-19	618	-2	278	-1	188	1	68	5	84	-15
<b>Xolair</b> <sup>3</sup> Asthma, allergies	496	10	496	10	-	-	-	-	-	-
<b>Kadcyla</b> <sup>3</sup> Breast cancer	483	3	186	-1	145	-2	21	-4	131	19



Phesgo	388	70	126	36	169	55	19	-	74	165
Breast cancer										
Herceptin <sup>3</sup>	364	-17	67	-22	77	-17	4	-41	216	-14
Breast and gastric cancer										
Evrysdi	356	7	135	16	137	27	20	13	64	-29
Spinal muscular atrophy										
Alecensa	355	4	104	4	72	3	43	3	136	5
Lung cancer										
MabThera/Rituxan <sup>3</sup>	351	-18	204	-21	39	-20	4	-20	104	-11
Blood cancer, RA										
Avastin <sup>3</sup>	324	-15	99	-22	21	-27	51	-33	153	3
Various cancer types										
Activase/TNKase <sup>3</sup>	296	4	282	4	-	-	-	-	14	7
Cardiac diseases										
Polivy	250	81	117	166	54	42	44	2	35	181
Blood cancer										
Gazyva/Gazyvaro <sup>3</sup>	213	16	100	7	62	17	6	-19	45	47
Blood cancer										
Pulmozyme <sup>3</sup>	112	-6	66	-15	20	0	-	27	26	22
Cystic fibrosis										
Mircera <sup>3</sup>	96	0	-	-	10	-8	9	-25	77	6
Anaemia										
CellCept <sup>3</sup>	94	0	5	-34	32	0	9	-10	48	8
Immunosuppressant										

<sup>\*\*</sup> Over 500%

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



# Diagnostics: key milestones in the first quarter of 2024

Product	Milestone
Regulatory	
Elecsys pTau217 test	FDA Breakthrough Device Designation for blood test to support earlier Alzheimer's disease diagnosis
Alzheimer's disease	<ul> <li>The Elecsys pTau217 plasma biomarker test is being developed as part of an ongoing partnership between Roche and Eli Lilly and Company</li> <li>Once approved, the test will aid healthcare providers in identifying amyloid pathology, a key feature of Alzheimer's disease</li> <li>Roche and Lilly believe the test could play an important role in improving access to early and accurate Alzheimer's diagnosis</li> <li>More information: Media Release, 11 April 2024</li> </ul>
<b>cobas Malaria</b> <b>test</b> Malaria	<ul> <li>FDA approval for the first molecular test to screen for malaria in blood donors</li> <li>The cobas Malaria test is the first FDA-approved molecular test to screen US blood donors for malaria</li> <li>Malaria is a serious and potentially fatal parasitic infection most commonly transmitted by mosquitoes that can also be spread through blood transfusion</li> <li>Roche is dedicated to saving patients' lives through diagnostic solutions that aid in the protection of the global blood supply from infectious diseases</li> <li>More information: Media Release, 26 March 2024</li> </ul>

# **Diagnostics sales**

Sales	CHF mil	lions	As % of	fsales	% change		
January-March	2024	2023	2024	2023	At CER	In CHF	
Diagnostics Division	3,478	3,714	100.0	100.0	2	-6	
Customer areas <sup>4</sup>							
Core Lab	1,925	1,928	55.4	51.9	9	0	
Molecular Lab <sup>5</sup>	620	683	17.8	18.4	-3	-9	
Near Patient Care <sup>6</sup>	570	774	16.4	20.8	-20	-26	
Pathology Lab	363	329	10.4	8.9	19	10	
Regions							
Europe, Middle East, Africa	1,188	1,253	34.2	33.8	2	-5	
North America <sup>5</sup>	1,055	1,120	30.3	30.3	-1	-6	



Asia-Pacific	992	1,098	28.5	29.4	1	-10
Latin America	243	243	7.0	6.5	14	0

More information on Roche sales in the first quarter of 2024:

- Q1 2024 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 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 fifteenth 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 <u>www.roche.com</u>.

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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 2023) and all total figures quoted are reported in CHF.
- [2] Pharmaceuticals Division base business: excluding COVID-19 medicine Ronapreve.

Diagnostics Division base business: excluding COVID-19-related products.

- [3] Products launched before 2015.
- [4] Core Lab: diagnostics solutions in the areas of immunoassays, clinical chemistry and CustomBiotech.

  Molecular Lab: diagnostics solutions for pathogen detection and monitoring, donor screening, sexual health and genomics, genomic tumour profiling.
  - Near Patient Care: diagnostics solutions in emergency rooms, medical practices or directly with patients and integrated personalised diabetes management.
  - Pathology Lab: diagnostics solutions for tissue biopsies and companion diagnostics.
- [5] Sales in the Molecular Lab customer area include sales from the Foundation Medicine business which moved under the responsibility of the Diagnostics Division from the Pharmaceuticals Division effective 1 January 2024. The comparative information for 2023 has been restated accordingly.
- [6] Sales in the new Near Patient Care customer area include sales from Diabetes Care and the Point of Care business, both previously shown as separate customer areas. The comparative information for 2023 has been restated accordingly.

### **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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