# **Media & Investor Release**



### Ad hoc announcement pursuant to Art. 53 LR

Basel, 25 July 2024

# Roche sales increase by 5% (CER) in first half of 2024; strong growth in second quarter – full-year earnings outlook raised

- **Group sales** were up by 5%<sup>1</sup> at constant exchange rates (CER) (stable in CHF) in the first half, driven by the high demand for both our medicines and diagnostics; excluding COVID-19-related products, sales increased by 8%
- **Group sales** growth accelerated to 9% (7% in CHF) in the second quarter as the decline in COVID-19-related sales no longer had an impact on overall sales
- Pharmaceuticals Division sales rose by 5% in the first half; strong growth of 8% in the base business<sup>2</sup> excluding COVID-19 effect was driven by continued high demand for our newer medicines to treat severe diseases; eye medicine Vabysmo was again the major growth driver
- Diagnostics Division sales rose by 5%, while growth in the base business<sup>2</sup>, which
  excludes the impact of COVID-19 sales, was 9% due to higher demand for
  immunodiagnostic products
- Core operating profit increased by 11% (4% in CHF), core earnings per share grew by 9% (1% in CHF) and IFRS net income was down by 4%
- Outlook for 2024 earnings raised
- Highlights:
  - US approval for Vabysmo prefilled syringe for three leading causes of vision loss and PiaSky for a rare blood condition; US filing acceptance for Susvimo in two leading causes of vision loss in adults with diabetes
  - US FDA Breakthrough Therapy Designation, priority review and filing acceptance for **inavolisib** (breast cancer); US FDA Breakthrough Therapy Designation for **Columvi** (blood cancer)
  - EU approval for Ocrevus subcutaneous injection (multiple sclerosis) and Alecensa (early-stage lung cancer); positive EU opinion for Vabysmo (retinal vein occlusion, a severe eye disease) and PiaSky in paroxysmal nocturnal haemoglobinuria (PNH), a rare blood condition; EU marketing authorisation application review initiated for Elevidys (Duchenne muscular dystrophy)



- Positive phase III data for Columvi (blood cancer), five-year data for Evrysdi (spinal muscular atrophy), four-year data for Vabysmo (DME, a severe eye disease), phase Ib data for CT-388 (obesity) and phase I data for CT-996 (obesity)
- CE mark for Accu-Chek SmartGuide, an Al-enabled continuous glucose monitoring solution offering critical predictions to people living with diabetes
- US approval of human papillomavirus (HPV) self-collection solution, the first available in the country to allow women to privately collect their samples; two new WHO prequalifications for cervical cancer screening tools, including HPV self-collection solution
- Launch of new analytical units, cobas c 703 and cobas ISE neo, to deliver higher testing capacity and increased automation for laboratories
- US emergency use authorisation for cobas liat four-in-one molecular test for some of the most prevalent respiratory viruses

Roche CEO **Thomas Schinecker**: "Our strong sales growth in the first half of 2024 reflects the high demand for our innovative medicines and diagnostics. In the second quarter, we saw an acceleration of our growth momentum as Group sales were no longer impacted by the decline in COVID-19 sales, resulting in very strong sales growth for the Group. Based on our strong half-year results, we are raising our earnings outlook for the full year.

We also received a number of important regulatory approvals in the last three months, including EU approval for Alecensa for a form of early-stage lung cancer, as well as for the subcutaneous injection of Ocrevus, which provides an additional treatment option for multiple sclerosis. I am particularly pleased about the US approval for the ready-to-use prefilled syringe of our eye medicine Vabysmo, which continues to be our main growth driver. In diagnostics, our new Accu-Chek SmartGuide solution for continuous blood glucose monitoring uses artificial intelligence to provide reliable blood glucose level forecasts for several hours."



Key figures	CHF mill	ions	% change			
January-June	2024	2023	At CER <sup>1</sup>	In CHF		
Group sales	29,848	29,779	5	0		
Pharmaceuticals Division sales	22,637	22,511	5	1		
Diagnostics Division sales	7,211	7,268	5	-1		
Core operating profit	11,293	10,911	11	4		
Core EPS – diluted (CHF)	10.23	10.10	9	1		
IFRS net income	6,697	7,563	-4	-11		

### Outlook for 2024 earnings raised

Roche expects an increase in **Group sales** in the mid single digit range (CER).

Core earnings per share are targeted to grow in the high single digit range (CER), excluding the impact from the resolution of tax disputes in 2023.

Roche expects to further increase its dividend in Swiss francs.

#### **Group results**

In the first half of 2024, **Group sales** were up by 5% at CER (stable in CHF) at CHF 29.8 billion. While the appreciation of the Swiss franc slowed against most currencies, it had an adverse impact on the results presented in Swiss francs compared to constant exchange rates.

Core operating profit grew by 11% (4% in CHF), driven by higher sales and cost management.

Core earnings per share increased by 9% (1% in CHF). IFRS net income was 4% lower (-11% in CHF), mainly due to the impairment of product and technology intangible assets in the research or development phase following strategic decisions. In addition, the IFRS result was impacted by the base effect of the release of provisions related to litigations in the first half of 2023.

The **Pharmaceuticals Division base business** grew by 8%, while **divisional sales** increased by 5% to CHF 22.6 billion, driven primarily by higher sales of Vabysmo (severe eye diseases), with growing demand for Phesgo (breast cancer), Ocrevus (multiple sclerosis), Polivy (blood



cancer) and Evrysdi (spinal muscular atrophy). These five medicines together generated total sales of CHF 7.3 billion, an increase of CHF 1.8 billion (CER) from the first half of 2023.

The eye medicine Vabysmo, launched in early 2022, remained a major growth driver, generating sales of CHF 1.8 billion on growing demand in all regions, mainly the US.

Sales of MabThera/Rituxan, Herceptin and Avastin decreased by a combined CHF 0.4 billion (CER) as the impact of biosimilar competition slowed further. Sales of the COVID-19 medicine Ronapreve were minimal compared with CHF 0.5 billion in the first half of 2023.

In the **United States**, sales grew by 5% as increased sales of Vabysmo, Polivy, Ocrevus and Xolair (food allergies) were partially offset by the continued decline in sales of medicines for which patent protection has expired. Vabysmo achieved CHF 1.4 billion in sales, showing a high uptake in both new patients and patients switching from other medications.

In **Europe**, sales surged by 10%, driven by demand for Vabysmo in France, the UK and Germany as well as by the continued uptake of Phesgo, Ocrevus, Hemlibra (haemophilia) and Evrysdi. This was partially offset by lower sales of medicines for which patent protection has expired and of Perjeta (breast cancer) due to ongoing conversion of patients to Phesgo.

Sales in **Japan** were down 28%, mainly due to the base effect of the supply of Ronapreve (COVID-19) to the government in the first half of 2023. Excluding this effect, sales in Japan were 5% lower as strong demand for Phesgo was more than offset by the impact of government price cuts.

Sales in the **International region** increased by 17%, led by demand for Perjeta, Evrysdi, Phesgo and Tecentriq (cancer immunotherapy). Sales in **China** increased by 14%, driven by Perjeta, Alecensa (lung cancer), Avastin (liver cancer), Xofluza (influenza) and Polivy.

The **Diagnostics Division base business** grew by 9%, while **divisional sales** increased by 5% to CHF 7.2 billion. Immunodiagnostic products, which include cardiac, oncology and thyroid tests, were the main growth drivers (11%). Additional growth impetus came from clinical chemistry (8%), advanced staining techniques in oncology (11%) and from companion diagnostics (46%).

The continued good growth in the division's base business was partially offset by the expected sales decline of COVID-19-related products. Sales of COVID-19 tests further declined to CHF 0.1 billion in the first half of 2024 from CHF 0.4 billion in the corresponding period last year.

Sales growth was reported across all regions, with the Europe, Middle East and Africa (EMEA) region growing by 4%, North America by 5%, Asia-Pacific by 3% and Latin America by 16%.



### Pharmaceuticals: key developments

Compound	Milestone
Regulatory	
Susvimo Severe eye disease	Roche to reintroduce Susvimo in the US for people with neovascular age-related macular degeneration (nAMD)  The FDA has approved updates to Susvimo, which will be available to US retina specialists and patients with nAMD in the coming weeks  Susvimo offers the first alternative to regular eye injections that are standard of care for nAMD, which impacts 20 million people worldwide and can cause blindness if left untreated  By continuously delivering medicine to the eye through a refillable implant, Susvimo is the first and only approved nAMD treatment shown to maintain vision with two refills a year  More information: Media Release, 8 July 2024
Vabysmo prefilled syringe Severe eye diseases	<ul> <li>FDA approves Vabysmo prefilled syringe (PFS) for three leading causes of vision loss</li> <li>Vabysmo PFS is the first and only syringe prefilled with an FDA-approved bispecific antibody to treat retinal conditions that can cause blindness</li> <li>Designed to simplify administration, Vabysmo PFS provides retina specialists a ready-to-use option</li> <li>Vabysmo PFS will be available for people living with nAMD, DME and RVO More information: Media Release, 5 July 2024</li> </ul>
Vabysmo Severe eye diseases	Vabysmo gets CHMP recommendation for third indication retinal vein occlusion (RVO)  • Positive recommendation is based on two phase III studies. In addition to robust retinal drying with Vabysmo, these data show early and sustained vision improvements, which are non-inferior to aflibercept  • If approved, Vabysmo would be the first and only bispecific antibody treatment available for the nearly one million people with RVO in the European Union  • Vabysmo is already approved in the US and Japan for RVO and in more than 95 countries around the world for people living with nAMD and DME  More information: Media Release, 28 June 2024
<b>PiaSky</b> Rare blood condition	<ul> <li>CHMP recommends EU approval of PiaSky for people with PNH, a rare, lifethreatening blood condition</li> <li>If approved, PiaSky would be the first monthly subcutaneous (SC) treatment for paroxysmal nocturnal haemoglobinuria (PNH) in the EU</li> <li>Additionally, with the option of self-administration, PiaSky may provide an alternative to existing intravenous (IV) C5 inhibitors, potentially helping to reduce treatment burden</li> <li>The recommendation is based on the results of the COMMODORE 2 study, where SC PiaSky given every month demonstrated equivalent disease control and comparable safety to IV eculizumab given every two weeks</li> <li>More information: Media Release, 28 June 2024</li> </ul>



<b>Ocrevus</b> Multiple sclerosis	Ocrevus subcutaneous administration approved by European Commission as first and only twice-a-year injection for relapsing and primary progressive multiple sclerosis  Ocrevus subcutaneous (SC) injection offers a new, 10-minute administration of Ocrevus with comparable efficacy and safety to intravenous infusion (IV) Ocrevus SC provides an additional treatment option without the need for IV facilities, expanding accessibility for patients Roche is working closely with national health systems in Europe to ensure people with multiple sclerosis can access Ocrevus SC as quickly as possible More information: Media Release, 25 June 2024
<b>Elevidys</b> Duchenne muscular dystrophy	<ul> <li>EMA has initiated review of the Elevidys Marketing Authorisation application for the treatment of Duchenne muscular dystrophy (DMD)</li> <li>If approved, Elevidys is expected to be the first and only gene therapy available in Europe to address the underlying cause of Duchenne muscular dystrophy</li> <li>Elevidys is already approved in the US, Qatar, Kuwait, UAE, Oman and Bahrain More information: Investor Update, 24 June 2024</li> </ul>
Alecensa Lung cancer	<ul> <li>European Commission approves Alecensa as the first and only targeted adjuvant treatment for people with ALK-positive early-stage lung cancer</li> <li>Alecensa reduced the risk of disease recurrence or death by an unprecedented 76% in people with ALK-positive resected non-small cell lung cancer (NSCLC), as demonstrated in the phase III ALINA study</li> <li>The approval of Alecensa addresses an urgent unmet need in the early-stage setting where about half of all people experience disease recurrence following surgery, despite adjuvant chemotherapy</li> <li>Early diagnosis and treatment of lung cancer can reduce the burden associated with progressive disease and give people the best possible chance of cure</li> <li>More information: Media Release, 10 June 2024</li> </ul>
Inavolisib Breast cancer	<ul> <li>FDA grants priority review to inavolisib for advanced hormone receptor-positive, HER2-negative breast cancer with a PIK3CA mutation</li> <li>Priority review recognises the best-in-class potential of the inavolisib-based regimen for patients in urgent need of new treatment options</li> <li>Additional analyses of INAVO120 were presented in an oral abstract session at the 2024 American Society of Clinical Oncology Annual Meeting</li> <li>The target action date for the FDA decision is 27 November 2024</li> <li>More information: Media Release, 29 May 2024</li> </ul>
<b>Inavolisib</b> Breast cancer	FDA grants Breakthrough Therapy Designation to inavolisib for advanced hormone receptor-positive, HER2-negative breast cancer with a PIK3CA mutation  • The designation is based on phase III INAVO120 results, showing the inavolisib-based regimen more than doubled progression-free survival compared with palbociclib and fulvestrant alone in the first-line setting  • Approximately 40% of people with hormone receptor-positive breast cancer have a PIK3CA mutation and often face poorer prognosis and resistance to endocrine treatment  • This is the 29th Breakthrough Therapy Designation for Roche's oncology portfolio, a testament to our enduring ambition to deliver transformative medicines for patients  More information: Media Release, 21 May 2024



### Phase III, pivotal and other key readouts; data presentations Susvimo New data for Susvimo demonstrate sustained efficacy in two serious diabetic eye Severe eye disease conditions Two-year phase III data presented at the 2024 American Society of Retina Specialists (ASRS) annual meeting show the potential of Susvimo as an alternative to eye injections to treat diabetic macular oedema (DME) and diabetic retinopathy (DR) Safety data were consistent with the known safety profile for Susvimo in people with DME and DR Additionally, the FDA has accepted the filing application for Susvimo in DME and DR based on one-year Pagoda and Pavilion study data Susvimo is a unique therapeutic approach that provides continuous delivery of medicine to the eye through a refillable implant More information: Media Release, 18 July 2024 Vabysmo Vabysmo shows extended durability, continued efficacy and a consistent safety Severe eye diseases profile in long-term diabetic macular oedema (DME) study More than 90% of patients had absence of DME after four years in a pre-specified exploratory endpoint People treated with Vabysmo sustained vision gains and anatomical improvements, with almost 80% receiving treatment at intervals of three or four months, in an exploratory analysis The study met all primary endpoints, showing safety data were consistent with the known safety profile of Vabysmo This is the largest long-term extension dataset in DME to date, demonstrating consistent positive results in a highly prevalent eye condition More information: Media Release, 17 July 2024 CT-996 Roche announces positive phase I results for its oral GLP-1 receptor agonist CT-996 Obesity for the treatment of people with obesity After four weeks of treatment, CT-996 demonstrated clinically meaningful weight loss of -7.3% (weight loss in placebo -1.2%; p < 0.001) Pharmacokinetic data support a once-daily oral dosing regimen for CT-996 The safety and tolerability profile was consistent with that of other oral GLP-1 receptor agonists and no unexpected safety signals were observed More information: Media Release, 17 July 2024 **Tiragolumab** Update on phase II/III SKYSCRAPER-06 study in metastatic non-squamous non-small Lung cancer cell lung cancer SKYSCRAPER-06, evaluating tiragolumab plus Tecentriq and chemotherapy, did not meet the primary endpoints of progression-free survival at primary analysis and overall survival at first interim analysis The combination of tiragolumab plus Tecentriq and chemotherapy showed reduced efficacy compared to the comparator arm Safety was consistent with previous studies; however, Roche intends to halt the trial due to reduced efficacy compared to the comparator arm More information: Media Release, 4 July 2024



<b>Columvi</b> Blood cancer	<ul> <li>Phase III STARGLO study demonstrates Columvi significantly extends survival in people with relapsed or refractory diffuse large B-cell lymphoma</li> <li>The study met its primary endpoint of overall survival with a 41% reduction in the risk of death in people with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) treated with Columvi plus chemotherapy</li> <li>This Columvi combination could provide a much-needed off-the-shelf treatment option for people with transplant-ineligible R/R DLBCL</li> <li>Data were featured in the congress press briefing and presented in the Plenary Abstracts Session at EHA 2024 as a late-breaking oral presentation</li> <li>More information: Media Release, 15 June 2024</li> </ul>
<b>Evrysdi</b> Spinal muscular atrophy	Five-year data for Evrysdi show the majority of treated children with a severe form of spinal muscular atrophy achieved or maintained the ability to sit, stand or walk  • After five years of treatment, 91% of children were alive — without treatment, children with type 1 SMA would not be expected to live past two years of age  • 96% of children treated with Evrysdi could swallow, 80% could feed without a feeding tube and 59% could sit without support for at least 30 seconds  • Evrysdi is now approved in more than 100 countries with over 15,000 patients treated globally  More information: Media Release, 7 June 2024
CT-388 Obesity	Positive phase Ib results for dual GLP-1/GIP receptor agonist CT-388 in people with obesity  Over 24 weeks, a once-weekly subcutaneous injection of CT-388 achieved a clinically meaningful and statistically significant mean placebo-adjusted weight loss of 18.8% (p < 0.001)  At week 24, 100% of CT-388 treated participants achieved >5% weight loss, 70% achieved >15% weight loss and 45% achieved >20% weight loss  In a subgroup with pre-diabetes at baseline, CT-388 treatment normalised glycaemia in all patients, indicating its strong impact on glucose homoeostasis  No new or unexpected safety signals were detected. Overall, CT-388 demonstrated a safety and tolerability profile consistent with its drug class  More information: Media Release, 16 May 2024



### Pharmaceuticals sales

Sales	CHF mi	llions	<b>A</b> s % o	f sales	% change		
January-June	2024	2023	2024	2023	At CER	In CHF	
Pharmaceuticals Division	22,637	22,511	100.0	100.0	5	1	
United States	11,882	11,573	52.5	51.4	5	3	
Europe	4,425	4,105	19.5	18.2	10	8	
Japan	1,366	2,210	6.0	9.8	-28	-38	
International*	4,964	4,623	22.0	20.6	17	7	

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, other

Top-selling medicines	Total		United States		Europe		Japan		International	
	CHF m	%	CHF m	%	CHFm	%	CHF m	%	CHF m	%
Ocrevus Multiple sclerosis	3,359	8	2,411	5	639	12	-	-	309	27
<b>Hemlibra</b> Haemophilia A	2,143	7	1,231	1	468	14	171	3	273	32
<b>Perjeta</b> <sup>3</sup> Breast cancer	1,921	-2	694	-7	341	-16	66	-30	820	14
<b>Tecentriq</b> Cancer immunotherapy	1,798	2	898	-8	429	10	182	-2	289	32
Vabysmo Eye diseases (nAMD, DME, RVO)	1,794	93	1,371	78	287	183	53	35	83	324



Actemra/RoActemra <sup>3</sup> RA, COVID-19	1,276	3	595	6	363	-3	146	7	172	4
<b>Xolair</b> <sup>3</sup> Asthma	1,110	10	1,110	10	-	-	-	-	-	-
Kadcyla <sup>3</sup> Breast cancer	999	6	381	1	288	-1	46	2	284	23
<b>Evrysdi</b> Spinal muscular atrophy	838	25	283	14	286	21	44	14	225	50
Phesgo Breast cancer	799	60	258	27	354	51	50	-	137	115
Alecensa Lung cancer	766	7	236	9	145	1	96	4	289	10
Herceptin <sup>3</sup> Breast and gastric cancer	740	-11	138	-19	154	-14	8	-44	440	-5
MabThera/Rituxan <sup>3</sup> Blood cancer, RA	706	-17	422	-19	77	-17	9	-23	198	-11
Avastin <sup>3</sup> Various cancer types	654	-16	199	-20	44	-20	102	-33	309	-4
Activase/TNKase <sup>3</sup> Cardiac diseases	593	-2	561	-3	-	-	-	-	32	17
<b>Polivy</b> Blood cancer	513	54	255	112	86	9	92	-1	80	107
Gazyva/Gazyvaro <sup>3</sup> Blood cancer	445	15	217	14	123	13	15	-16	90	29
Pulmozyme <sup>3</sup> Cystic fibrosis	225	-2	141	-8	39	2	-	26	45	20
Madopar <sup>3</sup> Parkinson's disease	200	13	-	-	50	1	-	-	150	17
CellCept <sup>3</sup> Immunosuppressant	197	4	12	-26	60	-5	18	-10	107	19

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



### **Diagnostics: key developments**

Product	Milestone					
Accu-Chek SmartGuide Diabetes management	CE mark for Al-enabled continuous glucose monitoring solution offering critical predictions to people living with diabetes  The Accu-Chek SmartGuide CGM solution provides accurate real-time glucose values for adults living with type 1 and type 2 diabetes on flexible insulin therapy  The built-in Al-trained algorithms will empower users to proactively intervene when their glucose levels require attention and before a complication can even occur  The solution is set to launch in selected European markets in the coming months More information: Media Release, 9 July 2024  Roche expands access to cervical cancer screening tools with two new WHO prequalification designations, including HPV self-collection  The World Health Organization (WHO) has awarded Roche's human papillomavirus (HPV) test prequalification designations for use on the cobas 5800 system and for self-collected samples on the cobas 5800, 6800 and 8800 systems  These designations build upon last June's WHO prequalification that included the cobas HPV test for use on the cobas 6800 and 8800 systems  WHO prequalification enables low- and middle-income countries (LMICs) to use Roche HPV screening solutions, including self-collection, in their national cervical cancer elimination programmes, which will greatly increase access  Every year, over 600,000 women worldwide are diagnosed with cervical cancer and over 340,000 die from this preventable disease caused by HPV infection. Nine out of 10 women who die from cervical cancer live in LMICs  More information: Media Release, 27 June 2024					
cobas 5800, 6800 and 8800 systems Human papillomavirus (HPV)						
cobas pro integrated solutions	<ul> <li>Roche launches new analytical units for cobas pro integrated solutions delivering greater efficiency and capacity to laboratories</li> <li>The cobas c 703 and cobas ISE neo analytical units deliver higher testing capacity and increased automation, helping to improve laboratory workflows and advance patient care</li> <li>The new cobas c 703 analytical unit offers industry-leading high-throughput clinical chemistry testing with up to 2,000 tests per hour and 70 reagent positions, doubling the existing clinical chemistry throughput on cobas pro integrated solutions</li> <li>The new cobas ISE neo analytical unit delivers more efficient ISE testing, reducing hands-on time through automated maintenance</li> <li>More information: Media Release, 24 June 2024</li> </ul>					
VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail assay B-cell lymphoma	Roche launches new highly sensitive test to more easily diagnose patients with B-cell lymphoma  The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail assay is the first clinically approved in-situ hybridisation (ISH) test with the sensitivity to assess the full spectrum of B-cell lymphoma subtypes  The test helps differentiate a B-cell cancer from a normal, reactive immune response, providing diagnostic certainty for healthcare providers and their patients  B-cell lymphoma accounts for approximately 85 percent of non-Hodgkin lymphoma (NHL) cases, which is the tenth most common cancer worldwide  More information: Media Release, 20 June 2024					



### cobas liat system

#### Infectious diseases

# Roche four-in-one molecular test for SARS-CoV-2, Influenza A/B viruses and RSV receives US FDA Emergency Use Authorisation

- The test uses highly sensitive PCR technology, requiring only a single nasal-swab sample to provide rapid, accurate qualitative detection and differentiation among four of the most prevalent respiratory viruses for which differential diagnosis can drive appropriate treatment
- It enables healthcare professionals to make confident clinical decisions and promptly determine appropriate treatment, with definitive results reported in just 20 minutes
- It expands Roche's extensive molecular point-of-care testing portfolio, offering greater flexibility to meet testing needs amid evolving regional prevalence of respiratory infections

More information: Media Release, 10 June 2024

#### Tina-quant lipoprotein (a) RxDx

## Cardiovascular diseases

# FDA Breakthrough Device Designation for blood test measuring Lp(a) – a key marker for hereditary cardiovascular risk

- Approximately one in five people worldwide have elevated Lp(a) levels, putting them at increased risk of cardiovascular diseases including myocardial infarction and stroke
- The Tina-quant Lp(a) assay measures lipoprotein (a) in a person's bloodstream, and will be made available on Roche's installed base of over 90,000 serum work area (SWA) systems worldwide
- The test was developed in collaboration with Amgen

More information: Media Release, 22 May 2024

# HPV self-collection solution

## Human papillomavirus (HPV)

# FDA approval for one of the first HPV self-collection solutions in the US, expanding access and screening options to help eliminate cervical cancer

- More than half of all US cervical cancer patients are underscreened, which makes reducing barriers to sample collection and increasing access to screenings crucial to ultimately helping eliminate this deadly disease
- Each year in the US, more than 13,000 patients are diagnosed with cervical cancer and approximately 4,000 die from this preventable disease, caused by HPV infection
- Roche's human papillomavirus (HPV) self-collection solution will improve access to testing by providing women the option to privately collect their own sample

More information: Media Release, 15 May 2024



### **Diagnostics sales**

Sales	CHF m	illions	As % o	f sales	% change		
January-June	2024	2023	2024	2023	At CER	In CHF	
Diagnostics Division	7,211	7,268	100.0	100.0	5	-1	
Customer Areas <sup>4</sup>							
Core Lab	4,069	3,935	56.4	54.1	10	3	
Molecular Lab <sup>5</sup>	1,275	1,288	17.7	17.7	3	-1	
Near Patient Care <sup>6</sup>	1,097	1,358	15.2	18.7	-14	-19	
Pathology Lab	770	687	10.7	9.5	17	12	
Regions							
Europe, Middle East and Africa	2,431	2,456	33.7	33.8	4	-1	
North America <sup>5</sup>	2,163	2,110	30.0	29.0	5	3	
Asia-Pacific	2,102	2,205	29.2	30.3	3	-5	
Latin America	515	497	7.1	6.9	16	4	

### More information on Roche performance in the first half of 2024:

- Half-Year 2024 Finance Report
- Half-Year 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>.

All trademarks used or mentioned in this release are protected by law.

#### 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 and directly with patients, including 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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