# Media Release



## Ad hoc announcement pursuant to Art. 53 LR

Basel, 3 February 2022

# Roche reports good results in 2021

- **Group sales** increase 9%<sup>1</sup> at constant exchange rates (CER); 8% in Swiss francs
- **Pharmaceuticals Division sales** increase 3%; continued strong demand for newly launched medicines more than offsets impact of biosimilars
- **Diagnostics Division sales** grow 29%; strong momentum in base business and continued high demand for COVID-19 tests
- Major approvals for medicines since the last quarter: United States: Susvimo and Vabysmo (age-related blindness) Europe: Gavreto (specific type of advanced lung cancer); Actemra/RoActemra (severe COVID-19); Ronapreve (non-hospitalised COVID-19 patients and prophylaxis)
- **Major approvals for diagnostics** since the last quarter: cobas 5800 (molecular laboratory system); Avenio Edge (sequencing sample preparation system); cobas pulse and cobas infinity edge (digital ecosystem for clinical decision support); additional SARS-CoV-2 tests
- **Promising pipeline:** 16 phase III trials initiated, 14 new compounds in phase III trials or filed for approval
- Repurchase of Roche shares from Novartis completed
- **Core earnings per share** (EPS) grow 6% (+3% in CHF)
- IFRS net income totals CHF 14.9 billion (+2%; -1% in CHF)
- Board proposes **dividend** increase to CHF 9.30. If approved by shareholders, this would be the 35<sup>th</sup> consecutive dividend increase

**Outlook for 2022**: Sales are expected to be stable or grow in the low-single digits (at constant exchange rates). Core earnings per share are targeted to grow in the low- to mid-single digit range (at constant exchange rates), including the accretive effect of the recent share repurchase. Roche expects to increase its dividend in Swiss francs further.

Roche anticipates sales of COVID-19 medicines and diagnostics to decrease by approximately CHF 2 billion to around CHF 5 billion, and sales losses to biosimilars in the current year to be roughly CHF 2.5 billion. Excluding those effects, Group sales are expected to grow in the high-single digit range.

4070 Basel Switzerland Group Communications Roche Group Media Relations



Key figures CHF millions			% cha	inge
January - December 2021	2021	2020	At CER <sup>1</sup>	In CHF
Group sales	62,801	58,323	9	8
Pharmaceuticals Division	45,041	44,532	3	1
<b>Diagnostics</b> Division	17,760	13,791	29	29
Core operating profit	21,897	21,536	4	2
Core EPS - diluted (CHF)	19.81	19.16	6	3
IFRS net income	14,935	15,068	2	-1

CEO Severin Schwan on the full-year results: "We achieved good results in 2021. The demand for our new medicines and diagnostics remains very high. I am particularly pleased with the progress of our product pipeline across several areas, including oncology, vision loss and neurological diseases. Based on our strong product portfolio in both divisions and the promising product pipeline, we are well positioned for future growth."

## **Group results**

In 2021, **Group** sales rose 9% (8% in CHF) to CHF 62.8 billion. **Core operating profit** increased 4% (2% in CHF), reflecting the strong underlying business performance, and **core EPS** grew 6% (3% in CHF). The Swiss franc's appreciation against almost all currencies affected the results expressed in Swiss francs compared to constant exchange rates.

**IFRS net income** was CHF 14.9 billion. This represents an increase of 2% (-1% in CHF), driven by the operating results.

In December, Roche completed the CHF 19.0 billion **repurchase of Roche shares** held by Novartis. This restores Roche's full strategic flexibility while retaining its operational scope of action.



**Pharmaceuticals Division** sales increased by 3% to CHF 45.0 billion. Strong demand for newly launched medicines to treat severe diseases, namely Hemlibra (haemophilia), Ocrevus (multiple sclerosis), Tecentriq (cancer), Evrysdi (spinal muscular atrophy), and Phesgo (cancer) drove this growth; medicines for the treatment of COVID-19 also contributed to sales growth (Ronapreve for high-risk COVID-19 patients and Actemra/RoActemra for severe COVID-19 pneumonia).

Overall, the medicines launched in the last ten years<sup>2</sup> contributed an additional CHF 5.7 billion in new sales.

The impact of competition from biosimilars for the cancer medicines Avastin, Herceptin and MabThera/Rituxan has slowed down as expected (combined CHF 4.5 billion of sales reduction); and the second half of the year saw signs of recovery from the COVID-19 pandemic.

In the **United States**, sales decreased by 2%. While sales of Actemra/RoActemra, Hemlibra, Ocrevus, Evrysdi and Tecentriq increased, the impact of biosimilars and the COVID-19 pandemic affected total growth as expected.

In **Europe**, sales grew 7%. Growth of recently launched medicines more than compensated for the impact of biosimilars and the COVID-19 pandemic.

In **Japan**, sales increased by 26%, driven by strong demand for new medicines. This more than compensated for competition from biosimilars and government price cuts.

Sales in the **International region** grew by 4%. In China, sales were stable: Growth of Perjeta, Alecensa and Heceptin was offset by the impact from biosimilars. Excluding China, sales increased by 6%, mainly driven by new product sales, partially offset by the biosimilars competition.

The **Diagnostics Division** reported strong sales growth of 29% to CHF 17.8 billion. The division's base business showed strong momentum throughout 2021 (overall +16%).

With sales totalling CHF 4.7 billion, Roche's leading portfolio of COVID-19 tests contributed significantly to the division's overall sales.

Sales grew strongly across the world: **Europe, Middle East and Africa** (EMEA) 37%, **Asia-Pacific** 29%, **North America** 16%, and **Latin America** 48%.

In December, Roche completed its share purchase agreement with long-term partner **TIB Molbiol** to expand their PCR-test portfolio in the fight against new infectious diseases. TIB Molbiol will continue to operate as a subsidiary within the Diagnostics Division.

```
F. Hoffmann-La Roche Ltd
```

4070 Basel Switzerland Group Communications Roche Group Media Relations



## Pharmaceuticals: promising pipeline

Oncology remained the primary area of research and development, with the cancer immunotherapy portfolio being a key driver. Ophthalmology, neuroscience and immunology represent other significant areas of late-stage investments. Roche now has 14 new compounds in late-stage development or registration.

#### Regulatory milestones in the fourth quarter 2021 (incl. January 2022)

#### Ophthalmology

Neovascular or "wet" age-related macular degeneration (nAMD) affects about 20 million people worldwide and is a leading cause of blindness in people over 60. In October, Roche launched **Susvimo** in the United States, a first-in-kind therapeutic approach for nAMD. Susvimo is the first and only eye implant with continuous drug delivery – an alternative to frequent eye injections that makes life much easier for people with the condition.

Diabetic macular edema (DME) is a vision-threatening complication of diabetic retinopathy. In January 2022, the FDA approved **Vabysmo** for the treatment of nAMD and DME - the first in a new class of eye medicines targeting two key pathways that drive retinal disorders. Vabysmo potentially offers durable vision outcomes with fewer eye injections than the current standard of care.

#### Oncology

RET gene alterations are key disease drivers in many types of cancer, including non-small cell lung cancer (NSCLC). Treatment options for people with RET fusion-positive advanced NSCLC have been limited to date. In November, the European Commission approved **Gavreto** for the treatment of adults with RET fusion-positive advanced NSCLC. Gavreto is the first and only precision medicine approved in the EU for first-line treatment of people with this specific form of cancer.

#### Neurosciences

Roche is investigating more than a dozen medicines for neurological disorders, including Alzheimer's, multiple sclerosis and rare diseases, such as spinal muscular atrophy (SMA). SMA is the leading genetic cause of death in babies. In January 2022, Roche announced that the FDA has granted priority review of a supplemental new drug application for the use of **Evrysdi** to treat pre-symptomatic babies under two months of age with SMA. Interim data showed that the majority of pre-symptomatic babies treated with Evrysdi for at least one year were able to sit, stand and walk within timeframes typical of healthy babies, as well as maintain swallowing.



# COVID-19

The COVID-19 pandemic has led to more than 5.6 million deaths so far, mostly involving hospitalised patients. While vaccines are mostly effective in preventing hospitalisation, there has been a high medical need for all those who have not been vaccinated or do not respond adequately to vaccines.

In November, **Ronapreve** was approved in Europe to treat non-hospitalised COVID-19 patients and for prophylaxis of the disease. Data showed that the antibody combination reduces the risk of hospitalisation in certain patients with mild to moderate disease and the risk of symptomatic COVID-19 infections in people exposed to the virus. While analyses have shown that Ronapreve does not retain neutralising activity against the Omicron variant, Ronapreve retains its activity against all other main variants of concern, including Delta. Activity of Ronapreve against potential future variants will be continually assessed.

In December, the European Commission extended the marketing authorisation for **Actemra/RoActemra** to include the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

## Key development milestones in the fourth quarter 2021

## Oncology

Diffuse large B-cell lymphoma (DLBCL) is an aggressive blood cancer. In 40% of people with DLBCL, the cancer returns after initial treatment, at which point treatment options are limited and survival is short. At the American Society of Hematology (ASH) congress in December, Roche showed that its **Polivy** combination therapy is the first in more than 20 years to significantly improve outcomes in previously untreated DLBCL compared to standard of care. Polivy reduces the risk of disease worsening or death by 27%.

Follicular lymphoma (FL) accounts for 20% of all blood cancer cases and can spread unnoticed in the body. Many people with FL do not respond to available therapies and there is currently no cure for this devastating disease. Roche also presented pivotal data for the novel cancer immunotherapy **mosunetuzumab** at ASH. Mosunetuzumab is a potential first-inclass treatment, showing high response rates in people with FL who have received two or more prior therapies. Roche recently submitted the marketing authorisation application for mosunetuzumab to the European Medicines Agency.

Latest data for **glofitamab** and **cevostamab** also underline the potential of this novel approach (T-cell engaging bispecific antibody immunotherapies) in the treatment of different types of blood cancers.

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Group Communications Roche Group Media Relations



Lung cancer is one of the leading causes of cancer deaths worldwide; non-small cell lung cancer (NSCLC) accounts for around 85% of all cases. In December, Roche announced new data from the first randomised phase II trial of an anti-TIGIT therapy. The data showed encouraging results for **tiragolumab** plus Tecentriq for people with PD-L1-positive metastatic NSCLC. The data suggest that combining anti-TIGIT and anti-PD-L1 cancer immunotherapies such as tiragolumab and Tecentriq could potentially represent a novel approach to addressing unmet needs in cancer.

## Haemophilia A

Haemophilia A is an inherited, serious disorder that affects the blood's ability to clot, leading to uncontrolled bleeding. In December, Roche presented interim results from a phase III study of **Hemlibra**. The medicine demonstrated a favourable safety profile and effective bleed control in people with moderate or mild haemophilia A without factor VIII inhibitors. Hemlibra thus continues to show benefit in additional haemophilia A populations, regardless of severity.

## COVID-19

The phase II study on **AT-527** did not meet its primary endpoint. After a thorough analysis of the evolving COVID-19 treatment landscape, Roche announced in November that it would be ending its partnership with Atea on the AT-527 programme as of February 2022.

	Compound	Indication	Milestone	
Regulatory	Xofluza	Influenza: healthy people; high-risk people; post exposure prophylaxis	EU approval	
	Evrysdi	Spinal muscular atrophy (SMA) type 1/2/3	EU approval	
	Vabysmo*	Neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME)	US approval; EU filing	
	Tecentriq	Adjuvant non-small cell lung cancer (NSCLC)	US approval; EU filing	
	Tecentriq	First-line PD-L1-positive NSCLC	EU approval	
·	Enspryng	Neuromyelitis optica spectrum disorder (NMOSD)	EU approval	
	Venclexta/Venclyxto+ azacitidine	Acute myeloid leukaemia	EU approval	

# Pharma: Key development milestones 2021 (incl. January 2022)

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Group Communications Roche Group Media Relations



	Ronapreve*	SARS-CoV-2	EU approval
	Susvimo*	nAMD (continuous delivery)	US approval; EU filing
	Actemra/RoActemra*	COVID-19 pneumonia	EU approval
	Gavreto*	RET-positive NSCLC	EU approval
	mosunetuzumab*	Relapsed or refractory follicular lymphoma (FL)	EU filing
Phase III /	Ronapreve	SARS-CoV-2 outpatient	Phase III study 2067
pivotal and other key readouts	SARS-CoV-2 post-exposure prophylaxis	Phase III study 2069 Phase II/III study 2066	
	Evrysdi	SMA type 1/2/3 switching study	Phase II RAINBOWFISH
tiragolumab + Tecentriq*	PD-L1-positive metastatic NSCLC (PD-L1- high)	Phase II CITYSCAPE	
·	Polivy + R-CHP*	First-line diffuse large B-cell lymphoma (DLBCL)	Phase III POLARIX**
	Hemlibra*	Moderate to mild haemophilia A	Phase III HAVEN 6**

\* Fourth quarter 2021 (incl. January 2022)

\*\* EU application for approval recently submitted

## Diagnostics: key launches in the fourth quarter (incl. January 2022)

Diagnostic solutions are the backbone of treatment decisions: Whether it's cancer, infectious diseases or other serious illnesses, the quest for better solutions to healthcare's greatest challenges depends on diagnostics.

## **Diagnostics instruments**

Access to reliable and accurate testing solutions is essential. In November, Roche launched the **cobas 5800**. This compact, fully automated molecular system provides efficiency, simplicity and timely results to laboratories of all sizes so clinicians can quickly determine the best treatment strategies for their patients.

In December, Roche launched the **cobas pulse** system, the first professional (point of care) blood glucose meter with digital capabilities similar to that of a smartphone. Its Androidbased operating system is loaded with industry-leading medical apps that can perform a range of clinically valuable functions – from clinical decision support to the measurement of vital signs and digital biomarkers.

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Group Communications Roche Group Media Relations



One of the major challenges in using next generation sequencing for diagnosis is the preparation of the samples. DNA is especially complex to prepare for sequencing and this process can be prone to human error. In December, Roche launched the **AVENIO Edge System:** it helps to simplify and automate next-generation sequencing sample preparation, thus reducing human error.

## **Digital solutions**

Healthcare professionals often face incomplete patient records and data silos across multiple IT systems. In December, Roche launched the **NAVIFY Oncology Hub**, a new digital solution that securely aggregates and organises patient data from disparate sources. It provides a central workspace where clinicians can quickly and easily access holistic, longitudinal patient data to inform more timely, personalised decisions across the cancer care continuum.

In addition, Roche introduced **cobas infinity edge** in January 2022. This cloud-based platform brings multiple capabilities together to create an open digital health ecosystem for "point of care" professionals. It enables the sharing of patients' data - from multiple sources - at the right time and place to the right caregivers. The platform connects an array of health status sources such as patients' electronic medical records (EMRs), third-party apps and point-of-care devices (e.g. Roche's new cobas pulse).

## **Oncology testing**

To treat cancer effectively, we must understand what drives it at a molecular level. In October, Roche launched the **AVENIO Tumor Tissue CGP Kit** to expand access to personalised cancer research. This is the first product developed jointly by Roche and Foundation Medicine (FMI), and the first example of oncology research where scientists have used FMI's comprehensive genomic profiling in their own laboratories.

Each year, around 340,000 women die from cervical cancer. This preventable cancer is caused by infection with high-risk types of the human papillomavirus (HPV). In October, Roche announced the IMPACT clinical trial data showing a clear benefit of the **CINtec Plus Cytology test** for women at higher risk of developing cervical cancer.

Early detection of lung cancer allows for more treatment options. In October, the **VENTANA PD-L1 Assay** received FDA approval as a companion diagnostic to identify people with nonsmall cell lung cancer who are eligible for Roche's cancer immunotherapy Tecentriq.



## **COVID-19 testing**

The pandemic has profoundly raised awareness of the role diagnostics play in disease prevention and management. The spread of the virus, and particularly the emergence of new variants, has heightened the need for reliable, high-quality testing.

In December, Roche's newly acquired subsidiary TIB Molbiol rapidly developed six **new test kits**. They help researchers detect mutations in the new Omicron variant and study its spread versus other variants.

Later in December, the FDA granted Emergency Use Authorization (EUA) for the **COVID-19 At-Home Rapid Antigen Test,** which delivers fast, reliable results for infections with SARS-CoV-2 and all known variants, including Omicron.

In January 2022, Roche launched the **SARS-CoV-2 & Flu A/B Rapid Antigen Test** in markets accepting the CE mark. The test (with results in 15-30 minutes) is intended for use by healthcare professionals to rapidly differentiate between SARS-CoV-2 and influenza virus A and B infections in people with COVID-19 or influenza symptoms.

Roche has analysed the publicly available sequences of Omicron and concluded that all of Roche PCR tests correctly identify SARS-CoV-2, including the Omicron variant.

CHF mil	llions	As % o	fsales	% change		
2021	2020	2021	2020	At CER	In CHF	
45,041	44,532	100.0	100.0	3	1	
22,505	23,647	50.0	53.1	-2	-5	
8,876	8,198	19.7	18.4	7	8	
4,506	3,765	10.0	8.5	26	20	
9,154	8,922	20.3	20.0	4	3	
	<b>2021</b> 45,041 22,505 8,876 4,506	45,041         44,532           22,505         23,647           8,876         8,198           4,506         3,765	2021         2020         2021           45,041         44,532         100.0           22,505         23,647         50.0           8,876         8,198         19.7           4,506         3,765         10.0	2021         2020         2021         2020           45,041         44,532         100.0         100.0           22,505         23,647         50.0         53.1           8,876         8,198         19.7         18.4           4,506         3,765         10.0         8.5	2021         2020         2021         2020         At CER           45,041         44,532         100.0         100.0         3           22,505         23,647         50.0         53.1         -2           8,876         8,198         19.7         18.4         7           4,506         3,765         10.0         8.5         26	

## Pharmaceuticals sales

\*Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

F. Hoffmann-La Roche Ltd

Group Communications Roche Group Media Relations



Top-selling pharmaceuticals	Tot	al	United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
Ocrevus	5,055	19	3,777	14	916	34	-	-	362	50
Perjeta	3,955	4	1,416	-1	1,112	-4	268	-4	1,159	24
Actemra/RoActemra	3,562	27	1,761	49	915	15	382	10	504	5
Tecentriq	3,315	24	1,688	11	713	22	518	66	396	53
Avastin	3,056	-37	922	-47	430	-66	674	-1	1,030	-15
Hemlibra	3,022	41	1,815	34	609	61	365	23	233	102
Herceptin	2,694	-28	636	-52	544	-19	82	-38	1,432	-9
MabThera/Rituxan	2,565	-38	1,552	-44	268	-30	42	-30	703	-24
Kadcyla	1,982	16	813	4	687	21	130	53	352	29
Xolair	1,942	5	1,942	5	-	-	-	-	-	
Ronapreve	1,630	-	-	-	727	-	645	-	258	-
Alecensa	1,356	18	366	10	297	11	247	8	446	40
Lucentis	1,353	-4	1,353	-4	-	-	-	-	-	-
Activase/TNKase	1,312	2	1,255	2	-	-	-	-	57	5
Esbriet	1,039	-5	732	-4	269	0	-	-	38	-28

\* Asia–Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, others

## Pharmaceuticals: established products

Actemra/RoActemra (CHF 3.6 billion, +27%). Rheumatoid arthritis, forms of juvenile idiopathic arthritis and giant cell arteritis, CAR T cell-induced severe or life-threatening cytokine release syndrome and COVID-19 pneumonia. The inclusion of this medicine in treatment guidelines for severe COVID-19-associated pneumonia by a number of countries drove sales growth, with the United States and Europe as major contributors.

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Group Communications Roche Group Media Relations



**Avastin** (CHF 3.1 billion, -37%). Advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, relapsed glioblastoma (a type of brain tumour) and liver cancer in combination with Tecentriq. Sales were strongly impacted by the uptake of biosimilars, mainly in the United States and Europe.

**Herceptin** (CHF 2.7 billion, -28%). HER2-positive breast cancer and HER2-positive metastatic gastric cancer. The sales decrease was mainly due to biosimilar uptake in the United States and Europe.

**MabThera/Rituxan** (CHF 2.6 billion, -38%). Forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales further decreased due to the biosimilar erosion as well as COVID-19 pandemic restrictions.

**Xolair** (CHF 1.9 billion, +5%, United States only). Chronic idiopathic urticaria and allergic asthma. Sales growth in the chronic idiopathic urticaria indication was partly offset by competition in the allergic asthma indication. Xolair remains the market leader in the larger allergic asthma indication.

## Pharmaceuticals: medicines launched since 2012

**Ocrevus** (first approved in 2017; CHF 5.1 billion, +19%). Relapsing and primary progressive forms of multiple sclerosis; 2-hour only infusion. The demand for this treatment in both indications remained strong, mainly in the United States, while the pandemic still had a certain negative impact. New and returning patients both boosted growth, the latter group generating stronger sales.

**Perjeta** (first approved in 2012; CHF 4.0 billion, +4%). HER2-positive breast cancer. Sales increased mostly due to high demand in China in both early and metastatic breast cancer settings. In the United States, sales of Perjeta declined by 1% due to certain patients being switched to Kadcyla and due to the launch of Phesgo in 2020.

**Tecentriq** (first approved in 2016; CHF 3.3 billion, +24%). Cancer immunotherapy (either alone or in combinations) for various types of cancer, e.g. lung, bladder, breast and liver cancer. Sales increased in all regions, most notably in Japan, primarily due to the demand for treatment of hepatocellular carcinoma (HCC). US sales were higher, driven by the new indications for HCC and first-line non-small cell lung cancer (NSCLC).

**Hemlibra** (first approved in 2017; CHF 3.0 billion, +41%). Haemophilia A with and without factor VIII inhibitors; only prophylactic treatment that can be administered subcutaneously once weekly, every two or every four weeks. Sales continued to show a strong uptake, especially in the United States and Europe.

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Group Communications Roche Group Media Relations



**Kadcyla** (first approved in 2013; CHF 2.0 billion, +16%). HER2-positive breast cancer. Sales growth was driven by the usage of Kadcyla in the early breast cancer setting. Sales benefited from patients switching to this new standard of treatment.

**Ronapreve** (first approved in 2021; CHF 1.6 billion<sup>3</sup>). Antibody combination for the treatment of recently diagnosed high-risk patients with mild to moderate COVID-19. Roche is responsible for distribution in Europe and other countries outside the United States, its partner Regeneron for the United States. The uptake has been strong, mainly in Japan and Europe.

**Alecensa** (first approved in 2015; CHF 1.4 billion, +18%). ALK-positive non-small-cell lung cancer. The global uptake continued with sales growth across all regions.

Esbriet (first approved in 2014; CHF 1.0 billion, -5%). Idiopathic pulmonary fibrosis (IPF).

**Gazyva/Gazyvaro** (first approved in 2013; CHF 678 million, +9%). Chronic lymphocytic leukaemia, rituximab-refractory follicular lymphoma and previously untreated advanced follicular lymphoma.

**Evrysdi** (first approved in 2020; CHF 602 million, >500%). Spinal muscular atrophy (SMA) in adults and children two months of age and older. Evrysdi helps infants to survive without permanent ventilation. It is the first and only medicine for SMA that can be administered at home. Evrysdi continued to show a strong uptake across all regions.

**Phesgo** (first approved in 2020; CHF 340 million, >500%). Early and metastatic HER2-positive breast cancer (fixed-dose combination of Perjeta and Herceptin for subcutaneous injection). Offers faster administration in just minutes, compared to hours with standard intravenous administration.

Erivedge (first approved in 2012; CHF 269 million, -1%). Advanced basal cell carcinoma.

**Polivy** (first approved in 2019; CHF 247 million, +48%). Relapsed or refractory diffuse large B-cell lymphoma; part of combination therapy; a fixed-duration treatment option for people with this aggressive form of blood cancer.

**Enspryng** (first approved in 2020; CHF 107 million, >500%). Rare autoimmune disease of the central nervous system (neuromyelitis optica spectrum disorder; NMOSD); first subcutaneous NMOSD treatment that can be self- or carer-administered at home. Enspryng has continued to show a very good uptake, with over 1,000 people with this rare disease treated with Enspryng to date (including newly diagnosed and previously treated patients).

**Rozlytrek** (first approved in 2019; CHF 49 million, +109%). Specific form of non-small cell lung cancer (NSCLC); solid tumours expressing a specific gene fusion; ROS1-positive, advanced NSCLC.

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Group Communications Roche Group Media Relations



**Susvimo** (first approved in 2021; CHF 1.0 million<sup>3</sup>). Eye implant with continuous drug delivery for nAMD treatment.

Dia	ano	stics	sales
νια	gno	SUCS	Sales

Sales	CHF m	illions	As % o	f sales	% change		
January - December 2021	2021	2020	2021	2020	At CER	In CHF	
Diagnostics Division	17,760	13,791	100.0	100.0	29	29	
Customer Areas							
Core Lab	7,473	6,194	42.1	44.9	21	21	
Molecular Lab	4,812	3,760	27.1	27.3	29	28	
Point of Care	2,583	1,079	14.5	7.8	138	139	
Diabetes Care	1,690	1,670	9.5	12.1	3	1	
Pathology Lab	1,202	1,088	6.8	7.9	12	10	
Regions							
Europe, Middle East, Africa	7,537	5,491	42.4	39.5	37	37	
North America	4,369	3,867	24.6	28.4	16	13	
Asia-Pacific	4,756	3,645	26.8	26.4	29	30	
Latin America	1,098	788	6.2	5.7	48	39	

**Core Lab**. Focuses on central labs; provides diagnostics solutions in the areas of immunoassays, clinical chemistry and custom biotech. Sales increased by 21% due to its immunodiagnostics business, with infectious and cardiac tests as main contributors. Sales grew across all regions, most strongly in EMEA and Asia-Pacific.

**Molecular Lab**. Focuses on molecular labs; provides diagnostics solutions for pathogen detection and monitoring, donor screening, sexual health and genomics. Sales grew 29%, led by the virology business. The Delta variant continued to push growth in COVID-19 testing such as high-throughput PCR tests. Sales increased in all regions, led by the North America and Asia-Pacific regions.

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Group Communications Roche Group Media Relations



**Point of Care**. Focuses on diagnostics solutions in emergency rooms, medical practices or directly with patients; includes SARS-CoV-2 rapid tests, blood gas and electrolyte tests. Continued significant sales growth of 138%. The SARS-CoV-2 Rapid Antigen test was the main growth driver, especially in the EMEA region.

**Diabetes Care**. Focuses on integrated personalised diabetes management for people with diabetes and healthcare professionals. Sales increased 3%, driven by the blood glucose monitoring business (such as the Accu-Chek Guide system).

**Pathology Lab**. Focuses on pathology labs; provides diagnostics solutions for tissue biopsies and companion diagnostics. These targeted diagnostics support the specific therapy decisions for each patient. Sales increased 12%. This was mainly due to growth in the advanced staining business.

## **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.

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 2020) and all total figures quoted are reported in CHF.
[2] Launches since 2012: Erivedge, Perjeta, Kadcyla, Gazyva/Gazyvaro, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi, Gavreto, Ronapreve, Susvimo
[3] recently approved; no growth figures available

#### 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.

#### **Roche Group Media Relations**

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

**Dr. Nicolas Dunant** Phone: +41 61 687 05 17

Dr. Barbara von Schnurbein Phone: +41 61 687 89 67

**Nina Mählitz** Phone: +41 79 327 54 74 **Sileia Urech** Phone: +41 79 935 81 48

**Karsten Kleine** Phone: +41 61 682 28 31

**Nathalie Meetz** Phone: +41 61 687 43 05

4070 Basel Switzerland Group Communications Roche Group Media Relations