Ad hoc announcement pursuant to Art. 53 LR

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Novartis delivers solid sales and profit growth. Strong performance of in-market brands supports confidence in mid-term growth outlook

- Q1 sales grew +5% (cc¹, +1% USD), core operating income grew +9% (cc, +3% USD)
 - Innovative Medicines (IM) sales grew +4% (cc, +1% USD) and core operating income +5% (cc, 0% USD)
 - o Strong performance of key growth brands including Entresto, Kesimpta, Cosentyx and Zolgensma
 - Sandoz sales grew +8% (cc, +2% USD) and core operating income +26% (cc, +21% USD), benefiting from a lower prior year comparison as business dynamics continued to normalize from COVID impacts
- Operating income grew +26% (cc, +18% USD) mainly due to higher sales, increased productivity and lower impairments
- Core operating income grew +9% (cc, +3% USD) with core margin increasing to 32.6% (+110 bps cc)
- Net income grew +15% (cc, +8% USD). Excluding the impact of Roche income, net income grew +32% (cc)
- Core EPS was USD 1.46 (+2% cc). Excluding the impact of Roche core income, core EPS grew +12% (cc)
- Free cash flow of USD 0.9 billion (-42% USD). The decrease was mainly due to the loss of Roche annual dividend paid out in March (PY USD 0.5 billion)
- New organizational structure announced to accelerate growth, strengthen pipeline and increase productivity (April)
- Q1 key innovation milestones:
 - o Pluvicto approved in the US for the treatment of progressive, PSMA positive mCRPC
 - o Vijoice approved in the US for the treatment of PIK3CA-related overgrowth spectrum (April)
 - o Beovu approved in the EU for the treatment of diabetic macular edema (DME)
 - o JDQ443 (KRAS G12C inhibitor) demonstrated anti-tumor activity with acceptable safety in NSCLC (April)
- Full-year 2022 group guidance confirmed²

Basel, April 26, 2022 - commenting on the quarter, Vas Narasimhan MD, CEO of Novartis, said: "Novartis delivered solid growth to start 2022, driven by our in-market key growth brands: Cosentyx, Entresto, Zolgensma and Kisqali. Our key launches including Kesimpta, Leqvio, Scemblix and Pluvicto are progressing well. Sandoz business dynamics continue to normalize from COVID impacts. The mid- stage pipeline remains on-track for 20+ potential significant pipeline assets with approval by 2026. The new organizational structure we announced is central to our growth strategy as a focused medicines company, making us more agile and competitive, enhancing patient and customer orientation, unlocking potential in our R&D pipeline, and driving value-creation through operational efficiencies."

Key figures¹

	Q1 2022	0	Roche investr impacts ³	nent	Reported		
		Q1 2021	% char	nge	Q1 2021	% chang	ge
	USD m	USD m	USD	сс	USD m	USD	cc
Net sales	12 531	12 411	1	5	12 411	1	5
Operating income	2 852	2 415	18	26	2 415	18	26
Net income	2 219	1 803	23	32	2 059	8	15
EPS (USD)	1.00	0.80	25	34	0.91	10	17
Free cash flow	920	1 075	-14		1 597	-42	
Core operating income	4 083	3 957	3	9	3 957	3	9
Core net income	3 251	3 100	5	11	3 413	-5	0
Core EPS (USD)	1.46	1.38	6	12	1.52	-4	2

¹ Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 35 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates in this Release refer to same period in prior year. ² Please see detailed guidance assumptions on page 6. ³ A reconciliation of 2021 IFRS results and non-IFRS measures core results and free cash flow to exclude the impacts of the 2021 divestment for uncertainty of our Roche investment can be found on page 40 of the Condensed Interim Financial Report. The free cash flow impact represents the dividend received in Q1 2021 from Roche in relation to the distribution of its 2020 net income.

Strategy Update

Novartis is a focused medicines company, continuing to build depth in five core therapeutic areas (Cardio-Renal, Immunology, Neuroscience, Solid Tumors and Hematology), strength in technology platforms (Gene Therapy, Cell Therapy, Radioligand Therapy, Targeted Protein Degradation and xRNA), and a balanced geographic footprint. Our confidence to grow in the near-term is driven by potential multibillion-dollar sales from: *Cosentyx, Entresto, Kesimpta, Zolgensma, Kisqali* and *Leqvio*. To fuel further growth through 2030 and beyond, we have 20+ new assets with significant sales potential that could be approved by 2026. The strategic review of Sandoz is progressing; we expect to provide an update, at the latest, by the end of 2022. We remain disciplined and shareholder focused in our capital allocation as we balance investing in our business, through organic investments and value-creating bolt-ons, with returning capital to shareholders via our growing annual dividend and share buybacks. Novartis continued to make significant strides in building trust with society and consistently integrating access strategies into how we research, develop and deliver our medicines; reaching over 55 million patients through various access approaches in 2021. We are committed to net zero emissions across our value chain by 2040. Our culture journey towards an inspired, curious and unbossed organization continues, in order to drive performance and competitiveness in the long-term.

In April, we announced a new organizational structure to accelerate growth, strengthen the pipeline and increase productivity. The Pharmaceuticals and Oncology business units are being integrated into an Innovative Medicines business with separate US and International commercial organizations to increase focus, strengthen competitiveness and drive synergies. A new Strategy & Growth function combining corporate strategy, R&D portfolio strategy and business development is being created to further strengthen the pipeline with high-value medicines across internal and external opportunities. A new Operations unit combining Novartis Technical Operations and Customer & Technology Solutions units aims to generate economies of scale, drive productivity and create a strong technology and operational foundation. With the changes, Novartis expects to deliver SG&A savings of at least USD 1 billion, to be fully embedded by 2024.

Financials

First quarter

Net sales were USD 12.5 billion (+1%, +5% cc) in the first quarter driven by volume growth of 11 percentage points, price erosion of 3 percentage points and the negative impact from generic competition of 3 percentage points.

Operating income was USD 2.9 billion (+18%, +26% cc), mainly due to higher sales, increased productivity and lower impairments, partly offset by higher R&D and M&S investments.

Net income was USD 2.2 billion (+8%, +15% cc), mainly driven by higher operating income, partly offset by the loss of Roche income. Excluding the impact of Roche income, net income grew +32% (cc). EPS was USD 1.00 (+10%, +17% cc), growing faster than net income, benefiting from lower weighted average number of shares outstanding. Excluding the impact of Roche income, EPS grew +34% (cc).

Core operating income was USD 4.1 billion (+3%, +9% cc). Core operating income margin was 32.6% of net sales, increasing by 0.7 percentage points (+1.1 percentage points cc).

Core net income was USD 3.3 billion (-5%, 0% cc), as growth in core operating income was offset by the loss of Roche core income. Excluding the impact of Roche core income, core net income grew +11% (cc). Core EPS was USD 1.46 (-4%, +2% cc), benefiting from lower weighted average number of shares outstanding. Excluding the impact of Roche core income, core EPS grew +12% (cc).

Free cash flow amounted to USD 0.9 billion (-42% USD), compared to USD 1.6 billion in the prior year quarter, mainly due to the loss of Roche annual dividend (prior year USD 0.5 billion) and unfavorable working capital, partly offset by favorable hedging results. Excluding the impact of Roche annual dividend, free cash flow declined -14% (USD).

Innovative Medicines net sales were USD 10.2 billion (+1%, +4% cc) with volume contributing 9 percentage points to growth. Sales growth was mainly driven by *Entresto*, *Kesimpta*, *Cosentyx*, *Xolair*, *Zolgensma* and *Kisqali*. Generic competition had a negative impact of 3 percentage points mainly due

to *Afinitor, Gleevec* and *Exjade*. Pricing had a negative impact of 2 percentage points. Sales in the US were USD 3.7 billion (+3%) and in the rest of the world were USD 6.5 billion (0%, +5% cc).

Sandoz net sales grew to USD 2.4 billion (+2%, +8% cc), benefiting from a lower prior year comparison as business dynamics continued to normalize from COVID impacts, with volume contributing 16 percentage points. Pricing had a negative impact of 8 percentage points. Sales in Europe grew +9% (cc), while sales in the US declined -2%. Global sales of Biopharmaceuticals grew to USD 515 million (+1%, +7% cc).

Q1 key growth drivers

Underpinning our financial results in the quarter is a continued focus on key growth drivers (ranked in order of cc contribution to Q1 growth) including:

Entresto	(USD 1,093 million, +42% cc) sustained strong growth with increased patient share across most markets, driven by demand in heart failure
Kesimpta	(USD 195 million) strong sales growth driven mainly by the US launch due to strong access and increased demand based on a favorable risk-benefit profile
Cosentyx	(USD 1,159 million, +12% cc) driven by demand led volume growth in the US and Europe, with accelerating growth in other international markets
Xolair	(USD 368 million, +17% cc) continued growth, driven by increasing demand in severe allergic asthma and chronic spontaneous urticaria
Zolgensma	(USD 363 million, +18% cc) growth was driven by expanding access in Europe and Emerging Growth Markets
Kisqali	(USD 239 million, +28% cc) grew across all geographies due to demand based on the longest overall survival benefit reported in HR+/HER2- advanced breast cancer
Jakavi	(USD 389 million, +14% cc) growth was driven by strong demand in the myelofibrosis and polycythemia vera indications
llaris	(USD 285 million, +18% cc) strong sales were driven by growth across all regions
Promacta/Revolade	(USD 491 million, +9% cc) showed growth across most regions, driven by increased use in chronic ITP and as first-line treatment for severe aplastic anemia
Tafinlar + Mekinist	(USD 403 million, +7% cc) grew due to demand in adjuvant melanoma and NSCLC
Mayzent	(USD 79 million, +47% cc) grew in MS patients showing signs of progression
Scemblix	(USD 25 million) launched in Q4 2021. Strong uptake demonstrating the high unmet need in CML
Sandoz Biopharmaceuticals	(USD 515 million, +7% cc) continued to grow in Europe and international markets
Emerging Growth Markets*	Overall, grew +12% (cc), with strong growth in China (+16% cc, USD 880 million). *All markets except the US, Canada, Western Europe, Japan, Australia, and New Zealand

Net sales of the top 20 Innovative Medicines products in 2022

	Q1 2022	% change	
	USD m	USD	cc
Cosentyx	1 159	10	12
Entresto	1 093	39	42
Gilenya	605	-14	-11
Lucentis	520	-5	0
Promacta/Revolade	491	6	9
Tasigna	461	-10	-7

Tafinlar + Mekinist	403	3	7
Jakavi	389	7	14
Xolair	368	10	17
Zolgensma	363	14	18
Sandostatin	320	-11	-9
llaris	285	11	18
Kisqali	239	23	28
Galvus Group	216	-18	-10
Exforge Group	200	-21	-19
Gleevec/Glivec	198	-27	-25
Kesimpta	195	nm	nm
Diovan Group	191	-11	-8
Afinitor/Votubia	138	-46	-43
Ultibro Group	132	-11	-6
Top 20 products total	7 966	3	7

nm= not meaningful

R&D update - key developments from the first quarter

New approvals

<i>Pluvicto</i> (lutetium Lu 177	Approved in the US as the first targeted radioligand therapy for the treatment of progressive, PSMA positive metastatic castration-resistant prostate cancer
vipivotide tetraxetan)	FDA also approved the complementary diagnostic imaging agent, Locametz® (kit for the preparation of gallium Ga 68 gozetotide injection)
Vijoice	Granted accelerated approval by FDA for treatment of adult and pediatric patients
(alpelisib)*	with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS)
Beovu	Approved in the EU for treatment of visual impairment due to diabetic macular edema

Regulatory updates

Jakavi	CHMP positive opinion for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease (GvHD) who have inadequate response to corticosteroids or other systemic therapies
Kymriah	CHMP positive opinion for adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy
Tislelizumab*	EMA validated filings for tislelizumab for advanced or metastatic esophageal squamous cell carcinoma after prior chemotherapy, advanced or metastatic NSCLC after prior chemotherapy, and in combination with chemotherapy for previously untreated advanced or metastatic NSCLC

Results from ongoing trials and other highlights

JDQ443 (KRAS G12C inhibitor)*	Demonstrated anti-tumor activity with acceptable safety in Ph1b/2 KontRASt-01 study in patients with advanced non-small cell lung cancer. Confirmed ORR was 57% (n= 4/7) at the recommended dose. Data was presented at AACR
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Kesimpta*	Data from ASCLEPIOS and the ALITHIOS open-label extension demonstrated long-term efficacy and safety with continued reduced risk of disability worsening for up to 4 years and stable IgG levels. KYRIOS study showed <i>Kesimpta</i> treated patients can mount an immune response to the COVID-19 mRNA vaccine
Kisqali	Ph3 MONALEESA-2 data showed a statistically significant overall survival increase of over 12 months for <i>Kisqali</i> -treated postmenopausal women with HR+/HER2- advanced or metastatic breast cancer. Additional analyses showed patients who received <i>Kisqali</i> plus letrozole as first-line therapy saw a 24% reduction in risk of death compared to those receiving letrozole alone, supporting first line use
Zolgensma	New data reinforces the transformational benefit of <i>Zolgensma</i> . Ph3 SPR1NT study demonstrated that children with three copies of the SMN2 back-up gene who were treated pre-symptomatically, achieved age-appropriate motor milestones. Descriptive post-hoc analyses of START, STR1VE-EU and STR1VE-US indicated children with SMA Type 1 achieved or maintained important measures of bulbar function following treatment including ability to speak and swallow
Others	Collaboration with Alnylam announced to leverage its proven, proprietary siRNA technology to develop targeted therapy to provide an alternative to transplantation for patients with liver failure
	License option agreement announced with Voyager Therapeutics for next- generation gene therapy vectors for neurological diseases

* Update was announced in early April 2022

Capital structure and net debt

Retaining a good balance between investment in the business, a strong capital structure and attractive shareholder returns remains a priority.

In Q1 2022, Novartis repurchased a total of 31.2 million shares for USD 2.7 billion on the SIX Swiss Exchange second trading line under the up-to USD 15 billion share buyback announced in December 2021. In addition, 1.1 million shares (for an equity value of USD 0.1 billion) were repurchased from employees. In the same period, 10.0 million shares (for an equity value of USD 0.3 billion) were delivered as a result of options exercised and share deliveries related to participation plans of employees. Novartis aims to offset the dilutive impact from equity based participation plans of employees over the remainder of the year. Consequently, the total number of shares outstanding decreased by 22.3 million versus December 31, 2021. These treasury share transactions resulted in an equity decrease of USD 2.5 billion and a net cash outflow of USD 2.4 billion.

As of March 31, 2022, net debt increased to USD 10.7 billion compared to USD 0.9 billion at December 31, 2021. The increase was mainly due to the USD 7.5 billion annual dividend payment and net cash outflow for treasury share transactions of USD 2.4 billion, partially offset by USD 0.9 billion free cash flow in Q1 2022.

As of Q1 2022, the long-term credit rating for the company is A1 with Moody's Investors Service and AA-with S&P Global Ratings.

2022 outlook

Barring unforeseen events

Innovative Medicines	Sales expected to grow mid single digit Core OpInc expected to grow mid to high single digit, ahead of sales
Sandoz	Sales expected to be broadly in line with prior year Core OpInc expected to decline low to mid single digit
Group	Sales expected to grow mid single digit Core OpInc expected to grow mid single digit

Our guidance assumes that we see a continuing return to normal global healthcare systems, including prescription dynamics, and that no *Sandostatin* LAR generics enter in the US.

Foreign exchange impact

If late-April exchange rates prevail for the remainder of 2022, the foreign exchange impact for the year would be negative 4 percentage points on net sales and negative 5 percentage points on core operating income. The estimated impact of exchange rates on our results is provided monthly on our website.

Executive Committee announcement

Novartis has appointed Aharon (Ronny) Gal Ph.D. as Chief Strategy & Growth Officer effective no later than August 1, 2022. Dr. Gal will lead the newly created Strategy & Growth function that combines corporate strategy, R&D portfolio strategy and business development. Dr. Gal joins Novartis from Sanford Bernstein where he is the Senior Analyst covering the US Biopharmaceutical industry. He brings over 20 years of life-sciences industry experience including financial research and analytics, management consulting and business development. He is a thought-leader in the healthcare sector and is widely recognized for his deep thematic research across therapeutic areas, technology platforms and key industry topics such as the US drug delivery system and efforts to reform it. Prior to joining Bernstein, Dr. Gal worked at Canon and the Boston Consulting Group. Dr. Gal was awarded a Ph.D. from the Massachusetts Institute of Technology and holds a B.Sc. from Emory University. He will report to Vas Narasimhan and join the Executive Committee of Novartis.

Key figures¹

		Excluding Roche investment			Reported		
			impacts ²	nent		reported	
Group	Q1 2022	Q1 2021	% chai	nge	Q1 2021	% chang	ge
	USD m	USD m	USD	CC	USD m	USD	CC
Net sales	12 531	12 411	1	5	12 411	1	5
Operating income	2 852	2 415	18	26	2 415	18	26
As a % of sales	22.8	19.5			19.5		
Core operating income	4 083	3 957	3	9	3 957	3	9
As a % of sales	32.6	31.9			31.9		
Net income	2 219	1 803	23	32	2 059	8	15
EPS (USD)	1.00	0.80	25	34	0.91	10	17
Core net income	3 251	3 100	5	11	3 413	-5	0
Core EPS (USD)	1.46	1.38	6	12	1.52	-4	2
Net cash flows from			_				
operating activities	1 649	1 608	3		2 130	-23	
Free cash flow	920	1 075	-14		1 597	-42	
Innovative Medicines	Q1 2022	Q1 2021	% chang				
	USD m	USD m	USD	CC			
Net sales	10 176	10 104	1	4			
Operating income	2 607	2 242	16	24			
As a % of sales	25.6	22.2					
Core operating income	3 652	3 666	0	5			
As a % of sales	35.9	36.3					
Sandoz	Q1 2022	Q1 2021	% chang				
	USD m	USD m	USD	CC			
Net sales	2 355	2 307	2	8			
Operating income	419	312	34	42			
As a % of sales	17.8	13.5					
Core operating income	538	445	21	26			
As a % of sales	22.8	19.3					
Corporate	Q1 2022	Q1 2021	% chang	е			
	USD m	USD m	USD	CC			
Operating loss	-174	-139	-25	-30			
Core operating loss	-107	-154	31	27			

¹Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 35 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates in this Release refer to same period in prior year. ² A reconciliation of 2021 IFRS results and non-IFRS measures core results and free cash flow to exclude the impacts of the 2021 divestment of our Roche investment can be found on page 40 of the Condensed Interim Financial Report. The free cash flow impact represents the dividend received in Q1 2021 from Roche in relation to the distribution of its 2020 net income.

Detailed financial results accompanying this press release are included in the Condensed Interim Financial Report at the link below: https://ml-eu.globenewswire.com/resource/download/0d330b95-7737-4a7c-96fe-ffb8d649b0a2/

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as "growth," "confidence," "confident," "outlook," "accelerate," "guidance," "launch," "focus," "progressing," "continue," "continuing," "continued," "continues," "driven," "long-term," "remains," "enhancing," "unlocking," "potential," "driving," "to build," "confidence," "to fuel," "can," ongoing," "progressing," "expect," "expects," "expected," "to provide," "committed," "could," "would," "to leverage," "outlook," "estimated," "pipeline," "priority," "transformative," "will," "integrating," "accelerating," or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, potential product launches, or regarding potential future revenues from any such products; or regarding potential future, pending or announced transactions, regarding potential future sales or earnings of the Group or any of its divisions; or by discussions of strategy, plans, expectations or intentions; or regarding the Group's liquidity or cash flow positions and its ability to meet its ongoing financial obligations and operational needs; or regarding the strategic review of Sandoz; or regarding our commitment to net zero emissions across our value chain by 2040; or regarding our new organizational structure. Such forwardlooking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. You should not place undue reliance on these statements. In particular, our expectations could be affected by, among other things: liquidity or cash flow disruptions affecting our ability to meet our ongoing financial obligations and to support our ongoing business activities; the potential that the strategic benefits, synergies or opportunities expected from our new organizational structure may not be realized or may be more difficult or take longer to realize than expected; the impact of a partial or complete failure of the return to normal global healthcare systems, including prescription dynamics; global trends toward healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the development of the products described in this press release; the uncertainties in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; safety, guality, data integrity, or manufacturing issues; uncertainties involved in the development or adoption of potentially transformational technologies and business models; uncertainties regarding actual or potential legal proceedings, investigations or disputes; our performance on environmental, social and governance measures; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

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About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

Novartis will conduct a conference call with investors to discuss this news release today at 14:00 Central European time and 8:00 Eastern Time. A simultaneous webcast of the call for investors and other interested parties may be accessed by visiting the Novartis website. A replay will be available after the live webcast by visiting <u>https://www.novartis.com/investors/event-calendar</u>.

Detailed financial results accompanying this press release are included in the condensed interim financial report at the link below. Additional information is provided on Novartis divisions and pipeline of selected compounds in late stage development and a copy of today's earnings call presentation can be found at <u>https://www.novartis.com/investors/event-calendar</u>.

Important dates

July 19, 2022	Second quarter & Half year 2022 results
September 21/22, 2022	Meet Novartis Management (starts at 1800 CET in Basel on September 21)
October 25, 2022	Third quarter & Nine months 2022 results