

Novartis International AG Novartis Global Communications CH-4002 Basel Switzerland

https://www.novartis.com https://twitter.com/novartisnews

# **MEDIA & INVESTOR RELEASE**

# Novartis R&D day spotlights attractive growth profile, underpinned by strong in-market brands, 20 potential high value pipeline assets, and technology platforms

- Focused medicines company delivering strong operational performance
- Building depth in five core therapeutic areas, strength in technology platforms, and a balanced geographic footprint
- Confident to grow sales 4%+ CAGR through 2026<sup>\*</sup>, driven by multi-billion dollar sales from Cosentyx<sup>®</sup>, Entresto<sup>®</sup>, Kesimpta<sup>®</sup>, Zolgensma<sup>®</sup>, Kisqali<sup>®</sup> and Leqvio<sup>®\*\*</sup>
- Up to 20 new assets with >1-billion dollar sales potential, set to potentially be approved by 2026, to fuel further growth through 2030 and beyond
- Cosentyx met primary efficacy endpoint in two hidradenitis suppurativa Ph3 studies, and ianalumab demonstrated efficacy in Ph2b Sjögren's study¹
- Next-generation T-Charge<sup>™</sup> platform validated as YTB323 showed 75% CR at 3 months in DLBCL<sup>2</sup> and PHE885 delivered 100% BOR in multiple myeloma<sup>3</sup>
- Pioneering shift to advanced technology platforms including: Targeted Protein Degradation, Cell Therapy, Gene Therapy, Radioligand Therapy, and xRNA

**Basel, December 2, 2021** — Novartis today holds an investor event to provide a comprehensive overview of the company's progress in advancing its industry-leading R&D engine.

Vas Narasimhan, CEO of Novartis, said "Novartis has transformed to become a focused medicines company, building depth in our core therapeutic areas and strength across key technology platforms. We expect to continue delivering strong operational performance, with 4%+ CAGR through to 2026\*, driven by the momentum of our multi-billion dollar in-market growth drivers. Up to 20 new assets with significant sales potential could be approved by 2026, which will fuel the next phase of growth and address major unmet needs. We are building the foundation for long-term differential growth by investing in advanced technology platforms and data science. Novartis remains disciplined and shareholder focused in its capital allocation priorities, as we continue to deliver on our strategy".

## New announcements at R&D Day 2021:

Cosentyx, our largest medicine by sales, showed topline results in moderate to severe hidradenitis suppurativa (HS), a potential new indication. Two Phase 3 studies (SUNRISE and SUNSHINE) met their primary endpoint, with more patients treated with Cosentyx achieving a HS Clinical Response (HiSCR), compared with placebo, at week 16. The safety of Cosentyx in HS was consistent with the therapy's known safety profile. The trials are ongoing to 52 weeks and are expected to complete in H2 2022. Regulatory filings are planned for 2022.

Novartis presents T-Charge™, a next generation CAR-T cell therapy platform, expected to increase CAR-T potency and have important process efficiencies to reduce turnaround time. In first-in-human trials to be presented at ASH 2021, lead candidates YTB323 and PHE885 showed 75% Complete Response in Diffuse Large B-Cell Lymphoma (DLBCL) at three months

and 100% Best Overall Response (BOR) in multiple myeloma, respectively. Novartis is developing T-Charge $^{\text{TM}}$  as the foundational platform for a wave of potentially transformative CAR-T cell therapies.<sup>2,3</sup>

## Phase 3 study starts planned or ongoing across 5 core therapeutic areas include:

- Cardio-Renal: Legvio (CVRR-LDL-C), pelacarsen (CVRR-Lp(a)), iptacopan (C3G; IgAN)
- **IHD:** Cosentyx (HS; GCA; lupus nephritis), ligelizumab (CSU; food allergy; CINDU), ianalumab (Sjögren's syndrome), remibrutinib (CSU)
- Neuroscience: Zolgensma (SMA IT), remibrutinib (MS)
- Oncology: Kisqali (HR+/HER2- BC adjuvant), <sup>177</sup>Lu-PSMA-617 (mCRPC, pretaxane; mHSPC), canakinumab (adjuvant NSCLC), NIS793 (PDAC), JDQ443 (NSCLC, 2/3L)
- Hematology: Iptacopan (aHUS; PNH), Scemblix® (CML 1L), sabatolimab (HR-MDS), and YTB323 (2L DLBCL)

(for abbreviations, see below)

Novartis announces a global co-development and co-commercialization agreement with UCB to bring disease-modifying therapies to people living with Parkinson's Disease. The agreement covers UCB0599, a potential first-in-class, small molecule, alpha-synuclein misfolding inhibitor currently in Phase 2 clinical development. In addition, upon completion of the ongoing Phase 1 program, there is an opt-in to co-develop UCB7853, an anti-alpha-synuclein antibody. Both assets could transform care for 10 million people living with Parkinson's Disease worldwide given the lack of disease-modifying therapies.<sup>4,5</sup>

Novartis also provides **a comprehensive overview of its mid- and late-stage pipeline assets** in five core therapeutic areas, highlighting: *Leqvio*, pelacarsen, iptacopan, *Cosentyx*, ligelizumab, remibrutinib, ianalumab, LNA043, branaplam, *Zolgensma*, *Kisqali*, <sup>177</sup>Lu-PSMA-617, sabatolimab, JDQ443, TNO155, *Scemblix* and NIS793.

Additionally, Novartis highlights the continued expansion of its pipeline and **capabilities in advanced technology platforms** that are expected to drive multiple waves of biopharmaceutical innovation. These include: T-Charge<sup>TM</sup>, Targeted Protein Degradation, Cell Therapy, Gene Therapy, Radioligand Therapy and xRNA.

## Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "could," "expect," "pipeline," "continued," "continue," "strategy," "drive," "deliver," "remains," "innovation," "pioneering," "expected," "mid- to long-term," "confident," "to grow," "to fuel," "growth," "progress," "potential," or similar to grow, "to fuel," "growth," "progress," "potential," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release; or regarding potential future revenues from such products; or regarding Cosentyx topline results in a new indication; or regarding the global co-development and co-commercialization agreement between Novartis and UCB; or regarding current and potential future or pending collaborations and alliances; or regarding T-Charge, a next generation CAR-T cell therapy platform being developed by Novartis. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions

or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; the potential that the strategic benefits, synergies or opportunities expected from the collaborations or alliances described, may not be realized or may be more difficult or take longer to realize than expected; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 contained in this press release as a result of new information, future events or otherwise.

#### **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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <a href="https://www.novartis.com">https://www.novartis.com</a>.

Novartis is on Twitter. Sign up to follow @Novartis at https://twitter.com/novartisnews
For Novartis multimedia content, please visit https://www.novartis.com/news/media-library
For questions about the site or required registration, please contact media.relations@novartis.com

#### **Abbreviations**

CVRR-LDL-C - Cardiovascular risk reduction - LDL-C; CVRR-Lp(a) - Cardiovascular risk reduction - Lp(a); C3G - Complement 3 glomerulopathy; IgAN - IgA nephropathy; HS - Hidradenitis suppurativa; GCA - Giant cell arteritis; CSU - Chronic spontaneous urticaria; CINDU - Chronic inducible urticaria; SMA IT - Spinal muscular atrophy - Intrathecal; MS - Multiple sclerosis; HR+/HER2- BC - Hormone receptor positive/ human epidermal growth factor receptor 2 positive breast cancer; mCRPC - Metastatic castration-resistant prostate cancer; mHSPC - Metastatic hormone-sensitive prostate cancer; NSCLC - Non-small cell lung cancer; PDAC - Pancreatic ductal adenocarcinoma; aHUS - Atypical hemolytic uremic syndrome; PNH - Paroxysmal nocturnal hemoglobinuria; CML - Chronic myelogenous leukemia; HR-MDS - Higher-risk myelodysplastic syndromes; DLBCL - Diffuse large B-cell lymphoma

## References

- Smolen J, Nash P, Tahir H, Schulze-Koops H, Li L, Hojnik M, Gellett A, Liu-Leage S, Pillai S, Mease P. lanalumab (VAY736), a Dual Mode of Action Biologic Combining BAFF Receptor Inhibition with B Cell Depletion, for Treatment of Primary Sjögren's Syndrome: Results of an International Randomized, Placebo Controlled Dose Range Finding Study in 190 Patients [abstract]. Arthritis Rheumatol. 2019; 71 (suppl 10). https://acrabstracts.org/abstract/ianalumab-vay736-a-dual-mode-of-action-biologic-combining-baff-receptor-inhibition-with-b-cell-depletion-for-treatment-of-primary-sjogrens-syndrome-results-of-an-international-randomized/. Accessed November 2021
- 2. Flinn, I. et al. A First-in-Human Study of YTB323, a Novel, Autologous CD19-Directed CAR-T Cell Therapy Manufactured Using the Novel T-Charge platform, for the Treatment of Patients (Pts) with Relapsed/Refractory (r/r) Diffuse Large B-Cell Lymphoma (DLBCL). Oral Presentation #740. 2021 American Society of Hematology (ASH) Annual Meeting, Dec 11-14, Atlanta, GA and Virtual.
- 3. Sperling, A. et al. Phase I Study of PHE885, a Fully Human BCMA-Directed CAR-T Cell Therapy for Relapsed/Refractory Multiple Myeloma Manufactured in<2 days Using the T-Charge. Poster #3864. 2021 American Society of Hematology (ASH) Annual Meeting, Dec 11-14, Atlanta, GA and Virtual.
- Parkinson's Foundation. Parkinson's Disease Statistics. https://www.parkinson.org/Understanding-Parkinsons/Statistics. Accessed November 2021.

<sup>\* 2020 – 2026</sup> CAGR calculated vs. 2020 base year.

<sup>\*\*</sup>Product and brand name are currently under FDA review.

5. Parkinson's Foundation. Parkinson's Disease Treatment. https://www.parkinson.org/Understanding-Parkinsons/Treatment. Accessed November 2021.

###

### **Novartis Media Relations**

E-mail: media.relations@novartis.com

Richard Jarvis Julie Masow

Novartis Strategy & Financial Comms Novartis US External Engagement

+41 79 584 23 26 (mobile) +1 862 579 8456

richard.jarvis@novartis.com Julie.masow@novartis.com

## **Novartis Investor Relations**

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central North America

 Samir Shah
 +41 61 324 7944
 Sloan Simpson
 +1 862 345 4440

 Thomas Hungerbuehler
 +41 61 324 8425
 Alina Levchuk
 +1 862 778 3372

 Isabella Zinck
 +41 61 324 7188
 Parag Mahanti
 +1 973-876-4912