Novartis expects to sustain long-term growth with a robust pipeline of 25+ potential blockbusters highlighted at R&D Day

- Uniquely positioned with global scale, focus on innovative medicines, diversification across therapeutic areas and exposure to cutting-edge platforms
- 60 projects in Phase 2 pipeline with 10+ advancing into Phase 3 or pivotal trials each year in 2020 and 2021; over 90% projected to be first-in-class or first-in-indication
- Emerging assets address areas of high unmet need including iscalimab in transplant and Sjögren’s syndrome, LNP023 in renal diseases and PNH, MBG453 in MDS, and TQJ230 in cardiovascular risk reduction
- Expected near-term launches include ofatumumab in relapsing MS, fevipiprant in asthma, radioligand therapy Lu-PSMA-617 in prostate cancer, Adakveo® in sickle cell disease and canakinumab in lung cancer
- Exploring over 40 new indications for in-market brands, including up to 7 for Cosentyx® alone, and others for Beovu®, Piqray® and Kisqalis®, to maximize potential of these medicines

London, December 5, 2019 – Today Novartis holds an investor event in London to provide a comprehensive overview of the company’s progress in advancing its industry-leading R&D pipeline.

Vas Narasimhan, CEO of Novartis, said “Novartis had a year of breakthrough innovation in 2019, with five potential blockbuster NME approvals. The near term brings yet another catalyst-rich period with pipeline progress across the portfolio that can sustain long-term growth. Our operational focus is beginning to show results including accelerating timelines, reducing costs and improving productivity without compromising quality. We look forward to delivering new transformational treatment options to patients and continuing to reimagine medicine to address some of the world’s greatest unmet healthcare needs.”

Key highlights to be presented at R&D Day 2019:

Emerging assets that address significant unmet need are being prioritized and advanced into pivotal trials in the coming years. Iscalimab (CFZ533) is a monoclonal antibody (mAb) against the CD40 receptor which has the potential to become the standard of care in transplant, and has demonstrated positive proof-of-concept in Sjögren’s syndrome, the second most common rheumatic autoimmune disease after rheumatoid arthritis. Trials are being initiated in six separate indications. LNP023, an oral Factor B inhibitor targeting the alternative complement pathway, is in parallel development for three rare renal diseases and in hematology for first-line paroxysmal nocturnal hemoglobinuria (PNH), with first results anticipated in 2020. In immuno-
The late stage pipeline has Phase 3 readouts and launches on the horizon that will drive near-to mid-term growth. Launch preparations are underway for ofatumumab (OMB157), a B-cell depleting treatment for relapsing multiple sclerosis, supported by a robust clinical profile including a new post-hoc analysis showing strong reductions in confirmed disability worsening. Fevipiprant (QAW039), an oral therapy for asthma, and Lu-PSMA-617 a radioligand therapy for prostate cancer, both have upcoming Phase 3 readouts and the potential to change standard of care. Ligelizumab (QGE031), a treatment for chronic spontaneous urticaria, with approximately 100-fold greater affinity to bind to IgE than Xolair®, has Phase 3 results and filing expected by the end of 2021. Pivotal studies of canakinumab (ACZ885), an IL-1 beta mAb for non-small cell lung cancer, are recruiting ahead of schedule in both the 1st line and 2nd line settings, with planned filings in 2021.

New indications are being pursued to maximize the potential of in-line brands. Cosentyx® (secukinumab) is our largest drug by sales, based on its three already approved indications, with plans in place to expand to 10 indications over the next 10 years. Future potential indications include non-contrast radiographic axial SpA, hidradenitis suppurativa, giant cell arteritis and lupus nephritis. Beovu® (brolucizumab-dbll) was launched in the US in October and is expanding the weight of evidence in wet AMD while exploring potential new indications, including diabetic macular edema (DME) and retinal vein occlusion (RVO). Piqray® (alpelisib) was recently approved by the FDA for breast cancer patients with a PIK3CA mutation, and development work has been initiated for five new indications, including PIK3CA-relative overgrowth syndrome (PROS), for which alpelisib received FDA Breakthrough Therapy and Orphan Drug designations. Kisqali® (ribociclib) showed positive overall survival data in two separate Phase 3 studies in 2019, and Novartis is accelerating the ongoing NATALEE adjuvant trial with potential registration in 2022 based on interim results.

Approximately 90 innovative new molecular entities (NMEs) are emerging from the Novartis Institutes for BioMedical Research (NIBR), creating a deep and diverse early-stage portfolio. The NIBR team has advanced several new therapeutic platforms to address difficult drug targets and diseases across oncology and other therapeutic areas, including a portfolio of molecular glues that features the SHP2 inhibitor TNO155 in development in for advanced solid tumors, including those harboring KRASG12C mutations.

In addition, Novartis has established leadership in three advanced therapy platforms: cell, gene and radioligand therapies. Each of these three platforms has a deep pipeline of investigational drugs or new indications, with a total of 16 advanced platform therapies now in clinical development.

For background slides and webcast (audio only) please refer to the following link: https://www.novartis.com/investors/event-calendar
The background slide decks will be available on December 5, 2019.

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 “expects,” “to sustain,” “long term,” “growth,” “near term,” “launches,” “pipeline,” “potential,” “blockbusters,” “focus,” “advancing,” “expected,” “projected,” “emerging,” “exploring,” “transformational,” “breakthrough innovation,” “catalyst rich,” “can,” “progress,” “portfolio,” “beginning to show results,” “look forward,” “being prioritized,” “advanced,” “positive proof-of-concept,” “being initiated,” “anticipated,” “on the horizon,” “near-term,” “mid-term,” “launch,” “underway,” “upcoming,” “ahead of schedule,” “planned,”
“being pursued,” “plans,” “launched,” “will,” “Breakthrough Therapy designation,” “Orphan Drug designation,” “accelerating,” “ongoing,” “has been initiated,” “investigational,” 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 the development or adoption of potentially transformational technologies, treatment modalities and business models; or regarding potential future or pending transactions, including the potential outcome, or financial or other impact on Novartis, of the proposed acquisition of The Medicines Company; or regarding potential future sales or earnings of the Group or any of its divisions, or potential shareholder returns; or by discussions of strategy, plans, expectations or intentions. Such forward-looking 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: global trends toward healthcare cost containment, including ongoing government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the proposed acquisition of The Medicines Company or the development of the products described in this press release as well as potential regulatory actions or delays with respect thereto; the potential that the strategic benefits, synergies or opportunities expected from the proposed acquisition of The Medicines Company may not be realized or may be more difficult or take longer to realize than expected; the successful integration of The Medicines Company into the Novartis Group subsequent to the closing of the transaction and the timing of such integration; potential adverse reactions to the proposed transaction by customers, suppliers or strategic partners; dependence on key personnel of The Medicines Company; dependence on third parties to fulfill manufacturing and supply obligations; the inherent uncertainties involved in predicting shareholder returns; the inherent uncertainties involved 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 that commenced in prior years and will continue this year; safety, quality, data integrity or manufacturing issues; uncertainties regarding actual or potential legal proceedings, including, among others, product liability litigation, disputes and litigation with business partners or business collaborators, government investigations generally, litigation and investigations regarding sales and marketing practices, and intellectual property disputes; uncertainties involved in the development or adoption of potentially transformational technologies, treatment modalities and business models; our performance on environmental, social and governance measures; political, economic and trade conditions, including uncertainties regarding the effects of ongoing instability in various parts of the world; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; uncertainties regarding potential significant breaches of data security or data privacy, 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 United States Securities and Exchange Commission (the “SEC”). 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.

Additional Information
This press release is neither an offer to purchase nor a solicitation of an offer to sell securities. On December 5, 2019, Novartis and its indirect wholly owned subsidiary, Medusa Merger Corporation (“Purchaser”), will file a Tender Offer Statement on Schedule TO with the SEC and The Medicines Company will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC, in each case with respect to the tender offer for the outstanding shares of common stock, par value USD 0.001, of The Medicines
Company (the “Offer”). The Tender Offer Statement (including the Offer to Purchase, the related Letter of Transmittal and other offer documents) and the Solicitation/Recommendation Statement contain important information that should be read carefully before any decision is made with respect to the Offer. Those materials and all other documents filed by, or caused to be filed by, Novartis, Purchaser or The Medicines Company with the SEC will be available at no charge on the SEC’s website at www.sec.gov. The Schedule TO Tender Offer Statement and related materials will be available for free under the “Investors – Financial Data – SEC Filings” section of Novartis’ website at https://www.novartis.com/investors/financial-data/sec-filings. The Schedule 14D-9 Solicitation/Recommendation Statement and such other documents will be available for free from The Medicines Company under the “Investors & Media” section of The Medicines Company’s website at https://www.themedicinescompany.com/investor/financial/.

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 more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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