

MEDIA & INVESTOR RELEASE

Sandoz Resolves Legacy Federal Government Civil Investigation in the U.S. Regarding Generic Drugs

- *Company previously disclosed settlement agreement in principle and fully provisioned for this resolution*

Basel, October 1, 2021 – Sandoz Inc., the U.S. subsidiary of Sandoz, has entered a settlement agreement with the Civil Division of the U.S. Department of Justice (DOJ) concerning the Department's years-long pricing investigation into the U.S. generic drug industry. This settlement is an expected outcome of the resolution the company reached in March 2020 with the DOJ Antitrust Division regarding the same investigation and underlying conduct. Today's settlement contains no new factual allegations against Sandoz, and the company fully provisioned for this settlement and disclosed the agreement in principle as part of the March 2020 resolution.

As recognized by the DOJ, Sandoz cooperated with the government's investigation. The conduct at issue here occurred at Sandoz from March 2013 through December 2015 in direct contravention of the company's values, policies and trainings in place at the time. The individuals implicated in the underlying conduct are no longer employed by the company. As part of the agreement, Sandoz will pay USD 185 million, plus interest from the date of the agreement in principle to settle, and has agreed to corporate integrity obligations with the Office of Inspector General of the U.S. Department of Health and Human Services through 2026.

Keren Haruvi, President of Sandoz Inc., said: "Today's settlement bookends the March 2020 resolution and resolves all outstanding federal government matters concerning the DOJ's investigation into our historical conduct. The agreement is consistent with our commitment to resolve legacy compliance matters and continuously improve our compliance and training programs and evolve our controls. We're moving forward and remain focused on pioneering new ways to help people around the world access high-quality medicines." Since the time of the referenced conduct, Sandoz has further evolved its compliance program in the spirit of continuous improvement. Given that this resolution includes a Corporate Integrity Agreement, Sandoz will be implementing controls designed to ensure compliance with the terms of this settlement. Sandoz strives to operate at the highest levels of sound governance as it reinforces its global leadership in generic pharmaceuticals and biosimilars covering all major therapeutic areas.

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 “expected,” “provisioned,” “will,” “commitment,” “to resolve,” “continuously,” “evolve,” “further evolved,” “implementing,” “strives,” “to operate,” “portfolio,” “purpose,” “ambition,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the generic and biosimilar products described in this press release, or regarding potential future revenues from such products, or regarding the resolution, the settlement agreement, the investigation into the generic pharmaceutical industry, our corporate integrity obligations, and the compliance activities described in this press release. 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 ongoing and future enhancements to our compliance activities, including with regards to our corporate integrity obligations, will be successful, or achieve any particular outcome, or in any particular time frame. Neither can there be any 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 the resolution, the settlement agreement, the ongoing and future enhancements to our compliance activities, including with regards to our corporate integrity obligations, and such products could be affected by, among other things, the possibility that our enhanced compliance activities may not successfully prevent or detect all future improper activities; regulatory actions or delays or government action generally; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional generic or biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; 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 Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical needs. Our ambition is to be the world’s leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2020 sales of USD 9.6 billion.

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