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MEDIA & INVESTOR RELEASE

Sandoz submits Marketing Authorization Application for proposed biosimilar trastuzumab to EMA

- *Submission is supported by comprehensive package of analytical, pre-clinical and clinical data, proposed biosimilar trastuzumab developed by EirGenix, Inc.*
- *Breast cancer is one of most common types of cancer in women, accounting for over 355,000 new cases in 2020 in Europe alone*[1]
- *Sandoz has been developing and providing oncology medicines for over 30 years, to expand access to and increase affordability of high quality medicines*

Basel, December 22, 2021 — Sandoz, a global leader in generic and biosimilar medicines, today announced that it has submitted a Marketing Authorization Application for a proposed biosimilar trastuzumab (150 mg, for intravenous use) developed by EirGenix, Inc. to the European Medicines Agency (EMA).

Trastuzumab is a monoclonal antibody used for the treatment of human epidermal growth factor receptor 2 positive (HER2-positive) breast cancer and metastatic gastric cancers[2]. Sandoz is seeking approval for the same indications as the reference medicine, based on a comprehensive package that includes analytical, preclinical, and clinical data.

“In 2020, breast cancer accounted for 28.7% of all new cancer cases diagnosed, making it the most frequently occurring cancer and first cause of cancer death among women in Europe[1]”, said Florian Bieber, Global Head of Biopharmaceuticals Development, Sandoz. “Biosimilars have enormous potential to improve cancer care. Today’s submission is an encouraging step forward in our mission to expand access to advanced biologics treatments to address the evolving needs of patients, healthcare professionals and healthcare systems.”

As part of the license agreement signed in April 2019, EirGenix, Inc. is responsible for development and manufacturing and Sandoz will have the right to commercialize the medicine upon approval in all markets excluding China and Taiwan. On December 20, 2021, Sandoz announced submission of a Biologics License Application for a proposed biosimilar trastuzumab (150 mg) to the US Food and Drug Administration.

Sandoz has been developing and providing oncology medicines for over 30 years. Today, it has more than 50 such medicines, including chemotherapeutics, biologics, hormones and supportive care treatments, for the treatment of a wide range of cancers. The collaboration with EirGenix, Inc. will enable Sandoz to build on its leading generic and biosimilar oncology portfolio to further expand patient access, while contributing to the sustainability of healthcare systems.

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,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” 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. 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. Neither can there be any guarantee that, if approved, such generic or biosimilar products will be approved for all indications included in the reference product’s label. 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; 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.

Sandoz on social media:
LinkedIn: https://www.linkedin.com/company/sandoz
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Instagram: https://www.instagram.com/sandozglobal

CEO Richard Saynor on LinkedIn: https://www.linkedin.com/in/richard-saynor/

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1. European Commission. Breast Cancer Burden Factsheet. Available from: https://ecis.jrc.ec.europa.eu/pdf/Breast_cancer_factsheet-Dec_2020.pdf [Last accessed: October 2021].
2. EMA. Herceptin® trastuzumab EPAR. https://www.ema.europa.eu/en/medicines/human/EPAR/herceptin [Last accessed: October 2021].

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