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Sandoz enters agreement for proposed trastuzumab biosimilar, currently in Phase III development, to treat selected HER2-positive cancer tumors

- *Collaboration covers proposed trastuzumab biosimilar in Phase III development for human epidermal growth factor receptor 2 positive (HER2+) breast and gastric tumors*
- *Per licence agreement, EirGenix, Inc is responsible for development and manufacturing; Sandoz has right to commercialize in all markets except China and Taiwan*
- *Agreement is third announced biosimilars collaboration for Sandoz in 18 months; will build on robust portfolio of eight approved molecules, with a further 10-plus in development*

Holzkirchen, Germany, April 30, 2018 – Sandoz, a Novartis division and a global leader in biosimilars, today announced that it has entered into an agreement to commercialize a proposed trastuzumab biosimilar. This medicine is currently in Phase III clinical development for treatment of human epidermal growth factor receptor 2 positive (HER2+) breast and specific gastric cancer tumors.

The agreement between Sandoz and EirGenix, Inc, a biotechnology manufacturing and development company that aspires to provide high-quality medicines for individuals and society, aims to bring to market a proposed biosimilar trastuzumab. EirGenix will maintain responsibility for development and manufacturing, and Sandoz has the right to commercialize the medicine upon approval in all markets excluding China and Taiwan.

According to the terms of the agreement, EirGenix will receive an upfront payment on signing, milestone payments, and is entitled to receive profit share payments for sales in the territories. This structure allows Sandoz to keep in-house resources focused on bringing forward a robust internal pipeline. The collaboration further expands the existing Sandoz oncology portfolio of four oncology biosimilar medicines, while enabling the company to further develop its strong hospital presence. Other specific terms of the agreement are confidential.

“Every year, approximately 300,000 people worldwide are diagnosed with HER2-positive breast cancer, which tends to spread more quickly than HER2-negative tumors, making swift treatment important. While targeted therapy is available, high out-of-pocket costs lead to limited treatment in the US and reimbursement issues have resulted in varying uptake in Europe”,[1,2] said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz. “Introducing biosimilars can help create earlier and expanded access to this important medicine, which is why I am so excited about the potential for this collaboration.”

Cancer places a significant and growing burden on healthcare systems around the world with the annual economic cost in 2010 estimated at approximately USD 1.16 trillion[3]. Biologics have helped to advance cancer care, and the reference medicine for trastuzumab is one of the top four cancer medicines by sales in 2018 with sales[4] of approximately USD 6.9 billion[5]. With the loss of exclusivity for the reference medicine, there continues to be a significant opportunity to introduce biosimilar competition to generate savings and increase access to this important medicine.

Sandoz biosimilars are helping patients, particularly in immunology, oncology and endocrinology, access medicines sustainably and affordably. The division has a leading global portfolio with eight marketed biosimilars and a further 10-plus in development. Half of the marketed biosimilar medicines are in oncology, with three in supportive cancer care and one for the treatment of blood cancers.

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Additional investigational oncology biosimilars are in the pipeline. Broadening the Sandoz oncology offering has benefits for payers, patients and healthcare systems overall.

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 “proposed,” “in development,” “will,” “has the right to,” “aims,” “upon approval,” “introducing,” “can,” “potential,” “growing,” “opportunity,” "portfolio," “investigational,” “pipeline,” “enables,” "purpose," "pioneer," “focused,” "can," "launch," "may," or similar terms, or by express or implied discussions regarding potential launches, marketing authorizations, new indications or labeling for proposed biosimilar trastuzumab or the other products described in this press release, or regarding potential future revenues from such products or the collaboration with EirGenix. 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. You should not place undue reliance on these statements. There is no guarantee that the collaboration with EirGenix will achieve any or all of its intended goals and objectives, or within any particular time frame. Neither can there be any guarantee that proposed biosimilar trastuzumab will be approved for sale or launched in any market, or within any particular time frame. Nor can there be any guarantee that proposed biosimilar trastuzumab, the other products described in this press release, or the collaboration with EirGenix will be commercially successful in the future. In particular, our expectations regarding such products and the collaboration with EirGenix 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 particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional competing versions of proposed biosimilar trastuzumab or such other products; our ability to obtain or maintain proprietary intellectual property protection; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit each of Sandoz or EirGenix from marketing its products; general political, economic and industry conditions; safety, quality or production 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 and a pioneer in the emerging field of prescription digital therapeutics. Our purpose is to pioneer access to healthcare by developing and commercializing novel, affordable approaches that address unmet medical need. Our broad portfolio of high-quality medicines, covering all major therapeutic areas and increasingly focused on value-adding differentiated medicines, accounted for 2018 sales of USD 9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.
Sandoz is on Twitter.

Sign up to follow @Sandoz global at http://twitter.com/Sandoz_Global.

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