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MEDIA & INVESTOR RELEASE

Sandoz receives positive CHMP opinion for breast and gastric cancer biosimilar trastuzumab

- *Positive CHMP opinion based on comprehensive package of analytical, pre-clinical and clinical data*
- *Breast and gastric cancers are among most common types of cancer, accounting together for nearly half a million new cases every year in Europe alone*[1,2]
- *Sandoz is committed to accelerating access to potentially life-changing treatments and continues to strengthen its oncology and supportive care portfolio*

Basel, September 18, 2023 — Sandoz, a global leader in generic and biosimilar medicines, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), has adopted a positive opinion recommending marketing authorization for their biosimilar trastuzumab (150 mg, for intravenous use), developed by EirGenix, Inc.

The positive opinion for Sandoz trastuzumab, a monoclonal antibody, covers treatment of human epidermal growth factor receptor 2 positive (HER2-positive) breast cancer and metastatic gastric cancers, the same indications as approved by EMA for the reference biologic.[1]

Sandoz and EirGenix signed a license agreement in April 2019. Under this agreement, EirGenix will remain responsible for the development and manufacturing of trastuzumab, while Sandoz will hold the rights to commercialize the medicine upon approval in respective markets.

Pierre Bourdage, Chief Commercial Officer, Sandoz, said: “Breast and gastric cancers are among the most frequently occurring in Europe and, combined, are responsible for nearly 200,000 deaths annually. Biosimilars have enormous potential to improve cancer care by substantially increasing access to these critical medicines.”

The impact of both breast and gastric cancers in Europe is significant. Each year, over 355,000 women are diagnosed with breast cancer and, with 92,000 deaths per year, it is the number one cause of cancer death among women.[2] Gastric cancer is the sixth most common of all cancer types and, with 107,000 deaths annually, it is the fourth most common cause of cancer-related death in Europe.[3] In up to 20% of breast cancers[4] and up to 30% of gastric cancers[5] diagnosed, an HER2 protein overexpression (or HER2 gene amplification) is detected resulting in an uncontrollable growth and division of cells.[2,4] HER2 cancers are particularly aggressive cancer types that respond well to targeted treatment.[6,7]

The comprehensive analytical, preclinical, and clinical data regulatory submission package included evidence derived from an extensive analytical characterization, in addition to results from a Phase I PK/PD study and a confirmatory Phase III study in breast cancer patients (EGC002). Both studies met their primary endpoints, confirming that the biosimilar matches the reference biologic in terms of pharmacokinetics as well as efficacy, safety and immunogenicity.

Sandoz is committed to helping millions of patients access critical and potentially life-changing biologic medicines sustainably and affordably across a range of areas including immunology, oncology, supportive care, and endocrinology. It has a leading global portfolio with eight marketed biosimilars and a further 25 assets in various stages of development. Since launching the first biosimilar in Europe in 2006, Sandoz has helped to create early and expanded patient access to life-altering medicines while increasing healthcare savings and creating competition that fuels further innovation.

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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 covers all major therapeutic areas.

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