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MEDIA & INVESTOR RELEASE

Sandoz reviewing options after Federal Circuit upholds lower court ruling in biosimilar Erelzi® case

- *Sandoz evaluating next steps, including potential appeal to US Supreme Court*
- *Ruling continues to prevent launch of important, affordable treatment option for US patients affected by chronic autoimmune and inflammatory diseases*
- *Sandoz remains deeply committed to making Erelzi available to US patients as soon as possible, contributing to a more sustainable healthcare system*

Holzkirchen, Germany, July 1, 2020 – Sandoz, a Novartis division and a global leader in biosimilars, today announced that the US Court of Appeals for the Federal District has ruled against Sandoz in patent litigation concerning the Sandoz biosimilar Erelzi® (etanercept-szzs) for reference medicine Enbrel®* (etanercept).

Today's decision upholds a prior ruling from the New Jersey District Court, which declared the Amgen patents valid. Sandoz is evaluating its options, which may include an appeal to the US Supreme Court.

"Sandoz will continue its efforts to make Erelzi available to US patients with autoimmune and inflammatory diseases," said Carol Lynch, President of Sandoz US and Head of North America. "Our company respects valid intellectual property, however Sandoz continues to believe the patents asserted by Amgen are not valid, and that it should not be able to use them to extend the drug's exclusivity."

Sandoz is the first company to receive approval from the US Food and Drug Administration (FDA) for a biosimilar etanercept. Erelzi has been approved in the US for more than three years, since August 2016, however Sandoz has been unable to launch this medicine in the US due to the ongoing patent litigation with Amgen.

With the trend towards increased spending on specialty medicines only expected to grow,[1] biosimilars play an important role in enabling more patients to access biologic medicines and may offer significant savings for patients, helping to alleviate the overburdened healthcare system.[2,3] Estimates suggest that a biosimilar etanercept could save the US healthcare system around USD one billion a year.[4]

"Biosimilars can make tremendous contributions to the sustainability of US healthcare[5] and enhance patient access to biologic medicines, which are often life-changing treatment options for patients with chronic illness," said Colin C. Edgerton, MD, a rheumatologist and Executive Chairman of the American Rheumatology Network. "Data and real-world experience affirm

there are no changes in safety and efficacy when patients switch between a biosimilar and a reference medicine.[6]"

Sandoz will continue to help millions of patients in oncology, immunology, endocrinology and other underserved therapy areas access biologic medicines sustainably and affordably. Sandoz was the first to launch a biosimilar in the US, and Erelzi is one of the company's four FDA-approved biosimilar medicines.[7]

About biosimilars

Biosimilars are approved biologics with comparable quality, safety and efficacy to existing biologics, and go through an extensive regulatory evaluation and approval process. A 10-year-plus growing body of real-world evidence in highly-regulated markets shows biosimilar adoption greatly increases usage of biologic medicines while delivering matched safety, efficacy and quality profiles.[8]

About Erelzi®
Erelzi is the Sandoz biosimilar of the reference medicine Enbrel®. Erelzi has been studied in a global development program, which included a comprehensive comparison of Erelzi and Enbrel® at the analytical, preclinical, and clinical levels. The program included preclinical studies, pharmacokinetic (PK) studies, and the Phase III confirmatory safety and efficacy EGALITY study. Erelzi is approved by the FDA for the following indications: adult rheumatoid arthritis (RA), ankylosing spondylitis (AS), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA) and moderate to severe plaque psoriasis (PsO).

Important Safety Information
Please see full Prescribing Information for Erelzi here:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761042s010lbl.pdf

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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 2019 sales of USD 9.7 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.

*Enbrel is a registered trademark of Immunex Corporation in the US.

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References

1. IQVIA IMS Health and Quintiles. "Biosimilars: Who Saves?". White Paper. Available at: https://www.iqvia.com/locations/united-states/library/white-papers/biosimilars-who-saves. Accessed on February 14, 2020.
2. IQVIA Institute for Human Data Science. Medicine use and spending in the US: a review of 2017 and outlook to 2022. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022. Accessed on February 14, 2020.
3. U.S. Food and Drug Administration. Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilar Action Plan [press release]. July 18, 2018. https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas. Accessed on February 14, 2020.
4. Data on file. US Healthcare Impact Biosimilar. Sandoz Inc. February 2020.
5. US Food and Drug Administration. Statement from FDA Commissioner Scott Gottlieb, M.D., on new actions advancing the agency's biosimilars policy framework. Available at: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-actions-advancing-agencys-biosimilars-policy. Accessed on February 14, 2020.
6. Cohen, Hillel, et al. Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes. Drugs. March 2018, Volume 78, Issue 4, pp 463–478. Available at https://www.ncbi.nlm.nih.gov/pubmed/29500555. Accessed on February 14, 2020.
7. U.S. Food and Drug Administration. "FDA approves Erelzi, a biosimilar to Enbrel". Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-erelzi-biosimilar-enbrel. Accessed on February 14, 2020.
8. The Biosimilars Council. The New Frontier for Improved Access to Medicines: Biosimilars & Interchangeable Biologic Products. Available at: https://biosimilarscouncil.org/resource/the-new-frontier-for-improved-access-to-medicines. Accessed on February 14, 2020

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