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MEDIA & INVESTOR RELEASE

US Supreme Court denies Sandoz petition to review biosimilar Erelzi® (etanercept-szzs) case

- *Decision not to review Federal Circuit July 2020 ruling continues to prevent Sandoz launch of more affordable Erelzi treatment option for US patients*
- *Sandoz is disappointed US patients affected by chronic autoimmune and inflammatory disease have to wait until 2029 for availability of biosimilar Erelzi*
- *Sandoz remains committed to pioneering access for patients and contributing to more sustainable healthcare by launching biosimilar and generic medicines*

Basel, Switzerland, May 17, 2021 – Sandoz, a global leader in biosimilar and generic medicines, today announced that the US Supreme Court has denied its petition to review the Federal Circuit's July 2020 decision concerning the Sandoz biosimilar Erelzi® (etanercept-szzs) for reference medicine Enbrel®* (etanercept). The Federal Circuit previously ruled against Sandoz in a divided decision upholding Amgen's patents.

"We are disappointed the Supreme Court decided not to review our case," said Keren Haruvi, President of Sandoz US and Head of North America. "Today's decision means Erelzi, a more affordable biosimilar, will not be available to US patients with autoimmune and inflammatory diseases until 2029; nonetheless we remain committed to providing important treatment options for patients affected by these diseases."

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 have saved the US healthcare system around USD one billion per year.[4]

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

About biosimilars

A biosimilar is a successor to a biological medicine (known as the "reference medicine") for which the patent has expired and exclusivity has been lost. Biosimilars have been shown to have equivalent efficacy and comparable safety and immunogenicity. Therefore, physicians and patients can expect the same clinical outcome.

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 being studied in a real world setting through COMPACT, a global non-interventional study conducted in countries such as Austria, Canada, France, Germany, Italy, Poland, Spain, Switzerland and United Kingdom. Erelzi is approved by the US 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).

Erelzi® is a registered trademark of Novartis AG.

Important Safety Information

Please see full Prescribing Information for Erelzi here:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761042lbl.pdf

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,” “seek,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” “reviewing,” “evaluating,” “ongoing,” “continues,” or similar terms, or by express or implied discussions regarding potential marketing approvals, launches, new indications or labelling for Erelzi and the other investigational or approved biosimilar 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 Erelzi or the other investigational or approved biosimilar products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time. Neither can there be any guarantee that Erelzi will be launched in the US at any particular time, or at all. Nor can there be any guarantee that Erelzi or such other products will be commercially successful in the future. In particular, our expectations regarding Erelzi and such other products could be affected by, among other things, litigation outcomes or other legal action, decisions or delays, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; 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; our ability to maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional biosimilar versions of such products; general political and economic conditions; 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 need. 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/
Twitter: https://twitter.com/sandoz_global
Facebook: https://www.facebook.com/sandozglobal/
Instagram: https://www.instagram.com/sandozglobal

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

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

References

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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]. Available at: https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas. Accessed on March 29, 2021.
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