SANDOZ A Novartis Division

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Sandoz will appeal District Court of New Jersey ruling in biosimilar Erelzi® (etanercept-szzs) US patent case

- *Sandoz to appeal court ruling to United States Court of Appeals for the Federal Circuit*
- *Ruling prevents launch of important, affordable treatment option for US patients affected by chronic autoimmune and inflammatory diseases*
- *Sandoz remains deeply committed to providing Erelzi® as soon as possible, contributing to a more sustainable healthcare system*

Holzkirchen, Germany, 9 August 2019 – Sandoz, a Novartis division and a global leader in biosimilars, today announced that the United States District Court of New Jersey ruled against Sandoz in patent litigation concerning the Sandoz biosimilar, Erelzi® (etanercept-szzs) for reference medicine Enbrel®* (etanercept). The company will appeal the ruling to the US Court of Appeals for the Federal Circuit, and the parties have agreed to an expedited appeal.

“Sandoz respectfully disagrees with the Court’s ruling, which prevents us from launching an additional treatment option for patients with autoimmune and inflammatory diseases,” said Carol Lynch, President of Sandoz US and Head of North America. “Valid intellectual property should be respected, however, we continue to consider the patents in this case to be invalid. Amgen asserted two patents that it obtained from Roche, in what we believe is an attempt to extend its US compound patent protection for etanercept to 2029. We will appeal this decision, and look forward to presenting our case to the Federal Circuit and bringing Erelzi to US patients as soon as possible.”

Sandoz is the first biosimilar company to receive FDA approval for a biosimilar etanercept. Erelzi has been approved for nearly three years, however Sandoz has been unable to launch the medicine due to the ongoing patent litigation from Amgen.

With the trend for 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 alleviate the overburdened healthcare system[2,3]. For example, the successful adoption of biosimilar Zarxio® (filgrastim-sndz) into clinical practice saved the US healthcare system approximately USD 500m in less than two years[4].

“Biologics are life-changing medicines, but can be costly, creating significant disparities in patient access that need to be challenged,” said Robin K. Dore, MD, Clinical Professor of Medicine, David Geffen School of Medicine at UCLA. “Biosimilars help increase patient access to these potentially life-saving medicines and real-world experience affirms that switching between a biosimilar and a reference medicine is safe and effective[5]. Biosimilars are one critical way to help enable sustainability of our healthcare system[6].” Estimates suggest that a biosimilar etanercept could save the US healthcare system around USD 1b a year[7].

All biosimilars go through an extensive regulatory evaluation and approval process. A ten-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].

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilars and is well-positioned to lead the industry based on its experience and capabilities in development, manufacturing and commercialization. Sandoz was the first to launch a biosimilar in the US, and Erelzi is one of the company’s three FDA-approved biosimilar medicines[9].

About Erelzi® (etanercept-szzs)
Erelzi (etanercept-szzs) 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. The FDA approved Erelzi on August 30, 2016 for all indications included in the reference product label at that time[9].

Erelzi is a registered trademark of Novartis AG.

Please see full Prescribing Information for Erelzi here**.**

About Zarxio® (filgrastim-sndz)
Zarxio (filgrastim-sndz) was approved by the US Food & Drug Administration (FDA) in 2015 for all indications included in the reference product's label. Zarxio was the first biosimilar in the US to be approved through the FDA biosimilars pathway established under the Biologics Price Competition and Innovation Act. The approval was based on a comprehensive package of analytical, preclinical, and clinical data, which confirmed that Zarxio is highly similar to the US-licensed reference product.

Zarxio is a registered trademark of Novartis AG.

Please see full Prescribing Information for Zarxio here.

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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 "will," "to appeal," "launch," "committed," "as soon as possible," "expedited," "strategy," "suggest," "could," "believe," "trend," "expected," "may," "can," "need," "potentially," "growing," "well-positioned," "launched," "potential," "investigational," "portfolio," or similar terms, or by express or implied discussions regarding potential marketing approvals, launches, new indications or labelling for Erelzi, Zarxio 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, Zarxio 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 will be approved or launched for all indications included in the reference product's label, or at any particular time. Nor can there be any guarantee that Erelzi, Zarxio or such other products will be commercially successful in the future. In particular, our expectations regarding Erelzi, Zarxio 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; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional 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; general political and economic conditions; safety, quality 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 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.

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

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