

MEDIA RELEASE

Sandoz files antitrust litigation against Amgen regarding patient access to etanercept biosimilar in the US

- Company aims to accelerate access to much-needed biosimilar to reference medicine Enbrel®* for US patients with disabling inflammatory diseases
- Despite FDA approval nearly a decade ago, etanercept biosimilar continues to be blocked
- Sandoz seeking damages in addition to clearing path for launch

Basel, April 14, 2025 – Sandoz (SIX:SDZ/OTCQX:SDZNY), the global leader in generic and biosimilar medicines, today announced the filing of an antitrust lawsuit in the US against Amgen, Inc. (Amgen), for extending and entrenching the dominant market position of its blockbuster medicine, Enbrel® (etanercept), first approved by the US Food and Drug Administration (FDA) in 1998.

Etanercept is a biologic medicine used to treat a range of disabling inflammatory diseases. Sandoz alleges that Amgen blocked competition from more cost-effective biosimilar competitors, including Sandoz etanercept biosimilar, Erelzi®+ (etanercept-szzs), by unlawfully purchasing and using certain patent rights to entrench its position in the market. In 2024, Enbrel® generated USD 3.3 billion in revenue in the US¹.

Sandoz received US FDA approval for Erelzi® in 2016, the same year the company launched the medicine in Europe. Today, Amgen is continuing to block entry of this important treatment option for approximately 7.5 million Americans living with chronic inflammatory diseases, including rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis²⁻⁶, many of whom could benefit from the cost savings and expanded access resulting from the introduction of high-quality, more-affordable biosimilar options.

Sandoz is seeking an injunction to prevent Amgen from using certain patent rights to block biosimilar competition and allow Sandoz to launch Erelzi® as soon as possible. The company is also seeking damages, which could be tripled under applicable laws. The lawsuit was filed in the US District Court for the Eastern District of Virginia.

*Enbrel® is a registered trademark of Amgen, Inc.

+Erelzi® is a registered trademark of Sandoz Inc.

About Erelzi® (etanercept-szzs)

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 US

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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](#).

DISCLAIMER

This Media Release contains forward-looking statements, which offer no guarantee with regard to future performance. These statements are made on the basis of management's views and assumptions regarding future events and business performance at the time the statements are made. They are subject to risks and uncertainties including, but not confined to, future global economic conditions, exchange rates, legal provisions, market conditions, activities by competitors and other factors outside of the control of Sandoz. Should one or more of these risks or uncertainties materialize or should underlying assumptions prove incorrect, actual outcomes may vary materially from those forecasted or expected. Each forward-looking statement speaks only as of the date of the particular statement, and Sandoz undertakes no obligation to publicly update or revise any forward-looking statements, except as required by law.

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ABOUT SANDOZ

Sandoz (SIX: SDZ; OTCQX: SDZNY) is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure 900 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,300 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2024, Sandoz recorded net sales of USD 10.4 billion.

REFERENCES

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