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MEDIA RELEASE

Sandoz launches biosimilar Pyzchiva® (ustekinumab) across Europe, to treat chronic inflammatory diseases

- Launch across Europe, starting today, strengthens well-established Sandoz immunology portfolio in Europe, leveraging existing footprint
- Pyzchiva® first ustekinumab biosimilar to launch in Europe with all reference medicine strengths, including 130mg vial initiation dose for Crohn's disease
- Pyzchiva® to treat adults with plaque psoriasis, psoriatic arthritis, Crohn's disease and pediatric plaque psoriasis

Basel, July 25, 2024 – Sandoz, the global leader in generic and biosimilar medicines, announces the launch of Pyzchiva®* (ustekinumab) across Europe, starting today. Pyzchiva®, developed and registered by Samsung Bioepis, is the first ustekinumab biosimilar to launch in Europe with all reference medicine strengths, including the 130mg vial initiation dose for Crohn's disease.

The launch strengthens our well-established immunology portfolio in Europe and leverages our existing footprint, with five biosimilars now marketed in this therapeutic area. Pyzchiva® is a key biosimilar driver, adding value and contributing to the company's mid-term growth strategy.

"Timely and expanded access to safe, effective and affordable medicines can improve quality of life for millions of people living with chronic inflammatory diseases. Our goal is to make potentially life-changing medicines accessible to patients across Europe. Pyzchiva® is one of the first ustekinumab biosimilars in Europe, which marks a significant milestone on that road."

Rebecca Guntern, President Europe, Sandoz

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Pyzchiva® is approved for treatment of adults with plaque psoriasis, psoriatic arthritis, Crohn's disease and pediatric plaque psoriasis for patients six years and older weighing over 60 kg.

Europe has the highest prevalence of psoriasis worldwide, affecting an estimated 6.4 million people and significantly impacting patients' quality of life.[1,2] Plaque psoriasis is the most common form of psoriasis, affecting 85% to 90% of patients with psoriasis.[3]

Sandoz entered into a development and commercialization agreement for biosimilar ustekinumab with Samsung Bioepis in September 2023. Under the terms of the agreement, Sandoz has the right to commercialize Pyzchiva® in the US, Canada, the European Economic Area, Switzerland, and the UK. Samsung Bioepis remains responsible for development, registration, intellectual property, manufacturing, and supply.

*Pyzchiva® is a trademark of Samsung Bioepis Co. Ltd.
**Stelara® is a trademark of Johnson & Johnson

About Pyzchiva® (ustekinumab)

Pyzchiva® (ustekinumab) has been developed as a biosimilar with equivalent efficacy and comparable safety to the reference medicine Stelara®**, a human monoclonal antibody against interleukin (IL)-12/23. Pyzchiva® is approved for treatment of adults with plaque psoriasis, psoriatic arthritis, Crohn's disease and pediatric plaque psoriasis for patients six years and older weighing over 60 kg.

Pyzchiva® is available as a 130 mg concentrate in a vial for solution for infusion, additionally, a 90 mg and a 45 mg concentrate solution for injection in a pre-filled syringe.

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.

References

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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 more than 100 nationalities work together to ensure 800 million patient treatments are provided annually by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,500 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 first biosimilar in 2006. In 2023, Sandoz recorded sales of USD 9.6 billion.

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