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MEDIA RELEASE

Sandoz confirms European Commission approval of Pyzchiva[®] (ustekinumab), further strengthening immunology offering

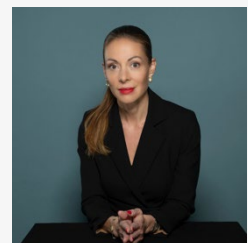
- Pyzchiva[®] approved as one of first ustekinumab biosimilars in Europe
- EC approval based on robust development program confirming match to reference medicine in terms of safety, efficacy and quality
- Sandoz remains committed to accelerating access to potentially life-changing treatments and continues strengthening immunology portfolio

Basel, April 22, 2024 – Sandoz, the global leader in generic and biosimilar medicines, today announces that the European Commission (EC) has granted marketing authorization for Pyzchiva[®] (biosimilar ustekinumab), developed and registered by Samsung Bioepis. Pyzchiva[®] is a key biosimilar value driver for the company over the mid-term and this approval is a major step in advancing Sandoz growth strategy.

Pyzchiva[®] is approved as a biologic therapy within gastroenterology, dermatology, and rheumatology.¹

“Chronic inflammatory diseases affect millions of people around the world and can have a profoundly negative impact on their quality of life. This approval is a crucial step towards offering European patients an additional safe and effective treatment option and further demonstrates our commitment to pioneer access to potentially life-changing medicines.”

**Rebecca Guntern,
President Sandoz
Europe**



The comprehensive regulatory submission package included extensive analytical, preclinical, and clinical data, including a Phase I PK/PD study and a Phase III confirmatory study.

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 (EEA), 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.

About Pyzchiva[®] (ustekinumab)

Pyzchiva[®] (ustekinumab) has been developed to match the reference medicine, a monoclonal antibody medication to interleukin (IL)-12/23 for the treatment of autoimmune disorders including within gastroenterology, dermatology, and rheumatology.¹

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 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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