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Ad hoc announcement pursuant to art. 53 SIX Swiss Exchange Listing Rules

MEDIA RELEASE

FDA approves biosimilar Pyzchiva® (ustekinumab-ttwe), to be commercialized by Sandoz in US

- Pyzchiva® (ustekinumab-ttwe) is approved by FDA for all indications of reference medicine
- FDA granted provisional determination for interchangeability designation for Pyzchiva®
- Extends Sandoz immunology portfolio and further strengthens biosimilar position
- Expected to be among first wave of ustekinumab biosimilars to launch in US

Basel, July 1, 2024 – Sandoz, the global leader in generic and biosimilar medicines, today announced that the US Food and Drug Administration (FDA) has approved biosimilar Pyzchiva®* (ustekinumab-ttwe) 45 mg/0.5 mL and 90 mg/mL pre-filled syringes for subcutaneous injection and 130 mg/26 mL (5 mg/mL) single-dose vial for intravenous infusion. Developed by Samsung Bioepis Co., Ltd, it is approved for all indications of its reference medicine and will be commercialized by Sandoz in the US. In addition, the FDA provisionally determined that Pyzchiva® would be interchangeable with the reference medicine as it is currently subject to an unexpired period of exclusivity for the first interchangeable biosimilar biological products.

Sandoz intends to launch Pyzchiva® in the US in February 2025, in accordance with the settlement and license agreement with Janssen Biotech Inc. previously announced by Samsung Bioepis Co., Ltd. Pyzchiva® is expected to be among the first wave of ustekinumab biosimilars to launch in the US.

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> “This approval reflects our dedication to ensuring high-quality treatments are universally accessible. By further expanding our immunology portfolio with affordable biosimilar alternatives, we continue to make significant strides towards achieving our goal of delivering life-changing medicines to the patients who need them.”

Claire D'Abreu-Hayling, Chief Scientific Officer Sandoz

Pyzchiva® is a key biosimilar value driver for the company over the mid-term, and this approval is a major step in advancing the Sandoz growth strategy by extending the US immunology portfolio.

Pyzchiva® is approved by the FDA for all indications of the reference medicine Stelara®† (ustekinumab), a human interleukin (IL)-12 and IL-23 antagonist,[1] including to treat adult patients with moderate to severe plaque psoriasis, active psoriatic arthritis, moderately to severely active Crohn’s disease and moderately to severely active ulcerative colitis, as well as pediatric patients with moderate to severe plaque psoriasis and active psoriatic arthritis.[2]

Leah M. Howard, J.D., President and CEO of the National Psoriasis Foundation, said: "Systemic medications like biologics are a key treatment option for many people to manage symptoms of psoriasis and psoriatic arthritis. Unfortunately, barriers to care, including costs, often prevent patients from getting the drug they are prescribed. Psoriatic disease is lifelong and chronic, leading to long-term treatment costs. Having more FDA-approved options can help make appropriate healthcare more affordable.”

Plaque psoriasis is the most common form of psoriasis, affecting approximately 80% to 90% of patients.[3]

The FDA granted approval to Samsung Bioepis based on the totality of the evidence, including robust clinical studies confirming that Pyzchiva® has equivalent efficacy and comparable safety as its reference medicine.

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.
†Stelara® is a registered trademark of JOHNSON & JOHNSON (USA).

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INDICATIONS
PYZCHIVA (ustekinumab-ttwe) is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, patients 6 years or older with active psoriatic arthritis, adult patients with moderately to severely active Crohn's disease, adult patients with moderately to severely active ulcerative colitis.

CONTRAINDICATIONS: Clinically significant hypersensitivity to ustekinumab or to any of the excipients.

WARNINGS AND PRECAUTIONS: ***Infections:*** Serious infections have occurred. Avoid starting PYZCHIVA during any clinically important active infection. If a serious infection or clinically significant infection develops, discontinue PYZCHIVA until the infection resolves. ***Theoretical Risk for Particular Infections:*** Serious infections from mycobacteria, salmonella and Bacillus Calmette-Guerin (BCG) vaccinations have been reported in patients genetically deficient in IL-12/IL-23. Consider diagnostic tests for these infections as dictated by clinical circumstances. ***Tuberculosis (TB):*** Evaluate patients for TB prior to initiating treatment with PYZCHIVA. Initiate treatment of latent TB before administering PYZCHIVA. ***Malignancies:*** Ustekinumab products may increase risk of malignancy. The safety of ustekinumab products in patients with a history of or a known malignancy has not been evaluated. ***Hypersensitivity Reactions:*** If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue PYZCHIVA. ***Posterior Reversible Encephalopathy Syndrome (PRES):*** If PRES is suspected, treat promptly and discontinue PYZCHIVA. ***Immunizations:*** Avoid use of live vaccines in patients during treatment with PYZCHIVA. ***Noninfectious Pneumonia:*** Cases of interstitial pneumonia, eosinophilic pneumonia and cryptogenic organizing pneumonia have been reported during post-approval use of ustekinumab products. If diagnosis is confirmed, discontinue PYZCHIVA and institute appropriate treatment.

ADVERSE REACTIONS: Most common adverse reactions are *Psoriasis (≥3%):* nasopharyngitis, upper respiratory tract infection, headache, and fatigue. *Crohn's Disease, induction (≥3%):* vomiting. *Crohn's Disease, maintenance (≥3%):* nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis. *Ulcerative colitis, induction (≥3%):* nasopharyngitis. *Ulcerative colitis, maintenance (≥3%):* nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.

This is not the complete list of all the safety information for PYZCHIVA. Please see full Prescribing Information for PYZCHIVA.

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

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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

1. Janssen Pharmaceuticals. Stelara® (Ustekinumab): Prescribing Information. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf [Last accessed: June 2024]
2. Pyzchiva®. Prescribing Information. Available at: BLA 761373 and BLA 761425 PI MG and IFU.pdf (sandoz.com) [Last accessed: June 2024]
3. Journal of the American Academy of Dermatology. Guidelines of Care for the Management Psoriasis and Psoriatic Arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. Available at: https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext [Last accessed: June 2024]

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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