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

MEDIA RELEASE

Sandoz launches biosimilar Pyzchiva® (ustekinumab-ttwe) in the US, offering new treatment for around 12 million patients[1-4]

- Key biosimilar value driver contributes to Sandoz global growth strategy and moves company closer to becoming #1 in biosimilars in US
- Strengthens US immunology portfolio and increases access to biologics for patients suffering from chronic inflammatory diseases, such as psoriasis and psoriatic arthritis
- Meeting a variety of patient needs, Pyzchiva® offers full suite of dosing options and extended stability compared with reference medicine

Basel, February 24, 2025 – Sandoz (SIX:SDZ/OTCQX:SDZNY), the global leader in generic and biosimilar medicines, announces the launch of Pyzchiva®* (ustekinumab-ttwe) in the US. From today, the medicine is commercially available to patients across the US.

Developed by Samsung Bioepis Co., Ltd., and commercialized by Sandoz, Pyzchiva® has been approved by the US Food and Drug Administration (FDA) for the treatment of certain chronic inflammatory diseases, with the same indications as reference medicine Stelara®**[5].

Pyzchiva® is a key biosimilar value driver for Sandoz, contributing to the company's overall growth strategy. The company ranks number one in biosimilars globally and across key markets in Europe. The commercial availability of Pyzchiva®, which builds on the US launch of Hyrimoz® in July 2023, marks an important step in the Sandoz strategic ambition to become number one in biosimilars in the US.

Keren Haruvi, President, Sandoz North America, said: "This is an important moment for millions of patients living with chronic autoimmune diseases.[1-4] The launch of Pyzchiva® reinforces our commitment to broaden access to treatment options for patients, while helping to build a more sustainable healthcare system in the US so that everyone can access the medicines they need, when they need them."

Pyzchiva® offers an affordable option for patients who could benefit from treatment with ustekinumab. It also provides the full suite of dosing options to meet the needs of a variety of patients and is expected to offer interchangeability in the first half of 2025. Pyzchiva® elevates the patient experience with extended stability, including the ability to be re-refrigerated, unlike the reference medicine.

Leah M. Howard, J.D., the president and CEO of the National Psoriasis Foundation, said: "Psoriasis and psoriatic arthritis are chronic diseases that can be treated with biologics, but those medications are often not as accessible or affordable as they should be for those who could benefit most from them. Biosimilars offer

great potential for putting these effective treatment options within reach of those who may have been previously unable to afford them."

Sandoz is providing comprehensive support resources for patients who are prescribed Pyzchiva®, including information about insurance coverage/benefit investigation, self-injection training, and a co-pay program for commercially insured patients.

This launch is in accordance with the settlement and license agreement with Johnson & Johnson for the US market, previously announced by Samsung Bioepis Co., Ltd. Sandoz entered into a 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, the UK and Brazil. Samsung Bioepis Co., Ltd. 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).

About Pyzchiva® (ustekinumab-ttwe)

Ustekinumab, the active ingredient in Pyzchiva®, is a human monoclonal antibody targeting IL-12 and IL-23, which are cytokines that when overproduced can cause inflammation. This inflammation plays a role in the development of certain autoimmune conditions. Pyzchiva® works by blocking IL-12 and IL-23 proteins.[6]

Pyzchiva® has been approved by the FDA 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.

Pyzchiva® is available in 45 mg/0.5 mL and 90 mg/mL pre-filled syringes, 130 mg/26 mL single-dose vials for intravenous injection, and 45 mg/0.5 mL subcutaneous single-dose vials.[6]

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.

SELECT IMPORTANT SAFETY INFORMATION

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.

About Hyrimoz® (adalimumab-adaz)

Adalimumab, the active ingredient in Hyrimoz®, is an inhibitor of tumor necrosis factor (TNF), a protein that is overproduced in certain autoimmune conditions — including rheumatoid arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis — causing inflammation and tissue destruction in joints, mucosa or skin. In some cases of autoimmune disease, the immune system damages the body's own tissues. Hyrimoz® targets and blocks the protein that contributes to disease symptoms.[7]

INDICATIONS

HYRIMOZ® (adalimumab-adaz) is a tumor necrosis factor (TNF)-blocker indicated for **Rheumatoid Arthritis (RA)**: reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. HYRIMOZ can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs). **Juvenile Idiopathic Arthritis (JIA)**: reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. HYRIMOZ can be used alone or in combination with methotrexate. **Psoriatic Arthritis (PsA)**: reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. HYRIMOZ can be used alone or in combination with non-biologic DMARDs. **Ankylosing Spondylitis (AS)**: reducing signs and symptoms in adult patients with active AS. **Crohn's Disease (CD)**: treatment of moderately to severely active CD in adults and pediatric patients 6 years of age and older. **Ulcerative Colitis (UC)**: treatment of moderately to severely active UC in adult patients. Limitations of Use: Effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF-blockers. **Plaque Psoriasis (Ps)**: treatment of adult patients with moderate to severe chronic Ps who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HYRIMOZ should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. **Hidradenitis Suppurativa (HS)**: treatment of moderate to severe HS in adult patients. **Uveitis**: Treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

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SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

See full prescribing information for complete boxed warning.

SERIOUS INFECTIONS: Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens. Discontinue HYRIMOZ if a patient develops a serious infection or sepsis during treatment. Perform test for latent TB; if positive, start treatment for TB prior to starting HYRIMOZ. Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

MALIGNANCY: Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including adalimumab products.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: *Serious infections:* Do not start HYRIMOZ during an active infection. If an infection develops, monitor carefully, and stop HYRIMOZ if infection becomes serious. *Invasive fungal infections:* For patients who develop a systemic illness on HYRIMOZ, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic. *Malignancies*: Incidence of malignancies was greater in adalimumab-treated patients than in controls. *Anaphylaxis or serious hypersensitivity reactions* may occur. *Hepatitis B virus reactivation:* Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop HYRIMOZ and begin anti-viral therapy. *Demyelinating disease:* Exacerbation or new onset, may occur. *Cytopenias, pancytopenia:* Advise patients to seek immediate medical attention if symptoms develop, and consider stopping HYRIMOZ. *Heart failure:* Worsening or new onset, may occur. *Lupus-like syndrome:* Stop HYRIMOZ if syndrome develops.

ADVERSE REACTIONS: Most common adverse reactions (>10%) are: infections (e.g. upper respiratory, sinusitis), injection site reactions, headache and rash.

DRUG INTERACTIONS: *Abatacept:* Increased risk of serious infection. *Anakinra:* Increased risk of serious infection. *Live vaccines:* Avoid use with HYRIMOZ.

This is not the complete list of all the safety information for HYRIMOZ. Please click to see the full Prescribing Information for HYRIMOZ, including Boxed Warnings and Medication Guide.

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 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 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 world's first biosimilar in 2006. In 2023, Sandoz recorded net sales of USD 9.6 billion.

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