Sandoz to launch Hyrimoz® (adalimumab-adaz) high-concentration formulation, marking Sandoz entrance into US immunology space

Jul 01, 2023

- *Hyrimoz® (adalimumab-adaz) high-concentration formulation (HCF) biosimilar offers US patients reduced injection volume in citrate-free formulation*
- *As one of the only adalimumab HCF biosimilars approved in the US, Hyrimoz HCF expands access for millions of people with serious inflammatory diseases*
- *Launch builds upon Sandoz global biosimilars legacy, with Hyrimoz 50 mg/mL having nearly 120 million days of patient experience across 41 countries*[1]

Basel, July 1, 2023 – Sandoz, a global leader in generic pharmaceuticals and biosimilars, today announced that the citrate-free high-concentration formulation (HCF) of its biosimilar Hyrimoz® (adalimumab-adaz) injection will be available in the United States starting July 1.

Hyrimoz HCF (100 mg/mL) is approved to treat all indications no longer covered by the regulatory exclusivity for the reference medicine, Humira®* (adalimumab), as of July 1, 2023, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis and hidradenitis suppurativa.[2]

Please see detailed indications at the end of this announcement.

"This is an important moment for Sandoz and for the millions of patients living with chronic inflammatory diseases in the US. With this launch, we are entering the US immunology market and continuing to fulfill our commitment to expand access to important medicines for patients," said Keren Haruvi, President North America, Sandoz Inc.

"Sandoz has a long history of developing and marketing biosimilars that generate healthcare savings and enhance competition that drives innovation in the market. We are pleased to continue this legacy in the US with Hyrimoz, which offers another treatment option for those who need adalimumab but might have previously been unable to access or afford this critical medicine."

Hyrimoz HCF offers a 50% reduction in injection volume compared to the 50 mg/mL concentration and can decrease the number of injections required for people who need at least 80 mg/0.8 mL dosing. The HCF formulation is citrate free and uses the same auto-injector as Hyrimoz 50 mg/mL, the Sensoready® pen, which is designed with patients in mind. The prefilled Sensoready pen is an ergonomic device with a triangular shape, buttonless injection for self-administration and a 360° viewing window for visual feedback.

Sandoz has established Sandoz One Source for Hyrimoz, a robust patient support program that provides

educational, reimbursement and affordability support. To learn more about Sandoz One Source and Hyrimoz, visit Hyrimoz.com.

Product photos available upon request.

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.[2]

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.

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 press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that, if approved, such generic or biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional generic or biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation

to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

References

1. Data on file (PSUR)
2. Hyrimoz. Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761071s015lbl.pdf

*Humira is a registered trademark of AbbVie Biotechnology Ltd

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About Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical needs. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering major therapeutic areas, accounted for 2022 sales of USD 9.2 billion.

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