Sandoz receives US FDA approval for biosimilar Hyrimoz® (adalimumab-adaz) high-concentration formulation

Mar 21, 2023

- *Biosimilar Hyrimoz® (adalimumab-adaz) high-concentration formulation (HCF) approved for seven indications of reference medicine Humira®**
- *With this approval, Sandoz adalimumab HCF biosimilar will offer US patients reduced injection volume in citrate-free formulation*
- *Sandoz continues to expand patient access to much-needed medications, increase healthcare savings and fuel innovation through increased competition*

Basel, March 21, 2023 – Sandoz, a global leader in generic pharmaceuticals and biosimilars, today announced that the US Food and Drug Administration (FDA) approved a citrate-free high-concentration formulation (HCF) of its biosimilar Hyrimoz® (adalimumab-adaz) injection.

The adalimumab citrate-free HCF (100 mg/mL) is approved to treat seven indications covered by the reference medicine, Humira®* (adalimumab), including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis and plaque psoriasis.[1]

Sandoz intends to launch the Hyrimoz citrate-free HCF in the US on July 1, 2023.

"As one of the first adalimumab high-concentration formulation biosimilars approved in the US, Hyrimoz HCF has the potential to expand access for millions of people who face the realities of living with a serious inflammatory disease and to enhance the patient experience," said Keren Haruvi, President, Sandoz Inc., Head of North America.

"Sandoz has more than two decades of experience researching, developing and bringing biosimilars to markets across the globe. We are excited to continue this leadership by providing patients with another treatment option to help manage their chronic conditions."

The FDA approval was based on a Phase I pharmacokinetics (PK) bridging study comparing the FDA-approved adalimumab 50 mg/mL to the citrate-free 100 mg/mL (HCF). This study met all of the primary objectives, demonstrating comparable PK and showing similar safety and immunogenicity of the adalimumab 50 mg/mL and adalimumab HCF.

"Biosimilars are extensively studied, FDA-approved treatments," said Steve Taylor, president and chief executive officer, Arthritis Foundation. "There are millions of patients affected by chronic inflammatory conditions that drastically impact their everyday lives. Given the high burden of disease for these conditions, biosimilars are one potential solution for healthcare providers and patients to consider, to ensure patients can take and stay on their medicines to help manage their disease and health outcomes."

The FDA approval of Hyrimoz HCF builds on the already approved and well-established Sandoz global biosimilar portfolio in immunology. Sandoz has nearly 120 million days of patient experience with Hyrimoz

across 40 countries.[2] When it launches, Hyrimoz HCF will represent the first launch of a Sandoz biosimilar in the US market in this specific disease space.

Sandoz is committed to helping millions of patients sustainably and affordably access critical and potentially life-changing biologic medicines across a range of areas including immunology, oncology, supportive care and endocrinology. Sandoz has a leading global portfolio with eight marketed biosimilars and a further 15+ in various stages of development.

Since launching the first biosimilar in the US in 2015, Sandoz has proven biosimilars create early and expanded patient access to life-altering medicines while increasing healthcare savings and creating competition that fuels innovation and development of new and enhanced treatments in areas of unmet need.

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.[1]

Please see the full [Prescribing Information] for Hyrimoz:
Hyrimoz_Highlights_Prescribing_Information.pdf (sandoz.com)

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looking statements contained in this press release as a result of new information, future events or otherwise.

References

1. Hyrimoz. Prescribing Information. Available at: Hyrimoz_Highlights_Prescribing_Information.pdf (sandoz.com)
2. Data on file (PSUR)

*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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