Sandoz receives approval by European Commission for Hyrimoz® (adalimumab) high-concentration formulation

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- *Biosimilar Hyrimoz® (adalimumab) citrate-free high-concentration formulation (HCF) is now approved in the EU for use in all indications of reference medicine Humira®**
- *HCF formulation adalimumab offers patients enhanced yet familiar experience through increased convenience and reduced injection volume*
- *Approval further solidifies expansion of Sandoz biosimilar immunology portfolio in Europe*

Basel, April 3, 2023 — Sandoz, a global leader in off-patent (generic and biosimilar) medicines, today announced that the European Commission (EC) granted marketing authorization in the European Union (EU) for a citrate-free high concentration formulation (HCF; 100 mg/mL) of its biosimilar Hyrimoz® (adalimumab).

The approval includes all indications covered by the reference medicine*: rheumatic diseases, Crohn's disease, ulcerative colitis, plaque psoriasis, uveitis and hidradenitis suppurativa.[1]

“Living with a chronic disease can take a significant toll on a patient’s quality of life. Biosimilars help patients to gain broader access to effective and high-quality treatments that improve their disease therapies,” said Rebecca Guntern, Head of Region Europe, Sandoz.

“With eight marketed biosimilars Sandoz is offering the broadest biosimilar portfolio and is the leading biosimilars company in Europe with more than two decades of experience. Today’s approval brings Sandoz one step closer to providing European patients with chronic conditions an additional treatment option that offers increased convenience and a reduction in injection volume.”

The adalimumab citrate-free HCF (100 mg/mL) formulation offers a 50 percent reduction in injection volume compared to the 50 mg/ml concentration and potentially decreases the number of injections required for patients who need 80 mg/mL or higher dosing. The HCF formulation is presented in the same auto-injector as currently available to patients, aiming for an enhanced yet familiar patient experience.

As part of the comprehensive submission package to the European Marketing Authorization, Sandoz conducted a Phase I pharmacokinetics (PK) bridging study comparing its approved adalimumab 50 mg/mL[2] with the 100 mg/mL (HCF). The study met all its primary objectives, demonstrating comparable pharmacokinetics and showing similar safety and immunogenicity between the two concentrations.

Recently, US Food and Drug Administration (FDA) also approved the citrate-free HCF of Hyrimoz® (adalimumab-adaz) injection.

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. It has a leading global portfolio with eight marketed biosimilars and a further 15+ in various

stages of development. Since launching the first biosimilar in Europe in 2006, 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 adalimumab

Adalimumab is a human immunoglobulin G1 (IgG(1)) monoclonal antibody targeting tumor necrosis factor alpha (TNF-a). The adalimumab reference medicine (Humira®*) was first approved with an adalimumab concentration of 50 mg/mL.[1] In 2015, the EMA and US FDA approved Humira® HCF, which contains adalimumab at a concentration of 100 mg/mL.

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References

1. EMA. Humira® EPAR Product Information. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/humira. [Accessed February 2023]
2. EMA. Hyrimoz® EPAR Product Information. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/hyrimoz. [Accessed February 2023]

*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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CEO Richard Saynor on LinkedIn: https://www.linkedin.com/in/richard-saynor/

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Sandoz Global Communications

Central		North America	
Chris Lewis	+49 174 244 9501	Leslie Pott	+1 609 627 5287

Novartis Media Relations
E-mail: media.relations@novartis.com

Central		North America	
Richard Jarvis	+41 79 584 2326	Julie Masow	+1 862 579 8456

Switzerland	
Satoshi Sugimoto	+41 79 619 2035

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 345 4440
Nicole Zinsli-Somm	+41 61 324 3809	Parag Mahanti	+1 973 876 4912
Isabella Zinck	+41 61 324 7188		

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