Sandoz International
Sandoz Global Communications
Industriestr. 25
83607 Holzkirchen
Germany

https://www.sandoz.com

MEDIA & INVESTOR RELEASE

Sandoz Application for proposed biosimilar adalimumab's high concentration formulation accepted by EMA

- *Submission supported by comprehensive analytical and clinical data from new Phase I bridging pharmacokinetics study*
- *Adalimumab's high-concentration 100 mg/mL formulation aims to provide an enhanced yet familiar experience for patients*
- *Submission builds on Sandoz' well established biosimilar immunology portfolio in Europe*

Basel, June 17, 2022 — Sandoz, a global leader in generic and biosimilar medicines, today announced that the European Medicines Agency (EMA) has accepted the application for high-concentration formulation 100 mg/mL (HCF) of its biosimilar Hyrimoz® (adalimumab) for regulatory review. The application includes all indications covered by the reference medicine*, including rheumatoid arthritis, Crohn's disease, ulcerative colitis, plaque psoriasis, and uveitis[1].

Upon an approval, the Hyrimoz (100 mg/mL) citrate-free HCF would offer reduced injection volume and potentially decrease the number of injections required for patients who need 80 mg dosing. Hyrimoz HCF will have the same auto injector as Hyrimoz 50 mg/mL, aiming for an enhanced yet familiar patient experience.

"At Sandoz, we are constantly looking for ways to meet the changing needs of patients and health care providers," said Florian Bieber, Global Head Biopharmaceuticals Development, Sandoz. "By committing to bring biosimilar formulations such as Hyrimoz citrate-free HCF to patients, we are serving a critical need in expanding access to important medicines and fueling pharmaceutical innovation."

As part of the comprehensive submission package to the EMA, Sandoz conducted a Phase I pharmacokinetics (PK) bridging study comparing Hyrimoz 50 mg/mL[2] and Hyrimoz HCF. This study met all its primary objectives, demonstrating comparable pharmacokinetics and showing similar safety and immunogenicity between the Hyrimoz 50 mg/mL and Hyrimoz HCF.

This potential approval of Hyrimoz HCF builds on the already approved and well-established Sandoz biosimilar portfolio in immunology, including Erelzi® (biosimilar etanercept), Zessly® (biosimilar infliximab) and Rixathon® (biosimilar rituximab, including rheumatoid arthritis indication). Sandoz' Hyrimoz 50 mg/mL was first approved by the European Commission in July 2018 and launched in several European countries shortly thereafter.

Sandoz is committed to help millions of patients access biologic medicines sustainably in areas including oncology and immunology. With a strong portfolio of eight marketed

biosimilars and a further 15+ in various stages of development, Sandoz has an unparalleled heritage and extensive expertise in the development, manufacturing and delivery of biosimilar medicines to patients and the healthcare community worldwide.

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.[2,3] In 2015, the EMA and US FDA approved Humira® HCF, which contains adalimumab at a concentration of 100 mg/mL.[4,5]

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.

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 2021 sales of USD 9.6 billion.

Sandoz on social media:
LinkedIn: **https://www.linkedin.com/company/sandoz**
Twitter: **https://twitter.com/sandoz_global**

Facebook: **https://www.facebook.com/sandozglobal/**
Instagram: **https://www.instagram.com/sandozglobal**

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

References

1. EMA. Humira® EPAR Product Information. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/humira. [Accessed June 2022]
2. EMA. Hyrimoz® EPAR Product Information. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/hyrimoz. [Accessed June 2022]

*Humira® is a registered trademark of AbbVie Biotechnology Ltd

# # #

Novartis and Sandoz Global Communications

Chris Lewis
Sandoz Global Communications
+49 174 244 9501 (mobile)
chris.lewis@sandoz.com

Richard Jarvis
Novartis Communications and Engagement
+44 7966 118 652
richard.jarvis@novartis.com

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

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	+1 862 778 5052
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		