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MEDIA & INVESTOR RELEASE

Sandoz receives positive CHMP opinion for citrate-free high concentration formulation of adalimumab biosimilar

- *Sandoz is seeking approval of high concentration formulation (HCF) adalimumab for use in all indications of reference medicine*
- *Upon approval, HCF formulation will offer patients enhanced yet familiar experience through increased convenience and reduced injection volume*
- *Recommendation further supports expansion of Sandoz biosimilar immunology portfolio in Europe*

Basel, January 30, 2023 — Sandoz, a global leader in off-patent (generic and biosimilar) medicines, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), has adopted a positive opinion for marketing authorization for a citrate-free high concentration formulation (HCF) of its biosimilar Hyrimoz® (adalimumab). The authorization includes all indications covered by the reference medicine*: rheumatoid arthritis, Crohn's disease, ulcerative colitis, plaque psoriasis and uveitis.[1]

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

“For people who live with a chronic condition, seemingly small adjustments to formulations can have a significant improvement on quality of life,” said Florian Bieber, Global Head Biopharmaceuticals Development, Sandoz. “Today’s positive opinion from the CHMP brings us closer to providing a treatment choice to patients that offers increased convenience and a reduction in injection volume.”

As part of the comprehensive submission package to the EMA, 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.

Sandoz is committed to helping 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.[1] In 2015, the EMA and US FDA approved Humira® HCF, which contains adalimumab at a concentration of 100 mg/mL.

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

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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 all major therapeutic areas, accounted for 2021 sales of USD 9.6 billion.

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