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Sandoz announces global resolution of biosimilar adalimumab patent disputes, securing patient access

- *Global resolution secures patient access to Sandoz biosimilar Hyrimoz® (adalimumab)¹ for the reference medicine Humira®[†]*
- *Resolution paves way for 2018 launch in key European markets and secures US market entry planned in 2023*

Holzkirchen, October 11, 2018 – Sandoz, a Novartis division and the global leader in biosimilars, today announced a global resolution of all intellectual property (IP) related litigation with AbbVie concerning the proposed Sandoz biosimilar Hyrimoz® (adalimumab)¹ for reference medicine Humira®[†] (adalimumab).

“In order to realize the promise of early and expanded access and healthcare savings, biosimilars must be available as soon as possible to the patients and physicians who need them. This settlement helps remove uncertainty regarding when our biosimilar adalimumab will be available and allows us to focus on expanding access for patients to the medicine they need to manage their chronic disease,” said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz.

Under the terms of the agreement, AbbVie grants Sandoz a non-exclusive license to AbbVie’s intellectual property relating to Humira®, beginning on certain dates in certain countries in which AbbVie has intellectual property. The license period will begin on October 16, 2018 in most countries in the European Union, and on other dates in various other countries outside the US where AbbVie has IP. In the US, the license period will begin on September 30, 2023.

Sandoz will pay royalties to AbbVie for licensing its Humira® patents. All litigation pending between the parties will be dismissed. AbbVie will make no payments to Sandoz. The precise terms are confidential between the parties.

Sandoz biosimilar adalimumab was recently approved by the European Commission (EC) for the 31 countries of the European Economic area, which comprises the 28 member countries of the European Union plus Norway, Iceland and Liechtenstein. It is the seventh approved Sandoz biosimilar medicine.

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 “secures,” “paves way,” “potentially,” “plan,” “expected,” “proposed,” “potential,” “can,” “will,” “look forward,” “believe,” “committed,” “investigational,” “portfolio,” “launch,” or similar terms, or by express or implied discussions regarding potential launches, marketing approvals, new indications or labelling for Hyrimoz and the other investigational or approved biosimilar products described in this press release, or regarding potential future revenues from Hyrimoz and such other biosimilar 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 Hyrimoz or the other investigational or approved biosimilar products described in this press release will be launched in any market, or at any particular time. Neither can there be any guarantee that Hyrimoz or such other products will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that, if approved, such products will be approved for all indications included in the reference product's label. Neither can there be any guarantee that Hyrimoz or such other products will be commercially successful in the future. In particular, our expectations regarding Hyrimoz and such other 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 biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political and economic conditions; safety, quality 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 is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people's lives. We contribute to society's ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients and we aspire to reach one billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global.

Follow our blog at www.sandoz.com/makingaccesshappen.

References:

1. European Medicines Agency. Hyrimoz. Key Facts. Available at: <https://www.ema.europa.eu/medicines/human/EPAR/hyrimoz>. Accessed October 2, 2018.

*Humira® (adalimumab) is marketed by AbbVie Deutschland GmbH & Co. KG in Europe and Humira® is a registered trademark of AbbVie Biotechnology, Inc.

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