SANDOZ A Novartis Division

Sandoz proposed biosimilar rituximab accepted for review by the FDA

Sep 12, 2017

- *Rituximab is indicated to treat blood cancers and immunological diseases such as rheumatoid arthritis*[1]
- *Sandoz believes the comprehensive data package submitted to the FDA for review confirms that our biosimilar rituximab matches the reference medicine in terms of safety, efficacy and quality*
- *The global leader in biosimilars, Sandoz has five biosimilars approved worldwide including biosimilar rituximab, which was approved in Europe* in June 2017*[2]

Holzkirchen, September 12, 2017 – Sandoz, a Novartis Division, and the pioneer and global leader in biosimilars, announced today that the US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) under the 351 (k) pathway for a proposed biosimilar to the reference medicine, Rituxan®† (rituximab).

Rituxan®† is used to treat blood cancers including non-Hodgkin's lymphoma (follicular lymphoma and diffuse large B-cell lymphoma) and chronic lymphocytic leukemia, as well as immunological diseases such as rheumatoid arthritis.

"The cost of treating cancer in the US is a major concern for many patients and their families as well as for the healthcare system[3]" said Mark Levick, MD PhD, Global Head of Development, Biopharmaceuticals. "With the FDA acceptance of our regulatory submission for proposed biosimilar rituximab, we plan to deliver patients a high-quality Sandoz biosimilar that, following approval, could help drive healthcare savings and increase competition, while freeing up resources for and supporting patient access in other areas of cancer care including innovative therapies."

The BLA consists of a comprehensive data package that includes analytical, preclinical and clinical data. Clinical studies included a pharmacokinetic/pharmacodynamic (PK/PD) trial in rheumatoid arthritis (ASSIST-RA)[4], and a Phase III confirmatory safety and efficacy study in

follicular lymphoma (ASSIST-FL)[5]. Sandoz believes these data provide confirmation that the proposed biosimilar matches the reference medicine in terms of safety, efficacy and quality.

Sandoz is committed to increasing patient access to high-quality biosimilars. As the pioneer and global leader in biosimilars, Sandoz has five biosimilars marketed worldwide, as well as a leading global pipeline. We plan to launch a total of five major oncology and immunology biosimilars between 2017 and 2020. This includes biosimilar rituximab, which was approved by the European Commission for use in Europe in June 2017 (marketed as Rixathon®).

Sandoz is well positioned to continue leading the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization. As a division of Novartis, the first global healthcare company to establish a leading position in both innovative and off-patent medicines, Sandoz benefits strongly from this unique blend of experience and expertise in many different market environments.

Sandoz also continues to champion policy and legislation that enables patients and the healthcare system to benefit from biosimilars. This was demonstrated by the recent US Supreme Court unanimous positive decision related to the Notice of Commercial Marketing (NCM). The Supreme Court ruled that NCM can be provided before FDA approval, accelerating patient access to future US biosimilars by 180 days. The Court also provided additional clarity on how the "patent dance," the process by which biosimilar manufacturers may provide confidential and proprietary information to the manufacturer of the reference medicine in the patent exchange process, will function.

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," "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 biosimilar 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 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 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 economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing issues, 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 2016 sales of USD 10.1 billion. In 2016, 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.

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* European Economic Area (EEA). The European Economic Area (EEA) provides for the free movement of persons, goods, services and capital within the internal market of the European Union (EU) between its 28 member states, as well as three of the four member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein, and Norway.
†Rituxan® is a trademark of BIOGEN MA INC.

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