

Sandoz proposed biosimilars rituximab and etanercept recommended for approval in Europe*

Apr 21, 2017

- *Sandoz receives positive CHMP opinions for biosimilars rituximab and etanercept to treat immunological diseases. Biosimilar rituximab also recommended to treat blood cancers*
- *Comprehensive data packages, confirming Sandoz biosimilars rituximab and etanercept match their respective reference medicines, were the basis for CHMP decisions*
- *Subject to EC** approval, Sandoz market leadership position extended as the only company to have five approved biosimilars in Europe¹*

Holzkirchen, April 21, 2017 – Sandoz, a Novartis division, and the pioneer and global leader in biosimilars, announced today that the Committee for Medicinal Products for Human Use (CHMP) has adopted positive opinions, separately recommending the approval of both Sandoz' biosimilar rituximab and biosimilar etanercept in Europe, to treat the same indications as their respective reference medicines.

“We are proud to help patients in Europe with blood cancers and immunological diseases by improving their access to effective treatments through the potential approval of not just one, but two new Sandoz biosimilar medicines,” said Mark Levick, MD PhD, Global Head of Development, Biopharmaceuticals, Sandoz. “Today’s recommendations from the CHMP will not only benefit patients, but they demonstrate our leadership in biosimilars and the strength of the Sandoz and Novartis immunology and oncology portfolios”.

If approved, Sandoz biosimilar rituximab may be used in all indications of the reference medicine, MabThera®†, which are non-Hodgkin’s lymphoma – follicular lymphoma and diffuse large B-cell lymphoma - chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis, and microscopic polyangiitis.

If Sandoz biosimilar etanercept is approved, it may be used in all indications of the reference medicine, Enbrel®‡, which are rheumatoid arthritis, axial spondyloarthritis (ankylosing spondylitis, non-radiographic axial spondyloarthritis), plaque psoriasis, psoriatic arthritis, juvenile idiopathic arthritis and pediatric plaque psoriasis.

The CHMP recommendations were based on two comprehensive development programs in which analytical, preclinical and clinical - including pharmacokinetic/pharmacodynamic – data were generated. The programs demonstrated biosimilarity of biosimilar rituximab and etanercept to their respective reference medicines²⁻⁸.

- Studies within the biosimilar rituximab development program included a pharmacokinetic/pharmacodynamic (PK/PD) trial in rheumatoid arthritis (ASSIST-RA)⁷ and a Phase III confirmatory safety and efficacy study in follicular lymphoma (ASSIST-FL)⁸.
- The biosimilar etanercept development program included an innovative Phase III confirmatory safety and efficacy study in moderate to severe plaque psoriasis (EGALITY), which included three treatment switches between the reference medicine and biosimilar etanercept⁴.

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global leader in biosimilars, and currently markets three biosimilars worldwide. Sandoz has a leading

biosimilar pipeline and, in addition to biosimilar rituximab and etanercept (Erelzi™ approved in 2016 by the FDA), plans to launch three more biosimilars of major oncology and immunology biologics across key geographies by 2020. As a division of the Novartis Group, Sandoz is well-positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization.

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.

* 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.

** European Commission

† MabThera® is a registered trademark of F. Hoffmann-La Roche AG

‡ Enbrel® is a registered trademark of Pfizer in Europe and Amgen in the US.

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “proposed,” “recommended,” “positive CHMP opinions,” “positive opinions,” “recommending,” “potential,”

“recommendations,” “will,” “may,” “committed,” “pipeline,” “plans,” “launch,” “well-positioned,” or similar terms, or by express or implied discussions regarding potential marketing approvals or labeling for biosimilar rituximab, biosimilar etanercept, or any of the other products in the Sandoz biosimilar pipeline, or regarding potential future revenues from biosimilar rituximab, biosimilar etanercept, and the other products in the Sandoz biosimilar pipeline. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 biosimilar rituximab, biosimilar etanercept, or any of the other products in the Sandoz biosimilar pipeline will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that, if approved, biosimilar rituximab or biosimilar etanercept will be approved for all indications included in the reference products’ respective labels. Nor can there be any guarantee that biosimilar rituximab, biosimilar etanercept, or any of the other products in the Sandoz biosimilar pipeline will be commercially successful in the future. In particular, management’s expectations regarding biosimilar rituximab, biosimilar etanercept, and such other Sandoz biosimilar pipeline products could be affected by, among other things, regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; competition in general, including potential approval of additional versions of biosimilar rituximab or biosimilar etanercept; global trends toward health care cost containment, including government, payor and general public pricing pressures; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling biosimilar rituximab, biosimilar etanercept, or its other biosimilar products; the particular prescribing preferences of physicians and patients; general economic and industry conditions; 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.

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