Sandoz receives approval in Europe for Erelzi® (biosimilar etanercept) to treat multiple inflammatory diseases

- *European Commission approves Sandoz Erelzi® to treat immunological diseases such as rheumatoid arthritis, psoriasis, and psoriatic arthritis*
- *Approval of Erelzi provides more treatment options for healthcare professionals and patients and opens another chapter in the Sandoz immunology portfolio*
- *Sandoz now has five biosimilars approved in Europe, including biosimilars of some of the world’s leading blockbuster biologics*1

Holzkirchen, June 27, 2017 — Sandoz, a Novartis division, and the pioneer and global leader in biosimilars, announced today that the European Commission (EC) has approved Erelzi® (biosimilar etanercept) for use in Europe*. Erelzi is approved for use in all indications of the reference medicine, Enbrel®†2,3.

“Immunology is a priority for us and today’s approval of Erelzi, the second in this therapy area in as many weeks, clearly demonstrates our commitment to patients. This can also be seen in the progress we are making in our immunology pipeline with two recent file acceptances in Europe” said Carol Lynch, Global Head, Biopharmaceuticals, Sandoz. “As part of the wider Novartis immunology portfolio, Erelzi further expands the offering to healthcare professionals and patients in Europe. Its availability is expected to result in more patients being treated with much-needed biologics.”

Erelzi is approved for rheumatoid arthritis, axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis), plaque psoriasis, and psoriatic arthritis, as well as juvenile idiopathic arthritis and pediatric plaque psoriasis. Erelzi is available in a pre-filled syringe and an auto-injector pen, SensoReady®, which has been designed for patient safety, comfort, and convenience.2

The EC approval was based on a comprehensive development program generating analytical, preclinical, and clinical — including pharmacokinetic (PK) — data. The program demonstrated that Erelzi matches its reference medicine in terms of safety, efficacy, and quality4–6.

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global leader in biosimilars, and now, with Erelzi, has five biosimilars approved in Europe. Sandoz has a leading biosimilar pipeline, and plans to launch three more biosimilars of major oncology and immunology biologics across 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 Erelzi
EC approval was based on a comprehensive development program, including analytical, preclinical, and clinical data, demonstrating biosimilarity to the reference medicine, Enbrel®. Clinical trials included:

- A PK study which demonstrated bioequivalence in the pharmacokinetic profiles of Erelzi and the reference medicine and did not reveal clinically relevant differences in safety, tolerability and immunogenicity4.
- The Phase III EGALITY study, which generated confirmatory efficacy, safety and immunogenicity data. The study included three treatment switches between the reference medicine and Erelzi. From baseline to Week 52, in both switched and continued treatment settings, EGALITY demonstrated no significant difference in mean Psoriasis Area and

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Severity Index (PASI) responses between Erelzi and the reference medicine. The primary endpoint of achieving equivalence in PASI 75 response rates at Week 12 was met. The EGALITY study also confirmed the comparable safety profile of the two medicines over 52 weeks. Immunogenicity was low, as expected with etanercept treatment.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "priority," "commitment," "can," "pipeline," "expected," "committed," "plans," "launch," "by 2020," "well-positioned," or similar terms, or by express or implied discussions regarding potential additional marketing approvals or labeling for biosimilar etanercept, or any of the other potential products in the Sandoz biosimilar pipeline, or regarding potential future revenues from biosimilar etanercept, the other marketed products in the Sandoz biosimilar portfolio, and the potential 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 etanercept or any of the other marketed products in the Sandoz biosimilar portfolio will be submitted or approved for sale in any additional markets, or at any particular time. Neither can there be any guarantee that any of the potential products in the Sandoz biosimilar pipeline will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that if approved, any of the potential products in the Sandoz biosimilar pipeline will be approved for any or all of the indications in the respective reference product’s label. Neither can there be any guarantee that biosimilar etanercept, the other marketed products in the Sandoz biosimilar portfolio, or the potential products in the Sandoz biosimilar pipeline will be commercially successful in the future. In particular, management’s expectations regarding biosimilar etanercept and such other biosimilar candidates and marketed 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 etanercept; 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 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.

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.
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