

Erelzi™ (etanercept), by Sandoz, is now available for patients in Canada for the treatment of multiple inflammatory diseases. ^[1]

Medicines ^[2]

- *Erelzi™ has been approved for use in Canada in a manner similar to Enbrel®, for the treatment of Rheumatoid Arthritis, Ankylosing Spondylitis, and Polyarticular Juvenile Idiopathic Arthritis¹.*
- *First biosimilar approved to treat juvenile idiopathic arthritis.*
- *Erelzi™ is the second Sandoz biosimilar available in Canada, strengthening Sandoz' leadership in biosimilars and Novartis' leading immunology portfolio.*

Boucherville, August 21, 2017 – Sandoz, a Novartis division and the pioneer and global leader in biosimilars, announced today that Erelzi™ (etanercept) is now available in Canada. In April 2017, Health Canada granted Erelzi™ a Notice of Compliance for treatment of moderately to severely active rheumatoid arthritis (RA) in adults with or without methotrexate and for reducing signs and symptoms of active ankylosing spondylitis (AS). Moreover, Erelzi™ is the only biosimilar approved for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients aged 4 to 17 years who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs), a condition that affects about one in 1,000 children in Canada.¹

“The EGALITY study has shown that Erelzi™ is safe and effective, and switching patients from Enbrel® to Erelzi™ can be performed safely without any loss of efficacy,” said Dr. Janet Pope, Professor of Medicine in the Division of Rheumatology, Epidemiology, and Biostatistics at the University of Western Ontario, Schulich School of Medicine, London. “For patients living with debilitating inflammatory arthritis diseases, this is an appropriate time to discuss new treatment and care options.”

Erelzi™ is available in a pre-filled syringe (PFS) and a pre-filled pen (PFP), SensoReady®, which has an ergonomic device for patients with limited dexterity. SensoReady® is available in 25 mg and 50 mg PFS, and is the only etanercept available in a 25 mg PFS.

According to a report published in 2011 by the Arthritis Alliance of Canada, there are approximately 300,000 people in Canada (0.9 per cent of the Canadian adult population)

living with rheumatoid arthritis. In other words, about 1 in 136 workers is suffering from RA, and within a generation, this will increase to 1 in 68 workers. Approximately 50,000 Canadians affected by rheumatic conditions have either significant difficulty or no capacity to dress and groom themselves, walk, wash, or use a toilet². It is estimated that about only 15 per cent of those patients currently have access to biologics.³

“Biologics have revolutionized the treatment and prevention of many disabling and life-threatening diseases. However, they are contributing to the rising costs of healthcare, and this may restrict access to these important medicines,” said Michel Robidoux, President and General Manager of Sandoz Canada. “Unfortunately, as it stands today, not all Canadians living with debilitating disease have the same access to biologics. There is a growing population that has a relatively high prevalence of immunological diseases, such as rheumatoid arthritis. Launching Erelzi™ is another concrete example of how Sandoz is making access happen by offering high-quality medicines at a more affordable price, which will deliver important savings to healthcare system.”

A biosimilar is a biologic that is launched after the loss of patent exclusivity on the originator biologic. It is a highly similar biological medicinal product having demonstrated therapeutic equivalence to a reference product and hence comparable efficacy, safety, tolerability and immunogenicity profiles. Biosimilars can increase access to effective treatments for patients, as well as reduce the ongoing economic burden currently existing in the Canadian healthcare system that is impacting patients, physicians and payers.

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global leader in biosimilars. Erelzi™ is the fifth biosimilar on the European market. Sandoz has a leading biosimilar pipeline and 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 Erelzi™

Erelzi™ (etanercept) is the Sandoz biosimilar of the reference medicine Enbrel®. Erelzi™ has been studied in a global development program, which included a comprehensive comparison of Erelzi™ and Enbrel® at the analytical, preclinical, and clinical levels. The program included preclinical studies, pharmacokinetic (PK) studies, and the Phase III confirmatory safety and efficacy EGALITY study.

Health Canada approval was based on a comprehensive development program consisting of comparative analytical, preclinical, and clinical data demonstrating biosimilarity to the reference medicine, Enbrel®.

Studies included: analytical (extensive comparative physicochemical and functional assessment of Erelzi™ and the reference biologic drug), preclinical, Phase I pharmacokinetic (PK), and the Phase III confirmatory study EGALITY– an innovative, safety, immunogenicity, pharmacokinetic and efficacy study in a sensitive indication to detect potential differences between Erelzi™ and Enbrel®.

The totality of evidence demonstrates that Erelzi™ is highly similar to Enbrel® in terms of structure, function, PK, efficacy, safety and immunogenicity. Based on this evidence, Health Canada granted market authorization to Erelzi™ for use in ankylosing spondylitis (AS), for the

treatment of moderately to severely active rheumatoid arthritis (RA) in adults, and polyarticular juvenile idiopathic arthritis (JIA) in patients aged 4 to 17 years who have had an inadequate response to one or more DMARDs⁴.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “potential,” “can,” “soon,” “committed,” or similar terms, or by express or implied discussions regarding potential additional marketing approvals or labeling for Erelzi™, or any of the other potential products in the Sandoz biosimilar pipeline, or regarding potential future revenues from Erelzi™, 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 Erelzi™ 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 Erelzi™ 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 Erelzi™, 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 Erelzi™ 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 Erelzi™; 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 Canada is part of Sandoz International GmbH and a subsidiary of Swiss multinational Novartis AG. A leader in its field, Sandoz Canada develops, manufactures, markets and distributes a broad line of generic, biosimilar, consumer and specialty products.

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 global 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.

www.sandoz.ca [3]

TM: Erelzi is a trademark owned or used under license by Sandoz Canada Inc.

®: Enbrel is a trademark owned by its registrant.

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For interview opportunities, please contact Annick Lambert (see contact information below).

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¹ Sandoz Canada did not seek a marketing authorization for the treatment of psoriatic arthritis or plaque psoriasis at this time.

² http://www.arthritisalliance.ca/images/PDF/eng/Initiatives/20111022_2200_impact_of_arthritis.pdf [7]

³ <http://acrabstracts.org/abstract/temporal-trends-in-drug-prescription-ut...> [8]

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[7] http://www.arthritisalliance.ca/images/PDF/eng/Initiatives/20111022_2200_impact_of_arthritis.pdf

[8] <http://acrabstracts.org/abstract/temporal-trends-in-drug-prescription-utilization-and-costs-among-rheumatoid-arthritis-ra-patients-show-wide-regional-variation-despite-universal-drug-coverage/>