

## **New indication approved for Sandoz Erelzi® (etanercept) in the Treatment of Psoriatic Arthritis** <sup>[1]</sup>

### Medicines <sup>[2]</sup>

- Erelzi is the only etanercept biosimilar to be indicated for reducing the signs and symptoms of psoriatic arthritis (PsA) in adult patients.
- Up to 90,000 Canadians have or may have PsA, a disease which affects both men and women in equal numbers. <sup>1</sup>

**Boucherville, January 21, 2019** – Sandoz Canada Inc., a division of Novartis AG, announced today that Health Canada has approved Erelzi (etanercept), a biosimilar of Enbrel® (etanercept), for the treatment of psoriatic arthritis (PsA) in adult patients, making Erelzi the only etanercept biosimilar to have obtained approval for this indication in Canada.

More specifically, Sandoz Canada Inc. received a Notice of Compliance from Health Canada on January 17, 2019 for Erelzi to be used for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in adult patients with psoriatic arthritis (PsA).<sup>2</sup> Erelzi can be used in combination with methotrexate in adult patients who do not respond adequately to methotrexate alone.

Between 10 and 30% of psoriasis patients will develop psoriatic arthritis.<sup>3</sup> Psoriatic arthritis is a type of inflammatory arthritis and autoimmune disease. The joints are the target of the immune attack causing swelling, pain and inflammation of the joints. In most people, psoriatic arthritis starts after the onset of psoriasis.

“We have the ability to improve access to different treatment options for patients suffering from this debilitating disease,” said Michel Robidoux, President and General Manager of Sandoz Canada. “The approval of Erelzi to also manage psoriatic arthritis can, in addition, help reduce healthcare system costs by making available a cost-effective biosimilar treatment option for this form of arthritis.”

A biosimilar biologic drug, or biosimilar, is a biologic drug demonstrated to be similar to a brand name drug already authorized for sale (known as the reference biologic drug). Biosimilars may enter the market after the expiry of reference biologic drug patents and data protections. For more information about biosimilars, please read Health Canada’s factsheet.<sup>4</sup> 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.<sup>5</sup>

Sandoz is committed to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global leader in biosimilars and markets eight biosimilars in Europe and two in Canada.

## **About Erelzi**

Erelzi 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 between Erelzi and Enbrel®.

Erelzi was initially approved by Health Canada in April 2017 for: treatment of moderately to severely active rheumatoid arthritis (RA) in adults, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients aged 4 to 17 years and reducing signs and symptoms of active ankylosing spondylitis (AS).<sup>6</sup>

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

## **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 Canada

Sandoz Canada is part of Sandoz International GmbH, a global leader in generic pharmaceuticals and biosimilars and a subsidiary of Swiss multinational Novartis AG. A leader in its field, Sandoz Canada develops, markets and distributes a broad line of generic, biosimilar, consumer and specialty products.

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For interview opportunities, please contact Isabelle Troitzky (see contact information below).

## For further information:

Isabelle Troitzky  
Sandoz Canada Inc.  
+1 450 641 4903 ext. 2725  
[isabelle.troitzky@sandoz.com](mailto:isabelle.troitzky@sandoz.com) [5]

## References

1. The Arthritis Society: <https://arthritis.ca/getmedia/5ec4341d-fe11-49d5-ad05-c79928fb10fa/what-...> [6]. Accessed on January 9, 2019.
2. Erelzi® (etanercept) is not indicated for the treatment of plaque psoriasis at this time.
3. The Arthritis Society: [\(a-z\)/types/psoriatic-arthritis">https://www.arthritis.ca/about-arthritis/arthritis-types-](https://www.arthritis.ca/about-arthritis/arthritis-types-) [7](a-z)/types/psoriatic-arthritis. Accessed on January 9, 2019.
4. Fact Sheet: Biosimilars: Government of Canada: <https://www.canada.ca/en/health-canada/services/drugs-health-products/bi...> [8]. Accessed on January 9, 2019.
5. Potential Savings from Biosimilars in Canada: Government of Canada: <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1304> [9]. Accessed on January 9, 2019.
6. Sandoz Canada: <https://www.sandoz.ca/en/our-work/biopharmaceuticals/erelzi> [10]. Accessed on January 9, 2019.

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[2] <https://www.sandoz.ca/en/stories/medicines>  
[3] <https://www.sandoz.ca>

[4] <https://www.linkedin.com/company/sandoz-canada/>

[5] <mailto:isabelle.troitzky@sandoz.com>

[6] <https://arthritis.ca/getmedia/5ec4341d-fe11-49d5-ad05-c79928fb10fa/what-is-psoriatic-arthritis-infographic.pdf>

[7] <https://www.arthritis.ca/about-arthritis/arthritis-types->

[8] <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html>

[9] <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1304>

[10] <https://www.sandoz.ca/en/our-work/biopharmaceuticals/erelzi>