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Sandoz Canada completes its 5th biosimilar launch with new biosimilar Hyrimoz® (adalimumab) [1]

Global Impact [2]

- *Hyrimoz® for use in nine indications covered by the reference medicine* in the fields of rheumatology, gastroenterology and dermatology.*
- *New Sandoz biosimilar to broaden access to critical adalimumab biologic treatment and free up resources that could be directed to patient care.*
- *Sandoz expands industry-leading portfolio of marketed biosimilars to 5** in Canada building on its worldwide experience.*

Boucherville, February 16, **2021** – Sandoz Canada Inc. announced today the launch of Hyrimoz® (adalimumab injection, reference biologic drug: Humira®), which was authorized for sale in Canada by Health Canada on November 4, 2020 as one of the four Sandoz biosimilars to be authorized in Canada in the last 11 months. Hyrimoz® is indicated for the treatment of nine (9) of the twelve life-threatening or serious debilitating conditions in adults and children covered by the reference medicine*, including the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, hidradenitis suppurativa, psoriasis and adult uveitis.

"We are very excited to bring our adalimumab biosimilar Hyrimoz® to market by building on the successful launch of Hyrimoz® in Europe in 2018 and our worldwide experience with biosimilars," declared Karine Matteau, Vice President, Bio-Generic Hospital/Physician channel and Head of Biosimilars at Sandoz Canada. "It is an important step as we pursue our ambition to become the leading biosimilars and generics company in Canada."

Hyrimoz® is a fully human tumor necrosis factor (TNF) blocker which helps to reduce inflammation. Itis available in 40 mg/0.8 mL and 20 mg/0.4mL in single-use prefilled syringe, and in 40 mg/0.8 mL in SensoReady® Pen autoinjector designed for patients with limited dexterity.

“Adalimumab is an important biologic therapy used by over 42,000 Canadian patients[1] whose lives can be critically impacted by their conditions. Hyrimoz® will increase access to this high-quality, affordable biologic treatment for Canadian healthcare professionals and their patients,” commented Dr. Mauricio Ede, Vice President Medical and Scientific Officer. “ We are also making available to patients a well-established patient support program, providing guidance with reimbursement navigation, financial assistance, administrative support, injection and nurse support services, as well as education and pharmacy support services for patients, throughout their treatment journey.”

‘’Biologics have revolutionized the treatment of many disabling and life-threatening conditions including inflammatory bowel disease (IBD). However, they also contribute to the rising costs of healthcare, which limit access to these and other effective therapies. Biosimilars match their reference biologics, in term of efficacy, safety, and tolerability. They also present an opportunity to reduce costs and extend access to more IBD patients,’’ commented Dr. John K. Marshall, Professor of Medicine and Director, Division of Gastroenterology at McMaster University.

“When treating patients with a chronic disease in dermatology, it is important to have several options available, and adalimumab remains an important choice in dermatologists’ armamentarium” said Dr. Charles Lynde, Associate Professor in the Department of Medicine at the University of Toronto and Medical Director of the Lynde Institute for Dermatology and Lynderm Research. “Phase III trials have demonstrated switching patients from Humira® to Hyrimoz® can be performed safely without any loss of efficacy. With the launch of this important biosimilar, we can contribute to freeing up more resources that can be directed to patient care, thereby unlocking value for our provincial and national health systems.”

Sandoz Canada has successfully completed the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations for Hyrimoz®, which is the first step in securing public reimbursement. We are actively working on securing reimbursement with both private and public payers.

“As a division of Novartis, we pride ourselves as being one company delivering both innovation and sustainability to the healthcare system in Canada. Our biosimilars portfolio in Canada currently includes six biologic medicines covering the therapeutic areas of oncology, immunology and endocrinology, and we look forward to continuing to expand it as market exclusivity of more original biologics come to an end,” added Michel Robidoux, President and General Manager of Sandoz Canada.

About Biosimilars

A biosimilar is a biologic medicine that has demonstrated it is highly similar and has no clinically meaningful differences in efficacy and safety compared to an original-brand biologic[2] already authorized for sale. Biosimilars may become commercially available following the expiry of patents and data protection periods of the original-brand biologic medicine. Since 2009, Health Canada has approved 35 biosimilars.[3]

The Patented Medicines Pricing Review Board has estimated that private and public drug plans across Canada could save from CA$294 million to CA$1.136 billion by 2021 for established biosimilars available in Canada for at least two years across a portfolio of products and from CA$222 million to CA$447 million by 2023 for new biosimilars that recently entered the Canadian market[4]. The broader use of biosimilar medicines, including the implementation of biosimilar switching policies, can also help public and private drug plans improve their sustainability by adding new medicine listings and expanding existing medication coverage for patients.

For further information on biosimilars in Canada, visit ***BiosimilarsGeneration.ca*** [3].

® *Trademark owned by the registered owner.*

*Humira® (adalimumab) is a registered trademark of AbbVie Biotechnology, Inc.
**The Sandoz portfolio of biosimilars includes 6 authorized biosimilars among which 5 are currently marketed (at February 15, 2020).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “potential,” “can,” “soon,” “planned” or similar expressions, or by express or implied statements regarding potential marketing or new labelling approvals for Hyrimoz® or other potential products in the Sandoz pipeline of biosimilars, or regarding potential future revenues from the sale of Hyrimoz® or other marketed products from the Sandoz biosimilars portfolio or potential future revenues from the Sandoz portfolio of biosimilars in development. You should not place undue reliance on these statements. These forward-looking statements reflect management’s current beliefs and expectations regarding future events and involve known and unknown risks and significant uncertainties. Should one or more of these risks or uncertainties materialize, or should any of the underlying assumptions prove incorrect, actual results could differ materially from those set forth in the forward-looking statements. There can be no guarantee that Hyrimoz® or any other marketed product from the Sandoz portfolio of biosimilars will be submitted or approved for sale in other markets, or at any particular time. There can also be no guarantee that potential products from the Sandoz portfolio of biosimilars under development will be submitted or approved for sale in other markets, or at any particular time. There can also be no guarantee that, if approved, potential products in the Sandoz portfolio of biosimilars in development will be approved for all indications listed on the label of the reference product. There can also be no guarantee that Hyrimoz®, other marketed products in the Sandoz portfolio of biosimilars or other potential products in the Sandoz portfolio of biosimilars in development will be commercially successful in the future. In particular, management’s expectations regarding Hyrimoz® and other biosimilar candidates and marketed products could be affected by, among other things, regulatory actions, delays or government regulation generally; uncertainties inherent in research and development, including the results of clinical studies and further analysis of existing clinical data; competition in general, including potential approval of new versions of Hyrimoz®; the global trend toward rationalizing healthcare costs, including pricing pressures and reimbursement issues from healthcare payers, the general public and governments; the outcome of litigation, including intellectual property litigation and other legal actions to prevent or restrict the sale of Sandoz biosimilar products; physicians’ and patients’ particular prescription preferences; general economic and industry conditions; impacts of the COVID-19 pandemic; manufacturing, safety or quality issues; and other risks and factors referred to in Novartis AG’s Form 20-F on file with the US Securities and Exchange Commission. Sandoz is providing the information in this press release as of today and does not undertake any obligation to update any forward-looking statements described herein as a result of new information, future events or otherwise, except as required by the law.

About Sandoz

Sandoz is a world leader in generics and biosimilars and a division of the Swiss multinational Novartis. A true leader in its field, Sandoz Canada markets and distributes a wide range of generics, biosimilars and specialty products.

www.sandoz.ca [4]

Follow us on LinkedIn: https://www.linkedin.com/company/sandoz-canada/ [5]

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