Biosimilars switch policies update: British Columbia expands its Biosimilars Initiative to include rituximab [1]

Global Impact [2]

??Sandoz Canada launches two new biosimilars Ziextenzo® and Riximyo®

- *Sandoz Canada reaches a negotiated agreement with the Pan-Canadian Pharmaceutical Alliance (pCPA) for both medicines*
- *Riximyo® is now covered in British Columbia and Ontario for patients in need of rituximab*
- *Both Riximyo® and Ziextenzo® will be available in hospitals and cancer centres in addition to retail pharmacies across Canada*

Boucherville, August 19, 2020 – Sandoz Canada Inc. announces it has reached a negotiated agreement with the Pan-Canadian Pharmaceutical Alliance (pCPA) and launched Ziextenzo® (pegfilgrastim, reference biologic drug: Neulasta®) and Riximyo® (rituximab, reference biologic drug: Rituxan®) in Canadian hospitals and pharmacies. This follows the recent approval of the two biosimilars by Health Canada [3].

Ziextenzo® (pegfilgrastim) was approved by Health Canada on April 21, 2020. It is a long-acting form of recombinant human granulocyte colony-stimulating factor (r-metHuG-CSF), or filgrastim. The use of **Ziextenzo®** has been approved to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive antineoplastic agents. Neutropenia is one of the most serious side effects of chemotherapy[1].

Riximyo®**(rituximab)** was approved by Health Canada on April 28, 2020. It belongs to a family of medicines called monoclonal antibodies. Antibodies are proteins that are produced to bind to another protein, called an antigen. Riximyo® has been approved for the treatment of non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukemia (CLL), as well as the autoimmune disease rheumatoid arthritis (RA).

Pursuing the pCPA agreement, Riximyo® is now reimbursed in Ontario effective July, 2020 through Limited Use as well as Exceptional Access Program [4] for certain indications, and funding in hospitals will be provided by Cancer Care Ontario [5]. In addition, British Columbia has recently announced the reimbursement of Riximyo® effective August 1, 2020 through BC Cancer [6].

“We are very pleased with British Columbia’s and Ontario’s decision for improving access and offering public reimbursement to this treatment for patients in need of rituximab” said Michel Robidoux, President and General Manager of Sandoz Canada. “Sandoz is a global leader and a pioneer in biosimilars research, development, manufacturing and commercialization. As such, we have a vertically integrated model. The addition of Ziextenzo® and Riximyo® in Canada will provide greater access to Canadian patients in the immunology and oncology areas.”

“In addition to our agreement with the Pan-Canadian Pharmaceutical Alliance for both biosimilars, we are currently working with individual provinces to include these medicines on formulary coverage. This is great news for patients and their healthcare professionals as we expand biologic treatment options for patients with life-threatening or serious debilitating conditions. The launches also allow for a broader use of biosimilars that can help reduce growing costs to the healthcare system and generate savings that can be reinvested in healthcare resources,” explains Karine Matteau, Vice President, Bio-Generic Hospital/Physician channel and Head Biosimilars at Sandoz Canada.

A patient support program will be available to patients treated by these biosimilars, providing guidance with reimbursement navigation, financial assistance, administrative support, as well as education for patients.

About Biosimilars

As patents and data protection expire for original-brand medicines, other manufacturers may produce new versions of the biologic medicines called biosimilars. To receive Health Canada authorization, a biosimilar must demonstrate it is highly similar and has no clinically meaningful differences in efficacy and safety compared to an original-brand (“reference”) biologic[2]. Since 2009, Health Canada has approved 24 biosimilars of original-brand biologics present on the Canadian market[3].

The Patented Medicines Pricing Review Board has estimated that private and public drug plans across Canada could save from $332 million CDN to $1.81 billion CDN in the third year following biosimilar entry across a portfolio of product[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*** [7] , which aims to support and educate patients, healthcare professionals and Canadians by providing policy updates from public drug plans, as well as evidence-based information and resources from Canadian, international research and clinical communities, and patient organizations representing Canadians living with chronic diseases who take biologic medicines.

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 Ziextenzo® and Riximyo® or other potential products in the Sandoz pipeline of biosimilars, or regarding potential future revenues from the sale of Ziextenzo® and Riximyo® 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 Ziextenzo® and Riximyo® 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 Ziextenzo® and Riximyo®, 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 Ziextenzo® and Riximyo® 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 Ziextenzo® and Riximyo®; 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; 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 International GmbH is a world leader in generics and biosimilars and a division of the Swiss multinational Novartis AG. A true leader in its field, Sandoz Canada markets and distributes a wide range of generics, biosimilars and specialty products.

www.sandoz.ca [8]

Follow us on LinkedIn: https://www.linkedin.com/company/sandoz-canada/ [9]

References

1. Canadian Cancer Society : Managing side effects / Low white blood cell count https://www.cancer.ca/en/cancer-information/diagnosis-and-treatment/managing-side-effects/low-white-blood-cell-count/?region=on [10]
2. Health Canada Biosimilars Fact Sheet: Biosimilars Explained. https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html [11]
3. Canadian Biologic Drug Market, Biosimilars Canada (12 months ending March 2020)
4. Potential savings associated with biosimilars in Canada: Government of Canada: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1304 [12]

-30-

For interview requests, please contact Isabelle Troïtzky (see contact information below).

Information:

Isabelle Troïtzky

Sandoz Canada Inc.

+1-514 220-0085

isabelle.troitzky@sandoz.com [13] / communications.canada@sandoz.com [14]

Links
[1] https://www.sandoz.ca/en/stories/global-impact/launch-twobiosimilars
[2] https://www.sandoz.ca/en/stories/global-impact
[3] https://www.sandoz.ca/en/news/media-releases/sandoz-canada-receives-health-canada-approval-launch-two-oncology-biosimilars
[4] http://www.health.gov.on.ca/en/pro/programs/drugs/formulary43/summary_edition43_20200724.pdf
[5] https://www.cancercareontario.ca/en/drugformulary/drugs/monograph/44031
[6] http://www.bccancer.bc.ca/systemic-therapy-site/Documents/2020%20ST%20Updates/ST%20Update_August%202020.pdf
[7] http://www.BiosimilarsGeneration.ca
[8] https:///C:/Users/patton/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/IJE30NLJ/www.sandoz.ca
[9] https://www.linkedin.com/company/sandoz-canada/
[10] https://www.cancer.ca/en/cancer-information/diagnosis-and-treatment/managing-side-effects/low-white-blood-cell-count/?region=on
[11] https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html

[12] http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1304
[13] mailto:isabelle.troitzky@sandoz.com
[14] mailto:communications.canada@sandoz.com