Fresenius Kabi Canada Launches IDACIO® (adalimumab injection) a Biosimilar to HUMIRA® (adalimumab) for the Treatment of Multiple Chronic Inflammatory Conditions

Biosimilars offer patients access to affordable, meaningful medicines

Toronto ON, February 18, 2021 - Fresenius Kabi Canada, a health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition, announced today it has introduced IDACIO®, an adalimumab biosimilar, in Canada. The drug is available immediately for all indications of the reference medicine in the areas of rheumatology, gastroenterology and dermatology. IDACIO received marketing authorization from Health Canada on October 30, 2020 and is the first biosimilar product introduced in North America by Fresenius Kabi.

"Our philosophy is 'caring for life' and this authorization is the latest example of Fresenius Kabi providing meaningful and affordable medications to Canadian patients," said Matthew Rotenberg, CEO, Fresenius Kabi Canada. "As a partner to the Canadian health care system, we are known for our high-quality standards and manufacturing capabilities and now for biosimilars we have invested in comprehensive programs that will make the use of our product seamless for patients and assist physicians in delivering optimal care."

KabiCare, Fresenius Kabi Canada's patient support program, provides patients with information, tools, and support to help them during their treatment. KabiCare is a program tailored to patients and health care providers, offering reimbursement navigation, financial assistance, as well as customized services to complement individual clinic processes.

The Health Canada authorization of IDACIO was based on the evidence submitted to Health Canada including analytical, preclinical, and clinical data in healthy volunteers and patients.[i] Indications have been granted on the basis of similarity between the biosimilar and the reference biologic drug and IDACIO has demonstrated similar pharmacokinetics, efficacy, safety and immunogenicity to the reference product in the clinical development program.[ii,iii,iv]

"It is really important to have biosimilars in Canada as they offer equal value to patients at less cost," said Dr. Janet Pope, MD MPH, Professor of Medicine, Rheumatologist, Western University. "Biosimilars approved by Health Canada have successfully gone through a rigorous review for their safety and benefit. They should help in the sustainability of our health care."

About IDACIO

IDACIO was developed by Fresenius Kabi. Health Canada authorized IDACIO for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, adult and adolescent hidradenitis suppurativa, adult and paediatric Crohn's disease, ulcerative colitis, adult non-infectious uveitis and pediatric chronic non-infectious anterior uveitis.[i]

About Fresenius Kabi Canada

Bringing over 100 years of global experience and over 30 years in Canada, Fresenius Kabi Canada is a long-term partner to Canadian health care. It is committed to upholding the same quality standards in developing and producing biosimilars as originator biologics, while supporting the unique needs of Canadian patients, practitioners and the health care system.

Fresenius Kabi has grown to be a leading supplier of IV generic drugs in Canada. Its product portfolio also includes IV compounding pharmacies, infusion therapies and parenteral nutrition products as well as the devices for administering these products.

Fresenius Kabi believes health care should never be "one size fits all." That's why the company is taking a thoughtful approach to addressing the unique needs of Canadian patients, practitioners and the health care system as a whole. As a partner to the system, Fresenius Kabi works closely with health care professionals, payers and patients, to develop value-added services that improve patient care.

For more information, please visit https://www.fresenius-kabi.com/en-ca/ and for more information about biosimilars, please visit www.fresenius-kabi.com/en-ca/products/biosimilars

About Fresenius Kabi
Fresenius Kabi is a global healthcare company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. Fresenius Kabi's product portfolio comprises a comprehensive range of I.V. generic drugs, infusion therapies and clinical nutrition products as well as the devices for administering these products. In the field of biosimilars, Fresenius Kabi focuses on autoimmune diseases and oncology. In 2019, Fresenius Kabi launched its first biosimilar product. Within transfusion medicine and cell therapies, Fresenius Kabi offers products for collection of blood components and extracorporeal therapies.

With its corporate philosophy of "caring for life", the company is committed to putting essential medicines and technologies in the hands of people who help patients and finding the best answers to the challenges they face.

For more information, please visit https://www.fresenius-kabi.com/en-ca/.

Forward Looking Statements
This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. Fresenius Kabi does not undertake any responsibility to update the forward-looking statements in this release.

Contact for press releases:
Matt Kuhn
Fresenius Kabi
Matt.kuhn@fresenius-kabi.com
1-847-220-3033

[i] IDACIO® Product Monograph. October, 2020

[ii] Hyland E, et al. Comparison of the pharmacokinetcis, safety and immunogenicity of MSB11022, a biosimilars of adalimumab, with Humira® in healthy subjects. *Br J Clin Pharmacol*. 2016;82(4):983–932

[iii] Hercogova J et al. A randomized, double-blind trial comparing the efficacy, safety and immunogenicity of MSB11022, a proposed biosimilar of adalimumab, versus adalimumab originator in patients with moderate-to-severe plaque psoriasis. *Am Acad Dermatol*. 2018;79(3):AB21

[iv] Hercogova J et al. AURIEL-PsO: a randomized, double-blind phase III equivalence trial to demonstrate the clinical similarity of the proposed biosimilar MSB11022 to reference adalimumab in patients with moderate-to-severe chronic plaque-type psoriasis. Br J Dermatol. 2020; 182: 316-326