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Organon Canada Announces Availability of a High-Concentration, Citrate-Free Formulation of HADLIMA[®], a Biosimilar to Humira^{*}

- HADLIMA[®] 40 mg/0.4 mL offers a higher concentration compared to HADLIMA[®] 40 mg/0.8 mL.
- The availability of both low and high concentration citrate-free options will help enhance patient care for Canadians through more treatment options, while reinforcing Organon's commitment towards biosimilars.

Kirkland, Quebec, October 26, 2023 – Organon Canada, a subsidiary of Organon (NYSE: OGN), a global healthcare company with a focus on women's health, today announced the availability of HADLIMA[®] (adalimumab), a biosimilar for Humira^{*} (adalimumab), in a high-concentration, citrate free (40 mg/0.4 mL) version. The launch of the new higher concentration formulation (40 mg/0.4 mL) (compared to HADLIMA[®] 40 mg/0.8 mL) offers physicians and patients with more options for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis, ankylosing spondylitis (AS), psoriatic arthritis, adult Crohn's disease, ulcerative colitis, adult and adolescent hidradenitis suppurativa, plaque psoriasis, adult and pediatric uveitis.¹

"The launch of a citrate-free, high concentration formulation of HADLIMA[®] means more access to advanced treatment options for Canadians experiencing certain chronic autoimmune conditions, including inflammatory bowel diseases," said Dr. Peter Lakatos, Gastroenterologist at the McGill University Health Centre (MUHC) and Professor of Medicine at McGill University.

With this launch, the company reinforces its commitment of offering patients more treatment options and reducing healthcare costs by increasing access to biosimilars. HADLIMA[®] was previously approved by Health Canada as a low-concentration formulation (40 mg/0.8 mL) in May 2018 and subsequently in a high-concentration (40 mg/0.4 mL) in December 2022.²

"The launch of citrate-free high concentration HADLIMA[®] is important for biosimilars in Canada and for Canadians gaining expanded access to treatment options," said Michael Casia, President and Managing Director, Organon Canada. "Organon Canada is committed to the continued expansion of its biosimilar portfolio, helping to strengthen our healthcare system and support patients in need."

HADLIMA[®] was developed and manufactured by Organon's collaborator Samsung Bioepis which also developed and manufactured its other biosimilars portfolio including ONTRUZANT[®], AYBINTIO[®], BRENZYS[®] and RENFLEXIS[®].

About Organon

Organon is a global healthcare company formed to focus on improving the health of women throughout their lives. Organon offers more than 60 medicines and products in women's health in addition to a growing biosimilars business and a large franchise of established medicines across a range of therapeutic areas. Organon's existing products produce strong cash flows that support investments in innovation and future growth opportunities in women's health and biosimilars. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 10,000 employees with headquarters located in Jersey City, New Jersey.

For more information, visit www.organon.ca and connect with us on [LinkedIn](#).

Cautionary Note Regarding Forward-Looking Statements

Some statements and disclosures in this press release are "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as "may," "expects," "intends," "anticipates," "plans," "believes," "seeks," "estimates," "will," or words of similar meaning. These forward-looking statements are based on Organon's current plans and expectations and are subject to a number of risks and uncertainties that could cause Organon's plans and expectations, including actual results, to differ materially from the forward-looking statements.

Risks and uncertainties that may affect Organon's future results include, but are not limited to, an inability to fully execute on the product development and commercialization plans for HADLIMA[®] in the United States due to Organon's inability to realize the benefits of its SB5 HADLIMA[®] biosimilar; efficacy, safety, or other quality concerns with respect to marketed products, including market actions such as recalls, withdrawals, or declining sales; political and social pressures, or regulatory developments, that adversely impact demand for, availability of, or patient access to Organon's products; general economic factors, including recessionary pressures, interest rate and currency exchange rate fluctuations; general industry conditions and competition; the impact of the ongoing COVID-19 pandemic and emergence of variant strains; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances; new

products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Organon's ability to accurately predict its future financial results and performance; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of Organon's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Organon undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Organon's filings with the Securities and Exchange Commission ("SEC"), including Organon's Annual Report on Form 10-K for the year ended December 31, 2022, available at the SEC's Internet site (www.sec.gov).

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References: 1. HADLIMA[®] Product Monograph. Organon Canada Inc. December 14, 2022. Available at: https://www.organon.com/canada-en/hadlima-pm_e. 2. Health Canada. Notice of Compliance Search Results, available at: <https://health-products.canada.ca/noc-ac/nocInfo?no=20841>. Accessed on October 4, 2023.

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