



Alvotech and JAMP Pharma Announce Receipt of Marketing Authorization for Jamteki™ (AVT04), the First Biosimilar of Stelara® (ustekinumab)

November 14, 2023

Pr Jamteki™ is the second biosimilar developed under this partnership that receives marketing authorization in Canada.

REYKJAVIK, Iceland and BOUCHERVILLE, Quebec, Nov. 14, 2023 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and JAMP Pharma Group ("JAMP Pharma"), a Canadian owned pharmaceutical organization headquartered in the Greater Montreal area, announced today that Health Canada has granted JAMP Pharma marketing authorization for AVT04, a biosimilar to Stelara® (ustekinumab) developed by Alvotech. AVT04 will be marketed under the brand name Jamteki™.

The currently approved presentations of Jamteki™ are a 45mg/0.5mL pre-filled syringe with a passive safety device for subcutaneous injection (PFS-SD) and the 90mg/mL PFS-SD. This is the second biosimilar to receive marketing authorization, developed under an exclusive commercialization partnership between Alvotech and JAMP Pharma. Last year, the partners launched Simlandi®, a biosimilar to Humira® (adalimumab).

"The introduction of Jamteki™ is in line with our current biosimilar product offering and showcases JAMP Pharma's commitment to evolve in this market," said Louis Pilon, President and CEO at JAMP Pharma. "Alvotech is an innovative and strategic partner, enabling Canadian patients to benefit from ustekinumab at a lower cost. Patients will also benefit from the expertise of our Patient Support Program – JAMP Care™ – for an optimal and seamless transition."

"We are very pleased to receive marketing authorization for our second biosimilar in Canada with JAMP Pharma," said Robert Wessman, Chairman and CEO of Alvotech. "Strong demand for biosimilars in Canada indicates that there is a need for affordable quality biologics in the Canadian market. This is an important step for us and for our joint objective to offer broader access to more affordable healthcare."

In February 2022, JAMP Pharma announced the creation of BioJAMP™ as part of its goal to establish itself as a leader in the Canadian biosimilars market. BioJAMP™ and the JAMP Care™ patient support programs are both designed to simplify the transition process to biosimilar medicines for patients and caregivers.

JAMP Pharma and Alvotech announced their exclusive partnership for the commercialization of biosimilars in Canada in January 2022 then expanded the agreement in October 2022. In addition to Simlandi® (adalimumab), which was launched in Canada in April 2022, and Jamteki™ (ustekinumab), the partnership also includes four biosimilar candidates in clinical development, as well as two biosimilar candidates in pre-clinical development.

About AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar of Stelara® (ustekinumab). Ustekinumab binds to two cytokines, IL-12 and IL-23, that are involved in inflammatory and immune responses [1]. AVT04 has been approved in Japan, Canada and the European Medicines Agency (EMA) has recommended market authorization in the 27 member states of the European Union, as well as Norway, Iceland and Liechtenstein, pending a final decision by the European Commission.

[1] [Product information \(canada.ca\)](#)

Use of trademarks

Humira® is a registered trademark of AbbVie Biotechnology Ltd. Stelara® is a registered trademark of Johnson & Johnson

About JAMP Pharma Group

JAMP Pharma Group is Canadian based with its head office located in the Greater Montreal area. Having experienced exceptional growth over the past 10 years, JAMP Pharma Group is present in all segments of the pharmaceutical market with a portfolio of more than 325 molecules and is one of the leaders in the industry in terms of annual prescription volume [2]. With more than 130 new products authorized for sale by Health Canada in the last 3 years, the JAMP Pharma Group is the Canadian leader in product launches [3], enhancing the new treatment options available in Canada, including many specialty drugs. In addition to its generic division, the JAMP Pharma Group has several divisions such as Orimed, BioJAMP, Wampole, Laboratoire Suisse and Cosmetic Import, also offering prescription and branded products, biosimilar products, 180 over-the-counter products with a diverse range of vitamins, supplements, and natural products. The JAMP Care® patient support program is designed to assist patients, as well as healthcare professionals, in taking specialty medications and biosimilars offered by the JAMP Pharma Group. Website: JAMP Pharma Group (<https://www.jamppharma.ca/en/>)

[2] Source: Pharmaceutical manufacturers with the highest volume of prescriptions in Canada between January 2018 and September 2023 Based in part on data obtained under license from IQVIA Solutions Canada, regarding the following service: CDH, MAT August 2018 to September 2023 All rights reserved. This statement is not necessarily that of IQVIA Solutions Canada Inc. or any of its affiliates or subsidiaries.

[3] Source: Pharmaceutical manufacturers with the highest volume of reported product launches in Canada between 2016 and 2022 Based in part on data obtained under license from IQVIA Solutions Canada, regarding the following service: CDH, MAT 2016/01 to 2022/12. All rights reserved. This statement is not necessarily that of IQVIA Solutions Canada Inc. or any of its affiliates or subsidiaries.

About Alvotech

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Alvotech's current pipeline includes eight disclosed biosimilar candidates aimed at treating

autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech has formed a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian countries and large parts of South America, Africa and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

Forward Looking Statements

Certain statements in this communication may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements generally relate to future events or the future financial operating performance of Alvotech and may include, for example, Alvotech's expectations regarding its expected future business, financial performance, the use of proceeds from the private placement, and the future utilization of the Yorkville facility. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential", "aim" or "continue", or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the outcome of any legal proceedings that may be instituted against Alvotech or others following the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech; (2) changes in applicable laws or regulations; (3) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (4) Alvotech's estimates of expenses and profitability; (5) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (6) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (7) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (8) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (9) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (10) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (11) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (12) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (13) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (14) the potential impact of the ongoing COVID-19 pandemic on the FDA's review timelines, including its ability to complete timely inspection of manufacturing sites; (15) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, and the ongoing and evolving COVID-19 pandemic on the Alvotech's business, financial position, strategy and anticipated milestones; (16) future liquidity and financing needs, which may impact the anticipated utilization of the Yorkville facility or other financing sources; and (17) other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in documents that Alvotech may from time to time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed. The recipient agrees that it shall not seek to sue or otherwise hold Alvotech or any of its directors, officers, employees, affiliates, agents, advisors, or representatives liable in any respect for the provision of this communication, the information contained in this communication, or the omission of any information from this communication.

CONTACTS

JAMP Pharma

Alexandra Lewicki, M.Sc.
Marketing & Communication Director
alewicki@jamppharma.com

Alvotech

Benedikt Stefansson
Investor Relations and Global Communications
alvotech.ir@alvotech.com