



Alvotech Announces Expected Global Market Entry Dates for AVT04 Biosimilar to Stelara® (ustekinumab)

February 15, 2024

REYKJAVIK, Iceland, Feb. 15, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced that it has reached settlement agreements with Johnson & Johnson in Japan, Canada and in the European Economic Area (EEA) for AVT04, a biosimilar to Stelara® (ustekinumab). Regulatory approval for AVT04 in these markets has already been granted. Market applications for AVT04 are currently pending in additional global markets, including in the U.S.

Market entry of AVT04 in Canada is expected in Q1 2024. Launch of AVT04 in Japan is anticipated after the upcoming round of National Health Insurance reimbursement price listings, in May 2024. Entry to the first European markets is expected as soon as possible after the expiration date of the European Supplementary Protection Certificate (SPC) for Stelara, which is in late July 2024.

"We look forward to working with our commercial partners in launching the first biosimilar to Stelara in these global markets, thereby increasing patient access to a vital biologic," said Robert Wessman, Chairman and CEO of Alvotech.

Market authorization for AVT04 in Japan is held by Alvotech's commercial partner Fuji Pharma Co. Ltd., where the biosimilar will be marketed as Ustekinumab BS (F). Alvotech's commercial partner and market authorization holder for AVT04 in Canada is JAMP Pharma Group, where the biosimilar will be marketed as Jamteki®. In the EEA, Alvotech's commercial partner and market authorization holder for AVT04 is STADA Arzneimittel AG, where the trade name for AVT04 will be Uzpruvo®.

In June 2023, Alvotech and Teva, the commercialization partner for AVT04 in the U.S., reached a settlement and license agreement with Johnson & Johnson, that grants an entry date for AVT04 in the U.S. no later than February 21, 2025, pending approval of the Biologics License Application by the U.S. Food and Drug Administration, which is expected by the Biosimilar User Fee Act goal date of April 16, 2024.

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 EEA, which includes in the 27 member states of the European Union, as well as Norway, Iceland and Liechtenstein. Market applications are pending in other global markets, including the U.S.

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 and financial performance. 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 including AVT04; (6) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations including for AVT04; (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 including AVT04; (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.

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