



Alvotech Provides Update on Status of U.S. Biologics License Application for AVT04

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REYKJAVIK, Iceland, Oct. 12, 2023 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today that the US Food and Drug Administration (FDA) has issued a complete response letter (CRL) for Alvotech's Biologics License Application (BLA) for AVT04, a biosimilar candidate to Stelara[®] (ustekinumab).

As expected, the CRL noted that certain deficiencies, which were conveyed following the FDA's inspection of the company's Reykjavik facility that concluded in March 2023, must be satisfactorily resolved before the application can be approved. No other deficiencies in the application were noted by the FDA. Alvotech intends to resubmit the BLA for AVT04 to the FDA shortly, which would likely trigger a six-month review period and a new Biosimilar User Fee Act (BsUFA) goal date.

"AVT04 has recently been approved in Japan, and other marketing applications for AVT04 are currently awaiting approval in other major markets. Based on our latest interactions with the FDA we are currently expecting that the agency will reinspect our facility in the beginning of next year. We look forward to being able to bring AVT04 to U.S. patients, pending a satisfactory inspection and BLA approval, no later than in February 2025, in accordance with our license entry date agreement," said Robert Wessman, Chairman and CEO of Alvotech.

In June 2023 Alvotech and Teva, the exclusive 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.

About AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar candidate to 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. Dossiers are currently under evaluation in other major markets globally.

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; 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.

[1] <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf>

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