



Alvotech to Present Clinical Study Data for AVT04, a Proposed Biosimilar to Stelara®, at 2023 American Academy of Dermatology (AAD) Annual Meeting

March 17, 2023

- *Alvotech to present two posters related to pharmacokinetics and confirmatory clinical studies for AVT04 (ustekinumab), a proposed biosimilar to Stelara®*
- *Marketing applications for AVT04 have been submitted in major markets including U.S. and Europe*

REYKJAVIK, Iceland, March 17, 2023 (GLOBE NEWSWIRE) -- Alvotech ([NASDAQ: ALVO](#)), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced the presentation of two posters related to its clinical studies in support of biosimilarity and clinical comparability of Alvotech's AVT04 (ustekinumab) and the reference product Stelara® at the 2023 American Academy of Dermatology (AAD) Annual Meeting, March 17-21 in New Orleans.

Earlier this year, Alvotech announced two regulatory updates for AVT04. In [February 2023](#) Alvotech announced that a Marketing Authorization Application (MAA) filing for the biosimilar candidate was accepted by the European Medicines Agency's (EMA) and in [January 2023](#) that a Biologics License Application (BLA) was accepted for review by the U.S. Food and Drug Administration's (FDA).

Alvotech's poster, titled "Assessment of Bioequivalence Between Candidate Biosimilar AVT04 and Reference Ustekinumab," details a pharmacokinetic (PK) study, [AVT04-GL-101](#), conducted with healthy adult volunteers. The study involved a single dose, 3-arm, parallel design to compare pharmacokinetics, safety, tolerability, and immunogenicity of a single 45mg/0.5mL subcutaneous dose of AVT04 with US-licensed Stelara and EU-approved Stelara. In [May 2022](#), Alvotech announced positive top-line results from the AVT04 PK study.

The second poster, titled "Assessment of Therapeutic Equivalence Between Candidate Biosimilar AVT04 and Reference Ustekinumab," details a confirmatory clinical study, [AVT04-GL-301](#). The randomized, double-blind, multicenter study was designed to demonstrate equivalent efficacy and to compare safety and immunogenicity between AVT04 and Stelara® in patients with moderate to severe chronic plaque-type psoriasis. In [May 2022](#), Alvotech announced that the confirmatory study had met its primary endpoint, with results demonstrating therapeutic equivalence between Alvotech's biosimilar candidate and the reference product.

The posters will be available to view on the conference platform during the conference starting on March 17, 2023. Further information about the 2023 AAD Annual Meeting can be found [here](#).

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. AVT04 was developed using an Sp2/0 host cell line and is manufactured using a continuous perfusion process. AVT04 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

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 contains eight 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/EEA, UK, Switzerland), Fuji Pharma Co., Ltd (Japan), 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 or operating performance of Alvotech and may include, for example, Alvotech's expectations regarding capitalization through equity or debt financing, future growth, results of operations, performance, including cost of product revenue, future capital and other expenditures, competitive advantages, partnerships, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, the potential approval, including for AVT04 by the FDA, the EMA and other regulatory agencies and commercial launch of its product candidates, the timing of the announcement of clinical study results, the commencement of patient studies, regulatory applications, and completion of regulatory review, regulatory approvals and market launches. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential" 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) the ability to maintain stock exchange listing standards; (3) changes in applicable laws or regulations; (4) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (5) Alvotech's estimates of expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (8) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (9) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (10) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (11) 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; (12) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (13) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (15) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (16) 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; (17) 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 Company's business, financial position, strategy and anticipated milestones; and (18) 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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