



## Update on U.S. Regulatory Status of AVT02, Alvotech's Proposed High-Concentration, Interchangeable Biosimilar to Humira®

December 22, 2022

- U.S. Food and Drug Administration (FDA) has confirmed that the goal date for an approval decision on Alvotech's license application for AVT02 is April 13, 2023
- FDA has completed review of Alvotech's application of AVT02 as an interchangeable to high-concentration of Humira® and confirmed that the data provided are sufficient to support a determination of interchangeability; approval requires satisfactory outcome of upcoming facility reinspection
- Alvotech is anticipating a facility reinspection by the FDA in the first quarter of 2023

REYKJAVIK, Iceland, Dec. 22, 2022 (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 FDA has granted a new Biosimilar User Fee Amendment (BsUFA) goal date of April 13, 2023, for Alvotech's original Biologics License Application (BLA) for AVT02 as biosimilar to Humira®. Approval of the application requires satisfactory outcome of a reinspection of Alvotech's facility in Reykjavik, Iceland. Alvotech is working with the FDA to schedule a reinspection in the first quarter of 2023.

Communications from the FDA regarding Alvotech's application supporting interchangeability of AVT02, including a Complete Response Letter received on December 20, 2022, confirmed that the application review is complete. The key requirement for approval is the same as for the original BLA, which is a satisfactory outcome of the facility reinspection.

"I'm very pleased to receive confirmation from the FDA that it has completed its review of the interchangeability application for AVT02 and that approval can be granted after Alvotech has fulfilled the agency's inspection requirements. We remain excited about the anticipated launch of AVT02 in the U.S. on July 1, 2023 and strongly believe that Alvotech's interchangeable biosimilar will increase patient access in the U.S. to this important therapy," said Robert Wessman, Founder and Executive Chairman of Alvotech.

AVT02 has been launched in 17 markets around the world, including Canada, Germany, and France and has received marketing approval in 35 countries. In March of 2022, Alvotech reached a [settlement agreement](#) that grants Alvotech a license entry date in the United States of July 1, 2023. Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), is Alvotech's exclusive strategic partner for the commercialization of AVT02 in the United States.

### About AVT02

AVT02 is a monoclonal antibody and has been approved as a biosimilar to Humira® (adalimumab) in the 27 EU member countries, Norway, Lichtenstein, Iceland, the UK, Switzerland, Canada, Australia and Saudi Arabia. It is currently marketed in sixteen countries in Europe and in Canada. Dossiers are under review in multiple countries, including in the United States.

### 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), 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](http://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 and may include, for example, Alvotech's expectations regarding regulatory review and interactions, the timing and results of the facility inspection by the FDA, satisfactory responses to the FDA's inspection findings and resolution of deficiencies conveyed following the inspection of Alvotech's manufacturing site, the potential approval and commercial launch of its product candidates, the timing of the announcement of clinical study results, regulatory approvals and market launches, the estimated size of the total addressable market of Alvotech's pipeline products, competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events. 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) 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) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (8) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (9) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (10) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (11) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (12) 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; (13) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (14) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (15) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (16) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (17) 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; (18) 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 (19) 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**

### **Alvotech Investor Relations and Global Communications**

Benedikt Stefansson

[alvotech.ir@alvotech.com](mailto:alvotech.ir@alvotech.com)