



## Alvotech to Present Switching Study Data for AVT02, a Proposed Biosimilar to Humira®, at 2022 American College of Rheumatology Conference

November 10, 2022

- *Alvotech will present two posters and will be featured in an Ignite Talk related to its switching study for AVT02*
- *The switching study was conducted to investigate the pharmacokinetics, immunogenicity, efficacy and safety in patients undergoing repeated switches between Humira and AVT02*
- *Alvotech is the only known company that has both developed a high-concentration biosimilar candidate to Humira and completed a switching study to support interchangeability*

REYKJAVIK, Iceland, Nov. 10, 2022 (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 will present two posters and will be featured in an Ignite Talk related to its switching study for AVT02 at the American College of Rheumatology (ACR) Convergence Conference, being held in Philadelphia on November 10-14, 2022.

The posters and Ignite Talk will provide detail on the data from Alvotech's switching study for AVT02, a proposed high-concentration (100 mg/mL), citrate-free interchangeable biosimilar candidate for Humira® (adalimumab), conducted to investigate the pharmacokinetics (PK), immunogenicity, efficacy and safety in patients undergoing repeated switches between Humira and AVT02.

Alvotech is the only known company that has both developed a high-concentration biosimilar candidate to Humira and [completed a switching study](#) to support potential regulatory approval as an interchangeable product. Alvotech's Biologics License Application (BLA) for interchangeability between AVT02 and Humira® was [accepted by the US Food and Drug Administration \(FDA\) in February 2022](#) and is currently under review by the FDA.

Demonstration of interchangeability of biosimilars with originator products is a key component in supporting clinical practice by reducing healthcare costs and increasing patient access to biologic therapies. The biosimilarity of AVT02 to Humira has been previously assessed in both a [PK study and a confirmatory efficacy and safety study](#), which supported the assessment of biosimilarity of AVT02.

Alvotech's poster titled "A Clinical Study Designed to Support a Demonstration of Interchangeability Between AVT02 and Humira®" will be presented in the Virtual Poster Hall on Saturday November 12, 2022, from 1:00 – 3:00 PM Eastern Time (ET).

A second poster titled "Ex vivo Comparative Immunogenicity Assessment (EVCIA) to Determine Relative Immunogenicity in Chronic Plaque Psoriasis in Participants Receiving Humira® or Undergoing Repeated Switches Between Humira and AVT02" will be presented in the Virtual Poster Hall on Sunday November 13, 2022, from 9:00 – 10:00 AM ET.

On Monday November 14, 2022, at 2:15 PM ET, Steve Feldman, MD, Ph.D., Professor of Dermatology, Wake Forest University School of Medicine will give an Ignite Talk on the Center City Stage titled "A Clinical Study Designed to Support a Demonstration of Interchangeability between AVT02 and Reference Adalimumab (Humira®)."

Posters and presentation details will be available to view on the conference platform during the conference. Further information about the ACR's 2022 Convergence conference can be found [here](#).

### About AVT02 (adalimumab)

AVT02 is a monoclonal antibody and an approved biosimilar to Humira® (adalimumab) in the EU, the United Kingdom, Switzerland, Norway, Iceland, Lichtenstein (Hukyndra®) and Canada (Simlandi™). AVT02 dossiers are under review in multiple countries, including 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.

### Alvotech 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. For example, Alvotech's expectations regarding 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, regulatory review and interactions, the success of its commercial partnerships, the potential and timing of approvals and commercial launches of its product candidates, including for AVT02, the estimated size of the total addressable market of Alvotech's pipeline products, and the potential of Alvotech's pipeline products, including AVT02, to reduce healthcare costs and increase patient access to biologic therapies. 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) 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; (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, including AVT02; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products, including AVT02; (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; 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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