



## Alvotech Announces Positive Results from a Pharmacokinetic Similarity Study for AVT04, a Proposed Biosimilar to Stelara®

May 16, 2022

- Results from pharmacokinetic (PK) similarity study demonstrate bioequivalence of AVT04 (ustekinumab) to the reference product Stelara®

**Reykjavik, ICELAND** (May 16, 2022) – Alvotech Holdings S.A. (“Alvotech”), a global biotech company focused solely on the development and manufacture of biosimilar medicines for patients worldwide, today announced positive top-line results from a pharmacokinetic (PK) study for AVT04, Alvotech’s proposed biosimilar to Stelara® (ustekinumab).

The PK similarity study (AVT04-GL-101) utilized 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®, as well as EU-approved Stelara®. The study results demonstrated bioequivalence between AVT04 and the reference products.

Ustekinumab is a human IgG1k monoclonal antibody that binds with specificity to the p40 protein subunit used by both the interleukin-12 and interleukin-23 cytokines. Stelara® is prescribed to treat a variety of inflammatory conditions including psoriatic arthritis, Crohn’s disease, ulcerative colitis, and plaque psoriasis. In 2021, Stelara’s worldwide net sales exceeded US\$9 billion, making it one of the highest grossing biologic medicines. Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is the exclusive strategic partner for the commercialization of AVT04 in the United States. STADA is Alvotech’s exclusive strategic partner for AVT04 for the European market.

We are delighted at the continued progress of our pipeline of biosimilar candidates. This continued progress demonstrates the strength of Alvotech’s purpose-built biosimilar platform.

**RÓBERT WESSMAN**

Founder and Chairman of Alvotech

We are pleased with the successful outcome of the AVT04 PK similarity study and the continued progress of our overall pipeline. We expect the results from our confirmatory efficacy and safety study for AVT04 before the end of the 2nd quarter.”

**JOSEPH MCCLELLAN**

Chief Scientific Officer

Alvotech’s product portfolio includes AVT02, a biosimilar to Humira® (adalimumab). In addition to AVT04, Alvotech is advancing six other biosimilar candidates, using its highly integrated platform for development and manufacturing. Alvotech has established a global network of commercial partnerships in major markets, with the goal of expeditiously delivering its cost-effective biosimilar medicines to patients worldwide.

On December 7, 2021, Alvotech and Oaktree Acquisition Corp. II (NYSE: OACB.U, OACB, OACB WS), a special purpose acquisition company sponsored by an affiliate of Oaktree Capital Management, L.P., (“OACB”) [announced](#) they had entered into a definitive business combination agreement. Upon completion of the transaction, the combined company’s securities are expected to be traded on NASDAQ under the symbol “ALVO.” On May 11, 2022, Alvotech and OACB [announced](#) that the extraordinary general meeting of shareholders of OACB to approve the pending business combination between Alvotech, OACB and the legal entity named Alvotech, previously named Alvotech Lux Holdings S.A.S., (“TopCo”) is scheduled to be held on June 7, 2022.

### **About the [AVT04-GL-101](#) pharmacokinetics, safety, and tolerability study**

The AVT04-GL-101 pharmacokinetic (PK) study was conducted in Australia and New Zealand and enrolled 294 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®, as well as EU-approved Stelara®.

### **About AVT04 (ustekinumab)**

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara® (ustekinumab). AVT04 was developed using the Sp2/0 host cell line and is manufactured using a continuous perfusion process. Ustekinumab binds to two cytokines called interleukin-12 and interleukin-23 that are involved in inflammatory and immune responses. Abnormal regulation of these cytokines has been associated with immune mediated diseases, such as psoriasis, psoriatic arthritis, Crohn’s disease, and ulcerative colitis.

### **About AVT02 (adalimumab)**

AVT02 is a monoclonal antibody and a biosimilar to Humira® (adalimumab), which inhibits tumor necrosis factor alpha (TNF-alpha). AVT02 is not approved outside of the EU, UK, and Canada. AVT02 dossiers are under review in multiple countries; in the US the initial BLA for approval as a biosimilar is in deferred status, pending the result of FDA inspections.

### **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 diseases, and cancer. For more information, please visit [www.alvotech.com](http://www.alvotech.com).

### **Additional Information**

In connection with the proposed business combination between OACB, Alvotech Holdings S.A. and TopCo, the parties have filed with the U.S. Securities and Exchange Commission a Registration Statement on Form F-4 (as amended or supplemented through the date hereof, the "Registration Statement") containing a proxy statement of OACB and a prospectus of TopCo. The Registration Statement has been declared effective by the SEC and OACB has mailed a definitive proxy statement/prospectus related to the proposed Business Combination to its shareholders. The extraordinary general meeting of shareholders of OACB to approve the business combination is scheduled to be held on June 7, 2022. This communication does not contain all the information that should be considered concerning the proposed Business Combination and is not intended to form the basis of any investment decision or any other decision in respect of the proposed Business Combination. OACB's shareholders and other interested persons are advised to read the definitive proxy statement/prospectus and other documents filed in connection with the proposed Business Combination, as these materials will contain important information about Alvotech Holdings S.A., OACB and the proposed Business Combination. Shareholders of OACB can also obtain copies of the definitive proxy statement/prospectus and other documents filed with the SEC, without charge at the SEC's website at [www.sec.gov](http://www.sec.gov), or by directing a written request to: Oaktree Acquisition Corp. II, 333 South Grand Avenue, 28th Floor, Los Angeles, California 90071.

### **Participants in the Solicitation**

OACB and Alvotech Holdings S.A. and their directors and executive officers may be deemed participants in the solicitation of proxies from OACB's shareholders with respect to the Business Combination. A list of the names of those directors and executive officers and a description of their interests in OACB is contained in OACB's annual report on Form 10-K for the fiscal year ended December 31, 2021, which was filed with the SEC and is available free of charge at the SEC's website at [www.sec.gov](http://www.sec.gov), or by directing a written request to Oaktree Acquisition Corp. II, 333 South Grand Avenue, 28th Floor, Los Angeles, California 90071. Additional information regarding the interests of such participants is contained in the definitive proxy statement/prospectus for the proposed Business Combination.

TopCo and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of OACB in connection with the proposed Business Combination. A list of the names of such directors and executive officers and information regarding their interests in the proposed Business Combination are included in the definitive proxy statement/prospectus for the proposed Business Combination.

### **Forward-Looking Statements**

Certain statements in this communication may be considered "forward-looking statements." Forward-looking statements generally relate to future events or the future financial operating performance of OACB or Alvotech. For example, Alvotech's expectations regarding future growth, results of operations, performance, future capital and other expenditures including the development of critical infrastructure for the global healthcare markets, 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; the timing of the announcement of clinical trial results, including safety study for AVT04; the timing of the extraordinary general meeting of shareholders of OACB to approve the business combination; and the potential approval and commercial launch of AVT02. 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 OACB and its management, and Alvotech and its management, as the case may be, are inherently uncertain and are inherently subject to risks, variability and contingencies, many of which are beyond OACB's and Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the occurrence of any event, change or other circumstances that could give rise to the termination of negotiations and any subsequent definitive agreements with respect to the Business Combination; (2) the outcome of any legal proceedings that may be instituted against OACB, the combined company or others following this announcement of the Business Combination and any definitive agreements with respect thereto; (3) the inability to complete the Business Combination due to the failure to obtain approval of the shareholders of OACB, to obtain financing to complete the Business Combination or to satisfy other conditions to closing; (4) the inability to execute final agreement with respect to the loan facility with Sculptor on acceptable terms or at all; (5) the inability to consummate the transactions contemplated by the SEPA; (6) changes to the proposed structure of the Business Combination that may be required or appropriate as a result of applicable laws or regulations or as a condition to obtaining regulatory approval of the Business Combination; (7) the ability to meet stock exchange listing standards following the consummation of the Business Combination; (8) the risk that the Business Combination disrupts current plans and operations of Alvotech as a result of the announcement and consummation of the Business Combination; (9) the ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition, the ability of the combined company to grow and manage growth profitably, maintain key relationships and retain its management and key employees; (10) costs related to the Business Combination; (11) changes in applicable laws or regulations; (12) the possibility that Alvotech or the combined company may be adversely affected by other economic, business, and/or competitive factors; (13) Alvotech's estimates of expenses and profitability; (14) Alvotech S.A.'s ability to develop, manufacture and commercialize its product candidates in its pipeline; (15) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical trials or future regulatory approvals or marketing authorizations; (16) Alvotech S.A.'s ability to obtain and maintain regulatory approval or authorizations of its product candidates, including the timing or likelihood of expansion into additional markets or geographies; (17) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (18) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (19) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (20) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (21) 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 (22) other risks and uncertainties set forth in the section entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in OACB's annual report on Form 10-K for the fiscal year ended December 31, 2021, in the Registration Statement or in other documents filed by OACB with the SEC. There may be additional risks that neither OACB nor Alvotech presently know or that OACB and Alvotech currently believe 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. Neither OACB nor Alvotech undertakes 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 and OACB disclaim 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, OACB or any of their respective 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.

**No Offer**

This communication is for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy any securities pursuant to the proposed transaction or otherwise, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended.

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