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# Alvotech Clinical Study Results Demonstrate Therapeutic Equivalence between Biosimilar Candidate AVT04 and Reference Product Stelara®

- The confirmatory clinical, safety and efficacy study for AVT04, biosimilar candidate to Stelara® (ustekinumab) met its primary endpoint
- AVT04 (ustekinumab) is part of a broader pipeline of Alvotech's biosimilars and biosimilar candidates, which includes AVT02 (adalimumab), a biosimilar to Humira®
- Alvotech is the second company to announce positive top-line results from a patient study utilizing a biosimilar candidate to Stelara®

REYKJAVIK, ICELAND (May 24, 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 results from a confirmatory clinical study for AVT04, Alvotech's proposed biosimilar to Stelara® (ustekinumab). Alvotech is the second company to announce positive results from a patient study utilizing a biosimilar candidate to Stelara®. 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 the company's exclusive strategic partner for AVT04 for the European market.

In 2021, Stelara's® worldwide net sales exceeded US\$9 billion, making it one of the highest grossing biologic medicines. Ustekinumab is a human IgG1k monoclonal antibody that binds with specificity to the p40 protein subunit present in both the IL-12 and IL-23 cytokines. Stelara® is prescribed to treat a variety of inflammatory conditions including psoriatic arthritis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

The confirmatory clinical trial (AVT04-GL-301) is a randomized, double-blind, multicenter study 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. The study met its primary endpoint, with results demonstrating therapeutic equivalence between Alvotech's biosimilar candidate and Stelara®. In addition, no clinically meaningful differences in safety were observed through week 28. Earlier this month, Alvotech announced positive top-line results from a pharmacokinetic (PK) similarity study for AVT04.

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"The progress of our proposed biosimilar to Stelara® highlights the advantage of our global, vertically integrated platform," said Robert Wessman, Founder and Chairman of Alvotech. "Completing this clinical milestone, less than one year since we recruited the first subject, truly demonstrates the success of our clinical development and integrated approach to rapidly advancing multiple high-quality biosimilar candidates."

Mark Levick, Chief Executive Officer of Alvotech, added: "We believe that using the same type of host cell line as the reference product enables matching the post-translational modifications to the best extent possible."

Alvotech's portfolio of eight products and product candidates includes AVT02 (adalimumab), a biosimilar to Humira® and seven proposed biosimilars, inclusive of AVT04 (ustekinumab), a proposed biosimilar to Stelara®. Alvotech has built a highly integrated platform focused on development and manufacturing and has established a global network of commercial partnerships in all 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 S.A. 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-301 efficacy, safety, and immunogenicity study

The AVT04-GL-301 study was conducted in four countries in Europe and enrolled 581 patients. It was a randomized, double-blind, multicenter study designed to demonstrate equivalent efficacy and to compare safety and immunogenicity between AVT04 and Stelara® (ustekinumab) in patients with moderate to severe chronic plaque-type psoriasis. The study met its primary endpoint, with results demonstrating therapeutic equivalence between Alvotech's biosimilar candidate and Stelara®. In addition, no clinically meaningful differences in safety were observed through week 28. The primary efficacy endpoint was Psoriasis Area and Severity Index (PASI) percent improvement from Baseline at Week 12. The key secondary endpoints include additional efficacy parameters, like quality-of-life scores, safety, immunogenicity, tolerability parameters, and pharmacokinetic (PK) data.

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### About AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara<sup>®</sup> (ustekinumab). AVT04 was developed using an Sp2/0 host cell line and is manufactured using a continuous perfusion process. The Sp2/0 host cell line allows for more efficient sialyation of the molecule as compared to Chinese hamster ovary (CHO) cells and is the same type of host cell line used to produce Stelara<sup>®</sup>. Ustekinumab binds to two cytokines, IL-12 and IL-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<sup>®</sup> (adalimumab). AVT02 is approved in the EU, the United Kingdom, Switzerland, Norway, Iceland, Lichtenstein (Hukyndra<sup>®</sup>) and Canada (Simlandi<sup>™</sup>). AVT02 dossiers are under review in multiple countries; in the U.S. 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 disease, and cancer. For more information, please visit 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

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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, 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, 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

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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 forwardlooking 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-

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#### 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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