



FDA Accepts Alvotech's BLA Supporting Interchangeability for ATV02, a High Concentration, Citrate-Free Biosimilar Candidate for Humira®

February 28, 2022

Alvotech is the only known company to have both developed a high-concentration biosimilar to Humira and conducted a switching study to support interchangeability.

Reykjavik, Iceland (February 28, 2022) — Alvotech Holdings S.A. ("Alvotech"), a global biopharmaceutical company focused solely on the development and manufacture of biosimilar medicines for patients worldwide, announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's Biologics Licensing Application (BLA) for ATV02 (100 mg/mL) that includes new data supporting interchangeability between ATV02 and Humira. The data are from a randomized study (AVT02-GL-302; NCT04453137) in patients that demonstrate bioequivalence of repeated switches between administration of Humira and AVT02 to administration of Humira without switching. As previously [announced](#), no significant differences were observed in clinical efficacy, safety or immunogenicity between the switching cohort and the reference product cohort.

The U.S. FDA has communicated a goal date of December 2022 to reach a decision on the BLA.

Alvotech is the only known company that has both developed a high-concentration biosimilar candidate to Humira and conducted a switching study, to support potential approval as an interchangeable product. While both low-concentration and high-concentration strengths of Humira are marketed in the U.S. today, over 80 percent of the prescriptions are for the high-concentration strengths. In 2021, AbbVie's sales of Humira topped \$20.7 billion, making it the highest grossing pharmaceutical product in the world, excluding COVID-19 vaccines. 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.

We believe the potential combination of interchangeability with our high-concentration strength of AVT02 reflects a proactive approach to biosimilar development as well as our commitment to patients.

RÓBERT WESSMAN

Founder and Chairman of Alvotech

Achieving interchangeability for AVT02 would be a key enabler in our mission to deliver on our commitment to the sustainability of healthcare systems.

MARK LEVICK

CEO of Alvotech

In the U.S., an interchangeable product is a biosimilar product that meets additional requirements outlined by the Biologics Price Competition and Innovation Act. As part of fulfilling these additional requirements, information is needed to show that an interchangeable product is expected to produce the same clinical result as the reference product in any given patient. Also, for products administered to a patient more than once, the risk in terms of safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product will have been evaluated. An interchangeable product may be substituted for the reference product without the involvement of the prescriber (1).

1 [US Food and Drug Administration](#)

AVT02 has received approval in Europe, Canada, and the United Kingdom. In the U.S., Alvotech announced in September 2021 that the FDA is deferring action on its BLA that was accepted in November 2020. The FDA can [defer action](#) when no deficiencies have been identified and the application otherwise satisfies the requirements for approval, but an inspection(s) is necessary yet cannot be completed due to factors including travel restrictions. Alvotech continues to work with the FDA to coordinate the required inspection(s). Currently, inspections have been scheduled for the requisite facilities and are expected to occur in Q1 and Q2 of 2022.

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., [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."

About Alvotech

Alvotech is a biopharmaceutical company 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, and cancer. For more information, please visit www.alvotech.com.

About AVT02

AVT02 is a monoclonal antibody and a biosimilar to Humira (adalimumab). AVT02 is not approved outside of the EU, Canada, and the United Kingdom. AVT02 dossiers are under review in multiple countries; in the U.S. the BLA is in deferred status, pending FDA inspection(s).

About AVT02-GL-302:

AVT02-GL0302 is a multicenter, randomized, double-blind, parallel-group study to evaluate PK, efficacy, safety, and immunogenicity between patients receiving Humira and patients undergoing repeated switches between Humira and AVT02, followed by an optional safety Extension Phase. The study is composed of 3 phases: (1) a lead-in phase, where all patients receive Humira; (2) a switching phase, where one cohort receive Humira and one

cohort switches between AVT02 and Humira; and (3) an optional open-label extension phase, where all patients receive AVT02. The study enrolled 568 participants.

Additional Information

In connection with the proposed business combination (the "Business Combination") between OACB and Alvotech. OACB and Alvotech have filed with the U.S. Securities and Exchange Commission (the "SEC") a Registration Statement on Form F-4 (the "Registration Statement") containing a preliminary proxy statement of OACB and a preliminary prospectus of Alvotech Lux Holdings S.A.S., and after the Registration Statement is declared effective, OACB will mail a definitive proxy statement/prospectus related to the proposed Business Combination to its shareholders. 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, when available, the preliminary proxy statement/prospectus and the amendments thereto and 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, OACB and the proposed Business Combination. When available, the definitive proxy statement/prospectus and other relevant materials for the proposed Business Combination will be mailed to shareholders of OACB as of a record date to be established for voting on the proposed Business Combination. Shareholders of OACB will also be able to obtain copies of the preliminary proxy statement/prospectus, the definitive proxy statement/prospectus and other documents filed with the SEC, without charge, once available, at the SEC's website at www.sec.gov, or by directing a written request to: OACB, 333 South Grand Avenue, 28th Floor, Los Angeles, California 90071.

Participants in the Solicitation

OACB and Alvotech 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/A for the fiscal year ended December 31, 2020 (as amended December 13, 2021), which was filed with the SEC and is available free of charge at the SEC's web site at www.sec.gov, or by directing a written request to OACB, 333 South Grand Avenue, 28th Floor, Los Angeles, California 90071. Additional information regarding the interests of such participants will be contained in the proxy statement/prospectus for the proposed Business Combination when available.

Alvotech Lux Holdings S.A.S 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 will be included in the proxy statement/prospectus for the proposed Business Combination when available.

Forward-Looking Statement

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; 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) 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; (5) the ability to meet stock exchange listing standards following the consummation of the Business Combination; (6) 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; (7) 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; (8) costs related to the Business Combination; (9) changes in applicable laws or regulations; (10) the possibility that Alvotech or the combined company may be adversely affected by other economic, business, and/or competitive factors; (11) Alvotech's estimates of expenses and profitability; (12) pending litigation related to AVT02; (13) 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 (14) 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/A for the fiscal year ended December 31, 2020 (as amended May 19, 2021) 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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