



## Alvotech and STADA pave way to launching HUKYNDRA®(AVT02), a citrate-free, high-concentration biosimilar to Humira® by resolving European patent dispute with AbbVie

April 6, 2022

- Upon launch, HUKYNDRA® will be one of two citrate-free, high-concentration adalimumab biosimilars on the European market.
- All intellectual-property disputes related to market entry of Alvotech's AVT02 (adalimumab) in the U.S. and Europe are now resolved.

**Reykjavik, Iceland & Bad Vilbel, Germany. April 6, 2022** – Alvotech Holdings S.A. ("Alvotech"), a global biopharmaceutical company focused solely on the development and manufacture of biosimilar medicines for patients worldwide, has today announced the resolution of all intellectual property disputes with AbbVie in Europe and selected markets outside of Europe, related to its AVT02 biosimilar candidate. This paves the way for Alvotech's exclusive strategic partner STADA to commercialize AVT02, a citrate-free, high-concentration (100 mg/mL) biosimilar to Humira® (adalimumab) in European countries under the HUKYNDRA® brand name.

Under the terms of the European patent resolution, AbbVie has granted Alvotech a non-exclusive, royalty bearing license to AbbVie's intellectual property relating to Humira® in Europe and in selected markets outside of Europe, thus paving the way for greater patient access to adalimumab.

This resolution is an important step in Alvotech's mission to bring more sustainable healthcare to patients in need and we look forward to launching our first biosimilar in the European market with STADA.

RÓBERT WESSMAN

Founder and Chairman of Alvotech

With all intellectual-property issues now resolved, STADA is preparing to launch the HUKYNDRA citrate-free, high-concentration biosimilar broadly across Europe. STADA is Alvotech's exclusive strategic partner for commercializing AVT02 in Europe and selected other territories.

HUKYNDRA will be the first of what we anticipate will be a continuous stream of biosimilar launches across a broad range of therapeutic categories through our partnership with Alvotech. We are committed to working with partners to bring competition to the biologic medicines sector, thereby delivering value and facilitating patient access.

PETER GOLDSCHMIDT

CEO of STADA

HUKYNDRA is the first of seven molecules covered by an [exclusive biosimilars agreement](#) signed between Alvotech and STADA in November 2019. This broad partnership includes biosimilar candidates aimed at treating autoimmunity, oncology, and ophthalmology conditions.

In December 2021, the partners announced that they had received approval from the European Commission for AVT02 (adalimumab), now called HUKYNDRA in Europe, the company's citrate-free, 100 mg/mL high concentration biosimilar to Humira®, for the 27 member countries of the European Union plus Norway, Iceland and Liechtenstein.

HUKYNDRA is [authorized for use](#) in treating a range of inflammatory conditions including rheumatoid arthritis, plaque psoriasis and Crohn's disease. Adalimumab inhibits tumor necrosis factor alpha, which is a protein in the body involved in inflammation. Humira® was the highest grossing medicine in the world in 2021 (excluding COVID-19 vaccines) with global sales of over \$20 billion.

In February 2022, the US Food and Drug Administration (FDA) accepted for review a Biologics Licensing Application (BLA) for AVT02 (100 mg/mL), Alvotech's citrate-free, high-concentration biosimilar, that includes new data supporting interchangeability between AVT02 and Humira®, for the U.S. market. The application was supported by [positive results](#) from a switching study that demonstrates bioequivalence and comparable efficacy, safety and immunogenicity of repeated switches between administration of Humira® and AVT02.

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

### About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2021, STADA achieved group sales of EUR 3,249.5 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of

EUR 776.5 million. As of 31 December 2021, STADA employed 12,520 people worldwide.

### **About AVT02**

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

### **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](http://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 for the fiscal year ended December 31, 2021, which was filed with the SEC and is available free of charge at the SEC's web site at [www.sec.gov](http://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; (14) the commercial launch of AVT02 in Canada, the United States, Europe or elsewhere; and (15) 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 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.

**CONTACTS****ALVOTECH****Investor Relations**

Stephanie Carrington

ICR Westwicke

[Stephanie.Carrington@westwicke.com](mailto:Stephanie.Carrington@westwicke.com)

(646) 277-1282

**Media Relations**

Sean Leous

ICR Westwicke

[Sean.Leous@westwicke.com](mailto:Sean.Leous@westwicke.com)

(646) 866-4012

Corporate Communications

[Alvotech.media@alvotech.com](mailto:Alvotech.media@alvotech.com)

**STADA*****Additional information for journalists:***

STADA Arzneimittel AG - Media Relations

Stadastrasse 2-18

61118 Bad Vilbel - Germany

Phone: +49 (0) 6101 603-165

Fax: +49 (0) 6101 603-215

E-Mail: [press@stada.de](mailto:press@stada.de)

Or visit us on the Internet at [www.stada.com/press](http://www.stada.com/press)

***Additional information for capital market participants:***

STADA Arzneimittel AG - Investor & Creditor Relations

Stadastrasse 2-18

61118 Bad Vilbel – Germany

Phone: +49 (0) 6101 603-4689

Fax: +49 (0) 6101 603-215

E-mail: [ir@stada.de](mailto:ir@stada.de)

Or visit us on the Internet at [www.stada.com/investor-relations](http://www.stada.com/investor-relations)

**OAKTREE ACQUISITION CORP. II****Investor Relations**

[info@oaktreeacquisitioncorp.com](mailto:info@oaktreeacquisitioncorp.com)

**Media Relations**

[mediainquiries@oaktreecapital.com](mailto:mediainquiries@oaktreecapital.com)