

STADA and Alvotech broaden European patients' options by launching Hukyndra® high-concentration, citrate-free adalimumab

June 9, 2022



- Hukyndra® offers a comprehensive range of presentations to the EU adalimumab biosimilars market.
- Adalimumab marks the first molecule introduced through STADA's partnership with Alvotech to bring biosimilars across immunology, oncology and ophthalmology indications to patients and their caregivers in Europe.
- Initial launch markets include France, Germany, Finland, and Sweden.

Bad Vilbel & Reykjavik, 9 June 2022 – STADA is offering Hukyndra®, the Alvotech-developed high-concentration, citrate-free formulation biosimilar of adalimumab to patients and their caregivers in selected European countries, including France, Germany, Finland, and Sweden. Launches in further European countries are scheduled over the coming months.

The biosimilar to Humira®, with its 100 mg/mL adalimumab in 40 mg/0.4 mL custom-designed pre-filled auto-injector pen as well as 40 mg/0.4 mL and 80 mg/0.8 mL pre-filled syringe presentations, offers a comprehensive range of biosimilar presentations and devices designed with ease of patient use in mind.

Adalimumab marks the first biosimilar to be commercialized by STADA under a development and manufacturing partnership with Alvotech that, in total, spans seven biosimilars and biosimilar candidates across autoimmunity, oncology, and ophthalmology indications^[1]. The partners' goal is to make available these European-made biosimilars to European patients and caregivers over the coming months and years. The pipeline includes the AVT04 ustekinumab biosimilar candidate, for which Alvotech recently announced clinical study results demonstrating therapeutic equivalence to the reference product Stelara®^[2].

Head of Global Specialty, EVP, Bryan Kim commented: "Our Hukyndra high-concentration alternative to Humira® – STADA's fifth marketed biosimilar after epoetin zeta, pegfilgrastim, teriparatide and bevacizumab – adds to STADA's growing portfolio of biosimilar and specialty care assets aimed at broadening patient access, adding value and supporting sustainable European healthcare systems."

"Although biosimilar medicines have been marketed in Europe for over 16 years, significant unmet needs exist for patients to access key therapies," Kim continued. "Through the combination of Alvotech's scientific and manufacturing expertise with STADA's pan-European commercial excellence, we can deliver a portfolio of high-quality biologic products to patients in Europe, with a goal of expanding access to critical therapies. Positively impacting the lives of European patients with inflammatory disorders with our high-concentration, citrate-free alternative to Humira® is fully in line with STADA's purpose of caring for people's health as a trusted partner."

Anil Okay, Alvotech's chief commercial officer, commented: "We are thrilled to take this important step with STADA into multiple European markets. The commercial partnership with STADA allows Alvotech to leverage its strengths as a purpose-built R&D and manufacturing platform, singularly focused on biosimilars, which are of vital importance for healthcare systems globally."

In November 2021, STADA received approval from the European Commission for the Hukyndra high-concentration 100 mg/mL adalimumab biosimilar in the 27 EU member countries plus Norway, Iceland and Liechtenstein^[3]. Developed by Alvotech under the AVT02 name, the biosimilar is authorized for all of the reference product's indications, treating a range of inflammatory conditions in adults and children, including arthritis, psoriasis, Crohn's disease and ulcerative colitis. In April 2022, Alvotech and STADA announced that they had paved the way to launching their Hukyndra biosimilar to Humira® by resolving all intellectual property disputes in Europe with the manufacturer of the reference product^[4].

Manufactured entirely in Europe by Alvotech, STADA's Hukyndra biosimilar offers an alternative to Humira with no clinically meaningful differences in terms of safety, quality and efficacy. Hukyndra is a patient-friendly option because of attributes that correlate with less injection-site pain, including an administered volume that is half of low-concentration adalimumab biosimilars, a citrate-free buffer and a thin 29G needle^[5].

STADA is supporting Hukyndra launches in individual national markets through tailored educational materials and well as dedicated patient support programs.

About AVT02 (adalimumab)

AVT02 is a monoclonal antibody and a biosimilar to Humira® (adalimumab). AVT02 is approved in the EU, the United Kingdom, Switzerland, Norway, Iceland, Liechtenstein (Hukyndra®) and Canada (Simlandi™). 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 AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara® (ustekinumab). AVT04 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not yet been established by regulatory authorities and is not claimed.

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 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 U.S., 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. (NYSE and TASE: TEVA; US), STADA Arzneimittel AG (EU and select other territories), Fujii Pharma Co., Ltd (TSE: 4554; Japan), Cipla/Cipla Gull/Cipla Med Pro (NSE: CIPLA; Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (SWX: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. (NASDAQ and TASE: KMDA; Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (1795:TT; 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.

About Oaktree Acquisition Corp. II

The Oaktree Acquisition Corp. II franchise was formed to partner with high-quality, growing companies to facilitate their successful entry to the public markets. By leveraging the deep capabilities and experience of its sponsor, an affiliate of Oaktree, which manages \$164 billion in assets under management as of March 31, 2022, Oaktree Acquisition Corp. II seeks to provide best-in-class resources and execution, coupled with a focus on long-term partnership and shareholder value creation. For more information about Oaktree Acquisition Corp. II, please visit www.oaktreeacquisitioncorp.com.

Additional Information

In connection with the Business Combination, OACB, Alvotech S.A. and the legal entity named Alvotech, previously named Alvotech Lux Holdings S.A.S., ("TopCo") 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.

This communication is not intended to form the basis of any investment decision. Investors and other interested persons are advised to read the Registration Statement and other documents filed in connection with the Business Combination, as these materials contain important information about Alvotech S.A., OACB, the Business Combination, and the combined company after the Business Combination. Shareholders of OACB can also obtain copies of the Registration Statement 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.

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; the potential approval and commercial launch of its product

candidates; and the timing of the closing of the Business Combination and expected first day of trading of TopCo's securities on The Nasdaq Stock Market LLC and The Nasdaq First North Growth Market. 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 satisfy 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) the ability to meet or maintain stock exchange listing standards following the consummation of the Business Combination; (7) the risk that the Business Combination disrupts current plans and operations of Alvotech; (8) 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; (9) costs related to the Business Combination; (10) changes in applicable laws or regulations; (11) the possibility that Alvotech or the combined company may be adversely affected by other economic, business, and/or competitive factors; (12) Alvotech's estimates of expenses and profitability; (13) Alvotech's ability to develop, manufacture and commercialize the product candidates in its pipeline; (14) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical trials or future regulatory approvals or marketing authorizations; (15) Alvotech'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; (16) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (17) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (18) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (19) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (20) 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 (21) 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. 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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.

STADA 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

Or visit us on the Internet at www.stada.com/press

STADA 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

Or visit us on the Internet at www.stada.com/investor-relations

Alvotech:

Investor Relations

Stephanie Carrington
ICR Westwicke
Stephanie.Carrington@westwicke.com
(646) 277-1282

Media Relations

Sean Leous
ICR Westwicke
Sean.Leous@westwicke.com
(646) 866-4012

Corporate Communications

Alvotech.media@alvotech.com

[1] [Alvotech and STADA Agree on Strategic Biosimilar Partnership](#)

[2] [Alvotech Clinical Study Results Demonstrate Therapeutic Equivalence between Biosimilar Candidate AVT04 and Reference Product Stelara® - Alvotech - Setting a new standard in biosimilars](#)

[3] [Union Register of medicinal products - Public health - European Commission \(europa.eu\)](#)

[4] [Alvotech and STADA pave way to launching HUKYNDR® \(AVT02\) | STADA - Alvotech and STADA pave way to launching HUKYNDR®\(AVT02\), a citrate-free, high-concentration biosimilar to Humira® by resolving European patent dispute with AbbVie - Alvotech - Setting a new standard in biosimilars](#)

[5] [Subcutaneous Injection of Drugs: Literature Review of Factors Influencing Pain Sensation at the Injection Site - PubMed \(nih.gov\)](#)