



## Alvotech and STADA Increase Access to Adalimumab for Patients in Switzerland with the Launch of Hukyndra®

September 22, 2022

- *Hukyndra® increases availability of high-concentration, low-volume, citrate-free presentations of adalimumab*
- *Exclusive partnership between Alvotech and STADA in Europe includes Hukyndra® and six biosimilar candidates*

REYKJAVIK, Iceland and BAD VILBEL, Germany, Sept. 22, 2022 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and STADA Arzneimittel AG (STADA), announced today the launch of Hukyndra®, a high-concentration, low-volume, citrate-free formulation, biosimilar to Humira® (adalimumab), in Switzerland.

Hukyndra (adalimumab) is marketed by Spirig HealthCare AG, STADA's subsidiary in Switzerland. Hukyndra is available in 80 mg/0.8 mL and 40 mg/0.4 mL presentations in a safety device for self-administration and 40 mg/0.4 mL in a pre-filled auto-inject pen, designed with the ease of patients in mind.

"Significant unmet needs for access to biologics exist for patients across Europe," said Bryan Kim, Head of Global Specialty, EVP of STADA. "Our partnership with Alvotech enables STADA to deliver a broad range of high-quality biosimilars to European patients. Launches of Hukyndra in multiple markets is evidence of our commitment to broader access to critical therapies."

Anil Okay, Chief Commercial Officer of Alvotech, remarked, "We are pleased to leverage Alvotech's strength as a purpose-built end-to-end biosimilars development and manufacturing platform through our partnership with STADA, to broaden patient access to cost-effective biologics across Europe."

STADA and Alvotech announced an exclusive partnership agreement [in November 2019](#), that spans Hukyndra and six biosimilar candidates in total, across autoimmunity, oncology, and ophthalmology indications. Alvotech is responsible for development and manufacturing, while STADA is responsible for the commercialization.

In [November 2021](#), STADA received approval from the European Commission for Hukyndra, in the 27 EU member states, plus Norway, Iceland and Lichtenstein. The biosimilar has now also been approved in the UK and Switzerland. Hukyndra has already launched in Austria, Estonia, France, Finland, Germany, Lithuania, Slovakia, and Sweden.

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

### About Hukyndra (adalimumab)

Hukyndra is a monoclonal antibody and a biosimilar to Humira® (adalimumab) that inhibits tumor necrosis factor. Hukyndra has been approved in the EU, Norway, Iceland, Lichtenstein, the UK, Switzerland, and Canada (as Simlandi™). Dossiers are under review in multiple countries, including in the United States.

### 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 United States, 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. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), 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. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (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](http://www.alvotech.com). None of the information on the Alvotech website shall be deemed part of this press release.

### 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 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.

### Forward-Looking Statements

Certain statements in this communication may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements generally relate to future events or the future financial operating performance of Alvotech. For example, Alvotech's expectations regarding 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, regulatory review and

interactions, the success of its commercial partnerships, including its partnership with STADA, the potential approval and commercial launch of its product candidates, the timing of regulatory approvals and market launches, the estimated size of the total addressable market of Alvotech's pipeline products, and the commercial success of Hukyndra in Switzerland and other countries. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential", "aim" 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 Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the outcome of any legal proceedings that may be instituted against Alvotech or others following the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech; (2) the ability to maintain stock exchange listing standards; (3) changes in applicable laws or regulations; (4) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (5) Alvotech's estimates of expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (8) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (9) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (10) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (11) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (12) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (13) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (15) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (16) 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 (17) other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in documents that Alvotech may from time to time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes 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. Alvotech does not undertake 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 disclaims 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 or any of its 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.

## **CONTACTS**

### **Alvotech Investor Relations and Global Communication**

Benedikt Stefansson

[alvotech.ir@alvotech.com](mailto:alvotech.ir@alvotech.com)

### **STADA information for journalists**

STADA Arzneimittel AG - Media Relations

Stadastrasse 2-18, 61118 Bad Vilbel - Germany

Phone: +49 (0) 6101 603-165

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)

### **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](mailto:ir@stada.de)

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