Alvotech and STADA Broaden Access to Hukyndra® adalimumab biosimilar in Europe

December 7, 2022

- Hukyndra® (adalimumab) launches in Belgium, Bulgaria, Croatia, Czech Republic, Latvia, Romania, and Slovenia, increasing availability of high-concentration, citrate-free adalimumab in Europe
- Follows initial introduction of Hukyndra in nine countries: Austria, Estonia, Finland, France, Germany, Lithuania, Slovakia, Sweden, and Switzerland
- Adalimumab is first product launched through an exclusive strategic partnership announced by Alvotech and STADA in November 2019 covering biosimilar candidates across immunology, oncology, and ophthalmology indications

REYKJAVIK, Iceland and BAD VILBEL, Germany, Dec. 07, 2022 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO) and STADA are contributing to the availability of high-quality biologic treatments in Europe by rolling out their Hukyndra high-concentration, low-volume, citrate-free formulation of adalimumab in several European countries.

Through a strategic partnership, Alvotech is supplying to STADA Hukyndra (adalimumab) autoinjectors and pre-filled syringes with drug product and drug substance manufactured in its vertically integrated European facility in Reykjavik, Iceland. Following initial launches since June 2022, STADA is now marketing Hukyndra through its local subsidiaries in Belgium, Bulgaria, Croatia, Czech Republic, Latvia, Romania, and Slovenia. STADA is supporting adalimumab launches in individual national markets through tailored educational materials and dedicated patient-support programs.

“Significant unmet needs for access to biologic treatments for autoimmune conditions, including adalimumab, exist for patients across Europe,” stated Bryan Kim, Head of Global Specialty Care, EVP, at STADA. “Launching Hukyndra in further European is evidence of our commitment to broadening patient access to critical therapies. We look forward to working with Alvotech to make high-quality biosimilars available to patients and their caregivers.”

Anil Okay, Chief Commercial Officer of Alvotech, remarked: “We are very pleased with the reception of Hukyndra in the European market, and believe the patient-friendly autoinjector design we have introduced supports commercial success. The partnership with STADA continues to broaden access to cost-effective biologics across Europe in line with our shared vision.”

In November 2019, STADA and Alvotech announced an exclusive partnership agreement covering biosimilar candidates across immunology, oncology and ophthalmology indications. Alvotech is primarily responsible for development and manufacturing, while STADA is responsible for commercialization.

In November 2021, STADA received a marketing authorization from the European Commission for Hukyndra, a high-concentration adalimumab, in the 27 EU member states, plus Iceland, Lichtenstein and Norway. The biosimilar has also been approved in Switzerland and the UK.

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; the same biosimilar is approved in Canada as Simlandi™ and Australia as Ciptunec™, Ardalicip™. Dossiers are under review in multiple countries, including in the United States.

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 non-prescription 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 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. None of the information on the Alvotech website shall be deemed part of this press release.

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 Europe and other parts of the world. 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; (17) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, and the ongoing and evolving COVID-19 pandemic on the Company's business, financial position, strategy and anticipated milestones; and (18) 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. 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