Alvotech and Bioventure Announce Approval of AVT02 (adalimumab) in Egypt

August 29, 2023

- Approval of Adalimumab-EVA™ represents the second biosimilar approval under the strategic partnership between Alvotech and Bioventure

REYKJAVIK, Iceland and DUBAI, United Arab Emirates, Aug. 29, 2023 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO) and Bioventure, a wholly owned subsidiary of GlobalOne Healthcare Holding LLC, today announced that the Egyptian Drug Authority (EDA) has approved the manufacturing and distribution of AVT02 (adalimumab) a biosimilar for Humira®, which is commonly indicated for the treatment of rheumatoid arthritis and several other inflammatory diseases, under the trade name Adalimumab-EVA ™.

A biosimilar is a biologic medicine that is highly similar to and has no clinically meaningful differences from an existing approved biologic medicine or reference product. The development and advancement of biologics has provided novel and life-changing treatments across therapeutic areas and for a variety of chronic diseases. The introduction of biosimilars frequently leads to higher utilization of the molecule as lower costs offer increased access to patients [1].

“We are very pleased with the approval of AVT02 in Egypt. Alvotech’s mission is to increase patient access worldwide to more affordable biologics and this represents another important milestone in our partnership covering the Middle East and North Africa,” said Robert Wessman, Chairman and CEO of Alvotech.

“Remaining determined in our commitment to enhance healthcare access and improve patient well-being, today we mark an important milestone as Bioventure and Alvotech celebrate the approval of AVT02 in Egypt,” stated Ashraf Radwan, CEO of Global One Healthcare Holding and Bioventure. “At Bioventure, we are dedicated to developing products and services that enhance patients' quality of life, driven by our vision of a world where the benefits of biotechnology are accessible to all.”

Bioventure is Alvotech’s exclusive strategic partner for the commercialization of AVT02 (adalimumab) and other biosimilar candidates in the Middle East and North Africa. Alvotech handles development and manufacturing, while Bioventure is responsible for commercialization. The partnership earlier announced the approval of AVT02 in Saudi Arabia, where it will be marketed as Simlandi ™.

[1] IQVIA (2023) “Biosimilars in the United States 2023-2027”.

About AVT02
AVT02 is a monoclonal antibody and has been approved as a biosimilar to Humira® (adalimumab) in several countries globally, including the 27 member states of the European Union, Norway, Lichtenstein, Iceland, the UK, Switzerland, Canada, Australia, Egypt and Saudi Arabia. It is currently marketed in multiple European countries and in Canada. Dossiers are also under review in multiple countries globally.

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), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), 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.

About Bioventure
Established as the investment arm of GlobalOne Healthcare Holding LLC, Bioventure aims to support innovation, business development, and global reach of value-added healthcare solutions. Bioventure’s three-strand approach includes licensing, investment, and increased market access. It helps pharmaceutical companies license biosimilars and new innovative products, as well as expanding market presence and manufacturing capabilities. The company is the exclusive license holder for Alvotech’s biosimilar portfolio and pipeline within Middle East and Africa. Bioventure partners with late-stage biotech as well as health/medtech startups, to help drive innovation and excellence within the region. It does so through licensing, registration, acquisition, and strategic investment. For more information, please visit Bioventure, visit: www.yasholding.ae/bioventure/

About GlobalOne Healthcare
GlobalOne Healthcare Holding LLC (GHH) operates as the Healthcare Division of Yas Holding LLC. With investments in leading bio-pharmaceuticals and innovative manufacturing solutions, GHH is delivering on its commitment to improve healthcare outcomes and patient quality of life. GHH’s healthcare portfolio focuses on the provision of world-class healthcare services across a range of areas including customised clinical and non-clinical hospital management and healthcare consultancy services. Our companies specialise in biopharma, hospital management, medical supply chain, manufacturing, and occupational health.

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 and may include, 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 submissions, review and interactions, including the resubmission of a BLA for AVT02 and a potential reinspection of Alvotech’s manufacturing facility, the satisfactory responses to the FDA’s inspection findings and resolution of other deficiencies conveyed following the inspection of Alvotech’s manufacturing site, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, including for AVT04, and market launches, the estimated size of the total addressable market of Alvotech’s pipeline products, the availability of financing options, including the size, timeline, securities, terms and conditions of, and use of proceeds from, a potential financing. 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 raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing standards; (4) changes in applicable laws or regulations; (5) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (6) Alvotech’s estimates of expenses and profitability; (7) Alvotech’s ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (8) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (9) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (12) the ability of Alvotech’s partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) 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; (14) the success of Alvotech’s current and future collaborations, joint ventures, partnerships or licensing arrangements; (15) Alvotech’s ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (16) Alvotech’s ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech’s products and product candidates; (18) 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; (19) 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 (20) 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. 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