



Alvotech and Bioventure Announce Approval of AVT02 (adalimumab) as Simlandi in Saudi Arabia

January 24, 2023

- *AVT02 as Simlandi™ is the first biosimilar approved under the strategic partnership between Alvotech and Bioventure*

REYKJAVIK, Iceland and DUBAI, United Arab Emirates, Jan. 24, 2023 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO) and Bioventure, a wholly owned subsidiary of GlobalOne Healthcare Holding LLC ("GHH"), the healthcare division of Yas Holding LLC, today announced that the Saudi Food & Drug Authority ("SFDA") has approved the manufacturing and distribution of AVT02, a biosimilar for Humira® (adalimumab), which is commonly indicated for the treatment of rheumatoid arthritis and several other inflammatory diseases. The biosimilar will be marketed as Simlandi™ in Saudi Arabia.

A biosimilar is a biologic medicine that is highly similar to and has no clinically meaningful differences from an existing approved biologic medicine but can be more affordable than the reference product. In the last twelve months reported, ending on October 1, 2022, Humira (adalimumab) was the world's highest-grossing pharmaceutical product, other than COVID-19 vaccines, with global sales of US\$21 billion, according to the manufacturer of the reference product [1].

"The approval of Simlandi by the SFDA marks an important milestone for local patients and physicians," said **Ashraf Radwan, Division CEO of GlobalOne Healthcare Holding**. "We are proud to partner with Alvotech, who share our mission to lower the cost burden on healthcare systems and improve patient quality of life. We look forward to bringing this essential treatment to patients in Saudi Arabia as well as other key markets in the Middle East and North Africa."

Robert Wessman, Founder, Chairman and CEO of Alvotech, added: "Approval in Saudi Arabia is a significant step in Alvotech's journey to offer broader access worldwide to more affordable biologics. We believe that biosimilars are important in addressing inflationary pressures for healthcare systems in all markets, especially where the penetration of biologics has been depressed due to high cost and lack of access."

Bioventure is Alvotech's exclusive strategic partner for the commercialization of Simlandi in the Middle East and North Africa. Bioventure and Alvotech have [previously](#) entered into license agreements for multiple biosimilars.

Under the terms of the license agreement for AVT02 between Alvotech and Bioventure, Alvotech will handle development and manufacturing, while Bioventure will be responsible for the commercialization of the biosimilar. This is the first biosimilar approved under this strategic partnership.

[1] Source: Quarterly financial reports by AbbVie

About AVT02 / Simlandi™ (adalimumab)

AVT02, marketed as Simlandi™ in Saudi Arabia, is a monoclonal antibody and approved biosimilar to Humira® (adalimumab), which inhibits tumor necrosis factor. The same biosimilar has been approved in the 27 countries of the European Union, Norway, Iceland, Liechtenstein, the UK and Switzerland as Hukynda®; in Australia as Ciptunec™ / Ardalicip™ and in 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. 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 expand market presence and manufacturing capabilities. The company is the exclusive license holder for Alvotech's biosimilar portfolio and pipeline within the 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: www.yasholding.ae/bioventure/

About GlobalOne Healthcare

GlobalOne Healthcare Holding LLC 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 review and interactions, the success of its commercial partnerships, including its partnership with Bioventure, potential milestone and royalty payments, the potential approval and commercial launch of its product candidates, the timing of regulatory approvals and market launches, including in Saudi Arabia, and the estimated size of the total addressable market of Alvotech's pipeline products, and the commercial success of AVT02 in Saudi Arabia, the Middle East, North Africa and other countries, Alvotech's ability to improve global access to affordable biologics, the effect of biosimilars on inflationary pressures for healthcare systems. 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) changes in applicable laws or regulations; (3) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (4) Alvotech's estimates of expenses and profitability; (5) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline including AVT02; (6) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (7) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (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 AVT02, 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, including the partnership with Bioventure; (13) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products, including AVT02; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products, including AVT02; (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. 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