European Medicines Agency Confirms Acceptance of Marketing Application for AVT03, a Proposed Biosimilar to Prolia® and Xgeva®

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REYKJAVIK, Iceland, Oct. 10, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today that the European Medicines Agency (EMA) has accepted a Marketing Authorization Application for AVT03, a proposed biosimilar candidate to Prolia® and Xgeva® (denosumab).

“EMA acceptance marks an important step towards making AVT03 available to patients and caregivers in Europe,” said Joseph McClellan, Chief Scientific Officer of Alvotech. “Successful progression in the development of multiple biosimilar candidates demonstrates how Alvotech is able to leverage its end-to-end biosimilars platform in support of broader access to affordable biologic medicines.”

Alvotech develops and manufactures AVT03. STADA Arzneimittel AG and Dr. Reddy’s Laboratories SA, have entered into agreements with Alvotech for the commercialization of AVT03, each partner with semi-exclusive commercial rights in Europe, including Switzerland and the UK.

In July 2024, Alvotech announced positive topline results from a confirmatory patient study for AVT03. The AVT03-GL-C01 study, which met its primary endpoints, demonstrated clinical similarity of AVT03 to Prolia in terms of efficacy, safety, immunogenicity, and pharmacokinetics (PK) in 532 postmenopausal women with osteoporosis. Primary endpoints were also met in both the AVT03-GL-P01 study, which assessed the PK, safety, and tolerability of AVT03 compared to Prolia in 209 healthy adult participants, and the AVT03-GL-P03 study that assessed the PK, safety, and tolerability of AVT03 compared to Xgeva in 208 healthy adult participants.

Prolia is indicated to treat osteoporosis in postmenopausal women and in men at increased risk of fracture; bone loss in men receiving treatment for prostate cancer that increases their risk of facture; and bone loss in adults at increased risk of fractures who are treated long term with oral or injected corticosteroids [1]. Xgeva is used to prevent bone complications in adults with advanced cancer that has spread to the bone, as well as to treat giant cell tumor of bone in adults and adolescents whose bones have fully developed [2].

Across all indications, the European denosumab market is currently valued at approximately US$1 billion [3]. Biosimilar competition to Prolia and Xgeva could expand patient access considerably at the same or lower overall costs.

In 2019 the total direct cost of osteoporotic fractures in the European Union, Switzerland and UK, was estimated at US$63 billion, excluding the individual disease burden. An estimated 32 million individuals in Europe had osteoporosis, 80% of which were women, but 70% of women eligible for treatment did not receive osteoporosis treatment [4].

About AVT03 (denosumab)

AVT03 is a human monoclonal antibody and a biosimilar candidate to Prolia® and Xgeva® (denosumab). Denosumab targets and binds with high affinity and specificity to the RANK ligand membrane protein, preventing the RANK ligand/RANK interaction from occurring, resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction [1]. AVT03 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

Use of trademarks

Prolia and Xgeva are registered trademarks of Amgen Inc.

Sources

[1] Prolia product information, EMA
[2] Xgeva product information, EMA
[3] IQVIA
[4] Key Statistics for Europe, International Osteoporosis Foundation

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. Two biosimilars, to Humira® (adalimumab) and Stelara® (ustekinumab) are already approved and marketed in multiple global markets. The current development pipeline includes nine disclosed 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), Dr. Reddy’s (EEA, UK and US), Biogaran (FR), 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 https://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 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, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, and market launches. 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 ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (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 respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (10) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (11) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (12) 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; (13) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (14) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (15) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (16) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (17) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, conflicts in Ukraine, the Middle East and other global geopolitical tension, 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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