Alvotech Announces Positive Topline Results from Confirmatory Patient Study for AVT03, a Proposed Biosimilar for Prolia® and Xgeva®

July 2, 2024

- *Positive topline results demonstrate clinical similarity between AVT03 and the reference biologic, Prolia® (denosumab)*
- *Two additional studies comparing the pharmacokinetics, safety, and tolerability of AVT03 to Prolia and Xgeva, respectively, have also met their primary endpoint*
- *Alvotech expects to file marketing applications for AVT03 later this year for major global markets*

REYKJAVIK, Iceland, July 02, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specialized in the development and manufacture of biosimilar medicines for patients worldwide, announced today positive topline results from a confirmatory patient study for AVT03, a proposed biosimilar to Prolia® (denosumab) and Xgeva® (denosumab). The study met its primary endpoints. The objective of the study is to demonstrate clinical similarity of AVT03 to Prolia in terms of efficacy, safety, immunogenicity, and pharmacokinetics (PK) in postmenopausal women with osteoporosis. The results will be used to support additional indications for AVT03 as a proposed biosimilar to Xgeva, based on extrapolation.

“We are pleased with these results, demonstrating clinical similarity between AVT03 and the reference biologic. In addition, we have now obtained positive topline results from two PK studies, that show equivalent PK, safety, and tolerability of AVT03 compared to Prolia and Xgeva, respectively. These clinical milestones underline the capabilities of our dedicated biosimilar platform and continued diversification of our portfolio. We expect to file marketing applications for AVT03 for major global markets later this year,” said Joseph McClellan, Chief Scientific Officer of Alvotech.

Prolia (denosumab) is indicated for the treatment of osteoporosis in postmenopausal women and for bone loss in adult men and women at increased risk of fracture. Xgeva (denosumab), which is the same biologic in a different presentation, is indicated for prevention of skeletal-related events such as pathological fractures in adults with advanced malignancies involving bone. It is also indicated for the treatment of giant cell tumor in bone.

The confirmatory patient study, AVT03-GL-C01, is a randomized, double-blind, parallel design, repeat dose, two arm, multicenter study comparing the efficacy, safety, immunogenicity, and pharmacokinetic profiles of AVT03 and Prolia in postmenopausal women with osteoporosis. Approximately 532 participants, postmenopausal women 50 years or older diagnosed with osteoporosis, were randomly assigned between the two arms. Each participant receives three doses of either AVT03 or Prolia, at six-month intervals. The study included a re-randomization in the Prolia arm, with participants receiving a third dose of either AVT03 or Prolia. The primary outcome measures were change from baseline in bone mass density (BMD) and a biomarker for bone resorption. The primary endpoints were measured at 6 and 12 months, but all participants will be followed until an end of study visit after 18 months from the initial dose.

The AVT03-GL-P01 study, assessed the PK, safety, and tolerability of AVT03 compared to Prolia in 209 healthy adult participants, and the AVT03-GL-P03 study assessed the PK, safety, and tolerability of AVT03 compared to Xgeva in 208 healthy adult participants. Both studies met their primary endpoints.

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. Biosimiliarity has not been established by regulatory authorities and is not claimed.

[1] https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Prolia/prolia_pi.pdf

Use of trademarks
Prolia and Xgeva are registered trademarks of Amgen Inc.

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 has launched two biosimilars. 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 (US, EU), 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 and may include, for example, Alvotech's expectations regarding its ability to satisfy conditions precedent to close the transaction and draw down the loan, to comply with the covenants of the Facility and to exercise its rights under the facility, the expected use of proceeds from the Facility, potential future financings or strategic transactions, Alvotech's competitive advantages, business prospects and opportunities including product launches, pipeline product development, revenue and diversification, 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 revenue, expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (8) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (9) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (10) 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; (11) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (12) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (13) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (14) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (15) 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; (16) Alvotech's ability to meet the conditions precedent to close Facility and comply with the covenants of the Facility 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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