Alvotech Initiates a Pharmacokinetic Study for AVT03, a Proposed Biosimilar for Prolia® and Xgeva®

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- *Prolia® and Xgeva® (denosumab) are indicated for the treatment of bone disease, with combined sales of nearly US$5.3 billion in 2021*
- *AVT03 (denosumab) is the 4th product in Alvotech's portfolio to enter clinical studies*

REYKJAVIK, Iceland, July 20, 2022 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today the initiation of a pharmacokinetic study for AVT03 (denosumab), a biosimilar candidate to Prolia® and Xgeva®. The clinical study will assess the pharmacokinetics, safety and tolerability of AVT03 compared to Prolia® in healthy adult male subjects.

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. In 2021, combined net revenues worldwide from sales of Prolia® and Xgeva® were nearly US$5.3 billion[1].

"Rapid progress in the development of our product portfolio exemplifies the capabilities of Alvotech's biosimilars platform. This milestone in the AVT03 program is a further step in our important mission to improve lives by expanding access to affordable biologic medicines," said Joseph McClellan, Chief Scientific Officer.

Alvotech's current portfolio of eight products and product candidates target treating autoimmune disease, eye disorders, osteoporosis, respiratory disease, and cancer. Of these, four products have either been launched or entered clinical studies. Alvotech has launched its first marketed product AVT02 (adalimumab), a biosimilar to Humira®, in Europe and Canada. In May, Alvotech announced positive topline results from both a confirmatory clinical, safety and efficacy study and from a pharmacokinetic (PK) study for AVT04 (ustekinumab), a proposed biosimilar to Stelara®. In July, Alvotech announced the initiation of a confirmatory clinical study for AVT06 (aflibercept), a proposed biosimilar to Eylea®.

[1]Based on manufacturer's reported sales

About Alvotech

Alvotech specializes in making biosimilars, to improve lives by expanding access to affordable biologic medicines. Founded by Robert Wessman, Alvotech seeks to be a global leader in the biosimilar space by delivering high-quality, cost-effective biologics, enabled by a vertically integrated approach from R&D to fill and finish manufacturing. To enable global reach, Alvotech has formed a network of strategic commercial partnerships in over 90 countries, in the United States, Canada, Europe, Asia, Latin America, Africa and the Middle East. Alvotech's current portfolio of eight biosimilars and biosimilar candidates, includes AVT02 (adalimumab), a biosimilar to Humira® which is approved and marketed in Europe (Hukyndra®) and Canada (Simlandi®) and seven biosimilar candidates targeting immunology, oncology, respiratory, bone disease and ophthalmology. For more information, please visit www.alvotech.com.

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. 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.

About AVT02 (adalimumab)

AVT02 is a monoclonal antibody and a biosimilar to Humira® (adalimumab), which inhibits tumor necrosis factor (TNF). AVT02 is not approved outside of the EU, Norway, Iceland, Lichtenstein, the UK, Switzerland, and Canada. AVT02 dossiers are under review in multiple countries; in the U.S. the initial BLA for approval as a biosimilar is in deferred status, pending finalization of the BLA application review.

About AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara® (ustekinumab). Ustekinumab binds to two cytokines called interleukin-12 and interleukin-23 that are involved in inflammatory and immune responses. Abnormal regulation of these cytokines has been associated with immune mediated diseases, such as psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. AVT04 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.

About AVT06 (aflibercept)

AVT06 is a recombinant fusion protein and a biosimilar candidate to Eylea® (aflibercept). Aflibercept binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability. AVT06 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.

Forward-Looking Statements

Certain statements in this communication may be considered "forward-looking statements." 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, expected patient enrollment, the potential approval and commercial launch of its product candidates and the timing of the announcement of clinical study results, regulatory approvals and market launches, and the estimated size of the total addressable market of Alvotech's pipeline products. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential" 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, with Alvotech as the surviving company; (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 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 product candidates, 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; and (17) other risks and uncertainties set forth in the section entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" that Alvotech may from time to time file or furnish with the SEC. 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