



Alvotech and STADA add to strategic alliance through denosumab partnership

June 11, 2024

- STADA assumes marketing license for Alvotech's proposed biosimilar referencing Prolia[®]/Xgeva[®] (denosumab) in Europe, including Switzerland and the UK, as well as rights in selected markets in Central Asia and the Middle East
- This partnership for the osteoporosis and cancer-related molecule builds on the two company's existing strategic alliance in Europe. The first product launched through the alliance was Hukyndra[®], a high-concentration biosimilar to Humira[®] (adalimumab)
- Extended alliance comes as the partners prepare to launch Uzpruvo[®], a biosimilar to Stelara[®] (ustekinumab) in Europe following the expiry of applicable intellectual-property rights¹

REYKJAVIK, Iceland and BAD VILBEL, Germany, June 11, 2024 (GLOBE NEWSWIRE) -- Alvotech and STADA are strengthening their existing strategic alliance for high-quality, cost-effective biosimilars by extending their partnership to cover AVT03, a clinical-stage biosimilar candidate referencing the Prolia[®]/Xgeva[®] (denosumab) medicines for osteoporosis and cancer-related bone loss respectively.

Under the terms of the agreement, Alvotech will be responsible for development and manufacturing at its state-of-the-art facility in Reykjavik, Iceland. STADA will become marketing authorization holder, upon approval of AVT03, and will assume semi-exclusive commercial rights in Europe, including Switzerland and the UK, as well as exclusive commercial rights in selected countries in Central Asia and the Middle East.

In parallel with the commercial agreement for AVT03, the two partners have agreed to extend STADA's commercial rights to biosimilars to Humira[®] (adalimumab) and Stelara[®] (ustekinumab) to Commonwealth of Independent States (CIS) countries in Central Asia. Alvotech will also regain commercial rights from STADA to AVT06, a proposed biosimilar to Eylea[®] (aflibercept).

STADA's Global Specialty Head, Bryan Kim, commented: "As European market leader with our teriparatide osteoporosis treatment, Movymia[®], STADA sees a major opportunity to offer patients and clinicians a further treatment with denosumab. With a strong presence in oncology among our six currently marketed biosimilars, broadening our alliance with Alvotech enables us to direct our resources efficiently and effectively."

Anil Okay, Chief Commercial Officer of Alvotech, remarked: "We look forward to continuing to work with STADA on increasing patient availability of more affordable biologics in the denosumab market, as we have already done with our citrate-free, high-concentration biosimilar to Humira[®]. This expansion of our commercial alliance further validates Alvotech's unique focus on biosimilar development and manufacturing, strong end-to-end capability and expertise."

Denosumab is a human monoclonal IgG2 antibody that targets the protein RANKL, which is essential for the formation, function and survival of osteoclasts, the cell type responsible for bone resorption. Increased osteoclast activity stimulated by RANKL is a key mediator of bone destruction in metastatic bone disease. Denosumab binds to RANKL with high affinity and specificity, preventing the interaction between RANKL and RANK. This leads to a reduction in osteoclast numbers and function, and a decrease in bone resorption and cancer-induced bone destruction.

An estimated 32 million Europeans, equating to 5.6% of the continent's total population aged 50 years and older, had osteoporosis in 2019². Of these Europeans, around four in five, or 25.5 million, were female. The International Osteoporosis Foundation (IOF) calculates the total direct cost in 2019 of osteoporotic fractures in the 27 European Union member states, Switzerland and the UK at €56.9 billion (US\$61.9 billion).

About AVT03

AVT03 is a biosimilar candidate for Prolia[®] and Xgeva[®] (denosumab), medicines for osteoporosis and bone cancer, respectively. Denosumab is a human monoclonal IgG2 antibody that targets the protein RANKL, which is essential for the formation, function and survival of osteoclasts, the cell type responsible for bone resorption. 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.

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), 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 STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 115 countries. In financial year 2023, STADA achieved group sales of EUR 3,734.8 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 802.1 million. As of 31 December 2023, STADA employed 11,667 people worldwide.

Alvotech 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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¹ Uzpruvo is not currently approved for the ulcerative colitis indication, as the originator still has exclusivity for this indication.

² [Key statistic for Europe | International Osteoporosis Foundation](#)

