European Medicines Agency Confirms Acceptance of Marketing Authorization Application for AVT05, a Proposed Biosimilar to Simponi® (golimumab)

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REYKJAVIK, Iceland and LONDON, Nov. 04, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and Advanz Pharma, a UK headquartered global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines in Europe, today announced that the European Medicines Agency (EMA) has accepted a Marketing Authorization Application for AVT05, Alvotech's proposed biosimilar to Simponi ® (golimumab), a biologic used to treat several chronic inflammatory diseases. This is believed to be the first marketing authorization application filing announced globally for a biosimilar candidate to Simponi. The approvals process is anticipated to be completed in the fourth quarter of 2025.

"This is a welcome milestone for us, our partners, patients and caregivers, as we take one step closer to being able to offer access to biosimilar Simponi®," said Joseph McClellan, Chief Scientific Officer of Alvotech. "We believe having the capability and know-how inhouse to utilize a host cell line and process also used to manufacture the reference biologic, has given us an important head start in developing a biosimilar candidate to Simponi®."

"The EMA's acceptance of the application for AVT05 represents a significant step forward in expanding treatment options for patients with chronic inflammatory diseases across Europe," said Nick Warwick, Chief Medical Officer of Advanz Pharma. "We are committed to improving patient access to high-quality biologic medicines."

Alvotech and Advanz Pharma first announced in February 2023 that the companies had entered into a commercialization agreement, for AVT23, a proposed biosimilar to Xolair® (omalizumab). In May 2024, the partners announced an expansion of the strategic partnership, to include five additional biosimilar candidates being developed by Alvotech, AVT05, AVT16 a proposed biosimilar to Entyvio® (vedolizumab) and three additional early-stage biosimilar candidates which remain undisclosed. In June 2024, the partners announced that they had entered into a commercialization agreement for AVT06, a proposed biosimilar to Eylea® low dose (2 mg) and AVT29, a biosimilar candidate for Eylea® high dose (8 mg).

In April 2024 Alvotech announced positive top-line results from a confirmatory clinical study comparing efficacy, safety, and immunogenicity between AVT05 and Simponi® in patients with moderate to severe rheumatoid arthritis. In November 2023, Alvotech announced positive topline results from a pharmacokinetic study which assessed the pharmacokinetics, safety, and tolerability of AVT05 compared to Simponi® in healthy adult participants.

About AVT05

AVT05 is a biosimilar candidate for Simponi® and Simponi Aria® (golimumab). Golimumab is a monoclonal antibody that inhibits tumor necrosis factor alpha (TNF alpha). Elevated TNF alpha levels have been implicated in several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis [1]. AVT05 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 AVT16

AVT16 is a human monoclonal antibody and a biosimilar candidate to Entyvio® (vedolizumab). AVT16 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 AVT06/AVT29

AVT06/AVT29 is a recombinant fusion protein and a biosimilar candidate to Eylea® (aflibercept), which binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [2]. AVT06/AVT29 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 AVT23

AVT23 is a monoclonal antibody and proposed biosimilar to Xolair® (omalizumab). AVT23 is an investigational compound and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

Sources

[1] EMA, Simponi product information

[2] EMA, Eylea product information

Use of trademarks

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.

Please visit our investor portal, and our website or follow us on social media on LinkedIn, Facebook, Instagram, X and YouTube.

About Advanz Pharma
Partner of choice in specialty, hospital, and rare disease medicines, Advanz Pharma is a global pharmaceutical company with the purpose to improve patients' lives by providing and enhancing the specialty, hospital, and rare disease medicines they depend on. Our headquarters are in London, UK. We have commercial sales in more than 90 countries globally and have a direct commercial presence in more than 20 countries, including key countries in Europe, the US, Canada, and Australia, a Centre of Excellence in Mumbai, India, as well as an established global distribution and commercialization partner network. Advanz Pharma's product portfolio and pipeline comprises innovative medicines, specialty generics & biosimilars, and originator brands. Our products cover a broad range of therapeutic areas, including hepatology, gastroenterology, anti-infectives, critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Our ambition is to be a partner of choice for the commercialization of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. In line with our ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to our dedicated and highly qualified employees, acting in line with our company values of entrepreneurship, speed, and integrity.

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 complete the development and gain marketing authorization for AVT05, AVT16 or AVT23, 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 develop and manufacture biosimilar candidates in Alvotech's current pipeline and manufacture approved and marketed biosimilars; (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 and (16) 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. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. 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Advanz Pharma Forward Looking Statements
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which speak of the date of this press release. Statements contained in this press release regarding past trends or events should not be taken as a representation that such trends or events will continue in the future. No obligation is assumed to update any forward-looking statements. The information contained in this press release is provided as at the date of this document and is subject to change without notice.

CONTACTS

ALVOTECH
Benedikt Stefansson, VP Investor Relations and Global Communications
alvotech.ir@alvotech.com

Advanz Pharma
Courtney Baines
Tel: +44 7776 516979
courtney.baines@advanzpharma.com