European Medicines Agency Confirms Acceptance of Marketing Application for AVT06, a Proposed Biosimilar to Eylea® (aflibercept)

August 15, 2024

- *The approvals process is anticipated to be completed in the third quarter of 2025*

REYKJAVIK, Iceland and LONDON, Aug. 15, 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 AVT06, Alvotech's proposed biosimilar to Eylea ® (aflibercept). The process to obtain marketing authorization could be completed in the third quarter of 2025.

"EMA acceptance takes us a step closer to making AVT06 available in Europe, which is good news for patients and caregivers," said Joseph McClellan, Chief Scientific Officer of Alvotech. "The successful development of multiple biosimilar candidates, demonstrates how Alvotech leverages its end-to-end biosimilars platform in support of broader access to affordable biologic medicines."

Dr. Nick Warwick, Chief Medical Officer for Advanz Pharma, said "This milestone is an important step towards providing patients with more treatment options and further strengthens Advanz Pharma's commitment to expand access to specialty, hospital, and rare disease medicines across Europe."

Alvotech is responsible for development and commercial supply of AVT06. Advanz Pharma is responsible for registration and has exclusive commercialization rights in Europe, except for France and Germany where the rights are semi-exclusive. French pharmaceutical company Biogaran holds semi-exclusive registration and commercialization rights for France. Alvotech is also developing AVT29, a biosimilar candidate for Eylea® high dose (8 mg). Advanz Pharma and Biogaran will also commercialize AVT29, for the same countries as AVT06.

Eylea® is a widely used biologic for the treatment of eye disorders, including diseases which can lead to vision loss or blindness, such as wet Age-related Macular Degeneration (AMD), macular edema, and diabetic retinopathy. In 2023, reported sales of Eylea® in Europe were $2.9 billion and cumulative global sales were $5.9 billion [1].

In January 2024, Alvotech announced positive top-line results from a confirmatory clinical study (AVT06-GL-C01) comparing the efficacy, safety, and immunogenicity of AVT06 with Eylea in patients with neovascular (wet) AMD. The study met its primary endpoint, with results demonstrating therapeutic equivalence and comparable safety including immunogenicity between Alvotech's biosimilar candidate and Eylea.

About AVT06/AVT29 (aflibercept)
AVT06/AVT29 is a recombinant fusion protein and a biosimilar candidate to Eylea® (aflibercept) 2 mg and 8 mg dose, which binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [2]. AVT06/AVT29 are investigational products and have not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

Sources
[1] Regeneron Full Year 2023 Earnings Press Release
[2] Eylea product information

Use of trademarks
Elyea is a registered trademark of Regeneron Pharmaceuticals Inc. and Bayer AG.

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 (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 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 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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