



European Marketing Application for AVT23, a Proposed Biosimilar to Xolair® (omalizumab), Accepted by the European Medicines Agency

October 6, 2025

LONDON and REYKJAVIK, Iceland, Oct. 06, 2025 (GLOBE NEWSWIRE) -- Advanz Pharma Holdco Limited ("Advanz Pharma"), a UK headquartered global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines in Europe and Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced that the European Medicines Agency (EMA) has accepted a Marketing Authorization Application for AVT23, a proposed biosimilar to Xolair® (omalizumab).

Nick Warwick, Chief Medical Officer of Advanz Pharma said, "The EMA's acceptance of the marketing application for AVT23 marks an important milestone in our mission to expand access to high-quality, affordable biologic medicines for patients across Europe. We look forward to working with Alvotech to bring this important therapy closer to the patients who need it."

"Bringing us a step closer to offering this important therapy in respiratory disease more broadly, is excellent news for our partnership with Advanz Pharma, patients and caregivers. Alvotech is focused on leveraging its end-to-end biosimilars platform in support of broader access to affordable biologic medicines," said Joseph McClellan, Chief Scientific and Technical Officer of Alvotech.

Alvotech developed AVT23 in collaboration with Kashiv BioSciences LLC, and Advanz Pharma has licensed commercial rights in the European Economic Area (European Union, Norway, Iceland and Lichtenstein), UK, Switzerland, Canada, Australia and New Zealand. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) accepted a Marketing Authorization Application for AVT23 earlier this year.

Omalizumab is a prescription biologic medicine used to improve the control of severe persistent asthma caused by an allergy. It is also used to treat long-term itchy rash (chronic spontaneous urticaria) and inflamed lining of the nose and sinuses with swellings in the nose (severe chronic rhinosinusitis with nasal polyps).

About AVT23

AVT23 is a proposed biosimilar to Xolair® (omalizumab). Omalizumab is a humanized monoclonal antibody that targets free immunoglobulin E (IgE). Xolair®, which contains omalizumab, is indicated for severe persistent allergic asthma, chronic spontaneous urticaria and chronic rhinosinusitis with nasal polyps (CRSwNP) [1]. AVT23 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.

Sources

[1] [Xolair EMA product information](#)

Use of trademarks

Xolair® is a registered trademark of Novartis 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](#) 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. 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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