



Advanz Pharma and Alvotech receive European approval for Mynzepli®, Biosimilar to Eylea®

August 21, 2025

- *Mynzepli® (afibercept) is approved in all European Economic Area member countries for the treatment of various retinal diseases including neovascular (wet) age-related macular degeneration (AMD)*
- *Approval is based on comprehensive analytical, non-clinical and clinical similarity data, including a confirmatory efficacy study comparing Mynzepli® with the reference biologic Eylea® in patients with neovascular AMD*

REYKJAVIK, Iceland and LONDON, Aug. 21, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide and 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, today announced that the European Commission has approved Mynzepli® as a biosimilar to Eylea® (afibercept), in a pre-filled syringe and vial.

"Timely access to effective therapies is essential for individuals affected by retinal diseases. With millions of Europeans impacted, the approval of Mynzepli represents important progress in providing innovative and affordable treatment options. This helps to ensure that patients throughout Europe have improved access to vision-preserving care, regardless of financial or logistical barriers," said Joseph McClellan, Chief Scientific and Technical Officer of Alvotech.

Nick Warwick, Chief Medical Officer of Advanz Pharma, said "The approval of Mynzepli® marks an important milestone in our mission to broaden access to high-quality and affordable medicines for patients across Europe."

The centralized marketing authorization is valid in all European Economic Area (EEA) countries, including the 27 member states of the European Union, as well as Norway, Iceland and Lichtenstein. In 2024, global sales of Eylea® were about US\$9 billion, and one third of these sales were in Europe [1].

Mynzepli® is approved for all adult indications approved for the reference biologic, neovascular (wet) age-related macular degeneration (AMD), or visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), diabetic macular oedema (DME) or myopic choroidal neovascularization (myopic CNV). Mynzepli® will be available as a 40 mg/mL solution for injection in a pre-filled syringe and 40 mg/mL solution for injection in a vial.

In January 2024 Alvotech announced positive top-line results from a confirmatory clinical study with its biosimilar candidate to Eylea®, known as AVT06, comparing the efficacy, safety, and immunogenicity of the proposed biosimilar to Eylea® in patients with neovascular (wet) AMD. The study met its primary endpoint, with results demonstrating therapeutic equivalence between Alvotech's biosimilar candidate and Eylea® [1]. The European Commission's decision to issue a marketing authorization came after the European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion on approving AVT06, as Mynzepli® (afibercept). Dossiers for AVT06 are currently under review in multiple countries globally, including the United States and Japan.

About Mynzepli® (afibercept)

Mynzepli® (afibercept) is a recombinant fusion protein which has now been approved in the European Economic Area as a biosimilar to Eylea® (afibercept). Afibercept binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [2].

Sources

[1] Agostini, H. et.al. (2025). A randomized, double-masked parallel-group, multicenter clinical study evaluating the efficacy and safety of the biosimilar candidate AVT06 compared to the reference product afibercept in participants with neovascular age-related macular degeneration. Expert Opinion on Biological Therapy, 1–15. <https://doi.org/10.1080/14712598.2025.2519531>

[2] [Product information](#)

Use of trademarks

Eylea® is a registered trademark of 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's current pipeline includes eight 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), 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 Advanz Pharma

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. Advanz Pharma's 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, biosimilars & specialty generics, and originator brands. Advanz Pharma's products cover a broad range of therapeutic areas, including hepatology, rheumatology, gastroenterology, anti-infectives, critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Advanz Pharma's 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 Advanz Pharma's ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to Advanz Pharma's dedicated and highly qualified employees, acting in line with Advanz Pharma's 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 or operating performance of Alvotech and may include, for example, Alvotech's expectations regarding future growth, results of operations, performance, future capital and other expenditures, 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, regulatory review and interactions, the timing of the announcement of clinical study results, the commencement of patient studies, regulatory applications, 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 ability to reach development milestones under commercial partnership agreements; (2) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing; (4) changes in applicable laws or regulations; (5) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (6) Alvotech's estimates of expenses and profitability; (7) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (12) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) 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; (14) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (15) Alvotech's ability, and that of its commercial partners to execute their commercialization strategy for approved products; (16) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (18) 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; (19) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, and the ongoing and evolving COVID-19 pandemic on the Alvotech's business, financial position, strategy and anticipated milestones; and (20) 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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Advanz Pharma Forward-Looking Statements

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