



Alvotech and Advanz Pharma announce first known regulatory submission worldwide for proposed biosimilar to Eylea® 8 mg

October 14, 2026

AVT29 submitted to the European Medicines Agency as a line extension to the existing marketing authorization for Mynzepli® (aflibercept 2 mg)

High-dose aflibercept offers the potential to reduce treatment frequency for patients with retinal diseases

REYKJAVIK, Iceland and LONDON, UK (October 14, 2026) - Alvotech (NASDAQ: ALVO; ALVO-SDB), a global biotechnology company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and Advanz Pharma Holdco Limited ("Advanz Pharma"), a global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines, today announced the submission of a European regulatory application for AVT29, a proposed biosimilar to Eylea® 8 mg (aflibercept 114.3 mg/mL), which is marketed as Eylea HD® in the United States. Based on publicly available information, this marks the first regulatory submission worldwide for a proposed biosimilar to Eylea® 8mg.

The application was submitted as a line extension to the existing European marketing authorization for Mynzepli® (AVT06, 2 mg aflibercept, 40 mg/mL), Alvotech's biosimilar to Eylea® 2 mg.

Eylea® is used to treat certain retinal diseases through injections directly into the eye. According to the approved European product information, the 8mg formulation allows treatment intervals of 16 weeks for certain patients, compared with the standard eight-week maintenance interval for the original 2 mg formulation, potentially reducing the frequency of maintenance injections and reducing the treatment burden for patients^[2].

According to publicly reported financial results, the 8mg formulation accounted for approximately 57% of combined global Eylea® 2mg and 8mg sales by value in the second quarter of 2026, up from approximately 30% in the same period in 2025^[3].

"To our knowledge, this is the first regulatory submission anywhere in the world for a proposed biosimilar to Eylea 8 mg. This is an important achievement for Alvotech and demonstrates the strength of our in-house development capabilities," said Lisa Graver, Chief Executive Officer of Alvotech. "We recognized early the potential of high-dose aflibercept and invested in developing both the 2 mg and 8 mg formulations. Building on the European approval of Mynzepli, this milestone positions us at the forefront of the next wave of aflibercept biosimilars and reflects our commitment to broadening access to high-quality biologic medicines."

Steffen Wagner, Chief Executive Officer of Advanz Pharma, said: "This submission represents an important milestone in our partnership with Alvotech and our shared commitment to improving access to high-quality, affordable medicines. Following the European approval of Mynzepli, we are pleased to be advancing a high-dose formulation that could offer additional treatment options for patients and healthcare professionals across Europe."

Mynzepli® received European Commission approval in August 2025 as a biosimilar to Eylea® 2 mg (aflibercept 40 mg/mL), in both vial and prefilled syringe presentations, for the treatment of various retinal diseases.

Under the companies' partnership agreement, Alvotech is responsible for development and commercial supply of AVT06 and AVT29, while Advanz Pharma is responsible for registration and commercialization in Europe. Advanz Pharma holds exclusive commercialization rights in Europe, except in Germany and France, where the rights are semi-exclusive.

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About AVT06

AVT06 is a biosimilar to Eylea® (aflibercept). Aflibercept binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability^[1]. AVT06 has been approved under the brand names Mynzepli® (aflibercept) and Afiveg® (aflibercept) in the European Economic Area, Mynzepli® (aflibercept) in the United Kingdom and under the name AFLIBERCEPT BS for marketing in Japan.

About AVT29

AVT29 is Alvotech's proposed biosimilar to Eylea® 8 mg (aflibercept), a biologic medicine used to treat retinal diseases that can cause vision loss. AVT29 is an investigational product and has not received regulatory approval. Biosimilarity has not yet been established by regulatory authorities.

Use of trademarks

Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc. and Bayer AG.

Sources

[1] [Mynzepli® product information](#)

[2]EMA: [Eylea® summary of product characteristics](#)

[3]Regeneron Pharmaceuticals Inc.: [Regeneron Reports Second Quarter 2026 Financial and Operating Results](#)

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. 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 commercialisation 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 commercialisation 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. For more information, please visit our [Website](#) or [LinkedIn](#).

About Alvotech

Alvotech is a biotechnology 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. Five biosimilars are already approved and marketed in multiple global markets, including biosimilars to Humira® (adalimumab), Stelara® (ustekinumab), Simponi® (golimumab), Eylea® (aflibercept) and Prolia®/Xgeva® (denosumab). The current development pipeline includes disclosed biosimilar candidates aimed at treating autoimmune disorders, eye disorders, 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. 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.

For more information, please visit our [website](#) or follow us on social media on [LinkedIn](#), [Facebook](#), [Instagram](#), and [YouTube](#).

Advanz Pharma Forward Looking Statements

Certain statements in this press release are forward-looking statements. These statements may be identified by words such as "anticipate", "expectation", "belief", "estimate", "plan", "target", "project", "will", "may", "should" or "forecast" and similar expressions, or by their context. Although Advanz Pharma believes that these assumptions were reasonable when made, by their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial consequences of the plans and events described herein. Actual results may differ from those set forth in the forward-looking statements as a result of various factors (including, but not limited to, future global economic conditions, changed market conditions affecting the industry, intense competition in the markets in which Advanz Pharma operates, costs of compliance with applicable laws, regulations and standards, diverse political, legal, economic and other conditions affecting Advanz Pharma's markets, and other factors beyond the control of Advanz Pharma. Neither Advanz Pharma nor any of its directors, officers, employees, advisors, or any other person is under any obligation to update or keep current the information contained in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You should not place undue reliance on forward-looking statements, 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.

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 include, for example, Alvotech's expectations regarding competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, regulatory submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, market launches and financial projections. 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 factors 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. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, assurance, prediction or definitive statement of a fact or probability. 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. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed.