Alvotech and Teva Secure U.S. Settlement Date for AVT06, a Proposed Biosimilar to Eylea®

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According to the settlement agreement, the proposed biosimilar to Eylea® (aflibercept) can be marketed in the U.S., if approved by the FDA, in the fourth quarter of 2026, or earlier under certain circumstances

REYKJAVIK, Iceland and TEL AVIV, Israel and PARSIPPANY, N.J., Dec. 19, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), today announced that they have reached a settlement and license agreement with Regeneron Pharmaceuticals Inc. concerning the launch of AVT06, Alvotech's proposed biosimilar to Eylea ® (aflibercept) in the United States. The settlement grants a license entry date for AVT06 in the United States in the fourth quarter of 2026, or earlier under certain circumstances.

"Following recent marketing approvals in both Europe and Japan, we are delighted to secure a U.S. settlement date for our biosimilar candidate to Eylea®, an important biologic for the treatment of retinal diseases. This positions Alvotech and our commercial partner Teva very well for a successful launch in the U.S. market next year, pending FDA approval," said Robert Wessman, Chairman and CEO of Alvotech.

AVT06 has been approved for marketing as an aflibercept biosimilar in the United Kingdom, Japan and the 30 countries of the European Economic Area, which includes all 27 member states of the European Union in addition to Norway, Iceland and Liechtenstein.

In January 2024, Alvotech announced positive top-line results from a confirmatory clinical study comparing the efficacy, safety, and immunogenicity of AVT06 to Eylea® (aflibercept) in patients with neovascular (wet) AMD. The study met its primary endpoint, with results demonstrating high similarity between Alvotech's biosimilar candidate and Eylea ® [1].

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About AVT06
AVT06 is a proposed biosimilar to Eylea® (aflibercept). Aflibercept binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [2]. AVT06 has been approved under the brand name Mynzepli® (aflibercept) for marketing in the United Kingdom and European Economic Area and under the name AFLIBERCEPT BS for marketing in Japan.

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 aflibercept in participants with neovascular age-related macular degeneration. Expert Opinion on Biological Therapy, 1–15. https://doi.org/10.1080/14712598.2025.2519531

[2] Eylea® product label, accessed on December 18, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125387s087lbl.pdf

Use of trademarks
Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.

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. Alvotech's current pipeline includes eight disclosed biosimilar candidates aimed at treating autoimmune disorders, eye disease, 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. 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 Teva
Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is transforming into a leading innovative biopharmaceutical company, enabled by a world-class generics business. For over 120 years, Teva's commitment has never wavered. From innovating in the fields of neuroscience and

immunology to providing complex generic medicines, biosimilars and pharmacy brands worldwide, Teva is dedicated to addressing patients' needs, now and in the future. At Teva, We Are All In For Better Health. To learn more about how, visit www.tevapharm.com.

Forward-Looking Statements (Alvotech)

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.

Cautionary Note Regarding Forward-Looking Statements (Teva)

This Press Release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to: our ability to commercialize the biosimilar product candidate to Eylea® (aflibercept) under the strategic partnership with Alvotech, once regulatory approval is obtained; our ability to successfully compete in the marketplace, including our ability to develop and commercialize additional pharmaceutical products; our ability to successfully execute our Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, and to sustain and focus our portfolio of generic medicines; and other factors discussed in our Quarterly Report on Form 10-Q for the third quarter of 2025, and in our Annual Report on Form 10-K for the year ended December 31, 2024, including in the sections captioned "Risk Factors" and "Forward-looking statements." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.