



## **Alvotech announces resubmission of U.S. Biologics License Applications for AVT05, a proposed biosimilar to Simponi® and Simponi Aria®, and AVT06, a proposed biosimilar to Eylea®**

June 4, 2026

REYKJAVIK, Iceland, June 04, 2026 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO; ALVO-SDB), a global biotechnology company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced the resubmission to the U.S. Food and Drug Administration (FDA) of Biologics License Applications (BLAs) for AVT05, a proposed biosimilar to Simponi® and Simponi Aria® (golimumab), and AVT06, a proposed biosimilar to Eylea® (aflibercept) 2 mg.

Under a partnership with Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), Alvotech is responsible for the development and manufacturing of AVT05 and AVT06, while Teva is responsible for commercialization.

The resubmissions follow the submission of Alvotech's response to the FDA's Post-Application Action Letter (PAAL) related to the company's Reykjavik manufacturing facility. In addition, the company has submitted responses to observations from a routine cGMP surveillance FDA inspection at the facility, completed in May 2026, and has continued to strengthen its quality systems and manufacturing operations as part of its ongoing enhancement program.

The company expects the FDA to conduct a six-month review of the resubmitted applications, consistent with the applicable regulatory timelines.

AVT03, Alvotech's proposed biosimilar to Prolia® and Xgeva® (denosumab), is partnered with Dr. Reddy's Laboratories Ltd. which, as applicant, is responsible for the U.S. regulatory submission.

"These resubmissions represent an important milestone following extensive work across our manufacturing and quality organization," said Lisa Graver, Chief Executive Officer of Alvotech. "We have worked closely with the FDA throughout this process, including responding to the agency's Post-Application Action Letter and supporting a routine inspection of our Reykjavik facility in May. As previously disclosed, we believe the outcome of the recent inspection demonstrated the strong cGMP fundamentals of the site and the robustness of the improvements implemented since last year. We remain focused on execution, operational discipline and bringing high-quality biosimilars to patients worldwide."

AVT05 is a proposed biosimilar to Simponi® and Simponi Aria® (golimumab), biologic medicines used to treat a variety of chronic inflammatory conditions. AVT06 is a proposed biosimilar to Eylea® (aflibercept) 2 mg, a biologic medicine used to treat several serious retinal disorders, including conditions that may lead to vision loss or blindness.

### **About AVT05**

AVT05 is a biosimilar to Simponi® (golimumab) that has been approved in multiple markets globally including in the European Economic Area (EEA), the United Kingdom, and Japan. In the United States, AVT05 is being developed as a biosimilar candidate to Simponi® as a subcutaneous formulation and Simponi Aria® as an intravenous formulation.

### **About AVT06**

AVT06 is a biosimilar to Eylea® (aflibercept) 2 mg that has been approved in multiple markets globally, including in the European Economic Area (EEA), the United Kingdom, Japan and Canada.

### **About AVT03**

AVT03 is a biosimilar to Prolia® and Xgeva® (denosumab) that has been approved in multiple markets globally, including the EEA, the UK and Japan.

### **About Simponi® and Simponi Aria®**

Simponi® (golimumab) is a subcutaneous tumor necrosis factor (TNF) blocker and Simponi Aria® (golimumab) is the intravenous formulation. Simponi and Simponi Aria are approved for a range of chronic inflammatory diseases including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis and polyarticular juvenile idiopathic arthritis.

### **About Eylea®**

Eylea® (aflibercept) is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of several retinal diseases including neovascular (wet) age-related macular degeneration, diabetic macular edema and retinal vein occlusion.

### **About Prolia® and Xgeva®**

Prolia® / Xgeva® (denosumab) is a monoclonal antibody used to treat osteoporosis and to prevent skeletal-related events in patients with certain cancers involving bone.

### **Use of trademarks**

Simponi® and Simponi Aria® are trademarks of Johnson & Johnson. Eylea® is a trademark of Regeneron Pharmaceuticals Inc. Prolia® and Xgeva® are trademarks of Amgen. Reference to these trademarks does not imply any affiliation between Alvotech, Teva or Dr. Reddy's and the trademark owners.

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**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 biosimilars 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 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. 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 [investor portal](#), and our [website](#) or follow us on social media on [LinkedIn](#), [Facebook](#), [Instagram](#) and [YouTube](#).

**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 the regulatory progress and expected timing of BLA resubmission for AVT05 and AVT06, the adequacy of the improvements on cGMP since last year, competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, 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.

