



Alvotech announces FDA acceptance for review of Biologics License Application for AVT80, expanding proposed biosimilar program for Entyvio® to subcutaneous presentations

August 31, 2026

REYKJAVIK, Iceland, August 31, 2026 - Alvotech (NASDAQ: ALVO; ALVO-SDB), a global biotechnology company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a Biologics License Application (BLA) for AVT80, a proposed interchangeable biosimilar to Entyvio® (vedolizumab) prefilled syringe and autoinjector for subcutaneous administration.

Under a partnership with Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), Alvotech is responsible for the development and manufacturing of AVT80, while Teva is responsible for commercialization.

"FDA's acceptance for review of our BLA for AVT80 is another important milestone for our vedolizumab biosimilar program," said Joseph McClellan, Chief Operating Officer of Alvotech. "Together with our BLA for AVT16, which was accepted for review in May, the program encompasses both intravenous and subcutaneous presentations, including a prefilled syringe and autoinjector."

Entyvio is a biologic medicine approved for the treatment of adults with moderately to severely active ulcerative colitis and Crohn's disease.

The BLA submission is supported by a comprehensive data package, including analytical, pharmacokinetic, and immunogenicity data generated to support the demonstration of biosimilarity between AVT80 and the reference product.

AVT80 has been submitted as a proposed interchangeable biosimilar. In the United States, an interchangeable biosimilar may be substituted for the reference product at the pharmacy without the intervention of the prescriber, subject to applicable laws. If approved, AVT80 would add to the range of biosimilar options available to patients and healthcare providers in the United States.

In February 2026, Alvotech announced positive results from a [pivotal pharmacokinetic study](#) for AVT80. The randomized, double-blind, single-dose, parallel-group, three-arm study compared AVT80 to Entyvio in healthy adult participants and met all its primary endpoints. Based on regulatory advice, the clinical study is considered pivotal to support the demonstration of clinical similarity for both AVT16 and AVT80.

About AVT80 and AVT16

AVT80 is a proposed interchangeable biosimilar candidate to Entyvio (vedolizumab), a humanized monoclonal antibody. It is being developed as a prefilled syringe and autoinjector for subcutaneous administration. AVT80 complements AVT16, Alvotech's proposed interchangeable biosimilar to Entyvio for intravenous administration for which the FDA [accepted a BLA for review in May 2026](#). In the European Union, the European Medicines Agency has validated a Marketing Authorization Application covering both AVT16 (lyophilized vial) and AVT80 (pre-filled syringe and autoinjector).

Together these two candidates form part of Alvotech's broader pipeline of biosimilar candidates in immunology aimed at expanding access to biologic medicines in major therapeutic areas.

AVT16 and AVT80 are investigational products and have not received regulatory approval in any markets. Biosimilarity and interchangeability have not been established by regulatory authorities and are not claimed.

About Entyvio

Entyvio (vedolizumab) is an integrin receptor antagonist indicated for the treatment of adults with moderately to severely active ulcerative colitis and Crohn's disease. Vedolizumab targets and binds specifically to the alpha-4-beta-7 integrin, which is involved in the migration of certain white blood cells into gastrointestinal tissue.

Use of trademarks

Entyvio is a registered trademark of Millennium Pharmaceuticals, Inc. The use of this trademark is solely for the purpose of identifying the reference product. Alvotech and Teva do not claim any rights to the trademark.

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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 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](#).

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.