



## Alvotech Provides Update on the Status of U.S. Biologics License Application for AVT05

November 2, 2025

REYKJAVIK, Iceland, Nov. 02, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) for Alvotech's Biologics License Application (BLA) for AVT05, in a prefilled syringe and autoinjector presentations, a biosimilar candidate to Simponi® (golimumab).

The CRL noted that certain deficiencies, which were conveyed following the FDA's pre-license inspection of Alvotech's Reykjavik manufacturing facility that concluded in July 2025, must be satisfactorily resolved before this BLA for AVT05 can be approved. The FDA did not identify any other deficiencies with the application. The facility remains FDA approved to manufacture and continues supplying currently commercialized products.

Sales of Simponi in the U.S. in the first half of 2025 were less than \$300 million, according to data published by IQVIA. Currently, there are no FDA approvals for a biosimilar to Simponi.

"As previously discussed, following the inspection of our facility, Alvotech submitted a comprehensive response to the FDA detailing our Corrective and Preventive Action (CAPA) plan. While we are disappointed in receiving the CRL, we expect to resolve any outstanding issues and will continue to work with the FDA to bring this first-to-market biosimilar to patients in the U.S.," said Robert Wessman, Chairman and CEO of Alvotech.

Following the receipt of the CRL, Alvotech has reevaluated its outlook for 2025. Total revenues in 2025 are now expected to be \$570-\$600 million and adjusted EBITDA \$130-\$150 million, lower than previously provided. The lowered adjusted EBITDA outlook is primarily driven by expected continuation of investments related to resolving certain facility issues, which also require a temporary slowdown in production. These investments, however, also serve to support Alvotech's future growth plans and new product launches.

### 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](http://www.alvotech.com). None of the information on the Alvotech website shall be deemed part of this press release.

### 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.

### ALVOTECH INVESTOR RELATIONS AND GLOBAL COMMUNICATIONS

Benedikt Stefansson, VP  
[alvotech.ir@alvotech.com](mailto:alvotech.ir@alvotech.com)