



Alvotech Announces Positive Top-Line Results from Pivotal Pharmacokinetic Study for Proposed Biosimilar to Entyvio®

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- *The study, which assessed the pharmacokinetics, safety, tolerability and immunogenicity of AVT80 compared to Entyvio® in healthy adult participants, met all its primary endpoints*

REYKJAVIK, Iceland, Feb. 05, 2026 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotechnology company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today positive top-line results from a pharmacokinetic (PK) study for AVT80, a biosimilar candidate to Entyvio® (vedolizumab).

The PK study ([AVT80-GL-P01](#)), which compared AVT80 to Entyvio in healthy adult participants, met all its primary endpoints. This was a randomized, double-blind, single dose, parallel-group design, 3-arm study, designed to demonstrate the PK similarity, and to investigate safety, tolerability, and immunogenicity profiles of AVT80 and Entyvio in healthy adult participants after administration of a single 108 mg/0.68 mL subcutaneous (SC) injection.

"We are very pleased with this result, which is an important milestone in the development of our proposed biosimilar to Entyvio, allowing us to proceed towards regulatory submissions. This milestone further underlines the strength of our platform approach to biosimilars development and manufacture, combining a well-designed and executed clinical study with the design of a high-quality manufacturing process and strong analytical capabilities," said Joseph McClellan, Chief Operating Officer.

Alvotech is currently developing AVT16, a proposed biosimilar to Entyvio for intravenous administration and AVT80, a proposed biosimilar to Entyvio for subcutaneous administration. The [AVT80-GL-P01](#) study satisfies the demonstration of PK similarity for both the subcutaneous and intravenous routes of administration to Entyvio. Based on regulatory advice, the AVT80-GL-P01 clinical study is considered pivotal to support the demonstration of clinical similarity for AVT16 and AVT80.

Entyvio (vedolizumab) is indicated for the treatment of adult patients with moderate to severe Ulcerative Colitis, a disease that causes inflammation and ulcers in the lining of the bowel, and moderate to severely active Crohn's disease, a disease that causes inflammation of the digestive tract. In 2025 combined net revenues world-wide from the sales of Entyvio were about US\$6.4 billion [1].

About AVT16/AVT80

AVT16 and AVT80 contain a human monoclonal antibody (vedolizumab) and are biosimilar candidates to Entyvio®. Vedolizumab targets and binds specifically to the alpha-4-beta-7 protein, which is preferentially expressed on T helper lymphocytes (white blood cells) which migrate into the gastrointestinal tract and cause inflammation, characteristic of Ulcerative Colitis and Crohn's disease [2]. AVT16 and AVT80 are investigational products and have not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

For further information, contact:

Media

Benedikt Stefansson
Sarah MacLeod
alvotech.media@alvotech.com

Investors

Dr Balaji V Prasad (US)
Patrik Ling (SE)
Benedikt Stefansson (IS)
alvotech.ir@alvotech.com

Sources

[1] [Takeda Quarterly Results](#)
[2] [Entyvio product information, EMA](#)

Use of trademarks

Entyvio is a trademark of Millennium Pharmaceuticals.

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. Two biosimilars, Humira® (adalimumab) and Stelara® (ustekinumab) are already approved and marketed in multiple global markets. 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. 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), Dr. Reddy's (EEA, UK and US), Biogaran (FR), 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 <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](#).

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.