Alvotech Initiates Confirmatory Patient Study for AVT16, a Proposed Biosimilar to Entyvio®

September 25, 2024

- *Alvotech is one of two companies known to have initiated a global or multi-country confirmatory patient study for a biosimilar candidate to Entyvio®*
- *Sales of Entyvio (vedolizumab) were about $5.4 billion globally in the last 12 months up to June 30, 2024*
- *Entyvio is indicated for the treatment of Ulcerative Colitis and Crohn's disease*

REYKJAVIK, Iceland, Sept. 25, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specialized in the development and manufacture of biosimilar medicines for patients worldwide, announced today the initiation of a confirmatory patient study for AVT16, a biosimilar candidate to Entyvio® (vedolizumab). The objective of the study is to demonstrate comparative efficacy, safety, and immunogenicity of AVT16 and Entyvio, in male and female participants 18-80 years old with moderate to severe active Ulcerative Colitis. Alvotech is one of two companies known to have initiated a global or multi-country confirmatory patient study for a biosimilar candidate to Entyvio.

Entyvio (vedolizumab) is indicated for the treatment of adult patients with moderate to severe Ulcerative Colitis, a disease causing inflammation and ulcers in the lining of the bowel, and moderate to severely active Crohn's disease, a disease causing inflammation of the digestive tract. In the last twelve months until June 30, 2024, combined net revenues worldwide from sales of Entyvio were about US$5.4 billion [1].

"We are proud to be able to initiate the confirmatory patient study for AVT16, adding another important biosimilar candidate in clinical development to our pipeline. Alvotech's growing pipeline and portfolio of marketed biosimilars, leveraging our dedicated comprehensive R&D and manufacturing platform, demonstrates our commitment to improving people's lives globally by increasing access to cost-effective biologic medicines," said Joseph McClellan, Chief Science Officer of Alvotech.

The AVT16-GL-C01 multicenter study has a double-blind parallel design with 2 arms. Participants will receive either AVT16 or Entyvio, and all participants will be followed to determine efficacy of the treatment using a standardized score for Ulcerative Colitis disease activity.

Alvotech's current biosimilars portfolio targets autoimmune disease, eye disorders, bone disease, respiratory disease, and cancer. Two biosimilars, to Humira® (adalimumab) and Stelara® (ustekinumab) are already approved and marketed in multiple global markets. Alvotech expects to file marketing applications for three biosimilar candidates in the course of 2024, while AVT16 is one of six disclosed biosimilar programs in earlier stages of development.

About AVT16

AVT16 is a human monoclonal antibody and a biosimilar candidate to Entyvio® (vedolizumab). 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 Chron's disease [2]. AVT16 is an investigational product and has not received regulatory approval in any country. Biosimiliarity has not been established by regulatory authorities and is not claimed.

About AVT02 (adalimumab)

AVT02 is a monoclonal antibody and has been approved as a biosimilar to Humira® (adalimumab) in over 50 countries globally, including the U.S., Europe, Canada, Australia, Egypt, Saudi Arabia and South Africa. It is currently marketed in the U.S. as SIMLANDI and under private label, in Europe as HUKYNDRA, in Canada as SIMLANDI and in Australia as ADALACIP. Dossiers are also under review in multiple countries globally.

About AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar to Stelara® (ustekinumab). It has been launched in Canada as JAMTEKI, in the EEA as UZPRUVO, and in Japan as USTEKINUMAB BS (F). It has been approved in the U.S. as SELARSDI. Dossiers are also under review in multiple countries globally.

Sources

[1] IQVIA [2] Entyvio product information, EMA.

Use of trademarks

Entyvio is a trademark of Millennium Pharmaceuticals, Inc. Humira is a registered trademark of AbbVie Inc. Stelara is a registered trademark of Johnson & Johnson Inc.

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. Two biosimilars, to 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.

Please visit our investor portal, and our website or follow us on social media on LinkedIn, Facebook, Instagram, X 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 generally relate to future events or the future financial operating performance of Alvotech and may include, for example, Alvotech's expectations regarding its ability to complete clinical patient studies successfully and receive marketing authorization, estimates with respect to its development programs and trials, including design, duration, timing, recruitment costs, screening and enrollment for those trials, including the ongoing AVT16-GL-C01 trial, addressable market size of Alvotech's biosimilars and biosimilar candidates, Alvotech's competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, regulatory submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, and market launches. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential", "aim" or "continue", or the negatives of these terms or variations of them or similar terminology. 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: (1) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (2) the ability to maintain stock exchange listing standards; (3) changes in applicable laws or regulations; (4) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (5) Alvotech's estimates of revenue, expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (8) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (9) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (10) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (11) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (12) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (13) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (14) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (15) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, conflicts in Ukraine, the Middle East and other global geopolitical tension, on the Company's business, financial position, strategy and anticipated milestones; and (16) other risks and uncertainties 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. 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