



Alvotech and Teva Announce Filing Acceptance of U.S. Biologics License Applications for AVT05, a Proposed Biosimilar to Simponi® and Simponi Aria® (golimumab)

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REYKJAVIK, Iceland and PARSIPPANY, N.J., Jan. 27, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), today announced that the U.S. Food and Drug Administration (FDA) has accepted for review Biologics License Applications (BLA) for AVT05, Alvotech's proposed biosimilar to Simponi® and Simponi Aria® (golimumab), which are prescribed to treat a variety of inflammatory conditions. These are the first U.S. BLA filing acceptances announced for a biosimilar candidate to golimumab. The FDA review process for these applications is anticipated to be completed in the fourth quarter of 2025.

"This is a significant step towards being able to offer U.S. patients access to biosimilar golimumab," said Joseph McClellan, Chief Scientific Officer of Alvotech. "Our in-house capability allowing us to match the cell line and process used to manufacture the reference biologic, has given us an important head start in developing a biosimilar candidate to Simponi® and Simponi Aria® for global markets."

Thomas Rainey, Senior Vice President, U.S. Biosimilars at Teva, added, "Biosimilars are ushering a new treatment paradigm and have become an integral staple in the healthcare ecosystem. Teva's strategic partnership with Alvotech underscores our commitment to continue to bring cost-saving options to more patients and deliver better outcomes for those with inflammatory conditions."

In April 2024, Alvotech announced positive top-line results from a confirmatory clinical study comparing efficacy, safety, and immunogenicity between AVT05 and Simponi® in patients with moderate to severe rheumatoid arthritis. Previously, in November 2023, Alvotech announced positive topline results from a pharmacokinetic study which assessed the pharmacokinetics, safety, and tolerability of AVT05 compared to Simponi® in healthy adult participants.

In August 2020, Alvotech and Teva entered into a strategic partnership for the exclusive commercialization of five of Alvotech's biosimilar product candidates, including AVT05. The partnership has since expanded and now includes a total of nine products. Alvotech handles development and manufacturing using its purpose-built end-to-end platform, while Teva is responsible for commercialization in the U.S., which leverages Teva's experience and extensive sales and marketing infrastructure.

Since Alvotech and Teva entered into the strategic partnership, two biosimilars developed under the partnership have achieved FDA approval. In February 2024, the FDA approved SIMLANDI® (adalimumab-ryvk), the first high-concentration, citrate-free interchangeable biosimilar to Humira® (adalimumab). SIMLANDI was launched in the U.S. in May 2024. In April 2024, the FDA approved SELARSDI™ (ustekinumab-aekn) as a biosimilar to Stelara® (ustekinumab). U.S. market entry date for SELARSDI™ is planned for February 2025.

About AVT05

AVT05 is a biosimilar candidate for Simponi® and Simponi Aria® (golimumab). Golimumab is a monoclonal antibody that inhibits tumor necrosis factor alpha (TNF alpha). Elevated TNF alpha levels have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.¹ AVT05 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

About SIMLANDI (adalimumab-ryvk)

SIMLANDI 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. The biosimilar is currently marketed in the U.S. as SIMLANDI and under private label as adalimumab-ryvk, in Europe as HUKYNDRA®, in Canada as SIMLANDI and in Australia as ADALACIP®. Applications are also under review in multiple countries globally.

About SELARSDI™ (ustekinumab-aekn)

SELARSDI is a monoclonal antibody and has been approved as a biosimilar to Stelara® (ustekinumab). Ustekinumab binds to two cytokines, IL-12 and IL-23, which are involved in inflammatory and immune responses.² This biosimilar was launched in Canada as JAMTEKI®, in Europe as UZPRUVO® and in Japan as USTEKINUMAB BS (F)®. It has been approved in the U.S. as SELARSDI. Applications are also under review in multiple countries globally.

Use of trademarks

Simponi®, Simponi Aria® and Stelara® are registered trademarks of Johnson & Johnson. Humira® is a registered trademark of AbbVie 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 our [investor portal](#) or our [website](#). None of the information on the Alvotech website shall be deemed part of this press release.

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a global pharmaceutical leader, harnessing its generics expertise and stepping up innovation to continue the momentum behind the discovery, delivery, and expanded development of modern medicine. For over 120 years, Teva's commitment to bettering health has never wavered. Today, the company's global network of capabilities enables its ~37,000 employees across 57 markets to push the boundaries of scientific innovation and deliver quality medicines to help improve health outcomes of millions of patients every day. To learn more about how Teva is all in for better health, visit www.tevapharm.com.

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 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 the development and gain marketing authorization for AVT05, Alvotech's competitive advantages, business prospects and opportunities including product launches, pipeline product development, revenue and diversification, 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 develop and manufacture biosimilar candidates in Alvotech's current pipeline and manufacture approved and marketed biosimilars; (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. 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. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. 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. The recipient agrees that it shall not seek to sue or otherwise hold Alvotech or any of its directors, officers, employees, affiliates, agents, advisors, or representatives liable in any respect for the provision of this communication, the information contained in this communication, or the omission of any information from this communication.

Teva Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to: our ability to commercialize Alvotech's biosimilar product candidate to Simponi[®] and Simponi Aria[®] (golimumab) under the strategic partnership with Alvotech, once regulatory approval is obtained; our ability to successfully compete in the marketplace, including our ability to develop and commercialize additional pharmaceutical products; our ability to successfully execute our Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development, and to sustain and focus our portfolio of generic medicines; and other factors discussed in our Quarterly Report on Form 10-Q for the third quarter of 2024, and in our Annual Report on Form 10-K for the year ended December 31, 2023, including in the section captioned "Risk Factors." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

Sources

1. Simponi[®] (golimumab) FDA product label. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125289s150lbl.pdf. Accessed on January 14, 2025.

2. Selarsdi™ (ustekinumab-aekn) FDA product label https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761343s000lbl.pdf. Accessed on January 14, 2025.

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