



Alvotech and Advanz Pharma Receive Marketing Approval Across the European Economic Area for Gobivaz[®], a First-in-Market Biosimilar to Simponi[®] (golimumab)

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REYKJAVIK, Iceland and LONDON, Nov. 20, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide and Advanz Pharma Holdco Limited ("Advanz Pharma"), a UK headquartered global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines in Europe, today announced that the European Commission (EC) has granted marketing authorizations in the European Economic Area (EEA) for Gobivaz[®], Alvotech's biosimilar to Simponi[®] (golimumab).

The authorizations cover Gobivaz[®] 50 mg/0.5 mL and 100mg/mL in both pre-filled syringe with passive needle safety guard and autoinjector formats, for the treatment of adults with rheumatoid arthritis in combination with methotrexate, psoriatic arthritis with or without methotrexate, axial spondyloarthritis, ulcerative colitis and for the treatment of juvenile idiopathic arthritis in children 2 years of age and older in combination with methotrexate. The approvals apply across the European Economic Area. The EC approval follows the positive opinion issued in September by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).

"This milestone marks the second biosimilar to receive approval through our partnership with Advanz Pharma and further strengthens the commercial presence we are building in Europe. As the first biosimilar to Simponi[®] (golimumab) to gain approval in the European market, we are committed to expanding access to high quality biologic medicines for people living with immune-mediated diseases while providing value to healthcare systems throughout the region," said Robert Wessman, Chairman and Chief Executive Officer of Alvotech.

"We welcome the EC approval of Gobivaz[®], an important milestone in our partnership with Alvotech. Expanding access to high-quality biosimilars is central to Advanz Pharma's mission, and this approval enables us to offer patients across Europe a valuable new treatment option for immune-mediated diseases," said Steffen Wagner, Chief Executive Officer, Advanz Pharma.

Under the partnership between Alvotech and Advanz Pharma, Alvotech is responsible for the development and commercial supply of Gobivaz[®], while Advanz Pharma holds the registration and exclusive commercialization rights in the EEA and the UK.

The EC approval of Gobivaz[®] was based on a totality of evidence, including analytical and clinical data. In April 2024, Alvotech announced positive top-line results from a confirmatory clinical study comparing efficacy, safety, and immunogenicity between its biosimilar candidate AVT05 and the reference product Simponi[®] in patients with moderate to severe rheumatoid arthritis (clinicaltrials.gov/study/NCT05842213). In November 2023, Alvotech announced positive top-line results from a pharmacokinetic study which assessed the pharmacokinetics, safety, and tolerability of AVT05 compared to Simponi[®] in healthy adult participants (clinicaltrials.gov/study/NCT05632211).

About AVT05

AVT05 (golimumab) has been approved as Golimumab BS (golimumab) in Japan and as Gobivaz (golimumab) in the European Economic Area. Dossiers are under review in multiple countries globally. Golimumab is a monoclonal antibody that inhibits tumor necrosis factor alpha (TNF alpha). Elevated TNF alpha levels have been implicated in several chronic inflammatory diseases such as rheumatoid arthritis [1].

Sources

[1] [Simponi product information](#)

Use of Trademarks

Simponi[®] is a registered trademark of Johnson & Johnson. Gobivaz[®] is a trademark of Advanz Pharma.

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 established 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. None of the information on the Alvotech website shall be deemed part of this press release.

About Advanz Pharma

Partner of choice in specialty, hospital, and rare disease medicines. Advanz Pharma is a global pharmaceutical company with the purpose to improve patients' lives by providing and enhancing the specialty, hospital, and rare disease medicines they depend on. Our headquarters are in London, UK. We have commercial sales in more than 90 countries globally and have a direct commercial presence in more than 20 countries, including key countries in Europe, the US, Canada, and Australia, a Centre of Excellence in Mumbai, India, as well as an established global distribution and commercialization partner network. Advanz Pharma's product portfolio and pipeline comprises innovative medicines, biosimilars & specialty generics,

and originator brands. Our products cover a broad range of therapeutic areas, including hepatology, rheumatology, gastroenterology, anti-infectives, critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Our ambition is to be a partner of choice for the commercialization of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. In line with our ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to our dedicated and highly qualified employees, acting in line with our company values of entrepreneurship, speed, and integrity.

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.

Advanz Pharma Forward Looking Statements

Certain statements in this press release are forward-looking statements. These statements may be identified by words such as "anticipate", "expectation", "belief", "estimate", "plan", "target", "project", "will", "may", "should" or "forecast" and similar expressions, or by their context. Although Advanz Pharma believes that these assumptions were reasonable when made, by their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial consequences of the plans and events described herein. Actual results may differ from those set forth in the forward-looking statements as a result of various factors (including, but not limited to, future global economic conditions, changed market conditions affecting the industry, intense competition in the markets in which Advanz Pharma operates, costs of compliance with applicable laws, regulations and standards, diverse political, legal, economic and other conditions affecting Advanz Pharma's markets, and other factors beyond the control of Advanz Pharma. Neither Advanz Pharma nor any of its directors, officers, employees, advisors, or any other person is under any obligation to update or keep current the information contained in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You should not place undue reliance on forward-looking statements, which speak of the date of this press release. Statements contained in this press release regarding past trends or events should not be taken as a representation that such trends or events will continue in the future. No obligation is assumed to update any forward-looking statements. The information contained in this press release is provided as at the date of this document and is subject to change without notice.

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