Alvotech Announces Marketing Approval in Japan of Three New Biosimilars

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REYKJAVIK, Iceland, Sept. 19, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced that its commercialization partner in Japan, Fuji Pharma Co., Ltd. ("Fuji Pharma"), has received marketing approval for three new biosimilars from the Japanese Ministry of Health, Labor and Welfare. The biosimilars approved for the Japanese market are AVT03, a biosimilar to Ranmark® (denosumab), AVT05, a biosimilar to Simponi® (golimumab) and AVT06, a biosimilar to Eylea® (aflibercept). Based on publicly available information, AVT05 is the first golimumab biosimilar to be approved for sale in major markets globally.

"We are thrilled to receive marketing approvals for three additional biosimilars in Japan, after our successful launch last year with Fuji Pharma of our biosimilar to Stelara®," said Robert Wessman, chairman and CEO of Alvotech. "We look forward to increasing access in Japan to these vital biologic medicines and serve the growing need for quality biologics that can lower the cost of treating patients with chronic diseases."

AVT03, approved in Japan as DENOSUMAB BS 120 mg/1.4 mL in a vial for subcutaneous injection, is a biosimilar to Ranmark® (denosumab), which is marketed in some other countries globally as Xgeva® (denosumab). The biosimilar is approved in Japan for treatment of bone lesions due to multiple myeloma or due to metastases of solid tumors.

AVT05, approved in Japan as GOLIMUMAB BS 50 mg PFS for subcutaneous injection, is a biosimilar to Simponi® (golimumab). The biosimilar is approved in Japan for treatment of Rheumatoid Arthritis (including prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments.

AVT06, approved in Japan as AFLIBERCEPT BS 40 mg/mL solution in PFS for IVT injection and 40 mg/mL vial kit for IVT injection, is a biosimilar to Eylea® (aflibercept). The biosimilar is approved in Japan for treatment of Age-related Macular Degeneration associated with subfoveal choroidal neovascularization, Macular Oedema secondary to retinal vein occlusion and choroidal neovascularization in pathologic myopia.

In May 2024, Alvotech and Fuji Pharma launched the first biosimilar to Stelara® (ustekinumab) in Japan. The partnership agreement between Alvotech and Fuji Pharma was announced in November 2018. In addition to the four approved biosimilars, Alvotech has also licensed commercial rights in Japan to Fuji Pharma for two biosimilar candidates currently under development.

Use of trademarks
Ranmark® is a registered trademark of Daiichi Sankyo, Xgeva® is a registered trademark of Amgen, Stelara® and Simponi® are a registered trademarks of Johnson and Johnson, Eylea® is a registered trademark of Bayer AG.

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

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 or operating performance of Alvotech and may include, for example, Alvotech's expectations regarding future growth, results of operations, performance, future capital and other expenditures, 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 review and interactions, the satisfactory responses to the FDA's inspection findings and resolution of other deficiencies conveyed following the re-inspection of Alvotech's manufacturing site, the potential approval, by the FDA and other regulatory agencies and commercial launch of its product candidates, the timing of the announcement of clinical study results, the commencement of patient studies, regulatory applications, approvals and market launches, and the estimated size of the total addressable market of Alvotech's pipeline products. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential" 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 reach development milestones under commercial partnership agreements including the partnership with Fuji Pharma; (2) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing; (4) changes in applicable laws or regulations; (5) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (6) Alvotech's estimates of expenses and profitability; (7) Alvotech's ability to develop, manufacture and

commercialize the products and product candidates in its pipeline; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners, including Fuji Pharma, to gain approval from regulators for planned clinical studies, study plans or sites; (12) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) 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; (14) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements, including the partnership with Fuji Pharma; (15) Alvotech's ability, and that of its commercial partners, including Fuji Pharma, to execute their commercialization strategy for approved products; (16) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (18) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, on Alvotech's business, financial position, strategy and anticipated milestones; and (19) 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.

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