



Alvotech and Fuji Pharma Expand Partnership Adding a New Biosimilar Candidate

January 13, 2023

REYKJAVIK, Iceland and TOKYO, Jan. 13, 2023 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and Japanese pharmaceutical company Fuji Pharma Co., Ltd. ("Fuji", Tokyo Stock Exchange: 4554) have decided to expand their existing exclusive commercialization partnership covering Japan, by adding a new undisclosed biosimilar candidate.

"We are pleased to expand our successful collaboration with Fuji. Just recently, we announced the submission of an application for marketing approval in Japan for the first biosimilar candidate developed under our partnership," said Robert Wessman, Founder, CEO and Chairman of Alvotech.

"This extension to our existing agreement aligns with our common objective, which is to increase patient access to vital biologic medicines in the growing Japanese market," said Takayuki Iwai, Fuji's President and CEO.

The exclusive partnership agreement was first announced by Alvotech and Fuji in [November 2018](#), and previously extended in [December 2020](#) and [February 2022](#), now covering seven biosimilars including the new candidate, to be developed and manufactured by Alvotech, and commercialized by Fuji in Japan. In [October 2022](#) the partners announced the submission of an application to the Japanese Ministry of Health, Labor and Welfare for marketing approval of the first biosimilar candidate developed under the companies' partnership.

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 contains eight 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), 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 Fuji Pharma

Fuji Pharma Co., Ltd. is a Tokyo Stock Exchange (TSE) listed, Japan-based pharmaceutical company mainly engaged in the manufacture and sale of prescription based pharmaceutical products. Fuji Pharma focuses on development and commercialization of hormone medicines for obstetrics and gynecology therapies, as well as injectable drugs including diagnostic pharmaceutical products. Fuji Pharma was among the pioneers in Japan to develop and obtain biosimilar approval in Japan for G-CSF in 2013. In its Mid-Term Business Plan (FY9/2020-9/2024), Fuji Pharma aims to become the No. 1 biosimilar manufacturer in Japan by FY9/2029.

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. For example, Alvotech's expectations regarding 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 success of its commercial partnerships, including its partnership with Fuji, the potential approval and commercial launch of its product candidates, the timing of regulatory approvals and market launches, the estimated size of the total addressable market of Alvotech's pipeline products, and commercial success in Japan and other countries. 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 outcome of any legal proceedings that may be instituted against Alvotech or others following the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech; (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 expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (8) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (9) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (10) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (11) the ability of Alvotech or its partners to obtain and maintain regulatory approval or authorizations of its products, including in Japan; (12) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements, including the partnership with Fuji; (13) Alvotech's ability, and that of its commercial partners, including Fuji, to execute their commercialization strategy for approved products; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (15) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (16) the potential impact of the ongoing COVID-19 pandemic on the review timelines of regulators, including the Japanese Ministry of Health, Labor and Welfare, including its ability to complete timely inspection of manufacturing sites; and

(17) 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.

CONTACTS

Alvotech Investor Relations and Global Communications

Benedikt Stefansson

[alvotech.ir\[at\]alvotech.com](mailto:alvotech.ir[at]alvotech.com)