# Teva Pharmaceuticals and Alvotech Provide Update on Strategic Biosimilars Partnership

July 24, 2023

TEL AVIV, Israel and PARSIPPANY, N.J. and REYKJAVIK, Iceland, July 24, 2023 (GLOBE NEWSWIRE) -- Teva Pharmaceuticals, Inc., a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), a global leader in generic and innovative medicines and Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced that they have agreed to expand their existing strategic partnership agreement. Teva will also acquire subordinated convertible bonds to be issued by Alvotech.

The partners continue working closely on matters concerning pending approval in the U.S. for AVT02, an interchangeable high-concentration biosimilar candidate for Humira® (adalimumab). The existing strategic partnership agreement also includes four other biosimilar candidates, one of which is AVT04, a proposed biosimilar for Stelara® (ustekinumab), which is currently pending U.S. Food and Drug Administration (FDA) approval.

The expansion to the existing strategic partnership agreement pertains to exclusive commercialization in the U.S. by Teva of two new biosimilar candidates and line extensions of two current biosimilar candidates in the partnership, to be developed, and manufactured by Alvotech. The agreement includes milestone payments, the majority paid following product approvals and upon achieving significant sales milestones. Teva and Alvotech will share profit from the commercialization of the biosimilars. All other financial terms and product details remain confidential.

The agreement also includes increased involvement by Teva regarding manufacturing and quality at Alvotech's manufacturing facility. Teva is actively supporting Alvotech on-site in Iceland to be fully ready for an FDA inspection.

Teva has agreed to acquire subordinated convertible bonds to be issued by Alvotech pursuant to a convertible bond instrument, dated December 20, 2022, for $40 million. Teva's investment will be used by Alvotech as part of the funding for continued development of its biosimilars pipeline over the near-term.

"We welcome Teva's continued partnership and this expansion of our partnership agreement," said Robert Wessman, Chairman and CEO of Alvotech. "We remain focused on preparing for a successful pre-approval inspection and resolving any outstanding issues identified by the FDA to be able to bring our biosimilar candidates to patients in the U.S. with Teva as soon as possible."

"Teva remains fully committed to its leadership in biosimilars and the partnership with Alvotech," said Sven Dethlefs, Executive Vice President, North America Commercial. "We remain optimistic about additional compounds in the pipeline and continued progress with AVT02 and ATV04."

**About AVT02**

AVT02 is a monoclonal antibody and has been approved as a biosimilar to Humira® (adalimumab) in several countries globally, including the 27 member states of the European Union, Norway, Lichtenstein, Iceland, the UK, Switzerland, Canada, Australia, and Saudi Arabia. It is currently marketed in multiple European countries and in Canada. Dossiers are also under review in multiple countries globally.

**About AVT04 (ustekinumab)**

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara® (ustekinumab). Ustekinumab binds to two cytokines, IL-12 and IL-23, that are involved in inflammatory and immune responses [1]. AVT04 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. Stelara is a registered trademark of Johnson & Johnson.

[1] https://www.janssenlabels.com/package-insert/product-monograph/prescribinginformation/STELARA-pi.pdf

**No Offer**

This communication is not a public offer of securities for sale in the United States. This communication is for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy any securities in the United States or elsewhere, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction.

**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.

**About Teva**

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people's lives for more than a century. We are a global leader in generic and innovative medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day and are served by one of the largest and most complex supply chains in

the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of innovative medicines and biopharmaceutical products. Learn more at www.tevapharm.com.

**Forward Looking Statements (Alvotech)**

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 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, including the resubmission of a BLA for AVT02 and a potential reinspection of Alvotech's manufacturing facility, the satisfactory responses to the FDA's inspection findings and resolution of other deficiencies conveyed following the inspection of Alvotech's manufacturing site, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, including for AVT04, and market launches, the estimated size of the total addressable market of Alvotech's pipeline products, the availability of financing options, including the size, timeline, securities, terms and conditions of, and use of proceeds from, a potential financing. 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 raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing standards; (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) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (9) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners 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; (15) Alvotech's ability, and that of its commercial partners, 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 potential impact of the ongoing COVID-19 pandemic on the FDA's review timelines, including its ability to complete timely inspection of manufacturing sites; (19) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, and the ongoing and evolving COVID-19 pandemic on the Company's business, financial position, strategy and anticipated milestones; and (20) 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. 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**Forward Looking Statements (Teva)**

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 the expansion of our strategic partnership with Alvotech and the ability to achieve expected results from investments in biosimilar candidates including to obtain U.S. regulatory approval for AVT02 the proposed biosimilar to Humira® and AVT04, the proposed biosimilar to Stelara® (ustekinumab), as well as from the investment in Alvotech's subordinated convertible bonds; our ability to successfully compete in the marketplace, including our ability to develop and commercialize biopharmaceutical products, competition for our innovative medicines, including AUSTEDO®, AJOVY® and COPAXONE®, our ability to achieve expected results from investments in our product pipeline, our ability to develop and commercialize additional pharmaceutical products, and the effectiveness of our patents and other measures to protect our intellectual property rights; our substantial indebtedness which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us; our business and operations in general, including, the impact of global economic conditions and other macroeconomic developments and the governmental and societal responses thereto, and costs and delays resulting from the extensive pharmaceutical regulation to which we are subject; compliance, regulatory and litigation matters, including failure to comply with complex legal and regulatory environments; other financial and economic risks; and other factors discussed in our Quarterly Report on Form 10-Q for the first quarter of 2023 and in our Annual Report on Form 10-K for the year ended December 31, 2022, 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.

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