Alvotech Announces Australian Marketing Authorization for AVT02, a Biosimilar to Humira®

November 14, 2022

- *Increases availability of cost-effective high-concentration low-volume adalimumab in Australia*
- *First approved biosimilar from the partnership with Cipla, which also includes four other biosimilar candidates*

REYKJAVIK, Iceland and MUMBAI, India, Nov. 14, 2022 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide announced today that the Therapeutic Goods Administration of Australia has granted marketing authorization to Cipla Australia Pty Ltd ("Cipla") for Alvotech's AVT02, a high-concentration low-volume biosimilar to Humira® (adalimumab).

Alvotech's biosimilar to Humira ® (adalimumab) is approved in Australia for marketing as a 40 mg/0.4 mL and 80 mg/0.8 mL solution in a pre-filled syringe and 40 mg/0.4 mL solution in a pre-filled pen, designed with the ease of patients in mind. In Australia, the biosimilar will be marketed as Ciptunec™ and Ardalicip™.

"We are very pleased about the marketing authorization in Australia, following approval and successful launches of Alvotech's high concentration biosimilar to Humira® in multiple markets in Europe and Canada. As we are dedicated to improving global access to affordable biologics, we welcome this step in our journey," said Mark Levick, CEO of Alvotech.

"The first approved biosimilar in Cipla's partnership with Alvotech marks an important milestone. We look forward to extending our footprint in the biosimilars market by increasing the availability of cost-effective high-concentration low-volume adalimumab for Australian patients," said Nishant Saxena, CEO, International Business (Europe & Emerging Markets), of Cipla.

This is the first approved biosimilar from an exclusive commercialization partnership between Alvotech and Cipla, announced in July 2019. In November 2020, the partners extended their partnership to South Africa and in January 2021, the partners entered into an additional license and supply agreement for Australia and New Zealand for four biosimilar other candidates under development by Alvotech targeting immunology, ophthalmology, oncology, and bone disease.

About AVT02 / Ciptunec™ / Ardalicip™ (adalimumab)

AVT02, marketed as Ciptunec / Ardalicip in Australia, is a monoclonal antibody and approved biosimilar to Humira® (adalimumab), which inhibits tumor necrosis factor. Approved indications for Ciptunec / Ardalicip in Australia include rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease in adults and children (≥ 6 years; weighing ≥ 40 kg), ulcerative colitis, psoriasis in adults and children, hidradenitis suppurativa in adults and adolescents (from 12 years of age) and uveitis. The same biosimilar has been approved in the EU, Norway, Iceland, Lichtenstein, the UK, Switzerland as Hukyndra®; and in Canada and Saudi Arabia as Simlandi™. Dossiers are under review in multiple countries, including in the United States.

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.

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 1955, 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 review and interactions, the success of its commercial partnerships, including its partnership with Cipla, potential milestone and royalty payments, 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 the announcement of clinical study results, regulatory approvals and market launches, including in Australia, and the estimated size of the total addressable market of Alvotech's pipeline products, and the commercial success of Ciptunec/Ardalicip, in Australia and other countries, and Alvotech's ability to improve global access to affordable biologics. 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 including Ciptunec/Ardalicip; (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 respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (10) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (11) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (12) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including Ciptunec/Ardalicip, including the timing or likelihood of expansion into additional markets or geographies; (13) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements, including the partnership with Cipla; (14) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products, including Ciptunec/Ardalicip; (15) Alvotech's ability to manufacture sufficient commercial supply of its approved products, including Ciptunec/Ardalicip; (16) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (17) 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; and (18) 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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