STADA and Alvotech secure approval for Uzpruvo, Europe's first ustekinumab biosimilar to Stelara

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- Marketing authorization issued in European Economic Area for Uzpruvo®, the first biosimilar to Stelara®, a biologic therapy within gastroenterology, dermatology, and rheumatology
- Authorization paves way for biosimilar competition in the approximately €2.5 billion (US$2.7 billion) EU ustekinumab market as soon as possible after expiry of intellectual-property rights in July 2024
- Approval for the Uzpruvo biosimilar is based on comprehensive package comprising analytical, non-clinical and clinical similarity data, including the AVT04-GL-301 confirmatory comparative efficacy and safety clinical trial in patients with moderate to severe chronic plaque-type psoriasis

BAD VILBEL, Germany and REYKJAVIK, Iceland, Jan. 10, 2024 (GLOBE NEWSWIRE) -- Partners STADA and Alvotech today announced that the European Commission issued a marketing authorization for Uzpruvo® (AVT04), a biosimilar candidate to Stelara® (ustekinumab). The centralized marketing authorization for Europe's first ustekinumab biosimilar is valid in all European Economic Area (EEA) countries, including the 27 European Union (EU) Member States as well as in Iceland, Liechtenstein, and Norway.

This European marketing authorization for Uzpruvo paves the way for market entry as soon as possible, following the expiry in July 2024 of a European Supplementary Protection Certificate (SPC) for Stelara.

Biosimilar competition in the €2.5 billion (US$2.7 billion) EU ustekinumab market could significantly expand patient access to this life-changing biologic therapy within gastroenterology, dermatology, and rheumatology.

STADA's Global Specialty Head, Bryan Kim, commented: "This first marketing authorization for biosimilar ustekinumab in Europe offers the potential to expand substantially patient access through competition. By adding to our current roster of six marketed biosimilars, STADA looks forward to offering Europe's gastroenterologists, dermatologists, and rheumatologists a further cost-effective treatment option."

Anil Okay, Chief Commercial Officer of Alvotech, remarked: "We look forward to spearheading biosimilars competition in the ustekinumab market and increasing patient access to biologic therapies for inflammatory conditions as we have done with our adalimumab biosimilar, launched last year."

The European Commission's decision to issue a marketing authorization came after the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency's (EMA) in November 2023 adopted a positive opinion on approving Uzpruvo with the indications Crohn's disease, psoriasis and psoriatic arthritis.

Under a strategic partnership begun in 2019, Alvotech is primarily responsible for developing and manufacturing the AVT04 ustekinumab biosimilar. STADA holds commercial rights within Europe, where the company already markets six approved biosimilars, including in gastrointestinal, dermatology and rheumatology indications. These include a high-concentration, citrate-free adalimumab biosimilar developed and marketed through the partnership between Alvotech and STADA.

In February 2023, the partners announced that that the EMA had accepted their marketing authorization application for AVT04, based on a comprehensive package of analytical and clinical data. This included data from the AVT04-GL-301 confirmatory clinical, safety and efficacy study that met its primary endpoint, with results demonstrating therapeutic equivalence between AVT04 and Stelara in patients with moderate to severe chronic plaque-type psoriasis. Pharmacokinetic similarity was demonstrated in the AVT04-GL-101 study.

Ustekinumab is a human IgG1κ monoclonal antibody (mAb). Uzpruvo is produced in Sp2/0 cells using the perfusion process, like the reference product Stelara. Ustekinumab selectively targets the p40 protein, a component common to both IL-12 and IL-23 cytokines that play crucial roles in treating immune-mediated diseases like Crohn's disease, psoriasis and psoriatic arthritis.

With around 95,000 patients already using ustekinumab in the top-4 EU markets plus the UK, Stelara ranks among Europe's top-10 medicine brands by value with annual sales in excess of €2.5 billion (US$2.7 billion). Biosimilar competition upon expiry of EU exclusivity rights for Stelara offers a significant opportunity to improve patient access at the same, or even lower, costs to European healthcare systems.

About STADA Arzneimittel AG
STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2022, STADA achieved group sales of EUR 3,797.2 million and reported earnings before interest, taxes, depreciation, and amortization (EBITDA) of EUR 884.7 million. As of 31 December 2022, STADA employed 13,183 people worldwide.

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), Advanz Pharma (EEA), 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 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 STADA, potential milestone and royalty payments, the potential approval and commercial launch of its product candidates, the timing of regulatory approvals and market launches, including in Europe, and the estimated size of the total addressable market of Alvotech's pipeline products, and the commercial success of AVT04, in Europe and other parts of the world, Alvotech's ability to improve global access to affordable biologics, and the effect of biosimilars on inflationary pressures for healthcare systems. 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) changes in applicable laws or regulations; (3) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (4) Alvotech's estimates of expenses and profitability; (5) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline, including AVT04; (6) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (7) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (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) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including AVT04, including the timing or likelihood of expansion into additional markets or geographies; (12) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements, including the partnership with STADA; (13) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products, including AVT04; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products, including AVT04; (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 FDA's review timelines, 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. 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