STADA and Alvotech launch Uzpruvo, the first approved ustekinumab biosimilar to Stelara, across Europe

July 22, 2024

- Launch of European-made Uzpruvo in Europe comes immediately upon expiry of exclusivity rights for the molecule used to treat certain conditions in gastroenterology[1], dermatology and rheumatology
- Creates competition at earliest opportunity, enabling straightforward switching to broaden patient access and control costs in a growing market, with accessible indications currently estimated at approximately €2.4 billion
- Ustekinumab is the second immunology biosimilar brought to market through the partnership between STADA and Alvotech, following the 2022 launch of the Hukyndra high-concentration adalimumab brand

BAD VILBEL, Germany and REYKJAVIK, Iceland, July 22, 2024 (GLOBE NEWSWIRE) -- STADA and Alvotech have launched Uzpruvo®, the first approved biosimilar to Stelara® in Europe, across a majority of European countries. This includes the largest markets in the region, where pricing and reimbursement approvals have been secured for market entry. The pioneering launch comes immediately upon expiry of exclusivity rights linked to the European reference molecule patent, offering patients, physicians and payers expanded access at the earliest possible opportunity to a life-altering medicine used in certain indications within gastroenterology[1], dermatology and rheumatology. Launches in further European countries are scheduled over the coming months, following national price approvals, via a fully European supply chain.

“Launching Uzpruvo at the earliest opportunity in Europe’s largest pharmaceutical markets, promotes access by creating competition,” stated STADA CEO Peter Goldschmidt. “This opportunity to improve patient access through wider usage of a life-changing biological treatment emphasizes STADA’s purpose of Caring for People’s Health as a Trusted Partner.”

“We are delighted at the launch of Uzpruvo in Europe and to be first-to-market,” commented Robert Wessman, Chief Executive Officer of Alvotech. “This launch symbolizes the robustness of our platform, the value of our partnership with STADA, and our collective focus on the importance of biosimilars.”

In January 2024, Uzpruvo became the first ustekinumab biosimilar to be approved by the European Commission as having equivalent efficacy, safety, pharmacokinetics and immunogenicity to the Stelara® reference product.[2] Uzpruvo is indicated for Crohn’s disease and psoriatic arthritis in adults, as well as plaque psoriasis in adults and children aged from 6 years. Uzpruvo® is currently not approved for the ulcerative colitis indication, since the originator still has exclusivity for this indication.

Uzpruvo is offered in a pre-filled syringe format featuring a thinner needle than the reference product and is latex-free to minimize the risk of allergic reactions. Uzpruvo was developed, and is manufactured and packaged, entirely within Europe, and has a 36-month shelf life.

“With comparable safety, efficacy and immunogenicity, Uzpruvo gives clinicians an opportunity for a seamless and simple switch for their patients, who can benefit from a thinner needle and latex-free syringe,” commented STADA’s Global Specialty Head, Bryan Kim. “Physicians and patients can have full confidence that STADA has more than 15 years of experience in enhancing patient access through high-quality biosimilars in Europe, having launched our first biosimilar in 2008.”

Ustekinumab is the second immunology biosimilar brought to market through the strategic partnership between STADA and Alvotech, following the 2022 launch of the Hukyndra high-concentration, citrate-free adalimumab therapy. The partners also recently announced a development, manufacturing and marketing alliance for a proposed biosimilar to Prolia®/Xgeva® (denosumab) candidate, AVT03. Alvotech is responsible for development and manufacturing of biosimilars within the partnership at its facility in Reykjavik, Iceland, that benefits from nearly 100% domestically produced renewable energy, including geothermal and hydroelectric power which is aligned with both companies’ core commitments to sustainability.

Overall, Uzpruvo is STADA’s seventh biosimilar supplied in Europe, with the German group also offering biosimilars in the bone health, nephrology, oncology and ophthalmology therapeutic sectors, alongside differentiated specialty therapies in nephrology and neurology.

Alvotech is a global leader in the biosimilar space and boasts a portfolio and pipeline of 11 biosimilars and biosimilar candidates covering a wide variety of indications. Alvotech, through its partnership network has now launched biosimilar to Stelara in Canada, Japan, and now in Europe.

About STADA Arzneimittel AG
STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 115 countries. In financial year 2023, STADA achieved group sales of EUR 3,735 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 802 million. As of 31 December 2023, STADA employed 11,667 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 has launched two biosimilars. The current development pipeline includes nine 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), Dr. Reddy's (US, EU), 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 its ability to satisfy conditions precedent to close the transaction and draw down the loan, to comply with the covenants of the Facility and to exercise its rights under the facility, the expected use of proceeds from the Facility, potential future financings or strategic transactions, Alvotech's competitive advantages, business prospects and opportunities including product launches, pipeline product development, revenue and diversification, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, regulatory submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, and market launches. 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 ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (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 revenue, expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (8) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (9) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (10) 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; (11) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (12) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (13) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (14) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (15) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, conflicts in Ukraine, the Middle East and other global geopolitical tension, on the Company's business, financial position, strategy and anticipated milestones; (16) Alvotech's ability to meet the conditions precedent to close Facility and comply with the covenants of the Facility 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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[1] Uzpruvo® is currently not approved for the ulcerative colitis indication, since the originator still has exclusivity for this indication

[2] Union Register of medicinal products - Public health - European Commission (europa.eu)