# Pressemitteilung

## EMA bestätigt die Annahme des Antrags für AVT04, ein vorgeschlagenes Biosimilar zu Stelara® (Ustekinumab)

- Die Partner Alvotech und STADA haben den Zulassungsantrag (MAA) für Ustekinumab zur Einreichung bei der Europäischen Arzneimittelagentur (EMA) angenommen
- EMA-Stellungnahme zu AVT04 könnte bereits in der zweiten Hälfte des Jahres 2023 erfolgen
- Die Referenzmarke Stelara® (Ustekinumab) wird zur Behandlung einer Reihe von entzündlichen Erkrankungen verschrieben

**Reykjavik, Island & Bad Vilbel, Deutschland – 9. Februar 2023 -** Alvotech (NASDAQ: ALVO), ein globales Biotech-Unternehmen, das sich auf die Entwicklung und Herstellung von Biosimilar-Arzneimitteln für Patienten weltweit spezialisiert hat, und das internationale Pharmaunternehmen STADA gaben heute bekannt, dass die Europäische Arzneimittel-Agentur (EMA) den Zulassungsantrag für AVT04, Alvotechs vorgeschlagenes Biosimilar zu Stelara® (Ustekinumab), angenommen hat. Die Unternehmen gehen davon aus, dass die EMA bereits in der zweiten Jahreshälfte 2023 eine Empfehlung für die Marktzulassung von AVT04 abgeben könnte.

"Wir freuen uns, dass wir der Bereitstellung von AVT04 für Patienten in Europa einen Schritt nähergekommen sind", sagte Joseph McClellan, Chief Scientific Officer von Alvotech. "Unser Ziel ist es, den wachsenden Bedarf an einem breiteren Zugang zu erschwinglichen biologischen Arzneimitteln zu decken, und Alvotechs End-to-End-Plattform für Biosimilars ist darauf ausgelegt, die Entwicklung und Herstellung mehrerer Produkte gleichzeitig zu unterstützen."

"Die Zulassung durch die EMA ist ein wichtiger Meilenstein, um Patienten und Ärzten in Europa eine zusätzliche Behandlungsoption für entzündliche Erkrankungen zur Verfügung zu stellen", kommentierte Bryan Kim, Head of Specialty bei STADA. "Die Zulassung von Ustekinumab würde die umfangreiche Palette von sechs zugelassenen Biosimilars von STADA in Europa ergänzen, ein Portfolio, zu dem auch eine hochkonzentrierte, zitratfreie Version von Adalimumab gehört, die wir im Rahmen unserer strategischen Partnerschaft mit Alvotech auf den Markt gebracht haben."

Im November 2019 gaben Alvotech und STADA eine strategische Partnerschaft zur Vermarktung von acht von Alvotech entwickelten Biosimilar-Kandidaten in Europa bekannt. Im Dezember 2022 hatten die Unternehmen mit hochkonzentriertem Adalimumab die Vermarktung und den Vertrieb des ersten Biosimilars der Partnerschaft in 16 Ländern in Europa aufgenommen.

Im Mai 2022 gab Alvotech bekannt, dass eine bestätigende klinische Sicherheits- und Wirksamkeitsstudie für AVT04 ihren primären Endpunkt erreicht hat, indem sie die therapeutische Äquivalenz zwischen Alvotechs Biosimilar-Kandidat und dem Referenzprodukt bei Patienten mit mittelschwerer bis schwerer chronischer Psoriasis vom Plaque-Typ nachgewiesen hat.  Anfang Mai 2022 gab Alvotech außerdem positive Ergebnisse einer pharmakokinetischen (PK) Ähnlichkeitsstudie für AVT04 bekannt.

* Stelara® ist eine eingetragene Marke von Johnson & Johnson

**Über AVT04 (Ustekinumab)**
AVT04 ist ein monoklonaler Antikörper und ein Biosimilar-Kandidat zu Stelara® (Ustekinumab). Ustekinumab bindet an zwei Zytokine, IL-12 und IL-23, die an Entzündungs- und Immunreaktionen beteiligt sind [1]. AVT04 ist ein Prüfpräparat und hat in keinem Land eine Zulassung erhalten. Die Biosimilarität wurde von den Zulassungsbehörden nicht festgestellt und wird auch nicht behauptet.

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

**Über die STADA Arzneimittel AG**
Die STADA Arzneimittel AG hat ihren Sitz im hessischen Bad Vilbel. Das Unternehmen setzt auf eine Drei-Säulen-Strategie bestehend aus Generika, Spezialpharmazeutika und Consumer Healthcare Produkte. Weltweit vertreibt die STADA Arzneimittel AG ihre Produkte in rund 120 Ländern. Im Geschäftsjahr 2021 erzielte STADA einen Konzernumsatz von 3.249,5 Millionen Euro und ein Ergebnis vor Zinsen, Steuern und Abschreibungen (EBITDA) von 776,5 Millionen Euro. Zum 31. Dezember 2021 beschäftigte STADA weltweit 12.520 Mitarbeiter.

**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.

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pipeline products, 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. 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) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (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 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 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; (14) Alvotech’s ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (15) Alvotech’s ability to manufacture sufficient commercial supply of its approved products; (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; (18) 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 (19) 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

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