EMA Confirms Acceptance of Application for AVT04, a Proposed Biosimilar to Stelara® (ustekinumab)

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BAD VILBEL, HESSEN, GERMANY, February 9, 2023 /EINPresswire.com/ -- EMA Confirms Acceptance of Application for AVT04, a Proposed Biosimilar to Stelara® (ustekinumab)

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>
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- EMA opinion on AVT04 could come as soon as the second half of 2023
- Reference brand Stelara® (ustekinumab) is prescribed to treat a variety of inflammatory conditions

Reykjavik, Iceland & Bad Vilbel, Germany – 9 February 2023 – Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and global pharmaceutical company STADA today announced that the European Medicines Agency (EMA) has accepted a Marketing Authorization Application for AVT04, Alvotech's proposed biosimilar to Stelara® (ustekinumab). The companies anticipate that the EMA could give recommend approving a marketing authorization for AVT04 as soon as in the second half of 2023.

"We are pleased to be able to progress closer to making AVT04 available to patients in Europe," said Joseph McClellan, Chief Scientific Officer of Alvotech. "Our goal is to meet an increasing need for broader access to affordable biologic medicines and Alvotech's end-to-end biosimilars platform is designed to support the development and manufacture of multiple products simultaneously."

"The EMA's acceptance for filing marks a key milestone in making an additional treatment option for inflammatory conditions available to patients and physicians in Europe," commented STADA's Head of Specialty, Bryan Kim. "Authorization for ustekinumab would add to STADA's extensive

range of six approved biosimilars in Europe, a portfolio that includes a high-concentration, citrate-free of adalimumab brought to market through our strategic partnership with Alvotech."

In November 2019, Alvotech and STADA announced a strategic partnership to commercialize eight biosimilar candidates developed by Alvotech in Europe. As of December 2022, the companies had launched marketing and sales of the first biosimilar in the partnership, high-concentration adalimumab, in 16 countries in Europe.
In May 2022, Alvotech announced that a confirmatory clinical, safety and efficacy study for AVT04 had met its primary endpoint, in demonstrating therapeutic equivalence between Alvotech's biosimilar candidate and the reference product in patients with moderate to severe chronic plaque-type psoriasis. Earlier in May 2022, Alvotech also announced positive top-line results from a pharmacokinetic (PK) similarity study for AVT04.

* Stelara® is a registered trademark of Johnson & Johnson

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.

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

About STADA Arzneimittel AG
STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and non-prescription consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2021, STADA achieved group sales of EUR 3,249.5 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 776.5 million. As of 31 December 2021, STADA employed 12,520 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), 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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