

# Alvotech and Advanz Pharma Sign Commercialization Agreement for Proposed Biosimilar to Eylea® LD/HD in Europe

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- Advanz Pharma secures rights to commercialize Alvotech's biosimilar candidate for Eylea <sup>®</sup> in Europe
- Advanz Pharma will leverage its existing specialty and hospital capabilities in Europe to ensure successful market registration, commercialization, and patient access

REYKJAVIK, Iceland and LONDON, June 18, 2024 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide and Advanz Pharma, a UK headquartered global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines in Europe, today announced that the companies have entered into an exclusive partnership agreement regarding the supply and commercialization of Alvotech's proposed biosimilar to Eylea<sup>®</sup> (aflibercept). Alvotech is currently developing AVT06, a proposed biosimilar to Eylea<sup>®</sup> low dose (2 mg) and AVT29, a biosimilar candidate for Eylea<sup>®</sup> high dose (8 mg).

Eylea<sup>®</sup> is a widely used biologic for the treatment of eye disorders, including diseases which can lead to vision loss or blindness, such as wet AMD, macular edema, and diabetic retinopathy. In 2023, reported sales of Eylea<sup>®</sup> in Europe were \$2.9 billion [1].

Under the agreement, Alvotech will be responsible for development and commercial supply of AVT06 and AVT29, and Advanz Pharma will be responsible for registration and commercialization. Advanz Pharma has exclusive commercialization rights in Europe, except for Germany and France where the rights are semi-exclusive. The commercialization agreement includes an upfront payment to Alvotech with subsequent payments upon certain development and commercialization milestones.

"We value our growing partnership with Advanz Pharma which started early last year and has now been expanded to a total of seven biosimilar candidates. We share a common vision for the growth of the biosimilars market and a strong commitment to providing broader patient access to more affordable biologics," said Anil Okay, Chief Commercial Officer of Alvotech.

Susanna El-Armale, Chief Corporate Development Officer at Advanz Pharma, said: "We are excited to reinforce our collaboration with Alvotech by adding an impactful and meaningful product to our growing pipeline. This partnership leverages our combined strengths and reinforces Advanz Pharma as a partner of choice for the commercialization of specialty pharmaceuticals in Europe."

In January 2024 Alvotech announced positive top-line results from a confirmatory patient study evaluating the efficacy, safety, and immunogenicity of AVT06 compared with Eylea<sup>®</sup> in patients with neovascular (wet) AMD. The study met its primary endpoint, with results demonstrating therapeutic equivalence between Alvotech's biosimilar candidate and Eylea<sup>®</sup>.

In February 2023 Alvotech and Advanz Pharma announced that the companies had entered into an exclusive agreement for the commercialization of AVT23, a proposed biosimilar to Xolair<sup>®</sup> (omalizumab). The agreement covers the European Economic Area, UK, Switzerland, Canada, Australia, and New Zealand. In May 2023 Alvotech and Advanz Pharma announced that the companies had expanded their partnership to include biosimilar candidates to Simponi<sup>®</sup> (golimumab) and Entyvio<sup>®</sup> (vedolizumab) and as well as three additional early-stage, undisclosed biosimilar candidates.

## About AVT06/AVT29

AVT06/AVT29 is a recombinant fusion protein and a biosimilar candidate to Eylea<sup>®</sup> (aflibercept), which binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [2]. AVT06/AVT29 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.

## Sources

[1] IQVIA sales data

[2] https://www.regeneron.com/downloads/evlea\_fpi.pdf

## **Use of Trademarks**

Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc. and Bayer AG

#### **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 includes eight 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), 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 fillings, disclosures and other reports made available by its partners. For more information, please visit <a href="https://www.alvotech.com">www.alvotech.com</a>. None of the

information on the Alvotech website shall be deemed part of this press release.

For more information please visit our investor portal, and our website or follow us on social media on LinkedIn, Facebook, Instagram, X and YouTube.

## **About Advanz Pharma**

Partner of choice in specialty, hospital, and rare disease medicines. Advanz Pharma is a global pharmaceutical company with the purpose to improve patients' lives by providing and enhancing the specialty, hospital, and rare disease medicines they depend on. Our headquarters are in London, UK. We have commercial sales in more than 90 countries globally and have a direct commercial presence in more than 20 countries, including key countries in Europe, the US, Canada, and Australia, a Centre of Excellence in Mumbai, India, as well as an established global distribution and commercialization partner network. Advanz Pharma's product portfolio and pipeline comprises innovative medicines, specialty generics & biosimilars, and originator brands. Our products cover a broad range of therapeutic areas, including hepatology, gastroenterology, anti-infectives, critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Our ambition is to be a partner of choice for the commercialization of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. In line with our ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to our dedicated and highly qualified employees, acting in line with our company values of entrepreneurship, speed, and integrity.

#### **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 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 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 expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (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 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 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; 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. 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Certain statements in this press release are forward-looking statements. These statements may be identified by words such as "anticipate", "expectation", "belief", "estimate", "plan", "target", "project", "will", "may", "should" or "forecast", and similar expressions, or by their context. Although ADVANZ believes that these assumptions were reasonable when made, by their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial consequences of the plans and events described herein. Actual results may differ from those set forth in the forward-looking statements as a result of various factors including, but not limited to, future global economic conditions, changed market conditions affecting the industry, intense competition in the markets in which Advanz operates, costs of compliance with applicable laws, regulations and standards, diverse political, legal, economic and other conditions affecting Advanz's markets, and other factors beyond the control of Advanz. Neither ADVANZ nor any of its directors, officers, employees, advisors, or any other person is under any obligation to update or keep current the information contained in this press release or revise any forward-looking statements, which speak of the date of this press release. Statements contained in this press release regarding past trends or events should not be taken as a representation that such trends or events will continue in the future. No obligation is assumed to update any forward-looking statements. The information contained in this press release is provided as at the date of this document and is subject to change without notice.

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