UK High Court Rules in Favor of Alvotech Paving Way for Manufacture and Market Entry of AVT06, biosimilar to Eylea® (aflibercept)

November 10, 2025

REYKJAVIK, Iceland, Nov. 10, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced today the outcome of expedited infringement proceedings before the UK High Court by Regeneron Pharmaceuticals Inc. ("Regeneron") and Bayer AG ("Bayer") against Alvotech and its contract manufacturing organization (CMO) in the United Kingdom. The court rejected Regeneron's and Bayer's injunction request in relation to manufacturing activities at Alvotech's CMO in the UK for Alvotech's biosimilar to Eylea ® (AVT06). The decision will support commercial launches of Alvotech's biosimilar in the European Economic Area, the UK and other countries after the expiry date for Supplementary Protection Certificates (SPCs) for Eylea®, which is November 23, 2025.

"The outcome of this case was never in doubt in my mind, but we are of course very pleased to have obtained this decision by the UK High Court. This will allow Alvotech to proceed with its manufacturing activities and supports bringing our biosimilar to Eylea to patients and caregivers in Europe and the rest of the world," said Robert Wessman chairman and CEO of Alvotech. "It took years to put an SPC waiver system in place, and it is very important for European biosimilars manufacturers that the waiver system is functional and not abused. An important objective is to bring biosimilars production and jobs back into Europe. This decision by the UK High Court is therefore not only a victory for Alvotech and its partners, but also for patients and caregivers in Europe and in the rest of the world who need better access to quality biologics."

The case focused on the issue of an SPC waiver exempting certain acts of third-party manufacturers from infringement. The SPC regulation provides that SPCs should not block manufacturing of biosimilars for stockpiling during six months before the SPC expiry, in support of product launches in the European Economic Area and the UK, as well as export to countries outside this region during the lifetime of the SPC. The decision of the UK High Court means that Alvotech and its CMO can continue to manufacture and store AVT06 in the UK, for later distribution in the UK, EEA and rest of the world.

Alvotech announced on August 21, 2025, that the European Commission had approved AVT06 as a biosimilar to Eylea®, for marketing in the European Economic Area. The UK Medicines and Healthcare products Regulatory Agency (MHRA) approved AVT06 for marketing in the UK on August 28, 2025.

About AVT06 (aflibercept)
AVT06 (aflibercept) is a recombinant fusion protein and has been approved in Japan, the United Kingdom and the European Economic Area as a biosimilar to Eylea® (aflibercept), which binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability [1]. Dossiers for AVT06, are currently under review in multiple countries globally, including the United States.

[1] AVT02 EEA product info

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. Two biosimilars, to Humira® (adalimumab) and Stelara® (ustekinumab) are already approved and marketed in multiple global markets. 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 (EEA, UK and US), Biogaran (FR), 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 https://www.alvotech.com. 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, and YouTube.

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 include, for example, Alvotech's expectations regarding competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, regulatory submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, market launches and financial projections. 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 factors 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 additional risks that Alvotech does not presently know or

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