



Alvotech announces completion of FDA surveillance inspection at Reykjavik facility

May 11, 2026

- **Company remains on track for BLA resubmissions in the second quarter**

REYKJAVIK, ICELAND – May 11, 2026 – Alvotech (NASDAQ: ALVO; ALVO-SDB), a global biotechnology company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announces that the U.S. Food and Drug Administration (FDA) has completed a routine cGMP surveillance inspection of the company's manufacturing facility in Reykjavik, Iceland.

At the conclusion of the inspection on May 8, 2026, the FDA issued a Form 483. The company believes the observations can be addressed quickly and do not raise any substantial issues with the site or its operations.

Based on the outcome of the inspection, Alvotech is well positioned to resubmit the relevant Biologics License Applications this quarter, once the final data have been compiled.

More importantly, the company believes the outcome of this inspection demonstrates the strong cGMP fundamentals of the site and the robustness of all the improvements the company has implemented since last year.

Alvotech continues to expect FDA approval for the relevant BLAs during 2026.

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About Alvotech

Alvotech is a biotechnology 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 biosimilars by delivering high-quality, cost-effective products and services, enabled by a fully integrated approach and broad in-house capabilities. Five biosimilars are already approved and marketed in multiple global markets, including biosimilars to Humira® (adalimumab), Stelara® (ustekinumab), Simponi® (golimumab), Eylea® (aflibercept) and Prolia®/Xgeva® (denosumab). 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. 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 that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, assurance, prediction or definitive statement of a fact or probability. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed.