Alvotech announces successful closure of FDA inspection of manufacturing facility

July 29, 2026

REYKJAVIK, ICELAND (July 29, 2026) — Alvotech (NASDAQ: ALVO; ALVO-SDB) (the "Company"), a global biotechnology company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced that the U.S Food and Drug Administration (FDA) has closed its inspection of the company's manufacturing facility in Reykjavik, Iceland, conducted in May 2026. The FDA has confirmed the inspection classification of the manufacturing site is Voluntary Action Indicated (VAI).

"This is an important milestone for Alvotech and reflects the significant work our teams have undertaken to further strengthen our quality systems and manufacturing operations," said Lisa Graver, CEO of Alvotech. "With the conclusion of the FDA's recent inspection, we are confident that the actions we have taken have effectively addressed the observations identified. We continue to work with the FDA to advance our recent Biologics Licence Applications towards approval."

Alvotech continues to advance its pipeline of biosimilar candidates. The company recently announced the resubmission of Biologics License Applications (BLAs) for AVT05, Alvotech's biosimilar to Simponi® (golimumab), and AVT06, Alvotech's biosimilar to Eylea® (aflibercept), and the acceptance by the FDA of the submission of a BLA for AVT16, Alvotech's proposed biosimilar to Entyvio® (vedolizumab) to the FDA in June 2026.

Alvotech continues to work closely with health authorities worldwide to bring high-quality, affordable biologic medicines to patients.

For further information, contact:

Media
Benedikt Stefansson
Sarah MacLeod
alvotech.media@alvotech.com

Investors
Dr. Balaji V Prasad (US)
Benedikt Stefansson (IS)
alvotech.ir@alvotech.com

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 the biosimilar space 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 13 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.

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

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