

Press Release



January 20, 2026
Fuji Pharma Co., Ltd.

Marketing Approval for new specification of Ustekinumab Biosimilar

— USTEKINUMAB BS 90 mg Syringe for S.C. Injection 「F」 —

Tokyo, Japan - Fuji Pharma Co., Ltd. ("Fuji") has announced that it has received marketing approval for a new specification of USTEKINUMAB biosimilar.

The newly approved drug, USTEKINUMAB BS 90mg Syringe for S.C. Injection 「F」 ("Product") contains a different active ingredient dosage compared to the USTEKINUMAB BS 45mg Syringe for S.C. Injection 「F」 launched in May 2024. Previously, only the product containing 45mg of the active ingredient was available. The Product contains double that amount, 90mg. This enables treatment with a single injection for patients requiring a 90mg dose of ustekinumab. Furthermore, as described above, this Product represents a new specification not found in the preceding biosimilar in Japan. It is part of our meaningful efforts to enhance patient convenience and improve efficiency in healthcare settings.

Aligned with our Mid-Term Business Plan (FY9/2020-9/2024), Fuji's objective is to become the top biosimilar manufacturer in Japan by FY9/2029. To that end, Fuji plans to broaden its biosimilar product range to serve the Japanese healthcare market, benefiting patients, medical professionals, and healthcare economics.

Therapeutic category	Product name	Original drug in Japan
Human anti-human IL-12/23p40 monoclonal antibody preparation	USTEKINUMAB BS 90mg Syringe for S.C. Injection 「F」	— (The specified unit)

This product was developed from the biosimilar pipeline agreed upon between Fuji Pharma and Alvotech (Headquarters: Iceland) in November 2018, as announced in the "[Submission of a Marketing Approval Application for the 1st Biosimilar Product Developed under Alvotech Partnership](#)" dated October 17, 2022.

[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 fourteen 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 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.

[Status of biosimilars agreed with Alvotech]



Note

The financial forecasts and other projections provided in this release are based on information available at the time of its compilation and it therefore contains an element of uncertainty and potential risks. Actual results may differ significantly from these forecasts for a number of reasons. It should also be noted that the views and/or facts presented here may be altered or deleted without prior notification. Information in this release about pharmaceuticals (including items in the pipeline) is not provided for the purpose of marketing or advertising or of supplying medical advice.

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