Announcement of Application for Manufacturing and Marketing Approval of Tocilizumab Biosimilar in Japan

This material is an English translation of the press release issued on March 26, 2025 in Japanese, and the Japanese release is given priority regarding content and interpretation.

March 26, 2025

Mochida Pharmaceutical Co., Ltd.
AYUMI Pharmaceutical Corporation

Mochida Pharmaceutical Co., Ltd. (Head office: Shinjuku-ku, Tokyo, President: Naoyuki Mochida, hereinafter “Mochida”) and AYUMI Pharmaceutical Corporation (Head office: Chuo-ku, Tokyo, President: Jugo Tsumura, hereinafter “AYUMI”) announce that today Mochida submitted an application for manufacturing and marketing approval of the Tocilizumab biosimilar (development code: RGB-19, hereinafter “the product”) to the Ministry of Health, Labour and Welfare.

The product is a Tocilizumab biosimilar jointly developed by Mochida and Gedeon Richter Plc. from Hungary. This application is based on the results of a Phase I clinical study conducted in Japan with 110 healthy adults and a Phase III clinical study conducted in Japan with 368 patients with rheumatoid arthritis. Both studies met their primary endpoints, demonstrating clinical equivalence between the product and the reference biologic.

Based on a collaboration agreement between Mochida and AYUMI for the domestic sales of the product, AYUMI will manage sales after obtaining manufacturing and marketing approval. Mochida and AYUMI have previously collaborated on the sales of the Etanercept biosimilar, launched in 2018, and the Adalimumab biosimilar, launched in 2021. Through the launch of the product, Mochida and AYUMI aim to expand treatment options for conditions such as rheumatoid arthritis and to meet the needs of patients and healthcare professionals.