

## Announcement of positive topline results for RGB-19, a biosimilar to Tocilizumab

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January 15, 2025

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Shinjuku-ku, Tokyo, President: Naoyuki Mochida, hereinafter “Mochida”) announces today positive topline results from Phase I and Phase III clinical studies conducted in Japan for a biosimilar of tocilizumab (development code: RGB-19).

The Phase I clinical study aimed to evaluate the equivalence of pharmacokinetics between RGB-19 and the reference biologic in healthy adult males. The Phase III clinical study was a multicenter efficacy and safety comparability study in patients with rheumatoid arthritis. Both studies met their primary endpoints, demonstrating clinical similarity between RGB-19 and the reference biologic.

RGB-19 has been developed jointly by Mochida and Gedeon Richter Plc. (Head office: Budapest, Hungary, CEO: Gábor Orbán, hereinafter “Richter”) and both clinical studies took place in Japan. Based on the results of the studies, Mochida expects to file for marketing authorization applications for RGB-19 in Japan, while Richter expects to do so in major global markets outside of Japan.

“It is our pleasure to announce the successful development of RGB-19 in collaboration with Richter. We have obtained positive results from clinical trials and believe that obtaining approval and launching RGB-19 will contribute to improving the quality of life for patients with rheumatoid arthritis and other conditions, as well as reducing their financial burden.” said Taiji Hayano, Executive Managing Officer, Head of Clinical Research and Development Division at Mochida.

“These clinical results, a proof of our successful collaboration with our highly respected partner, Mochida, underline the capability of our dedicated biosimilar platform. Our tocilizumab biosimilar is yet another important step to broaden our portfolio and upon approval it would further strengthen our offering of affordable medicines to a wide range of patients.” said Dr. Erik Bogsch, Head of the Biotechnology Business Unit at Richter.

#### About Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. ([www.mochida.co.jp](http://www.mochida.co.jp)), headquartered in Tokyo/Japan, has been committed to research and development of innovative pharmaceutical products since its establishment in 1913 thereby providing distinctive medicines to the medical field. Currently, the core pharmaceutical business focuses resources on the targeted areas of cardiovascular medicine, obstetrics and gynecology, psychiatry and gastroenterology, while also providing medicines for intractable disease and generics including biosimilars, to meet medical needs. In particular, Mochida has top-class achievements in the development and approval of biosimilars in Japan, contributing to the expansion of treatment options for patients and providing economic value to healthcare.

#### About Gedeon Richter Plc.

Gedeon Richter Plc. ([www.gedeonrichter.com](http://www.gedeonrichter.com)), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, China, Latin America, and Australia. Having reached a market capitalization of EUR 4.3bn (USD 4.7bn) by the end of 2023, Richter's consolidated sales were approximately EUR 2.1bn (USD 2.3bn) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, Central Nervous System, and Cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's Healthcare field worldwide. Richter is also active in biosimilar product development, manufacture and commercialization.