



GEDEON RICHTER

Richter announces positive topline results for RGB-19, a biosimilar to tocilizumab

Budapest, 15 January 2025 - Gedeon Richter („Richter”) announces today positive topline results from Phase I and Phase III clinical studies for its proposed biosimilar to RoActemra® tocilizumab – development code: RGB-19.

The Phase I clinical study evaluated 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 endpoints demonstrating clinical similarity between RGB-19 and the reference biologic.

RGB-19 has been developed jointly by Richter and Mochida Pharmaceutical Co., Ltd. (“Mochida”) and both clinical studies were conducted in Japan. Based on the results of the studies Richter expects to file for marketing authorization applications for RGB-19 in major European markets in the coming months, while Mochida expects to file for marketing authorization application for RGB-19 in Japan.

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

“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.

Tocilizumab, the first biologic to inhibit IL-6 signaling, is indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, juvenile idiopathic polyarthritis, giant cell arteritis, cytokine release syndrome and COVID-19. The results of the studies will be used to support all indications for tocilizumab biosimilar RGB-19 based on extrapolation.

About Gedeon Richter

Gedeon Richter Plc. (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.

[Chemical Works of Gedeon Richter Plc.](http://www.gedeonrichter.com)

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About Mochida Pharmaceutical

Mochida Pharmaceutical Co., Ltd. (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 medicine for intractable disease as well as generics including biosimilars, to meet medical needs.

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