GEDEON RICHTER

Richter Receives Positive CHMP Opinion for Marketing Authorisation for Tuyory®, its Biosimilar Tocilizumab in Multiple Indications

Budapest, 27 February 2026 – Gedeon Richter Plc. ("Richter") announces today that it received a positive opinion from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending that marketing authorization be granted in Europe for Tuyory®, its proposed biosimilar to RoActemra® tocilizumab. Tuyory® has been developed jointly by Richter and Mochida Pharmaceutical Co., Ltd.

"The positive CHMP opinion for Tuyory® is an important step towards receiving the European marketing authorization of this essential medicine. It is Richter's second monoclonal antibody biosimilar approval and adds to our rheumatology and immunology portfolio. It is a significant milestone in our commitment to expanding access to high-quality, affordable biologic therapies for patients across Europe." said Dr. Erik Bogsch, Head of the Biotechnology Business Unit at Richter.

About Tuyory®

Tocilizumab, the active ingredient of Tuyory® inhibits IL-6 signaling and is indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, juvenile idiopathic polyarthritis, giant cell arteritis, cytokine release syndrome and COVID-19.
Tuyory® can be administered intravenously and subcutaneously, with dosing regimens and presentations identical to those of the reference medicine.

About Gedeon Richter Plc.

Richter aspires to be a global innovator in key scientific fields, while dedicated to making medicines more accessible worldwide. Founded in 1901, headquartered in Hungary, with a market capitalization of EUR 4.8bn and sales of EUR 2.3bn in 2025, it operates Central Europe's largest R&D hub. Novel research drives breakthroughs in Neuropsychiatry and Women's Healthcare, while Biotechnology and General Medicines strengthen the affordable treatment portfolio. Committed to sustainable growth, Richter invests in R&D, manufacturing excellence, and digitalization to advance medical innovation. Learn more at www.gedeonrichter.com

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