



GEDEON RICHTER

The European Commission approves Bio-Thera's BAT2206 (USYMRO[®], a biosimilar ustekinumab), to be commercialized by Richter in Europe

Budapest, 27 August 2025 – Gedeon Richter Plc. ("Richter") announces today that the European Commission (EC) granted marketing authorization for BAT2206 (ustekinumab), a biosimilar – developed by Bio-Thera Solutions Inc. ("Bio-Thera") – referencing Stelara[®]. This decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on 19 June 2025. Richter will market BAT2206 in Europe under the brand name USYMRO[®].

"We are pleased that Richter will further strengthen patient access to biosimilars in Europe through bringing USYMRO[®] to market. As a result of Bio-Thera's success in gaining EC approval, Richter is expanding its biosimilar portfolio subsequent to the recent EC approvals of its in-house developed denosumab biosimilars" – said Dr. Erik Bogsch, Head of the Biotechnology Business Unit of Richter.

Bio-Thera and Richter entered into a license and commercialization agreement for USYMRO[®] (BAT2206) in October 2024. Under the terms of the agreement, Bio-Thera is responsible for the development and manufacturing of the product, and Richter obtained exclusive rights to commercialize the medicine in the EU, the UK and Switzerland and selected other countries.

About USYMRO[®] (ustekinumab)

USYMRO[®] is a biosimilar to Janssen's Stelara[®] which is a human monoclonal antibody that inhibits the bioactivity of human IL-12 and IL-23 by preventing shared p40 subunit from binding to the IL-12Rβ1 receptor chain of IL-12 (IL-12Rβ1/β2) and IL-23 (IL-12Rβ1/23R) receptor complexes on the surface of immune cells. IL-12 and IL-23 are involved in inflammatory and immune responses, such as natural killer cell activation, CD4+ T-cell differentiation and following relative cytokines stimulated release. Abnormal regulation of IL-12 and IL-23 have been implicated as important contributors to chronic inflammation, including psoriasis, psoriatic arthritis (PsA), and Crohn's disease (CD). Neutralizing human IL-12 and IL-23 by USYMRO[®] to prevent the relevant cell signaling in the Th1 or Th17 lineages can effectively block the pathologic processes of these immune disorders.

About Gedeon Richter Plc.

Richter aspires to be a global innovator in some key scientific fields, while dedicated to making medicines more accessible worldwide. Founded in 1901, headquartered in Hungary, with a market capitalization of EUR 4.7bn and sales of EUR 2.2bn in 2024, it operates Central Europe's largest R&D hub. Its research drives breakthroughs in Neuropsychiatry and Women's Healthcare, while Biotechnology and General Medicines strengthen its 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

Chemical Works of Gedeon Richter Plc.

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About Bio-Thera Solutions

Bio-Thera Solutions, Ltd., a leading innovative, global biopharmaceutical company in Guangzhou, China, is dedicated to researching and developing novel therapeutics for the treatment of cancer, autoimmune, cardiovascular, eye diseases, and other severe unmet medical needs, as well as biosimilars for existing, branded biologics to treat a range of cancer and autoimmune diseases. As a leader in next generation antibody discovery and engineering, the company has advanced multiple candidates into late-stage development, including five approved products: QLETLI® (adalimumab) and BETAGRIN® (bevifibatide citrate) Injection in China, STARJEMZA® (ustekinumab) in the US and Usymro® (ustekinumab) in the EU, and TOFIDENCE®/BAT1806 (tocilizumab) and AVZIVI® (bevacizumab-trjnj) in the US and in EU, a/k/a POBEVCY® in China. In addition, the company has more than 20 promising candidates in clinical trials, focusing on immuno-oncology in the post-PD-1 era and targeted therapies such as antibody-drug conjugates (ADCs). For more information, please visit www.bio-thera.com/en/ or follow us on X (@bio_thera_sol) and WeChat (Bio-Thera).

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