Bio-Thera and Richter Execute Exclusive Commercialization Agreement for BAT2206, a Proposed Stelara® Biosimilar, for EU countries, UK, Switzerland and other selected countries

Guangzhou, China/Budapest, Hungary, 9 October 2024 – Bio-Thera Solutions (688177:SH; "Bio-Thera"), a commercial-stage biopharmaceutical company developing a pipeline of innovative therapies and biosimilars, and Gedeon Richter ("Richter") announce today they have reached an exclusive commercialization and license agreement for BAT2206, a biosimilar candidate to Stelara® (ustekinumab).

Under the agreement, Bio-Thera will maintain responsibility for development, manufacturing, and supply of BAT2206 and Bio-Thera has filed BAT2206 for regulatory approval with EMA on 1 July 2024. Richter will have exclusive rights to commercialize the product in the European Union (EU), the UK, Switzerland and selected other countries.

Bio-Thera will receive an upfront payment of USD 8.5 million, as well as further development and commercial milestones of up to USD 101.5 million, subject to the fulfillment of certain conditions.

"We are pleased to establish this partnership with Gedeon Richter for BAT2206", said Dr. Shengfeng Li, CEO of Bio-Thera. *"BAT2206 is an important product to Bio-Thera and we believe that Richter is the right partner for helping Bio-Thera bring BAT2206 to the most patients possible in the EU and UK."*

"We are pleased to announce that Richter has made another important step towards building a robust biosimilar portfolio across its core commercial region" – said Dr. Erik Bogsch, Head of the Biotechnology Business Unit of Richter. *"Subsequent to the acquisitions made earlier this year and the recent news of our denosumab filing, the current deal with Bio-Thera reinforces Richter's presence and biosimilar portfolio in Europe."*

About BAT2206 (ustekinumab)

BAT2206 is a proposed 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 from binding to the IL-12Rβ1 receptor protein expressed on the surface of immune cells. IL-12 and IL-23 are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. IL-12 and IL-23 have been implicated as important contributors to the chronic inflammation that is a hallmark of Crohn's disease and ulcerative colitis, among many other autoimmune diseases. In the EU, Stelara® is currently approved for the treatment of 1) moderate to severe plaque psoriasis in adults and children above the age of 6 years whose condition has not improved with, or who cannot use, other systemic (whole-body) psoriasis treatments, 2) active psoriatic arthritis, alone or combined with methotrexate, in adults, when the condition has not improved enough with other treatments called disease-modifying anti-rheumatic drugs (DMARDs), 3) moderately to severely active Crohn's disease in adults whose condition has not improved enough with other treatments for Crohn's disease or who cannot receive such treatments, 4) moderately to severely active ulcerative colitis in adults whose condition has not improved enough with other treatments for ulcerative colitis or who cannot receive such treatments.

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 three approved products: QLETLI® in China, and TOFIDENCE™/ BAT1806 and Avzivi®/Pobevcy® in the US, EU and 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 ADCs. For more information, please visit www.bio-thera.com/en/ or follow us on Twitter (@bio_thera_sol) and WeChat (Bio-Thera).

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 developing, manufacturing and commercializing biosimilars for the treatment of osteoporosis, rheumatoid arthritis and other auto-immune diseases.

1. Stelara® is a registered trademark of Johnson & Johnson
2. QLETLI® is a registered trademark of Bio-Thera Solutions, Ltd.
3. TOFIDENCE™ is a trademark of Biogen MA Inc.
4. Avzivi® is a registered trademark of Sandoz AG
5. POBEVCY® is a registered trademark of Bio-Thera Solutions, Ltd.

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