
Bio-Thera Solutions and Hikma Pharmaceuticals announce exclusive commercialization and license agreement for BAT2206 in the US, a proposed biosimilar referencing Stelara® (ustekinumab)

Guangzhou and London, 27 August 2021 – Bio-Thera Solutions, Ltd. (688177.SH) and Hikma Pharmaceuticals PLC (LSE: HIK) today announced that they have entered into a commercialization and license agreement to commercialize BAT2206, a monoclonal antibody that is a proposed biosimilar referencing Stelara® (ustekinumab), in the United States (US). BAT2206 is currently in a global Phase III clinical trial.

Under the agreement, Bio-Thera will maintain responsibility for development, manufacturing, and supply of BAT2206. Hikma will have exclusive rights to commercialize the product in the US. The agreement also provides Hikma with a first-right-to-negotiate to add Europe (excluding CIS countries). Bio-Thera is eligible for an upfront payment of \$20 million as well as further development and commercial milestones of up to \$130 million.

“Partnering with Hikma to commercialize BAT2206, our ustekinumab biosimilar, further validates the high quality of the work performed at Bio-Thera,” said Dr. Shengfeng Li, CEO of Bio-Thera Solutions. “We are proud to expand our network of partners to include another great company like Hikma.”

“This partnership provides us with a unique opportunity to enter the biosimilar market in the US, building on our position as a leading generic manufacturer in the US,” said Siggj Olafsson, Chief Executive Officer of Hikma. “Tapping into the growth of the biosimilar market in the US has been an area of focus for Hikma. Our established commercial presence in the US market and Bio-Thera’s strong technical capabilities for the development and manufacturing of biological products are highly complementary and we are excited by the potential this partnership offers.”

About BAT2206 (ustekinumab)

BAT2206 is a proposed biosimilar to Jansen’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. Stelara® is currently approved for the treatment of active psoriatic arthritis (PsA) in adults, alone or in combination with MTX, the treatment of patients 6 years or older with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy, the treatment of moderately to severely active Crohn’s disease (CD) in adults, and the treatment of moderately to severely active ulcerative colitis (UC) in adults.

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Enquiries

Bio-Thera Solutions

Bert E. Thomas IV
Senior Vice President, Business Development

+1 410 627 1734 (mobile)
bethomas@bio-thera.com

Hikma Pharmaceuticals PLC

Susan Ringdal
EVP, Strategic Planning and Global Affairs

+44 (0)20 7399 2760/ +44 7776 477050
uk-investors@hikma.uk.com

Steve Weiss
David Belian
US Communications and Public Affairs

+1 732 720 2830/ +1 732 788 8279
+1 732 720 2814/+1 848 254 4875
uscommunications@hikma.com

About Bio-Thera Solutions, Ltd.

Bio-Thera Solutions, Ltd., a leading commercial-stage biopharmaceutical company in Guangzhou, China, is dedicated to researching and developing novel therapeutics for the treatment of cancer, autoimmune, cardiovascular diseases, and other serious unmet medical needs, as well as biosimilars for existing, branded biologics to treat a range of cancer and autoimmune diseases. As a leader in the next generation antibody discovery and engineering, the company has advanced six candidates into late-stage clinical trials and one of which, QLETLI® (格乐立®), a biosimilar to adalimumab, is available to patients in China. In addition, the company has multiple candidates in early stage clinical or entering clinical studies, including differentiated and innovative anti-OX40, anti-TIGIT, and anti-PD-L1/CD47 bispecific antibodies. For more information, please visit www.bio-thera.com/en/ or follow us on Twitter ([@bio_thera_sol](https://twitter.com/bio_thera_sol)) and WeChat (Bio-Thera).

About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/stable Fitch)
Hikma helps put better health within reach every day for millions of people around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Bio-Thera Solutions Cautionary Note Regarding Forward-Looking Statements

This news release contains certain forward-looking statements relating to BAT2206 or the product pipelines in general of Bio-Thera Solutions. Readers are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The forward-looking statements include, among others, those containing "could," "may," "should," "will," "would," "anticipate," "believe," "plan," "promising," "potentially," or similar expressions. They reflect the company's current views with respect to future events that are based on what the company believes are reasonable assumptions in view of information currently available to Bio-Thera Solutions and are not a guarantee of future performance or developments. Actual results and events may differ materially from information contained in the forward-looking statements as a result of a number of factors, including, but not limited

to, risks and uncertainties inherent in pharmaceutical research and development, such as the uncertainties of pre-clinical and clinical studies, for example, the development processes could be lengthy and in vitro or early, small scale clinical trial results may not translate into desired results in vivo or in large scale clinical studies. Other risks and uncertainties include challenges in obtaining regulatory approvals, manufacturing, marketing, competition, intellectual property, product efficacy or safety, changes in global healthcare situation, changes in the company's financial conditions, and changes to applicable laws and regulations, etc. Forward-looking statements contained herein are made only as of the date of their initial publication. Unless required by laws or regulations, Bio-Thera Solutions undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, changes in the company's views or otherwise.

1 Stelara® is a registered trademark of Johnson & Johnson Corporation

2 QLETLI® is a registered trademark of Bio-Thera Solutions, Ltd.

3 格乐立® is a registered trademark of Bio-Thera Solutions, Ltd.