

Press release

Bio-Thera and STADA Reach Exclusive Agreement for BAT2506, a Proposed Golimumab Biosimilar, in the EU and UK

- Bio-Thera and STADA have reached an exclusive commercialization and license agreement for BAT2506, a biosimilar candidate to Simponi® (golimumab)
- Bio-Thera will maintain responsibility for development, manufacturing, and supply of BAT2506
- STADA will have exclusive rights to commercialize the product in the EU, the UK, Switzerland and selected other countries under its own marketing authorization

Guangzhou, China/Bad Vilbel, Germany – 28 May 2024 – Bio-Thera Solutions (688177:SH), a commercial-stage biopharmaceutical company developing a pipeline of innovative therapies and biosimilars, and global specialty, generic and consumer healthcare medicines company STADA Arzneimittel AG have reached an exclusive commercialization and license agreement for BAT2506, a biosimilar candidate to Simponi® (golimumab).

Under the agreement, Bio-Thera Solutions (“Bio-Thera”) will maintain responsibility for development, manufacturing, and supply of BAT2506. STADA Arzneimittel AG (“STADA”) 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 US\$10 million, as well as further development and commercial milestones of up to US\$147.5 million, subject to the fulfillment of certain conditions.

Executive Board: Peter Goldschmidt (CEO) / Simone Berger / Miguel Pagan Fernandez / Boris Döbler
Chairman of the Supervisory Board: Dr. Günter von Au

“STADA is one of the premier biosimilar companies in Europe, and we are pleased to establish a partnership with STADA for BAT2506”, said Dr. Shengfeng Li, CEO of Bio-Thera. “We look forward to working with STADA to bring BAT2506 to immunology patients in Europe.”

“With global sales in 2023 of US\$2.2 billion, including more than US\$1 billion outside of the US, golimumab represents a compelling opportunity to broaden patient access to biological treatments and build scale in immunology alongside our approved adalimumab and ustekinumab biosimilars. Bio-Thera’s broad expertise in biologic medicines, including with two biosimilars already approved by the US Food and Drug Administration, makes it an attractive partner for STADA,” commented STADA’s head of Global Specialty, Bryan Kim.

Golimumab is a human IgG1 monoclonal antibody that targets tumor necrosis factor alpha (TNF- α), a pro-inflammatory molecule. Binding of golimumab to TNF- α results in reductions in C-reactive protein (CRP), Interleukin 6 (IL-6), Intercellular Adhesion Molecule 1 (ICAM-1), Matrix Metalloproteinase 3 (MMP-3), and Vascular Endothelial Growth Factor (VEGF), all inflammatory markers.

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 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](https://twitter.com/bio_thera_sol)) and WeChat (Bio-Thera).

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 115 countries. In financial year 2023, STADA achieved group sales of EUR 3,734.8 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 802.1 million. As of 31 December 2023, STADA employed 11,667 people worldwide.

Bio-Thera Cautionary Note Regarding Forward-Looking Statements

This news release contains certain forward-looking statements relating to BAT2506, 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. 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. Simponi[®] 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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