Press Release

Golimumab biosimilar Gotenfia from STADA and Bio-Thera receives positive CHMP opinion

- Positive opinion from European Medicines Agency supports approval for golimumab biosimilar Gotenfia® developed by Bio-Thera and to be marketed by STADA
- Recommendation from EMA's CHMP committee is based on a robust analytical, non-clinical and clinical data package comparing the biosimilar candidate to the Simponi® reference product
- Bio-Thera is responsible for development, manufacturing and supply; STADA for commercialization in the EU, the UK, Switzerland and selected other countries

Bad Vilbel, Germany/Guangzhou, China – 12 December 2025 – Global specialty, generic and consumer healthcare medicines company STADA and Bio-Thera Solutions (688177:SH), a commercial-stage biopharmaceutical company developing a pipeline of innovative therapies and biosimilars, today received a positive opinion from the European Medicines Agency (EMA), recommending approval for their Gotenfia® (golimumab) biosimilar candidate referencing Simponi®.

The EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended that the European Commission grant a marketing authorization for Gotenfia® for several chronic inflammatory autoimmune diseases. The CHMP's positive opinion will now be referred for the European Commission to grant marketing authorization for the product that was developed by Bio-Thera under the code BAT2506.

Following approval, the monoclonal antibody would be supplied as 50mg/0.5mL and 100mg/mL in a pre-filled syringe. The marketing authorization would apply across the 27 member states of the European Union, in addition to Norway, Iceland and Lichtenstein.

“This CHMP positive opinion marks a significant step towards bringing competition and improving patient access to a well-established anti-TNF therapy with annual European sales in the region of €700 million,” commented STADA’s Global Specialty Head, Ian Henshaw. “We look forward to employing STADA’s almost 20 years of experience in supplying high-quality biosimilars in Europe – not least adalimumab and ustekinumab in immunology – to bring a convenient, once-monthly treatment option to rheumatologists, gastroenterologists and the patients they serve.”

“Bio-Thera is committed to being one of the premier biosimilar developers and manufacturers in the world,” said Shengfeng Li, CEO of Bio-Thera Solutions. “Building on the strong presence we have established in the US through approvals and launches, this positive CHMP recommendation helps to establish Bio-Thera as a major biosimilar developer and manufacturer serving patients in Europe.”

The positive CHMP opinion on Gotenfia®/BAT2506 was based on the totality of evidence comprising a comprehensive analytical, non-clinical and clinical data package. Based on the totality of evidence, it was demonstrated that BAT2506 is biosimilar to its reference product.

Bio-Thera and STADA entered into a license and commercialization agreement for golimumab in May 2024[1]. Under the terms of the agreement, Bio-Thera is responsible for the development, manufacturing and supply. STADA holds exclusive rights to commercialize the product in the European Union (EU), the UK, Switzerland and selected other countries.

[1] *Bio-Thera and STADA Reach Exclusive Agreement for BAT2506 | STADA*

The two companies earlier this year announced an extension of their alliance to cover the immunosuppressant monoclonal antibody tocilizumab[2].

About Gotenfia/BAT2506 (golimumab)

Gotenfia/BAT2506 is a proposed biosimilar to Simponi® which 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. The reference medicine golimumab has been approved in Europe for several indications including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

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 over 100 countries. In financial year 2024, STADA achieved group sales of € 4,059 million and adjusted constant-currency earnings before interest, taxes, depreciation and amortization (adj. cc EBITDA) of € 886 million. As of 31 December 2024, STADA employed 11,649 people worldwide.

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 EU, and TOFIDENCE®/BAT1806 (tocilizumab) and AVZIVI® (bevacizumab-tnjn) 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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[2] *Bio-Thera & STADA Extend Biosimilars Alliance to Tocilizumab | STADA*

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, for example, the development processes could be lengthy and high in vitro affinity may not translate to desired results in vivo or successful 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.

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