Press Release

STADA and Bio-Thera receive European Marketing Authorization for Gotenfia, a Biosimilar to Simponi

- European Commission grants approval for Gotenfia®, a golimumab biosimilar to Simponi® that was developed by Bio-Thera and will be marketed by STADA
- Launch preparations are underway to bring the second approved golimumab biosimilar to patients across Europe in the coming weeks and months
- Bio-Thera is responsible for development, manufacture and supply; STADA for commercialization in the EU, the UK, Switzerland and selected other countries

Bad Vilbel, Germany/Guangzhou, China – 13 February 2026 – 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, have received a marketing authorization from the European Commission[1] for their Gotenfia® (golimumab) biosimilar referencing Simponi®.

The authorization of Gotenfia® for several chronic inflammatory autoimmune diseases, which applies across the European Union (EU and European Economic Area (EEA), follows a recommendation[2] in December 2025 from the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency (EMA). Launch preparations are underway to bring this therapeutic option to patients across Europe in the coming weeks and months. Being the second biosimilar to Simponi® approved in the EU, Gotenfia® – developed

[1] Union Register of medicinal products - Public health - European Commission

[2] Positive CHMP opinion for Golimumab from STADA and Bio-Thera | STADA

by Bio-Thera under the product code BAT2506 – will significantly spur market competition, which is expected to increase treatment access for many more patients at lower unit costs.

“Having received the European marketing authorization, our 11th for a biosimilar in total, we look forward to increasing competition on this well-established anti-TNF therapy,” commented STADA’s Global Specialty Head, Bryan Kim. “We know from our years of experience supplying adalimumab and ustekinumab biosimilars the considerable impact that access to biological treatments for chronic autoimmune and inflammatory conditions can have on patients’ quality of life.”

“Bringing this convenient, once-monthly treatment option to rheumatologists, gastroenterologists and the patients they serve marks a major milestone in Bio-Thera’s commitment to being one of the premier biosimilar developers and manufacturers in the world,” said Shengfeng Li, CEO of Bio-Thera Solutions. “Building on our prior approvals and launches in the US and EU, this European authorization further establishes Bio-Thera as a major global biosimilar developer and manufacturer.”

The marketing authorization and positive CHMP opinion on Gotenfia® were based on the totality of evidence comprising a comprehensive analytical, non-clinical and clinical data package demonstrating that Gotenfia® is biosimilar to its reference product. The marketing authorization for Gotenfia® 50mg/0.5mL and 100mg/mL solution for injection in pre-filled syringes with passive needle safety guards applies across the 27 EU member states, in addition to Norway, Iceland and Lichtenstein.

Bio-Thera and STADA entered into a license and commercialization agreement for BAT2506 in May 2024[3]. Under the terms of the agreement, Bio-Thera is responsible for development, manufacture and commercial supply. STADA holds exclusive rights to commercialize the

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

product in the European Union (EU), the UK, Switzerland and selected other countries. In 2025, the two partners announced an extension of their alliance to cover the immunosuppressant monoclonal antibody tocilizumab[4] for which launch preparations are also underway.

About Gotenfia®/BAT2506

Gotenfia®/BAT2506 is a 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. Gotenfia® has been approved in Europe for several indications including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

Use of Trademarks

Simponi® is a registered trademark of Johnson & Johnson. Gotenfia® is a registered trademark of STADA.

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.

[4] Bio-Thera & STADA Extend Biosimilars Alliance to Tocilizumab | STADA

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).

Bio-Thera Cautionary Note Regarding Forward-Looking Statements

This news release contains certain forward-looking statements relating to Gotenfia® (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.

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