

**NOT FOR RELEASE, PUBLICATION OR DISTRIBUTION, DIRECTLY OR INDIRECTLY, IN WHOLE OR IN PART, IN OR INTO THE UNITED STATES OF AMERICA, AUSTRALIA, CANADA OR JAPAN OR ANY OTHER JURISDICTION IN WHICH SUCH DISTRIBUTION OR RELEASE WOULD BE UNLAWFUL OR REQUIRE REGISTRATION OR ANY OTHER MEASURES.**

## **Press release**

### **Bio-Thera and STADA Extend Biosimilars Alliance to Tocilizumab**

- Bio-Thera and STADA agree to extend their biosimilars alliance to cover tocilizumab, a targeted immunomodulatory monoclonal antibody directed against the interleukin-6 receptor, indicated for the treatment of multiple inflammatory and autoimmune disorders
- Bio-Thera will have responsibility for development, manufacturing, and supply of the biosimilar to Roche's RoActemra® reference brand
- 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 – 25 August 2025** – 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 agreed to extend their biosimilars alliance to cover tocilizumab, an immunosuppressant monoclonal antibody indicated for certain inflammatory conditions. The effectiveness of the agreement covering tocilizumab is subject to shareholder approval.

Bio-Thera will maintain responsibility for development, manufacturing, and supply of the tocilizumab biosimilar to Roche's RoActemra® reference brand. STADA, including its affiliates, will have exclusive rights to commercialize the

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

biosimilar in the European Union (EU), the UK, Switzerland and selected other countries under its own marketing authorization.

This agreement for tocilizumab builds upon an existing partnership on similar terms for BAT2506, a biosimilar candidate to Simponi® (golimumab), that the two companies announced in May 2024<sup>1</sup>. A marketing authorization application (MAA) for BAT2506 has subsequently been accepted by the European Medicines Agency (EMA).

“Benefiting from a proven track record in immunology, STADA ranks among the premier biosimilar companies in Europe,” said Dr. Shengfeng Li, CEO of Bio-Thera. “We look forward to extending our partnership to bring biosimilar tocilizumab to patients in Europe.”

“With global RoActemra/Actemra sales in 2024 reported at approximately €2.8 billion, including around US\$700 million in Europe despite the advent of biosimilar competition, tocilizumab represents a compelling opportunity to broaden patient access to biological treatments and build scale in immunology alongside our approved adalimumab and ustekinumab biosimilars that hold leading positions in several European countries. Bio-Thera’s expertise in developing and manufacturing biologic medicines makes it an appealing partner for STADA,” commented STADA’s head of Global Specialty, Ian Henshaw.

In June 2024, tocilizumab 20mg/ml concentrate for solution developed by Bio-Thera under the BAT1806 code received a marketing authorization for the vials that is valid throughout the EU<sup>2</sup>. This followed a positive opinion issued by the European Medicines Agency that the biosimilar to Roche’s RoActemra reference brand be approved as a medicine to treat several arthritic conditions.

---

<sup>1</sup> [Bio-Thera Solutions, Ltd.; Bio-Thera and STADA Reach Exclusive Agreement for BAT2506 | STADA](#)

<sup>2</sup> [Union Register of medicinal products - Public health - European Commission](#)

### **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® in the US, and BAT1806/TOFIDENCE™ (tocilizumab) and AVZIVI® (bevacizumab-txn) 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/](http://www.bio-thera.com/en/) or follow us on X([@bio\\_thera\\_soln](https://twitter.com/bio_thera_soln)) 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 over 100 countries. In financial year 2024, STADA achieved group revenues 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.

### **Bio-Thera Cautionary Note Regarding Forward-Looking Statements**

*This news release contains certain forward-looking statements relating to BAT1806, 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*

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

*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, 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.*

**Bio-Thera Contact for additional information:**

Bert E. Thomas IV

Phone: +1.410.627.1734

Email: [bethomas@bio-thera.com](mailto:bethomas@bio-thera.com)

**STADA information for journalists:**

STADA Arzneimittel AG - Media Relations

Stadastrasse 2-18

61118 Bad Vilbel - Germany

Phone: +49 (0) 6101 603-165

E-Mail: [press@stada.de](mailto:press@stada.de)

Or visit us on the Internet at [www.stada.com/press](http://www.stada.com/press)

Follow [@STADAGroup](#) on LinkedIn

**STADA information for capital market participants:**

STADA Arzneimittel AG - Investor & Creditor Relations

Stadastrasse 2-18

61118 Bad Vilbel – Germany

Phone: +49 (0) 6101 603-4689

Fax: +49 (0) 6101 603-215

E-mail: [ir@stada.de](mailto:ir@stada.de)

Or visit us on the Internet at [www.stada.com/investor-relations](http://www.stada.com/investor-relations)

Executive Board: Peter Goldschmidt (CEO) / Simone Berger / Miguel Pagan Fernandez / Boris Döbler

Chairman of the Supervisory Board: Dr. Günter von Au