Biogen and Bio-Thera Announce Positive Results From Phase 3 Study of BAT1806, a Proposed Biosimilar Referencing Actemra® (Tocilizumab)

June 1, 2021

The comparative study met its primary endpoints and showed equivalent efficacy and comparable safety profile in patients with moderate-to-severe rheumatoid arthritis

CAMBRIDGE, Mass. and GUANGZHOU, China, June 01, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Bio-Thera Solutions, Ltd. (688177.SH) today announced results from the Phase 3 study of BAT1806, a proposed biosimilar referencing ACTEMRA®/RoACTEMRA® (tocilizumab). The study met its primary endpoints, demonstrating equivalence to the reference medicine in patients with moderate to severe rheumatoid arthritis (RA) inadequately controlled by methotrexate therapy. The primary endpoint in the study was the American College of Rheumatology 20 percent response criteria (ACR20).

ACTEMRA/RoACTEMRA's primary indication is for moderate to severe rheumatoid arthritis in adults as well as juvenile idiopathic polyarthritis, systemic juvenile idiopathic arthritis, giant cell arteritis and cytokine release syndrome. Biosimilars are products that demonstrate similar efficacy and safety to the originator's reference product, with the advantage that they can be more affordable for patients and healthcare systems. In 2020 global sales of ACTEMRA were 2.8 billion CHF. Biogen has exclusive regulatory, manufacturing and commercial rights to BAT1806 in all countries excluding China (including Hong Kong, Macau and Taiwan).

"We are excited about these results and believe BAT1806 demonstrates equivalence in efficacy and pharmacokinetics as well as a comparable safety and immunogenicity profile to the reference product," said Ian Henshaw, head of global biosimilars at Biogen. "Biosimilars have the potential to generate cost savings, healthcare sustainability and, if approved, BAT1806 would enable us to bring an additional therapeutic option to patients."

"We are pleased to report on our third proposed biosimilar with positive Phase 3 study results. These results demonstrate the potential of our proposed tocilizumab biosimilar to be a safe and effective treatment," said Shengfeng Li, Ph.D., chief executive officer at Bio-Thera Solutions. "Bio-Thera is committed to increasing patient access to innovative medicines through the development of high-quality biosimilars."

Biogen and Bio-Thera announced a commercialization and license agreement in April 2021 to develop, manufacture and commercialize BAT1806. As satisfactory results were met, Biogen will make a payment of $30 million to Bio-Thera Solutions. Should certain commercial milestones be achieved, Bio-Thera Solutions will be eligible to receive potential milestone payments. Biogen will also pay Bio-Thera Solutions tiered royalties.

About Biosimilars

Biosimilars are biologic products that have been demonstrated to be similar in efficacy, safety and immunogenicity to the originator's approved reference product, with the advantage that they offer cost savings to healthcare systems. Biosimilars may lower healthcare system costs broadly, creating headroom for innovation and could enable governments to potentially redirect savings to priorities such as increasing access to transformative therapies.

About BAT1806 Phase 3 Trial Design

The BAT1806 clinical trial was a global, randomized, multicenter, double-blind, parallel-group, Phase 3 active-control study designed to evaluate the safety, efficacy, immunogenicity and PK of BAT1806 compared to ACTEMRA®/RoACTEMRA® in 621 patients with moderate to severe rheumatoid arthritis with inadequate response to methotrexate. More information regarding the BAT1806 Phase 3 clinical trial, including inclusion and exclusion criteria and primary and secondary outcome measures, can be found here: https://clinicaltrials.gov/ct2/show/study/NCT03830203

Results of the study will be presented at a future medical meeting or summarized in publication.

About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

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 five 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 clinical trials and IND-enabling studies, including differentiated and innovative anti-OX40, anti-TIGIT antibodies. For more information, please visit www.bio-thera.com/en/ or follow us on Twitter (@bio_thera_sol) and WeChat (Bio-Thera).

Biogen Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the potential benefits, safety and efficacy of BAT1806; the potential clinical effects of BAT1806; results from the Phase 3 study of BAT1806; data presentations for BAT1806; potential regulatory discussions, submissions and approvals and the timing thereof; the anticipated benefits and potential of Biogen's agreement with Bio-Thera Solutions; risks and uncertainties associated with drug development and commercialization; the potential of Biogen's commercial business and pipeline programs; Biogen's strategy and plans; and potential cost healthcare savings related to biosimilars. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation, actual timing and content of submissions to and decisions made by the regulatory authorities regarding BAT1806; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including BAT1806; risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of BAT1806, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; uncertainty as to whether the anticipated benefits of the Biogen's agreement with Bio-Thera Solutions can be achieved; risks of legal actions, regulatory scrutiny or other challenges to biosimilars; the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition; the risks of doing business internationally, including currency exchange rate fluctuations; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

Bio-Thera Solutions 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 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.

References:

1. ACTEMRA® is a registered trademark of Genentech, Inc.
2. Company reported sales

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