Biogen and Bio-Thera Solutions Present Positive Phase 3 Data for Tocilizumab Biosimilar Candidate at the Annual European Congress of Rheumatology (EULAR 2022)

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CAMBRIDGE, Mass. and GUANGZHOU, China, June 03, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Bio-Thera Solutions, Ltd. (688177.SH) today presented positive Phase 3 data for BIIB800 (BAT1806), a biosimilar candidate referencing ACTEMRA®/ROACTEMRA® (tocilizumab), anti-interleukin-6 receptor monoclonal antibody, at the Annual European Congress of Rheumatology (EULAR 2022).

Data from the Phase 3 comparative clinical trial demonstrated that the investigational biosimilar candidate BIIB800 has equivalent efficacy and comparable safety and immunogenicity profile to the reference tocilizumab product. The double-blind 52-week Phase 3 study randomized 621 patients with moderate to severe rheumatoid arthritis to receive either BIIB800 or the reference tocilizumab administered intravenously every 4 weeks at a dose of 8 mg/kg for the first 24 weeks.

The primary endpoints were ACR20* response at week 12 and week 24. The ACR20 response rates in the BIIB800 group and the reference tocilizumab group were 68.97% vs. 64.82% at week 12 and 69.89% vs. 67.94% at week 24. The estimated difference between the two groups were within the pre-defined equivalence margins (4.15% (95% CI - 3.63 to 11.93) at week 12 and 1.94% (90% CI -4.04 to 7.92; 95% CI -5.18 to 9.07) at week 24. The treatment groups were comparable in terms of serum trough tocilizumab levels, incidence of treatment emergent adverse events and anti-drug antibody positivity and hence demonstrated comparable pharmacokinetics, safety and immunogenicity.

“At Biogen, we are advancing development of pipeline of biosimilar candidates like BIIB800 with the goal of optimizing the management of chronic immune mediated inflammatory diseases and helping more patients and healthcare systems across the world to benefit from biologics,” said Mourad Farouk Rezk, MD, Head of Global Medical and Development Biosimilars at Biogen. “Biogen is committed to the scientific progress in the treatment of various immunologic conditions that accelerate our ability to tackle these complex diseases.”

“Bio-Thera is proud to have the Phase 3 data for BIIB800 (BAT1806) presented to doctors, researchers, and patients at the EULAR conference. These results highlight the expertise and commitment of Bio-Thera to develop the highest quality biosimilars of important therapeutic products to expand patient access around the globe,” said Dr. Shengfeng Li, CEO of Bio-Thera Solutions.

The abstract is available online at the website of EULAR 2022 which has been held both virtually through the Congress platform and on-site in Copenhagen, Denmark between June 1-4, 2022.

ACTEMRA®/ ROACTEMRA® is indicated for moderate to severe rheumatoid arthritis in adults as well as juvenile idiopathic polyarthritis, systemic juvenile idiopathic arthritis, giant cell arteritis, chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome, systemic sclerosis-associated interstitial lung disease (approved by FDA) and coronavirus disease 2019 (COVID-19) (under emergency use authorization by FDA), and severe COVID-19 (approved by EMA).

On April 8th, 2021, Biogen and Bio-Thera Solutions, Ltd. entered into a commercialization and license agreement to develop, manufacture and commercialize BIIB800 (BAT1806). Biogen has exclusive regulatory, manufacturing and commercial rights to BIIB800 in all countries excluding China (including Hong Kong, Macau and Taiwan).

About the BIIB800 Phase 3 Trial

The BIIB800 clinical trial was a global, randomized, multicenter, double-blind, parallel-group, Phase 3 active-control study designed to evaluate the efficacy, safety, PK and immunogenicity of BIIB800 compared to ACTEMRA®/ROACTEMRA® in 621 patients with moderate to severe rheumatoid arthritis with inadequate response to methotrexate. Out of the 621 total patients enrolled in the Phase 3 Trial, 253 (40.7%) patients were from China and 368 (59.3%) patients were from Europe. More information regarding the BIIB800 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

About Biogen

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological 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, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and developed the first and only approved treatment to address a defining pathology of Alzheimer’s disease. Biogen is also commercializing biosimilars and focusing on advancing one of the industry’s most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company’s operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

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

About Bio-Thera Solutions, Ltd.

Bio-Thera Solutions, Ltd., a leading global biotechnology 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. A leader in next generation antibody discovery and engineering, the company has advanced six candidates into late-stage clinical trials and has two approved products, QLETLI® and POBEVCY® in China. In addition,

the company has multiple promising candidates in early clinical trials and IND-enabling studies, focusing on immuno-oncology, ADC targeted therapies, autoimmune diseases, and other severe and emerging unmet medical needs. 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 and results that may be achieved through Biogen's proposed agreement with Bio-Thera Solutions; the anticipated completion and timing of the proposed transaction; the potential benefits, safety and efficacy of BAT1806; 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, risks that the proposed transaction will not be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed transaction can be achieved; 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 obtain regulatory approvals in certain jurisdictions, failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; 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:

*ACR20 is a 20% improvement in the American College of Rheumatology response criteria

1. ACTEMRA®/ROACTEMRA® is a registered trademark of Genentech, Inc.

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