FDA Accepts Biogen Biologics License Application for BIIB800, A Biosimilar Candidate Referencing ACTEMRA® (tocilizumab)

December 9, 2022

CAMBRIDGE, Mass., Dec. 09, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) – announced that the U.S. Food and Drug Administration (FDA) has accepted for review the abbreviated Biologics License Application (aBLA) for BIIB800, a biosimilar candidate referencing ACTEMRA®[1] (tocilizumab), an anti-interleukin-6 receptor monoclonal antibody.

ACTEMRA® is indicated for several indications, including moderate to severe rheumatoid arthritis in adults as well as juvenile idiopathic polyarthritis and systemic juvenile idiopathic arthritis.

“The FDA filing is supported by Phase 3 data from a comparative clinical trial demonstrating equivalent efficacy and a comparable safety and immunogenicity profile to the reference product,” said Ian Henshaw, Head of Global Biosimilars at Biogen. “We look forward to working with regulators to bring this potential treatment option for people with immune mediated inflammatory diseases.”

As previously reported, positive Phase 3[2] data for BIIB800 up to week 24 was presented at the European Congress of Rheumatology on June 3, 2022. The BIIB800 clinical program included a Phase 3 multicenter, multinational, randomized, double-blind, parallel-group, active-control global study, designed to evaluate the efficacy, safety, pharmacokinetics and immunogenicity of BIIB800 compared to ACTEMRA® in 621 patients with moderate to severe rheumatoid arthritis with inadequate response to methotrexate. The data from the Phase 3 comparative clinical trial demonstrated that the biosimilar candidate BIIB800 has equivalent efficacy and comparable safety and immunogenicity profile to the reference tocilizumab product. The one-year Phase 3 results were presented at the American College of Rheumatology (ACR) on November 10, 2022.

Biosimilars are biological products that have been demonstrated to be similar in efficacy and safety to the originator’s reference product, with the advantage that they offer healthcare savings and promote sustainable access to therapies. Savings in the United States from 2020 until 2024 as a result of biosimilars across therapeutic areas are projected to exceed $100 billion.[3]

In September 2022, the Marketing Authorization Application (MAA) for BIIB800 was accepted for review by the European Medicines Agency (EMA).

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

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 pipelines in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Twitter, LinkedIn, Facebook, YouTube.

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 BIIB800; potential benefits of our collaboration with Bio-Thera; 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 risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of BIIB800, 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.

References:

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

2. https://ard.bmj.com/content/annrheumdis/81/Suppl_1/388.2.full.pdf Leng X, et al. Ann Rheum Dis. 2022;81(suppl. 1):388
3. IQVIA Institute for Human Data Science. Biosimilars in the United States 2020–2024 Competition, Savings, and Sustainability Institute Report, Sep 29, 2020. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024

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