Biogen Announced EMA Filing Acceptance of BIIB800, A Biosimilar Candidate Referencing RoACTEMRA® (tocilizumab)

September 30, 2022

CAMBRIDGE, Mass., Sept. 30, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for BIIB800, a biosimilar candidate referencing RoACTEMRA®[1] (tocilizumab), an anti-interleukin-6 receptor monoclonal antibody. RoACTEMRA® is indicated in Europe as an intravenous formulation for severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate, moderate to severe rheumatoid arthritis in adults who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists, as well as for the treatment of patients from 2 years of age with juvenile idiopathic polyarthritis who have responded inadequately to previous therapy with methotrexate, patients from 2 years of age with active systemic juvenile idiopathic arthritis who have responded inadequately to prior therapy with NSAIDs and systemic corticosteroids. RoACTEMRA® is also used to treat chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults or paediatric patients 2 years of age or older, and severe coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation. The MAA includes positive Phase 3[2] data for BIIB800 from the clinical program of a multicenter, multinational, randomized, double-blind, parallel-group, active-control study, designed to evaluate the efficacy, safety, pharmacokinetics (PK) and immunogenicity of BIIB800 compared to RoACTEMRA® in 621 patients with moderate to severe rheumatoid arthritis with inadequate response to methotrexate. The Phase 3 data from the comparative clinical trial demonstrated that the biosimilar candidate BIIB800 has equivalent efficacy and a comparable PK, safety and immunogenicity profile to reference tocilizumab and these positive results were presented at the European Congress of Rheumatology on June 3, 2022.

“The EMA filing acceptance for BIIB800 brings us a step closer to potentially offering broader patient access to another more affordable and important new biosimilar treatment option in Europe, and we look forward to continued engagement with the EMA throughout the review process,” said Ian Henshaw, Head of Global Biosimilars at Biogen. “If approved, BIIB800 will be a valuable treatment option for people with chronic immune mediated inflammatory diseases. We believe our biosimilar offerings are essential as we collaborate with payers and health authorities with the goal of generating savings to ensure sustainable healthcare systems.”

On April 8th, 2021, Biogen and Bio-Thera Solutions, Ltd. entered into a commercialization and license agreement 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).

Biosimilars are products that have been demonstrated to be similar in efficacy and safety to the originator’s reference product, with the advantage that they offer cost savings and promote sustainable access to therapies. Biogen is committed to advancing development, manufacturing and commercialization of additional biosimilar candidates with the goal of optimizing the disease management with biosimilars and helping more people and healthcare systems across the world to benefit from biologics treatments.

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.

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.

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.

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 commercialization and license with Bio-Thera Solutions; the potential benefits, safety and efficacy of BIIB800; 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 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®/RoACTEMRA® is a registered trademark of Genentech, Inc.

2. https://ard.bmj.com/content/annrheumdis/81/Suppl_1/388.2.full.pdf

MEDIA CONTACT:
Biogen
Dan Haro
+ 1 617 914 6936
public.affairs@biogen.com

INVESTOR CONTACT:
Biogen
Mike Hencke
+1 781 464 2442
IR@biogen.com