Biogen Receives Positive CHMP Opinion for TOFIDENCE™ (tocilizumab), a Biosimilar Referencing ROACTEMRA®

April 25, 2024

- CHMP positive opinion is based on a robust analytical, non-clinical and clinical data package comparing TOFIDENCE™ to the reference product ROACTEMRA®

CAMBRIDGE, Mass., April 25, 2024 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for TOFIDENCE™ (tocilizumab), a biosimilar monoclonal antibody referencing ROACTEMRA®[1]. The intravenous formulation of TOFIDENCE has been recommended for approval for the treatment of moderate to severely active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis and COVID-19.

The CHMP's positive opinion will now be referred to the European Commission (EC), which will decide whether to grant marketing authorization for TOFIDENCE. If a marketing authorization is granted by the EC, TOFIDENCE will be an addition to the existing biosimilars portfolio of three widely prescribed anti-TNF biosimilars commercialized by Biogen in Europe: BENEPALI (etanercept), IMRALDI (adalimumab) and FLIXABI (infliximab), offering an extension to the cost-effective treatment options with an additional mechanism of action.

"The positive CHMP recommendation for TOFIDENCE marks another positive step toward helping more people with inflammatory and immune-mediated conditions gain access to leading therapies," said Ian Henshaw, Global Head of Biosimilars at Biogen. "Positive CHMP recommendation for TOFIDENCE is testament to our continuing efforts to develop and deliver high-quality and proven biologic medicines to more patients, healthcare providers and healthcare systems in Europe."

This positive CHMP opinion on TOFIDENCE was based on the totality of evidence comprising a comprehensive analytical, non-clinical and clinical data package. Extensive analytical characterization of the structural, physicochemical, and biological properties of TOFIDENCE was conducted and supports equivalence with the reference biologic product. Additionally, a randomized double-blind, single-dose, three-arm, parallel group Phase 1 study compared the pharmacokinetics, safety and immunogenicity of TOFIDENCE with both the EU and US reference tocilizumab in healthy volunteers, while a randomized, double-blind, multi-dose, three-arm, parallel group Phase 3 study compared TOFIDENCE with tocilizumab to establish equivalent efficacy and comparable pharmacokinetic, safety and immunogenicity profiles, in subjects with rheumatoid arthritis inadequately controlled by methotrexate. The totality of evidence demonstrated TOFIDENCE is a biosimilar of the reference biologic.

Biogen and Bio-Thera entered into a commercialization and licensing agreement for TOFIDENCE (BAT1806/BIIB800) in April 2021. Under the agreement, TOFIDENCE, developed by Bio-Thera, is to be commercialized by Biogen in the European Union. Under the agreement, Biogen has exclusive regulatory, manufacturing, and commercial rights to TOFIDENCE in all countries excluding China (including Hong Kong, Macau and Taiwan).

About TOFIDENCE (tocilizumab)
TOFIDENCE (tocilizumab), an inteleukin-6 receptor antagonist, is a treatment developed as a biosimilar to the reference product ROACTEMRA. TOFIDENCE is indicated for the treatment of moderate to severe active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis and COVID-19.

Indications
Rheumatoid Arthritis (RA)
Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to, or who were intolerant to, one or more Disease-Modifying Anti-Rheumatic Drug (DMARD) or tumor necrosis factor (TNF) antagonist.

Adult patients with severe, active and progressive RA not previously treated with methotrexate (MTX).

In these patients, TOFIDENCE can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have responded inadequately to previous therapy with MTX. In these patients, TOFIDENCE™ can be given as monotherapy in case of intolerance to MTX or where continued treatment with methotrexate (MTX) is inappropriate.

Systemic Juvenile Idiopathic Arthritis (SJIA)
Patients 2 years of age and older with active systemic juvenile idiopathic arthritis who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. TOFIDENCE™ can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Coronavirus disease 2019 (Covid-19)
Adult patients who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, 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 TOFIDENCE; 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 commercialization of TOFIDENCE™, 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 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 speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

References:

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

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