Biogen Announces Topline Results From Phase 2 Study of Gosuranemab, an Anti-Tau Antibody, for Alzheimer's Disease

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CAMBRIDGE, Mass., June 16, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced topline results from its Phase 2 TANGO study of gosuranemab (BIIB092), an investigational anti-tau antibody that was being evaluated as a potential treatment for Alzheimer's disease.

Gosuranemab did not meet its primary efficacy endpoint of change from baseline at week 78 on the Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB) compared to placebo in patients with mild cognitive impairment (MCI) due to Alzheimer's disease and mild Alzheimer's disease dementia. No treatment benefit was seen on exploratory efficacy endpoints, including the Alzheimer's Disease Assessment Scale–Cognitive Subscale (ADAS-Cog 13), the Alzheimer Disease Cooperative Study Activity of Daily Living (ADCS-ADL), the Mini-Mental State Examination (MMSE) and the Functional Assessment Questionnaire (FAQ). Gosuranemab was well-tolerated overall, and safety outcomes were consistent with previous studies of the molecule.

Gosuranemab is an antibody directed against the N-terminus of tau. Target engagement was demonstrated with lowering of N-terminal tau in cerebrospinal fluid (CSF), consistent with prior studies. However, in the TANGO Study, no statistically significant treatment effect was observed on tau-PET at week 78 for any of the dose groups.

"While we are disappointed by the results of the Phase 2 study of gosuranemab, we know that the path to innovation is not a straight line, and that we always learn from each trial. We are investing in a broad neuroscience pipeline, including other tau approaches for Alzheimer's disease," said Alfred Sandrock, Jr., M.D., Ph.D., Head of Research and Development at Biogen. "We extend our deepest gratitude to the participants, site staff and the broader Alzheimer's disease community who contributed to the TANGO study."

Based on these results, the TANGO study has been terminated. Biogen will discontinue clinical development of gosuranemab. Analyses of additional data, including CSF biomarkers, are ongoing, and Biogen plans to present these TANGO results at an upcoming medical congress.

About the Phase 2 TANGO Study
The Phase 2 TANGO (NCT03352557) study of gosuranemab was a 78-week double-blind, placebo-controlled, parallel-group trial to evaluate both safety and efficacy on slowing rates of clinical progression in subjects with mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or with mild AD, followed by a dose-blind long term extension period. The study enrolled 654 participants across 97 sites. Participants aged 50–80 years with gradual and progressive change in memory function over more than 6 months, who met all of the clinical criteria for MCI due to AD or mild AD, had a CDR-SB of 0.5 for MCI due to AD or 0.5 or 1 for mild AD, a MMSE score of 22 to 30 (inclusive), a CDR Memory Box score of ≥0.5 and demonstrating amyloid-positivity by CSF or amyloid-PET were randomized to receive IV low, medium or high dose gosuranemab or placebo, once every 4 weeks. The primary endpoint of the study was safety.

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. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor Statement
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, about results from the TANGO study; the potential clinical effects of gosuranemab; data readouts and presentations for gosuranemab; the identification and treatment of Alzheimer's disease; our research and development program for the treatment of Alzheimer's disease; the potential of our commercial business and pipeline programs; and risks and uncertainties associated with drug development and commercialization. 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, unexpected concerns may arise from additional data, analysis or results obtained during our clinical trials; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates,; the occurrence of adverse safety events; the risks of unexpected hurdles, costs or delays; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release.

We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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