Biogen Reports Top-Line Results from Phase 2 Study in Progressive Supranuclear Palsy

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The primary endpoint of the Phase 2 PASSPORT study was not met, and further development of gosuranemab in progressive supranuclear palsy (PSP) will not be pursued

CAMBRIDGE, Mass., Dec. 13, 2019 (GLOBE NEWSWIRE) -- Today, Biogen Inc. (Nasdaq: BIIB) announced topline results from the Phase 2 PASSPORT study of gosuranemab (BIIB092) for progressive supranuclear palsy (PSP). The primary endpoint, as measured by the PSP rating scale (PSPRS) at week 52, was not statistically significant. In addition, the study did not demonstrate efficacy on key clinical secondary endpoints. Based on these results, Biogen will discontinue development of gosuranemab for PSP and other primary tauopathies.

"We are disappointed with the efficacy results of the Phase 2 PASSPORT study," said Alfred Sandrock Jr., M.D., Ph.D., Executive Vice President, Research and Development and Chief Medical Officer at Biogen. "We remain unwavering in our commitment to advancing therapies that have the potential to address the significant unmet medical needs of people with neurodegenerative diseases who are faced with limited to no treatment options."

Safety results of the PASSPORT study were generally consistent with previous studies of gosuranemab. Detailed results of this study will be made available in a future scientific forum.

Biogen will continue its ongoing Phase 2 TANGO study of gosuranemab for mild cognitive impairment due to Alzheimer's disease (AD) or mild AD, given differences in disease pathology.

About Gosuranemab
Gosuranemab (BIIB092) is a humanized monoclonal antibody that targets N-terminal tau. Gosuranemab-mediated removal of N-terminal tau is being studied to evaluate whether it slows the progression of disease in tauopathies.

TANGO, a Phase 2 study, is designed to evaluate the safety and tolerability of gosuranemab in participants with mild cognitive impairment due to Alzheimer's disease or with mild Alzheimer's disease.

Biogen licensed gosuranemab from Bristol-Myers Squibb Company.

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, neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology and pain.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and 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, including statements about results from the Phase 2 PASSPORT study; the potential clinical effects of gosuranemab; the potential benefits, safety and efficacy of gosuranemab; the clinical development program, clinical trials, data readouts and presentations related to gosuranemab; the potential of our commercial business and pipeline programs, including gosuranemab; 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, uncertainty of success in the development and potential commercialization of gosuranemab; the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected; 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, including gosuranemab; the occurrence of adverse safety events; the risks of other 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 third party collaboration risks. 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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