Biogen Idec Reports Top-Line Results from Phase 3 Trial Investigating Dexpramipexole in People with Amyotrophic Lateral Sclerosis (ALS)

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-- EMPOWER trial fails to demonstrate efficacy in primary and key secondary endpoints --

WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) reported top-line results of EMPOWER, a Phase 3 trial investigating dexpramipexole in people with amyotrophic lateral sclerosis (ALS). The trial did not meet its primary endpoint, a joint rank analysis of function and survival, and no efficacy was seen in the individual components of function or survival. The trial also failed to show efficacy in its key secondary endpoints. Additional analyses of multiple subpopulations failed to demonstrate any efficacy among these groups. Based on these results, Biogen Idec will discontinue development of dexpramipexole in ALS.

"We share the disappointment of members of the ALS community, who had hoped that dexpramipexole would offer a meaningful new treatment option," said Douglas E. Williams, Ph.D., Executive Vice President of Research and Development at Biogen Idec. "Nevertheless, the EMPOWER trial represents a significant contribution to ALS research, and Biogen Idec is committed to advancing ALS science. We continue to work with researchers around the world to understand the causes of ALS and find potential treatments for people with ALS."

The company intends to present detailed results at a future medical conference.

EMPOWER Trial

EMPOWER was a randomized, double-blind, placebo-controlled Phase 3 trial which enrolled 943 people with ALS at 81 sites in 11 countries. Patients were randomized on a one-to-one basis to receive either dexpramipexole or placebo. The primary endpoint was a joint rank analysis of function and survival, known as the Combined Assessment of Function and Survival (CAFS). In addition to CAFS, the trial individually evaluated functional decline, survival and respiratory decline, among other measures.

"As a physician who has treated people with ALS, I hoped with all my heart for a different outcome," said Douglas Kerr, M.D., Ph.D., Director of Neurodegeneration Clinical Research at Biogen Idec. "While these results were not what we expected, we hope these data will provide a foundation for future ALS research."

Biogen Idec's Commitment to ALS Research

Biogen Idec has several programs underway in ALS. The company recently entered into a research collaboration with Duke University and HudsonAlpha Institute to sequence the genomes of up to 1,000 people with ALS over the next five years in an effort to gain a deeper understanding about the fundamental genetic causes of the disease. Duke and HudsonAlpha will work with several world-class researchers who have deep expertise and experience with ALS and the genes associated with the disease.

Biogen Idec recently created a research consortium in collaboration with several leading academic research centers to identify new approaches to treating ALS. Each of the centers involved in this consortium brings different scientific and technical expertise and a shared goal of improving the understanding of ALS from a basic science perspective.

In addition, Biogen Idec has committed significant funds to the University of Massachusetts Medical School ALS Champion Fund. The funding will drive awareness of ALS and support basic and clinical science research into potential treatments for ALS and other neurodegenerative diseases.

About Biogen Idec

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies and the company generates more than $5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

Safe Harbor

This press release contains forward-looking statements, including statements about potential treatments for ALS. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on the company's current beliefs and expectations. Drug development involves a high degree of risk, and only a small number of research and development programs results in the commercialization of a product. Success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. In addition, clinical trials may indicate that product candidates have harmful side effects or raise other safety concerns that may significantly reduce the likelihood of regulatory approval. For more detailed information on the risks and uncertainties associated with Biogen Idec's drug development activities, please review the Risk Factors section of Biogen Idec's most recent annual or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and the company assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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