Biogen Idec and Abbott Announce Positive Top-Line Results from the First Registrational Trial for Daclizumab HYP in Relapsing-Remitting Multiple Sclerosis

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SELECT Study Demonstrates Significant Reductions in Annualized Relapse Rate and Meets Key Secondary Endpoints

Full Data to Be Presented at an Upcoming Medical Meeting

WESTON, Mass. & ABBOTT PARK, Ill.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Abbott (NYSE: ABT) today announced positive top-line results from SELECT, a global, registrational Phase 2b clinical trial designed to evaluate the investigational compound daclizumab high-yield process (DAC HYP) in people with relapsing-remitting multiple sclerosis (RRMS) over one year. Results showed that DAC HYP, administered subcutaneously once every four weeks, significantly reduced annualized relapse rate by 54 percent in the 150 mg dose arm ($p< 0.0001$) and 50 percent in the 300 mg dose arm ($p=0.0002$) compared to the placebo arm at one year. DAC HYP met key secondary endpoints for the 150 mg and 300 mg arms, respectively, providing a highly statistically significant reduction in the cumulative number of new gadolinium-enhancing (Gd+) lesions between weeks eight and 24 (69%; 78%); in the number of new or newly enlarging T2 hyperintense lesions at one year (70%; 79%); and in the reduction in the proportion of patients who relapsed (55%; 51%). DAC HYP also showed a trend toward improvement in quality of life measures at one year.

The SELECT trial also investigated DAC HYP's effect on disability progression as measured by the expanded disability status scale (EDSS) as a tertiary endpoint. Findings showed that DAC HYP reduced the risk of sustained disability progression at one year by 57 percent in the 150 mg dose arm and by 43 percent in the 300 mg dose arm compared to placebo. Additional analyses are ongoing and the companies anticipate presenting detailed data at an upcoming medical meeting.

"The exciting results for DAC HYP, along with previous clinical data, support our continued investigation of this candidate as a promising new approach to treating multiple sclerosis," said Doug Williams, Ph.D., Biogen Idec's Executive Vice President of Research and Development. "DAC HYP's convenient once-monthly, subcutaneous administration, combined with a strong efficacy profile, suggest that it may provide an attractive option for MS patients. We hope to confirm the results of SELECT in our second registrational trial, DECIDE."

"These results bring us one step closer in the development of a potential new treatment option for multiple sclerosis, an area of medicine where there continues to be a significant need for novel approaches for patients," said Eugene Sun, M.D., Vice President, Global Pharmaceutical Clinical Development, Abbott. "We look forward to continued analysis of the SELECT data and the opportunity to present these results in full context at an upcoming scientific forum."

In the SELECT trial, the overall incidence of adverse events and treatment discontinuations were similar in all study arms. Serious infections (2% versus 0%), serious cutaneous events (1% versus 0%) and liver function test abnormalities greater than five times the upper limit of normal (4% versus <1%) occurred more frequently in DAC HYP-treated patients than in the placebo group. There was one death in SELECT due to a complication of a psoas muscle abscess in a patient recovering from a serious skin adverse event and one in the ongoing dose blinded extension study (SELECTION) due to possible autoimmune hepatitis; a contributory role for DAC HYP in these events could not be excluded.

In addition to SELECT, DAC HYP is being studied in a Phase 3 registrational clinical trial called DECIDE, which is currently enrolling patients. DECIDE is evaluating the efficacy and safety of once-monthly subcutaneous DAC HYP as a monotherapy compared to interferon beta 1-a therapy over two to three years of treatment.

About SELECT

SELECT was a global, randomized, double-blind, placebo-controlled, one-year, dose-ranging study to determine the safety and efficacy of DAC HYP in 600 patients with RRMS. The study evaluated two doses of DAC HYP (150 mg or 300 mg every four weeks) and had a greater than 90 percent study completion rate in all treatment groups. The primary endpoint was the reduction in annualized relapse rate in patients with RRMS at one year. Secondary endpoints included the reduction in the cumulative number of new gadolinium-enhancing (Gd+) lesions between weeks eight and 24, in the number of new or newly enlarging T2 hyperintense lesions at one year, and in the proportion of patients with RRMS who relapsed, as well as improvement in quality of life measures in patients with RRMS at one year. Additional endpoints assessed the safety and tolerability of DAC HYP.

About DAC HYP

Daclizumab high-yield process (DAC HYP) is a subcutaneous formulation of daclizumab and an investigational therapy for the treatment of RRMS, the most common form of MS. DAC HYP is a humanized monoclonal antibody that binds to CD25, a receptor subunit that is expressed at high levels on T cells that are thought to become abnormally activated in autoimmune conditions, such as MS. Data from previous clinical trials showed that DAC HYP increases $CD56^{bright}$ NK cells, which target the activated immune cells that can play a key role in MS without causing general immune cell depletion.

About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for the treatment of serious diseases with a focus on neurological 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 $4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

Biogen Idec Safe Harbor

This press release contains forward-looking statements, including statements about the development of potential new treatments for MS. These statements may be identified by words such as "believe," "expect," "may," "plan," "will" and similar expressions, and are based on our current beliefs

and expectations. Drug development involves a high degree of risk. Factors which could cause actual results to differ materially from our current expectations include the risk that unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information or may fail to approve any potential new therapy, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and other activities, please read the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the SEC. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements.

About Abbott

Abbott (NYSE: ABT) is a global, broad-based health care company devoted to the discovery, development, manufacturing and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs nearly 90,000 people and markets its products in more than 130 countries.

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