Biogen Idec and Abbott Present Positive Data for Daclizumab HYP from Select Phase 2B Trial at ECTRIMS/ACTRIMS

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-Results Show DAC HYP Reduces Annualized Relapse Rate by Up To 54 Percent-

WESTON, Mass. & ABBOTT PARK, Ill.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) and Abbott (NYSE: ABT) announced additional results from the SELECT Phase 2b trial, the first of two registrational studies designed to evaluate the investigational compound daclizumab high-yield process (DAC HYP) in people with relapsing-remitting multiple sclerosis (RRMS). Results showed that DAC HYP, administered subcutaneously once every four weeks, met the trial's primary endpoint by significantly reducing the annualized relapse rate by 54 percent in the 150 mg dose group ($p<0.0001$) and 50 percent in the 300 mg dose group ($p=0.0002$) compared to the placebo group at one year. These data were presented in a late-breaking oral presentation at the 5th Joint Triennial Congress of the European and Americas Committees on Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS) in Amsterdam.

"These data from SELECT position DAC HYP as a potentially impactful new treatment option for multiple sclerosis (MS) with the convenience of a once-monthly subcutaneous injection, a first for patients," said Alfred Sandrock, M.D., Biogen Idec's Senior Vice President of Development. "We hope to see a similar effect on relapses and disability progression in the Phase 3 DECIDE trial, DAC HYP's second registrational trial, which is currently underway."

In SELECT, more than 90 percent of patients in the DAC HYP groups completed the study. In addition to meeting the primary endpoint, both doses of DAC HYP met key secondary endpoints, including measures of magnetic resonance imaging (MRI). In a sub-study for a pre-specified subset of patients, both 150 mg and 300 mg of DAC HYP provided a significant reduction in the cumulative number of new gadolinium-enhancing (Gd+) lesions between weeks eight and 24 (69%; 78%; $p<0.0001$). Both doses also provided a significant reduction in new or newly enlarging T2 hyperintense lesions (70%; 79%; $p<0.0001$). In a tertiary endpoint, both 150 mg and 300 mg of DAC HYP also significantly reduced the number of new Gd+ lesions on the week 52 MRI (79%; 86%; $p<0.0001$).

"We continue to be very encouraged by the clinical profile for DAC HYP, particularly the annualized relapse rate and disability progression results that we have seen in the data from the SELECT study," said John M. Leonard, M.D., Abbott's Senior Vice President of Global Pharmaceutical Research & Development. "We are pleased that the Abbott-Biogen Idec collaboration continues to make excellent progress in advancing the development of a potential new MS therapy."

DAC HYP reduced the proportion of patients who relapsed by 55 percent in the 150 mg group ($p<0.0001$) and by 51 percent in the 300 mg group ($p=0.0003$). The results from the trial also showed an improvement in quality of life (QoL), as measured by the Multiple Sclerosis Impact Scale (MSIS-29) physical score, in the DAC HYP 150 mg group ($p=0.0007$) and a trend favoring benefit in the 300 mg group ($p=0.1210$) compared to the placebo group.

SELECT also investigated the effect of DAC HYP 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 12-week sustained disability progression at one year by 57 percent in the 150 mg dose group ($p=0.021$) and by 43 percent in the 300 mg dose group ($p=0.091$) compared to placebo.

"Despite significant advances in the treatment of MS, there continues to be a need for additional treatment options for people with MS," said Dr. Gavin Giovannoni, M.D., Barts and The London School of Medicine and Dentistry, U.K. "DAC HYP's mechanism of action increases CD56 ^{Bright} NK cells, which are thought to target abnormally activated immune cells that may play a role in MS without depleting the immune system. This mode of action, combined with the strong efficacy profile in SELECT and convenient dosing schedule of one subcutaneous injection per month, suggest that it could be a promising therapy for patients in need."

The overall incidence of adverse events (AEs) and treatment discontinuations were similar in all study groups. Serious adverse events (SAEs) over the course of the study, excluding MS relapse, occurred in six percent in the placebo group, seven percent in the 150 mg dose group and nine percent in the 300 mg dose group. 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 groups 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; a contributory role for DAC HYP could not be excluded.

The SELECT data was presented in a late-breaking platform presentation, called *A randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of daclizumab HYP monotherapy in relapsing-remitting multiple sclerosis: primary results of the SELECT trial,* on Saturday, October 22, 2011.

About SELECT

SELECT was a Phase 2b global, randomized, double-blind, placebo-controlled, one-year, dose-ranging study to determine the safety and efficacy of DAC HYP in patients with RRMS. SELECT evaluated two doses of DAC HYP: 150 mg or 300 mg every four weeks. 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 Gd+ lesions between weeks eight and 24, in the number of new or newly enlarging T2 hyperintense lesions at one year, 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.

The SELECT study analyzed 600 randomized patients, 18 to 55 years of age. Patients participating in the study were required to have RRMS per McDonald criteria 1-4 and a baseline EDSS score between 0.0 and 5.5, as well as either one or more MS relapses in the 12 months prior to randomization, or Gd+ lesion activity on brain MRI within six weeks of randomization. Patients were randomized in a ratio of 1:1:1 to three treatment groups: 150 mg of DAC HYP (n=201), 300 mg of DAC HYP (n=203), and placebo (n=196).

About DAC HYP

Daclizumab high-yield process (DAC HYP) is a subcutaneous formulation of daclizumab in late-stage clinical development 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.

DAC HYP is being currently studied in the DECIDE Phase 3 clinical trial, which is evaluating the efficacy and safety of once-monthly subcutaneous DAC HYP as a monotherapy compared to interferon beta 1-a therapy.

About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for serious diseases with a focus on neurology, immunology and hemophilia. 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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