Biogen Idec and AbbVie Announce Positive Top-Line Results from Phase 3 Study Investigating Daclizumab High-Yield Process in Multiple Sclerosis

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− DAC HYP Demonstrated Superiority Over Interferon Beta-1a in Annualized Relapse Rate –

− Positive Results Set Stage for Regulatory Filings –

CAMBRIDGE, Mass. & NORTH CHICAGO, Ill.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ:BIIB) and AbbVie (NYSE:ABBV) announced positive top-line results from the Phase 3 DECIDE clinical trial, designed to evaluate the superiority of once-monthly, subcutaneous daclizumab high-yield process (DAC HYP) when compared to intramuscular interferon beta-1a (IFN β-1a), as a potential treatment for relapsing-remitting multiple sclerosis (RRMS), the most common form of multiple sclerosis (MS). Results showed that DAC HYP was superior on the study's primary endpoint, demonstrating a statistically significant 45 percent reduction in annualized relapse rate (ARR) compared to IFN β-1a ($p<0.0001$).

"The results of the DECIDE study are compelling, with DAC HYP demonstrating robust efficacy compared to a current standard of MS care," said Gilmore O'Neill, vice president, Global Neurology Clinical Development, Biogen Idec. "As a potential once-monthly therapy with a novel mechanism of action, we believe that, if approved, DAC HYP will be an important treatment option for people living with MS."

"The positive results in the DECIDE study represent achievement of an important milestone in the development of DAC HYP as a potential new treatment option for MS patients," said Michael Severino, M.D., executive vice president, Research and Development and chief scientific officer, AbbVie. "Together, the companies are committed to working with regulatory agencies on filing plans for DAC HYP."

DAC HYP showed superiority on the first secondary endpoint, number of new or newly enlarging T2-hyperintense lesions at week 96, with a 54 percent reduction relative to IFN β-1a ($p<0.0001$). On the second secondary endpoint, DAC HYP reduced the risk of three month confirmed disability progression as measured by the Expanded Disability Status Scale (EDSS) by 16 percent over IFN β-1a, which was not statistically significant ($p=0.16$). Using a pre-specified sensitivity analysis that accounted for 67 patients who did not have a confirmatory disability assessment, DAC HYP showed a 21 percent reduction in the risk of sustained disability progression ($p=0.047$).

The safety profile of DAC HYP in the study was consistent with what has been observed in prior studies. The overall incidence of adverse events was comparable across the DAC HYP and IFN β-1a treatment groups. In patients treated with DAC HYP compared to IFN β-1a, there was an increased incidence of serious infections (4 percent vs. 2 percent), serious cutaneous reactions (2 percent vs. < 1 percent), and elevations of liver transaminases greater than 5 times the upper limit of normal (6 percent vs. 3 percent). There were 4 deaths in the IFN β-1a group and 1 death in the DAC HYP group, none of which was considered treatment related.

Biogen Idec and AbbVie plan to work with regulatory agencies to determine appropriate timelines for filing. The companies intend to present detailed results from DECIDE at a future medical conference.

About DECIDE

DECIDE was a two to three year, Phase 3, global, randomized, double-blind, multicenter study designed to determine if DAC HYP would provide superior outcomes for certain clinical endpoints compared to treatment with IFN β-1a. The study enrolled more than 1,800 people with RRMS in 28 countries. DECIDE was an active comparator study with two groups: 150 mg of subcutaneous DAC HYP every four weeks was compared to IFN β-1a 30 mcg intramuscular injection once weekly.

The primary endpoint in DECIDE was the reduction in ARR. Secondary endpoints included the number of new or newly enlarging T2-hyperintense lesions, the proportion of patients with sustained disability progression (EDSS), the proportion of relapse-free patients and the proportion of patients who experienced a worsening physical impact score on the Multiple Sclerosis Impact Scale (MSIS-29).

After completing the DECIDE study, patients have the option to participate in an open-label extension study called EXTEND.

The DAC HYP development program also includes the previously completed pivotal, placebo controlled, double-blind SELECT study.

About Daclizumab High-Yield Process

DAC HYP is a new form of humanized monoclonal antibody that binds to CD25, a receptor subunit that is expressed at high levels on T-cells that become abnormally activated in MS. DAC HYP modulates IL-2 signaling without causing general immune cell depletion. DAC HYP is believed to work by decreasing abnormally-activated T-cells and pro-inflammatory lymphoid tissue inducer cells, and increasing $CD56^{bright}$ natural killer (NK) cells, important cells that help regulate the immune system.

Biogen Idec and AbbVie are jointly developing DAC HYP.

About Avonex® (Interferon β-1a)

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. AVONEX is indicated for the treatment of patients with relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with MS. Symptoms of depression, suicidal ideation, or psychosis, and cases of suicide, have been reported with increased frequency with patients receiving AVONEX. Severe hepatic injury, including cases of hepatic failure has been reported rarely in patients. Rare cases of anaphylaxis have been reported. While beta interferons do not have any known direct cardiac toxicity, cases of congestive heart failure, cardiomyopathy, and cardiomyopathy with congestive heart failure have been reported in patients without known predisposition. Decreased peripheral blood counts have been reported from post-marketing experience. Seizures have been reported in patients using AVONEX, including patients with no prior history of seizure. Autoimmune disorders of

multiple target organs have been reported. Routine periodic blood chemistry, hematology, liver function, and thyroid function tests are recommended. AVONEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The most common side effects associated with AVONEX treatment are flu-like symptoms, including chills, fever, myalgia, and asthenia.

For additional important safety information, and the United States full prescribing information, please visit www.AVONEX.com.

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. For product labeling, press releases and additional information about the Company, please visit www.biogenidec.com.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. AbbVie employs approximately 25,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

Biogen Idec Safe Harbor

This press release contains forward-looking statements, including statements about the potential of daclizumab high-yield process as an MS treatment option and plans for regulatory filings. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. Drug development and commercialization involve 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 further studies, or may fail to approve or may delay approval of our drug candidates, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our 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 we assume no obligation to update any forward-looking statements.

AbbVie Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in AbbVie's 2013 Annual Report on Form 10-K/A, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

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