Detailed Results from Biogen Idec and AbbVie's Pivotal Phase 3 Decide Study Further Define the Efficacy and Safety Profile of ZINBRYTA™ (Daclizumab High-Yield Process)

September 12, 2014

– Data Confirm ZINBRYTA™ is Superior to AVONEX® in Reducing Annualized Relapse Rate –

– First Presentation of Full DECIDE Results at ACTRIMS-ECTRIMS Meeting –

CAMBRIDGE, Mass. & NORTH CHICAGO, Ill.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) and AbbVie (NYSE: ABBV) announced the full results from the Phase 3 DECIDE clinical trial, which show ZINBRYTA™ (daclizumab high-yield process), dosed subcutaneously once a month, demonstrated a statistically significant improvement in reducing disease activity in people with relapsing-remitting multiple sclerosis (RRMS) compared to AVONEX® (interferon beta-1a).

These results are being presented at the Sixth Triennial Joint Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS) in Boston.

"The full results from DECIDE demonstrate that ZINBRYTA significantly improved key measures of multiple sclerosis disease activity compared to AVONEX, including reducing annualized relapse rate and new brain lesion development," said Ludwig Kappos, M.D., chair, Department of Neurology and head, MS-Research Group, University Hospital, Basel, Switzerland, and lead investigator for DECIDE. "These results help us better understand ZINBRYTA as a potential treatment option for people with relapsing-remitting MS."

DECIDE Detailed Efficacy Results

DECIDE was a two- to three-year, Phase 3, global, randomized, double-blind study that evaluated whether ZINBRYTA would provide superior outcomes for certain clinical endpoints compared to AVONEX. The study enrolled more than 1,800 patients with RRMS.

Primary Endpoint:

- Patients on ZINBRYTA demonstrated a statistically significant 45 percent reduction in annualized relapse rate (ARR) compared to patients treated with AVONEX ($p<0.0001$).

Secondary Endpoints:

- ZINBRYTA demonstrated superiority in reducing the number of new or newly enlarging T2-hyperintense lesions at week 96, with a 54 percent reduction relative to AVONEX ($p<0.0001$).
- The risk of three-month confirmed disability progression, as measured by the Expanded Disability Status Scale (EDSS), was reduced by 16 percent in patients treated with ZINBRYTA compared to those on AVONEX ($p=0.16$). This was not statistically significant.
- Seventy-three percent of ZINBRYTA patients were relapse-free compared to 59 percent of AVONEX patients (nominal $p<0.0001$) at week 96.
- The risk of meaningful worsening in the physical impact of multiple sclerosis (MS) (> 7.5 point worsening in the Multiple Sclerosis Impact Scale [MSIS-29] physical score) was reduced by 24 percent in the ZINBRYTA group compared to the AVONEX group (nominal $p=0.018$).

"For people living with multiple sclerosis, there continues to be a need for new medicines that work in different ways," said Gilmore O'Neill, vice president, Multiple Sclerosis Research and Development, Biogen Idec. "If approved, ZINBRYTA would offer a novel mechanism to treating MS, in a self-administered, once-monthly dosing regimen."

DECIDE Safety Results

The safety profile of ZINBRYTA in the DECIDE study was generally consistent with the Phase 2 studies. The overall incidence of adverse events was comparable across the ZINBRYTA and AVONEX treatment groups.

In patients treated with ZINBRYTA compared to AVONEX, there was an increased incidence of serious infections (4 percent vs. 2 percent). The pattern and types of infections seen in the ZINBRYTA group were consistent with what has been previously observed in the MS population.

Also consistent with previous studies, patients in the ZINBRYTA group had a greater incidence of cutaneous adverse events (37 percent vs. 19 percent) and serious cutaneous reactions (2 percent vs. < 1 percent); and elevations of liver transaminases greater than five times the upper limit of normal (6 percent vs. 3 percent). There were four deaths in the AVONEX group and one death in the ZINBRYTA group, none of which was considered treatment related.

Based on the efficacy and safety data from the ZINBRYTA clinical development program, Biogen Idec and AbbVie plan to file marketing applications for ZINBRYTA with regulatory authorities during the first half of 2015.

"The results from DECIDE further support the potential of ZINBRYTA and we look forward to submitting the data for this investigational therapy to

regulatory agencies," said Michael Severino, M.D., executive vice president, Research and Development and chief scientific officer, AbbVie.

ZINBRYTA data will be presented:

- **Friday, Sept. 12 at 8:15 a.m. ET, Platform Presentation:** *Primary Results of DECIDE: A Randomized, Double-Blind, Double-Dummy, Active-Controlled Trial of Daclizumab HYP vs. Interferon β-1a in RRMS Patients (FC1.1)*

Additional ZINBRYTA data were presented:

- **Thursday, Sept. 11 at 3:30 p.m. ET, Poster Presentation:** *Brain MRI Results of DECIDE: A Randomized, Double-Blind Trial of DAC HYP vs. IFNβ-1a in RRMS Patients (P051)*
- **Thursday, Sept. 11 at 3:30 p.m. ET, Poster Presentation:** *Safety and Tolerability of Daclizumab HYP Treatment in Relapsing-Remitting Multiple Sclerosis: Results of the DECIDE Study (P094)*

About DECIDE

DECIDE was a two- to three-year, Phase 3, global, randomized, double-blind, multicenter study designed to determine if ZINBRYTA would provide superior outcomes for certain clinical endpoints compared to treatment with AVONEX. The study enrolled more than 1,800 patients with RRMS in 28 countries. DECIDE was an active comparator study with two groups: 150 mg of subcutaneous ZINBRYTA every four weeks was compared to AVONEX 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). Secondary endpoints were rank ordered and tested with a sequential closed testing procedure to control inflation of type I error due to multiple endpoints. If a comparison was not statistically significant, then all endpoints of a lower rank were not significant per the closed testing procedure.

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

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

About ZINBRYTA™ (daclizumab high-yield process)

ZINBRYTA (daclizumab high-yield process) is an investigational drug and is a new form of a humanized monoclonal antibody that selectively binds to the high-affinity interleukin-2 (IL-2) receptor subunit (CD25) that is expressed at high levels on T-cells that become abnormally activated in MS. ZINBRYTA modulates IL-2 signaling without causing general immune cell depletion. ZINBRYTA 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 ZINBRYTA.

About AVONEX® (interferon beta-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, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For product labeling, press releases and additional information about the Company, please visit http://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 ZYNBRYTA (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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