



Biogen Idec and Abbott Announce Enrollment of First Patient in Global Phase III Study of Daclizumab for Relapsing-Remitting Multiple Sclerosis

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Active Comparator Study Designed to Examine the Safety and Efficacy of Daclizumab Formulated for Monthly Subcutaneous Dosing

CAMBRIDGE, Mass. & ABBOTT PARK, Ill.--([BUSINESS WIRE](#))--[Biogen Idec](#) (NASDAQ: BIIB) and [Abbott](#) (NYSE: ABT) today announced enrollment of the first patient in a global Phase III study evaluating the efficacy and safety of daclizumab compared to interferon beta-1a ([AVONEX®](#)) in patients with relapsing-remitting multiple sclerosis (RRMS), the most common form of multiple sclerosis (MS). The trial, called DECIDE, will investigate a subcutaneous formulation of daclizumab intended for monthly administration, which has the potential to provide a new immunomodulatory approach for treating MS. Under the terms of the collaboration agreement, Biogen Idec will make a \$30 million milestone payment to Abbott. This payment is due upon enrollment of the first patient in the DECIDE trial.

"Despite significant advances in MS therapy, many patients continue to experience disease activity. The MS community is eager for new treatment approaches," said Ludwig Kappos, M.D., Head, MS-Research Group, University Hospital, Basel, Switzerland, and lead investigator for the study. "As shown in previous studies, daclizumab appears to selectively target immune cells that are thought to become activated in MS and cause damage to the central nervous system."

DECIDE is a global Phase III, randomized, double-blind, active-comparator study expected to enroll approximately 1,500 RRMS patients in 28 countries. The trial will investigate a subcutaneous formulation of daclizumab intended for once-monthly administration as a monotherapy compared to treatment with interferon beta 1-a, one of the most common treatments for MS. Daclizumab is also being investigated in the ongoing Phase IIb registration-enabling SELECT trial, which is evaluating the efficacy and safety of monthly subcutaneous doses of either 150 mg or 300 mg of daclizumab monotherapy.

"The DECIDE study builds on the positive results we saw in the CHOICE trial, which showed that daclizumab, when added to interferon beta, significantly reduced MS lesions compared to interferon beta therapy alone," said Alfred Sandrock, M.D., Ph.D., Senior Vice President of Neurology Research and Development at Biogen Idec. "Initiating this trial demonstrates our commitment to developing new treatment options for patients who suffer from this terrible disease."

"Initiating the Phase III DECIDE trial is a tremendous milestone for the collaboration as it brings daclizumab one step closer to becoming a potential new treatment option for patients with MS," said Eugene Sun, M.D., Vice President, Global Pharmaceutical Clinical Development, Abbott. "Extensive preclinical and clinical experience with daclizumab suggest this drug holds promise as a new approach for the treatment of MS, and we look forward to expanding our knowledge further with the DECIDE trial."

Multiple sclerosis, one of the most common neurological disorders, affects more than 2.5 million people worldwide. In MS, certain immune cells, called T-cells, become activated and are believed to migrate to the central nervous system (CNS), releasing cytokines that injure nerve fibers in the CNS and cause the symptoms of MS.

Daclizumab is a humanized monoclonal antibody that binds to CD25, a receptor subunit that is expressed at low levels on resting T-cells and at high levels on T-cells that are thought to become activated in response to MS. Daclizumab is believed to work by selectively targeting these activated T-cells without causing general T-cell depletion.

Data from the Phase II CHOICE trial demonstrated that daclizumab 2mg/kg administered subcutaneously every two weeks in combination with interferon beta (IFN β) therapy led to a 72 percent reduction in the number of new or enlarged MS lesions when compared to IFN β therapy alone in patients with active, relapsing forms of MS. Additional analysis from the study revealed that daclizumab led to an increase of a subset of natural killer cells (CD56^{bright} NK cells) that help regulate the immune system. This increase was associated with a significant reduction in MS lesion formation. The incidence of common adverse events was similar in all treatment groups. Some serious adverse events occurred in daclizumab treated patients, which were most commonly infections that resolved with standard interventions.

About DECIDE

DECIDE (Daclizumab HYP Efficacy Compared to Interferon Beta 1-a Study for Multiple Sclerosis) is a two- to three-year, Phase III, multicenter, double-blind, randomized, parallel-group, monotherapy, active-control study designed to determine the efficacy and safety of daclizumab versus interferon beta 1-a, one of the most common MS treatments, in patients with RRMS. The trial is expected to enroll approximately 1,500 RRMS patients in 28 countries. The study will include patients between the ages of 18 to 55 years with an Expanded Disability Status Scale (EDSS) score ranging from 0.0 to 5.0.

The primary objective of the study is to determine the efficacy of daclizumab compared to interferon beta 1-a in preventing MS relapse, with annualized relapse rate as the primary endpoint. The study will also examine the efficacy of daclizumab compared to interferon beta 1-a in slowing functional decline and disability progression and in maintaining quality of life.

During the 96- to 144-week treatment period, all study participants will receive either a subcutaneous injection of daclizumab 150 mg once every four weeks or weekly injections of interferon beta 1-a.

About Daclizumab

Daclizumab is a humanized monoclonal antibody that binds to the CD25 alpha subunit of the high affinity IL-2 receptor. CD25 is expressed at low levels on resting T-cells (immune cells) and at high levels on T-cells that can become activated in response to autoimmune conditions such as MS. Daclizumab is believed to work by selectively binding to and inhibiting this receptor on activated T-cells without causing T-cell depletion. Daclizumab is an investigational agent in clinical development for the treatment of MS under a collaboration between Facet Biotech, acquired by Abbott in April 2010,

and Biogen Idec. Daclizumab is currently being studied in two registrational clinical trials in patients with MS.

About Multiple Sclerosis

Multiple sclerosis is a chronic, unpredictable and progressive disease of the central nervous system that causes inflammation and destruction of the myelin sheath – the protective layer that surrounds the body's nerve fibers. This destruction may result in cognitive impairment, physical disability and fatigue. According to the National Multiple Sclerosis Society, MS affects about 400,000 people in the U.S. and more than 2.5 million people worldwide. Relapsing-remitting multiple sclerosis (RRMS) affects about 85 percent of the newly diagnosed MS population. RRMS is characterized by clearly defined flare-ups followed by periods of partial or complete recovery or remission.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients worldwide benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 83,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's website at www.abott.com

Biogen Safe Harbor

This press release contains forward-looking statements regarding the development of daclizumab in multiple sclerosis. These statements 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 we may not fully enroll our planned clinical trials, unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information, further studies, or may fail to approve the drug, or we may encounter other unexpected hurdles. Other factors that may cause actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are discussed in Biogen Idec's filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" sections of Biogen Idec's periodic reports on Form 10-K and Form 10-Q filed with the SEC. Forward-looking statements, like all statements in this press release, speak only as of the date of this press release (unless another date is indicated). Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

Abbott Forward Looking Statement

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. Abbott 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. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Item 1A, "Risk Factors," to our Annual Report on Securities and Exchange Commission Form 10-K for the year ended Dec. 31, 2009, and in Item 1A, "Risk Factors," to our Quarterly Report on Securities and Exchange Commission Form 10-Q for the period ended March 31, 2010, and are incorporated by reference. Abbott undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments.

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