



Biogen Idec Announces Enrollment of First Patient in Phase II BG-12 Combination Trial in Multiple Sclerosis

June 15, 2010

EXPLORE Trial to Evaluate Oral BG-12 as Combination Therapy for Patients Who Continue to Experience Disease Progression Despite Ongoing Treatment

CAMBRIDGE, Mass.--([BUSINESS WIRE](#))--[Biogen Idec](#) (NASDAQ: BIIB) today announced enrollment of the first patient in a multicenter Phase II clinical trial designed to evaluate its investigational oral therapy BG-12 (dimethyl fumarate) in combination with commonly used first-line treatments in patients with relapsing-remitting multiple sclerosis (RRMS). The trial, called EXPLORE, will evaluate the safety and tolerability of BG-12 when administered with beta interferons (IFN β) or glatiramer acetate (GA) to patients who continue to have evidence of disease activity despite receiving consistent monotherapy for at least a year. Efficacy endpoints will also be assessed in a subset of patients.

"An ongoing treatment challenge in MS is that many patients continue to experience disease activity despite being on therapy," said Alfred Sandrock, M.D., Ph.D., Senior Vice President of Neurology Research and Development at Biogen Idec. "The goal of the EXPLORE trial is to evaluate whether BG-12 may be a safe and effective agent to use in combination with other MS therapies, an important consideration for patients for whom new treatment strategies are needed."

BG-12 is the first compound in trials for the treatment of MS that has been shown to activate the Nrf2 transcriptional pathway. Experimentally, the Nrf2 pathway has demonstrated neuroprotective and anti-inflammatory properties. Activation of this pathway in MS patients may potentially prevent further cell damage and tissue loss caused by the disease. Preclinical studies have shown that activation of the Nrf2 pathway defends against oxidative-stress induced neuronal death, protects the blood-brain barrier and supports maintenance of myelin integrity in the central nervous system. Central nervous system inflammation and damage may trigger the symptoms common in RRMS such as fatigue, cognitive deterioration and physical disability.

Data from the Phase IIb study in RRMS, combined with experimental data showing BG-12's ability to activate the Nrf2 pathway, continue to support its evaluation as a monotherapy in two extensive ongoing Phase III MS studies, DEFINE and CONFIRM, which are fully enrolled. These data also support its further investigation as a combination therapy in EXPLORE.

"The MS community is eager for new treatment options for this debilitating disease," said Robert Fox, M.D., Staff Neurologist and Medical Director at the Cleveland Clinic Mellen Center for Multiple Sclerosis Treatment and Research. "BG-12 may offer patients an additional treatment strategy. Its potential to both reduce inflammation and promote neuroprotection, its safety data to date, as well as its oral administration, support this study of BG-12 as a possible combination therapy for MS."

"The EXPLORE trial is another demonstration of Biogen Idec's commitment to MS," said Dr. Sandrock. "We have one of the most extensive MS pipelines in the industry, with multiple programs that target pathways thought to be critical in treating MS. This pipeline includes late-stage programs such as BG-12, PEGylated interferon beta 1a, and daclizumab, earlier-stage programs such as anti-LINGO, and several preclinical programs."

About EXPLORE

EXPLORE is an open-label, multicenter Phase II clinical trial that will enroll approximately 100 RRMS patients in the United States currently receiving IFN β or GA as monotherapy. Patients in the trial must have received consistent therapy with IFN β or GA for at least one year prior to enrolling in the trial and have evidence of disease activity. EXPLORE will primarily evaluate the tolerability and safety of BG-12 as a combination therapy by the incidence and type of adverse events (AEs), serious AEs and AEs leading to discontinuation of study treatment, as well as the incidence and type of laboratory abnormalities and MS disease activity in all study patients. In a subset of patients, the study will also investigate the efficacy of BG-12 in combination with IFN β or GA by evaluating the mean number of new and total gadolinium-enhancing (Gd+) lesions on brain MRI scans.

Patients enrolled in EXPLORE will have monthly MRIs. They will continue on their prescribed treatments (IFN β or GA) for two months, at which point they will receive 240 mg of BG-12 three times daily in combination with their existing treatment for an additional six months.

About BG-12

BG-12 (BG00012, dimethyl fumarate) is an investigational oral therapy in Phase III clinical development as a monotherapy for the treatment of relapsing-remitting multiple sclerosis (RRMS), the most common form of MS, and in Phase II clinical development for rheumatoid arthritis (RA). BG-12 received Fast Track designation in MS from the U.S. Food and Drug Administration (FDA), which may expedite U.S. regulatory review. Biogen Idec retains full worldwide commercial rights to BG-12.

The Phase IIb study of BG-12, which was published in *The Lancet*, showed that BG-12 as a monotherapy reduced the number of new gadolinium enhancing (Gd+) lesions by 69 percent in patients with RRMS when compared to treatment with placebo ($p < 0.0001$). The presence of Gd+ lesions is thought to indicate continuing inflammatory activity within the central nervous system. Results from this study stimulated further evaluation of BG-12's potential for neuroprotection.

About MS

MS 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 MS Society, MS affects about 400,000 people in the United States and more than 2.5 million people worldwide. RRMS affects about 85 percent of the MS population. RRMS is characterized by clearly defined flare-ups followed by periods of partial or complete recovery or remission.

Dr. Fox is a paid speaker and conducts research for Biogen Idec.

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.

Safe Harbor

This press release contains forward-looking statements about the development of BG-12. These statements are based on our current beliefs and expectation. 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 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. Additional risks and uncertainties are described in the Risk Factors section of our reports on Form 10-K and Form 10-Q and in other reports we file with the SEC. These forward-looking statements speak only as of the date of this press release, and we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

Contact:

Biogen Idec
MEDIA CONTACT:
Kate Weiss, 617-914-6524
or
INVESTOR CONTACT:
Kia Khaleghpour, 617-679-2812