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BG-12 Psoriasis Study Meets Primary Endpoint; Oral Compound Also Being Studied for MS in Phase II Trial

CAMBRIDGE, Mass., SAN DIEGO & LUCERNE, Switzerland--(BUSINESSWIRE)--April 7, 2005--Biogen Idec (NASDAQ: BIIB) and Fumapharm AG today announced results from a Phase III study designed to evaluate the efficacy and safety of BG-12, an oral fumarate, in the treatment of moderate to severe psoriasis. The trial met the primary endpoint and patients receiving BG-12 demonstrated a statistically significant clinical improvement as measured by a lower median psoriasis severity score after 16 weeks of treatment than patients receiving placebo.

"These data will be used to support a filing for market authorization in Germany this year," said Burt A. Adelman, M.D., Biogen Idec's Executive Vice President, Development. "We will work with our partner, Fumapharm, to determine the next steps for the BG-12 program. Additional Phase III studies would need to be conducted for applications in the US and the rest of Europe."

The trial, conducted by Fumapharm, was a multicenter, double-blind, placebo-controlled Phase III study of 175 patients with moderate to severe psoriasis. Patients were randomized to receive placebo (n=70) or 720 mg of BG-12 a day (n=105) for 16 weeks. Patients were evaluated using the psoriasis area and severity index (PASI), a common measure of overall psoriasis severity. The primary endpoint was the PASI score at 16 weeks.

At 16 weeks, the median PASI was 5.8 for the BG-12 group and 14.2 for the placebo group. Median percentage reduction from baseline PASI was 68% for patients receiving BG-12 and 10% for patients receiving placebo.

In the study, the most commonly reported adverse events were flushing and diarrhea. In addition, one patient was hospitalized for pneumonia and one patient was hospitalized for kidney stones. The data from the study will be presented at an upcoming medical meeting.

Biogen Idec also announced that a Phase II study of BG-12 in patients with relapsing-remitting multiple sclerosis (MS) was initiated in November 2004. The study, being conducted in Europe, is a placebo-controlled, dose-ranging study designed to assess the efficacy and safety profile of BG-12. The primary endpoint of the study will be an MRI measurement of the amount of brain lesion activity at six months. Approximately 250 patients are expected to be enrolled in the study across 10 countries.

About BG-12

In October 2003, Biogen Idec licensed exclusive worldwide rights to develop and market BG-12 from Fumapharm AG, a privately held pharmaceutical company headquartered in Lucerne, Switzerland. BG-12 is an oral fumarate derivative with an immunomodulatory mechanism of action. Biogen Idec is evaluating BG-12 in a range of diseases, including psoriasis and MS.

This press release contains forward-looking statements regarding the development of BG-12. These statements are based on our current beliefs and expectations. They are subject to the risks inherent in drug development, including the risks that the effects of the product in larger clinical trials may not be as expected or that there may be safety issues or other problems or delays that arise during clinical trials, unexpected technical or manufacturing hurdles, or intellectual property disputes. There is no certainty that the risk/benefit profile of the drug will be acceptable to the Company or to regulatory authorities for a particular indication. Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in animal models or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. For more detailed information on the risks and uncertainties associated with these forward looking statements and Biogen Idec's other activities see the periodic and other reports that Biogen Idec has filed with the SEC. Biogen Idec does not undertake any obligation to publicly update any forward-looking statements.

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