biogen idec

July 8, 2005

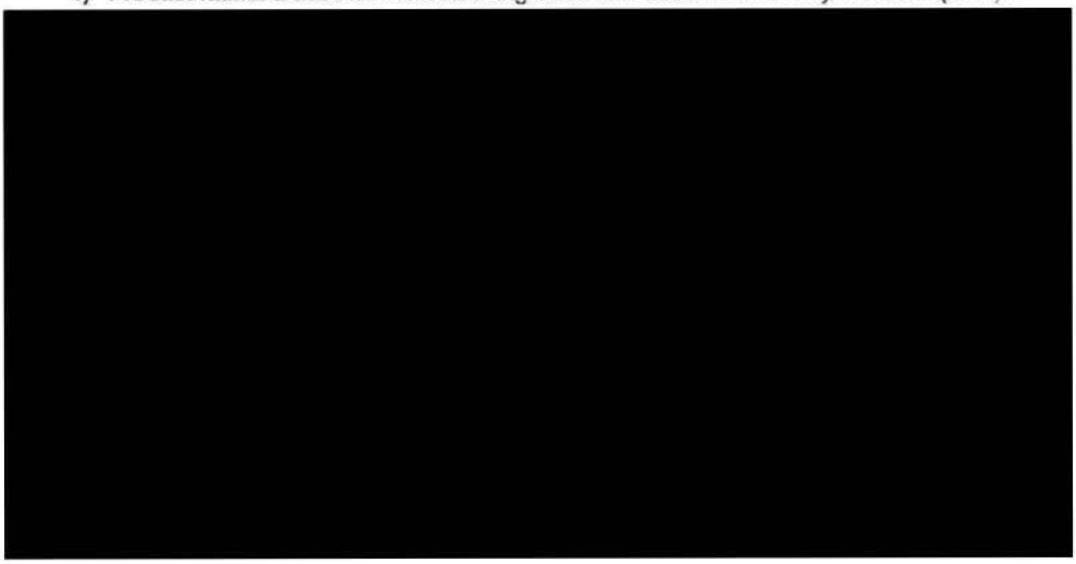
Russell G. Katz, M.D
Director, Division of Neuropharmacological Drug Products
Office of Drug Evaluation I, HFD-120
Woodmont II, 4th Floor Document Room
1451 Rockville Pike,
Rockville, MD 20852

RE: Request for Type B Meeting – Pre-IND Meeting

Dear Dr. Katz:

Biogen Idec, Inc. is requesting a face-to-face meeting to discuss BG00012, a compound that is being developed as an oral drug product for the treatment of Relapsing Remitting Multiple Sclerosis. The information for the requested meeting is as follows:

1) **Product name:** BG00012. The active ingredient in BG00012 is dimethyl fumarate (DMF).



3) **Proposed indication:**
The proposed indication is for the treatment of relapsing-remitting multiple sclerosis.

4) **Type of meeting being requested:** Type B – Pre-IND Meeting.

5) **Purpose of the meeting:** Biogen Idec intends to file an IND in Q4 2005 for BG00012 to initiate a Phase 1 clinical study. In this regard, we would like to discuss with the Agency (a) the chemistry, manufacturing and controls information, nonclinical pharmacology and toxicology data and clinical pharmacology and safety data that will be submitted in support of an IND; and (b) an overall clinical development plan to support registration of BG00012 as monotherapy for the treatment of relapsing remitting multiple sclerosis.

6) **Meeting objective:** The objectives of this meeting are to (a) discuss existing pre-clinical pharmacology and toxicology and clinical data in support of an IND; and (b) to discuss and agree on the design of a Phase I "Thorough QT/QTc" clinical study evaluating the safety of BG00012.

[redacted]

8) **Listing of specific questions:**

Pre-clinical

1) [redacted] Based on the totality of the non-clinical data provided in the information package, it is proposed that no additional nonclinical studies are necessary to support initiation of Phase 3 studies with BG00012 drug product in patients with relapsing-remitting multiple sclerosis. Does the FDA agree that preclinical data provided in the information package are sufficient to support the initiation of the Phase 3 clinical trials?

2) [redacted]

[redacted]

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[redacted]

7) **List of sponsor participants:**

[redacted]

Gilmore O'Neill, Associate Director, Medical Research

[redacted]

8) **Supporting documentation:** An information package will be submitted to the Agency four weeks in advance of the meeting.

[redacted]

Should you have any questions regarding this request, please contact [redacted]

Sincerely Yours,

[redacted]

Senior Vice President, Regulatory Affairs
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Attachment 1