(S43) BASELINE CHARACTERISTICS OF PATIENTS IN PHASE 3 STUDIES OF BG-12 IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background: BG-12, an oral therapy that exhibits anti-inflammatory and potentially neuroprotective mechanisms of action, is in phase 3 clinical trials for relapsing-remitting multiple sclerosis (RRMS). DEFINE and CONFIRM are ongoing trials with the primary objective of determining whether BG-12 is effective in reducing clinical relapses at 2 years. Objectives: To describe the baseline patient characteristics in two randomized, multicenter, double-blind, placebo-controlled phase 3 studies. Methods: The main inclusion criteria for DEFINE and CONFIRM were age 18 to 55 years; confirmed diagnosis of RRMS (McDonald criteria); baseline Expanded Disability Status Scale (EDSS) score of ≤5.0; and at least one relapse within the 12 months prior to randomization or having gadolinium-enhancing lesion(s) on brain magnetic resonance imaging (MRI) performed within the 6 weeks prior to randomization. Participants had to have a prior brain MRI study demonstrating lesion(s) consistent with MS. BG-12 was administered at a dose of 240 mg either two or three times daily in both studies. In CONFIRM, glatiramer acetate was used as the reference comparator and was administered at 20 mg daily subcutaneously. Assessments included relapses, MRI lesions, brain atrophy, and magnetization transfer ratio (MTR), as well as progression of disability as determined by EDSS scores. Results: A total of 1237 and 1431 patients were randomized in DEFINE and CONFIRM, respectively. Baseline demographics for DEFINE and CONFIRM were mean ± SD age at baseline, 38.4 ± 9.1 and 37.6 ± 9.2 years; female, 74% and 71%; white, 83% and 89%. In DEFINE, a mean of 5.5 years had elapsed since diagnosis. Over the previous 3 years, patients had a mean of 2.5 relapses, and in the last 12 months they had a mean of 1.3 relapses. A mean of 6.5 months had elapsed since the last relapse. In CONFIRM, a mean of 4.9 years had elapsed since diagnosis. Over the previous 3 years, patients had a mean of 2.5 relapses, and in the last 12 months they had a mean of 1.4 relapses. A mean of 6.2 months had elapsed since the last relapse. Patients’ mean baseline EDSS score was 2.41, with 17% having EDSS scores ≥4 (DEFINE), and 2.53, with 16% having EDSS scores ≥4 (CONFIRM). Conclusions: Baseline demographics for patients in these studies suggest that these groups have characteristics broadly comparable with contemporary trials and each other. This comparability will be further evaluated with the presentation of baseline MRI results.

Supported by: Biogen Idec, Inc


Keywords: disease-modifying treatment in MS