INTRODUCTION

Delayed-release dimethyl fumarate (DMF) is approved in the United States and Europe for the treatment of relapsing forms of multiple sclerosis (MS) and for relapsing forms of multiple sclerosis (MS), respectively, and in the European Union and Canada for the treatment of relapsing–remitting MS (RRMS).

Clinical trials demonstrated a significant improvement in disability status in patients with RRMS to placebo-controlled clinical trials.1

OBJECTIVE

• To describe the safety and tolerability of delayed-release DMF as add-on therapy to beta-interferon (IFNβ) or glatiramer acetate (GA) in patients with RRMS during the add-on therapy period.

METHODS

• Study Design

• Safety Experience in Add-on Therapy Period of EXPLORE

• Baseline characteristics of the 104 patients who completed the monotherapy period and were dosed with delayed-release DMF plus IFNβ or GA are summarized in Table 1.

• Adverse events (AEs) and serious AEs leading to treatment discontinuation

RESULTS

• Patients

• A total of 104 patients were included in this study. 57 patients were in the DMF add-on therapy period (Weeks -8, -4, and Week 0) and 47 patients were in the IFNβ add-on therapy period. As expected, baseline characteristics were well matched between treatment groups (Table 1).

• Laboratory abnormalities

• The most common AE in both treatment groups during the add-on therapy period was flushing, followed by GI events (Table 3).

• Safety Experience in Add-on Therapy Period of EXPLORE

• There was no overall increased risk of infection in either group (Table 4).

• Adverse events (AEs) and serious AEs leading to treatment discontinuation

• There were no reported opportunistic infections or deaths.

• The most common AEs in both treatment groups during the add-on therapy period were flushing, followed by skin reactions and fatigue (Table 3).

• There was no increased risk of opportunistic infections or deaths among patients receiving delayed-release DMF.

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CONCLUSIONS

• DMF add-on therapy is well tolerated in patients with RRMS in combination with beta-interferon or glatiramer acetate.

• The overall safety profile was similar to the known safety profile of delayed-release DMF monotherapy.

• The efficacy analysis was only exploratory, and no adjustment for multiple comparisons or missing value imputation was performed.

• The study was sponsored by Biogen Idec and Novartis; research grant funding from Novartis.

• Secondary Efficacy Endpoints in EXPLORE

• The efficacy analysis was only exploratory, and no adjustment for multiple comparisons or missing value imputation was performed.

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