INTRODUCTION

- Delayed-release dimethyl fumarate (DMF; also known as gastro-resistant DMF) demonstrated significant efficacy and a favorable benefit-risk profile vs. placebo in patients with relapsing-remitting multiple sclerosis in 2 Phase 3 trials.1,2
- In an integrated analysis of the DEFINE and CONFIRM studies, patients treated with DMF showed improved health-related quality of life vs. placebo as assessed by patient-reported outcomes (PROs), including the Physical and Mental Component Summary Scores (PCS and MCS, respectively) of the 36-Item Short-Form Health Survey (SF-36), the global assessment of well-being visual analog scale (VAS), and the EuroQol-5 Dimensions (EQ-5D VAS).3

RESULTS

- Of 333 patients enrolled in RESPOND, 318 received 21 dose of DMF and did not have any major protocol deviations; 168 completed the study, 61 discontinued treatment, and 26 withdrew from the study. Reasons for DMF treatment discontinuation included adverse events, efficacy reasons, lost to follow-up, investigator decision, and death (1 death was reported; the cause was not related to DMF treatment).
- Baseline characteristics are presented in Table 1.
- Notably, there was a higher percentage of older patients in RESPOND than in DEFINE/CONFIRM integrated analysis: 45% of patients were ≥50 years of age in RESPOND vs. 12% in DEFINE/CONFIRM integrated analysis.13
- In RESPOND, 26% of patients were aged 55 years or older vs. 55% in DEFINE and 58% in CONFIRM.
- And 45% of patients were 250 years of age or younger in RESPOND vs. 12% in DEFINE and 13% in CONFIRM.1,2
- Additionally, there was a greater percentage of black patients in the RESPOND compared with the Phase 3 clinical trials: 8.2% of patients were black or African American in RESPOND, 2% in DEFINE and 1% in CONFIRM.1,2
- And 0.3% of patients were Asian in RESPOND vs. 9% in DEFINE and 8% in CONFIRM.1,2
- Reasons for treatment discontinuation of most recent GA are presented in Table 2.

OBJECTIVES

- To present 6-month interim analysis results from the RESPOND study.

METHODS

- RESPOND is a Phase 4, prospective, multicenter, open-label, single-arm, 12-month observational study in the United States (ClinicalTrials.gov identifier: NCT01932921).
- Eligibility criteria include: Age 18 years or older, receiving treatment for relapsing-remitting or secondary progressive MS, and unable to take or who are intolerant to GA.
- Relapse data are collected from medical records.
- PROs completed by patients before DMF initiation and at 6 and 12 months post treatment initiation.
- Fourteen-item Treatment Satisfaction Questionnaire for Medication (TSQM-14)
- SF-36 version 1, standard recall
- Five-item Modified Fatigue Impact Scale (MFIS-5)
- Seven-item Beck Depression Inventory (BDI-7)
- Work Productivity and Impairment Questionnaire: Multiple Sclerosis (WPAI-SM)
- Eight-Item Morrissey Medication Adherence Scale (MMAS-8)
- Patient-Reported Expanded Disability Status Scale (PREDDS).

CONCLUSIONS

- The 6-month interim analysis of RESPOND suggests that DMF may be associated with lower ARR and improvement on PROs in patients with MS switching to DMF after suboptimal response to GA.
- ARR at 6 months of DMF treatment was lower than the ARR at 12 months before treatment initiation (Figure 1).
- The majority of patients (95%) experienced no relapse after 6 months of DMF treatment.
- Statistically significant improvements from baseline at 6 months were observed for SF-36 PCS and MCS, TSQM-14, BDI-7, and MFIS-5 scores.
- RESPOND is ongoing; data collection is projected to be completed in mid-2016.

REFERENCES


DISCLOSURES

- MK: Speaker for Biogen, EMD Serono, Genzyme, Biogen, Novartis, and Pfizer. MA: Speaker for Biogen, EMD Serono, Genzyme, Biogen, Novartis, and Pfizer.
- TS: Speaker for Biogen, EMD Serono, Genzyme, Biogen, Novartis, and Pfizer.
- JJ: Speaker for Biogen, EMD Serono, Genzyme, and Novartis. LT: Speaker for Biogen, EMD Serono, Genzyme, Biogen, Novartis, and Pfizer.
- Other employees of and hold stock/stock options in Biogen.

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