(S146) EFFECTS OF NATALIZUMAB ON FATIGUE IN MULTIPLE SCLEROSIS: FINDINGS FROM THE ENER-G STUDY

J.A. Wilken,¹ R.L. Kane,¹ C.L. Sullivan,² M. Gudesblatt,¹ S.M. Lucas,⁴ R.J. Fallis,⁵ A. Pace,⁶ R. Kim⁶

¹Veterans Affairs Medical Center, Washington, DC; ²Neurology, Georgetown University Medical Center, Washington, DC; ³South Shore Neurologic Associates, Bay Shore, NY; ⁴Neurology, University of Washington, Seattle, WA; ⁵Neuroscience, St Thomas Hospital, Nashville, TN; ⁶Biogen Idec, Inc, Cambridge, MA

Background: Natalizumab treatment has demonstrated a positive impact on quality of life for patients with multiple sclerosis (MS). Fatigue is a common and disabling symptom of MS and may also contribute to cognitive difficulties experienced by patients. Objectives: To determine the effects of natalizumab treatment on fatigue in patients with relapsing MS. Methods: ENER-G is a 12-month, multicenter, open-label, single-arm study. The primary end point is change in Visual Analog Scale for Fatigue (VAS-F) 12 weeks (3 months) after initiating natalizumab. Secondary end points include changes in the Modified Fatigue Impact Scale (MFIS) and the Fatigue Severity Scale (FSS) at 3, 6, and 12 months, as well as in VAS-F at 6 and 12 months. Patients who exhibited fatigue (defined as an average VAS-F ≥ 60 across three visits) were selected for enrollment. Cognition data are also being collected as a tertiary end point. Results: A total of 89 patients were enrolled; 28 have completed the study. The mean ± SD age was 41.3 ± 7.72 years; 89.9% of patients were female. The median disease duration was 8 years (range, 1–39); the median Expanded Disability Status Scale (EDSS) score was 3.0 (range, 0.0–5.5); and the mean number of relapses during the past year was 1.6 ± 1.18. All patients had received prior therapy for MS, with 51% receiving at least two prior therapies. At the time of this analysis, the median number of natalizumab infusions was 6 (range, 1–13). A significant improvement in VAS-F scores was observed from baseline (mean, 77.7 ± 10.19) to week 12 (mean change, −14.8 ± 17.16; P < .0001). Significant improvements were also seen for changes in FSS scores from baseline (median, 6.3; range, 3.9–7.0) to week 12 (median change, −0.4; range, −2.9 to 1.4; P < .0001) and in total MFIS scores from baseline (mean, 59.1 ± 12.21) to week 12 (mean change, −7.3 ± 11.82; P < .0001), as well as in all individual components of the MFIS (all P ≤ .0002). Conclusions: Fatigue, as determined by patient-reported VAS-F, MFIS, and FSS, was significantly improved 12 weeks after initiating natalizumab therapy. Building upon earlier presentations of preliminary results, data up to 1 year and findings from analyses exploring the association between baseline characteristics and changes in fatigue will be presented.

Supported by: Biogen Idec, Inc, and Elan Pharmaceuticals, Inc


Keywords: disease-modifying treatment in MS, quality of life in MS, symptomatic treatment of MS