INTRODUCTION

- Results from the TYSABRI® Observational Program (TOP) showed that natalizumab treatment was most effective in treatment-naïve patients and in patients with lower Expanded Disability Status Scale (EDSS) scores; however, the use of natalizumab in early multiple sclerosis (MS) has not been systematically studied.

- Natalizumab treatment is associated with a risk of progressive multifocal leukoencephalopathy (PML), a central nervous system infection caused by the JC virus (JCV). 3

- Since the presence of anti-JCV antibodies is a known risk factor for PML, the benefit-risk profile of natalizumab is enhanced if natalizumab is used in patients who test negative for anti-JCV antibodies.

OBJECTIVES

- The primary objective of STRIVE is to assess characteristics associated with freedom from clinical disease activity (no 24-week confirmed EDSS progression and no relapses) – the primary endpoint – in treatment-naïve patients and in patients with prior MS treatment history.

STUDY DESIGN

- STRIVE is a 12-month, multicenter, single-arm, single-year observation study of patients who are initiating natalizumab. Enrollment started in December 2011. Approximately 300 patients at 145 centers are planned to be enrolled.

- Patients receive natalizumab 300 mg intravenously every 4 weeks.

- The initial TYSABRI® infusion can cause anxiety after the baseline assessments were completed. It was preferred that the first natalizumab infusion be administered on the same day as the baseline visit or 2 weeks after the baseline visit.

- Key inclusion criteria include:
  - Patients 18-65 years of age with an EDSS of 0-6.5 for 3 years' duration.
  - At least one relapse in the past 12 months.
  - Inadequate MS treatment history.
  - Male or female age 18 years or older with a body weight ≥50 kg. 4

- Key exclusion criteria include:
  - Any prior treatment with natalizumab.
  - Anti-JCV antibody positive at any time point prior to screening.
  - Contraindication to treatment with natalizumab as described in the US prescribing information.
  - History of PML, or other opportunistic infections, or an increased risk for such infections.
  - History of diagnosis of primary progressive MS and/or secondary progressive MS.
  - Receiving immunosuppressive or immunomodulatory therapy or had prior history of immunosuppressive use.

RESULTS

- As of March 6, 2013, 80 patients have been enrolled. One patient discontinued treatment due to an adverse event.

- Median baseline EDSS score was 1.9 (0.99); median multiple sclerosis severity score (MSSS) was 5.7 (2.0).

- The majority of patients (53.8%, n=43) had no钆(+++) lesions at baseline (Figure 1).

- The median duration of treatment varied among prior MS treatments, ranging between 8 days and 203 (152.7) days (Table 4).

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- A total of 88 (85%) of patients in the study had received prior MS treatment, with a mean treatment duration of 203 (152.7) days (Table 1).

- Of the patients who received prior treatments, 71% had received GA (60.7%, n=19) and/or IFNβ (52.3%, n=16) (Table 1).

- The majority of patients (65.5%, n=52) had no 24-week confirmed EDSS progression or no relapses at month 12 (Table 3).

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