(W09) SURPASS STUDY TO EVALUATE THE POTENTIAL BENEFITS OF SWITCHING MULTIPLE SCLEROSIS THERAPY


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Background: Although glatiramer acetate (GA) and interferon beta (IFNβ) therapies effectively reduce disease activity in many patients with relapsing-remitting multiple sclerosis (RRMS), some patients continue to experience disease activity despite treatment. There is no Class 1 evidence on which to base treatment decisions in these patients, and no studies have directly compared GA or IFNβ with natalizumab. Objectives: SURPASS has been designed to rigorously assess treatment options, including switching to natalizumab, in MS patients with disease activity during therapy with GA or subcutaneous IFNβ-1a (SC IFNβ-1a). The main objective is to compare the efficacy of switching to natalizumab versus receiving GA or SC IFNβ-1a. These data will evaluate the potential benefits of early intervention with a highly effective therapy for management of RRMS.

Methods: SURPASS is a randomized, active-comparator, open-label, rater-blinded, parallel-group study. Eligible patients must be 18 to 60 years of age, have RRMS with an Expanded Disability Status Scale score of ≤5.5, and have experienced disease activity, defined as either ≥1 clinical relapse or ≥2 new magnetic resonance imaging lesions (gadolinium-enhancing [Gd+] and/or T2-hyperintense), during the first 6 to 18 months of GA or SC IFNβ-1a therapy. Results: Approximately 1800 patients at 250 centers in 25 countries will be randomized 2:1:1 to receive natalizumab 300 mg by intravenous infusion once monthly, GA 20 mg SC once daily, or SC IFNβ-1a 44 μg 3 times per week for up to 24 months. The primary end point is annualized relapse rate. Other end points include change in T2 lesion volume, proportion of patients free of disease activity (no clinical relapses, Gd+ or new/enlarging T2 lesions, or ≥1 point progression on the EDSS sustained for 12 weeks), quality of life (by the Multiple Sclerosis Impact Scale and other instruments), safety, and tolerability. Enrollment will commence in early 2010.

Conclusions: SURPASS will provide Class 1 evidence to assist physicians in making informed and objective treatment decisions by directly comparing natalizumab with other approved therapies. An important rationale for SURPASS is the assumed importance of proactive monitoring and therapy decision making for RRMS patients early in the disease course.

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