(S65) ORAL FINGOLIMOD (FTY720) VERSUS PLACEBO IN RELAPSING-REMITTING MULTIPLE SCLEROSIS: BASELINE DATA FROM A TWO-YEAR PHASE 3 TRIAL (FREEDOMS II)

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Background: Oral fingolimod (FTY720), a sphingosine 1-phosphate receptor modulator, is the first in a novel class of drugs under evaluation for the treatment of relapsing-remitting multiple sclerosis (RRMS). In two completed phase 3 studies (TRANSFORMS and FREEDOMS), daily oral FTY720 for 12 months was significantly more effective on clinical and magnetic resonance imaging (MRI) measures than both intramuscular (IM) interferon beta-1a (IFNβ-1a) and placebo in patients with RRMS. FREEDOMS II is a further 24-month, global, randomized, double-blind, placebo-controlled phase 3 trial to assess the safety and efficacy of FTY720 in patients with RRMS. Objectives: To report trial design, demographics, and MS disease characteristics of the FREEDOMS II trial. Methods: In this study, RRMS patients (aged 18–55 years; 2005 McDonald criteria) with Expanded Disability Status Scale (EDSS) score of 0 to 5.5 and ≥1 relapse in the previous year (or ≥2 in the previous 2 years) are randomized to once-daily FTY720 (0.5 mg or 1.25 mg) or placebo. The primary end point is annualized relapse rate. The key secondary end point is treatment effect on 3-months confirmed disability progression (1-point EDSS score increase from baseline or 0.5-point increase if baseline EDSS score was ≥5.5). Other end points include MRI measures of disease activity and brain volume, other relapse and disability measures, quality of life, and performance of daily activities measured by the Patient Reported Indices in Multiple Sclerosis (PRIMUS) instrument and the Modified Fatigue Impact Scale. Results: A total of 1083 patients (mean/median age, 41 years; 78% female) were randomized. At baseline, the mean (median) duration of MS was 10.0 (8.5) years, with patients experiencing an average of 1.5 relapses in the year prior to randomization and 2.3 relapses in the 2 years prior to randomization. Mean (median) baseline EDSS score was 2.5 (2.5). Approximately 73% of patients had previously received disease-modifying treatment: 38% received IM IFNβ-1a, 26% subcutaneous IFNβ-1a, 22% IFNβ-1b, 41% glatiramer acetate, and 6% natalizumab. Conclusions: The baseline characteristics of patients in FREEDOMS II are consistent with a relapsing MS population, a finding similar to those of previous therapeutic studies in MS.

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