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Early Clinical Efficacy of Fingolimod Compared with Interferon-beta-1a in Relapsing Multiple Sclerosis

Daniel Ontaneda[1], Barry Singer,[2] Xiangyi Meng,[3] Kathleen Hawker[3]

[1]Cleveland Clinic Main Campus, Cleveland, OH, USA; [2]MS Center for Innovations in Care, St Louis, MO, USA; [3]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

Background: The interval between the start of multiple sclerosis (MS) treatment and onset of efficacy is an important consideration in therapy selection for relapsing forms of the disease. In FREEDOMS and FREEDOMS II, fingolimod 0.5 mg significantly reduced the risk of relapse within 3 months compared with placebo. Treatment effects in delaying time to first confirmed MS relapse were observed as early as Day 64 in FREEDOMS II and Day 82 in FREEDOMS.

Objective: To examine the onset of clinical efficacy of fingolimod 0.5 mg compared with intramuscular (IM) interferon-beta-1a using pooled data from three phase 3 studies, and the TRANSFORMS study alone.

Methods: Pooled data from the 2-year FREEDOMS and FREEDOMS II and 1-year TRANSFORMS studies were analysed for treatment differences between fingolimod 0.5 mg and interferon beta-1a (IM) on relapses within the first 12 months. In addition, the same analysis was conducted using data from the TRANSFORMS study only. Estimate of the time at which the treatment effect on first confirmed relapse became significant was obtained using the Z-test for hypothesis generation without adjustment for multiple comparisons.

Results: Compared with interferon-beta-1a (IM; n=431), fingolimod 0.5 mg significantly delayed the time to first relapse ($p \leq 0.0001$), reaching significance at Day 119 (approximately 4 months) and remaining significant thereafter in both the TRANSFORMS only group (n=429) and the pooled phase 3 study group (n=1212). The proportion of patients free from confirmed relapse on fingolimod 0.5 mg in the TRANSFORMS only group and the pooled phase 3 study group, versus on interferon beta-1a (IM) were 93.2% and 92.4% versus 89.5% at Month 3, 89.0% and 87.6% versus 81.5% at Month 6, and 82.6% and 81.3% versus 69.3% at Month 12, respectively. Additional data relating to relapse outcomes will be presented in the poster.

Conclusions: Compared with interferon-beta-1a (IM), fingolimod reduced the time to first relapse and differences were significant within 4 months of treatment initiation.