Background: Oral fingolimod (FTY720), a sphingosine 1-phosphate receptor modulator, targets multiple sclerosis (MS) via actions in the immune system and demonstrated effects on magnetic resonance imaging (MRI)–detected inflammatory activity and brain-volume loss. Objectives: To report MRI findings from a 12-month phase 3 study that evaluated fingolimod versus intramuscular (IM) interferon beta-1a (IFNβ-1a; TRANSFORMS) and from a 24-month phase 3 study that evaluated fingolimod versus placebo (FREEDOMS) in patients with relapsing-remitting MS (RRMS). Methods: In two phase 3, double-blind studies, RRMS patients (aged 18–55 years; 2005 revised McDonald criteria) with Expanded Disability Status Scale (EDSS) scores of 0 to 5.5 and ≥ 1 relapse in the previous year (or ≥ 2 in the previous 2 years) were randomized to receive once-daily fingolimod (0.5 mg or 1.25 mg), weekly IFNβ-1a 30 μg (TRANSFORMS), or placebo (FREEDOMS). The principal MRI end point in both studies was the number of new or enlarging T2 lesions (at 12 months in TRANSFORMS and at 24 months in FREEDOMS). Other measures included T1 gadolinium-enhancing and T1-hypointense lesion counts, lesion-volume change, and change in brain volume. Results: Baseline MRI characteristics were well balanced across all groups in both studies. MRI data are presented for patients in whom scans were available. T2 lesion count was significantly reduced compared with controls in both studies. In TRANSFORMS, there was a 31% to 42% reduction in mean lesion count (1.7 lesions for fingolimod 0.5 mg, 1.5 for fingolimod 1.25 mg) compared with IM IFNβ-1a (2.6 lesions), while in FREEDOMS, there was a 74% reduction in mean lesion count (2.5 lesions compared with placebo (9.8 lesions; P < .01 for all comparisons). Other MRI lesion measures showed similar treatment benefit and will be presented. Brain-volume loss was significantly greater in control groups than in fingolimod groups in both studies at all time points measured. Conclusions: Treatment with oral fingolimod significantly reduced MRI inflammatory activity and brain-volume loss compared with IM IFNβ-1a and placebo in two separate studies involving patients with RRMS.

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