**INTRODUCTION AND PURPOSE**

- Fingolimod, a sphingosine 1-phosphate receptor modulator, is the first and only US Food and Drug Administration (FDA)-approved once-daily oral therapy for relapsing multiple sclerosis (MS).

- Extensive clinical trial experience has demonstrated the efficacy of fingolimod treatment for relapsing MS.

- 2 phase 2 studies (LUDI and LUDI-II) in Europe, Canada, and Japan have shown the efficacy of fingolimod vs placebo in patients with relapsing MS.

- Findings from 2 global 3 phase 3 studies confirmed the results of the phase 2 studies and demonstrated the superior efficacy of fingolimod vs placebo and interferon β-1a intramuscular (IM) in patients with relapsing MS.

- Recently reported results from an additional phase 3 trial comparing fingolimod with placebo in patients with relapsing MS provided further evidence of the clinical benefits of fingolimod in this patient population.

- The objective of this presentation is to present current clinical efficacy data across the fingolimod clinical development program.

**METHODS**

- 5 multicenter, randomized, double-blind clinical trials have evaluated the efficacy of fingolimod in patients with relapsing forms of MS: 2 phase 2 studies (LUDI and LUDI-II) and 3 phase 3 studies (Fingolimod Research Evaluating Efficacy of Daily Oral Therapy in Multiple Sclerosis (FREEDOMS), Trial Assessing Injectable Interferon Versus Fingolimod Oral in Relapsing-Remitting Multiple Sclerosis (FREEDOMS-2), and FREEDOMS-2).

- Phase 2 studies (LUDI and LUDI-II) were 6-month studies conducted in Europe and Canada. Patients were randomly assigned to once-daily fingolimod 1.25 or 5.0 mg or placebo.

- Phase 3 studies (FREEDOMS, FREEDOMS-2, and FREEDOMS-2) were 24-month studies conducted in Japan, patients were randomly assigned to once-daily fingolimod 0.5 or 1.25 mg or placebo.

- Key inclusion criteria for the phase 2 studies were age 18-55 years, diagnosis of relapsing-remitting MS according to the revised McDonald criteria, a score of 0-5.5 on the Expanded Disability Status Scale, and relapse in the previous year or ≥2 in the previous 2 years.

- In FREEDOMS, patients who previously received IFN-β or glatiramer acetate were required to discontinue therapy ≥3 months before randomization.

**RESULTS**

**Efficacy**

- At all doses, treatment with fingolimod significantly reduced ARR vs comparators (Figures 1A & 1B).

- Fingolimod 0.5 mg reduced ARR by 48%-54.0% vs placebo (32.20), FREEDOMS, FREEDOMS-II and by 51.6% vs IFN-β-1a (MR) (TRANSFORMS).

- Fingolimod 1.25 mg reduced ARR by 54.9%-60.0% vs placebo (32.20), LUDI-II, and by 38.3% vs IFN-β-1a (TRANSFORMS).

- Fingolimod 5.0 mg reduced ARR by 53.2% vs placebo (32.20).

- Fingolimod significantly increased the proportion of patients who were relapse free at study endpoint (6 to 2 vs yr comparators).

- In the phase 2 studies, treatment with fingolimod resulted in 66.0%-66.0% of patients remaining free from relapse at study endpoint, compared with 64.9%-66.0% of patients receiving placebo.

**CONCLUSIONS**

- Across 5 studies in ~4000 patients with relapsing MS, fingolimod demonstrated consistently robust clinical efficacy.

- At the FDA-approved dose of 0.5 mg, once-daily treatment with oral fingolimod for a duration of 6 months to 2 years reduced the ARR by the following: 48%-54% vs placebo.

- The 0.5 mg dose of fingolimod also significantly increased the proportion of patients from relapse compared with placebo or IFN-β-1a IM.

- Those outcomes were observed across 2 fingolimod doses and across multiple ethnic and geographic regions in comparison with placebo or IFN-β-1a IM.

**REFERENCES**


