Efficacy Outcomes in Patients Randomized to Fingolimod or Injectable Disease-Modifying Therapies in PREFER: Effect of Previous Treatment Cycles

Samuel F Hunter, Florian P Thomas1,3, Xiangyi Meng4, Lesley Schofield4, Scott Kolodny5, Nadia Tenenbaum6, Bruce AC Cren, on behalf of the PREFER investigators

1Advanced Neurosciences Institute, Franklin, TN, USA; 2Hackensack Meridian School of Medicine at Seton Hall University, South Orange, NJ, USA; 3Teckman Pharmaceuticals Corporation, Hackensack, New Jersey, NJ, USA; 4UCSF Weill Institute for Neurocognition and Neurodegeneration, University of California San Francisco, San Francisco, CA, USA

Introduction
- Fingolimod 0.5-mg is a once-daily, oral therapy for relapsing forms of multiple sclerosis (MS) approved for first-line use in many countries.
- Advances in disease-modifying therapies (DMTs) suggest high-therapy efficacies in patients with relapsing MS should be considered as a first-line therapy for patients with active disease.
- Previous iDMTs are known to be cannibalized as a second-line therapy following one or more ineffective disease-modifying therapies (DMTs), such as glatiramer acetate (GA).
- PREFER is a 3-arm, Phase 4, active-controlled, parallel-group, multi-center, treatment-naive and previous relapsing-remitting MS with fingolimod and fingolimod with GA.

Methods
- Study design: PREFER was conducted as a second-line therapy following one or more ineffective disease-modifying therapies (DMTs), such as glatiramer acetate (GA).
- Inclusion criteria: Treatment-naive or had previously received one class of iDMT at San Francisco, CA, USA.
- Exclusion criteria: Age ≥18 years.
- PREFER was 0.5-mg in a once-daily, oral therapy for relapsing forms of multiple sclerosis (MS) approved for first-line use in many countries.
- Efficacy Outcomes in Previous Treatment Cycles

Results
- In total, 425 patients were randomized, and 79 (18.7%) were included in the full analysis set (fingolimod, n=208; groups A, B, and C). The mean (SD) age of patients was 52.0 (10.0) years.
- Retention on randomized treatment over 12 months was assessed. A total of 117 sites in the USA (Figure 1).
- Most patients randomized to an iDMT subsequently switched to fingolimod (58.5%); 15.6% remained on the same iDMT and 25.9% switched to an alternative, on-study treatment.
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- Post-fingolimod group A (previously received two iDMTs): –0.42% (–0.62, –0.21)
- Post-fingolimod group B (previously received one iDMT): –0.37% (–0.52, –0.21)
- Post-fingolimod group C (previously received no iDMT): 0.19% (0.05, 0.33)

Figure 1. Effect of iDMT cycles on ARR in PREFER

Conclusions
- Understanding the impact of previous treatments could help inform treatment decision-making in early stages of MS.
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References
- 2. Background on HSCT for MS. Genentech, Sanofi Genzyme and Teva Neuroscience.

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