Real-world patient retention and satisfaction on fingolimod versus platform injectable disease-modifying therapies in early RRMS: results from PREFER*MS*

P011

Heidi Crayton[1], Brian Steingo[2], DeRen Huang[3], Xiangyi Meng[4], Lesley Schofield[4], Kristen Johnson[4], Nadia Tenenbaum[4] on behalf of the PREFER*MS* investigators

[1]MS Center of Greater Washington, Vienna, VA, United States; [2]Sunrise Medical Group, Sunrise, FL, United States; [3]Neurology and Neuroscience Associates, Unity Health Network, Akron, OH, United States; [4]Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States

CONCLUSIONS

- **The advantages of fingolimod over injectable DMTs in terms of patient retention and satisfaction support the use of fingolimod in patients with early RRMS in the real-world setting**

BACKGROUND

- Multiple sclerosis (MS) is a chronic, demyelinating, immune-mediated disease of the central nervous system[1,2]
- Typically, platform injectable disease-modifying therapies (iDMT) are used first-line, but suboptimal adherence to iDMT classes is common[3,4]
- High-efficacy drugs such as fingolimod can be prescribed as first- or second-line therapy and thus can be used early in the disease course[5]
- The Prospective, Randomized, active-controlled, open-label study to Evaluate patient retention of Fingolimod versus approved first-line disease-modifying therapies in adults with Relapsing–remitting Multiple Sclerosis (PREFER*MS*) was the first large, randomized study of treatment retention and patient satisfaction comparing fingolimod with iDMTs over a period of 12 months

OBJECTIVE

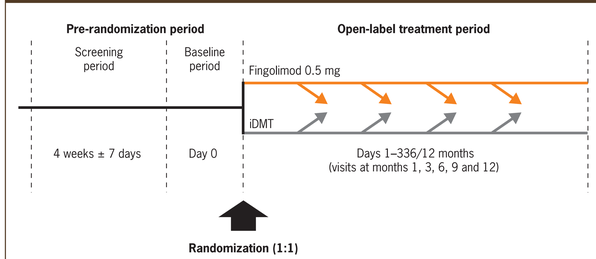
- To examine patient retention and satisfaction with fingolimod compared with iDMTs in PREFER*MS*; a randomized, prospective real-world study of patients with early relapsing–remitting MS (RRMS)

METHODS

Study design

- PREFER*MS* was a 12-month, phase 4, open-label, active-controlled, randomized, multicenter study conducted at 117 investigational sites in the USA
- At enrollment, patients with RRMS[6] were treatment-naïve, or had received only one iDMT class (interferon β or glatiramer acetate)
- Patients were randomized (1:1) to fingolimod 0.5 mg or to a pre-selected iDMT, and followed up quarterly for 12 months (**Figure 1**)
- A single on-study treatment switch was allowed after a minimum of 3 months of treatment, unless related to efficacy or safety; switches due to efficacy or safety were allowed at any month following randomization (**Figure 1**)

Figure 1. PREFER*MS* study design



Patients were allowed one switch from randomized treatment
Reason for switch <3 months: safety or efficacy
Reason for switch at 3–12 months: safety, efficacy, tolerability or convenience

Analyses

- The primary endpoint was the percentage of patients retained on randomized treatment for 12 months
- Patient satisfaction was assessed using the Medication Satisfaction Questionnaire (MSQ),[7] a clinician-administered, patient-rated, single-item assessment asking the question, "Overall, how satisfied are you with your current medication?"
- MSQ responses were scored on a 7-point Likert scale ranging from extremely satisfied to extremely dissatisfied
- Sample size and power calculations were based on retention rates only
- No adjustments were made for multiple comparisons
- Statistical tests are described in the footnotes that accompany the tables and figures

RESULTS

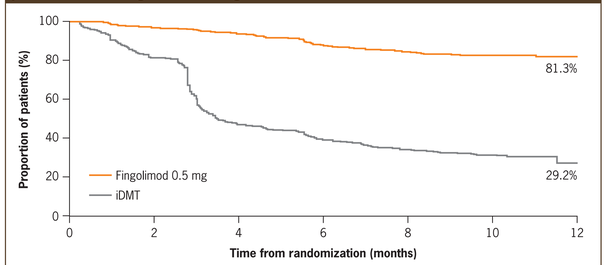
- In total, 875 patients were randomized (fingolimod, n=436; iDMT, n=439). At baseline, mean time since diagnosis was 4.3 years (considered an early RRMS population) and the mean Expanded Disability Status Scale (EDSS) score was 2.4. Patient demographic and baseline characteristics were similar in both treatment groups (**Table 1**)
- Of the 861 patients (98.4%) who completed the study (full analysis set), 477 (55.4%) completed the study while still receiving the randomized treatment (**Figure 2**)
- Patient retention was significantly higher with fingolimod than with iDMT (352 [81.3%] vs 125 [29.2%]; p<0.0001) (**Figure 2**)
- The distribution of responses regarding treatment satisfaction was weighted more towards very/extremely satisfied in the fingolimod group than in the iDMT group
  - Between-group differences were significant at months 3, 6, 9 and 12 (data not shown), and at last assessment during the randomized phase (p<0.001) (**Figure 3a**)
- At last assessment in the entire study period (which includes any post-treatment-switch phase), treatment satisfaction among patients randomized to iDMT was weighted more towards extremely satisfied than it was at last assessment during the randomized phase (**Figure 3b**), implying that switching to fingolimod was associated with an increase in treatment satisfaction
- Most patients who switched from randomized treatment were in the iDMT group (90.5%); the majority of these patients switched owing to injection-related reasons, including injection-site reactions and influenza-like symptoms (59.9% of the total switches made) (**Figure 4**)

Table 1. Summary of patient demographic and baseline characteristics

Demographic and baseline characteristics[a]	Fingolimod 0.5 mg (n=436)	iDMT (n=439)	p-value
Age, years	41.5 (10.84)	41.9 (10.39)	0.6310
Sex, n (%) Male Female	 125 (28.7) 311 (71.3)	 110 (25.1) 329 (74.9)	0.2282
Race, n (%) Caucasian Black Asian Native American Pacific Islander Other	 355 (81.4) 69 (15.8) 1 (0.2) 1 (0.2) 0 10 (2.3)	 355 (80.9) 72 (16.4) 1 (0.2) 1 (0.2) 2 (0.5) 8 (1.8)	0.6553
Height, cm	168.5 (8.99)	167.5 (10.06)	0.1388
Weight, kg	82.94 (20.1)	83.56 (22.3)	0.6651
BMI, kg/m^2	29.19 (6.70)	29.76 (7.55)	0.2335
Duration of MS since diagnosis, years	n=434 4.42 (6.67)	n=434 4.21 (5.94)	0.6314
Duration of MS since first symptoms, years	n=434 7.29 (8.21)	n=434 7.21 (7.66)	0.8871
Number of relapses in the past year	n=430 0.6 (0.95)	n=436 0.6 (0.94)	0.6041
Number of relapses in the past 2 years	n=430 0.9 (1.51)	n=436 0.9 (1.41)	0.6752
EDSS score	n=433 2.36 (1.56)	n=427 2.44 (1.51)	–
T2 lesion volume, cm^3	n=431 7.65 (11.60)	n=415 7.44 (10.17)	–
Normalized brain volume, cm^3	n=431 1521.42 (83.9)	n=412 1511.19 (90.5)	–
Number of gadolinium-enhancing lesions	n=429 1.08 (3.75)	n=414 0.85 (3.03)	–

[a]Data shown are mean (SD) unless stated otherwise
Treatment group comparisons were made using the Cochran–Mantel–Haenszel test for categorical variables and a two-sample *t*-test for continuous variables
BMI, body mass index

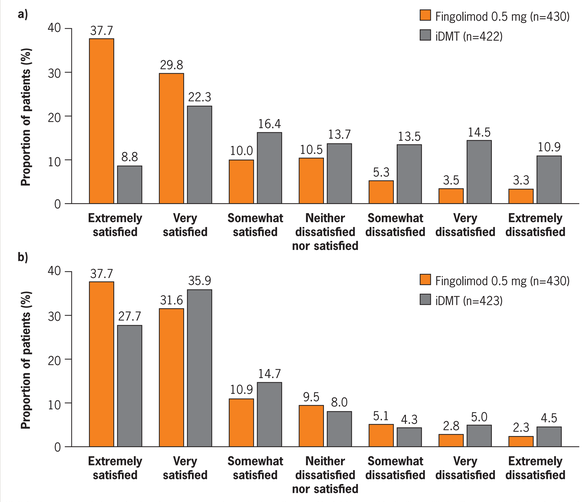
Figure 2. Retention rates in PREFER*MS* during the open-label randomized treatment period, tested for significance using four statistical methods



	Fingolimod 0.5 mg (n=433)	iDMT (n=428)	Total (N=861)
Completed study on randomized treatment, n (%)	352 (81.3)	125 (29.2)	477 (55.4)
Statistical method	**Test**	**Statistic**	**p-value**
Cochran–Mantel–Haenszel	χ^2	234.5138	<0.0001
Logistic regression	Odds ratio	10.5095	<0.0001
Cox proportional hazard	Hazard ratio	0.1595	<0.0001
Kaplan–Meier	Log-rank	NA	<0.0001
Normal approximation	Difference (95% CI)	0.5209 (0.46, 0.58)	

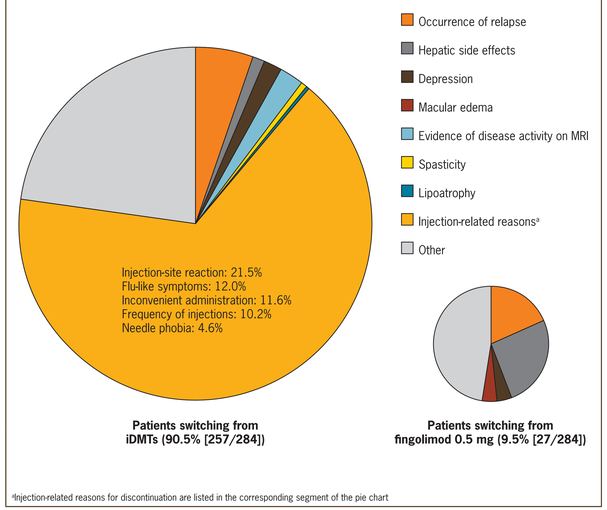
Cochran–Mantel–Haenszel, logistic regression and the Cox proportional hazard models are adjusted for treatment and treatment naivety. Kaplan–Meier log-rank test is adjusted for treatment, and normal approximation is performed using continuity correction. Note: for all percentages, the denominator is the total number of patients (n) in the treatment group

Figure 3. Patient satisfaction in response to the question "Overall, how satisfied are you with your current medication?" assessed at last assessment during a) the randomized phase[a] and b) the entire study period including switches[b]



Statistical comparison between treatment groups was performed using a Cochran–Mantel–Haenszel test with modified ridit scores adjusted for treatment and treatment naivety
[a]Significant differences between treatment groups were observed at all assessments (p<0.001)
[b]Significant differences between treatment groups were observed at all assessments (p<0.05)

Figure 4. Primary reasons for switching from randomized treatment during the open-label treatment period (pie chart area is proportional to the number of patients who switched treatment)



[a]Injection-related reasons for discontinuation are listed in the corresponding segment of the pie chart

References

1. Sospedra M, Martin R. Annu Rev Immunol. 2005;23:683–747.
2. Trapp BD, et al. New Engl J Med. 1998;338:728–785.
3. Cohen BA, Rieckmann P. Int J Clin Pract. 2007;61:1922–1930.
4. Wong J, et al. Can J Neurol Sci. 2011;38:429–433.
5. Novartis Pharmaceuticals Corporation. Prescribing information – Gilenya®. 2016. https://www.pharma.us.novartis.com/product/pi/pdf/gilenya.pdf (Accessed 8 March 2016).
6. Polman C, et al. Ann Neurol. 2011;69:292–302.
7. Vernon MK, et al. Schizophr Res. 2010;118:271–278.

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