Key results from PREFERENCES: real-world patient retention and outcomes on fingolimod versus platform injectable disease-modifying therapies in early relapsing–remitting MS

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CONCLUSIONS

• Fingolimod is associated with higher therapeutic retention, improved clinical and MRI outcomes, and greater treatment satisfaction than iDMTs in patients with early RRMS

BACKGROUND

• Multiple sclerosis (MS) is a chronic, demyelinating, immune-mediated disease of the central nervous system

• Injectable disease-modifying therapies (iDMTs) are typically used for relapsing-remitting disease, but subcutaneous administration to iDMTs in classes is complex

• Injectable therapies such as glatiramer acetate are often used as second-line therapy. Fingolimod 0.5 mg is approved as a first-line therapy, and can be used early in the disease course

• PREFERENCES:Prospective, Randomized, active-controlled, open-label study to Evaluate patient retention of Fingolimod as approved for in-line disease-modifying therapies in adults with relapsing-remitting Multiple Sclerosis. This was the first large randomized study of treatment retention comparing fingolimod with iDMTs over 12 months

OBJECTIVE

• To compare therapeutic retention with Fingolimod 0.5 mg versus iDMTs in PREFERENCES

METHODS

Study design
• Phase 1, 2004 (open-label); phase 2, 2005 (randomized, active-controlled, multicenter; study conducted at 167 sites in the USA)

• Excluded patients with FMR1 were treatment-experienced or had received only one iDMT (cladribine or glatiramer acetate)

• Study drug was Fingolimod 0.5 mg

• The trial was designed to accommodate patients who failed prior treatments (Figure 1; Table 1).

• Treatment satisfaction (as measured by the Medication Satisfaction Questionnaire [MSQ]) was greater in Fingolimod 0.5 mg and iDMTs is significant, p<0.0001

RESULTS

• 975 patients with RRMS were randomized (Fingolimod, n=433; EXP, n=442). At baseline, mean time since diagnosis was 4.3 years (standard deviation is 9.4 years) and the Expanded Disability Status Scale (EDSS) score was 2.4. Patient demographic and baseline characteristics were similar between treatment groups (Table 2).

• The clinical and MRI outcomes were expressed as the annualized relapse rate and brain volume loss, respectively (ARR and BVL, respectively).

• The ARR and BVL were lower in Fingolimod 0.5 mg than with iDMT (ratio, 0.70; p=0.084), despite shorter iDMT exposure (Figure 3).

• Clinical and MRI outcomes were derived from the pooled open-label randomized treatment phase (Figure 4).

• Safety assessments: All adverse events (AEs) were mild or moderate in severity

• AEs at any time

• Safety outcomes for all treatments were consistent with the respective US prescribing information

CONCLUSIONS

Clinical and MRI outcomes
• There was a statistical trend for a lower annualized relapse rate in patients treated with fingolimod than in those treated with iDMT (Table 3: ARR, 0.20; p=0.049), despite shorter iDMT exposure (Figure 3a)

• At last assessment (Figure 3c), there was no significant difference between Fingolimod and iDMT groups in ARR

• There was a statistically significant difference in ARR between those treated with Fingolimod (0.20 per year) and iDMT (0.29 per year, ratio, 0.69; p=0.000)

• Lower lesion volume loss at month 6 (Figure 3b: 0.30 per year); significant difference at last assessment (p=0.037)

• Lower new gadolinium-enhancing lesions (0.003 per year) (Table 3)

• Lower new or relapse T2 lesions (0.003 per year)

• Lower new active lesions (0.003 per year)

• A greater mean reduction from baseline in total Gd+ lesion count (0.003 per year) (Table 3)

Safety assessments
• Most adverse events (AEs) were mild or moderate in severity

• AEs at any time

• Most frequent treatment discontinuations in the Fingolimod group were related to injection site reactions, fatigue, and influenza-like symptoms (Table 2)

• Safety outcomes for all treatments were consistent with the respective US prescribing information

REFERENCES


D0CUMENTATION

Figure 4. Key patient-reported outcomes from PREFERENCES: MSQ scores at last assessment

Patient-reported outcomes
• Treatment satisfaction (as measured by the Medication Satisfaction Questionnaire (MSQ)) was greater in the Fingolimod group than in the iDMT group (mean 0.003; 95% CI 0.000 to 0.006) at last assessment (Figure 4)

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