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Four-year Expanded Disability Status Scale (EDSS) outcomes in patients treated with fingolimod in the Phase 3 and extension trial program

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Background/objective: Assessment of long-term disability status is important for characterizing the benefit-risk profile of disease modifying MS therapies, although a lack of control group and selective drop-outs may produce bias. Here we explored longitudinal Expanded Disability Status Scale (EDSS) outcomes in fingolimod treated patients in the FREEDOMS, FREEDOMS 2 and TRANSFORMS Phase 3 and extension trials.

Design/methods: EDSS data from patients initiating fingolimod in Phase 3 or extension were pooled for post-hoc analysis. Kaplan–Meier (KM) estimates of proportions not reaching EDSS 4, 6 and 7 were calculated from start of fingolimod 0.5 mg or any dose (all-FTY). Proportions with EDSS score less than or equal to the baseline score at start of fingolimod (FTY-BL), and decreased compared to FTY-BL, after 24, 36 and 48 months were analyzed descriptively.

Results: The pooled 0.5 mg/all-FTY (N = 1641/3283) cohorts had median (25th, 75th percentile) treatment exposures of 967/918 (556/1343, 482/1325) days. KM estimates of proportions not reaching EDSS 4, 6 and 7, were 71.3%, 87.8% and 96.7% for 0.5 mg and 69.5%, 87.0% and 96.3% for all-FTY. At months 24 (N=1324/2580), 36 (N=909/1727) and 48 (N=587/1110), the proportions with EDSS score less than or equal to FTY-BL were, 67.9%, 64.7% and 66.8% for 0.5 mg and 69.0%, 66.4% and 66.2% for all-FTY. Of these, EDSS was improved at months 24, 36 and 48 compared to FTY-BL in 15.7%, 17.4% and 17.4% for 0.5 mg and 17.5%, 18.7% and 18.5% for all-FTY.

Conclusion: Most Phase 3 and extension trial patients treated with fingolimod in either dose for up to 4.9 years remained free of the need for walking assistance. Approximately two-thirds of fingolimod patients continuing on treatment had the same or better EDSS score after 2, 3 and 4 years of treatment, while 16–18% had improved scores. Absence of a control group and selective dropouts may bias these results.