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SWITCHING THERAPY TO FINGOLIMOD IMPROVES CLINICAL AND MRI OUTCOMES

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Objectives To evaluate the long-term efficacy outcomes in patients with high-disease-activity switching from placebo to fingolimod, from the FREEDOMS extension study.

Methods Patients either continued on the fingolimod dose assigned in the core phase (continuous-group 'c-group') or were re-randomised from placebo to fingolimod (switch-group 's-group'). Clinical and MRI outcomes (Month 0–24, core/ Month 24–48, extension) for fingolimod 0.5mg are presented for the following high-disease-activity subgroups: Group-1 (n=110), interferon-beta (IFN) therapy in previous year and \geq relapse in year-1 vs. year-2;; Group-2 (n=106), IFN therapy in previous year+ \geq 1 relapse in year-1 with either \geq 1 Gd+ T1 lesion or \geq 9 T2 lesions at baseline; Group-3 (n=90), treatment-naïve rapidly evolving severe RRMS patients (\geq 2 relapses in year-1 and \geq 1 baseline Gd+-lesion).

Results Annualized relapse rates were sustained from the core into extension phase for 'c-group' (Core/extension: Group-1: 0.16/0.20; Group-2: 0.23/0.25; Group-3: 0.26/0.20) and reduced in 's-group' (Group-1: 0.62/0.29; Group-2: 0.56/0.28; Group-3: 0.62/0.18). Greater proportions of switch patients were free from new/enlarging T2-lesions (Group-1: 16.7%/16.7%; Group-2: 14.3%/28.6%; Group-3: 16.7%/66.7%) and Gd+-lesions; (Group-1: 14.3%/85.7%; Group-2: 12.5%/87.5%; Group-3: 16.7%/83.3%).

Conclusion Highly active patients switched to fingolimod showed significant improvement in clinical and MRI outcomes. Continuous fingolimod treatment was associated with sustained low clinical disease activity.