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# Long-term safety of fingolimod: Interim evaluation of data from the longterms trial

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Background/objective: Multiple sclerosis patients participating in the fingolimod phase 2/3 core and extension studies were eligible to transfer to LONGTERMS, an open- label, multicentre, single-arm, long-term safety and toler- ability study. Here, we compared the long-term fingolimod (0.5 mg dose) safety data in the LONGTERMS study (up to data cut-off), with shorter-term (1–2 years) safety data pooled from the randomized controlled trials.

Design/methods: In this study, patients from two cohorts (Core Cohort, CC; LONGTERMS cohort, LC) were compared. Patients in CC [n=1212; median (range) exposure: 1.6 (0.01– 2.4) years] were pooled from the fingolimod 0.5 mg arms of the core phase 2/3 trials. Patients in LC [n=1655; median (range) exposure: 3.7 (0.01–7.4)] included CC and phase 2/3 core comparator patients transitioned to fingolimod 0.5 mg in their extensions. Incidence rates (number of patients experiencing <1 event/100 patient-years) were determined for adverse events (AEs) of special interest.

Results: The incidence rates for AEs of special interest were similar or lower in LC compared with CC, for: infections (LC, 68.3; CC, 91.0), skin cancer and other malignant neoplasms (LC, 0.7 and 0.4; CC, 1.3 and 0.4), thromboembolic events (LC, 0.9; CC, 1.0), hypertension (LC, 3.6; CC, 5.5), respiratory conditions (LC, 1.2; CC, 1.5) and reactivation of viral infections (LC, 5.3; CC, 5.9).

Conclusion: With long-term use of fingolimod (median: 3.7 years), incidence rates for AEs of special interest were comparable with those in controlled studies. There were no new safety signals detected with the long-term use of fingolimod.