DESIGN AND BASELINE CHARACTERISTICS OF PASSAGE AND UK UPDATE

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10.1136/jnnp-2014-309236.128

Background Fingolimod, 0.5 mg once-daily, is the first oral therapy approved for treatment of relapsing remitting multiple sclerosis (RRMS). PASSAGE consists of two long-term, prospective, multi-national, parallel-cohort, post-authorisation safety studies (PASS) and aims to monitor the overall long term safety profile of fingolimod (minimum 5 years) in MS patients treated according to routine medical practice and explore the incidence of selected safety outcomes.

Design/Methods PASSAGE includes MS patients newly starting on fingolimod or being treated with other approved DMTs. As patients are treated in accordance with the local license, PASSAGE in the UK will recruit highly active RRMS patients. The study plans to recruit 7,500 patients globally and 400 in the UK.

Results In global-PASSAGE at last data cut-off, 470 patients on fingolimod and 133 patients on other DMT were enrolled. For the fingolimod-cohort, mean duration of MS was 12.3 years, average number of relapses one year prior to study entry was 1.0 and mean baseline EDSS score was 3.2. For those with confirmed fingolimod administration records (343/470 patients), SAEs were reported in 4.1% and bradycardia in 2.3% of patients.

Conclusions/relevance This global, long-term, observational study will provide data to support the well-characterized safety and tolerability profile for fingolimod.