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Long-term efficacy and safety of fingolimod in paediatric multiple sclerosis patients: analysis of PARADIG*MS* study up to 6 years of treatment

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Introduction: Fingolimod demonstrated superior efficacy on relapses and MRI outcomes versus interferon (IFN) β-1a in patients with paediatric multiple sclerosis (PedMS), aged 10–17 years, in the core phase (CP) of PARADIG*MS* trial. The overall safety profile was similar to that seen in adults.
Objective: Assess long-term efficacy and safety of fingolimod in patients with PedMS treated up to 6 years in PARADIGMS CP and/or extension phase (EP).
Methods: PARADIG*MS* was a double-blind, active-controlled, randomised trial in PedMS patients with a CP up to 2 years (completed) followed by a 5-year, open-label EP (ongoing). The EP comprises patients who completed the CP i.e., those who received fingolimod in CP and EP (continuous fingolimod group) and those who switched from IFNβ-1a in CP to fingolimod in EP (switch group). Fingolimod was dosed at 0.5 mg/d or 0.25 mg/d based on body weight (with patients >40kg receiving the 0.5mg/d dose). Demographics, cumulative adjusted annualised relapse rate (ARR, 95% confidence interval [CI]), AEs and SAEs are presented for patients treated with fingolimod for up to 6 years (up to 2 years CP+4 years EP). Cut-off date for analysis was 4th of August 2021.
Results: A total of 215 patients entered the CP, with 171 continuing into the EP: continuous fingolimod group (n=95), switch group (n=76, of which 75 received fingolimod in EP). Mean age at study start (CP) was 15.3 (range 10–17). Median duration of fingolimod exposure was 2061 days for continuous fingolimod group and 1493 days for switch group. Adjusted ARR [95%CI] was 0.11 [0.08, 0.16] for the continuous fingolimod group in CP+EP (ARR with fingolimod in CP was 0.12 [0.08, 0.19]). In the switch group, ARR in CP+EP was 0.34 [0.25, 0.47], in CP whilst on interferon was 0.57 [0.41, 0.80] and in EP upon switch to fingolimod was 0.23 [0.15, 0.34]. Overall, most frequently reported AEs (>20%) were nasopharyngitis (43.5%), headache (34.1%), leukopenia (25.3%) and upper respiratory tract infection (21.2%). The nature of AEs and SAEs reported with long-term treatment were in line with the CP.
Conclusions: Patients treated with fingolimod for up to 6 years in PARADIG*MS*(CP and/or EP) showed that ARR remained low with continuous fingolimod and was reduced after switch from IFNβ-1a to fingolimod. No new safety signal was observed. These results continue to support the positive benefit-risk profile of fingolimod in PedMS patients.

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