Characterization of cladribine tablets treated MS patients in Finland

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Objective: To investigate the clinical use of cladribine tablets in Finland in a non-interventional cohort based on data from the Finnish MS registry.

Methods: All eligible patients who initiated cladribine tablets and were registered in the MS registry were included. Descriptive analysis was conducted using summary statistics. Time dependent endpoints were analyzed with Kaplan-Meier estimate.

Results: A total of 126 patients were included; 85.7% were females. Mean age at treatment onset was 35.1 years. Mean weight was 74.2 kg. Mean time since MS diagnosis was 5.7 years. A total of 32.5% of the patients were treatment naïve, 19% had one, 17.5% had two, and 31% had three or more previous treatments. Median EDSS at index d was 2.0 (range 0.0-6.0). Mean follow-up time was 11 months. A subset of patients (n=55) were followed for over a year. Mean ARR was 1.0 (n=55) one year prior to treatment initiation, and 0.1 (n=55) during follow-up. Mean time to first relapse for the patients who had symptoms and were followed for over a year (n=8) was 6.0 months (Q1-Q3 1.2-9.8). Three patients discontinued treatment. Reasons for discontinuation were inefficiency, change of diagnosis, and unknown. Two of the patients discontinuing treatment switched to other compounds (glatiramer acetate and natalizumab). Mean lymphocyte count (10^9/L) at baseline was 2.0 (SD 0.72), at 3 months 1.0 (SD 0.39), at 7 months 1.2 (SD 0.44), and at 12 months 1.4 (SD 0.48). Total number of AEs reported was 16 (n=12). The most commonly reported AEs were abdominal pain (n=2), nausea (n=2), herpes simplex (n=2), and headache (n=2). No SAEs were reported.

Conclusions: Cladribine tablets were well tolerated with only a few discontinuations. Lymphocyte counts were moderately decreased and recovered to normal limits within 12 months. ARR remained low, indicating a treatment response for cladribine tablets in this cohort.