Two years of experience with oral cladribine treatment in patients with multiple sclerosis in Poland: Real-world evidence from a retrospective cohort study during the COVID-19 pandemic.

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Introduction: In Poland, oral cladribine is reimbursed in naive patients with rapidly evolving severe relapsing-remitting multiple (MS) sclerosis and in relapsing-remitting MS after the failure of previous therapies defined as ≥2 relapses and >1 GD+ or > 2 T2 new lesions over 12 months.After more than 2 years of experience with cladribine treatment, we provide real-world data to support the efficacy and safety of oral cladribine reported in clinical trials.

Methods: In this retrospective, a non-interventional cohort study, we analysed the use of oral cladribine in 9 MS centres in Poland from October 2019 to June 2022.

Results: Of 140 patients enrolled, 66 completed the second-year treatment course. The mean age of patients was 35.6 years. The annualized relapse rate decreased from 1.49 at baseline to 0.33 at 12 months ($p<0.001$) and to 0.25 at 24 months ($p<0.001$). The median [IQR] EDSS was 2.5 [1.50,3.50] at baseline; EDSS stabilisation and improvement were achieved by 83.7% of patients (N=72) at 12 months and 89.6% of patients (N=26) at 24 months. No new active lesions were found on brain magnetic resonance imaging in 63.7% of patients after the first year and none in 81.8% patients after the second year. In addition, out of 89 patients with a full set of data, 38 (42.7%) had NEDA-3 after the first year; in the second year, out of 24 patients from the same group, 16 (66.7%) had NEDA-3. We observed one case of lymphopaenia leading to discontinuation. During cladribine treatment, 67.1% of the patients were vaccinated against SARS- CoV-2, and 27.9% had COVID-19 (mild or moderate disease, without hospitalizations).

Conclusions: Overall, our real-world data is in line with the efficacy and safety profile of oral cladribine reported in clinical trials. The results indicate that oral cladribine treatment was safe and well-tolerated during the pandemic period.