

Early clinical experience with cladribine tablets in a real-world aging patient population

Background:

Cladribine, a deoxyadenosine analogue, transiently and preferentially depletes B and T lymphocytes disrupting the central immune cascade in multiple sclerosis (MS). Cladribine tablets are an oral, short-course (four four-to-five-day courses over two years) disease-modifying therapy (DMT) indicated for the treatment of relapsing forms of MS. The efficacy and safety of cladribine tablets was demonstrated in clinical trials including the phase 3 CLARITY trial and its extension; however, the real-world clinical experience is still emerging. An area of growing interest is the use of DMTs in patients with advanced age. Understanding the risk/benefit profile of using a non-continuous immunosuppressive DMT in this population is of extreme importance given immunosenescence and the increasing comorbidities with age.

Objectives:

Here we report our early experience using cladribine tablets in a real-world US cohort of MS patients, many with advanced age. Outcomes presented include patient characteristics at treatment initiation, previous DMD use, safety, and lymphocyte counts.

Methods: Chart review

Results: We report on 77 patients who have initiated therapy with cladribine tablets by data cut-off (June 2021). Median age at cladribine tablets initiation was 46 years (range 24-71) and 40% of patients were 50 or older at initiation.

Median disease duration was 13 years (range 2-34) and median baseline EDSS was 4 (range 0-7.5). The mean number of prior DMTs was 2.5; only 4% of patients were treatment-naïve. Mean follow up was 365 days and 31% of patients completed both treatment courses by data cut-off. Overall, cladribine tablets were well tolerated. 34% of patients experienced lymphopenia with no patients experiencing grades 3 or 4 lymphopenia. No adverse events occurred in $\geq 3\%$ of patients. Updated data including preliminary efficacy data will be presented in the poster.

Conclusions: In this cohort of patients initiating cladribine tablets in the real-world, the initial treatment was well-tolerated, even among those with advanced age. There were no new safety signals. The side effect profile was consistent with that seen in the clinical trial program, even in an aging patient population where co-morbid conditions and immunosenescence may increase. Owing to short follow-up time, it was not possible to assess long-term outcomes. Ongoing follow-up will further expand on these results as more patients complete their full treatment course.