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Long Term Effectiveness of Cladribine in Patients Enrolled in the CLARITY Trial: Real World Experience from the Lebanese Cohort

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Background: Cladribine has been recently approved for treatment of relapsing remitting and active secondary multiple sclerosis (MS). However, long term data regarding its effectiveness beyond the trial period is still lacking.

Objective(s): To assess retrospectively long term effectiveness of cladribine tablets in patients with relapsing remitting MS (RRMS) enrolled in the pivotal CLARITY/CLARITY Extension trial, at the American University of Beirut MS Center-Lebanon.

Method(s): Patients receiving at least one dose of cladribine were included in the final analysis. Baseline characteristics were extracted including age, gender,disease duration, EDSS, number of relapses in the previous 2 years and MRI lesions.

Result(s): The following outcome events were collected from the time of enrollment till the last follow-up visit at our MS center: EDSS, relapses conversion to secondary progressive MS (SPMS), new or Gd+ lesions on MRI and initiation of new DMTs.

24 patients were enrolled in the Clarity study, 2 of whom received placebo during Clarity and did not go into the extension. The average study duration was 3.6 (SD=1) years and the average follow up duration after study end was 6.2 years (SD=2.9). Overall the whole follow up was 9.8 years (SD=2). Out of 22 patients 13 started a new DMT during follow up. The annualized relapse rate (ARR) was 0.20 (95%CI=0.12-0.33) during the study and 0.20 (95%CI=0.14-0.29) during the post-study follow up. Out of 22 patients only 3 had an EDSS increase (+1.5, +1.5, +3.5) over the whole follow up period, 13 had a decrease and 6 were stable. Out of 22 patient, 2 converted to SPMS during follow up. MRI data will be reported.

Conclusion: This is first report assessing the long term effectiveness of cladribine tablets in a cohort of patients enrolled in the original pivotal CLARITY/CLARITY Extension trials and followed for up to 10 years. Cladribine was highly effective inpreventing long term disability progression, relapses and conversion to SPMS.