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No Evidence of Disease Activity-3 Status Is Durable in Patients with Relapsing Multiple Sclerosis Receiving Cladribine Tablets: Clarity Extension

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Background: In clarity, CT3.5 showed efficacy vs placebo over 2-years in patients with RMS. NEDA-3 status was achieved in significantly more patients receiving CT3.5 than placebo. Efficacy with CT3.5 (clarity) was maintained in years-3/4 (clarity ext) when patients were randomised to placebo after a variable bridging interval (BRI; ≤116 weeks), during which CT3.5 was not administered. Objective: Determine NEDA-3 status in patients who received CT3.5 in clarity followed by placebo (CP3.5) or CT3.5 (CC7) in clarity ext.
Methods: Patients (CP3.5 n=98; CC7 n=186) were retrospectively analysed for NEDA-3 status (no relapse, no 6-month expanded disability status scale [EDSS] progression, no T1 gadolinium-enhancing or active T2 lesions). BRI between clarity and clarity ext was used as a proxy for when patients reached week 48 of clarity ext. Year 3–4 group: Patients with BRI ≤43 weeks (known NEDA status: CP3.5 n=54; CC7 n=98); year 4–5 group: Patients with BRI >43 weeks (known NEDA status: CP3.5 n=40; CC7 n=77). NEDA-3 differences in CP3.5 and CC7 groups were analysed by logistic regression with treatment and BRI as fixed effects.
Results: Year 3–4 group: Annual NEDA-3 achieved in 46% (25/54) and 48% (47/98) of the CP3.5 and placebo groups. Year 4–5 group: Annual NEDA-3 was observed in 35% (14/40) and 48% (37/77) of the CP3.5 and CC7 groups. Adjusting for BRI length, there was no significant difference between annual NEDA-3 in the CP3.5 (41.5%, 95%CI=32.4–60.0%) and CC7 (48.0%, 95%CI=40.2–64.4%) groups (p=0.31). BRI duration was not a significant variable (p=0.38). Similar patterns were observed when proportions of patients who were annual relapse-free and annual 6-month EDSS progression-free were examined.
Conclusions: Following CT3.5 treatment in clarity, NEDA-3 status (analysed post-hoc) was sustained up to 4 years after clarity baseline, and BRI was not a significant variable.