Durability of NEDA-3 Status in Patients with Relapsing Multiple Sclerosis Receiving Cladribine Tablets: CLARITY Extension

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INTRODUCTION

- In the CLARITY study, Cladribine Tablets 10 mg (3.5 mg/kg cumulative dose over 2 years; referred to as Cladribine Tablets 3.5 mg/kg) showed strong efficacy vs. placebo over 2 years in patients with relapsing multiple sclerosis (RMS).1
- No Evidence of Disease Activity-3 (NEDA-3) status was achieved in significantly more patients receiving Cladribine Tablets 3.5 mg/kg in CLARITY and who were then randomised in CLARITY Extension to either placebo (CP3.5 group) or Cladribine Tablets 3.5 mg/kg (CC7.0 group).

OBJECTIVE

- This was a post hoc analysis to determine NEDA-3 status in patients who received Cladribine Tablets 3.5 mg/kg in CLARITY and who were then randomised in CLARITY Extension to either placebo (CP3.5 group) or Cladribine Tablets 3.5 mg/kg (CC7.0 group).

METHODS

- The study design for CLARITY and CLARITY Extension is shown in Figure 1A.
- Patients were retrospectively analysed for NEDA-3 status (defined as patients with no relapse, no 6-month Expanded Disability Status Scale (EDSS) progression and no T1 gadolinium-enhancing or active T2 lesions) in the first year of CLARITY Extension for the CP3.5 group (n = 98) and CC7.0 groups (n = 186).
- Baseline demographics for the overall patient groups included in this analysis are shown in Table 1.

RESULTS

Proportion of patients achieving NEDA-3 status

- In the Year 3–4 group, annual NEDA-3 was achieved in 46% (25/54) of patients with known status in the CP3.5 group and 48% (47/98) in the CC7.0 group (Figure 2).
- For the Year 4–5 group, there was a numerical trend for a lower rate of annual NEDA-3 for patients in the CP3.5 group (35%; 14/40) than the CC7.0 group (48%; 37/77) (Figure 2).
- Adjusting for the length of the bridging interval, there was no significant difference between annual NEDA-3 in the CP3.5 (61.5%, 95% CI 32.4–66.0%) and CC7.0 (48.0%, 95% CI 40.2–64.4%) groups (odds ratio 1.3, 95% CI 0.8–2.2; P = 0.31).

Proportion of patients achieving individual components of the NEDA-3 composite endpoint

- As with NEDA-3 status, proportions of annual relapse-free, annual 6-month EDSS progression free (Figure 3) and freedom from T1 Gd+ and active T2 lesions (Figure 4) were largely similar, regardless of bridging interval duration.
- The exception was the CP3.5 Year 4–5 group in which there were fewer patients free of T1 Gd+ and active T2 lesions compared to other groups (Figure 4).

CONCLUSIONS

- In this post hoc analysis, patients treated in CLARITY with Cladribine Tablets 3.5 mg/kg and with either placebo or Cladribine Tablets 3.5 mg/kg in CLARITY Extension experienced sustained benefits for NEDA-3, or its components.
- NEDA-3 was lower in the CP3.5 Year 4–5 group than in the other groups, probably driven by lower rates of freedom from T1 Gd+ or T2 lesions.
- NEDA-3 outcomes, or its constituent elements, were not significantly different between patients in the Year 3–4 or Year 4–5 groups.

REFERENCES


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DISCLOSURES

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Cladribine Tablets are approved by the European Commission for the treatment of adult patients with highly active relapsing multiple sclerosis (RMS) as defined by clinical or imaging features.