All analyses (using SAS® software version 9.4 or higher) were performed in the intention-to-treat (ITT) population and presented by treatment.

Endpoints assessed in this analysis included ARR, proportion of patients relapse free, risk of 3- or 6-month CDP; proportion of patients with T1 Gd+ lesions, adjusted mean T2 lesion volume and number of T1 Gd+ lesions, adjusted mean T2 lesion volume, and number of T1 Gd+ lesions.

In the ITT population, 433 patients were assigned to cladribine tablets 3.5 mg/kg (baseline EDSS ≥3.5, N=161; EDSS ≤3.0, N=272) and 285 to placebo EDSS ≤3.0 (N=174). A high range of EDSS in this population was 5.5–6.5.

In recent Phase 3 trials, which used an Expanded Disability Status Scale (EDSS) score of ≥3 to define active SPMS, disease-modifying drugs achieved NEDA in 30–60% of patients with EDSS ≥3.5 or ≤3.0 in the baseline EDSS ≥3.5 group.

Table 1. Demographics and Disease Characteristics of Patients at CLARITY Baseline

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Placebo EDSS ≤3.0</th>
<th>Cladribine tablets 3.5 mg/kg, EDSS ≥3.5</th>
<th>Cladribine tablets 3.5 mg/kg, EDSS ≤3.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>79 (29.0)</td>
<td>62 (38.5)</td>
<td>75 (27.6)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>206 (71.0)</td>
<td>104 (61.5)</td>
<td>209 (72.4)</td>
</tr>
<tr>
<td>Age, years (mean [SD])</td>
<td>45.5 (10.8)</td>
<td>46.1 (10.7)</td>
<td>46.0 (10.7)</td>
</tr>
<tr>
<td>Relapses in prior 12 months, n (%)</td>
<td>28 (10.2)</td>
<td>41 (25.5)</td>
<td>44 (15.8)</td>
</tr>
<tr>
<td>Number of T1 Gd+ lesions, mean (SD)</td>
<td>2.5 (1.9)</td>
<td>2.5 (1.9)</td>
<td>2.4 (1.9)</td>
</tr>
<tr>
<td>Probability of remaining free of 3-month CDP</td>
<td>0.90 (0.05)</td>
<td>0.89 (0.05)</td>
<td>0.90 (0.05)</td>
</tr>
</tbody>
</table>

RESULTS

In the ITT population, 433 patients were assigned to cladribine tablets 3.5 mg/kg (baseline EDSS ≥3.5; EDSS ≥3.0 or ≤3.0) and 472 patients to placebo EDSS ≤3.0 (N=272).

In general, baseline demographic and disease characteristics were well-balanced between treatment groups (Table 1).

CONCLUSIONS

In this post hoc analysis of the 6-week CLARITY study, treatment with cladribine tablets 3.5 mg/kg resulted in similar improvements in relapse and MRI outcomes in patients with RMS regardless of baseline EDSS score.

These results are consistent with prior post hoc analyses of CLARITY that examined outcomes (relapse and MRI) by baseline EDSS score4–7.

REFERENCES


DISCLOSURES

The authors have no personal, financial, or other conflicts of interest. The sponsors had no role in the design of the study, the collection, analysis, or interpretation of data, or the writing of the manuscript. Any data that support the findings of this study are available from the corresponding author on reasonable request.

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