Safety and Tolerability of BG-12 in the Phase 3 CONFIRM Study


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OBJECTIVE

To evaluate the safety and tolerability of BG-12 in patients with MS in the Phase 3 CONFIRM Study (National Institutes of Health ClinicalTrials.gov Identifier: NCT02240475) and in an open-label, ongoing, Phase 4 Treatment Failure Study.

METHODS

Patients

Patients were randomized (1:1:1) to receive BG-12 or sodium hydrosulfite (SH) or placebo for 24 months in the placebo-controlled part of the Phase 3 CONFIRM Study and for up to 48 months in the Phase 4 Treatment Failure Study. Safety

The overall incidence of AEs in the BG-12 groups was similar to that in the placebo group.

RESULTS

Table 1: Summary of adverse events

<table>
<thead>
<tr>
<th>Event Category</th>
<th>Placebo</th>
<th>BG-12 2 mg</th>
<th>BG-12 10 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>All AEs</td>
<td>68%</td>
<td>70%</td>
<td>69%</td>
</tr>
<tr>
<td>Neuropsychiatric</td>
<td>8%</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>Cognitive</td>
<td>6%</td>
<td>7%</td>
<td>7%</td>
</tr>
</tbody>
</table>

Table 2: Incidence of serious adverse events

- No serious AEs were reported in patients receiving BG-12.

Figure 1: Incidence of serious adverse events by study month

Figure 2: Incidence of serious adverse events in subgroups

Figure 3: Incidence of serious adverse events by treatment group

DISCUSSIONS

The overall incidence of renal and urinary disorders was similar across treatment groups (19%, 18%, and 17% in placebo, BG-12 2 mg, and BG-12 10 mg, respectively).

No serious AEs were reported in any patient on BG-12 or placebo, and there were no deaths during the study.

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REFERENCES