Atogepant Significantly Reduces Mean Monthly Migraine Days in the Phase 3 Trial (ADVANCE) for the Prevention of Migraine

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RESULTS

Participants

• A total of 910 participants were randomized, including 902 in the safety population and 873 in the efficacy analysis population (modified intent-to-treat population)

• Across all treatment groups, 88.5% (805/901) of participants completed the 12-week double-blind treatment period

• Participants were on average 41.6 years of age and primarily female, white, and of average weight (Table 1)

• The mean (standard deviation [SD]) number of monthly migraine days ranged from 7.2 to 7.7 during the 3 months prior to starting treatment

Table 1. Baseline Demographics in the Safety Population

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Participants (n=228)</th>
<th>Age, mean (SD), y</th>
<th>Sex, female</th>
<th>Race, White</th>
<th>Ethnicity, non-Hispanic</th>
<th>BMI, mean (SD), kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>52.1 (14.9)</td>
<td>89.2%</td>
<td>87.4%</td>
<td>90.5%</td>
<td>30.8 (4.7)</td>
<td></td>
</tr>
<tr>
<td>Atogepant 10 mg QD</td>
<td>52.1 (14.9)</td>
<td>89.2%</td>
<td>87.4%</td>
<td>90.5%</td>
<td>30.8 (4.7)</td>
<td></td>
</tr>
<tr>
<td>Atogepant 30 mg QD</td>
<td>52.1 (14.9)</td>
<td>89.2%</td>
<td>87.4%</td>
<td>90.5%</td>
<td>30.8 (4.7)</td>
<td></td>
</tr>
<tr>
<td>Atogepant 60 mg QD</td>
<td>52.1 (14.9)</td>
<td>89.2%</td>
<td>87.4%</td>
<td>90.5%</td>
<td>30.8 (4.7)</td>
<td></td>
</tr>
</tbody>
</table>

Primary Efficacy Endpoint Was Met With All Atogepant Doses

• Statistically significant reductions in mean MMDs across the 12-week treatment period were observed across all atogepant treatment groups vs placebo (Figure 2)

Figure 2. Reductions From Baseline in Mean MMDs at 12 Weeks

Significant Improvements Were Achieved Across All 6 Secondary Endpoints

• Atogepant 30 mg and 60 mg met all 6 secondary endpoints; atogepant 10 mg met the first 4 secondary endpoints (Figure 3)

Figure 3. Improvements in Secondary Efficacy Endpoints

SAFETY

All atogepant doses demonstrated significant improvements over placebo for the primary endpoint of reduction in mean monthly migraine days

Atogepant appeared to be generally safe and well-tolerated with the most commonly reported adverse event being constipation

Atogepant offers the prospect of an effective and well-tolerated once-daily migraine preventive treatment

SAFETY

• Rates of adverse events (AEs) were similar across all treatment groups (Table 2)

• Serious AEs were reported by 2 participants in both placebo and atogepant 10 mg groups; none were reported for atogepant 30 mg or atogepant 60 mg

• Rates of discontinuation due to AEs were low across all treatment groups and not dose dependent

• Most commonly reported AEs were constipation and nausea; none were considered serious

• Constipation (7.7%, 7.0%, and 6.9% with atogepant 10 mg, atogepant 30 mg, and atogepant 60 mg, respectively, vs 5.5% with placebo)

• Nausea (5.0%, 4.4%, and 6.1% with atogepant 10 mg, atogepant 30 mg, and atogepant 60 mg, respectively, vs 1.8% with placebo)

• Cases of constipation were primarily mild (71.4%) or moderate (26.5%) in severity

• One was considered severe with atogepant 10 mg: worsening of pre-existing constipation; the participant was treated with over-the-counter medications, completed the trial, and entered the open-label extension

• All reported cases of nausea were mild (71.1%) or moderate (22.9%) in severity

Table 2. Adverse Events in the Safety Population

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Adverse events (%)</th>
<th>Placebo (n=217)</th>
<th>Atogepant 10 mg QD (n=221)</th>
<th>Atogepant 30 mg QD (n=224)</th>
<th>Atogepant 60 mg QD (n=222)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE (%)</td>
<td></td>
<td>6.4 (52)</td>
<td>27% (56)</td>
<td>19% (55)</td>
<td>24% (55)</td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
<td>5.4 (48)</td>
<td>4.4% (9)</td>
<td>4.4% (9)</td>
<td>4.9% (10)</td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td>6.5 (56)</td>
<td>7.7% (16)</td>
<td>7.0% (16)</td>
<td>6.9% (16)</td>
</tr>
</tbody>
</table>

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ADD INFO

Thank you to all the participants and investigators who participated in this study!