Efficacy, tolerability, and safety of onabotulinumtoxinA treatment for chronic migraine in patients with acute medication overuse: Analysis of the PREEMPT and COMPEL trials

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OBJECTIVE

To evaluate the efficacy, tolerability, and safety of onabotulinumtoxinA (onabotA) (BOTOX®) in patients treated for chronic migraine (CM) with or without acute medication overuse (MO).

INTRODUCTION

Background

• OnabotulinumtoxinA (OnabotA) is approved for the treatment of 26 therapeutic and cosmetic indications globally, including chronic migraine (CM).
• Treatment with onabotA is effective in individuals with medication overuse (MO).
• PREEMPT is a randomized, double-blind trial where participants received either onabotA or placebo for 24 weeks, followed by a 24-week open-label phase.
• COMPEL is a single-arm, open-label, prospective study designed to assess the safety and efficacy of onabotA in patients with CM.
• For each of COMPEL and PREEMPT, ~65% of participants had a history of acute medication overuse (MO).

This subanalysis examined the efficacy of onabotA treatment in participants with MO vs participants without MO (COMPEL), and participants from the PREEMPT trial with MO and without MO for onabotA vs placebo (PREEMPT).

This subanalysis also examined the safety of onabotA treatment pooled from the COMPEL and PREEMPT studies.

METHODS

Study Design

• PREEMPT: 24-week randomized, double-blind phase where participants received either onabotA or placebo, followed by a 32-week open-label phase where all participants received onabotA.
• COMPEL: Single-arm, open-label, multicenter, prospective study where all participants received onabotA.
• Per ICHD, MO was defined as taking acute medication ≥2 times per week in any week (depending on the medication category) during screening.

Outcomes

• PREEMPT: Change from baseline (CFB) in monthly headache days (MHD), moderate/severe MHD, 6-item headache impact test (HIT-6), and migraine-specific quality of life role function-restrictive (MSQ-RFR) score.
• COMPEL: CFB in MHD, moderate/severe MHD, and HIT-6 score.
• Pooled: Safety analysis in the form of treatment-related adverse events (TRAEs).

RESULTS

Baseline Demographics of Patients Treated With OnabotA or Placebo for CM

<table>
<thead>
<tr>
<th>Parameter</th>
<th>COMPEL Enrolled Population (N=349)</th>
<th>PREEMPT OnabotA (N=692)</th>
<th>PREEMPT Placebo/OnabotA (N=692)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, y</td>
<td>43.0 ± 11.3</td>
<td>41.0 ± 11.5</td>
<td>41.5 ± 11.6</td>
</tr>
<tr>
<td>Female, %</td>
<td>84.8</td>
<td>87.6</td>
<td>85.2</td>
</tr>
<tr>
<td>Causation, %</td>
<td>81.3</td>
<td>89.7</td>
<td>90.5</td>
</tr>
<tr>
<td>Mean monthly headache days (SD)</td>
<td>22.0 (4.8)</td>
<td>19.3 (3.6)</td>
<td>19.8 (3.6)</td>
</tr>
<tr>
<td>Mean monthly moderate/severe headache days (SD)</td>
<td>18.0 (5.7)</td>
<td>19.1 (3.6)</td>
<td>18.9 (4.0)</td>
</tr>
<tr>
<td>Mean HIT-6 total score</td>
<td>64.7</td>
<td>65.6</td>
<td>65.4</td>
</tr>
<tr>
<td>Acute medication overuse, %</td>
<td>63.7</td>
<td>64.8</td>
<td>65.2</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• OnabotA reduced monthly headache days (MHD), severe MHD, HIT-6 score, and MSQ score compared with placebo in patients with MO and without.

There was no significant difference in MHD, severe MHD, or HIT-6 score in patients with CM with or without MO treated with onabotA.

Patients with CM and MO treated with onabotA responded in similar frequency and amplitude to patients with CM without MO and displayed a similar safety profile.

REFERENCES

[List of references]

FINANCIAL SUPPORT

[Information about financial support]

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STUDY LIMITATIONS

[Study limitations]

This data was presented previously at the European Neurology Congress (ENOC), December 18, 2023, Vienna, Austria.

PREEMPT: Chronic Migraine Pain Trials; B/B, Botox®; B/P, Botox® vs Placebo; MO, medication overuse; CFB, change from baseline; Days, days; MHD, monthly headache days; HIT-6, 6-item headache impact test; MSQ, migraine severity questionnaire; RFR, role function restrictive; TRAEs, treatment-related adverse events; SD, standard deviation; *p<0.05, **p<0.01, ***p<0.005.