**Indications:** FYCOMPA (perampanel) is indicated as adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy age 12 years and older. FYCOMPA is a Schedule III controlled drug substance and is not approved for use in children.

**FDA APPROVED FOR TWO INDICATIONS**

Now FDA approved for PGTC seizures, FYCOMPA was previously approved as a monotherapy for the treatment of partial-onset seizures in patients with epilepsy age 12 years and older.

**EpiPrep and PGTC Seizures**

<table>
<thead>
<tr>
<th><strong>Seizure Type</strong></th>
<th><strong>Number of Patients (%)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial-onset seizures</td>
<td>162 patients, age 12 and older</td>
</tr>
<tr>
<td>Taking 1-3 antiepileptic drugs (AEDs)</td>
<td>Experiencing at least 3 PGTC seizures in the 8-week baseline period</td>
</tr>
</tbody>
</table>

**EFICACY AND SAFETY OF FYCOMPA FOR TREATMENT OF PGTC SEIZURES**

- A Phase 3, randomized, double-blind, placebo-controlled clinical trial (Study 322) among... 162 patients, age 12 and older.
- Taking 1-3 antiepileptic drugs (AEDs)
- Experiencing at least 3 PGTC seizures in the 8-week baseline period

**6.4% of patients (n=81) were at least 50% lower in the median PGTC seizure frequency**

- **Primary endpoint**
- **Secondary endpoint**

**64% of patients (n=81) were at least 50% lower in the median PGTC seizure frequency versus 3% of placebo patients (n=81)**

- **Primary endpoint**
- **Secondary endpoint**

**6.4% of patients (n=81) were at least 50% lower in the median PGTC seizure frequency versus 40% for the baseline period**

- **Primary endpoint**
- **Secondary endpoint**

**Patient-Reported Outcomes**

**The most frequently reported adverse event (greater than or equal to 10% and greater than or equal to placebo) in patients treated with FYCOMPA was dizziness.**

**Meaning of NOA**

**FYCOMPA blocks AMPA receptors (the primary excitatory neurotransmitter in the central nervous system) activity post-synaptically.**

**The precise mechanism by which FYCOMPA exerts its antiepileptic efficacy in humans is unknown.**

**Drug Interactions**

FYCOMPA may decrease the efficacy of contraceptives containing estrogens (e.g., birth control pills). Contraceptives containing estrogens may be considered. FYCOMPA may also be used in combination with other CNS depressants.

**Epilepsy and the Elderly**

Patients 65 years of age or older who have mild or moderate hepatic impairment and are taking FYCOMPA at doses above 4 mg/day should be monitored for sleeplessness and withdrawal symptoms.

**Suicidal Behavior and Ideation**

FYCOMPA may increase the risk of suicidal thoughts and behavior in patients with epilepsy, including those with a history of depression or other risk factors. Patients and caregivers should be advised to monitor patients for the emergence or worsening of depression, suicidal thoughts or behavior, and to seek medical help right away if these symptoms occur.

**Important Safety Information**

- **FDA-approved use of FYCOMPA is for the treatment of partial-onset seizures in patients with epilepsy age 12 years and older.**
- **Epilepsy and the Elderly:**
  - Patients 65 years of age or older who have mild or moderate hepatic impairment and are taking FYCOMPA at doses above 4 mg/day should be monitored for sleeplessness and withdrawal symptoms.

**Eisai is committed to ADVANCING EPILEPSY CARE and making contributions to help address the diversification of needs in this patient population as part of its corporate health care mission.**