EISAI TO SUSPEND TEMPORARILY COMMERCIAL DISTRIBUTION OF ANTIEPILEPTIC DRUG FYCOMPA® IN GERMANY

COMPANY WILL CONTINUE TO ENSURE ACCESS TO THE DRUG FOR PATIENTS IN NEED OF FYCOMPA TREATMENT

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that it has decided to suspend temporarily commercial distribution of the antiepileptic drug, AMPA receptor antagonist Fycompa® (perampanel) in Germany based on its belief that the German Federal Joint Committee (G-BA) failed to appropriately assess the value of Fycompa as an innovative new treatment in an additional benefit assessment conducted after German marketing approval was granted for the drug last year. Eisai’s primary concern in the country will conctcounty

[Notes to editors]

1. About the Treatment of Epilepsy

The goal of treating patients with epilepsy is seizures-free. Once epilepsy is diagnosed, a patient usually begins monotherapy (single-agent) treatment with an antiepileptic drug. In cases where the treatment's efficacy on seizure control is inadequate, the initial treatment can typically be replaced with a different monotherapy. In approximately 30-40% of patients, however, seizure control is not achieved even after undergoing two different monotherapy treatments and in these circumstances the patient can then opt to switch to a treatment that includes an adjunctive therapy. In these cases, it is drugs like Fycompa® that are approved as adjunctive therapies in treating epilepsy that are used as "add-ons" to the patient's existing monotherapy treatment. Furthermore, depending on the patient's symptoms, there may be multiple "add-on" adjunctive therapies being used at one time.

2. Glossary of Terms

1) German Federal Joint Committee (G-BA)

The German Federal Joint Committee (*Gemeinsamer Bundesausschuss*, G-BA) is the highest decision-making body of the joint self-governm

is designated a reference price group as well as a reimbursement price based on the price of the comparator used during the benefit assessment.

3. About Fycompa® (Perampanel)

Fycompa (perampanel), a novel chemical entity discovered and undergoing development by Eisai, is a highly selective, non-competitive AMPA -type glutamate receptor antagonist. Perampanel is the first antiepileptic treatment to reduce neuronal hyperexcitation associated with seizures by targeting glutamate activity at post-synaptic AMPA receptors. Perampanel has demonstrated broad-spectrum antiseizure effects in Phase II and III studies. The agent has received a positive opinion from the CHMP for the adjunctive treatment of partial-onset seizures in Europe, is currently under regulatory review for NDA in the United States, and is also being evaluated in Phase III studies in Japan. Furthermore, Eisai is conducting a global Phase III studies for generalized epilepsy and plans to conduct further studies for usage as monotherapy in the treatment of partial-onset seizures, Lennox-Gastaut syndrome and other forms of epilepsy as it seeks to expand the range of indications for which the drug is approved.

4. About Perampanel Phase III Studies

The clinical development plan for perampanel consisted of three global Phase III studies (Studies 306, 305 and 304) in which a total of 1,480 epilepsy patients with partial-ons

2) Study 305

- The 50% responder rates compared to placebo for the ITT population were:
  8 mg = 33.3% (p = 0.0018), 12 mg = 33.9% (p = 0.0006) versus 14.7% with placebo.
- The median percent change in seizure frequency for the ITT population were:
  8 mg = -30.5% (p = 0.0008), 12 mg = -17.6% (p = 0.0105) versus -9.7% with placebo
- The most reported adverse events were dizziness, fatigue, headache and somnolence.

3) Study 304

- The 50% responder rates compared to placebo for the ITT population were:
  8 mg = 37.6% (p = 0.0760), 12 mg = 36.1% (p = 0.0914) versus 26.4% with placebo
- The median percent change in seizure frequency for the ITT population were:
  8 mg = -26.3% (p = 0.0261), 12 mg = -34.5% (p = 0.0158) and placebo = -21.0%
- The most common side effects were dizziness, somnolence, irritability, headache, falls and ataxia.