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Eisai Co., Ltd.

EISAI ANNOUNCES LAUNCH OF ANTIEPILEPTIC DRUG FYCOMPA™ IN U.S.

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that on January 2, 2014, its U.S. subsidiary Eisai Inc. launched the AMPA receptor antagonist Fycompa™ (perampanel), a first-in-class antiepileptic drug (AED) discovered and developed in-house, in the United States as an adjunctive therapy for partial-onset seizures with or without secondary generalized seizures in patients with epilepsy aged 12 and older.

Fycompa is a highly selective, noncompetitive AMPA receptor antagonist discovered and developed by Eisai. With epileptic seizures being primarily mediated by the neurotransmitter glutamate, the agent works as a first-in-class AED that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. It is approved in more than 35 countries worldwide, mostly in Europe and North America, and has been already launched in Canada and in a number of European countries. In the United States, following approval by the U.S. Food and Drug Administration (FDA) in October 2012, Fycompa was recommended to the U.S. Drug Enforcement Administration (DEA) for scheduling classification under the country's Controlled Substances Act and subsequently placed as a Schedule III drug.

The number of patients with epilepsy in the United States is approximately 2.2 million people and approximately 150,000 people are estimated to be newly diagnosed with epilepsy in that country each year. Furthermore, some 60% of patients diagnosed with epilepsy in the United States have partial seizures, of which approximately 25% to 30% are unable to control their seizures with current treatment options. Fycompa, which has a mechanism of action different to that of other licensed AEDs, offers a new treatment option for epilepsy patients with partial-onset seizures. Indicated for a wide range of patients, including adults and adolescents over 12 years of age, the agent has the added benefit of once-daily oral dosing, which is expected to reduce the potential pill-burden a patient with epilepsy may experience as well as improve patient drug compliance.

Eisai defines epilepsy as a therapeutic area of focus and in the United States markets Zonegran® (under license from the originator Dainippon Sumitomo Pharma Co., Ltd.) as a treatment for partial-onset epilepsy in adults and BANZEL® (under license from the originator Novartis AG) as a treatment for Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy. By providing multiple treatment options as part of an extensive epilepsy product portfolio, Eisai seeks to make continued contributions to addressing the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.

[Please refer to the following notes for further information on epilepsy, Fycompa, the Phase III studies and Eisai's commitment to epilepsy.]

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[Notes to editors]

1. About Epilepsy

Epilepsy is a medical condition that produces seizures, affecting a variety of mental and physical functions. A patient is considered to have epilepsy after two or more unprovoked seizures. A seizure occurs when a brief, strong surge of electrical activity affects part or all of the brain. An individual can have various symptoms, from convulsions and loss of consciousness, to some that are not always recognized as seizures, such as blank staring, lip smacking, or jerking movements of arms and/or legs.

Epilepsy can develop at any age and 0.5% to 2% of people will develop epilepsy during their lifetime. Epilepsy reportedly affects nearly 1 million people in Japan, 2.4 million people in Europe (G5), 2.2 million people in the United States, and more than 50 million people worldwide. Epilepsy constitutes an area in which there are still significant unmet medical needs, with partial-onset epilepsy accounting for approximately 60% of all epilepsy cases in the United States, and from 25% to 30% of patients living with partial epilepsy in that country not achieving seizure freedom despite therapy with antiepileptic drugs (AEDs).

2. About Fycompa (Perampanel)

Fycompa (perampanel), a novel chemical entity discovered and developed by Eisai, is a noncompetitive AMPA-type glutamate receptor antagonist. Fycompa is the first AED to reduce neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors and has demonstrated its antiseizure effects in Phase II and III studies. The agent is currently approved in more than 35 countries and territories, including in Europe and the United States, as a treatment (once-daily oral dose) of partial-onset seizures and is also being evaluated in a Phase III study in Asia, including in Japan. Furthermore, Eisai is conducting a global Phase III perampanel study for generalized epilepsy and Phase II perampanel studies in Europe and the United States for partial-onset epilepsy in pediatric patients, as it seeks to expand the range of indications for which the drug is approved.

[Important Safety Information Summary in the United States]

Mental (Psychiatric) Problems

Fycompa may cause new or worse aggressive behavior (including homicidal behavior), hostility, anger, anxiety, or irritability, being suspicious or distrustful (believing things that are not true) or other unusual or extreme changes in behavior or mood. Patients should call their healthcare provider right away if they have any new or worsening mental problems while taking Fycompa.

Suicidal Thoughts and Actions

Antiepileptic drugs (AEDs), including Fycompa, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Patients should call their healthcare provider right away if they have any new or worsening symptoms of depression, any unusual or sudden changes in mood, feelings, behavior, or suicidal thoughts, behavior, or thoughts of self-harm that they have never had before or may be worse than before.

Dizziness, Vertigo (Sense of Spinning) and Problems Walking Normally

Patients may have problems walking normally if they are unsteady because they feel dizzy. These symptoms may increase when their dose of Fycompa is increased. A patient's risk of feeling dizzy and having problems walking normally may be higher if they are elderly.

Sleepiness and Tiredness

Fycompa may make a patient feel sleepy or tired. Patients should not drive, operate heavy machinery, or do other dangerous activities until they know how Fycompa affects them. A patient's risk of feeling sleepy and tired may be higher if they are elderly.

Falls

Taking Fycompa may increase a patient's chance of falling. These falls can cause serious injuries. A patient's risk of falling may be higher if they are elderly.

Withdrawal of Antiepileptic Drugs (AEDs)

Patients must not stop Fycompa without first talking to their healthcare provider. Stopping Fycompa suddenly can cause serious problems and can cause patients to have seizures more often.

3. About the 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 patients with epilepsy aged 12 years and older participated. The key goal of Study 306 was to identify the minimal effective dose and included four treatment arms (placebo, 2 mg, 4 mg, and 8 mg). Studies 304 and 305 included three arms (placebo, 8 mg, and 12 mg) and were to evaluate a more extended dose range.

The studies were similar in design: global, randomized, double-blind, placebo-controlled, dose-escalation, parallel-group studies. The primary and secondary endpoints were the same in all the studies: percentage change in seizure frequency, 50% responder rate, percentage reduction of complex partial plus secondarily generalized seizures, and evaluation for dose response. The primary endpoint for the European Medicines Agency (EMA) was the 50% responder rates, while for the U.S. Food and Drug Administration (FDA) it was the median percentage changes in seizure frequency. Specifically, the results showed:

Study 306

- ·The 50% responder rates compared to placebo for the intention-to-treat (ITT) population were: 20.6% (p=0.4863), 28.5% (p=0.0132), and 34.9% (p=0.0003) in the 2, 4, and 8 mg perampanel/day groups, respectively, versus 17.9% with placebo.
- ·The median percentage changes in seizure frequency for the ITT population shown were: 2 mg = -13.6% (p=0.4197), 4 mg = -23.3% (p=0.0026), 8 mg = -30.8% (p<0.0001), and placebo = -10.7%.
- ·The most frequent treatment-emergent adverse events were dizziness, headache and somnolence.

Study 305

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

Study 304

- ·The 50% responder rates compared to placebo for the ITT population were: 37.6% (p=0.0760) and 36.1% (p=0.0914) in the 8 mg and 12 mg perampanel/day groups, respectively, versus 26.4% with placebo.
- ·The median percentage changes in seizure frequency for the ITT population shown 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.

4. Eisai's Commitment to Epilepsy

Eisai defines epilepsy as a therapeutic area of focus. In addition to developing the AMPA receptor antagonist Fycompa globally, it currently markets Zonegran® (sodium/calcium channel-blocking antiepileptic agent under license from the originator Dainippon Sumitomo Pharma Co., Ltd. and marketed in Europe, the United States and Asia) as a monotherapy / adjunctive therapy in adults with partial-onset seizures and as an adjunctive therapy in pediatric patients with partial-onset seizures; Zebinix® (voltage-dependent sodium channel-blocking antiepileptic agent under license from the originator BIAL-Portela & Ca S.A. and marketed in Europe) as an adjunctive therapy in adults with partial-onset seizures; Inovelon®/BANZEL® (sodium channel-blocking novel triazole-derived antiepileptic agent under license from the originator Novartis AG and marketed in Europe, Asia, including Japan, and North America as an adjunctive treatment for seizures associated with Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy; and Fostoin® (water-soluble phenytoin prodrug co-promoted with Nobelpharma Co., Ltd. and marketed in Japan), an anticonvulsant agent used to treat status epilepticus and other conditions.