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Eisai Co., Ltd.

EISAI ANNOUNCES LAUNCH OF AMPA RECEPTOR ANTAGONIST FYCOMPA® FOR THE TREATMENT OF EPILEPSY

Europe first region in the world to gain access to this new first-in-class therapy

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it will launch the AMPA receptor antagonist Fycompa® (perampanel), a first-in-class antiepileptic agent discovered and developed in-house, in Europe ahead of other regions in the world for use as an adjunctive treatment for partial onset seizures, with or without secondarily generalized seizures, in patients aged 12 years and older. Following the launch of the agent in the United Kingdom today, Fycompa will also be launched successively in European Union member states such as Germany, Austria and Denmark.

Fycompa is a highly selective, non-competitive AMPA-type glutamate receptor antagonist. Epileptic seizures are primarily mediated by the neurotransmitter glutamate. As an AMPA receptor antagonist, Fycompa reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at post-synaptic AMPA receptors. In three global pivotal Phase III randomized, double-blind, placebo-controlled, dose-escalation studies which examined 1,480 epilepsy patients with partial-onset seizures, Fycompa consistently demonstrated excellent efficacy across all studies. The most commonly reported adverse events were dizziness, headache, somnolence, irritability, fatigue, falls and ataxia. Fycompa was first approved by the European Commission (EC) in July of this year as the first and only antiepileptic drug (AED) to target AMPA receptors.

There are an estimated six million people living with epilepsy in Europe, and it is said that some 33,000 people die from the disease each year. In particular, the successful management of partial-onset seizures, the most common form of epilepsy, remains a significant challenge, with around 30% of partial-onset seizure patients in Europe not achieving seizure freedom despite therapy with AEDs. Fycompa, which has a mechanism of action totally different to that of other licensed AEDs, is 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 also 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.

A New Drug Application for Fycompa was submitted in the United States in December 2011, while a Phase III clinical study is currently underway in Japan for the same indication. Eisai is also conducting a global Phase III study to evaluate the agent as a potential treatment for generalized epilepsy.

Eisai defines epilepsy as a therapeutic area of focus, with its currently marketed European epilepsy portfolio comprising Zonegran® (under license from the originator Dainippon Sumitomo Pharma Co., Ltd.) and Zebinix® (under license from the originator BIAL-Portela & Ca S.A.) for the treatment of adult epilepsy

patients with partial-onset seizures, and Inovelon® (under license from the originator Novartis AG) for the treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy. By enhancing its drug development capabilities in the field of epilepsy and providing multiple treatment options as part of an extensive epilepsy product portfolio, Eisai seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.

[Please refer to the following notes for further information on epilepsy, Fycompa, perampanel 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 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), 3 million people in the United States, and more than 50 million people worldwide. Epilepsy constitutes an area in which there are significant unmet medical needs, with up to a third of epilepsy patients with partial-onset seizures in Europe not achieving seizure freedom despite therapy with anti-epileptic drugs.

2. About AMPA Receptor Antagonist Fycompa® (perampanel)

Fycompa® (perampanel), a novel chemical entity discovered and developed by Eisai, is a highly selective, non-competitive AMPA-type glutamate receptor antagonist. Perampanel is the first anti-epileptic treatment to reduce neuronal hyperexcitation associated with seizures by targeting glutamate activity at post-synaptic AMPA receptors. Perampanel has demonstrated broad-spectrum anti-seizure effects in Phase II and III studies. The agent is approved in Europe for the treatment (once-daily oral dose) of partial-onset seizures, with a New Drug Application (NDA) currently under review in the United States. Perampanel is also being evaluated for the same indication in a Phase III study in Japan. Furthermore, Eisai is conducting a global Phase III study for generalized epilepsy as well as a Phase II study for partial-onset seizures in pediatric patients in the United States and Europe, and plans to conduct further studies to evaluate the agent as a 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.

3. 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-onset seizures 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, 2mg, 4mg, and 8mg). Studies 304 and 305 included three arms (placebo, 8mg, and 12mg) 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 EMA is 50% responder rate and the FDA is median percent change in seizure frequency.

Results of the studies are as follows.

1) Study 306

·The 50% responder rates compared to placebo for the ITT (intention-to-treat) population were:
2mg = 20.6% (p=0.4863), 4mg = 28.5% (p=0.0132), 8mg = 34.9% (p=0.0003) versus 17.9% with placebo.

·The median percent change in seizure frequency for the ITT population were:

2mg = -13.6% (p=0.4197), 4mg = -23.3% (p=0.0026), 8mg = -30.8% (p<0.0001) versus -10.7% with placebo

·The most frequent treatment-emergent adverse events were dizziness, headache and somnolence.

2) Study 305

·The 50% responder rates compared to placebo for the ITT population were:

8mg = 33.3% (p=0.0018), 12mg = 33.9% (p=0.0006) versus 14.7% with placebo.

·The median percent change in seizure frequency for the ITT population were:

8mg = -30.5% (p=0.0008), 12mg = -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:

8mg = 37.6% (p=0.0760), 12mg = 36.1% (p=0.0914) versus 26.4% with placebo

·The median percent change in seizure frequency for the ITT population were:

8mg = -26.3% (p=0.0261), 12mg = -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, Eisai currently markets Zonegran® (under license from the originator Dainippon Sumitomo Pharma Co., Ltd.; sodium/calcium channel blocking antiepileptic agent; marketed in Europe, the United States and Asia) and Zebinix® (under license from the originator BIAL-Portela & Ca S.A.; voltage-dependent sodium channel-blocking antiepileptic agent; marketed in Europe) as adjunctive therapies in adults with partial-onset seizures, and Inovelon®/Banzel® (under license from the originator Novartis AG; sodium channel-blocking novel triazole derived antiepileptic agent; marketed in Europe, Asia (Inovelon®), and the North America (BANZEL®)) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy.