No.14-68

November 21, 2014
Eisai Co., Ltd.

EISAI LAUNCHES ANTIEPILEPTIC DRUG FYCOMPA® IN HONG KONG

FIRST REGION IN ASIA TO GAIN ACCESS TO NEW FIRST-IN-CLASS THERAPY

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its Hong Kong subsidiary Eisai (Hong Kong) Co., Ltd. has launched the AMPA receptor antagonist Fycompa® (perampanel), a first-in-class antiepileptic drug (AED) discovered and developed in-house, in the region as an adjunctive treatment for partial-onset seizures with or without secondary generalized seizures in patients with epilepsy aged 12 years and older. This marks the first launch of Fycompa in the Asia region.

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 40 countries worldwide, mostly in Europe and North America, and has been already launched in over 15 countries around the world including the United States and a number of European countries.

Over half of the 50 million people with epilepsy worldwide are estimated to live in Asia[1]. As approximately some 60% of patients diagnosed with epilepsy have partial seizures, of which approximately 25% to 30% are unable to control their seizures with current treatment options, this is a disease with significant unmet medical needs. 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 aged 12 years and older, 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 considers epilepsy as a therapeutic area of focus and in addition to Fycompa, holds an extensive epilepsy product portfolio. By providing multiple treatment options in Asia, including Hong Kong, 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.

[1] Mac TL, Tran DS, Quet F, et al. Epidemiology, aetiology, and clinical management of epilepsy in Asia: a systematic review. Lancet Neurol 2007;6:533–543.

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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 55% of all epilepsy cases in Hong Kong, and from 20% to 40% of patients living with partial epilepsy in that country not achieving seizure freedom despite therapy with antiepileptic drugs (AEDs).

2. About Fycompa (Perampanel)

Fycompa, a novel chemical entity discovered and developed by Eisai, is a noncompetitive AMPA-type glutamate receptor antagonist. Fycompa is an antiepileptic drug that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. The agent is currently approved in more than 40 countries and territories, including Europe and the United States, as an adjunctive treatment (once-daily oral dose) of partial-onset seizures and is also being evaluated in a Phase III study (Study 335) in Asia, including Japan.

A Phase III study (Study 332) of the agent as an adjunctive therapy for the treatment of primary generalized tonic-clonic seizures (PGTC) conducted in the United States, Europe and Asia, including Japan, met its primary endpoint, and the regulatory applications for an indication expansion of the agent are under review in the United States and Europe. The company plans to submit a regulatory application covering both study 332 and study 335 in Japan in fiscal 2015. Furthermore, Eisai is conducting Phase II studies in Europe and the United States for partial-onset epilepsy in pediatric patients.

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:

<u>Study 306</u>

·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 considers 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 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.