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Eisai Co., Ltd.

EMA ACCEPTS EISAI'S LICENSE EXTENSION APPLICATION FOR ANTIEPILEPTIC AGENT ZONEGRAN® AS A MONOTHERAPY

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the European Medicines Agency (EMA) has accepted for review the company's application to extend the use of the antiepileptic agent Zonegran® (zonisamide) as a monotherapy.

Zonegran® was approved in Europe in March 2005 as an adjunctive therapy for the treatment of partial seizures (with or without secondary generalization) in adults with epilepsy. This latest license expansion application seeks approval to market the agent as a monotherapy for newly diagnosed epilepsy patients with partial seizures, with and without secondary generalization.

The application was based on a double blind, randomized, multicenter study designed to compare once-daily zonisamide with twice-daily controlled release carbamazepine as monotherapy in 583 adults with newly diagnosed partial-onset epilepsy. The study's primary endpoint was the proportion of seizure-free patients at six months. The results of the study showed that zonisamide was effective and well tolerated in newly diagnosed epilepsy patients when used as monotherapy. The statistical comparison between zonisamide and carbamazepine met the criterion of non-inferiority as recommended by treatment guidelines set out by the International League Against Epilepsy (ILAE).

Eisai positions epilepsy as a therapeutic area of focus, currently marketing Zonegran® and Zebinix® in Europe as adjunctive therapies for adult patients with partial-onset seizures (including patients with secondary generalization) as well as Inovelon® as an adjunctive therapy for seizures associated with Lennox-Gastaut syndrome. The company has also submitted an application, which is now under review, seeking approval to market the novel AMPA receptor antagonist perampanel (E2007) as an adjunctive therapy for epilepsy patients with partial-onset seizures that offers a completely different mechanistic approach to other antiepileptic drugs. By strengthening its development capabilities and offering multiple treatment options as part of its abundant epilepsy franchise 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 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. When a person has two or more unprovoked seizures, they are considered to have epilepsy. A seizure happens when a brief, strong surge of electrical activity affects part or all of the brain. An individual can have many 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 affects nearly 1 million people in Japan, 2.4 million people in Europe, 3 million people in the United States, and some 40 to 50 million people worldwide.

2. Eisai's Commitment to Epilepsy

Eisai positions epilepsy as a therapeutic area of focus and currently markets Zonegran® (sodium/calcium channel blocking antiepileptic agent; Europe, the United States, Asia) and Zebinix® (voltage-dependent sodium channel-blocking antiepileptic agent; Europe) as adjunctive therapies in adult patients with partial-onset seizures as well as Inovelon®/BANZEL® (sodium-channel blocking triazole derived antiepileptic agent; Europe, Asia/the United States) as an adjunctive therapy for seizures associated with Lennox-Gastaut syndrome, a severe form of childhood-onset epilepsy.

Furthermore, Eisai has submitted marketing authorization applications in Europe and the United States seeking approval of its novel AMPA receptor antagonist perampanel as a treatment for patients with partial-onset seizures that offers a completely different mechanistic approach to other antiepileptic drugs, with the European application already under review. Eisai also plans to conduct further studies for perampanel in primary tonic-clonic seizures, monotherapy in 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. By offering multiple treatment options as part of its abundant epilepsy franchise product portfolio, Eisai will make further contributions to address the diversified needs of and increase the benefits provided to epilepsy patients and their families.