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Eisai Co., Ltd.

U.S. FDA ACCEPTS RESUBMISSION OF AMPA RECEPTOR ANTAGONIST PERAMPANEL (E2007) NEW DRUG APPLICATION

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has accepted for review Eisai's resubmission of the New Drug Application (NDA) for perampanel (E2007), an investigational AMPA receptor antagonist, for the treatment of partial-onset seizures associated with epilepsy. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target date of October 22, 2012.

Acceptance of the NDA indicates that the FDA has found the company's resubmission to be sufficiently complete to review. Eisai originally submitted the perampanel NDA to the FDA in May 2011, however, resubmitted it in December 2011 after reformatting and reanalyzing some datasets in the dossier as requested by the FDA in a Refuse to File letter issued in July 2011.

Perampanel is a novel chemical entity discovered and being developed by Eisai. If approved, the agent will be the first in a new class of highly selective, non-competitive AMPA-type glutamate receptor antagonists. Eisai defines epilepsy as a therapeutic area of focus, and seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families by offering them multiple treatment options.

[Please refer to the following notes for further information on epilepsy, AMPA receptor antagonists, perampanel, and Eisai's Commitment to Epilepsy]

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[Notes to editors]

1. About Epilepsy

Epilepsy is a medical condition that produces seizures that affect a variety of mental and physical functions. A patient is considered to have epilepsy after two or more unprovoked seizures, which occur when a brief, strong surge of electrical activity affects part or all of the brain. An individual may experience 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. It has been reported that epilepsy affects nearly 1 million people in Japan, 2.4 million people in Europe, 3 million people in the United States, and more than 50 million people worldwide.

2. Epilepsy and AMPA Receptor Antagonists

Research suggests that the underlying mechanisms of epilepsy involve the overexcitement of neurons caused by the excitatory neurotransmitter glutamate. The excessive influx of calcium ions into the neurons that occurs as a result of this overexcitement is believed to lead to the abnormal activation of various enzymes and impediment of neural function. Accordingly, the blockade of glutamate receptors can be thought of as a potential therapeutic approach to treat neural dysfunction associated with epilepsy.

Glutamate receptors are classified into three subtypes: AMPA (α-amino-3-hydroxy-5-methyl-4-isoxazole propionate) receptors, NMDA (N-methyl-D-aspartate) receptors, and kainate receptors. Widely present in almost all excitatory neurons, AMPA receptors transmit signals stimulated by glutamate within the brain and are believed to play a role in central nervous system diseases characterized by excess neuroexcitatory signaling including epilepsy, neurodegenerative disorders, movement disorders and pain. At present there are no anti-epileptic drugs approved with a new mechanism that selectively blocks AMPA receptors.

3. About AMPA Receptor Antagonist Perampanel (E2007)

Discovered and being developed by Eisai, perampanel is a novel highly selective, non-competitive AMPA-type glutamate receptor antagonist that has demonstrated broad-spectrum anti-seizure effects in Phase II and III studies conducted in patients with partial onset seizures associated with epilepsy. If approved, perampanel will be the first in a new class of anti-epileptic drugs known as AMPA receptor antagonists.

A Marketing Authorization Application (MAA) seeking approval of perampanel as a novel treatment for partial-onset seizures in patients with epilepsy is currently under regulatory review in the European Union (EU). The agent is also being evaluated for the same indication in Phase III studies being conducted in Japan and for generalized epilepsy in global Phase III studies. Eisai also plans to conduct further studies to investigate the potential of perampanel as monotherapy for partial onset seizures and other forms of epilepsy such as Lennox Gastaut syndrome as it seeks to expand the range of approved indications for which the agent is approved.

4. Eisai's Commitment to Epilepsy

Eisai defines epilepsy as a therapeutic area of focus, currently marketing 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. The Group also markets Inovelon®/BANZEL® (under license from the originator Novartis AG; sodium channel-blocking novel triazole derived antiepileptic agent; marketed in Europe (Inovelon®), Asia (Inovelon®), and North America (BANZEL®) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy, and the anticonvulsant agent Fostoin® (Co-promotion partner: Nobelpharma Co., Ltd.; water-soluble prodrug of phenytoin; marketed in Japan) for use in the treatment of conditions such as status epilepticus.

By offering multiple treatment options as part of its abundant epilepsy product portfolio, Eisai will continue to make further contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.