No.11-81

December 26, 2011
Eisai Co., Ltd.

EISAI RESUBMITS AMPA RECEPTOR ANTAGONIST PERAMPANEL (E2007) NDA TO U.S. FDA

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it resubmitted the New Drug Application (NDA) for the investigational AMPA receptor antagonist perampanel for partial-onset seizures associated with epilepsy to the U.S. Food and Drug Administration (FDA) on December 22, 2011 (U.S. eastern standard time). This resubmission comes after the FDA issued a Refusal to File letter in July 2011 in which FDA requested reformatting and reanalyses of some datasets in the dossier. The application was originally submitted in May 2011.

FDA will determine acceptance of filing within 60 days of submission.

Perampanel is a novel chemical entity discovered and being developed by Eisai. If approved, perampanel 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 providing them with 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 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, 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. AMPA receptors, widely present in almost all excitatory neurons, 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, pain and psychiatric disorders. 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)

Perampanel is a novel chemical entity discovered and being developed by Eisai for the potential treatment of partial seizures in patients with epilepsy. Perampanel is a highly selective, non-competitive AMPA -type glutamate receptor antagonist that has demonstrated broad-spectrum anti-seizure effects in Phase II and III studies. If approved, perampanel will be the first product in this class of anti-epileptic drugs.

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, and Inovelon®/BANZEL® (under license from the originator Novartis AG; sodium channel-blocking novel triazole derived antiepileptic agent; marketed in Europe (Inovelon®), Asia (BANZEL®), and the North America (BANZEL®) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy.

A Marketing Authorization Application (MAA) seeking approval of the AMPA receptor antagonist 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 II studies being conducted in Japan as well as in global phase III studies for generalized epilepsy. Eisai also plans to conduct further studies to investigate the potential of perampanel as a monotherapy in partial-onset seizures and for the treatment of other forms of epilepsy such as Lennox-Gastaut syndrome. By offering multiple treatment options as part of its abundant product lineup, Eisai will continue to make contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.