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Eisai Co., Ltd.

EUROPEAN MEDICINES AGENCY ACCEPTS FOR REVIEW EISAI'S MAA FOR AMPA RECEPTOR ANTAGONIST PERAMPANEL (E2007)

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 Marketing Authorization Application (MAA) for the AMPA receptor antagonist perampanel (E2007) for the treatment of partial-onset seizures associated with epilepsy.

Acceptance of the MAA indicates that the EMA has found Eisai's submission to be sufficiently complete to review. The MAA was submitted to the EMA on May 25, 2011. A New Drug Application (NDA) has also been simultaneously submitted in the United States.

Perampanel (E2007), a novel chemical entity discovered and being developed by Eisai, is a highly selective, non-competitive AMPA-type glutamate receptor antagonist. If approved, perampanel will be the first product in this class of anti-epileptic drugs to help control seizures. Epilepsy affects 2.4 million people in Europe, nearly 3 million people in the United States, and an estimated 40 to 50 million people worldwide. Although there are many anti-epileptic drugs available, about a third of patients still continue to experience seizures[1)]. Epilepsy constitutes an area of high unmet medical need and Eisai has developed perampanel in epilepsy with the objective of offering a completely different mechanistic approach to previous molecules.

The submission is based on data from three global Phase III pivotal studies: Studies 306, 305 and 304, in which a total of 1,480 patients participated. The key goal of Study 306 was to identify the minimal effective dose and included 4 treatment arms (placebo, 2mg, 4mg, and 8mg). Studies 304 and 305 included 3 arms (placebo, 8mg, and 12mg) and evaluated 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: standard median percent seizure reduction and 50 percent responder rate. The most commonly reported adverse events (incidence greater than or equal to 10 percent) in all three studies were: dizziness, somnolence and headache. Each of the studies showed consistent results in the efficacy and tolerability of perampanel given as therapy in patients with refractory partial seizures.

Eisai has determined neurology as a therapeutic area of focus and seeks to introduce perampanel as a novel treatment alternative for epilepsy in anticipation that it will become the next global mainstay product in this area behind its anti-Alzheimer's agent Aricept®. Further studies are planned for perampanel in primary tonic-clonic seizures, monotherapy in partial-onset seizures and Lennox-Gastaut syndrome, a rare form of epilepsy that affects 1-4% of children with epilepsy. Eisai is committed to making 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,
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. 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 2.4 million people in Europe, 3 million people in the United States, and 40 to 50 million people worldwide.

2. Epilepsy and AMPA Receptor Antagonists

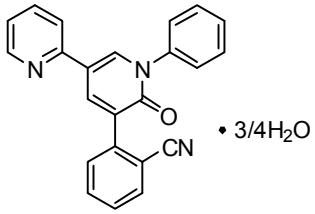
Research suggests that the underlying mechanisms of epilepsy involve the overexcitement of neurons caused by the excitatory neurotransmitter glutamate. The excessive influx of calcium ions into the neurons that occurs as a result of this overexcitement is believed to lead to the abnormal activation of 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.

Structure of perampanel



• $3/4H_2O$

4. Eisai's Commitment to Epilepsy

Eisai defines epilepsy as a therapeutic area of focus, currently marketing 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 adults with partial onset seizures, and Inovelon®/BANZEL® (sodium channel-blocking novel triazole derived antiepileptic agent; Europe, Asia/the United States) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of childhood-onset epilepsy.

Eisai 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 in order to provide benefits in a wider range of epilepsy treatment settings. 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.

Reference

1) Patrick Kwan, M.D., and Martin J. Brodie, M.D. ; Early identification of refractory epilepsy. New England Journal of Medicine 2000; 342: 314-9.