No.11-09

January 25, 2011
Eisai Co., Ltd.

EISAI TO SUBMIT MARKETING AUTHORIZATION APPLICATIONS IN THE U.S. AND EU FOR PERAMPANEL AS ADJUNCTIVE THERAPY FOR REFRACTORY PARTIAL SEIZURES IN PATIENTS WITH EPILEPSY

Submissions Planned for First Quarter of Fiscal 2011

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that it will submit marketing authorization applications in the United States and European Union for the investigational compound perampanel (E2007) based on the results of three Phase III pivotal studies. Perampanel is a first-in-class, highly selective non-competitive AMPA-type glutamate receptor antagonist, discovered and being developed by Eisai for adjunctive treatment of partial seizures in patients with epilepsy.

The clinical development plan for perampanel consisted of three global Phase III studies: Studies 304, 305, and 306, in which a total of 1,490 patients participated. 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, 50% responder rate, percentage reduction of complex partial plus secondarily generalized seizures, and evaluation for dose response. 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 were to evaluate a more extended dose range. Each of the studies showed consistent results in the efficacy and tolerability of perampanel given as an adjunctive therapy in patients with refractory partial seizures. Based upon these study results, Eisai intends to submit regulatory applications simultaneously in the U.S. and EU during the first quarter of our Fiscal Year 2011(year ending March 31, 2012).

The development of perampanel is an example of Eisai's *human health care* corporate mission. Eisai positions integrative neuroscience as a therapeutic area of focus, and is committed to the development of drugs such as perampanel, which the company believes will become the next leading product in the neurology arena behind Aricept®. Through these efforts, Eisai seeks to make further contributions to addressing the diversified needs of and increasing the benefits provided to epilepsy patients and their families.

[Please refer to the following notes for Epilepsy and Perampanel]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[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 3 million people in the United States, 2.4 million people in Europe, and 40 to 50 million people worldwide. Last year, another 200,000 people in the U.S. will be diagnosed with epilepsy.

2. **About Perampanel (E2007)**

Eisai is currently developing perampanel for the potential treatment of partial seizures in patients with epilepsy. Perampanel is a highly selective, non-competitive AMPA (a-amino.e(ilec4NATw[().e10a helTD0.)333 -1.66.EP iletieitil A