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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

Status of the E2007 (perampanel) Development Program - Termination of Parkinson's Disease Clinical Development and Focus on Neuropathic Pain and Epilepsy Indications -

E2007 (perampanel) is a first-in-class, orally administered, highly selective non-competitive AMPA-type glutamate receptor antagonist, in development by Eisai for several indications, including Parkinson's disease, neuropathic pain, epilepsy, multiple sclerosis and migraine prophylaxis.

The AMPA receptor is widely present in almost all excitatory neuronal synapses. It is believed to play a role in a large number of central nervous system (CNS) diseases with different underlying pathophysiology, including neurodegenerative disorders, movement disorders, pain and psychiatric disorders. Eisai has been pursuing development of of which are currentl Phase III. The most advanced indication is Parkinson's disease for v conducting three global Phase III studies (Studies 301, 302 and 309) add-on therapy to levodopa in patients with late-stage disease. Addi preparing for global Phase III studies for epilepsy and conducting tv neuropathic pain.

Following the completion of the first Phase III Study 301, we recently completed the second Phase III Study 302, which was primarily conducted in North America. Study 302 is a 20-week, double-blind, placebo-controlled study comparing two doses of 2mg and 4mg of perampanel to placebo. The results, compared with placebo, did not show a significant difference in the primary endpoint of reduction of "off" time (time when signs and symptoms of Parkinson's disease return as the effect of levodopa wears off). Perampanel was generally well tolerated. After analyzing the data, Eisai has decided to discontinue the Parkinson's disease program and not pursue regulatory submissions for this indication. Eisai will focus resources on two other ongoing indications, epilepsy and neuropathic pain, both of which have different pathophysiology from that of Parkinson's disease and robust scientific rationale.

Following the decision to terminate the Parkinson's disease indication, Eisai has also decided to terminate the third Parkinson's disease Phase III study (Study 309) and open label treatment extension studies. Perampanel was generally well tolerated throughout the program in this mostly elderly population. The decision to terminate the Parkinson's disease program is due to lack of efficacy over placebo seen in the recently completed two Phase III studies only, and is not predictive of activity in the other indications including epilepsy and neuropathic pain.

In preclinical models in Parkinson's disease, perampanel improved the effect of levodopa, and a Phase II study suggested that perampanel improved benefits with increasing doses. Responding to unmet medical need, Eisai pursued development of perampanel in Parkinson's disease as a first-in-class oral AMPA antagonist with a non-dopaminergic mechanism, which is different from that of existing drugs. The reason for the lack of statistical significance in effectiveness observed in the two completed Phase III studies for Parkinson's disease is being investigated carefully, but because the mechanism of perampanel is different from that of dopaminergic drugs such as levodopa and dopamine

Terminology

(1) Dopaminergic Drug
Dopaminergic drugs such as levodopa and dopamine agonists act directly at dopaminergic receptors, or improve the efficacy of dopamine by regulating its mechanism.

(2) Non-dopaminergic Drug
Drugs that show efficacy by a mechanism other than direct effects on the dopamine receptor or dopamine metabolism. They include the current Parkinson's disease treatments such as anti-cholinergic agents, NMDA inhibitors, etc.