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Eisai Co., Ltd.

EISAI PRESENTS NEW RESEARCH ON EPILEPSY PIPELINE, PORTFOLIO AT THE 29TH INTERNATIONAL EPILEPSY CONGRESS

-Looks to Expand Global Epilepsy Product Portfolio-

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that 35 abstracts highlighting the latest results from studies with its pipeline and portfolio products (perampanel: 5 abstracts, Zonegran®: 5 abstracts, Zebinix®: 25 abstracts) were presented at the 29th International Epilepsy Congress which took place in Italy (Rome) between August 28 and September 1, 2011. This research demonstrates Eisai's commitment to the area of epilepsy, underpinning the company's product portfolio strategy for the global market.

Epilepsy constitutes an area with significant unmet medical needs. Having positioned epilepsy as a therapeutic area of focus, Eisai offers multiple treatment options in Europe based on its abundant Epilepsy franchise product portfolio, which includes three currently marketed treatments: Zonegran® (under license from the originator, Dainippon Sumitomo Pharma Co., Ltd.) and Zebinix® (under license from the originator, BIAL-Portela & Ca S.A.), adjunctive therapies for adult patients with partial-onset seizures (including patients with secondary generalization); and Inovelon® (under license from the originator, Novartis AG), an adjunctive therapy for seizures associated with Lennox-Gastaut syndrome. In May of this year, the company also submitted an application, which is now under review by the European Medicines Agency (EMA), seeking approval to market its novel AMPA receptor antagonist perampanel as an adjunctive therapy for epilepsy patients with partial-onset seizures.

Eisai presented the findings from two Phase III studies it conducted with a view to obtaining regulatory approval for perampanel and Zonegran® for the first time at the IEC. Results of a Phase III study (Study 305) for perampanel for partial-onset seizures showed that once-daily perampanel, 8 mg and 12 mg, produced statistically significant reductions in median seizure frequency compared to placebo among epilepsy patients having partial-onset seizures while receiving treatment with one to three other epilepsy drugs. Results of a Phase III study (Study 312) with Zonegran® in pediatric epilepsy patients showed that Zonegran® was highly tolerable and exhibited potent anti-epileptic effects compared to placebo in partial-onset seizure patients on one or two other anti-epileptic drugs. The results of three pivotal studies with Zebinix® in epilepsy patients with partial-onset seizures as well as plans for additional clinical studies with the agent (pediatric patients, monotherapy) were also presented at the IEC.

Eisai is committed to maximizing its product portfolio in the area of epilepsy through both the development of new drugs and the life cycle management which includes indication expansion as it seeks to make 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 Study 305, Study 312, Epilepsy, and Eisai's Commitment to Epilepsy]

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[Notes to editors]

1. About Study 305: Perampanel

Study 305 is one of three Phase III studies in the EXPLORE (EXamining Perampanel Observations from Research Experience) clinical trial program. The study design was consistent among three studies: global multicenter, randomized, double-blind, placebo-controlled, dose escalation, parallel group studies in which 1,480 epilepsy patients participated. Study 305 involved 389 patients in the United States, European Union, Asia, Australia and South Africa who had uncontrolled partial-onset seizures and were taking one to three other epilepsy drugs. Patients were assigned to receive either 8 mg or 12 mg of perampanel or placebo once daily for 19 weeks (6 weeks of titration, 13 weeks of maintenance therapy) in additional to their regular treatment. In the study, responder rates (defined as 50 percent or greater reduction in seizure frequency) were 14.7 percent for placebo, 33.3 percent for 8 mg (p=0.002) and 33.9 percent for 12 mg (p=<0.001). Study results also showed that perampanel 8 mg once-daily reduced median seizure frequency by 30.5 percent (p=0.001) and perampanel 12 mg once-daily reduced median-frequency by 17.6 percent (p=0.0011) versus placebo (9.7 percent) among patients receiving treatment with one to three other epilepsy drugs. The most commonly reported treatment-emergent adverse events (TEAEs) occurring in Study 305 in 10 percent or more of patients included dizziness, fatigue, headache and somnolence. Discontinuations due to TEAEs were 4.4 percent for placebo, 9.3 percent for the 8 mg dose of perampanel, and 19 percent for the 12 mg dose of perampanel.

2. About Study 312: Zonegran® (zonisamide)

Study 312 was a double-blind, randomized, multicenter, placebo-controlled study conducted in the European Union and India to evaluate adjunctive zonisamide in 207 pediatric patients (6-17 years) with partial-onset seizures who were on one or two anti-epileptic drugs. Patients were assigned to receive either placebo or zonisamide for 20 weeks (8 weeks of titration, 12 weeks of maintenance therapy). The percentage of patients who completed the study was comparable between the zonisamide and placebo groups (86.9 percent of patients on zonisamide and 90 percent of patients on placebo). Results showed that the proportion of responders (defined as 50 percent or greater reduction in seizure frequency) after 12 weeks maintenance treatment, the study's primary endpoint, was significantly higher with zonisamide (50.5 percent) versus treatment with placebo (31.0 percent). Safety and tolerability assessments showed that the overall incidence of TEAEs was similar for zonisamide (55.1 percent) versus placebo (50.0 percent). There were low rates of serious TEAEs in the zonisamide and placebo groups (3.7 percent versus 2.0 percent), and TEAEs leading to withdrawal from the study (0.9 percent versus 3.0 percent). TEAEs reported more frequently with zonisamide versus placebo were decreased appetite (6.5 percent versus 4.0 percent), decreased weight (4.7 percent versus 3.0 percent), somnolence (4.7 percent versus 2.0 percent), vomiting (3.7 percent versus 2.0 percent) and diarrhea (3.7 percent versus 1.0 percent).

3. 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 percent to 2 percent of people will develop epilepsy during their lifetime. Epilepsy affects nearly 1 million people in Japan, 2.4 million people in Europe, 3 million people in the United States, and some 40 to 50 million people worldwide. While there is currently no cure for epilepsy, a number of antiepileptic

drugs that help control or eliminate seizures are used in the treatment of the disease. However, some 30 percent of patients are unable to achieve complete seizure control despite taking multiple anti-epileptic drugs.

4. Eisai's Commitment to Epilepsy

Eisai positions epilepsy as a therapeutic area of focus and currently markets 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 adult patients with partial-onset seizures as well as Inovelon®/BANZEL® (sodium-channel blocking triazole derived antiepileptic agent; Europe, Asia/the United States) as an adjunctive therapy for seizures associated with Lennox-Gastaut syndrome, a severe form of childhood-onset epilepsy.

Furthermore, Eisai submitted a marketing authorization application in the European Union (EU) seeking approval of its novel AMPA receptor antagonist perampanel as a treatment for adults with partial-onset seizures that offers a completely different mechanistic approach to other antiepileptic drugs. While this application was accepted for review, a U.S. New Drug Application for perampanel is currently being prepared for resubmission, while the agent in Phase II development in Japan. Eisai is currently conducting Phase III studies for perampanel in patients with generalized epilepsy as part of a global development program, and plans to conduct further studies for 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.

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