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Eisai Co., Ltd.

EMA ACCEPTS EISAI'S LICENSE EXTENSION APPLICATION FOR USE OF ANTIEPILEPTC AGENT ZONEGRAN® IN PEDIATRIC PATIENTS

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the license extension application submitted by its U.K. subsidiary Eisai Europe Ltd. for use of the antiepileptic agent Zonegran® (zonisamide) in the treatment of pediatric patients has been accepted for review by the European Medicines Agency (EMA). The application seeks to extend the currently approved use of adjunctive Zonegran in the treatment of partial seizures (with or without secondary generalization) from adults, to also include pediatric patients aged six years and above.

Zonegran is an antiepileptic drug (AED) originally created by Dainippon Pharmaceutical Co., Ltd. (currently Dainippon Sumitomo Pharma Co., Ltd.), for which Eisai has been pursuing the development of in Europe. The agent was first approved in March 2005 as an adjunctive therapy for the treatment of partial seizures (with or without secondary generalization) in adults with epilepsy, and is currently marketed by Eisai' subsidiaries in Europe. On June 27, 2012, Zonegran was subsequently approved as a monotherapy for partial seizures in adults with newly diagnosed epilepsy.

In a double-blind, randomized, multicenter, placebo-controlled, pivotal Phase III study (Study 312) conducted to evaluate adjunctive zonisamide in 207 pediatric patients (6-17 years) with partial seizures who were on one or two AEDs, results showed that the proportion of responders (defined as 50 percent or greater reduction in seizure frequency) was significantly higher with zonisamide versus treatment with placebo. The overall incidence of treatment emergent adverse events (TEAEs) was similar for zonisamide versus placebo. TEAEs reported more frequently with zonisamide versus placebo were decreased appetite, decreased weight, somnolence, vomiting and diarrhea.

Eisai defines epilepsy as a therapeutic area of focus. In addition to Zonegran, the company also markets two other products in Europe－Zebinix® (under license from the originator BIAL-Portela & Ca S.A.), as an adjunctive therapy in adult patients with partial seizures, and Inovelon® (under license from the originator Novartis GA), for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of childhood-onset epilepsy. In May 2012, Eisai also received a positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) for the use of the novel AMPA-type glutamate receptor antagonist Fycompa® (perampanel) for the adjunctive treatment of partial seizures in patients with epilepsy aged 12 years and older.

By strengthening its development capabilities and offering multiple treatment options as part of its abundant epilepsy franchise product portfolio, Eisai 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 Zonegran Study 312 and Eisai's Commitment to Epilepsy]

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

[Notes to editors]

1. About Zonegran® (zonisamide) Study 312

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 seizures who were on one or two antiepileptic 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).

2. 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 adult epilepsy patients with partial seizures, and Inovelon®/BANZEL® (under license from the originator Novartis AG; sodium channel-blocking novel triazole derived antiepileptic agent; marketed in Europe, Asia (Inovelon), and North America (BANZEL)) for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome, a severe form of early childhood-onset epilepsy. In June 2012, Zonegran was approved in the European Union for the additional indication of monotherapy for the treatment of partial seizures in adults with newly diagnosed epilepsy, and an application to extend the adjunctive use of the agent in the treatment of partial seizures to include pediatric patients was accepted for review. Eisai has also submitted marketing authorization applications to the regulatory authorities in the European Union and the United States seeking approval of the novel AMPA-type glutamate receptor antagonist Fycompa® (perampanel), for the adjunctive treatment of partial seizures in epilepsy patients. In May 2012, the company received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for the use of the agent for the stated indication. By providing multiple treatment options as part of its abundant epilepsy franchise product portfolio, Eisai seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.