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Eisai Co., Ltd.

## **EISAI RECEIVES EMA APPROVAL TO MARKET ZONEGRAN® MONOTHERAPY FOR TREATMENT OF EPILEPSY**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its U.K. subsidiary Eisai Europe Ltd. has received approval from the European Medicines Agency (EMA) to extend the use of the antiepileptic agent Zonegran® (zonisamide) as monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy.

Zonegran is an antiepileptic drug (AED) originally created by Dainippon Pharmaceutical Co., Ltd. (currently Dainippon Sumitomo Pharma Co., Ltd.). In Europe, the agent was developed by Eisai and first approved from EMA 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's subsidiaries in Europe. On June 22, 2012, an application to extend the adjunctive use of Zonegran in the treatment of partial seizures to include pediatric patients aged six years and above was accepted by the EMA for review.

This latest approval is based on clinical data from a double blind, randomized, multicenter study designed to compare once-daily Zonegran with twice-daily controlled release carbamazepine as monotherapy in 583 adults with newly diagnosed partial-onset epilepsy. The study's primary endpoint was the proportion of seizure-free patients at six months. The results of the study showed that Zonegran was effective in suppressing seizures and well tolerated in newly diagnosed epilepsy patients when used as monotherapy. The statistical comparison between Zonegran and carbamazepine met the criterion of non-inferiority as recommended by treatment guidelines set out by the International League Against Epilepsy (ILAE). The most common adverse events reported by participants in the study were headache, decreased appetite, somnolence, dizziness, decreased weight, fatigue, rash and fever.

There are an estimated six million people living with epilepsy in Europe and an estimated 50 million people worldwide. It is reported that more one third of patients newly diagnosed with epilepsy are unable to achieve satisfactory seizure control with existing treatments. 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 Eisai's Commitment to Epilepsy]**

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**[Notes to editors]**

**1. Eisai's Commitment to Epilepsy**

Eisai defines epilepsy as a therapeutic area of focus, currently marketing Zonegran<sup>®</sup> (under license from the originator Daiippon Sumitomo Pharma Co., Ltd.; sodium/calcium channel blocking antiepileptic agent; marketed in Europe, the United States and Asia) and Zebinix<sup>®</sup> (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<sup>®</sup>/BANZEL<sup>®</sup> (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<sup>®</sup> (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.

**Eisai's European Epilepsy Pipeline**

