



**Eisai Co., Ltd.**

4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan

Phone: 03-3817-5120

Fax: 03-3811-3077

*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.*

---

**FOR IMMEDIATE RELEASE**

No. 07-03

January 22, 2007

Eisai Co., Ltd.

***Inovelon*<sup>®</sup> receives Marketing Authorization Approval  
from European Commission**

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that on January 16 (U.K. time) the company's UK subsidiary Eisai Ltd. (Headquarters: London, Managing Director: Paul Hooper) received a marketing authorization approval for the anti-epileptic agent *Inovelon*<sup>®</sup> (rufinamide) indicated as adjunctive therapy in Lennox-Gastaut Syndrome (LGS) from the European Commission (EC).

Eisai Ltd. submitted the marketing authorization application for *Inovelon*<sup>®</sup> in March, 2005 to the European Medicines Agency through the centralized procedure. In November, 2006, the company received a positive opinion by the Committee for Medicinal Products for Human Use, which was ratified by EC at this time.

*Inovelon*<sup>®</sup> is a structurally novel compound that acts as a broad-spectrum anticonvulsant. The data used for approval by EC this time was based on the result from a clinical trial (double-blind, placebo-controlled, randomized, parallel-group trial), which studied the drug's safety and efficacy in adjunctive treatment of LGS, a severe form of epilepsy that develops in early childhood. As a result of the trial, *Inovelon*<sup>®</sup> exhibited significant reduction in seizure frequency compared to the placebo.

Eisai is currently enhancing its neurology franchise which includes *Aricept*<sup>®</sup> (donepezil) for treatment of Alzheimer's disease and anti-epilepsy agent *Zonegran*<sup>®</sup> (zonisamide). With the approval of *Inovelon*<sup>®</sup>, the company expects to make further contributions in fulfilling the needs of patients and improving benefits to patients and their families.

**[Please see the following note for the product information of *Inovelon*<sup>®</sup> approved by EC and the description of LGS]**

Contacts:

Corporate Communications Department  
Eisai Co., Ltd.  
81-3-3817-5036

## <Notes to Editor>

### **About *Inovelon*®**

*Inovelon*® is a structurally novel compound that acts as a broad-spectrum anticonvulsant originally discovered and developed by Novartis Pharma AG. Eisai signed an in-licensing agreement for the global rights of the compound with Novartis in February 2004. In October 2004, the drug is granted for an orphan status by EC for adjunctive treatment of LGS, a severe form of epilepsy that develops in early childhood.

### **Product Information**

- Generic Name: rufinamide
- Dosage : 100 mg tablet, 200 mg tablet, 400 mg tablet
- Approved Indication :  
Adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 4 years and older

### **About Lennox-Gastaut Syndrome (LGS)**

LGS is a severe form of generalized epilepsy that develops in early childhood caused by various brain disorders such as brain hemorrhage, encephalitis, developmental malformations of the brain, or metabolic abnormalities. Tonic seizures, where muscles contract continuously, along with developmental delay and behavioral problems, are the major symptoms associated with LGS. On the other hand, the most characteristic manifestation of LGS is a large variety of seizures, such as atonic seizures (sudden loss of muscle tone and consciousness, causing abrupt falls), and atypical absence (starting spells), and myoclonic (sudden muscle jerks). A surgical treatment may be employed, in case the symptoms are too difficult to manage with pharmacotherapy.

Today, an estimated number of 11,000 people in Western Europe (Austria, Denmark, Finland, France, Germany, Italy, Ireland, Spain, Sweden and UK) is said to be affected by LGS. Complete recovery, including freedom from seizures or normal development, is very unusual. There is a strong need for development of a new pharmaceutical medicine for this disorder.

###