

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.

Inovelon[®] recieves 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*[®] (rufinamide) indicated as adjunctive therapy in Lennox-Gastaut Syndrome (LGS) from the European Commission (EC).

Eisai Ltd. submitted the marketing authorization application for *Inovelon*[®] 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[®] 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*[®] exhibited significant reduction in seizure frequency compared to the placebo.

Eisai is currently enhancing its

benefits to patients and their families.

[Please see the following note for the product information of Inovelon \$ approved by EC and the description of LGS]

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<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