EISAI RECEIVES MANUFACTURING AND MARKETING AUTHORIZATION FOR ANTIEPILEPTIC AGENT INOVELON® IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that it has received manufacturing and marketing authorization in Japan from the Japanese Ministry of Health, Labour and Welfare (MHLW) for antiepileptic agent Inovelon® (rufinamide), approving the drug as an adjunctive therapy to other antiepileptic drugs (AEDs) in the treatment of Lennox-Gastaut syndrome (LGS), a rare disorder.

Rufinamide was designated by the MHLW’s “Study Group on Unapproved Drugs,” the predecessor to the “Study Group on Unapproved and Off-Label Drugs of High Medical Need,” in October 2009 as an unapproved drug for which development support would be provided. Following clinical development studies of rufinamide in Japan, Eisai later submitted a manufacturing and marketing authorization application for the drug to the MHLW in August 2012. Rufinamide has been designated as an orphan drug in Japan since June 2011.

LGS is one of the most severe and intractable forms of childhood-onset epilepsy. Characterized by multiple seizure types, the disorder is extremely difficult to control, with patients normally having to take several different AEDs. LGS also often leads to delayed intellectual development, behavioral disturbances, and frequent falls due to sudden loss of consciousness, and therefore has a significant impact on the of

[Notes to editors]

1. Product Outline

1) Product Name

Inovelon® Tablets 100 mg, Inovelon® Tablets 200 mg

2) Generic Name

Rufinamide

3) Indications and Usage

Inovelon is indicated as an adjunctive therapy to other antiepileptic drugs (AEDs) in the treatment of tonic and atonic seizures associated with

excessive electrical charges thought to cause seizures, so as to prolong their inactive state. Eisai entered into a license agreement with Novartis Pharma AG in February 2004, under which Novartis granted Eisai the exclusive worldwide rights to develop, use, manufacture and market rufinamide for any human therapeutic use excluding bipolar mood disorder, anxiety disorders and ophthalmologic disorders. The agent received approval in the European Union in January 2007 and in the United States in November 2008 as an adjunctive therapy to other AEDs in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS). Rufinamide is currently marketed in these regions under the brand names Inovelon® and Banzel®, respectively, in addition to the Asia region.

4. Clinical Study in Japan

A 12-week double-blind comparative study of rufix