EISAI ANNOUNCES LAUNCH OF ANTIEPILEPTIC AGENT INOVELON® TABLETS 100 mg, 200 mg IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that it will launch antiepileptic agent Inovelon

[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 Lennox-Gastaut syndrome (LGS) when therapy with other AEDs is considered inadequate.

4) Dosage and Administration

Children age four and older:

In children with a body weight of 15.0-30.0 kg, treatment with rufinamide should be initiated over two days at a daily dose of 200 mg/day divided into two doses and administered orally after meals. After the initiation period, the daily dose should be steadily increased by increments of 200 mg or less every other day until a target maintenance dose of 1,000 mg/day has been achieved. The maintenance dose should similarly be divided into two doses and administered orally after meals. Depending on symptoms, the daily dose may be increased or decreased provided that total dosage does not exceed 1,000 mg/day, and that increases are achieved by increments of 200 mg/day or less and no more frequently than every other day. In children with a body weight of 30.1 kg or greater, the recommended dosage and administration is the same as that of adults, as provided below.

Adults:

In adults, treatment with rufinamide should be initiated over two days at a daily dose of 400 mg/day divided into two doses and administered orally after meals. After the initiation period, the daily dose should be steadily increased by increments of 400 mg or less every other day until a target maintenance dose of 1,800 mg/day for patients with a body weight of 30.1-50.0 kg, 2,400 mg/day for patients with a body weight of 50.1-70.0 kg, or 3,200 mg/day for patients with a body mass of 70.1 kg or greater has been achieved. Respective maintenance doses should similarly be divided into two doses and administered orally after meals. Depending on symptoms, the daily dose may be increased or decreased provided that total dosage does not exceed the recommended maintenance dose, and that increases are achieved by increments of 400 mg/day or less and no more frequently than every other day.

5) Listed Price

Inovelon Tablets 100 mg: 79.70 yen per tablet

Inovelon Tablets 200 mg: 130.40 yen per tablet

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commonly treated with antiepileptic drugs (AEDs), patients whose seizures are difficult to manage with pharmacotherapy may have to undergo surgical treatment.

3. About Rufinamide

Rufinamide is a triazole derivative that is structurally unrelated to currently marketed antiepileptic drugs (AEDs). The agent is believed to exert its antiepileptic effects by regulating activity of sodium channels in the brain that carry 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 was approved as an adjunctive

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2013. Perampanel is currently in Phase III clinical development in Japan for partial-onset seizures and Eisai is also conducting Phase III clinical studies as part of a global development program for the drug in the treatment of generalized epilepsy. By offering multiple treatment options as part of an extensive epilepsy product portfolio, Eisai seeks to make further contributions to address the diversified needs of, and increase the benefits provided to, patients with epilepsy and their families.

[Product Photograph]