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Eisai Co., Ltd.

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® Tablets 100 mg and 200 mg (rufinamide) in Japan on May 29 as an adjunctive therapy to other antiepileptic drugs (AEDs) in the treatment of Lennox-Gastaut syndrome (LGS). The agent was designated by the Japanese Ministry of Health, Labour and Welfare (MHLW) as an orphan drug in June 2011; it received Japan manufacturing and marketing authorization on March 25, 2013, and was placed on the country's National Health Insurance (NHI) drug price list on May 24 of the same year.

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 and patients normally have to take several different AEDs. Furthermore, with patients prone to frequent falls due to sudden losses of consciousness caused by the tonic and atonic seizures associated with LGS, and with this form of epilepsy often also leading to delayed intellectual development and behavioral disturbances, the disorder significantly impacts on the quality of life of patients and their families.

Rufinamide is a triazole derivative that is structurally unrelated to currently marketed AEDs. It 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. The agent was designated by the MHLW's "Study Group on Unapproved Drugs," in October 2009 as an unapproved drug for which development support would be provided. Eisai later conducted a clinical study of rufinamide in Japan, the results of which demonstrated a statistically significant reduction in tonic and atonic seizure frequency versus placebo. The most frequently observed adverse reactions were somnolence (20.7%), decreased appetite (17.2%), vomiting (12.1%), and constipation (10.3%).

Eisai acquired the exclusive worldwide rights from Novartis Pharma AG in February 2004 to develop, manufacture and market rufinamide and currently markets the agent in more than 20 countries, including in Europe, the United States and Canada. Eisai defines epilepsy as a therapeutic area of focus and in Japan, in addition to the launch of Inovelon, the company is working to further expand its product lineup through endeavors such as its ongoing development of AMPA antagonist perampanel as a first-in-class treatment for seizures. Eisai will continue to make further contributions to address the diverse needs of, and increase the benefits provided to, patients living with intractable epilepsy and their families.

[Please refer to the following notes for a product outline, further information on Lennox-Gastaut syndrome, rufinamide, the clinical study in Japan, an overseas Phase III study and Eisai's commitment to epilepsy, and a product photograph.]

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[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

6) Packaging

Inovelon Tablets 100 mg: 100 tablets (10 blister packs containing 10 tablets each)

Inovelon Tablets 200 mg: 100 tablets (10 blister packs containing 10 tablets each)

2. About Lennox-Gastaut Syndrome (LGS)

One of the most rare and severe forms of epilepsy, LGS usually develops in preschool-aged children, many of whom have some kind of preexisting organic brain disorder, such as encephalopathy. LGS is not only characterized by frequent seizures and multiple seizure types, it is also accompanied by delayed intellectual development and personality disorders. The majority of patients with LGS experience tonic (muscle stiffening), atonic (sudden loss of muscle tone or drop attacks) and absence (brief loss of consciousness or staring) seizures. Tonic-clonic (grand mal), myoclonic (sudden muscle jerks) and other types of seizures may also occur. Tonic and atonic seizures lead to the sudden falls seen in LGS patients that are known as “drop attacks,” a primary cause of injury. Patients with LGS often wear protective helmets with face guards to protect against head injury from these attacks. Although LGS is most

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 therapy to other AEDs in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in the European Union in January 2007 under the brand name Inovelon® and in the United States in November 2008 under the brand name Banzel®. Rufinamide is currently marketed in more than 20 countries in Europe, the Americas and Asia.

4. Clinical Study in Japan

A 12-week double-blind comparative study of rufinamide versus placebo as an adjunctive therapy to other antiepileptic drugs (AEDs) was conducted in 59 patients with Lennox-Gastaut syndrome (LGS) aged between 4 and 30 years old. The trial took into account other, overseas trials of the drug; during the maintenance period, patients received either placebo or rufinamide at a dose of 1,000 mg, 1,800 mg, 2,400 mg or 3,200 mg daily depending on their weight. Results showed that the patients who were administered rufinamide experienced a significant reduction in tonic and atonic seizure frequency (change in seizure frequency; rufinamide arm: -24.2%; placebo arm: -3.3%; p=0.003) and overall seizure frequency (change in seizure frequency; rufinamide arm: -32.9%; placebo arm: -3.1%; p=<0.001). The most frequently observed adverse reactions in the 58 patients who were administered rufinamide in both the double-blind comparative study and a further, long-term study were somnolence (20.7%), decreased appetite (17.2%), vomiting (12.1%) and constipation (10.3%).

5. Phase III Clinical Study Overseas

A 12-week double-blind comparative study of rufinamide versus placebo as an adjunctive therapy to other antiepileptic drugs (AEDs) was conducted in 138 patients with Lennox-Gastaut syndrome (LGS) aged between 4 and 30 years old. During the maintenance period, patients received either placebo or rufinamide at a dose of 1,000 mg, 1,800 mg, 2,400 mg or 3,200 mg daily depending on their weight (target dose of approximately 45 mg/kg per day). Results showed that the patients who were administered rufinamide experienced a significant reduction in tonic and atonic seizure frequency (change in seizure frequency; rufinamide arm: -42.5%; placebo arm: 1.4%; p=<0.0001) and overall seizure frequency (change in seizure frequency; rufinamide arm: -32.7%; placebo arm: -11.7%; p=0.0015). The most frequently observed adverse reactions were somnolence, decreased appetite and vomiting.

6. Eisai's Commitment to Epilepsy

Eisai defines epilepsy as a therapeutic area of focus. In addition to Lennox-Gastaut syndrome (LGS) treatment Inovelon®/Banzel®, Eisai currently markets Zonegran® (sodium/calcium channel blocking antiepileptic agent marketed in Europe, the United States and Asia under license from the originator, Dainippon Sumitomo Pharma Co., Ltd.) and Zebinix® (voltage-dependent sodium channel-blocking antiepileptic agent marketed in Europe under license from the originator, BIAL-Portela & Ca S.A.) for the treatment of partial-onset seizures, and anticonvulsant agent Fostoin® (water-soluble pro-drug of phenytoin marketed in Japan with co-promotion partner Nobelpharma Co., Ltd.) for use in the treatment of conditions such as status epilepticus.

Eisai also received approval to market Fycompa® (perampanel), an AMPA antagonist discovered and developed in-house, as a first-in-class treatment for partial-onset seizures, in the European Union in July 2012 and in the United States in October 2012, with the drug having already been launched in seven countries across Europe as of May

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]