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Eisai Co., Ltd.

EISAI SATISFIES ALL-CASE STUDY REQUIREMENT FOR ANTIEPILEPTIC AGENT INOVELON®

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has received notification from Japan's Ministry of Health, Labour, and Welfare (MHLW) that the "all-case study" specified post-marketing observational study condition required at the time of approval of antiepileptic agent Inovelon® Tablets 100 mg and 200 mg (rufinamide) as an adjunctive therapy to other antiepileptic drugs (AEDs) for treatment of Lennox-Gastaut syndrome (LGS) has been cleared.

In March 2013, the MHLW approved Inovelon as an adjunctive therapy with other antiepileptic drugs for tonic and atonic seizures associated with LGS showing insufficient response to other antiepileptics, with the following condition: "Because of the very limited number of subjects included in the Japanese clinical trials, the applicant is required to conduct a post-marketing observational study in all patients until data from a certain number of patients is accumulated after its launch in the market, in order to identify the background information of patients treated with the product and collect safety and efficacy data on the product in the early post-marketing period, and thereby take necessary measures to ensure proper use of the product."

Based on the safety data in 702 patients and efficacy data in 495 patients submitted to the MHLW as the results of analyses of this all-case study, the MHLW has concluded that the all-case study was conducted properly and the necessary measures to ensure proper use of the product were sufficient to lift the condition.

Eisai will continually strive to promote the proper use of Inovelon and provide information about the product, thereby making further contributions to increase the benefits to patients and their families.

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[Notes to editors]

1. About Inovelon (rufinamide)

“Inovelon” 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 voltage-gated sodium channels in the brain involved in the overexcitement of neurons that potentially causes 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 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®. The agent is currently approved in more than 50 countries in the world.

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, 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 AEDs, patients whose seizures are difficult to manage with pharmacotherapy may have to undergo surgical treatment.

3. About the results of “all-case study” specified post-marketing observational study

The specified post-marketing observational study is conducted for the purpose of collecting and confirming side effect incidence by symptom, quality, efficacy and safety information in pediatric, geriatric, pregnant patients, patients with renal dysfunction, hepatic dysfunction, patients who use the drug for a long time or those patients with any limitations or conditions in drug use. The manufacturing and distributing company of the drug or the like undertakes the clinical study.

This study on Inovelon was conducted by central registration method to investigate the safety and efficacy of the agent, as well as factors that may affect them, in actual drug use under the approved conditions. The patients registered were all the 728 patients who started administration of the drug for treatment within the period from May 2013 through February 2014 in 189 medical facilities located in Japan. In the 702-safety analytical set, the common adverse drug reactions (ADRs) (incidence 3.00% or higher) were somnolence (18.23%), decreased appetite (9.83%), epilepsy (3.70%), status epilepticus (3.42%), dizziness (3.28%) and vomiting (3.28%). In addition, the common serious ADRs (incidence 1.00% or higher) were status epilepticus (3.42%) and epilepsy (1.28%). With respect to efficacy, a median mean change in tonic/atonic seizure frequency from the initiation of administration with the agent was -33.3% in the data for 495 patients at 6 months after initiation. The safety and efficacy obtained in this study is assessed as having no significant differences compared to the data obtained by the time of approval.