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Singapore: Eisai has submitted a marketing authorization application to Japan's Ministry of Health, Labor and Welfare (MHLW) for rufinamide (generic name), an antiepileptic agent developed by the company in Japan. Eisai is seeking approval to market the agent as an adjunctive therapy in the treatment of a rare disorder known as Lennox-Gastaut syndrome (LGS).

LGS is one of the most severe and intractable forms of childhood-onset epilepsy and is estimated to affect some 3,600 patients in Japan. Characterized by multiple seizure types, the disorder is extremely difficult to control, with patients normally having to take several different antiepileptic drugs (AEDs). The most common seizure types associated with LGS, tonic and atonic seizures, lead to the frequent falls due to sudden loss of consciousness. LGS often causes delayed intellectual development and behavioral disturbances, and therefore has a significant impact on the quality of life of both patients and their families.

In October 2009, 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", as an unapproved drug for which development support would be provided. In clinical studies conducted in Japan to assess efficacy and safety of the agent in LGS patients, rufinamide statistically significantly reduced the frequency of seizures associated with LGS compared to placebo, demonstrating an efficacy and safety profile consistent with overseas phase III studies used to support regulatory submissions filed in the European Union and the US.

Rufinamide received approval in the European Union in January 2007 and in the US in November 2008 as an adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in children four years and older and adults. The agent is currently marketed in these regions under the brand names Inovelon and Banzel, respectively.

Eisai defines epilepsy as a therapeutic area of focus, and is currently working on expanding its Japan epilepsy portfolio through the domestic development of rufinamide in addition to the AMPA receptor antagonist perampanel.