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Scotland approves Eisai's Fycompa

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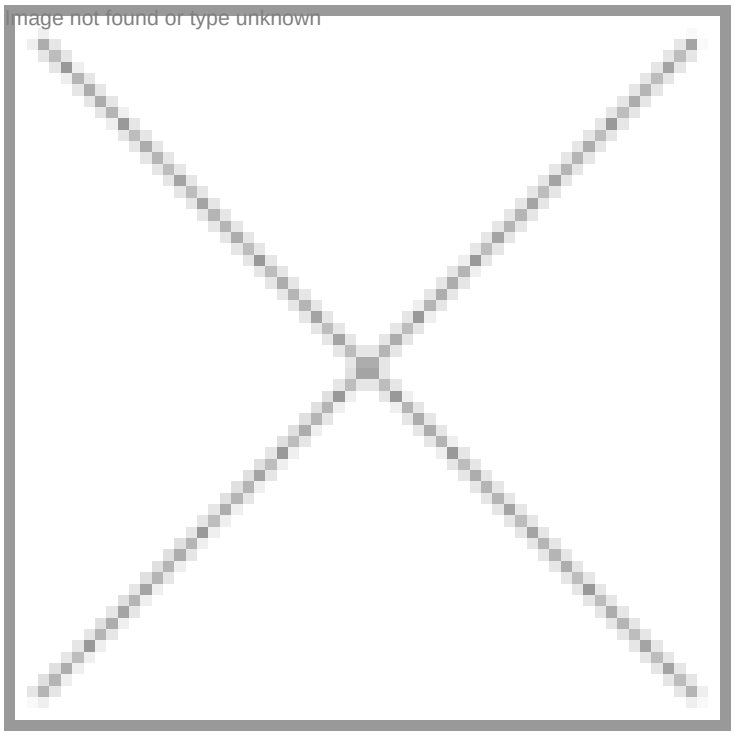

Singapore: Eisai announched that Scotland's health technology assessment (HTA) body, the Scottish Medicines Consortium (SMC), has approved Eisai's AMPA receptor antagonist Fycompa (perampanel) as a second-line adjunctive treatment in patients with refractory partial-onset epilepsy under National Health Service Scotland (NHS Scotland). The SMC approval of perampanel is the drug's first HTA worldwide.

SMC assessed perampanel from an efficacy, safety and health economics perspective based on three submitted placebo-controlled double-blind studies, based on a comparative health economic analysis that took into account overall costs (including drug costs, inpatient visits, A&E services, outpatient and GP visits) compared with existing antiepileptic drugs. SMC evaluated that perampanel was superior to placebo in terms of seizure control. Furthermore, perampanel was evaluated to be a cost-effective treatment taking into account the benefits of a Patient Access Scheme submitted by Eisai.

Approximately 54,000 people in Scotland have epilepsy, making it one of the most common neurological diseases, while an increasing trend in the incidence of epilepsy has also been observed in recent years. Furthermore, with approximately 30% of patients living with partial epilepsy not achieving seizure freedom despite therapy with existing antiepileptic drugs, there is a pressing need for effective new drugs in this field. Through the SMC approval, it is now possible for patients with epilepsy in Scotland to access the benefits of the new mechanism possessed by this drug under NHS Scotland.

Discovered and developed by Eisai, Fycompa is a highly selective, non-competitive AMPA-type glutamate receptor antagonist. Epileptic seizures are primarily mediated by the neurotransmitter glutamate. As an AMPA receptor antagonist, Fycompa reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at post-synaptic AMPA

receptors. Indicated for a wide range of patients, including adults and adolescents over 12 years of age, the agent also has the added benefit of once-daily oral dosing, which is expected to reduce the potential pill burden a patient with epilepsy may experience as well as improve patient drug compliance.

Fycompa was first approved by the European Commission (EC) in July of this year as the first and only antiepileptic drug to target AMPA receptors and is already being launched in various countries across Europe, including the United Kingdom. In the United States, Fycompa was approved by the US Food and Drug Administration (FDA) in October 2012 and is planned for launch once the U.S. Drug Enforcement Administration (DEA) has completed its scheduled investigation under the country's Controlled Substances Act.

Eisai will continue to make further contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.