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CNMPA approves Eisai's antiepileptic drug

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Tokyo headquartered Eisai Co., Ltd. has received a New Drug Approval for its in-house discovered and developed antiepileptic drug (AED) Fycompa® (perampanel) from the China National Medical Products Administration (NMPA) for use in an adjunctive treatment of partial onset seizures (with or without secondarily generalized seizures) in epilepsy patients 12 years of age and older.

Fycompa was designated for Priority Review by the NMPA due to its significant clinical benefits compared to existing treatments, and was approved in about 12 months since the submission in September 2018.

In China, it is estimated that there are approximately 9 million patients with epilepsy, approximately 60% of whom being affected by partial-onset seizures. About 40% patients with partial-onset seizures require adjunctive treatment. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs, this is a disease with significant unmet medical needs.

Fycompa is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories. Administered orally once-daily, it is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes.

Fycompa has been approved in over 60 countries around the world as an adjunctive treatment for partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older. In addition, Fycompa has been approved in over 55 countries as an adjunctive treatment for primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. In the United States, Fycompa is also indicated for monotherapy and adjunctive use in the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older.

Eisai considers neurology including epilepsy, a therapeutic area of focus. With this approval of Fycompa in China, Eisai pursues our mission to provide “seizure freedom” to a greater number of patients with epilepsy across the world living. Eisai seeks to address the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.