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Pediatric indication for partial-onset seizures accepted in China

October 16, 2020 | News

Supplementary new drug applications for anti-epileptic drug Fycompa as monotherapy for partial-onset seizures



Eisai Co., Ltd. on 16 Oct 2020 announced that the supplementary new drug applications for its in-house discovered and developed anti-epileptic drug (AED) Fycompa (generic name: perampanel) as monotherapy for partial-onset seizures and pediatric indication for partial onset seizures in patients with epilepsy 4 years or older have been accepted in China by the National Medical Products Administration.

The submission covering monotherapy for partial-onset seizures was based on subgroup analysis estimating monotherapy safety and efficacy within clinical studies of the combination therapy conducted globally including the United States, Europe and China on patients ages 12 years and older with partial-onset seizures (with or without secondarily generalized seizures). Additionally, results of the Phase III clinical study (FREEDOM) conducted in Japan and South Korea on untreated epilepsy patients ages 12 years to 74 years old with partial-onset seizures (with or without secondarily generalized seizures) were submitted as supplementary safety and efficacy data.

The submission covering partial-onset seizures in pediatric patients was based on the results of a Phase III clinical study of Fycompa as adjunctive therapy conducted globally on pediatric patients (ages 4 to less than 12 years) with inadequately controlled partial-onset seizures or primary generalized tonic-clonic seizures.

Fycompa is a first-in-class AED and a once-daily tablet discovered at Eisai's Tsukuba Research
Laboratories. The agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyper-excitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. Fycompa has been approved in China as an adjunctive treatment for partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older.