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Eisai receives EMA's CHMP approval for Antiepileptic agent Fycompa for pediatric use

September 23, 2020 | News

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Eisai Co., Ltd. on 23 announced that it has received a positive opinion from the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) on the license extension application submitted by its U.K. subsidiary Eisai Ltd. regarding the use of its in-house discovered and developed anti-epileptic agent (AED) Fycompa (generic name: perampanel) in the treatment of pediatric patients. The CHMP's positive opinion is to extend the use of Fycompa as adjunctive therapy for partial-onset seizures (POS) (with or without secondary generalization) by expanding the approved age range from 12 years and above to 4 years and above, and for primary generalized tonic-clonic seizures (PGTCS) from 12 years and above to 7 years and above.

The application, submitted to EMA in February 2019, was based on the results of Phase III (Study 311) and Phase II (Study 232) clinical studies conducted globally to evaluate Fycompa as adjunctive therapy in pediatric patients with POS or PGTCS. Study 311 evaluated the safety, tolerability, and exposure- efficacy relationship of Fycompa when administered as adjunctive therapy in pediatric patients aged 4 to less than 12 years with inadequately controlled POS or PGTCS. Study 232 evaluated the pharmacokinetics, efficacy, and long-term safety of Fycompa as adjunctive therapy in pediatric patients with epilepsy (from 2 to less than 12 years of age).

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 is postulated to reduce neuronal hyper-excitation associated with seizures by targeting glutamate activity at AMPA receptors on postsynaptic membranes. In Japan, Fycompa is currently approved for monotherapy and adjunctive use in the treatment of POS (with or without secondarily generalized seizures) in patients with epilepsy 4 years of age and older, as well as an adjunctive treatment for PGTCS in patients with epilepsy 12 years of age and older. Furthermore, Fycompa is also indicated for monotherapy and adjunctive use in the treatment of POS (with or without secondarily generalized seizures) in patients with epilepsy 4 years of age and older and for adjunctive therapy in the treatment of PGTCS in patients with epilepsy 12 years of age and older in the United States.