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EISAI ANNOUNCES EUROPEAN COMMISSION APPROVAL FOR FYCOMPA® (PERAMPANEL) USE IN CHILDREN WITH EPILEPSY

- Fycompa® (perampanel) is now approved for adjunctive treatment of partial-onset seizures with or without secondary generalised seizures in patients from 4 years of age and older, and primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE), providing a new treatment option for children in Europe[1]
- Epilepsy affects almost a million children in Europe and up to 20% will still experience uncontrolled seizures despite the currently available anti-epileptic treatments[2,3]
- This announcement strengthens Eisai's commitment to improving the lives of people of all ages with epilepsy, allowing them to be themselves and live the lives they want to with confidence.

HATFIELD, England, November 13, 2020 – Today, the European Commission (EC) has approved expanding the indication of anti-epileptic agent Fycompa (perampanel) to include the treatment of children with epilepsy. Perampanel will now be available as an adjunctive therapy for the treatment of partial-onset seizures (POS) with or without secondary generalised seizures in children from 4 years old and primary generalised tonic-clonic seizures (PGTC) in children from 7 years old with idiopathic generalised epilepsy (IGE).[1]

Nearly a million children and adolescents are estimated to have active epilepsy in Europe, with 100,000 new cases diagnosed each year.[2] Despite currently available treatments, up to 20% of paediatric patients have poorly controlled seizures, placing a burden on their quality of life and that of their family and carers.[3]

"Eisai is very pleased to be able to provide a new treatment option for children with epilepsy. We hope it will provide better seizure control for the patients that need it, allowing them, and their families, to live the life they want to with confidence," said Neil West, Vice President EMEA, Global Neurology Business Unit.

The approval was based on the results of two clinical studies, Study 311 (Phase III) and Study 232 (Phase II), conducted globally to evaluate perampanel (oral suspension) as an adjunctive therapy in paediatric patients.[4,5] Study 311 evaluated the safety and tolerability of perampanel when administered as an adjunctive therapy in paediatric patients (age 4 to <12 years) with inadequately controlled partial-onset seizures or generalised tonic-clonic seizures.[4] Study 232 evaluated the pharmacokinetics, efficacy, and long-term safety of adjunctive perampanel in paediatric patients (from 2 to <12 years of age).[5]

"The day to day impact of uncontrolled epilepsy in children can be very difficult for them to understand and manage, affecting all aspects of their lives from a very young age. Providing new treatment options to children must be done with caution, care and diligence, and I am very happy to have taken part in this study to be able to provide this new treatment option to children, and their families, who

are in desperate need of support with their condition," said Professor András Fogarasi, Head of Neurology at Bethesda Children's Hospital, Budapest and Principal Investigator on Study 311.

It is estimated that there are approximately 6 million patients with epilepsy in Europe, and although onset can occur at any age, the annual incidence of new cases is highest for children and adolescents (70 per 100,000).[6,2] Paediatric epilepsy can be particularly challenging for children due to neurocognitive, behavioural, social, and psychiatric difficulties occurring during an important period of learning and development.[7] This not only impacts on patients quality of life but can also add to the emotional burden felt by parents and caregivers.[8]

For Eisai, neurology, including epilepsy, is a therapeutic area of focus and in continued pursuit of our mission to provide "seizure freedom" to a greater number of patients living with epilepsy Eisai seeks to address the diverse needs of, as well as increasing the benefits provided to, patients with epilepsy and their families.

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About Eisai EMEA Neurology

At Eisai EMEA, everything we do is dedicated to giving our first thought to patients and their families through our human health care (*hhc*) philosophy. We are the European hub of Tokyo-based Eisai Co. Ltd., forming part of a multinational workforce working across a global network of R&D facilities, manufacturing sites and marketing subsidiaries.

Our collective passion and dedication to patient care is the driving force behind our efforts to discover and develop innovative medicines in therapeutic areas with a high unmet medical need, such as neurology. We take a holistic approach to support and care, focusing beyond symptom control to try and discover life-changing medicines for patients with neurological disorders.

Our mission is clear; we strive to make a significant long-lasting contribution to society in an ethical, compliant and sustainable way by embodying our *hhc* philosophy in everything we do.

For more information about Eisai in the EMEA region please visit www.eisai.eu.

About Fycompa (perampanel)

Fycompa® is a first-in-class anti-epileptic drug (AED) discovered and developed by Eisai. With epileptic seizures being mediated by the neurotransmitter glutamate, the agent is a highly selective, non-competitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors.

Fycompa is currently approved in more than 75 countries and territories, including Europe, Japan, Asia and the United States as adjunctive treatment for partial-onset seizures (with or without secondary generalised seizures) in patients with epilepsy 12 years of age and older. In addition, the medicine has been approved in more than 45 countries, including Europe, Japan, Asia and the United States, for treatment as an adjunctive therapy for primary generalised tonic-clonic (PGTC with IGE) seizures in patients with epilepsy 12 years of age and older.[9]

To date, Fycompa has been used to treat more than 270,000 patients worldwide across all indications.[10]

Eisai is conducting a global Phase III clinical study (Study 338) for the agent in patients with seizures associated with Lennox-Gastaut syndrome.

About Study 311
Study 311 was a global (United States, Europe, Japan, Asia), multicentre, open-label clinical study that evaluated the pharmacokinetics, safety, tolerability and efficacy of adjunctive Fycompa oral suspension in paediatric patients (aged 4 to <12) with inadequately controlled partial-onset seizures or primarily generalised tonic-clonic seizures.[4] Administration of once-daily Fycompa was titrated from 2mg/day up to a maximum dose of 16mg/day, and long-term safety was confirmed after 23 weeks of treatment.[4] In the 146 patients that completed the Core Study, efficacy was similar to that observed in patients 12 years of age and older.[4] The most common adverse events ((≥10%) observed in Study 311 were somnolence, nasopharyngitis, pyrexia, vomiting, dizziness, influenza, and irritability, which is consistent with the safety profile of Fycompa to date.[4]

About Study 232
Study 232 was a global (United States, Europe), multicentre, open-label clinical study with an extension phase to evaluate 63 paediatric patients with epilepsy (aged 2 to <12).[5] The study evaluated the pharmacokinetics, safety, tolerability and efficacy of Fycompa oral suspension taken at the same time as other AEDs. Administration of once-daily Fycompa was titrated from 0.015 mg/kg to 0.18 mg/kg, and long-term safety was confirmed after 11 weeks of treatment and an extension phase (41 weeks).[5] The adverse events (≥10%) observed in Study 232 were pyrexia, fatigue, vomiting, irritability, somnolence, dizziness and upper respiratory tract infection.[5]

About Epilepsy
It has been reported that epilepsy affects approximately 60 million people worldwide, affecting approximately 6 million people in Europe, 3.4 million people in the United States, 9 million people in China and 1 million people in Japan. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,[11] this is a disease with significant unmet medical need. Epilepsy can also impact many aspects of a person's life beyond their seizures, such as their mental and physical health, their social interactions, and their sleep, this alongside the stigma associated to the disease adds to the burden felt by people with epilepsy and their families.[8]

Epilepsy is broadly categorised by seizure type, with partial-onset seizures accounting for approximately 60% of epilepsy cases and generalised seizures accounting for approximately 40%.[11,12] In a partial-onset seizure, an abnormal electrical disturbance occurs in a limited area of the brain, and may subsequently spread throughout the brain, becoming a generalised seizure (known as a secondarily generalised seizure). In a generalised seizure, abnormal electrical disturbances occur throughout the brain, and can be followed by a loss of consciousness or physical symptoms manifested throughout the whole body.

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