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EMBARGOED UNTIL 00:01 CET February 1st 2016

EISAI AND ESTEVE SIGN NEW AGREEMENT TO CO-PROMOTE ANTI-EPILEPSY DRUG FYCOMPA® (PERAMPANEL) IN SPAIN

Hatfield, UK, February 1st, 2016 – Eisai enter into a new agreement with Esteve, a Spanish pharmaceutical company with a comprehensive neurology franchise, to co-promote Fycompa® (perampanel) in Spain from February 2016. Eisai and Esteve will launch the new indication for the adjunctive treatment of primary generalised tonic-clonic (PGTC) seizures in adults and adolescents (≥12 years) with idiopathic generalised epilepsy (IGE) in Spain in early 2016. Perampanel is also indicated in Spain for the adjunctive treatment of partial onset seizures, with or without secondary generalised seizures, in patients with epilepsy aged 12 years and older.¹

“We are pleased to further strengthen our relationship with Esteve under this new agreement to co-promote perampanel. This collaboration will ensure that we maximise access to our products for people with epilepsy [per indication] in Spain,” comments Gary Hendler, President and CEO, Eisai EMEA.

“The new collaboration with Eisai under the agreement to co-promote perampanel in Spain will further consolidate our presence in neurology, one of our priority areas, and allow us to continue our efforts to bring epilepsy treatments to patients who need them,” says Joe Sullivan, Managing Director of Esteve Farma

Epilepsy is a common neurological condition that causes recurrent seizures in the brain.² It is usually diagnosed in children and people over 65 years of age, although it can affect anyone.² Currently, up to 22,000 people are diagnosed with epilepsy each year in Spain, of whom around one third have seizures that are not completely controlled by their anti-epileptic therapy.³

The new agreement with Esteve in Spain demonstrates Eisai’s commitment in the therapeutic area of epilepsy and further exemplifies the company’s contribution to addressing the diversified needs of and increasing the benefits provided to patients and their families as shown by its human health care mission.

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Notes to Editors

About Fycompa® (perampanel)

Perampanel is a highly selective, non-competitive AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid)-type glutamate receptor antagonist. AMPA receptors, widely present in almost all excitatory neurons, transmit signals stimulated by the excitatory neurotransmitter glutamate within the brain and are believed to play a role in central nervous system diseases characterised by excess neuroexcitatory signalling including epilepsy.

Perampanel is indicated for the adjunctive treatment for partial onset seizures, with or without secondarily generalised seizures, in patients with epilepsy aged 12 years and older and for adjunctive treatment of primary generalised tonic-clonic seizures, in patients with idiopathic generalised epilepsy.

About Epilepsy

Epilepsy is one of the most common neurological conditions in the world, affecting approximately 6 million people in Europe, and an estimated 50 million people worldwide.⁴ It is a collection of syndromes that have many possible causes but often the cause is unknown. Epilepsy is a chronic disorder of the brain that affects people of all ages. It is characterised by abnormal discharges of neuronal activity causing seizures. Seizures can vary in severity, from brief lapses of attention or jerking of muscles, to severe and prolonged convulsions. Depending on the seizure type, seizures may be limited to one part of the body, or may involve the whole body. Seizures can also vary in frequency from less than one per year, to several per day.

For the majority of idiopathic generalised epilepsy patients, a primary generalised tonic-clonic (PGTC) seizure begins with or without an aura, which is followed by rigid muscle. This leads to violent muscle contraction (clonic phase) and a loss of consciousness. As this is a serious event, it is seen as a major hindrance on daily life. While the seizure generally only lasts a few minutes, the patient will often feel confused or drowsy for a short period of time before returning to normal.^{5,6} PGTC seizures can also result in risk of injury and sudden unexplained death in epilepsy (SUDEP).⁷

About Eisai EMEA in Epilepsy

Eisai is committed to developing and delivering highly beneficial new treatments to help improve the lives of people with epilepsy. The development of AEDs is a major strategic area for Eisai in Europe, the Middle East, Africa, Russia and Oceania (EMEA).

In the EMEA region, Eisai currently has four marketed treatments including:

- Fycompa® (perampanel) Perampanel is indicated for use as a once-daily, adjunctive therapy for both primary generalised tonic-clonic seizures with idiopathic generalised epilepsy and for adjunctive treatment of partial onset seizures, with or without secondary generalised seizures, in patients with epilepsy aged 12 years or older
- Inovelon® (rufinamide) for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in patients >4 years. (Rufinamide was originally developed by Novartis)
- Zonegran® (zonisamide) as monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy and as adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adults, adolescents and children aged six years and above. (Zonegran is under license from the originator Dainippon Sumitomo Pharma)
- Zebinix® (eslicarbazepine acetate) as adjunctive therapy in adult patients with partial onset seizures, with or without secondary generalisation (Zebinix is under license from BIAL)

About Eisai Co., Ltd.

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *human health care (hhc)* philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realise our *hhc* philosophy by delivering innovative products in multiple therapeutic areas with high-unmet medical needs, including Oncology and Neurology.

As a global pharmaceutical company, our mission extends to patients around the world through our investment and participation in partnership-based initiatives to improve access to medicines in developing and emerging countries.

For more information about Eisai Co., Ltd., please visit <http://www.eisai.com>

About Esteve

Esteve is a leading pharmaceutical chemical group based in Barcelona, Spain. Since it was founded in 1929, Esteve has been firmly committed to excellence in healthcare, dedicating efforts to innovative R&D of new medicines for unmet medical needs and focusing on high science and evidence-based research. ESTEVE has a strong partnership approach to drug discovery, development and commercialisation. The company works both

independently and in collaboration to bring new, differentiated best-in-class treatments to patients who need them. The company currently has a team of about 2300 professionals, and has subsidiaries and production facilities in several European countries, USA, China and Mexico.

For further information, please visit www.esteve.com

References

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- ¹ Fycompa, Summary of Product Characteristics. Available at: <http://www.medicines.org.uk/emc/medicine/26951> (Accessed January 2016)
 - ² Epilepsy Research UK. What is Epilepsy? Factsheet. Available from URL: http://epilepsyresearch.org.uk/wp-content/uploads/2012/03/1_what_is_epilepsy.pdf (Last accessed November 2015)
 - ³ García-Ramos R, et al. *Neurología*. 2011; 26:548–55.
[http://www.elsevier.es/sites/default/files/elsevier/eop/S2173-5808\(11\)00042-3.pdf](http://www.elsevier.es/sites/default/files/elsevier/eop/S2173-5808(11)00042-3.pdf) (Last accessed November 2015)
 - ⁴ Pugliatti M *et al.* Estimating the cost of epilepsy in Europe: A review with economic modeling. *Epilepsia* 2007; 48(12) 2224 - 2233
 - ⁵ Epilepsy Foundation. Types of seizures. Available at: <http://www.epilepsy.com/learn/types-seizures>. (Accessed November 2015)
 - ⁶ Epilepsy Foundation. IGE Summary. Available at: <http://www.epilepsy.com/information/professionals/about-epilepsy-seizures/idiopathic-generalized-epilepsies>. (Accessed November 2015)
 - ⁷ Smithson WH et al, *Curr Neurol Neurosci Rep* 2014 Dec; 14(12):502