Eisai is pleased to announce that perampanel has been approved in South Africa for the adjunctive treatment of partial-onset seizures, with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. Perampanel is the first anti-epileptic drug to be approved in South Africa in recent years.

Perampanel is the only licensed anti-epileptic drug to selectively and non-competitively target AMPA* receptors. These receptors play a critical role in the onset and spread of seizures.

Epilepsy affects one in every 100 people in South Africa, which amounts to an estimated half a million people living with the condition in the country. In addition, 20-40 per cent of people with newly-diagnosed epilepsy can become refractory to currently available treatments, which require further adjunctive medication.

Dr Dave Anderson, Specialist Adult Neurologist, Wits Donald Gordon Medical Centre, said:

“Many epileptic patients have poorly controlled seizures despite the plethora of treatments available. It is exciting to see the approval of a new treatment such as perampanel in South Africa. It will be a welcome addition to the clinician's arsenal of treatments and patients could benefit from its unique mode of action.”

The approval of perampanel is based on three pivotal Phase III studies (304, 305 and 306) and an open extension study 307, which show consistent results in the efficacy and tolerability of perampanel as an adjunctive therapy in patients with partial-onset seizures, with or without secondary generalisation. The most commonly reported adverse events were dizziness, somnolence, fatigue, headache, falls, irritability and ataxia.

To ensure access of perampanel to patients with epilepsy in South Africa, Eisai is collaborating with its regional partner Clinigen.

Johann Willemse, Chief Commercial Officer, Rest of World, Clinigen, said:

“Perampanel is the second product we are working on together with Eisai in South Africa. We have forged a strong partnership, based on Eisai’s innovative products and our ability to leverage our extensive distribution network in the region and local expertise. Together, we can enable access to perampanel where it is needed most.”
Neil West, Vice President Global Neurology Business Group, Eisai, said:

“Eisai is committed to the therapeutic area of neurology and to addressing the unmet medical needs of people with neurological conditions and their families. Ensuring patient access to new treatments underlines Eisai’s human health care mission, the company’s commitment to innovative solutions in disease prevention, cure and care for the health and wellbeing of people worldwide.”

*AMPA = alpha-amino-3-hydroxy-5-methyl-4-isoxazole-propionate

- Ends -

Notes to Editors

About Fycompa® (perampanel)
Perampanel is a first-in-class, non-competitive AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) glutamate receptor antagonist on post-synaptic neurons. 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 signaling, including epilepsy. Since launch, approximately 52,000 people living with epilepsy have been treated with perampanel.

About Epilepsy
Epilepsy is one of the most common neurological conditions in the world, affecting an estimated 50 million people worldwide. Epilepsy is a chronic disorder of the brain that affects people of all ages. It is characterised by abnormal discharges of neuronal activity which causes seizures. Seizures can vary in nature
and 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. Epilepsy has many possible causes but often the cause is unknown.

**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 anti-epileptic drugs is a major strategic area for Eisai in Europe, the Middle East, Africa, Russia and Oceania (EMEA).

**About Clinigen Group**
Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing access to medicines. Its mission is to deliver the right medicine to the right patient at the right time and is focused in three areas of global medicine supply; clinical trial, unlicensed and licensed medicines.

**Clinigen Clinical Trial Services** is the global market leader in the management and supply of commercial medicines for clinical trials.

The Group is also the trusted global leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet need, through three of its divisions: *Idis Managed Access* runs early access programs for innovative new medicines. *Idis Global Access* and *Link Healthcare* work directly with healthcare professionals to enable compliant access to unlicensed medicines on a global basis and niche essential licensed and generic medicines across Australasia, Africa and Asia (AAA region).

**Clinigen Specialty Pharmaceuticals** acquires global rights, revitalises and markets its own portfolio of niche hospital medicines.

For more information, please visit [www.clinigengroup.com](http://www.clinigengroup.com)

**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.

1. Fycompa South Africa MCC Approved Package Insert, dated 17 February 2017