



MEDIA RELEASE

RELEASE EMBARGOED TO 00.01 20 May 2008

**INOVELON® (RUFINAMIDE)
A NEW TREATMENT FOR LENNOX-GASTAUT SYNDROME
REDUCES DROP ATTACKS BY OVER 40%**

*First EMEA licensed treatment specifically for LGS offers
new hope for patients with epilepsy*

Eisai Europe Limited, (Headquarters: London, Chairman and CEO Yutaka Tsuchiya) today announced publication of the results of a major study of its new anti-epileptic agent *Inovelon* (rufinamide) indicated for adjunctive therapy in Lennox-Gastaut Syndrome (LGS)¹, a severe form of generalised epilepsy that develops in early childhood.

In the placebo-controlled study, published in the journal *Neurology*², *Inovelon* was found to produce a median reduction in seizure frequency of 42.5% ($p < 0.0001$) for drop attacks, and reduce the occurrence of total seizures by 32.7% ($p < 0.0015$). Results from the extension study suggested that for subjects continuing on *Inovelon*, seizure reduction appeared to be maintained in the long term (up to two years).³

Lead study author Dr Tracy Glauser, Professor of Pediatrics and Neurology at Cincinnati Children's Hospital, Ohio said "Lennox-Gastaut Syndrome is a devastating form of pediatric epilepsy usually resulting in multiple seizures occurring several times a day, and is often associated with impaired mental development. Existing antiepileptics offer only limited seizure control. Also, there may be difficulties with tolerability.

"Our study showed that as adjunctive therapy, *Inovelon* can reduce the number of drop attacks by over 40% and the occurrence of total seizures by nearly a third. We also found that the effect of *Inovelon* is maintained over the long term," he concluded.

The study authors noted that the ability of *Inovelon* to reduce total and tonic-atonic seizure frequency combined with its good tolerability make it an important addition to the therapeutic options for LGS.

Inovelon is a structurally novel compound and is the first treatment licensed by the European Medicines Agency (EMA) specifically for LGS.

Approximately 11,000 people across Western Europe are currently diagnosed with LGS, and it is hoped that *Inovelon*, used as the first choice adjunctive therapy, will contribute to improved patient and carer quality of life in line with Eisai's commitment to being an *hhc* (human health care) company.

Eisai has several other compounds in development for the treatment of neurological conditions, including epilepsy, in addition to its existing neurology medicines *Aricept*[®] (donepezil, for the treatment of mild to moderate Alzheimer's disease), and *Zonegran*[®] (zonisamide, for the treatment of partial epilepsy and secondarily generalised partial epilepsy.)

ENDS

Notes to editors

About LGS

Symptoms of LGS include a variety of seizure types, with tonic-atonic seizures being the most common. Atonic seizures (rapid loss of muscle tone and consciousness), and tonic seizures (where muscles contract continuously typically producing a stiffening of the legs and arms) lead to the sudden falls seen in LGS patients known as 'drop attacks'. Absence seizures (staring spells) and myoclonic seizures (sudden muscle jerks) are also commonly observed. All children with LGS will experience varying degrees of developmental delay and behavioral problems.

About Eisai Europe Ltd

Established in 1989, Eisai Europe Ltd. is the European pharmaceutical subsidiary of Eisai Co. Ltd., a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world. Through a global network of research facilities, manufacturing sites and marketing subsidiaries, Eisai actively participates in all aspects of the worldwide health care system. Eisai focuses its efforts in two therapeutic areas; integrative neurology and integrative oncology/critical care. Eisai employs more than 9,500 people worldwide.

About *Inovelon*[®]

Inovelon is a structurally novel compound that acts as a broad-spectrum anticonvulsant originally discovered and developed by Novartis Pharma AG. Eisai signed an in-licensing agreement for the compound with Novartis in February 2004. *Inovelon*, a structurally novel compound, is the first treatment licensed by the European Medicines Agency (EMA) specifically for LGS.

Availability

Commercial availability of *Inovelon* across Europe is dependant upon local regulatory requirements and pricing and reimbursement negotiations. *Inovelon* is currently available in the following markets;

Austria
Denmark
Finland
Germany
Iceland
Ireland
Norway
Spain
Sweden
United Kingdom

and will be launched in other European countries in due course.

For further information contact

Andrew Day
Communications Director
Eisai Europe Ltd
+44 (0)208 600 1400
+44 (0)7973 411 419

References

1. *Inovelon* SmPC, April 2008
2. *Neurology* (2008) e-pub 09 April 2008, "Rufinamide for generalized seizures associated with Lennox-Gastaut syndrome". Accessed online at www.neurology.org 14/05/2008
3. Data on file, Eisai Europe Ltd.