



**EISAI AND BIAL ANNOUNCE PARTNERSHIP AGREEMENT FOR  
THE EUROPEAN COMMERCIALISATION OF THE NOVEL  
ONCE DAILY ANTI-EPILEPTIC ZEBINIX<sup>®</sup>**

**EISAI SET TO BECOME AN EMERGING LEADER IN THE TREATMENT OF EPILEPSY**

Eisai Europe Ltd (London; Chairman & CEO Yutaka Tsuchiya), the European subsidiary of Eisai Co., Ltd. (Tokyo, President & CEO: Haruo Naito), and Bial-Portela & CA, S.A., (S. Mamede do Coronado, Portugal, CEO Dr Luis Portela) today announced the signing of a licence and co-promotion agreement in which Eisai receives a sole license to market, promote and distribute the novel once daily anti-epileptic Zebinix<sup>®</sup> (eslicarbazepine acetate), within Europe<sup>1</sup>.

Under the terms of the agreement, Bial will receive €95million consisting of an upfront payment plus milestone payments for further epilepsy approvals within Europe. Bial will maintain ongoing development and production rights and the option to co-promote with Eisai throughout Europe and will supply finished product to Eisai.

Zebinix<sup>®</sup>, subject to approval by the European Medicines Agency (EMA), will initially be indicated for the adjunctive treatment of partial-onset seizures, with or without secondary generalisation, in patients 18 years and older with epilepsy. Zebinix<sup>®</sup> was submitted to the EMA by Bial in March 2008 and approval is anticipated in Q2 2009.

The safety and efficacy of Zebinix<sup>®</sup> has been shown in three phase III double-blind, randomised placebo-controlled trials in 1,049 patients with partial onset seizures. Additionally, these subjects were followed up long term in an open label extension. In these studies, Zebinix<sup>®</sup> demonstrated significant sustained improvements in seizure frequency, reduced depressive symptoms, and significantly improved scores in health related quality of life.

"It is as important to consider the implications on the quality of a patient's day-to-day life, as well as effective seizure control, when making the therapeutic evaluation of a new anti epileptic agent," said Professor E. Ben-Menachem, University of Gothenburg, Sweden. "In addition to sustained reductions in seizure frequency, Zebinix<sup>®</sup> also demonstrated a significant improvement in patient quality of life and reduction in depressive symptoms."

<sup>1</sup> see Notes to Editors

Yutaka Tsuchiya, Chairman & CEO of Eisai Europe said “We are delighted to be working with Bial to bring to patients such a potentially promising new treatment for epilepsy. Zebinix<sup>®</sup> joins our existing successful portfolio of anti-epileptics, which includes Zonegran<sup>®</sup> (zonisamide) and Inovelon<sup>®</sup> (rufinamide). This helps us to fulfil our Corporate mission of ‘human health care’ (*hhc*), to provide innovative, high quality medicines to meet the ever changing unmet medical needs of the health care profession as well as patients and their families.”

Commenting on the deal, CEO of Bial, Dr Luis Portela, said “this partnership with Eisai is a landmark event for Bial in Europe. Zebinix<sup>®</sup> represents the first results of our R & D efforts in the CNS area. It is the result of many years of hard work and dedication and we believe Eisai is the right partner for Bial in Europe, an emerging leader in the field of epilepsy with the know-how and experience to make Zebinix<sup>®</sup> a leading choice for patients suffering with Epilepsy.”

## ENDS

**For further information please contact**

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### Notes to Editors

**1. Zebinix<sup>®</sup>** is the EU trade name for eslicarbazepine acetate.

#### **2. European Territories**

Austria, Belgium, Bulgaria, Czech Republic, Belarus, Bosnia, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Monaco, Netherlands, Norway, Poland, Romania, Russia, Serbia, Slovakia, Slovenia, Spain (co promotion with Bial from launch) Sweden, Switzerland, Turkey, Ukraine and United Kingdom.

#### **3. About epilepsy**

Epilepsy is a chronic neurological disease characterised by abnormal discharges of neuronal activity causing seizures. Clinically, these manifest as convulsions or jerking of muscles. Depending on the seizure type, seizures may be limited to one part of the body, or may be generalised to involve the whole body. Patients may also experience abnormal sensations, altered behaviour or altered consciousness. Epilepsy is a disorder with many possible causes. Often the cause of epilepsy is unknown. However, anything that disturbs the normal pattern of neuron activity - from illness to brain damage to abnormal brain development, can lead to seizures.

#### **4. About Zebinix**

Zebinix<sup>®</sup> (eslicarbazepine acetate), is a novel voltage gated sodium channel blocker. It specifically targets the inactivated state of the ion channel, preventing its return to the active state, and thereby reduces repetitive neuronal firing. The efficacy of Zebinix<sup>®</sup> has been demonstrated in 3 randomized, placebo controlled studies in 1049

patients with refractory partial onset seizures. Zebinix<sup>®</sup> also significantly improved patient's health related quality of life (HRQoL) as measured by the QOLIE-31 score during a one year open label extension of the above 3 studies. Zebinix<sup>®</sup> is given orally once daily. Zebinix<sup>®</sup> can be used as an add-on to carbamazepine (one of the most commonly utilized therapies for partial onset seizures) or with other anti-epileptics.

## 5. About Eisai

Eisai is one of the worlds leading R&D-based pharmaceutical companies, that has defined its corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call *human health care (hhc)*.

Eisai concentrates its R&D activities in three key areas

- **Integrative Neuroscience:** Alzheimer's disease, multiple sclerosis, neuropathic pain, epilepsy, depression, etc
- **Integrative Oncology: Anticancer therapies;** tumour regression, tumour suppression, antibodies, etc and **Supportive cancer therapies;** pain relief, nausea, etc
- **Vascular/Immunological Reaction:** Acute coronary syndrome, atherothrombotic disease, sepsis, rheumatoid arthritis, psoriasis, Crohn's disease, etc

With operations in the U.S., Asia, Europe and its domestic home market of Japan, we employ more than 10,000 people worldwide, and reported consolidated sales of over £3.53 billion in FY2007, an increase of 8.9% year on year. In Europe, Eisai undertakes sales and marketing operations in over 20 markets, including the United Kingdom, France, Germany, Italy, Spain, Switzerland, Sweden, Ireland, Austria, Denmark, Finland, Norway, Portugal, Iceland, Czech Republic, Hungary, and Slovakia.

For further information please visit our web site; [eisai.co.jp](http://eisai.co.jp)

## 6. About Bial

Founded in 1924, Bial is an international pharmaceutical group with products available in over 30 countries throughout four continents. BIAL is the largest Portuguese pharmaceutical company and is based in S. Mamede do Coronado, Portugal.

It is the partner of choice for many companies, having a strong presence in the Iberian peninsula as well as in over 10 countries in Latin America and in around 20 French or Portuguese speaking African countries.

Bial is strongly committed to therapeutic innovation investing approximately 20% of its turnover in research and development every year. Key research areas for BIAL are the central nervous system, the cardiovascular system and allergology. Bial currently has several other innovative programs under development, which the company expects to bring to the market within the next years, thereby strengthening its position throughout Europe.

Further information about Bial can be found at [www.bial.com](http://www.bial.com)