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*Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.*

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**FOR IMMEDIATE RELEASE**

No. 07-36

August 11, 2007

Eisai Co., Ltd.

**UK High Court Ordered NICE  
To Amend A Guidance for Alzheimer's Disease**

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that the company's UK subsidiary Eisai Limited (Headquarters: London, Managing Director: Paul Hooper) received a favorable ruling on August 10, 2007 (the UK time) from the UK High Court which found the Guidance for the treatment of Alzheimer's disease ("Guidance") issued by the National Institute for Health and Clinical Excellence (NICE) to be discriminatory. Eisai Limited applied for a Judicial Review of the process by which NICE reached its decision to ban anti-dementia medicines, including Eisai's *Aricept*® (generic name: donepezil hydrochloride), for NHS patients with newly diagnosed mild Alzheimer's disease in its Guidance. In today's ruling, the Court ordered NICE to amend the Guidance and also clearly ordered the followings:

1. The Court will declare that the Guidance in its current form is discriminatory and therefore unlawful.
2. For NICE to amend the discriminatory requirements in the Guidance within 28 days
3. For NICE to consult with Eisai and interested parties such as Alzheimer's Society for the amendment of guidance
4. For NICE to pay a part of Eisai's litigation cost

Eisai is committed to contribute to increase the benefit for mild Alzheimer's patients and their families through stable supply of its high-quality pharmaceutical products.

**[Please see the press release issued on August 10<sup>th</sup> as a reference to this release]**

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## Reference

### FOR IMMEDIATE RELEASE

No. 07-35

August 10, 2007

Eisai Co., Ltd.

### UK High Court Ruled NICE Guidance for Alzheimer's Disease Discriminatory

Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito) announced today that the company's UK subsidiary Eisai Limited (Headquarters: London, Managing Director: Paul Hooper) received a favorable ruling on August 10, 2007 (the UK time) from the UK High Court which found the Guidance for the treatment of Alzheimer's disease ("Guidance") issued by the National Institute for Health and Clinical Excellence (NICE) to be discriminatory. Eisai Limited applied for a Judicial Review of the process by which NICE reached its decision to ban anti-dementia medicines, including Eisai's *Aricept*<sup>®</sup> (generic name: donepezil hydrochloride), for NHS patients with newly diagnosed mild Alzheimer's disease in its Guidance. In today's ruling, the Court ordered NICE to produce a draft amendment for Guidance.

In January 2007, Eisai Limited, supported by its co-promotion partner Pfizer Limited (Managing Director: John Young), formally applied for a Judicial Review of the process by which NICE published its Guidance issued in November 2006, on the following grounds:

- **Procedural:** since NICE had repeatedly refused to disclose a fully working version of the cost effectiveness model used to evaluate the health economic value of the anti-dementia medicines, the process leading to NICE's decision breaches the principles of procedural fairness.
- **Irrationality:** some of the assumptions made or conclusions that led NICE's decision are irrational or cannot be supported, as insufficient data provided in the NICE's health economic evaluation for anti-dementia medicines which excludes critical information such as carers' cost.
- **Discrimination:** the use of Mini Mental State Examination (MMSE) scores as a rigid diagnostic tool discriminates against certain patient groups, as the result may not indicate the accurate stage when the exam is conducted with the people who have learning disabilities or whose first language is not English.

In its verdict, the court dismissed the challenges of procedural fairness and irrationality. Eisai Limited is currently reviewing possible further actions including the potential filing for a formal appeal on these two points.

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**[Please see the notes for the terms related to this press release]**

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## **<Notes to Editors>**

### **NICE Guidance for Alzheimer's Disease**

The National Institute for Health and Clinical Excellence (NICE) publishes Guidance for the standard NHS healthcare practice for treating medical conditions based on health economic evaluation of medicines, devices or procedures by the Health Technology Assessment. In producing the Guidance issued in November 2006, NICE evaluated the cost effectiveness of the anti-dementia treatments, including *Aricept*<sup>®</sup> which concluded that the medicines should be prescribed for NHS patients with moderate Alzheimer's disease but not for newly diagnosed mild Alzheimer's disease.

### **Mild Alzheimer's Disease**

There are various types of scales used for diagnosis of Alzheimer's disease stage. The Mini Mental State Examination (MMSE) score used in NICE's evaluation defines the progression stage of the disease on a scale that ranges from 0-30. On the MMSE scale, scores of 30-27 are considered normal while the scores of 26 and below indicates Alzheimer's disease with the scores of 26-21 indicates mild stage, 20-10 moderate, and scores of 10 or less are in severe stage.

### **Judicial Review**

Judicial Review is a legal process that allows the challenge of administrative decisions made by public bodies. To apply for judicial review, applications for permission must be made by claim form, which should be served on the defendant public body. If permission is granted, the court reviews the submitted documents and may conduct a hearing before it delivers a verdict.

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