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Eisai Co., Ltd.

## **MILESTONE RULING FOR ALZHEIMER'S DISEASE PATIENTS ANNOUNCED**

### ***NICE ISSUES NEW DRAFT GUIDANCE***

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that The National Institute for Health and Clinical Excellence (NICE), an special agency of the United Kingdom National Health Service (NHS), announced on October 7 (United Kingdom local time) new draft guidance which represents a significant step towards ensuring patients with Alzheimer's disease in England and Wales can receive treatment for their condition from the early stages of disease.

The new draft NICE guidance recommends that three key Alzheimer's disease medications (acetylcholinesterase inhibitors), including Aricept<sup>®</sup> (generic name: donepezil hydrochloride), should be made available to patients in England and Wales as options for managing mild to moderate disease. This is a significant change to an earlier 2006 NICE ruling which restricted access to patients with moderate disease only.

The provisional decision by NICE is an important milestone for the thousands of mild Alzheimer's disease patients who are currently unable to receive treatment for their condition. Early diagnosis and access to medication is critical to help reduce the impact of this devastating condition on patients, their families, and caregivers.

This announcement is expected to be widely welcomed as it supports the United Kingdom Department of Health's National Dementia Strategy (NDS). The NDS encourages the active management of Alzheimer's disease from its earliest stages to minimize the burden of the condition on patients, their caregivers and society. In addition, the need for greater access to dementia-specific treatments is in line with the recent Alzheimer's Disease International report which calls for governments to make dementia a higher health priority, to help tackle the huge burden of the disease.

Eisai strongly supports NICE's draft guidance recommending the use of Alzheimer's disease treatments such as Aricept<sup>®</sup> in the early stages of disease. While guidance regarding the use of anti-dementia treatments issued by NICE in 2000 recommended their use in patients with both mild and moderate Alzheimer's disease, the institute changed its original guidance in 2006, recommending that anti-dementia medications should be restricted to patients with moderate disease only. After a five year battle, the latest recommendation will once again allow patients to get the treatment they need right from the early stages, when they need it most.

The draft NICE recommendations on Alzheimer's disease treatment will now go into consultation, with final guidance expected in early 2011.

**[Please refer to the following information on the draft NICE guidance and Alzheimer's disease]**

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## **[Notes to editors]**

### **1. Additional information on the draft NICE guidance**

Three acetylcholinesterase (AChE) inhibitors (donepezil, galantamine and rivastigmine) are recommended as options for managing mild to moderate Alzheimer's disease (as per their license indications), under all of the following conditions:

- Only specialists in the care of patients with dementia should initiate treatment.
- Treatment should be continued only when it is considered to be having a worthwhile effect on cognitive, global, functional and behavioral symptoms.
- Patients who continue on the drug should be reviewed at least every six months using cognitive, global, functional and behavioral assessment.
- If prescribing an AChE inhibitor, treatment should normally be started with a drug with the lowest acquisition cost (taking into account required daily dose and the price per dose once shared care has started). However, an alternative AChE inhibitor could be prescribed if it is considered appropriate when taking into account adverse event profile, expectations around adherence, medical comorbidity, possibility of drug interactions and dosing profiles.

### **2. About Alzheimer's disease**

Currently, there are around 820,000 people living with Alzheimer's and other dementias in the United Kingdom, including an estimated 575,000 sufferers in England and 37,000 in Wales. Alzheimer's disease is the most common form of dementia, affecting 62% of dementia patients in the United Kingdom. This irreversible, progressive brain disorder gradually destroys memory, reasoning and thinking skills, and may eventually leave patients unable to carry out even the simplest tasks. Alzheimer's disease has impacts in many ways including physical, mental, nursing, medical and social impacts. Despite its burden, Alzheimer's remains a relatively overlooked disease. Just 2.5% of the government's medical research budget is devoted to dementia; in contrast a quarter is allocated to cancer research.