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Eisai Co., Ltd.

## **FDA ACCEPTS ARICEPT<sup>®</sup> PATCH (DONEPEZIL TRANSDERMAL SYSTEM) NDA FOR REVIEW**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for a new weekly transdermal patch formulation (once-weekly administration formulation) of the company's Alzheimer's disease agent Aricept<sup>®</sup>.

The Aricept<sup>®</sup> transdermal patch was developed in the United States by Teikoku Pharma USA, Inc. (Headquarters: California, President & CEO Masahisa Kitagawa, "Teikoku USA") based on license agreements concluded between Eisai and its parent company Teikoku Seiyaku Co., Ltd. (Headquarters: Kagawa, President & CEO: Shosaku Murayama, "Teikoku Seiyaku") in February 2009. The acceptance of the NDA indicates that the FDA deems the company's submission to be sufficiently complete to review. The NDA was submitted to the FDA for the treatment of mild, moderate and severe stages of Alzheimer's disease by Teikoku USA in June 2010. If approved, the new formulation will be marketed by Eisai's U.S. subsidiary Eisai Inc. and Eisai Inc. will co-promote with Pfizer Inc.

The Aricept<sup>®</sup> transdermal patch formulation employs a unique drug delivery system, making it the world's first weekly transdermal patch (once-weekly administration formulation) for the treatment of Alzheimer's disease. It was developed to provide a potential new treatment option to Alzheimer's disease patients who have trouble swallowing, as well as to reduce the burden on caregivers and family members who administer daily medication to their loved ones.

Eisai has been working proactively to enhance value for Alzheimer's disease patients by adding new indications and formulations of Aricept<sup>®</sup>. In August 2010, the company launched a new higher dose Aricept<sup>®</sup> 23 mg tablet in the United States as an additional dosing option for patients with moderate-to-severe Alzheimer's, adding to its already established line-up comprising Aricept<sup>®</sup> 5 mg and 10 mg tablets and Aricept<sup>®</sup> 5 mg and 10 mg orally disintegrating tablets. In submitting the NDA for the new transdermal patch formulation, Eisai seeks to further enhance the clinical value of Aricept<sup>®</sup>, thereby making further contributions to improving the quality of life (QOL) of patients and families living with Alzheimer's disease.

**[Please see the following notes for further information on Eisai's partnership with  
Teikoku Seiyaku and Teikoku USA]**

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**[Notes to Editors]**

■ **Overview of Eisai's partnership with Teikoku Seiyaku and Teikoku USA**

In February 2010, Eisai Co., Ltd. concluded license and option agreements with Teikoku Seiyaku and Teikoku USA regarding the development and marketing of a patch formulation of donepezil, an overview of which is as follows:

United States:	Development by Teikoku USA, exclusive marketing by Eisai
Japan:	Eisai granted option rights to enter exclusive license agreement for research, development and marketing
Other Territories:	Exclusive development and marketing by Eisai

Eisai also obtained option rights from Teikoku Seiyaku and Teikoku USA to enter into an exclusive license agreement for development and commercialization of the next generation product of the donepezil patch in all countries except Japan.