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## EISAI AMENDS LICENSE AGREEMENT WITH TEIKOKU PHARMA USA FOR ARICEPT<sup>®</sup> TRANSDERMAL PATCH SYSTEM

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the company has amended the section of the license agreement with Teikoku Pharma USA, Inc. (Headquarters: California, President & CEO: Masahisa Kitagawa, "TPU"), the U.S. subsidiary of Japan-based Teikoku Seiyaku Co., Ltd. (Headquarters: Kagawa, President & CEO: Misako Fujioka, "Teikoku Seiyaku"), pertaining to exclusive overseas marketing rights for the once weekly transdermal patch system for Aricept<sup>®</sup> (donepezil hydrochloride) for Alzheimer's disease.

The amendment allows TPU to be solely responsible for making all decisions regarding future development activities for Aricept transdermal patch system. Eisai has the option to obtain exclusive worldwide marketing rights. The license agreement was amended as a result of TPU's decision to withdraw the New Drug Application (NDA) for the approval of the transdermal patch system in the United States.

In June 2010, TPU submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of the patch system in the United States. The FDA issued a Complete Response Letter and after careful evaluation, TPU decided to withdrew the NDA on April 17, 2012 after determining that it would be difficult to respond to all the issues within the designated timeframe.

Eisai and Teikoku Seiyaku will continue to move forward with the development of a once daily Aricept transdermal system for the Japanese market based on the exclusive license agreement between the two companies concerning Japan research, development and marketing rights.

Eisai will draw on its abundant experience with Aricept accumulated thus far and make further contributions to improve the quality of life of patients, families and caregivers living with Alzheimer's disease.

## [Please refer to the following notes for further information on the development of Aricept in Japan]

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Eisai Co., Ltd.

## [Notes to editors]

## Development of Aricept<sup>®</sup> in Japan

Aricept<sup>®</sup>, discovered independently by Eisai, contains the acetylcholinesterase inhibitor donepezil hydrochloride as its active ingredient, and is the only drug approved in Japan for the treatment of all stages of Alzheimer's disease, from mild through severe. As the originator of Aricept, Eisai realizes the realities faced by dementia patients, the number of which is increasing every year in line with the aging of Japan's population, and is now in the process of developing a new dry syrup formulation (under regulatory review), a higher dose 23mg tablet (Phase III) and a once daily transdermal patch (Phase I) of Aricept to complement its existing Japan line up which comprises tablets, orally disintegrating tablets, fine granules and an oral jelly formulation. Eisai is also developing Aricept for the additional indication of Lewy body dementia (Phase III).