

FDA ISSUES COMPLETE RESPONSE LETTER FOR ARICEPT[®] PATCH (DONEPEZIL TRANSDERMAL SYSTEM)

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its partner Teikoku Pharma USA, Inc. (Headquarters: California, President & CEO Masahisa Kitagawa, "Teikoku USA") has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) concerning the New Drug Application (NDA) it submitted for a transdermal patch formulation of Aricept[®] (donepezil hydrochloride).

The FDA issues a Complete Response Letter to indicate the review cycle of an application is complete and there are still requirements to be fulfilled. The requirements of FDA are mainly formulation and usage. Eisai and Teikoku USA will work with FDA to assess the Complete Response Letter and determine next steps.

The Aricept[®] transdermal patch formulation was developed in the United States by Teikoku USA based on license agreements concluded between Eisai and its parent company Teikoku Seiyaku Co., Ltd. (Headquarters: Kagawa, President & CEO: Misako Fujioka) in February 2009. In June 2010, Teikoku USA submitted an NDA to the FDA seeking approval to use Aricept[®] transdermal patch in the treatment of mild, moderate and severe stages of Alzheimer's disease.

Eisai has been working proactively to enhance value for Alzheimer's disease patients by adding new indications and formulations of Aricept[®]. In August 2010, the Company launched a new higher dose Aricept[®] 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[®] 5 mg and 10 mg tablets and Aricept[®] 5 mg and 10 mg orally disintegrating tablets.

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120