**Eisai Co., Ltd.**

**4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan**

**Phone: 03- 3817-5120 Fax: 03- 3811-3077**

*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.*

**FOR IMMEDIATE RELEASE**
No. 09-49
November 25, 2009

Eisai Co., Ltd.

# FDA Accepts for Review Eisai's NDA for Aricept® 23mg Extended Release Tablets in the United States

Eisai Inc. (Headquarters: New Jersey, the United States, Chairman and CEO: Hajime Shimizu), the U.S. subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito), today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application for Aricept® 23 mg (generic name: donepezil hydrochloride) extended release tablets, a treatment for Alzheimer's disease (AD).

This new higher dose formulation of Aricept was developed to provide an additional treatment option for patients with moderate to severe AD, where there continues to be an unmet medical need, with the aim of increasing benefits relative to the currently marketed Aricept® 10 mg immediate release tablet. The NDA is based on a global Phase III study (double blind, comparative study) conducted primarily in the U.S. and Europe, comparing the 23 mg Aricept extended release tablet with the 10 mg Aricept immediate release tablet.

Aricept is an acetylcholinesterase inhibitor developed by Eisai. It increases brain levels of the neurotransmitter acetylcholine by inhibiting its breakdown by acetylcholinesterase to slow the overall progression of symptoms associated with AD. Aricept is currently approved in more than 90 countries around the world for the treatment of mild to moderate AD. It is also approved as a treatment for patients with severe AD in the U.S., Canada, Japan, and some Asian and South/Central American countries, etc.

It is estimated that approximately 5.3 million people in the U.S. have AD. AD is the most common cause of dementia, in which nerve cells in the brain decrease and the brain atrophies, causing a decline in cognitive function and personality change. AD affects not only patients, but also significantly impacts the lives of their families and caregivers as well as society as a whole.

Eisai hopes that the 23 mg Aricept extended release tablet will provide a valuable new treatment option for patients with moderate to severe AD and healthcare professionals. In addition to developing new formulations of Aricept, Eisai is committed to working on new AD treatments, actively conducting disease awareness activities and providing support to patients and their families, to make comprehensive contributions toward addressing the unmet needs and increasing benefits of patients living with AD.

**Contacts:**

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