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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. 09-24
July 2, 2009

Eisai Co., Ltd.

Current Status of the Development Programs of New Indications and Formulations of Aricept® for Enhancing Patient Value

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") is currently focusing on three clinical development programs related to its mainstay product Aricept® (donepezil hydrochloride) to further contribute to patients with Alzheimer's disease. As progress in these programs has been made, Eisai announces the current status of each one as follows:

1. Sustained Release Tablets

Eisai has completed a phase III study of 23 mg donepezil sustained release (SR) in patients with moderate to severe Alzheimer's disease. Donepezil SR is being developed to increase clinical benefits compared with currently marketed 10mg donepezil immediate release, raising the blood level of donepezil while maintaining favourable safety profile.

Based on the preliminary review of the data from this phase III study, Eisai plans to submit a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in August or September of this year.

2. Pediatric Use

Eisai filed a Proposed Pediatric Study Request (PPSR), an application that proposes a rationale and study design for pediatric studies, with the U.S. FDA in February of this year to evaluate the clinical benefits of donepezil in children with attention impairment following cancer treatment. Eisai received a notice from the U.S. FDA that there were insufficient grounds to issue a Written Request to obtain pediatric exclusivity. Eisai plans to complete the ongoing studies to provide important information on this therapeutic approach for an underserved patient population currently with limited treatment options.

3. Transdermal Patch Formulation

Clinical trials of a once-a-week transdermal patch formulation of donepezil, which include a bioequivalence study compared to the currently marketed formulation of donepezil, are currently being conducted by Teikoku Pharma USA, Inc. in the United States. An NDA submission to the U.S. FDA is planned for the middle of fiscal year 2009 with the results of the clinical trials. Eisai is working on this new formulation of donepezil based on agreements with Teikoku Seiyaku Co., Ltd. and its U.S. subsidiary, Teikoku Pharma USA, Inc.

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