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Eisai Co., Ltd.

EISAI ANNOUNCES U.S. FDA APPROVAL FOR NEW HIGHER DOSE ARICEPT® 23 MG TABLET FOR THE TREATMENT OF MODERATE-TO-SEVERE ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that its U.S. subsidiary Eisai Inc. has received approval from the U.S. Food and Drug Administration (FDA) for Aricept® (generic name: donepezil hydrochloride) 23 mg once daily tablet for the treatment of moderate-to-severe Alzheimer's disease (AD). Aricept® 23 mg tablet offers another dosing option for patients with moderate-to-severe AD for whom few treatments are available. Approximately 3.6 million Americans age 65 and older suffer with moderate-to-severe AD.

The approval of Aricept® 23 mg tablet is based on data from a large head-to-head study (Study 326) of 1,467 patients with moderate-to-severe AD, which showed that Aricept® 23 mg tablet demonstrated significant improvement in cognition compared to Aricept® 10 mg tablet. Two co-primary endpoints were examined: the Severe Impairment Battery (SIB), which measures cognition, and the Clinician's Interview-Based Impression of Change Plus Caregiver Input (CIBIC plus), which measures global function. While Aricept® 23 mg tablet, as compared to Aricept® 10 mg tablet, demonstrated a statistically significant improvement in SIB, it did not achieve statistically significant improvement in CIBIC plus. The changes in total score in the SIB (higher scores are better) was 2.6±0.58 in the 23 mg group compared to 0.4±0.66 in the 10 mg group, a difference of 2.2 ($p = 0.0001$), and the overall changes in score for the CIBIC plus (lower scores are better) was 4.23±1.07 in the Aricept® 23 mg tablet group compared to 4.29±1.07 in the 10 mg group, a difference of 0.06 ($p = 0.1789$). The most frequently reported adverse events (5 percent or more) with Aricept® 23 mg tablet were digestive symptoms such as nausea, vomiting, diarrhea and anorexia, which are commonly seen in patients taking acetylcholine esterase inhibitors.

AD is a progressive, neurodegenerative disease that affect

[Notes to editors]

1. About Aricept® Study 326, the pivotal study

The Aricept® 23 mg NDA submitted to the FDA was based on