

No.11-57 July 2

July 29, 2011 Eisai Co., Ltd.

## U.S. FDA PROVIDES RESPONSE TO PERAMPANEL NEW DRUG APPLICATION

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the U.S. Food and Drug Administration (FDA) has issued a Refusal to File letter in response to the company's New Drug Application (NDA) for perampanel (E2007), an investigational drug, for the treatment of partial-onset seizures associated with epilepsy which was submitted in May 2011. Perampanel is a highly selective non-competitive AMPA-type glutamate receptor antagonist, discovered and being developed by Eisai.

Upon preliminary review, the FDA requested reformatting and reanalysis of some datasets in the dossier to assist with a substantive review. Eisai believes that no new non-clinical or clinical studies are required to support this filing. This letter does not comment on the approvability of the drug, and no determination has been made with regard to the efficacy or safety of perampanel as part of the letter.

Eisai will work closely with the FDA to provide the information requested for resubmission of this application as quickly as possible in order to contribute to epilepsy patients and their families.

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