

No. 19-85

November 29, 2019  
Eisai Co., Ltd.

## **INVESTIGATION REPORT BY MINISTRY OF HEALTH, LABOUR AND WELFARE FOR FATAL CASE IN PHASE I CLINICAL STUDY FOR E2082**

As Eisai Co., Ltd. ("Eisai") previously announced on July 30, 2019, a volunteer subject who took part in a Phase I clinical study of E2082 for healthy adults in Japan died after completion of dosing study drug in June 2019. Eisai offers, once again, our deepest sympathies and extends sincere condolences to the family of the subject. All use of E2082 in clinical studies has already been discontinued, and Eisai has confirmed the safety of all other study volunteers.

Eisai reported the case to the Japanese Ministry of Health, Labour and Welfare (MHLW) and has been cooperating with the investigation of this Phase I clinical study of E2082 by the MHLW. Today the MHLW has announced the investigation report.

Eisai takes the results of this investigation very seriously and will strive to continue to enhance safety measures when conducting clinical studies. In particular, in the first clinical study (first-in-human study) for investigational drugs, Eisai will take measures in the preparation process of clinical study protocols, the monitoring of clinical studies, and the confirmation of medical institutions where studies are performed to further ensure the safety of volunteer subjects.

Eisai will continue to strive to conduct all research and development activities for pharmaceuticals with more safety in mind and be guided by high ethical standards.

Media Inquiries:

Public Relations Department,

Eisai Co., Ltd.

+81-(0)3-3817-5120