

No.17-68

November 29, 2017  
Eisai Co., Ltd.

## **RESUBMITTED NDA FOR ANTICANCER AGENT HALAVEN® ACCEPTED IN CHINA**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the China Food and Drug Administration (CFDA) has accepted for review the resubmitted New Drug Application (NDA) for Eisai's anticancer agent eribulin mesylate ("eribulin", product name: Halaven®).

In July 2016, Eisai submitted an NDA for eribulin for use in the treatment of locally advanced or metastatic breast cancer in China. However, in alignment with Chinese regulations, Eisai temporarily withdrew its application in June 2017 in order to submit additional documentation. The application was resubmitted once preparations of additional documentation were completed.

Eisai positions oncology as a key therapeutic area, and is aiming to discovery revolutionary new medicines with the potential to cure cancer. Eisai remains committed to maximizing the clinical value as well as exploring the potential clinical benefits of Halaven as it seeks to contribute further to addressing the diverse needs of, and increasing the benefits provided to, patients with cancer, their families, and healthcare providers in China and around the world.

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