No.20-82

December 4, 2020
Eisai Co., Ltd.

EISAI TO PRESENT ABSTRACTS ON ONCOLOGY PRODUCTS AND PIPELINE AT 43RD ANNUAL SAN ANTONIO BREAST CANCER SYMPOSIUM

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that presentations on a series of abstracts highlighting updates on its in-house discovered lenvatinib mesylate (product name: LENVIMA®, the orally available kinase inhibitor, "lenvatinib"), eribulin mesylate (product name: Halaven®, halichondrin class microtubule dynamics inhibitor, "eribulin"), and H3B-6545 (selective estrogen alpha receptor covalent antagonist), discovered at Eisai's U.S. research subsidiary H3 Biomedicine Inc., will be given at the 43rd San Antonio Breast Cancer Symposium (SABCS2020) Virtual Meeting, from December 8 to 11, 2020, in San Antonio, Texas in the United States.

At this symposium, regarding the combination therapy with lenvatinib and the anti-PD-1 therapy pembrolizumab (product name: KEYTRUDA®) from Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside of the United States and Canada), the results of the triple-negative breast cancer cohort in the basket-type Phase II clinical study (LEAP-005) for 6 types of previously treated, advanced solid tumors (Abstract No: PS12-07) is scheduled to be presented.
The results of analysis evaluating eribulin in the clinical practice in a subgroup of patients with metastatic breast cancer with a poor prognosis, in the United States, (Abstract No: PS13-37) will be published.
In addition, regarding H3B-6545, the results of evaluating tolerability, safety, and efficacy of Phase I/II clinical study for estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer (Abstract No: PD8-06) and others will be presented.

In March 2018, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of lenvatinib.

Eisai positions oncology as a key therapeutic area, and is aiming to discover revolutionary new medicines with the potential to cure cancer. Eisai will continue to create innovation in the development of new drugs based on cutting-edge cancer research, 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.

This release discusses investigational compounds and investigational uses for FDA-approved products. It is not intended to convey conclusions about efficacy and safety. There is no guarantee that any investigational compounds or investigational uses of FDA-approved products will successfully complete clinical development or gain FDA approval.

Major poster presentations at SABCS2020:

Product / Compound Abstract No.	Title / Scheduled Date and Time (local time: Central Standard Time)
Lenvatinib PS12-07	Lenvatinib plus pembrolizumab for previously treated, advanced triple-negative breast cancer: Early results from the multicohort phase 2 LEAP-005 study December 9 (Wed), 8:00 AM
Eribulin PS13-37	Effectiveness of eribulin in poor prognosis subgroups of metastatic breast cancer (mBC) patients (Elderly, African Americans, and patients with liver metastases) in the United States December 9 (Wed), 8:00 AM
H3B-6545 PD8-06	Phase I/II Trial of H3B-6545, a novel selective estrogen receptor covalent antagonist (SERCA), in estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer December 10 (Thu), 2:15-3:30 PM
H3B-6545 PS12-15	Pharmacokinetics of H3B-6545 in Patients with Locally Advanced or Metastatic Estrogen Receptor-Positive HER2 Negative Breast Cancer (ER+ and HER2- BC) December 9 (Wed), 8:00 AM
H3B-6545 PS12-23	Development of H3B-6545, a first-in-class oral selective ER covalent antagonist (SERCA), for the treatment of ERa^{WT} and ERa^{MUT} breast cancer December 9 (Wed), 8:00 AM

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

[Notes to editors]

1. About the Merck & Co., Inc., Kenilworth, N.J., U.S.A. and Eisai Strategic Collaboration

In March 2018, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A., known as MSD outside the United States and Canada, through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of LENVIMA. Under the agreement, the companies will jointly develop, manufacture and commercialize LENVIMA, both as monotherapy and in combination with KEYTRUDA, the anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, N.J., U.S.A.

In addition to ongoing clinical studies evaluating the KEYTRUDA plus LENVIMA combination across several different tumor types, the companies have jointly initiated new clinical studies through the LEAP (LEnvatinib And Pembrolizumab) clinical program and are evaluating the combination in 13 different tumor types (endometrial carcinoma, hepatocellular carcinoma, melanoma, non-small cell lung cancer, renal cell carcinoma, squamous cell carcinoma of the head and neck, urothelial cancer, biliary tract cancer, colorectal cancer, gastric cancer, glioblastoma, ovarian cancer and triple-negative breast cancer) across 19 clinical trials.

2. Eisai's Focus on Cancer

Eisai focuses on the development of anticancer drugs, targeting the tumor microenvironment (with experience and knowledge from existing in-house discovered compounds) and the driver gene mutation and aberrant splicing (leveraging RNA Splicing Platform) as areas (Ricchi) where real patient needs are still unmet, and where Eisai can aim to become a frontrunner in oncology. Eisai aspires to discover innovative new drugs with new targets and mechanisms of action from these Ricchi, with the aim of contributing to the cure of cancers.