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Eisai Co., Ltd.

## **EISAI TO PRESENT ABSTRACTS ON LENVATINIB AT 2021 GASTROINTESTINAL CANCERS 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<sup>®</sup>, the orally available kinase inhibitor, "lenvatinib") will be given at the Gastrointestinal Cancers Symposium Virtual Meeting, from January 15 to 17, 2021.

At this symposium, regarding the lenvatinib monotherapy, the real-world effectiveness among unresectable hepatocellular carcinoma (HCC) patients treated in United States clinical practices (Abstract No: 273), as well as the results of a post hoc analysis of patients with unresectable HCC who progressed to the Child-Pugh B stage in the Phase 3 REFLECT study (Abstract No: 298), will be presented.

In addition, the data to be presented regarding the combination therapy of lenvatinib plus pembrolizumab (product name: KEYTRUDA<sup>®</sup>), the anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the United States and Canada), are results from the biliary tract cancer cohort (Abstract No: 321), the colorectal cancer cohort (Abstract No: 94), and the gastric cancer cohort (Abstract No: 230) of the basket-type Phase 2 LEAP-005 clinical study for 6 types of previously treated advanced solid tumors.

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.

The full list of Eisai presentations are below.

<b>Product / Compound Abstract No.</b>	<b>Title / Scheduled Date and Time (local time: Eastern Standard Time)</b>
Lenvatinib 273	Real-world effectiveness of lenvatinib monotherapy among unresectable hepatocellular carcinoma patients treated in United States clinical practices January 15 (Fri)
Lenvatinib 298	Post hoc analysis in patients (pts) with unresectable hepatocellular carcinoma (uHCC) who progressed to Child-Pugh B (CPB) liver function in the phase 3 REFLECT study of lenvatinib (LEN) January 15 (Fri)
Lenvatinib + pembrolizumab 321	Lenvatinib plus pembrolizumab for patients with previously treated biliary tract cancers in the multicohort phase 2 LEAP-005 study January 15 (Fri)
Lenvatinib + pembrolizumab 94	LEAP-005: A phase 2, multicohort study of lenvatinib plus pembrolizumab in patients with previously treated selected solid tumors: results from the colorectal cancer cohort January 15 (Fri)
Lenvatinib + pembrolizumab 230	LEAP-005: A phase 2 multicohort study of lenvatinib plus pembrolizumab in patients with previously treated selected solid tumors: results from the gastric cancer cohort January 16 (Sat), 4:30 PM-5:15 PM (Accepted in poster highlight session)

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**[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 20 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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., U.S.A.