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Eisai Co., Ltd.

EISAI TO PRESENT ABSTRACTS ON LENVATINIB AT 2022 ASCO 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®, the orally available kinase inhibitor, "lenvatinib") will be given at the 2022 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium (#GI22), taking place in-person in San Francisco, California, and virtually, from January 20 to 22, 2022.

At this symposium, the results of a primary analysis of a prospective clinical study evaluating transcatheter arterial chemoembolization (TACE) therapy in combination strategy with lenvatinib (TACTICS-L) in patients with unresectable hepatocellular carcinoma (uHCC) in Japan (Abstract No: 417), as well as research updates on the Phase IV Study (STELLAR) to evaluate safety and tolerability of lenvatinib in patients with advanced/unresectable hepatocellular carcinoma (Abstract No: TPS485) and results from a clinical study to evaluate the efficacy of lenvatinib for conversion surgery in patients with uHCC (investigator-initiated study in Japan, Abstract No: 458), will be presented.

In addition, trial-in-progress (TiP) posters from the clinical program evaluating the combination therapy of lenvatinib plus pembrolizumab (product name: KEYTRUDA®), the anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the United States and Canada), include the Phase III LEAP-014 Study of the combination plus chemotherapy in patients with esophageal carcinoma squamous cell carcinoma (Abstract No: TPS367), Phase III LEAP-015 Study of the combination plus chemotherapy in patients with advanced/metastatic gastroesophageal adenocarcinoma (Abstract No: TPS369), Phase III Study LEAP-012 of the combination plus TACE in patients with intermediate-stage hepatocellular carcinoma not amenable to curative treatment (Abstract No: TPS494), and Phase II Study of the combination plus belzutifan in patients with advanced solid tumors (Abstract No: TPS669).

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 poster presentations is below.

Compound Abstract No.	Title / Scheduled Date
Lenvatinib 417	Transcatheter arterial chemoembolization therapy in combination strategy with lenvatinib in patients with unresectable hepatocellular carcinoma (TACTICS-L) in Japan: Primary analysis January 21 (Fri)
Lenvatinib TPS485*	A multicenter, observational, phase 4 study (STELLAR) to evaluate the safety and tolerability of lenvatinib (LEN) in patients with advanced or unresectable hepatocellular carcinoma (uHCC) January 21 (Fri)
Lenvatinib 458	Multicenter prospective study to evaluate the efficacy of lenvatinib to achieve conversion surgery for initially unresectable hepatocellular carcinoma : LENS-HCC trial (Investigator-initiated study in Japan) January 22 (Sat)
Lenvatinib + pembrolizumab TPS367*	LEAP-014: an open-label, randomized, phase 3 study of first-line lenvatinib plus pembrolizumab plus chemotherapy in esophageal carcinoma squamous cell carcinoma January 20 (Thu)
Lenvatinib + pembrolizumab TPS369*	LEAP-015: A randomized phase 3 study evaluating the efficacy and safety of first-line pembrolizumab plus lenvatinib plus chemotherapy versus chemotherapy in patients with advanced/metastatic gastroesophageal adenocarcinoma January 20 (Thu)
Lenvatinib + pembrolizumab TPS494*	LEAP-012 Trial in progress: Transarterial chemoembolization with or without lenvatinib plus pembrolizumab for intermediate-stage hepatocellular carcinoma not amenable to curative treatment January 20 (Thu)
Lenvatinib + pembrolizumab TPS669*	MK-6482-016：Phase 2, open-label study of pembrolizumab plus lenvatinib and belzutifan in patients with advanced solid tumors January 20 (Thu)

* The presentation with TPS (Trial in Progress Submission) attached to the abstract number indicates that the study is in the intermediate stage, and the presentation does not report the final study results.

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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 LENVIMA plus KEYTRUDA 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 more than 10 different tumor types across more than 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.