No. 20-54

September 11, 2020
Eisai Co., Ltd.

EISAI TO PRESENT ABSTRACTS ON ONCOLOGY PRODUCTS AND PIPELINE AT ESMO VIRTUAL CONGRESS 2020

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that a series of abstracts will be presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 from September 19 to 21, 2020. The abstracts highlight updates regarding Eisai's in-house discovered LENVIMA® (lenvatinib mesylate, the orally available kinase inhibitor, "lenvatinib"), Halaven® (eribulin mesylate, halichondrin class microtubule dynamics inhibitor, "eribulin") and its liposomal formulation.

There will be two oral presentations regarding the combination therapy of lenvatinib and Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside of the United States and Canada)'s anti-PD-1 antibody, KEYTRUDA® (pembrolizumab). Both of these presentations have been selected as Late-Breaking Abstracts. The interim results of the phase 2 study (LEAP-004) in advanced melanoma which had been treated with an anti-PD-1 or PD-L1 antibody (Abstract No: LBA44), as well as the interim results of the basket-type phase 2 study (LEAP-005) for 6 types (triple-negative breast cancer, ovarian cancer, gastric cancer, colorectal cancer, glioblastoma, and biliary tract cancer) of previously treated, advanced solid tumors (Abstract No: LBA41) will be presented.
There will also be an e-poster presentation (Abstract No: 346P) on the expansion cohort of HER2-negative breast cancer in a phase 1 study evaluating the eribulin liposomal formulation (E7389-LF) which aims to realize the efficient delivery to 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.

Oral Presentations*:

Product / Compound Abstract No.	Abstract title and scheduled presentation date and time (CEST)
Lenvatinib LBA44	Lenvatinib (len) plus Pembrolizumab (pembro) for advanced melanoma that progressed on a PD-1 or PD-L1 inhibitor: initial results of LEAP-004 September 19 (Sat), 16:32-16:44
Lenvatinib LBA41	LEAP-005: Phase 2 study of Lenvatinib plus Pembrolizumab in Patients With Previously Treated Advanced Solid Tumors September 20 (Sun), 14:25-14:37

*Late Breaking Abstracts will be available on demand via ESMO's website on September 19.

E-poster Presentations**:

Product / Compound Anstract No.	Abstract title
Lenvatinib 1313P	Phase 3 LEAP-006 Safety Run-In (Part 1): 1L Pembrolizumab (Pembro) + Chemotherapy (Chemo) With Lenvatinib (Len) for Metastatic NSCLC
Lenvatinib 973TiP	LEAP-010: Phase 3 Study of first-line pembrolizumab with or without lenvatinib in patients (pts) with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC)
Lenvatinib 1016TiP	LEAP-012 Trial in Progress: Pembrolizumab Plus Lenvatinib and Transarterial Chemoembolization (TACE) in Patients With Intermediate-Stage Hepatocellular Carcinoma (HCC) Not Amenable to Curative Treatment
Lenvatinib 710P	Phase 2 trial of lenvatinib (LEN) plus pembrolizumab (PEMBRO) for disease progression after PD-1/PD-L1 Immune Checkpoint Inhibitor (ICI) in metastatic clear cell (mcc) renal cell carcinoma (RCC): results by independent imaging review and subgroup analyses
Lenvatinib 719P	Correlative serum biomarker analyses: lenvatinib (LEN) plus pembrolizumab (PEMBRO) in a phase 1b/2 trial in advanced renal cell carcinoma (RCC)
Lenvatinib 1668TiP	A Multicenter, Open-Label, Randomized Phase 2 Study to Compare the Efficacy and Safety of Lenvatinib in Combination With Ifosfamide and Etoposide Versus Ifosfamide and Etoposide in Children, Adolescents and Young Adults With Relapsed or Refractory Osteosarcoma (OLIE; ITCC-082)
Lenvatinib 1923P	Assessment of the Efficacy and Safety of Lenvatinib for the Treatment of Radioiodine-Refractory Thyroid Cancer in Real-Life Practice in Russia
E7389-LF 346P	Phase 1 study of the liposomal formulation of eribulin (E7389-LF): Results from the HER2-negative breast cancer expansion
E7389-LF 583P	Effect of infusion rate, premedication, and prophylactic peg-filgrastim treatment on the safety of the liposomal formulation of eribulin (E7389-LF): Results from the expansion part of a phase 1 study
Eribulin 316P	Real-world treatment patterns and clinical effectiveness outcomes of eribulin in metastatic breast cancer patients in community oncology centers in the United States

**Abstracts and e-posters will be available on demand via ESMO's website on September 14 and 17 respectively.

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

[Notes to editors]

1. About the Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. 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 Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s anti-PD-1 therapy KEYTRUDA.

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 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 Halaven and Lenvima 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 become a frontrunner in oncology area. Eisai will discover innovative new drugs with new targets and mechanisms of action from these Ricchi, and aims to contribute to curing cancers.