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Eisai Co., Ltd.

EISAI TO PRESENT ABSTRACTS ON ONCOLOGY PRODUCTS AND PIPELINE AT ESMO 2019 CONGRESS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that a series of abstracts will be presented during the European Society for Medical Oncology (ESMO) 2019 Congress taking place in Barcelona, Spain, from September 27 to October 1, 2019. The abstracts highlight updates regarding Eisai's in-house discovered LENVIMA® (lenvatinib mesylate, the orally available kinase inhibitor, "lenvatinib"), and Halaven® (eribulin mesylate, "eribulin", halichondrin class microtubule dynamics inhibitor).

At the ESMO 2019 Congress, there will be an oral presentation of results from the final analysis of the endometrial carcinoma cohort of Study 111/KEYNOTE-146, a Phase Ib/II study evaluating the combination treatment of lenvatinib and Merck & Co., Inc., Kenilworth, NJ., U.S.A.'s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in select solid tumors (Abstract No.: 994O). The combination treatment was the first to be approved in the United States, Australia and Canada under the U.S. Food and Drug Administration's Project Orbis in September 2019.

A total of 11 poster presentations are scheduled, including one on the updated results of the lenvatinib plus pembrolizumab combination treatment in unresectable hepatocellular carcinoma in study 116/KEYNOTE-524, a Phase 1b study (Abstract No.: 747P), and the interim analysis evaluating the combination after disease progression after PD-1/PD-L1 immune checkpoint blockade in renal cell carcinoma (RCC) from 111/KEYNOTE-146 RCC cohort (Abstract No.: 1187PD). In addition, the latest data from a Phase I study for an eribulin liposomal formulation in solid tumors (Abstract No.: 348P) 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.

Oral Presentation:

Product	Abstract title and scheduled presentation date and time (local time)
Lenvatinib Abstract No.: 994O	Lenvatinib and pembrolizumab in advanced endometrial cancer Oral Presentation | September 29 (Sun), 09:30-9:45

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Major Poster Discussions:

Product	Abstract title and scheduled presentation date and time (local time)
Lenvatinib Abstract No.: 1676PD	Phase 1 combination dose-finding/phase 2 expansion cohorts of lenvatinib + etoposide + ifosfamide in patients (pts) aged 2 to ≤25 years with relapsed/refractory (r/r) osteosarcoma Poster Discussion | September 28 (Sat), 15:00-16:00
Lenvatinib Abstract No.: 747P	A phase 1b trial of lenvatinib (LEN) plus pembrolizumab (PEMBRO) in unresectable hepatocellular carcinoma (uHCC): Updated results Poster Display | September 29 (Sun), 12:00-13:00
Lenvatinib Abstract No.: 1063TiP	ENGOT-EN9/LEAP-001: a phase 3, randomized, open-label study of pembrolizumab plus lenvatinib versus chemotherapy for first-line treatment of advanced or recurrent endometrial cancer Poster Display | September 29 (Sun), 12:00-13:00
Lenvatinib Abstract No.: 1187PD	Phase 2 study of lenvatinib plus pembrolizumab for disease progression after PD-1/PD-L1 immune checkpoint blockade in metastatic clear cell renal cell carcinoma (mccRCC); Results of an interim analysis Poster Discussion | September 30 (Mon), 08:45-09:45
Lenvatinib Abstract No.: 1862PD	Impact of lung metastasis on the outcome in the phase 3 SELECT study with lenvatinib (LEN) in patients (pts) with radioiodine refractory differentiated thyroid cancer (RR-DTC) Poster Discussion | September 30 (Mon), 10:30-11:30
Lenvatinib Abstract No.: 1863PD	Prescription and Treatment Patterns of Lenvatinib (L) in Patients with Radioactive Iodine-Refractory Differentiated Thyroid Cancer (rDTC): A Retrospective Analysis of the Canadian Patient Support Program (PSP) Poster Discussion | September 30 (Mon), 10:30-11:30
Lenvatinib Abstract No.: 990TiP	Phase 3 LEAP-011 study: First-line Pembrolizumab (pembro) with Lenvatinib (len) in PD-L1 Positive patients (pts) with Advanced Urothelial Carcinoma (UC) Ineligible to Receive Cisplatin-Based chemotherapy (CT) and in Pts Ineligible for Platinum-Containing CT Poster Display | September 30 (Mon), 12:00-13:00
Lenvatinib Abstract No.: 1375TiP	Pembrolizumab (pembro) Plus Lenvatinib (len) for First - Line Treatment of patients (pts) With Advanced Melanoma: Phase 3 LEAP - 003 Study Poster Display | September 30 (Mon), 12:00-13:00
Eribulin Abstract No.: 1683P	One-year follow-up results of eribulin for soft-tissue sarcoma including rare subtypes in a real-world observational study in Japan Poster Display | September 28 (Sat), 12:00-13:00
Eribulin Abstract No.: 348P	Phase 1 study of liposomal formulation of eribulin (E7389-LF) in patients with advanced solid tumors: primary results of dose escalation Poster Display | September 29 (Sun), 12:00-13:00
Eribulin Abstract No.: 366P	Real-World 1-Year Survival Analysis of Patients with Metastatic Breast Cancer with Liver or Lung Metastasis Treated with Eribulin, Gemcitabine or Capecitabine Poster Display | September 29 (Sun), 12:00-13:00

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[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 and KEYTRUDA combination across several different tumor types, including renal cell carcinoma, the companies will jointly initiate new clinical studies through the LEAP (LEnvatinib And Pembrolizumab) clinical program, which will evaluate the combination to support 11 potential indications in six types of cancer. The LEAP clinical program also includes a new basket trial targeting six additional cancer types.

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.