No.21-73

September 14, 2021
Eisai Co., Ltd.

EISAI TO PRESENT ABSTRACTS ON ONCOLOGY PRODUCTS AND PIPELINE AT ESMO VIRTUAL CONGRESS 2021

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that presentations on a series of abstracts highlighting updates on its oncology products and pipeline will be given at the European Society for Medical Oncology (ESMO) Virtual Congress 2021, from September 16 to 21, 2021, including its in-house discovered lenvatinib mesylate (product name: LENVIMA®, an orally available multi-kinase inhibitor, "lenvatinib") and eribulin mesylate (product name: HALAVEN®, a halichondrin class microtubule dynamics inhibitor, "eribulin").

At this congress, differences in outcomes by histology and prior therapy in the pivotal Phase 3 Study 309/KEYNOTE-775 trial, which compared 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), with TPC (Treatment of Physician's Choice) in patients with advanced endometrial cancer, following at least one prior platinum-based regimen, will be presented as an oral presentation (Abstract No: 726MO). In addition, a subgroup analysis and safety update from the pivotal Phase 3 CLEAR study (Study 307/KEYNOTE-581), which compared the combination of lenvatinib plus pembrolizumab versus sunitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC) will be presented as an e-poster presentation (Abstract No: 660P). Additionally, e-poster presentations will be given on the outcomes of early clinical studies on a liposomal formulation of eribulin plus nivolumab (Abstract No: 980P), a CREB-binding protein (CBP)/β-catenin interaction inhibitor E7386 (Abstract No: 473P) and a compound derived from total synthesis of halichondrin, E7130 (Abstract No: 545P).

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.

Lenvatinib Abstract Topics

Product / Compound Abstract Type Abstract No.	Presentation Topic
Lenvatinib+Pembrolizumab mini oral 726MO	Outcomes by histology and prior therapy with lenvatinib plus pembrolizumab vs treatment of physician's choice in patients with advanced endometrial cancer (Study 309/KEYNOTE-775) September 19 (Sun) 5:55 p.m. Central European Summer Time
Lenvatinib+Pembrolizumab ePoster 660P	Phase 3 CLEAR Trial in Advanced Renal Cell Carcinoma (aRCC): Outcomes in Subgroups and Toxicity Update (Study 307/KEYNOTE-581)
Lenvatinib+Pembrolizumab ePoster 506TiP	Pembrolizumab Plus Lenvatinib Versus Standard of Care for Previously Treated Metastatic Colorectal Cancer (mCRC): Phase 3 LEAP-017 Study
Lenvatinib+Pembrolizumab ePoster 796P	Association Between Biomarkers and Clinical Outcomes of Lenvatinib (L) + Pembrolizumab (P) in Advanced Endometrial Cancer (EC): Results From KEYNOTE-146/Study 111
Lenvatinib ePoster 1746P	Health-related quality-of-life (HRQoL) analyses from Study 211-a phase 2 study in patients (pts) with radioiodine-refractory differentiated thyroid cancer (RR-DTC) treated with 2 starting doses of lenvatinib (LEN)
Lenvatinib +anti-PD-1 antibody ePoster 8P	The characterization of tumors associated with the antitumor activity of lenvatinib plus anti-PD-1 antibody combination therapy in a mouse syngeneic model panel

Eribulin Abstract Topics

Product / Compound Abstract Type Abstract No.	Presentation Topic
Eriburin ePoster 304P	Incidence and resolution of eribulin-induced peripheral neuropathy (IRENE) in patients with locally advanced or metastatic breast cancer (IRENE/Study 504)
Eriburin liposomal formulation +Nivolumab ePoster 980P	Phase 1b study of a liposomal formulation of eribulin (E7389-LF) + nivolumab (Nivo) in patients (pts) with advanced solid tumors (Study 120)

(continued on the following page)

Other Development Products Abstract Topics

Product / Compound Abstract Type Abstract No.	Presentation Topic
E7386 ePoster 473P	A phase 1 study of E7386, a CREB-binding protein (CBP)/β-catenin interaction inhibitor, in patients with advanced solid tumors including colorectal cancer (CRC) (Study 103)
E7130 ePoster 545P	First-in-human (FIH) study of E7130 in patients (pts) with advanced solid tumors: primary result of dose-escalation part (Study 101)

Other Abstract Topics

Abstract Type Abstract No.	Presentation Topic
ePoster 954P	Comparison of medical costs and outcome between hepatectomy and radiofrequency ablation for hepatocellular carcinoma (Real World Evidence in Japan)
ePoster 305P	Real World Health-related Quality of Life (HRQoL) among HER2-negative (HER2-) Advanced Breast Cancer (ABC) Patients in EU3 and US
ePoster 306P	Real World Study of Treatments Received and Treatment Satisfaction Among HER2- Advanced Breast Cancer (ABC) Patients in EU3 and US

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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® (lenvatinib). Under the agreement, the companies will jointly develop, manufacture and commercialize LENVIMA, both as monotherapy and in combination with KEYTRUDA® (pembrolizumab), 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 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.