No. 21-37

May 20, 2021
Eisai Co., Ltd.

EISAI TO PRESENT DATA ON ONCOLOGY PIPELINE AND PRODUCTS AT ASCO ANNUAL MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that the latest data regarding its oncology pipeline and products including in-house discovered lenvatinib mesylate (multikinase inhibitor, product name: LENVIMA®, "lenvatinib") and eribulin mesylate (halichondrin class microtubule dynamics inhibitor, product name: HALAVEN®, "eribulin") will be presented at the American Society of Clinical Oncology (2021 ASCO Annual Meeting*), to be held virtually from June 4 to 8, 2021.

* Abstracts will be made available on demand via ASCO's website at 5:00 PM on May 19th (ET).

At this meeting, there will be an oral presentation on the analysis of health-related quality-of-life (HRQoL) (Abstract No: 4502) of the pivotal Phase 3 CLEAR Study (Study 307/KEYNOTE-581) evaluating lenvatinib in combination with pembrolizumab (product name: KEYTRUDA®, "pembrolizumab"), the anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the United States and Canada) or in combination with everolimus versus sunitinib for the first-line treatment of patients with advanced renal cell carcinoma. Additionally, respective CLEAR poster presentations on analysis of depth of response and efficacy (Abstract No: 4560) and a post hoc analysis of effects of subsequent systemic anticancer medication (Abstract No: 4562) will be presented.
In addition, a poster presentation on the analysis of HRQoL (Abstract No: 5570) of the pivotal Phase 3 Study 309/KEYNOTE-775 evaluating lenvatinib in combination with pembrolizumab versus chemotherapy (treatment of physician's choice [TPC]) for the treatment of patients with advanced endometrial carcinoma (advanced uterine body cancer in Japan), following at least one prior platinum-based regimen is planned.

An oral presentation on results of the latest analysis of a Phase 2 study (LEAP-004) evaluating lenvatinib in combination with pembrolizumab for the treatment of patients with advanced melanoma who had been treated with an anti-PD-1 or PD-L1 immune checkpoint inhibitor (Abstract No: 9504) is also planned.

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 Plus Pembrolizumab Combination Therapy Abstract Topics

Cancer Type	Abstract Type Abstract No.	Presentation Topic
Renal Cell Carcinoma	Oral Presentation Abstract No: 4502	Health-related quality-of-life (HRQoL) analysis from the phase 3 CLEAR trial of lenvatinib (LEN) plus pembrolizumab (PEMBRO) or everolimus (EVE) vs sunitinib (SUN) for patients (pts) with advanced renal cell carcinoma (aRCC) (Study 307/KEYNOTE-581) Presentation Session: June 7 (Mon.) 8:00-11:00 AM EDT
	Poster Abstract No: 4560	Analysis of the CLEAR study in patients (pts) with advanced renal cell carcinoma (RCC): depth of response and efficacy for selected subgroups in the lenvatinib (LEN) + pembrolizumab (PEMBRO) and sunitinib (SUN) treatment arms (Study 307/KEYNOTE-581)
	Poster Abstract No: 4562	Post hoc analysis of the CLEAR study in advanced renal cell carcinoma (RCC): Effect of subsequent therapy on survival outcomes in the lenvatinib (LEN) + everolimus (EVE) vs sunitinib (SUN) treatment arms (Study 307/KEYNOTE-581)
	Online Publication Abstract No: e16542	Lenvatinib (LEN) + pembrolizumab (PEMBRO) treatment in patients (pts) with metastatic clear cell renal cell carcinoma (RCC): Final results of a phase 1b/2 trial (Study 111/KEYNOTE-146)
	Poster Abstract No: TPS4594*	A phase 1b/2 umbrella study of investigational immune and targeted combination therapies as first-line therapy for patients with advanced renal cell carcinoma (RCC)
	Poster Abstract No: TPS4595*	KEYNOTE-B61: Open-label phase 2 study of pembrolizumab in combination with lenvatinib as first-line treatment for non-clear cell renal cell carcinoma (nccRCC) (KEYNOTE-B61)

* 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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Cancer Type	Abstract Type Abstract No.	Presentation Topic
Endometrial Carcinoma	Poster Abstract No: 5570	Health-related quality of life (HRQoL) in advanced endometrial cancer (aEC) patients (pts) treated with lenvatinib plus pembrolizumab or treatment of physician's choice (TPC) (Study 309/KEYNOTE-775)
	Online Publication Abstract No: e17571	Systematic literature review of the real-world burden and use of chemotherapies for treatment of advanced or recurrent endometrial carcinoma
	Poster Abstract No: 5581	Treatment patterns and outcomes among patients with microsatellite stable (MSS) advanced endometrial cancer in the United States: Endometrial Cancer Health Outcomes (ECHO) retrospective chart review Study
Melanoma	Oral Presentation Abstract No: 9504	Lenvatinib (LEN) plus pembrolizumab (pembro) for patients (pts) with advanced melanoma and confirmed progression on a PD-1 or PD-L1 Inhibitor: Updated findings of LEAP-004 (LEAP-004 Study) Presentation Session: June 7 (Mon.) 8:00-11:00 AM EDT
Hepatocellular Carcinoma	Poster Abstract No: 4084	Exploratory circulating biomarker analyses: lenvatinib + pembrolizumab (L + P) in a phase 1b trial in unresectable hepatocellular carcinoma (uHCC) (116 Study)
Gastric Cancer	Poster Abstract No: 4030	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 (LEAP-005 Study)
Colorectal Cancer	Poster Abstract No: 3564	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 (LEAP-005 Study)
Biliary Tract Cancer	Poster Abstract No: 4080	Lenvatinib plus pembrolizumab for patients with previously treated biliary tract cancers in the multicohort phase 2 LEAP-005 study (LEAP-005 Study)

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Lenvatinib Monotherapy Poster Presentation Topics

Cancer Type	Abstract Type Abstract No.	Presentation Topic
Hepatocellular Carcinoma	Poster Abstract No: 4098	The cost effectiveness of lenvatinib versus atezolizumab and bevacizumab or sorafenib in patients with unresectable hepatocellular carcinoma (uHCC) in Canada
	Online Publication Abstract No: e16129	Real-world effectiveness of lenvatinib monotherapy among previously treated unresectable hepatocellular carcinoma patients in United States clinical practices
	Online Publication Abstract No: e16119	Impact of bodyweight (BW)-based starting doses on safety and efficacy of lenvatinib (LEN) in patients (pts) with hepatocellular carcinoma (HCC (304/202 Study)
	Online Publication Abstract No: e16151	The comparative efficacy of atezolizumab and bevacizumab vs. lenvatinib in patients with unresectable hepatocellular carcinoma (uHCC)
	Online Publication Abstract No: e16118	A multicenter observational study of Lenvatinib for unresectable hepatocellular carcinoma in Japan

Eribulin Poster Presentation Topics

Cancer Type	Abstract Type Abstract No.	Presentation Topic
Breast Cancer	Online Publication Abstract No: e13058	Real-world clinical effectiveness of eribulin in metastatic breast cancer patients with visceral metastases in the United States
Gastric Cancer	Poster Abstract No: 4025	Phase 1 study of the liposomal formulation of eribulin (E7389-LF): Results from the advanced gastric cancer expansion cohort (Study 114)

Pipeline and Other Poster Presentation Topics

Abstract Type Abstract No.	Presentation Topic
Online Publication Abstract No: e18836	Health care cost impact associated with adverse events (AEs) among treatments in third-line+ (3L+) relapsed/refractory follicular lymphoma (R/R FL)

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Abstract Type Abstract No.	Presentation Topic
Poster Abstract No: 4090	Phase I study of H3B-6527 in hepatocellular carcinoma (HCC) or intrahepatic cholangiocarcinoma (ICC) (Study 101)
Online Publication Abstract No: e13025	Phase 1b study of H3B-6545 in combination with palbociclib in women with metastatic estrogen receptor-positive (ER+), human epidermal growth factor receptor 2 (HER2)-negative breast cancer (Study 102)
Online Publication Abstract No: e13022	Relative bioavailability of H3B-6545 tablets versus capsules and drug-drug interaction between H3B-6545 and pantoprazole (Pharmacokinetics Study)
Poster Abstract No: 1018	Phase I/II study of H3B-6545, a novel selective estrogen receptor covalent antagonist (SERCA), in estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer (Study 101)
Poster Abstract No: 11039	Impact of *#ASCO* Twitter Impressions on the Oncology Community
Online Publication Abstract No: e18521	Perspectives on under-representation of minority patients (pts) in clinical trials

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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 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 14 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, pancreatic cancer and triple-negative breast cancer) across more than 20 clinical trials.