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Eisai Co., Ltd.

Eisai Demonstrates Commitment to Oncology Innovation at ASCO 2025

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today the presentation of clinical research across its oncology portfolio and pipeline during the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting (#ASCO25), which is taking place in Chicago, Illinois, and virtually, from May 30 to June 3.

Notable data include findings from the Phase 3 LEAP-002 study, which evaluated lenvatinib (LENVIMA®), the orally available multiple receptor tyrosine kinase inhibitor (TKI) discovered by Eisai, plus pembrolizumab (KEYTRUDA®), MSD’s (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, versus lenvatinib monotherapy for the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC). The poster presentation will feature long-term follow-up data providing further insights into lenvatinib’s role in the treatment landscape for patients affected by HCC (NCT03713593; Abstract #4095).

Additional research from Eisai's pipeline will focus on E7386, a CBP/β-catenin interaction inhibitor, in combination with lenvatinib. This includes a dose optimization trial-in-progress presentation (Abstract #TPS5632) and dose expansion findings (Abstract #5599) in patients with advanced or recurrent endometrial carcinoma (NCT04008797).

"At Eisai, our pursuit of scientific advancement is fueled by a deep commitment to our *human health care* concept. We believe patients deserve our best efforts, and we endeavor to deliver that by pushing boundaries in oncology research, particularly in challenging areas," said Dr. Corina Dutcus, Senior Vice President, Oncology Global Clinical Development Lead at Eisai Inc. " Our data at ASCO 2025 showcase this principle in action. The long-term follow-up data from LEAP-002 contribute to our ongoing body of research and further reinforce our understanding of LENVIMA's established role in unresectable hepatocellular carcinoma, while our pipeline work in advanced endometrial carcinoma represents our continued dedication to addressing areas with unmet medical needs through innovative therapeutic approaches."

An oral presentation will feature data from the final analysis of the Phase 3 LEAP-015 study evaluating lenvatinib plus pembrolizumab and chemotherapy versus chemotherapy in patients with advanced, metastatic gastroesophageal adenocarcinoma (NCT04662710; Abstract #4001).

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 presentations is included below. These abstracts will be made available via the ASCO website on Thursday, May 22, 2025, at 4:00 PM Central Daylight Time (CDT).

Cancer Type	Study/Compound	Abstract Title	Abstract Type & Details
Lenvatinib Plus Pembrolizumab			
Gastrointestinal Cancer	LEAP-002	LEAP-002 long-term follow-up: Lenvatinib plus pembrolizumab versus lenvatinib plus placebo for advanced hepatocellular carcinoma	Poster Session Abstract #4095 May 31, 2025 9:00 AM CDT
	LEAP-015	Lenvatinib plus pembrolizumab and chemotherapy versus chemotherapy in advanced, metastatic gastroesophageal adenocarcinoma: The Phase 3, randomized LEAP-015 study	Oral Abstract Session Abstract #4001 May 31, 2025 3:12 PM CDT
Melanoma	LEAP-003	First-line lenvatinib plus pembrolizumab versus placebo plus pembrolizumab in Chinese patients with unresectable or metastatic melanoma: results from LEAP-003	Poster Session Abstract #9553 May 31, 2025 9:00 AM CDT
Pipeline			
Gynecologic Cancer	E7386	Randomized study evaluating optimal dose, efficacy and safety of E7386 + lenvatinib versus treatment of physicians' choice in advanced/recurrent endometrial carcinoma previously treated with anti-PD-(L)1 immunotherapy	Poster Session Abstract #TPS5632 June 1, 2025 9:00 AM CDT
		E7386 Study 102: Global dose-expansion cohort of E7386 + lenvatinib (LEN) in patients (pts) with advanced endometrial cancer (aEC) that progressed on platinum-based chemotherapy (chemo) and an anti-PD-(L)1 immunotherapy (IO)	Poster Session Abstract #5599 June 1, 2025 9:00 AM CDT
Pan-Tumor	Systematic Review	The PRO-CTCAE in oncology clinical trials: Insights from a targeted literature review	For Online Publication

In March 2018, Eisai and MSD, through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of lenvatinib, both as monotherapy and in combination with pembrolizumab, MSD's anti-PD-1 therapy. Eisai and MSD are studying the lenvatinib plus pembrolizumab combination through the LEAP (**LE**nvatinib **A**nd **P**embrolizumab) clinical program in HCC and esophageal cancer across multiple clinical trials.

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[Notes to editors]

1. Eisai's Focus on Cancer

Eisai positions Oncology as one of its key strategic areas, and aims to contribute to the cure of cancers through the discovery of innovative new drugs with new targets and mechanisms of action under the Deep Human Biology Learning (DHBL) drug discovery and development organization.

By utilizing biomarker data obtained from our products to elucidate the mechanisms of the incidence and root causes of cancer, as well as drug resistance, and using Eisai Group's precision chemistry technology to turn undruggable intracellular therapeutic targets into druggable ones, we will create new backbone therapeutic drugs.

*1 KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

*2 E7386 is created through collaboration research between Eisai and PRISM BioLab Co., Ltd. (Headquarters: Kanagawa)

*3 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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