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Eisai Co., Ltd.

Eisai Highlights Breadth of Oncology Research at ESMO 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 European Society for Medical Oncology (ESMO) Congress 2025, which is taking place in Berlin, Germany from October 17 to 21.

Among the notable presentations is data from the Phase 3 Study 309/KEYNOTE-775 trial, which evaluated lenvatinib (LENVIMA®), the orally available multiple receptor tyrosine kinase inhibitor discovered by Eisai, plus pembrolizumab (KEYTRUDA®[*1]), MSD’s (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy versus treatment of physician's choice for patients with advanced endometrial carcinoma. The presentation will feature 5-year overall survival data providing deeper insights into long-term treatment for patients affected by this disease (NCT03517449; Abstract #1119P).

"The 5-year overall survival follow-up from Study 309/KEYNOTE-775 being presented at ESMO highlights the consistency of the study data over time, supporting the established role of lenvatinib plus pembrolizumab in the treatment landscape of endometrial cancer and underscoring Eisai's commitment to generating the long-term evidence that patients, families, and healthcare providers rely on to make informed treatment decisions," said Dr. Corina Dutcus, Senior Vice President, Oncology Global Clinical Development Lead at Eisai Inc. "Our research in endometrial cancer, alongside our data in renal cell carcinoma and innovative pipeline approaches, reflects our dedication to our *human health care* concept to address unmet medical needs and advance treatment options for people living with cancer."

Further endometrial cancer research includes additional 1-year follow-up results from the Phase 3 LEAP-001 study in first-line advanced or recurrent endometrial carcinoma (NCT03884101; Abstract #1114P), as well as a combined analysis examining post-(neo)adjuvant therapy outcomes from both the Study 309/KEYNOTE-775 and LEAP-001 studies (Abstract #1124P). In renal cell carcinoma (RCC), final analysis data from the CLEAR study comparing lenvatinib plus pembrolizumab versus sunitinib in patients with advanced RCC with or without bone metastases will be presented (NCT02811861; Abstract #2603P).

Research from Eisai's pipeline includes clinical and biomarker results from Study 102 evaluating E7386, a CREB-binding protein (CBP)/β-catenin interaction inhibitor, in combination with lenvatinib in patients with advanced or recurrent endometrial carcinoma (NCT04008797; Abstract #1153P).

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. Regular abstracts will be made available via the ESMO website on 12:05 AM Central European Summer Time (CEST) on Monday, October 13, 2025. Late-breaking abstracts accepted for presentation at ESMO as a Proffered Paper or Mini Oral will be published on the ESMO website at 12:05 AM CEST on the day of presentation. Posters will be on display from 9:00 AM – 5:00 PM CEST on the day of their poster session.

Cancer Type	Study/Compound	Presentation Title	Presentation Type & Details
Lenvatinib Plus Pembrolizumab			
Gynecologic Cancer	Study 309/ KEYNOTE-775	Lenvatinib plus pembrolizumab (L+P) vs treatment of physician's choice (TPC) for advanced endometrial cancer (EC): 5-Year outcomes from Study 309/KEYNOTE-775	Poster Session Presentation #1119P October 18, 2025
	LEAP-001	First-line lenvatinib + pembrolizumab (L+P) vs chemotherapy (CT) for advanced or recurrent endometrial cancer (EC): additional 1-year follow-up results from ENGOT-en9/LEAP-001	Poster Session Presentation #1114P October 18, 2025
	Study 309/ KEYNOTE-775 and LEAP-001	Lenvatinib + pembrolizumab (L+P) in participants (Pts) with advanced or recurrent endometrial cancer (aEC): Study 309/KEYNOTE-775 and ENGOT-en9/LEAP-001 post-(neo)adjuvant therapy outcomes	Poster Session Presentation #1124P October 18, 2025
Gastrointestinal Cancer	LEAP-014	Lenvatinib plus pembrolizumab and chemotherapy versus pembrolizumab and chemotherapy in untreated metastatic esophageal squamous cell carcinoma: the randomized Phase 3 LEAP-014 Study	Proffered Paper Session Presentation #LBA79 October 17, 2025 2:40-2:50 PM
Genitourinary Cancer	CLEAR	Final analysis of lenvatinib + pembrolizumab (L+P) vs sunitinib (S) in patients with advanced renal cell carcinoma (aRCC) with or without bone metastases in CLEAR	Poster Session Presentation #2603P October 18, 2025
Pipeline			
Gynecologic Cancer	E7386[*2]	Clinical and biomarker results from E7386 study 102: global dose-expansion cohort of E7386 + lenvatinib (LEN) in patients (pts) with advanced/recurrent endometrial cancer (aEC) that progressed on platinum-based chemotherapy (PBC) and an anti-PD-(L)1 immunotherapy (IO)	Poster Session Presentation #1153P October 18, 2025

The following presentations represent studies including lenvatinib treatment sponsored by MSD.

Cancer Type	Study/Compound	Presentation Title	Presentation Type & Details
Genitourinary Cancer	LITESPARK-010	Belzutifan plus lenvatinib for Chinese participants (pts) with previously treated advanced clear cell renal cell carcinoma (ccRCC): updated results of cohort 1 of the LITESPARK-010 study	Poster Session Presentation #2615P October 18, 2025
	KEYMAKER-U03A	First-line pembrolizumab-based regimens for advanced clear cell renal cell carcinoma: KEYMAKER-U03 substudy 03A	Proffered Paper Session Presentation #LBA96 October 18, 2025 8:30-8:40 AM
Melanoma	KEYMAKER-U02B	First-line pembrolizumab alone or with investigational agents for advanced melanoma: updated results from the phase 1/2 KEYMAKER-U02 substudy 02B	Poster Session Presentation #1621P October 20, 2025

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 the

anti-PD-1 therapy from MSD, pembrolizumab. Eisai and MSD are studying the lenvatinib plus pembrolizumab combination through the LEAP (**LE**nvatinib **A**nd **P**embrolizumab) clinical program. Lenvatinib plus pembrolizumab is approved in the U.S., the EU, Japan and other countries for the treatment of advanced RCC and certain types of advanced endometrial carcinoma. Lenvatinib is approved as KISPLYX for advanced RCC in the EU.

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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)