No.26-29

May 21, 2026
Eisai Co., Ltd.

Eisai Deepens Body of Clinical Evidence for LENVIMA® (Lenvatinib) Across Established Indications at ASCO 2026

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the presentation of clinical research across its oncology portfolio and pipeline during the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting (#ASCO26), which is taking place in Chicago, Illinois and online from May 29 to June 2.

Notable data include findings from a real-world evidence analysis comparing first-line lenvatinib (LENVIMA®), the orally available multiple receptor tyrosine kinase inhibitor (TKI) discovered by Eisai, versus dabrafenib (BRAF inhibitor) plus trametinib (MEK inhibitor) in patients with BRAF-mutated differentiated thyroid cancer (DTC). The poster presentation will share insights from real-world clinical practice to inform treatment considerations for patients with this molecularly defined subset of DTC (Abstract #6052). Currently, lenvatinib is recommended as a preferred Category 1 systemic therapy regimen for the treatment of progressive, radioactive iodine-refractory DTC in the National Comprehensive Cancer Network® (NCCN®)[*1] Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Thyroid Carcinoma.

An additional poster presentation will feature an analysis from the pivotal Phase 3 CLEAR study evaluating efficacy outcomes by patterns of progression in patients with advanced renal cell carcinoma (RCC) who received lenvatinib plus pembrolizumab (KEYTRUDA®[*2]) MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, versus sunitinib (multiple receptor TKI) in the first-line setting. These findings build on the body of evidence supporting the established role of lenvatinib plus pembrolizumab in the first-line treatment setting for patients with advanced RCC (NCT02811861; Abstract #4527). Lenvatinib in combination with pembrolizumab is recommended as a preferred Category 1 first-line systemic therapy regimen for the treatment of patients with advanced clear cell RCC and a preferred Category 2A systemic therapy regimen for the treatment of patients with advanced non-clear cell RCC in the NCCN Guidelines® for Kidney Cancer.

"Lenvatinib continues to play an important role in the treatment of some of the most difficult-to-treat cancers, supported by more than a decade of clinical and real-world evidence," said Dr. Corina Dutcus, Senior Vice President, Oncology Global Clinical Development Lead at Eisai Inc. "At ASCO 2026, Eisai is presenting new research that reinforces this foundation and deepens the clinical evidence for lenvatinib across its established indications, giving healthcare providers valuable information to help them care for their patients. This work, alongside our ongoing pipeline research, reflects Eisai's dedication to providing support for the communities we serve as part of our *human health care* concept."

Additional research from Eisai's pipeline includes an online publication highlighting analyses from Phase 1 trials evaluating E7386[*3], a CREB-binding protein (CBP)/β-catenin interaction inhibitor, to inform cardiac safety assessments in early-stage oncology development (Abstract #e24005).

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 21, 2026, at 5:00 PM EDT.

Cancer Type	Study/Compound	Abstract Title	Abstract Type & Details
Lenvatinib			
Thyroid Cancer	Real-world evidence	First-line lenvatinib versus dabrafenib plus trametinib (D+T) in BRAF-mutated differentiated thyroid cancer (DTC): insights from real-world data	Poster Session Abstract #6052 May 30, 2026 2:30-5:30 PM EDT / 1:30-4:30 PM CDT
Lenvatinib Plus Pembrolizumab			
Genitourinary Cancer	CLEAR	Efficacy outcomes by patterns of progression in patients with advanced renal cell carcinoma from the phase 3 CLEAR trial	Poster Session Abstract #4527 May 31, 2026 10:00 AM-1:00 PM EDT / 9:00 AM-12:00 PM CDT
Pipeline			
Pan-Tumor	E7386	Leveraging E7386 phase 1 trials for cardiac safety: Gaining concentration-QTc insights to inform early-stage oncology development	For Online Publication Abstract #E24005

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

Cancer Type	Study	Abstract Title	Abstract Type & Details
Lung Cancer	KEYNOTE-495/KeyImPaCT	Final analysis of the biomarker-directed, randomized, phase 2 KEYNOTE-495/KeyImPaCT study of pembrolizumab (P)-based combination therapy for non–small cell lung cancer (NSCLC)	Poster Session Abstract #8584 May 31, 2026 10:00 AM-1:00 PM EDT / 9:00 AM-12:00 PM CDT
Genitourinary Cancer	KEYNOTE-365	Phase 1b/2 study of pembrolizumab plus lenvatinib or pembrolizumab coformulated with vibostolimab in participants (pts) with metastatic neuroendocrine prostate cancer (NEPC): KEYNOTE-365 cohorts F and H	Poster Session Abstract #5055 May 31, 2026 10:00 AM-1:00 PM EDT / 9:00 AM-12:00 PM CDT

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 MSD's anti-PD-1 therapy, pembrolizumab. KEYTRUDA plus LENVIMA 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.

The following presentation includes a study on taletrectinib treatment sponsored by Nuvation Bio Inc. (Corporate Headquarters: New York, “Nuvation Bio”).

Cancer Type	Study	Abstract Title	Abstract Type & Details
Lung Cancer	TRUST-II	Patient-reported outcomes (PROs) and health-related quality of life (HRQoL) with taletrectinib in advanced ROS1 + non-small cell lung cancer (NSCLC) from the TRUST-II study	Poster Session Abstract #8629 May 31, 2026 10:00 AM-1:00 PM EDT / 9:00 AM-12:00 PM CDT

In January 2026, we acquired from Nuvation Bio the exclusive rights to develop, obtain regulatory approval for, and commercialize taletrectinib, next-generation ROS1 inhibitor for the treatment of ROS1-positive non-small cell lung cancer (NSCLC) in Europe, the Middle East, North Africa, Russia, Turkey, Canada, Australia, New Zealand, Singapore, the Philippines, Indonesia, Thailand, Malaysia, Vietnam, and India. Following the submission of a marketing authorization application (MAA) to the European Medicines Agency (EMA) in March 2026, which was validated and accepted for full approval consideration with a standard review timeline, additional filings are planned for the U.K., Canada and other regions included in Eisai’s licensed territories.

The following presentation includes a study on serplulimab treatment sponsored by Shanghai Henlius Biotech, Inc. (Headquarters: Shanghai, “Henlius”).

Cancer Type	Compound	Abstract Title	Abstract Type & Details
Gastric Cancer	serplulimab	Neoadjuvant/adjuvant serplulimab vs. placebo combined with chemotherapy for PD-L1–positive gastric cancer: A randomized, double-blind, multicenter phase 3 study	Rapid Oral Abstract Session Abstract #4009 June 1, 2026 2:15 PM-3:45 PM EDT / 1:15 PM-2:45 PM CDT

In February 2026, we acquired from Henlius the exclusive rights to commercialize serplulimab, a novel anti-PD-1 monoclonal antibody in Japan. In Japan, Henlius is currently conducting a Phase II bridging clinical trial for extensive-stage small cell lung cancer (ES-SCLC), and plans to submit an application for fiscal year 2026 based on the results of this trial as well as the Phase III clinical trial data that supported approvals for this indication in China and Europe.

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[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 NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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

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

###