

No.26-58

Oct 16, 2026  
Eisai Co., Ltd.

## Eisai Deepens Its Oncology Evidence Base at ESMO Congress 2026

*Findings from the Phase 3 LITESPARK-011 and LITESPARK-012 studies reflect continued research into LENVIMA® (lenvatinib)-based combination regimens for patients with advanced renal cell carcinoma*

*Exploratory biomarker analysis from the Phase 3 LEAP-001 study adds to translational insights in advanced or recurrent endometrial cancer, alongside new findings from “Patients Raise Their Voices” survey*

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 2026, taking place in Madrid from October 23 to 27. Together, the presentations reflect Eisai's ongoing commitment to generating evidence that can help inform treatment decisions for patients facing difficult-to-treat cancers.

“The research we are presenting at ESMO spans the full arc of a patient’s journey, from first-line treatment of advanced disease through disease progression, and reflects our commitment to driving progress in patient care at every stage,” said Corina Dutcus, M.D., Senior Vice President, Oncology Global Clinical Development Lead at Eisai Inc. “In advanced renal cell carcinoma, this means continuing to generate new evidence across the continuum of care, building on the established role of LENVIMA-based combinations. In endometrial cancer, we will present exploratory biomarker findings from the Phase 3 LEAP-001 study and a patient advocacy-led survey highlighting the experiences of people living with the disease across their care journey. Across both areas, this work reflects our *human health care* mission, which places patients at the center of everything we do and guides our efforts to deliver meaningful innovations that can improve their lives.”

### Renal Cell Carcinoma (RCC) Research

Among the notable presentations are new analyses from the Phase 3 LITESPARK-011 ([NCT04586231](#)) and LITESPARK-012 ([NCT04736706](#)) studies evaluating LENVIMA® (lenvatinib)-based regimens in advanced RCC. The final analysis from LITESPARK-011 will be presented in a proffered paper session (Presentation #3587O). Data from the Phase 3 LITESPARK-011 study supported the recent U.S. Food and Drug Administration (FDA) approval of WELIREG® (belzutifan), MSD's (Merck & Co., Inc., Rahway, N.J., U.S.) oral hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, plus LENVIMA, the orally available multiple receptor tyrosine kinase inhibitor discovered by Eisai, for adult patients with advanced RCC with a clear cell component (ccRCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor [see FDA news release [here](#)]. Additional LITESPARK-011 research includes a rapid oral presentation examining the relationship between health-related quality of life (HRQoL) and efficacy in the trial (Presentation #3595RO).

A proffered paper featuring findings from the Phase 3 LITESPARK-012 study evaluating two investigational regimens for the first-line treatment of patients with advanced ccRCC compared to KEYTRUDA®

(pembrolizumab), MSD's anti-PD-1 therapy, plus LENVIMA (Presentation #3586O) will also be presented. KEYTRUDA plus LENVIMA is recommended as a preferred Category 1 first-line systemic therapy regimen for the treatment of patients with advanced ccRCC and a preferred Category 2A systemic therapy regimen for the treatment of patients with advanced non-clear cell RCC in the National Comprehensive Cancer Network® (NCCN®)\* Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Kidney Cancer.

### Endometrial Cancer Research

Eisai will highlight an exploratory biomarker analysis from the Phase 3 LEAP-001 study ([NCT03884101](#)) that evaluated patients with advanced or recurrent endometrial cancer treated with first-line KEYTRUDA plus LENVIMA versus chemotherapy (Presentation #4360P). These exploratory findings add to the translational insights generated from LEAP-001 and reflect ongoing efforts by Eisai to learn from every clinical study to help deepen understanding of endometrial cancer biology and treatment response.

Eisai will also present findings from a survey examining the perspectives and experiences of people living with endometrial cancer in the U.S. across the care journey (Presentation #1256P). Conducted in collaboration with leading patient advocacy organizations, the survey explored topics including the impact of treatment on daily life, treatment preferences, and the role of shared decision-making between patients and physicians.

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. All regular abstracts accepted for presentation at the ESMO Congress 2026 will be published online via the ESMO website at 6:05 PM EDT on Sunday, October 18, 2026 (12:05 AM CEST on Monday, October 19, 2026). Posters will be on display from 9:00 AM – 5:00 PM local time in Madrid on the day of their poster session.

| Cancer Type                       | Study         | Presentation Title                                                                                                                                                                                                                        | Presentation Type & Details<br>(local time in Madrid)                    |
|-----------------------------------|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| <b>Lenvatinib plus Belzutifan</b> |               |                                                                                                                                                                                                                                           |                                                                          |
| Renal Cell Carcinoma              | LITESPARK-011 | Final analysis of the phase 3 LITESPARK-011 study: belzutifan (bel) plus lenvatinib (len) versus cabozantinib (cabo) for advanced renal cell carcinoma (RCC) after anti-PD-(L)1 therapy                                                   | Proffered Paper<br>Presentation #3587O<br>October 25, 2026<br>8:30-10:00 |
|                                   | LITESPARK-011 | Relationship between health-related quality of life (HRQoL) and efficacy in LITESPARK-011: Belzutifan (belz) + lenvatinib (len) versus cabozantinib (cabo) in advanced clear cell renal cell carcinoma (ccRCC) after anti-PD-(L)1 therapy | Rapid Oral<br>Presentation #3595RO<br>October 25, 2026<br>14:45-16:15    |
|                                   | LITESPARK-012 | First-line pembrolizumab + lenvatinib + belzutifan or MK-1308A + lenvatinib in advanced RCC: randomized open-label phase 3 LITESPARK-012 study                                                                                            | Proffered Paper<br>Presentation #3586O<br>October 25, 2026<br>8:30-10:00 |

| <b>Lenvatinib Plus Pembrolizumab</b>  |                     |                                                                                                                                                                                                        |                                                                                       |
|---------------------------------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Endometrial Cancer                    | LEAP-001            | First-Line Lenvatinib + Pembrolizumab (L + P) vs Chemotherapy (CT) for Advanced/Recurrent Endometrial Cancer (EC): Biomarker Analysis From ENGOT-en9/LEAP-001                                          | <a href="#">Poster</a><br>Presentation #4360P<br>October 23, 2026                     |
| Hepatocellular Carcinoma              | LEAP-012            | Phase 3 LEAP-012 Study of Lenvatinib + Pembrolizumab vs Dual Placebo With Transarterial Chemoembolization (TACE) for Unresectable Non-metastatic Hepatocellular Carcinoma: Long-term OS Results        | <a href="#">Rapid Oral</a><br>Presentation #1678RO<br>October 26, 2026<br>14:45-16:15 |
| Head and Neck Squamous Cell Carcinoma | LEAP-009            | End-of-trial safety results of the phase 2 LEAP-009 trial of lenvatinib (lenva) plus pembrolizumab (pembro) for recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC)                 | <a href="#">Poster</a><br>Presentation #1555P<br>October 26, 2026                     |
| <b>Lenvatinib plus Everolimus</b>     |                     |                                                                                                                                                                                                        |                                                                                       |
| Renal Cell Carcinoma                  | Real-World Evidence | Treatment patterns and clinical outcomes among advanced renal cell carcinoma patients receiving treatments after checkpoint inhibitor therapy: Real World Data from the German research platform CARAT | <a href="#">Online Publication</a><br>Presentation #3692eP                            |

In March 2018, Eisai and MSD through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of LENVIMA. Under the agreement, the companies jointly develop, manufacture and commercialize LENVIMA, both as monotherapy and in combination with MSD's anti-PD-1 therapy, KEYTRUDA, and HIF-2 $\alpha$  inhibitor, WELIREG.

The following presentation includes findings from a survey examining the perspectives and experiences of people living with endometrial cancer across the care journey.

| <b>Cancer Type</b> | <b>Study</b>   | <b>Presentation Title</b>                                  | <b>Presentation Type &amp; Details</b>                            |
|--------------------|----------------|------------------------------------------------------------|-------------------------------------------------------------------|
| Endometrial Cancer | Patient Survey | Endometrial Cancer (EC): Patients (Pts) Raise Their Voices | <a href="#">Poster</a><br>Presentation #1256P<br>October 26, 2026 |

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

| <b>Cancer Type</b> | <b>Study</b> | <b>Presentation Title</b>                                                                                                                                                                | <b>Presentation Type &amp; Details</b>                            |
|--------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Lung Cancer        | TRUST-II     | Updated Efficacy and Safety of Taletrectinib in Patients with Advanced ROS1+ Non-Small Cell Lung Cancer (NSCLC) After Prior Entrectinib Exposure: Results from the Global TRUST-II Study | <a href="#">Poster</a><br>Presentation #2643P<br>October 26, 2026 |

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, an MAA was submitted to and validated by the UK Medicines and Healthcare products Regulatory Agency (MHRA) in June 2026 using the International Recognition Pathway (IRP). Additional filings are planned for 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 | Study   | Presentation Title                                                                                                                      | Presentation Type & Details                                                |
|-------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Lung Cancer | ASTRIDE | Randomized trial of serplulimab or atezolizumab plus chemotherapy in USA patients with extensive-stage small cell lung cancer (ASTRIDE) | Proffered Paper<br>Presentation # 3809O<br>October 26, 2026<br>14:55-15:05 |

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 Eisai’s 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 WELIREG® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, N.J., U.S.A.
- \*2 KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, N.J., U.S.A.
- \*3 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.

###