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Eisai Co., Ltd.

# EISAI TO PRESENT RESEARCH FROM ONCOLOGY PORTFOLIO AND PIPELINE AT ESMO CONGRESS 2023

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the presentation of research across various types of cancer from its oncology portfolio and pipeline during the European Society for Medical Oncology (ESMO) Congress 2023, which is taking place virtually and in-person in Madrid, Spain from October 20 to 24.

Notable presentations include a post-hoc analysis of tumor response by baseline characteristics of the metastases from the pivotal Phase 3 CLEAR (Study 307)/KEYNOTE-581 trial, which evaluated lenvatinib (LENVIMA®), the orally available multiple receptor tyrosine kinase inhibitor discovered by Eisai, plus pembrolizumab (KEYTRUDA®), anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, versus sunitinib for the first-line treatment of patients with advanced renal cell carcinoma (NCT02811861; Presentation: #1903P). An exploratory analysis from the pivotal Phase 3 Study 309/KEYNOTE-775 trial of outcomes for patients with advanced endometrial cancer who completed treatment with pembrolizumab and continued with lenvatinib will also be presented (NCT03517449; Presentation: #748P).

"As a research and development-focused company driven by our *hhc* (*human health care*) concept, we strive to make a difference in the lives of patients and their families by advancing the science of cancer medicine with our robust portfolio and pipeline," said Dr. Takashi Owa, Chief Scientific Officer, Senior Vice President, Eisai Co., Ltd. "At this year's ESMO meeting, analyses from the pivotal Phase 3 CLEAR and Study 309/KEYNOTE-775 trials may provide greater insights into the treatment of patients with advanced renal cell carcinoma and certain types of advanced endometrial carcinoma. We also look forward to sharing data for lenvatinib and from our pipeline, as well as engaging in critical scientific exchange with the community in service of moving oncology research forward."

Additional data from the LEAP (**LE**nvatinib **A**nd **P**embrolizumab) clinical program to be presented include safety-run-in results from the Phase 3 LEAP-014 trial evaluating lenvatinib plus pembrolizumab and chemotherapy as a treatment option for patients with metastatic esophageal squamous cell carcinoma (NCT04949256; Presentation: #1534P). A network meta-analysis of lenvatinib versus key comparators as first-line treatment for patients with unresectable hepatocellular carcinoma will also be presented during a poster session (Presentation: #1007P).

Research from Eisai's pipeline will be featured in a poster presentation of findings from the dose-expansion portion of a Phase 1 study evaluating E7389-LF, a liposomal formulation of eribulin, as a potential first-line chemotherapy treatment option for patients with metastatic/advanced HER2-negative breast cancer (Presentation: #405P). Additionally, insights from preclinical research on farletuzumab ecteribulin (FZEC, formerly known as MORAb-202), a folate receptor alpha (FRα)-targeting antibody drug conjugate (ADC), in endometrial cancer will be presented (Presentation: #786P).

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 presentations is included below. These abstracts will be made available via the ESMO website on Monday, October 16, 2023, at 12:05 AM CEST.

| Cancer Type | Study/Compound | Abstract Title | Abstract Type & Details |
|---|---|---|---|
| **Lenvatinib Plus Pembrolizumab** | | | |
| Genitourinary Cancer | CLEAR | Tumor response by baseline metastases in patients with renal cell carcinoma treated with lenvatinib plus pembrolizumab vs sunitinib: post hoc analysis of the CLEAR trial | Poster Session<br>Presentation #1903P<br>October 23, 2023<br>9:00 AM-5:00 PM CEST |
| Gynecologic Cancer | Study 309/ KEYNOTE-775 | Outcomes for patients with advanced endometrial cancer who completed pembrolizumab and continued lenvatinib in the phase 3 Study 309/KEYNOTE-775 | Poster Session<br>Presentation #748P<br>October 22, 2023<br>9:00 AM-5:00 PM CEST |
| Gastrointestinal Cancer | LEAP-014 | First-line lenvatinib plus pembrolizumab and chemotherapy for metastatic esophageal squamous cell carcinoma: safety run-in results from the phase 3 LEAP-014 study | Poster Session<br>Presentation #1534P<br>October 23, 2023<br>9:00 AM-5:00 PM CEST |
| **Lenvatinib** | | | |
| Gastrointestinal Cancer | Network Meta-Analysis | Network meta-analysis of lenvatinib vs key comparators in first-line unresectable hepatocellular carcinoma | Poster Session<br>Presentation #1007P<br>October 23, 2023<br>9:00 AM-5:00 PM CEST |
| | Real-World Evidence_ Liver Cancer | Safety and efficacy of lenvatinib in patients with unresectable hepatocellular carcinoma in real-world practice in Korea | Poster Session<br>Presentation #987P<br>October 23, 2023<br>9:00 AM-5:00 PM CEST |
| **Eribulin** | | | |
| Breast Cancer | Eribulin | Health outcomes of treatment sequences with eribulin or other single agents' chemotherapy for treating relapsed metastatic HER2-negative breast cancer | Poster Session<br>Presentation #462P<br>October 21, 2023<br>9:00 AM-5:00 PM CEST |
| **Pipeline** | | | |
| Breast Cancer | E7389-LF | E7389-LF as a first-line chemotherapy for patients with metastatic/advanced HER2-negative breast cancer: Results from a phase 1 study dose-expansion part | Poster Session<br>Presentation #405P<br>October 21, 2023<br>9:00 AM-5:00 PM CEST |
| Gynecologic Cancer | Farletuzumab Ecteribulin (FZEC) | Antitumor activity of farletuzumab ecteribulin in a panel of endometrial cancer patient-derived xenografts with four different molecular subtypes | Poster Session<br>Presentation #786P<br>October 22, 2023<br>9:00 AM-5:00 PM CEST |

In March 2018, Eisai and Merck & Co., Inc., Rahway, NJ, USA (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 lenvatinib, both as monotherapy and in combination with the pembrolizumab, anti-PD-1 therapy from Merck & Co., Inc., Kenilworth, NJ, USA. Eisai and Merck & Co.,

Inc., Kenilworth, NJ, USA are studying the lenvatinib plus pembrolizumab combination through the LEAP (**LE**nvatinib **A**nd **P**embrolizumab) clinical program in various tumor types across multiple clinical trials.

In June 2021, Eisai and Bristol Myers Squibb entered into an exclusive global strategic collaboration agreement for the co-development and co-commercialization of FZEC. Eisai and Bristol Myers Squibb are currently investigating FZEC in multiple studies including: a Phase 1/2 clinical study for select solid tumors including endometrial cancer, a Phase 2 clinical study for non-small cell lung cancer, and a Phase 2 clinical study for ovarian cancer, peritoneal cancer and fallopian tube cancer.

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**[Notes to editors]**

**1. Eisai's Focus on Cancer**

Eisai acknowledges "Oncology" as one of its key strategic areas, and will continue to focus on the discovery and development of anti-cancer drugs within drug discovery domains including "tumor microenvironment", "proteostasis disruption", "cell linage and cell differentiation", and "inflammation, hypoxia, oxidative stress and cell senescence" under the Deep Human Biology Learning (DHBL) drug discovery and development organization. Eisai aspires to discover innovative new drugs with new targets and mechanisms of action from these *domains* with the aim of contributing to the cure of cancers.

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

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