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Eisai Co., Ltd.

EISAI ACCELERATES PROGRESS IN ONCOLOGY RESEARCH WITH NEW DATA AT ESMO CONGRESS 2024

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 2024, which is taking place virtually and in-person in Barcelona, Spain from September 13 to 17.

First presentation of results from the first interim analysis of the Phase 3 LEAP-012 trial evaluating lenvatinib (LENVIMA®), the orally available multiple receptor tyrosine kinase inhibitor discovered by Eisai, plus pembrolizumab (KEYTRUDA®), the anti-PD-1 therapy from Merck & Co., Inc., Rahway, NJ, USA, in combination with transarterial chemoembolization (TACE) for the treatment of patients with unresectable, non-metastatic hepatocellular carcinoma (HCC) will be featured in an ESMO Presidential Symposium (NCT04246177; Presentation: #LBA3).

"The late-breaking data from the Phase 3 LEAP-012 trial add to a growing body of research that we have undertaken in hepatocellular carcinoma, reinforcing Eisai's longstanding commitment to people living with this devastating disease," said Dr. Takashi Owa, Chief Scientific Officer, Senior Vice President, Eisai Co., Ltd. "We are eager to share these findings at ESMO, alongside our other research on lenvatinib monotherapy and in combination with pembrolizumab, and pipeline developments, as this crucial scientific exchange fuels our mission to accelerate progress in oncology and help improve the lives of patients and families affected by cancer."

Additionally, a Mini Oral presentation will feature real-world evidence for patients with radioiodine-refractory differentiated thyroid cancer (RAI-R DTC) treated with lenvatinib monotherapy in Europe and Canada (Presentation: #1926MO). Research into the use of lenvatinib monotherapy in patients with HCC from the Phase 4 STELLAR study (Presentation: #964P) and from a real-world study utilizing the LINK (Liver cancer IN Korea) research network (Presentation: #972P) will be shared in poster presentations. An exploratory analysis from the Phase 3 LEAP-001 trial evaluating tumor response with lenvatinib plus pembrolizumab for patients with advanced or recurrent endometrial carcinoma will also be presented (NCT03884101; Presentation: #737P).

Research from Eisai's pipeline includes a quality-of-life analysis from the Phase 3 EMERALD study in Japan evaluating either Eisai's eribulin (HALAVEN®) or a taxane in combination with trastuzumab and pertuzumab in patients with HER2-positive, locally advanced or metastatic breast cancer (NCT03264547; Presentation: #373P); findings from a Phase 1b dose-expansion cohort evaluating E7386 (a CBP/β-catenin interaction inhibitor) in combination with lenvatinib in patients with advanced endometrial carcinoma with progression following prior anti-PD-(L)1 immunotherapy and platinum-based

chemotherapy (NCT04008797; Presentation: #738P); as well as presentations for BB-1701, an antibody drug conjugate which combines an anti-HER2 antibody with Eisai's approved anticancer drug eribulin via its linker, in previously-treated patients with HER2-positive or HER2-low unresectable or metastatic breast cancer (NCT06188559; Presentation: #437TiP) and non-small cell lung cancer patients with HER2 mutation/amplification (Presentation: #1296P; presented by Bliss Biopharmaceutical Co., Ltd), respectively.

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 Monday, September 9, at 12:05 AM Central European Summer Time (CEST). 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 the 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**	**Abstract Title**	**Abstract Type & Details**
Lenvatinib Plus Pembrolizumab			
Gastrointestinal Cancer	LEAP-012	Transarterial chemoembolization (TACE) with or without lenvatinib (len) plus pembrolizumab (pembro) for intermediate stage hepatocellular carcinoma (HCC): phase 3 LEAP-012 study	Presidential Symposium (Proffered Paper Session) Presentation #LBA3 September 14, 2024 5:36-5:48 PM CEST
Endometrial Carcinoma	LEAP-001	Characterization of tumor response with lenvatinib plus pembrolizumab (LEN + Pembro) in the ENGOT-en9/LEAP-001 study	Poster Session Presentation #737P September 14, 2024
Lenvatinib			
Differentiated Thyroid Cancer	Real-World Evidence	Radioiodine-refractory differentiated thyroid cancer (RAI-R DTC) patients treated with lenvatinib monotherapy: real-world treatment patterns and clinical outcomes in Europe and Canada	Mini Oral Presentation Presentation #1926MO September 13, 2024 4:05-4:10 PM CEST
Gastrointestinal Cancer	Real-World Evidence	Efficacy and safety of lenvatinib vs. sorafenib in hepatocellular carcinoma: a multi-center real-world study from the LINK research network	Poster Session Presentation #972P September 16, 2024
	STELLAR	Lenvatinib (L) and sorafenib (S) in patients (pts) with advanced or unresectable hepatocellular carcinoma (uHCC): an international, multicenter, phase 4 study (STELLAR)	Poster Session Presentation #964P September 16, 2024

Eribulin			
Breast Cancer	JBCRG-M06/ EMERALD	Quality-of-life outcomes in patients with HER2-positive, locally advanced or metastatic breast cancer treated with eribulin mesylate in combination with trastuzumab and pertuzumab in the phase 3 JBCRG-M06/EMERALD study	Poster Session Presentation #373P September 16, 2024
Pipeline			
Endometrial Carcinoma	E7386	Global, phase 1b dose-expansion cohort of E7386 + lenvatinib (LEN) in patients (pts) with advanced (a) endometrial cancer (EC) that progressed on platinum-based chemotherapy (CTx) and an anti-PD-(L)1 immunotherapy (IO)	Poster Session Presentation #738P September 14, 2024
Breast Cancer	BB-1701	An open-label, multicenter, phase 2 study to evaluate the safety and efficacy of BB-1701, a novel antibody drug conjugate (ADC) targeting HER2, in previously treated patients (pts) with HER2+ or HER2-low unresectable or metastatic (M) breast cancer (BC)	Poster Session Presentation #437TiP September 16, 2024
Non-Small Cell Lung Cancer	BB-1701	A phase 2 study to evaluate the efficacy and safety of BB-1701 in advanced or metastatic NSCLC patients with HER2 mutation/amplification (Presented by Bliss Biopharmaceutical Co., Ltd.)	Poster Session Presentation #1296P September 14, 2024

In March 2018, Eisai and Merck & Co., Inc., Rahway, NJ, USA (known as MSD outside of 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 anti-PD-1 therapy from Merck & Co., Inc., Rahway, NJ, USA, pembrolizumab. Eisai and Merck & Co., Inc., Rahway, 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 May 2023, Eisai entered into a joint clinical trial collaboration agreement with Bliss Biopharmaceutical (Hangzhou) Co., Ltd. (Headquarters: Zhejiang Province, China, “BlissBio”), for BB-1701, a HER2-targeting antibody drug conjugate (ADC), with option rights for a strategic collaboration. Eisai is currently investigating BB-1701 in a Phase 2 clinical trial in Japan and the United States for breast cancer, and BlissBio is investigating a Phase 1/2 clinical trial in the United States and China for HER2-expressing solid tumors.

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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.

*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 TiP (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.

*4 The majority of participants in the Phase 3 LEAP-012 trial had intermediate stage HCC per Barcelona Clinic Liver Cancer (BCLC) staging, however, the study also enrolled participants with other BCLC stages.