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Eisai Co., Ltd.

Eisai Presents New Data From its Oncology Portfolio and Pipeline at ESMO Congress 2022

Late-Breaking Presentation on the Phase 3 LEAP-002 Study Investigating the Lenvatinib plus Pembrolizumab Combination Versus Lenvatinib Monotherapy in Patients With Unresectable Hepatocellular Carcinoma

Two Mini-Oral Presentations on the Pivotal Phase 3 CLEAR and Study 309/KEYNOTE-775 Trials Demonstrate the Clinical Benefit of Lenvatinib plus Pembrolizumab and the Combination's Potential Across Difficult-to-Treat Cancers

Post-Hoc Analysis of Three Pivotal Phase 3 Studies on Eribulin's Efficacy in Newly-Defined HER2-low Metastatic Breast Cancer Showcases Eisai's Commitment to Advancing Understanding of Our Medicines

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 2022, which is taking place virtually and in-person in Paris, France from September 9 to 13.

A late-breaking oral presentation of detailed results from the LEAP (**L**envatinib **A**nd **P**embrolizumab) clinical program including the final analysis of the Phase 3 LEAP-002 trial will be featured in a Proffered Paper session ([NCT03713593](#); Presentation: #LBA34). The study evaluated the combination of lenvatinib plus anti-PD-1 antibody pembrolizumab from Merck & Co., Inc., Rahway, NJ, USA versus lenvatinib monotherapy as a first-line treatment for patients with unresectable hepatocellular carcinoma. Additionally, two mini-oral presentations will feature updated efficacy and safety data from the pivotal Phase 3 CLEAR (Study 307)/KEYNOTE-581 trial evaluating the combination in patients with advanced renal cell carcinoma ([NCT02811861](#); Presentation: #1449MO) and Phase 3 Study 309/KEYNOTE-775 trial evaluating the combination in patients with advanced endometrial carcinoma ([NCT03517449](#); Presentation: #525MO).

In addition, a new post-hoc analysis of three pivotal Phase 3 studies (Study 301/[NCT00337103](#), Study 304/[NCT02225470](#) and the EMBRACE trial/Study 305/[NCT00388726](#)) evaluating the efficacy of eribulin (HALAVEN[®]) versus other chemotherapies (capecitabine, vinorelbine and Treatment of Physician's Choice [TPC], respectively) in patients living with metastatic breast cancer whose tumors have low or no HER2-expression will be presented during a poster session (Presentation: #259P).

"We look forward to presenting data at ESMO, showcasing Eisai's latest research on both lenvatinib and eribulin, with the goal of continuing to help people living with various types of cancer," said Dr. Takashi Owa, Chief Scientific Officer, Deep Human Biology Learning, Senior Vice President, Eisai Co., Ltd.

“Presentations on the LEAP clinical program as well as new analyses for eribulin reinforce our commitment to the ongoing research of our portfolio in an effort to better serve patients and healthcare providers.”

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 pembrolizumab. To date, more than 15 trials have been initiated under the LEAP clinical program, which is evaluating the combination across multiple tumor types.

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 are available. All late-breaking abstracts will be made available Thursday, September 8, 2022, at 12:05 AM CEST.

Cancer Type	Study	Abstract Title	Abstract Type & Details
LEAP clinical program			
Gastrointestinal Cancers	LEAP-002	Primary results from the phase 3 LEAP-002 study: lenvatinib plus pembrolizumab versus lenvatinib as first-line (1L) therapy for advanced hepatocellular carcinoma (aHCC)	<u>Proffered Paper Session</u> Presentation #LBA34 September 10, 2022 8:30-8:40 AM CEST Richard S. Finn, MD Geffen School of Medicine, University of California, Los Angeles
	LEAP-015	First-line lenvatinib (Len) + pembrolizumab (pembro) + chemotherapy vs. chemo in advanced/metastatic gastroesophageal adenocarcinoma: LEAP-015 safety run-in	<u>Poster Session</u> Presentation #1223P September 12, 2022 12:00-12:20 PM CEST Kohei Shitara, MD National Cancer Center Hospital East, Kashiwa, Japan

Genitourinary Cancer	CLEAR (Study 307)/ KEYNOTE-581	Updated efficacy of lenvatinib (LEN) + pembrolizumab (PEMBRO) vs sunitinib (SUN) in patients (pts) with advanced renal cell carcinoma (aRCC) in the CLEAR study	<u>Mini Oral Session</u> Presentation #1449MO September 11, 2022 2:45-2:55 PM CEST Camillo G. Porta, MD Interdisciplinary Department of Medicine, University of Bari
Gynecologic Cancer	Study 309/ KEYNOTE-775	Updated efficacy and safety of lenvatinib (LEN) + pembrolizumab (pembro) vs treatment of physician's choice (TPC) in patients (pts) with advanced endometrial cancer (aEC): Study 309/KEYNOTE-775	<u>Mini Oral Session</u> Presentation #525MO September 11, 2022 4:30-4:35 PM CEST Vicky Makker, MD Medical Oncology, Memorial Sloan Kettering Cancer Center
Eribulin			
Breast Cancer	Study 301, Study 304 and EMBRACE trial/Study 305	Efficacy of eribulin mesylate in HER2-low metastatic breast cancer (MBC): results from three phase 3 studies	<u>Poster Session</u> Presentation #259P September 10, 2022 11:20-11:40 AM CEST Peter A. Kaufman, MD Division of Hematology and Oncology, University of Vermont Cancer Center

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

[Notes to editors]

1. Eisai's Focus on Cancer

Eisai focuses on the development of anticancer drugs, targeting the tumor microenvironment (with experience and knowledge from existing in-house discovered compounds) and the driver gene mutation and aberrant splicing (leveraging RNA Splicing Platform) as areas (*Ricchi*) where real patient needs are still unmet, and where Eisai can aim to become a frontrunner in oncology. Eisai aspires to discover innovative new drugs with new targets and mechanisms of action from these *Ricchi*, with the aim of contributing to the cure of cancers.

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