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Eisai Co., Ltd.

## **EISAI AIMS TO ADVANCE GASTROINTESTINAL CANCER TREATMENT WITH RESEARCH ACROSS MULTIPLE TUMOR TYPES AT ASCO GI 2023**

***Highlights Include an Update from the Dose Escalation Part of a Phase 1 Study Evaluating the Novel Anticancer Agent, E7386, in Advanced Solid Tumors Including Colorectal Cancer***

***Research from the LEAP (LEnvatinib And Pembrolizumab) Clinical Program May Provide New Information About Treating Patients with Unresectable Hepatocellular Carcinoma***

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the presentation of research across various types of gastrointestinal cancers during the 2023 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium (#GI23), which is taking place in-person in San Francisco, California and virtually from January 19-21.

Notable data include an update from the dose-escalation part of a Phase 1 Study evaluating E7386<sup>1</sup>, a CREB-binding protein (CBP) /  $\beta$ -catenin interaction inhibitor, in patients with advanced solid tumors including colorectal cancer ([NCT03833700](#); Abstract: #106). Based on these additional analyses, further investigation of safety, preliminary efficacy, pharmacokinetics and biomarker analyses of E7386 is ongoing using two dose levels in the expansion part.

Research from the LEAP (LEnvatinib And Pembrolizumab) clinical program includes a poster presentation featuring a health-related quality of life analysis from the Phase 3 LEAP-002 trial investigating the lenvatinib (LENVIMA<sup>®</sup>) plus pembrolizumab (KEYTRUDA<sup>®2</sup>) combination versus lenvatinib plus placebo as a first-line treatment for patients with unresectable hepatocellular carcinoma ([NCT03713593](#); Abstract: #506). Additional presentations on Eisai's oncology pipeline showcase Eisai's investigational compound, E7389-LF, a new liposomal formulation of eribulin, in combination with nivolumab in patients with solid tumors. Efficacy and safety were evaluated in expansion cohorts, including an esophageal cancer cohort ([NCT04078295](#); Abstract: #337) and a gastric cancer cohort ([NCT04078295](#); Abstract: #339).

"We are eager to share new data at the annual symposium where specialists in gastrointestinal cancers gather from all over the world, including findings from a Phase 1 study evaluating the novel investigational anticancer agent, E7386, in advanced solid tumors including colorectal cancer," said Dr. Takashi Owa, Chief Scientific Officer, Senior Vice President, Eisai Co., Ltd. "Our findings across colorectal, esophageal, gastric and liver cancer illustrate Eisai's commitment to further oncology research for people living with gastrointestinal cancers, who account for over one quarter of the global cancer incidence<sup>1</sup>."

In March 2018, Eisai and Merck (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 Merck's anti-PD-1 therapy pembrolizumab. To

date, more than 10 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. The majority of abstracts are currently available on the ASCO website. The late-breaking abstracts will be released at the time of presentation during the symposium.

<b>Cancer Type</b>	<b>Study/Compound</b>	<b>Abstract Title</b>	<b>Abstract Type &amp; Details (Pacific Standard Time)</b>
<b>Pipeline</b>			
Solid Tumors	E7386	A phase 1 study of E7386, a CREB-binding protein (CBP)/ $\beta$ -catenin interaction inhibitor, in patients (pts) with advanced solid tumors including colorectal cancer: updated dose-escalation part	<u>Poster Presentation</u> Abstract #106 January 21, 2023 6:30-7:55 AM
	E7389-LF	Gastric cancer (GC) cohort of a phase 2 trial of E7389-LF (liposomal formulation of eribulin) in combination with nivolumab	<u>Poster Presentation</u> Abstract #339 January 19, 2023 12:00-1:30 PM
	E7389-LF	The esophageal cancer cohort of a phase 2 trial of E7389-LF (liposomal formulation of eribulin) + nivolumab	<u>Poster Presentation</u> Abstract #337 January 19, 2023 12:00-1:30 PM
<b>LEAP clinical program</b>			
Gastrointestinal Cancers	LEAP-015	First-line lenvatinib plus pembrolizumab plus chemotherapy versus chemotherapy in advanced/metastatic gastroesophageal adenocarcinoma: (LEAP-015): Safety run-in results (Encore presentation)	<u>Poster Presentation</u> Abstract #411 January 19, 2023 12:00-1:30 PM
	LEAP-002	Health-related quality of life (HRQoL) impact of lenvatinib (len) plus pembrolizumab (pembro) versus len plus placebo (pbo) as first-line (1L) therapy for advanced hepatocellular carcinoma (aHCC): Phase 3 LEAP-002 study	<u>Poster Presentation</u> Abstract #506 January 20, 2023 12:00-1:30 PM
<b>Real World Evidence</b>			
Gastrointestinal Cancer	Real-world data	Prevalence of historical medical conditions or comorbidities with potential role in clinical decision making related to suitability of immuno-oncologic plus IV antiangiogenic therapy in newly diagnosed first-line unresectable hepatocellular carcinoma in the United States	<u>Poster Presentation</u> Presentation #511 January 20, 2023 12:00-1:30 PM

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**[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.

\*1 E7386 is created through collaboration research between Eisai and PRISM BioLab Co., Ltd. (Headquarters: Kanagawa)

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

1. Melina A. et al. Global Burden of 5 Major Types of Gastrointestinal Cancer. *Gastroenterology*. 2020 July; 159(1): 335-349. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8630546/pdf/nihms-1758791.pdf>

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