No.23-37

May 24, 2023
Eisai Co., Ltd.

EISAI DELIVERS NEW DATA AND HIGHLIGHTS CONTINUED PROGRESS OF ONCOLOGY PORTFOLIO AND PIPELINE AT ASCO 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 2023 American Society of Clinical Oncology (ASCO) Annual Meeting (#ASCO23), which is taking place virtually and in-person in Chicago, Illinois from June 2 to 6.

Notable research includes an oral presentation of results from the final pre-specified overall survival analysis of the pivotal Phase 3 CLEAR (Study 307)/KEYNOTE-581 trial, which evaluated lenvatinib (LENVIMA®) plus pembrolizumab (KEYTRUDA®) versus sunitinib for the first-line treatment of patients with advanced renal cell carcinoma (Abstract #4502). A post hoc analysis from the REFLECT trial evaluating lenvatinib monotherapy versus sorafenib in the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC) will also be shared in a poster presentation (Abstract #4078).

"The outlook for advanced renal cell carcinoma has evolved in recent years, and the final analysis from the pivotal CLEAR trial to be presented at ASCO represents another step forward for patients and an opportunity to provide their physicians with long-term data," said Dr. Takashi Owa, Chief Scientific Officer, Senior Vice President, Eisai Co., Ltd. "New data for lenvatinib and from our oncology pipeline showcase Eisai's continued commitment to driving innovation and exploring novel therapeutic modalities in our ambition to live out our *human health care* concept, our corporate mission to meet the needs of more people who face a cancer diagnosis."

Additional data from Eisai's pipeline include a poster presentation of findings from a phase 1b study of E7386, a CREB-binding protein (CBP) / β-catenin interaction inhibitor, in combination with lenvatinib in patients with advanced HCC (Abstract #4075), and the small cell lung cancer cohort of a phase 1b/2 trial evaluating E7389-LF, a new liposomal formulation of eribulin, in combination with nivolumab (Abstract #8593). Insights from preclinical testing of farletuzumab ecteribulin (FZEC), formerly known as MORAb-202, and MORAb-109, antibody drug conjugates (ADC), in rare gynecologic cancers will also be published online (Abstract # e17634).

Furthermore, Bliss Biopharmaceutical Co., Ltd. (BlissBio) will present a poster at the conference with results from the first-in-human study of BB-1701, a HER2-targeting ADC (Abstract #3029). Eisai entered into a joint development agreement with BlissBio for BB-1701 with option rights for a strategic collaboration in April 2023. A Phase 1/2 clinical study of BB-1701 in the U.S. and China for HER2-expressing solid tumors is currently underway.

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 on Thursday, May 25, 2023 at 4:00 PM Central Daylight Time (CDT).

Cancer Type	Study/Compound	Abstract Title	Abstract Type & Details
Lenvatinib Plus Pembrolizumab			
Genitourinary Cancer	CLEAR	Final prespecified overall survival (OS) analysis of CLEAR: 4-year follow-up of lenvatinib plus pembrolizumab (L+P) vs sunitinib (S) in patients (pts) with advanced renal cell carcinoma (aRCC)	Oral Abstract Session Abstract #4502 June 5, 2023 11:54 AM CDT
Lenvatinib			
Gastrointestinal Cancer	REFLECT	Efficacy of lenvatinib (LEN) vs sorafenib (SOR) in the first-line (1L) treatment of patients (pts) with unresectable hepatocellular carcinoma (uHCC): A post hoc analysis of patients with nonviral etiology from REFLECT	Poster Session Abstract #4078 June 5, 2023 8:00 AM CDT
Pipeline			
Lung Cancer	E7389-LF	Phase 2 small cell lung cancer (SCLC) cohort of a phase 1b/2 trial of a liposomal formulation of eribulin in combination with nivolumab	Poster Session Abstract #8593 June 4, 2023 8:00 AM CDT
Gastrointestinal Cancers	E7386 (plus lenvatinib)	A phase 1b study of E7386, a CREB-binding protein (CBP)/β-catenin interaction inhibitor, in combination with lenvatinib in patients with advanced hepatocellular carcinoma	Poster Session Abstract #4075 June 5, 2023 8:00 AM CDT
Gynecologic Cancer	Farletuzumab Ecteribulin (FZEC)	Preclinical testing of farletuzumab ecteribulin (FZEC [MORAb-202]) and MORAb-109, folate receptor α and mesothelin targeting antibody-drug conjugates (ADCs), in rare gynecologic cancers	Online Publication Abstract #e17634 May 25, 2023 4:00 PM CDT
Solid tumors	BB-1701 (Presented by BlissBio)	A first-in-human, open label, multiple dose, dose escalation, and cohort expansion phase 1 study to investigate the safety, tolerability, pharmacokinetics and antitumor activity of BB-1701 in patients with locally advanced/metastatic HER2-expressing solid tumors	Poster Session Abstract #3029 June 3, 2023 8:00 AM CDT
Additional Research			
Pan-tumor	Systematic review	Anti-drug antibodies related to CTLA-4, PD-1 or PD-L1 inhibitors across tumour types: A systematic review	Online Publication Abstract #e14600 May 25, 2023 4:00 PM CDT

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 Merck's anti-PD-1 therapy pembrolizumab. Eisai and Merck are studying the LENVIMA plus KEYTRUDA combination through the LEAP (**LE**nvatinib **A**nd **P**embrolizumab) clinical program in various tumor types across more than 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 farletuzumab ecteribulin (FZEC, formerly known as MORAb-202), a folate receptor alpha (FRα)-targeting ADC. Eisai and Bristol Myers Squibb are currently investigating FZEC in multiple studies including: a Phase 1/2 clinical study in the United States and Europe for solid tumors including endometrial cancer, a Phase 2 clinical study in the United States and Europe for non-small cell lung cancer, and a Phase 2 clinical study in Japan, the United States and Europe for ovarian cancer, peritoneal cancer and fallopian tube cancer.

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

[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.

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