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Eisai Co., Ltd.

EISAI SHOWCASES ONCOLOGY PORTFOLIO AND PIPELINE AT ASCO 2024

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the presentation of research across multiple types of cancer from its oncology portfolio and pipeline during the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting (#ASCO24), which is taking place virtually and in-person in Chicago, Illinois from May 31 to June 4.

Notable data includes an oral presentation on biomarker analyses from the pivotal Phase 3 CLEAR (Study 307)/KEYNOTE-581 trial (NCT02811861), which evaluated lenvatinib (LENVIMA®) plus pembrolizumab (KEYTRUDA®) versus sunitinib for the first-line treatment of patients with advanced renal cell carcinoma (Abstract #4504). An analysis of patterns of disease progression and subsequent therapy from this trial will also be presented in a poster presentation (Abstract #4524).

"At Eisai, we let the science drive us to new approaches that accelerate progress in oncology, while also remaining grounded in our *human health care* concept that reinforces our commitment to prioritize the needs of patients and families impacted by a cancer diagnosis," said Dr. Takashi Owa, Chief Scientific Officer, Senior Vice President, Eisai Co., Ltd. "With this in mind, we look forward to sharing research that provides further insight into the role of lenvatinib plus pembrolizumab as a first-line standard of care option in advanced renal cell carcinoma, as well as research that explores various modalities in our pipeline for the potential treatment of advanced diseases with the goal of improving patients' lives."

Other key research of note from Eisai's pipeline include an oral presentation of Phase 3 data from the JBCRG-M06/EMERALD study in Japan evaluating trastuzumab and pertuzumab in combination with Eisai's eribulin mesylate or a taxane in patients with HER2-positive, locally advanced or metastatic breast cancer (NCT03264547; Abstract #1007). Additional pipeline research to be presented in poster sessions include an overview of a Phase 2 study of BB-1701, an antibody drug conjugate targeting HER2, in previously treated patients with HER2-positive or HER2-low unresectable or metastatic breast cancer (NCT06188559; Abstract #TPS1122), findings from a Phase 1b trial of tasurgratinib (development code: E7090) with or without endocrine therapies for patients with ER-positive, HER2−negative recurrent/metastatic breast cancer after receiving a CDK4/6 inhibitor (NCT04572295; Abstract #3103), as well as the dose-expansion part of a Phase 1b global study of E7386 in combination with lenvatinib in patients with hepatocellular carcinoma and other solid tumors including endometrial cancer (NCT04008797; Abstract #TPS3169).

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. These abstracts will be made available via the ASCO website on Thursday, May 23, 2024 at 4:00 PM Central Daylight Time (CDT).

Cancer Type	Study/Compound	Abstract Title	Abstract Type & Details
Lenvatinib Plus Pembrolizumab			
Genitourinary Cancer	CLEAR	Biomarker analyses in patients with advanced renal cell carcinoma (aRCC) from the phase 3 CLEAR trial	Oral Abstract Session Abstract #4504 June 3, 2024 9:00 AM CDT
Genitourinary Cancer	CLEAR	Lenvatinib plus pembrolizumab (L+P) vs sunitinib (S) in advanced renal cell carcinoma (aRCC): Patterns of progression and subsequent therapy in the CLEAR trial	Poster Session Abstract #4524 June 2, 2024 9:00 AM CDT
Melanoma	LEAP-004	Lenvatinib (len) plus pembrolizumab (pembro) in patients with advanced melanoma that progressed on anti-PD-(L)1 therapy: Over 4 years of follow-up from the phase 2 LEAP-004 study	Poster Session Abstract #9559 June 1, 2024 1:30 PM CDT
Lenvatinib			
Differentiated Thyroid Cancer	Real-World Evidence	Patients with radioiodine-refractory differentiated thyroid cancer (RAI-R DTC) with BRAF V600E and/or K601E Mutation Status – A real-world view of effectiveness of lenvatinib monotherapy	Poster Session Abstract #6098 June 2, 2024 9:00 AM CDT
Gastrointestinal Cancer	REFLECT	ctDNA analysis of patients (pts) with unresectable hepatocellular carcinoma (uHCC) treated with lenvatinib (LEN) or sorafenib (SOR) as 1L therapy	Poster Session Abstract #4094 June 1, 2024 1:30 PM CDT
Eribulin			
Breast Cancer	JBCRG-M06/ EMERALD	Trastuzumab and pertuzumab in combination with eribulin mesylate or a taxane as first-line chemotherapeutic treatment for HER2-positive, locally advanced or metastatic breast cancer: results of a multicenter, randomized, non-inferiority phase 3 trial in Japan (JBCRG-M06/EMERALD)	Oral Abstract Session Abstract #1007 June 1, 2024 5:00 PM CDT
Pipeline			
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 human epidermal growth factor receptor 2 (HER2), in previously treated patients with HER2-positive (HER2+) or HER2-low unresectable or metastatic breast cancer (BC)	Poster Session Abstract #TPS1122 June 2, 2024 9:00 AM CDT
	tasurgratinib	Phase Ib trial of tasurgratinib (E7090) with or without endocrine therapies for patients (pts) with ER+, HER2− recurrent/metastatic breast cancer (BC) after receiving a CDK4/6 inhibitor	Poster Session Abstract #3103 June 1, 2024 9:00 AM CDT
	H3B-6545	H3B-6545 in women with locally advanced/metastatic estrogen receptor-positive (ER+), HER2 negative (-) breast cancer (BC)	Rapid Oral Session Abstract #1015 June 3, 2024 11:30 AM CDT

	H3B-6545	H3B-6545 + palbociclib in patients (pts) with locally advanced/metastatic estrogen receptor-positive (ER+), HER2 negative (-) breast cancer (BC)	Poster Session Abstract #1051 June 2, 2024 9:00 AM CDT
Solid tumors	E7386	Dose-expansion part of a phase 1b global study of E7386 in combination with lenvatinib (LEN) in patients (pts) with hepatocellular carcinoma (HCC) and other solid tumors including endometrial cancer (EC)	Poster Session Abstract #TPS3169 June 1, 2024 9:00 AM 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 lenvatinib plus pembrolizumab combination through the LEAP (**LE**nvatinib **A**nd **P**embrolizumab) clinical program in various tumor types across more than multiple clinical trials.

In May 2023, Eisai entered into a joint development 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 and BlissBio are currently investigating BB-1701 in a Phase 2 clinical trial in Japan and the United States for breast cancer and 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 TPS (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.

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