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Eisai Co., Ltd.

Eisai Furthers Oncology Research Across Multiple Cancers at ASCO GI and ASCO GU 2024

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the presentation of oncology research at two upcoming medical meetings taking place in-person in San Francisco, California and virtually. First, the company will share findings in hepatocellular carcinoma (HCC) and cholangiocarcinoma during the 2024 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium (#GI24), which is taking place from January 18-20. Eisai will also present research results in renal cell carcinoma (RCC) during the 2024 ASCO Genitourinary Cancers Symposium (#GU24), which is taking place from January 25-27.

Key Data from Eisai's Pipeline and Portfolio to be Presented at ASCO GI 2024

Notable findings from Eisai's pipeline include results from a single-arm Phase 2 trial evaluating tasurgratinib (formerly E7090) as a treatment for patients with fibroblast growth factor receptor 2 (*FGFR2*) gene fusion positive cholangiocarcinoma (NCT04238715; Abstract: #471). Tasurgratinib, for which a marketing authorization application was submitted in Japan in December 2023, is an orally available selective tyrosine kinase inhibitor of FGFR1-3. An analysis of tumor biomarkers in patients with advanced HCC from a Phase 1b study of E7386[*1], a CREB-binding protein (CBP) / β-catenin interaction inhibitor, in combination with lenvatinib, will also be presented (NCT04008797; Abstract: #535).

Additional data from the LEAP (LEnvatinib And Pembrolizumab) clinical program include longer term efficacy and safety results from the Phase 3 LEAP-002 trial, which evaluated lenvatinib (LENVIMA®), the orally available multiple receptor tyrosine kinase inhibitor (TKI) discovered by Eisai, plus pembrolizumab (KEYTRUDA®[*2]), the anti-PD-1 therapy from Merck & Co., Inc., Rahway, NJ, USA, versus lenvatinib monotherapy as a first-line treatment for patients with unresectable HCC (NCT03713593; Abstract: #482).

The list of notable ASCO GI 2024 presentations is included below. These abstracts will be made available via the ASCO website on Tuesday, January 16, 2024, at 2:00 PM PST.

ASCO GI 2024			
Cancer Type	**Study/Compound**	**Abstract Title**	**Abstract Type & Details (Pacific Standard Time)**
Pipeline			
Gastrointestinal Cancer	E7090	Pivotal single-arm, phase 2 trial of tasurgratinib for patients with fibroblast growth factor receptor-2 gene fusion-positive cholangiocarcinoma	Poster Session Abstract #471 January 19, 2024 12:30-2:00 PM

Gastrointestinal Cancer	E7386	Analysis of tumor biomarkers in patients with advanced hepatocellular carcinoma from a phase 1b study of E7386, a CREB-binding protein/β-catenin interaction inhibitor, in combination with lenvatinib	Poster Session Abstract #535 January 19, 2024 12:30-2:00 PM
Lenvatinib Plus Pembrolizumab			
Gastrointestinal Cancer	LEAP-002	Lenvatinib plus pembrolizumab versus lenvatinib alone as first-line therapy for advanced hepatocellular carcinoma: longer-term efficacy and safety results from the phase 3 LEAP-002 study	Poster Session Abstract #482 January 19, 2024 12:30-2:00 PM

Key Data from Eisai's Pipeline and Portfolio to be Presented at ASCO GU 2024

Subgroup analyses from the pivotal Phase 3 CLEAR (Study 307)/KEYNOTE-581 trial, which evaluated lenvatinib plus pembrolizumab versus sunitinib for the first-line treatment of patients with advanced renal cell carcinoma (aRCC), will be featured in a rapid oral abstract session (NCT02811861; Abstract: #364) and a network meta-analysis to assess the efficacy of lenvatinib plus pembrolizumab compared with other first-line treatment options for patients with aRCC will also be presented in a poster session (Abstract: #482). Extended follow-up results from the Phase 2 KEYNOTE-B61 trial evaluating the combination as a first-line treatment for patients with non-clear cell RCC will be shared in a poster presentation (NCT04704219; Abstract: #2) by Merck & Co., Inc., Rahway, NJ, USA. Finally, a poster featuring real-world evidence on the use of lenvatinib plus everolimus in previously treated patients with aRCC (Abstract: #437) will also be presented.

The list of notable ASCO GU 2024 presentations is included below. These abstracts will be made available via the ASCO website on Monday, January 22, 2024, at 2:00 PM PST.

ASCO GU 2024			
Cancer Type	**Study/Compound**	**Abstract Title**	**Abstract Type & Details (Pacific Standard Time)**
Lenvatinib Plus Pembrolizumab			
Genitourinary Cancer	CLEAR	Subgroup analyses of efficacy outcomes by baseline tumor size in the phase 3, open-label CLEAR trial	Rapid Oral Abstract Session Abstract #364 January 27, 2024 1:00-2:15 PM
Genitourinary Cancer	Network Meta-Analysis	Network meta-analysis to assess comparative efficacy of lenvatinib plus pembrolizumab compared with other first-line treatments for management of advanced renal cell carcinoma	Poster Session Abstract #482 January 27, 2024 7:00 AM
Genitourinary Cancer	KEYNOTE-B61	First-line pembrolizumab plus lenvatinib for non-clear cell renal carcinomas: Extended follow-up of the Phase 2 KEYNOTE-B61 Study (Presented by Merck & Co., Inc., Rahway, NJ, USA)	Poster Session Abstract #2 January 27, 2024 7:00 AM

Lenvatinib Plus Everolimus			
Genitourinary Cancer	Real World Evidence	Lenvatinib plus everolimus in patients with pre-treated advanced renal cell carcinoma: Real world evidence	Poster Session Abstract #437 January 27, 2024 7:00AM

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 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.

This release discusses investigational compounds and investigational uses for Food and Drug Administration (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.

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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 "microenvironment", "proteostasis disruption", "cell lineage 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 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.

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