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Eisai Co., Ltd.

EISAI CONTRIBUTES TO THE SCIENCE OF CANCER MEDICINE AT ASCO 2022

Data on Farletuzumab Ecteribulin (MORAb-202) Showcase Eisai's Advanced Chemistry Capabilities and Commitment to Identifying Novel Approaches in Treating Cancer to Improve Outcomes for Patients

Presentations Featuring Post-Hoc Analyses from the LEAP (LEnvatinib And Pembrolizumab) Clinical Program May Provide New Information About Treating Patients with Advanced Renal Cell Carcinoma and Advanced Endometrial Carcinoma

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today the presentation of research across various types of cancer from its oncology portfolio during the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting (#ASCO22), which is taking place virtually and in-person in Chicago from June 3 to 7. Notable presentations include a poster discussion of safety and efficacy data (NCT03386942; Abstract: #5513) from the platinum-resistant ovarian cancer cohort expansion of a Phase 1 study evaluating the antibody drug conjugate (ADC) co-developed by Eisai and Bristol Myers Squibb (Headquarters: the United States), farletuzumab ecteribulin (MORAb-202), as well as a poster presentation featuring dose optimization findings for farletuzumab ecteribulin (NCT03386942; Abstract: #3090).

"Safety and efficacy analyses in platinum-resistant ovarian cancer for farletuzumab ecteribulin suggest antibody drug conjugates may represent a promising therapeutic strategy for these patients with limited treatment options," said Dr. Takashi Owa, President, Oncology Business Group at Eisai. "Eisai's first antibody drug conjugate combines our in-house developed anti-folate receptor alpha antibody and our anticancer agent eribulin using an enzyme cleavable linker, illustrating our dedication to building on our medicines to improve cancer care for more patients."

New research from the LEAP (LEnvatinib And Pembrolizumab) clinical program evaluating lenvatinib (LENVIMA®) plus pembrolizumab (KEYTRUDA®), the anti-PD-1 therapy from Merck & Co., Inc., Rahway, NJ, USA, includes subgroup analyses from the pivotal Phase 3 CLEAR (Study 307)/KEYNOTE-581 trial evaluating the combination in patients with advanced renal cell carcinoma (RCC) and Phase 3 Study 309/KEYNOTE-775 trial evaluating the combination in patients with advanced endometrial carcinoma (EC). A poster discussion will evaluate the impact of subsequent therapies in patients with advanced RCC receiving the combination (NCT02811861; Abstract: #4514); while a poster presentation will discuss the efficacy of next line therapy after treatment with lenvatinib plus pembrolizumab in advanced EC (NCT03517449; Abstract: #5587).

"The combination of lenvatinib plus pembrolizumab has helped to expand physicians' arsenal of treatment options for patients living with advanced renal cell carcinoma and advanced endometrial carcinoma around the world," said Richard C. Woodman, MD, Chief Clinical Officer, Oncology Business Group at Eisai. "Our data at ASCO 2022 demonstrate our commitment to continuing to investigate the combination through post-hoc analyses with the goal of providing healthcare professionals with tools to support them in making

better-informed treatment decisions for their patients."

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 20 trials have been initiated under the LEAP clinical program, which is evaluating the combination across more than 10 different tumor types.

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, a folate receptor alpha (FRα)-targeting ADC. Eisai and Bristol Myers Squibb are currently investigating farletuzumab ecteribulin in FRα-positive solid tumors (inclusive of endometrial, ovarian, lung and breast cancers) in two studies: a Phase 1 clinical study in Japan and a Phase 1/2 clinical study in the United States.

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 have been made available on Thursday, May 26, 2022, at 5:00 PM EDT and will be available on demand via ASCO's website.

Cancer Type	**Study/Compound**	**Abstract Title**	**Abstract Type & Details**
Pipeline			
Gynecologic Cancer	Farletuzumab Ecteribulin	Safety and Efficacy of MORAb-202 in Patients (pts) With Platinum-Resistant Ovarian Cancer (PROC): Results From the Expansion Part of a Phase 1 Trial.	<u>Poster Discussion</u> Abstract #5513 **June 4, 2022** 5:30 PM EDT Shin Nishio, MD, PhD Kurume University School of Medicine
	Farletuzumab Ecteribulin	Dose Optimization for MORAb-202, an Antibody-Drug Conjugate (ADC) Highly Selective for Folate Receptor-Alpha (FRα), Using Population Pharmacokinetic (PPK) and Exposure-Response (E-R) Efficacy and Safety Analyses.	<u>Poster Presentation</u> Abstract #3090 **June 5, 2022** 9:00 AM EDT Seiichi Hayato Eisai

Lenvatinib Combinations (Plus Pembrolizumab, Pembrolizumab and Chemotherapy or Pembrolizumab and Belzutifan)			
Genitourinary Cancer	CLEAR (Study 307)/ KEYNOTE-581	Impact of subsequent therapies in patients (pts) with advanced renal cell carcinoma (aRCC) receiving lenvatinib plus pembrolizumab (LEN + PEMBRO) or sunitinib (SUN) in the CLEAR study	Poster Discussion Abstract #4514 **June 4, 2022** 5:42 PM EDT Martin H. Voss, MD Memorial Sloan Kettering Cancer Center
Gynecologic Cancer	Study 309/ KEYNOTE-775	Efficacy of next line of therapy after treatment with lenvatinib (LEN) in combination with pembrolizumab (pembro) versus treatment of physician's choice (TPC) in patients (pts) with advanced endometrial cancer (aEC): exploratory analysis of Study 309/KEYNOTE-775	Poster Presentation Abstract #5587 **June 4, 2022** 2:15 PM EDT Vicky Makker, MD Memorial Sloan Kettering Cancer Center
Gastrointestinal Cancers	LEAP-014	First-line lenvatinib plus pembrolizumab plus chemotherapy in esophageal squamous cell carcinoma: LEAP-014 trial in progress	Poster Presentation Abstract #TPS4167 **June 4, 2022** 9:00 AM EDT Jong-Mu Sun, MD Samsung Medical Center, Sungkyunkwan University School of Medicine
	MK-6482-016	Phase 2 Open-label Study of Pembrolizumab Plus Lenvatinib and Belzutifan in Patients With Advanced Solid Tumors	Poster Presentation Abstract #TPS4173 **June 4, 2022** 9:00 AM EDT Robin K. Kelley, MD University of California San Francisco
Lenvatinib			
Gastrointestinal Cancer	REFLECT	Characterization of tumor responses in patients (pts) with unresectable hepatocellular carcinoma (uHCC) treated with lenvatinib in REFLECT	Poster Presentation Abstract #4078 **June 4, 2022** 9:00 AM EDT Masatoshi Kudo, MD Kindai University Faculty of Medicine
Additional Research			
Gynecologic Cancer	ECHO EU Treatment Pattern	Treatment patterns and outcomes among patients with recurrent or advanced endometrial cancer in Europe: Endometrial Cancer Health Outcomes Europe (ECHO EU) Study	Online Publication Abstract #e17627 **May 26, 2022** 5:00 PM EDT Vimalanand S Prabhu, PhD Merck & Co., Inc., Rahway, NJ, USA

Genitourinary Cancer	Translational Research	Exploratory analysis on crosstalk between intra-tumor immunity and FGF/FGFR pathway in clear cell renal cell carcinoma	Online Publication Abstract #e16525 **May 26, 2022** 5:00 PM EDT Takafumi Narisawa, MD Yamagata University Faculty of Medicine

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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.