NEW DATA FROM INVESTIGATIONAL STUDY OF LENVIMA® (LENVATINIB) AND KEYTRUDA® (PEMBROLIZUMAB) COMBINATION IN THREE DIFFERENT TUMOR TYPES PRESENTED AT THE SOCIETY FOR IMMUNOTHERAPY OF CANCER'S 33RD ANNUAL MEETING

First presentation of LENVIMA and KEYTRUDA combination data in patients with metastatic non-small cell lung cancer, metastatic melanoma and metastatic urothelial carcinoma from Study 111/KEYNOTE-146

New data support ongoing broad clinical program for LENVIMA and KEYTRUDA combination across multiple tumor types

Tokyo and Kenilworth, N.J., Nov. 9, 2018 – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Merck & Co., Inc., Kenilworth, N.J., U.S.A. (NYSE: MRK), known as MSD outside the United States and Canada, today announced results from presentations of new data and analyses of LENVIMA® (lenvatinib), an orally available kinase inhibitor discovered by Eisai, in combination with Merck's & Co., Inc., Kenilworth, N.J., U.S.A.'s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in three different tumor types – metastatic non-small cell lung cancer (NSCLC) (Abstract #11147), metastatic melanoma (Abstract #11187) and metastatic urothelial carcinoma (Abstract #11201).

These data from the Study 111/KEYNOTE-146 Phase 1b/2 trial will be presented at the 33rd Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in Washington, D.C. from November 9-11. In the interim analyses of the studies across three tumor types, the LENVIMA and KEYTRUDA combination demonstrated encouraging anti-tumor activity and was generally well tolerated. These data support further evaluation of the combination. LENVIMA and KEYTRUDA are not approved for use in combination in any cancer types today.

"We are increasingly confident that these interim analyses of new clinical trial data on the combination of LENVIMA and KEYTRUDA in non-small cell lung cancer, melanoma and urothelial cancer continue to verify the potential of this combination," said Dr. Takashi Owa, Vice President and Chief Medicine Creation Officer, Oncology Business Group at Eisai. "Through our collaboration with Merck & Co., Inc., Kenilworth, N.J., U.S.A., we are doing our utmost to be able to provide this combination to patients in need of new treatment options as soon as possible."

"These early promising data being presented support the clinical strategy behind our study of KEYTRUDA in combination with LENVIMA across a range of different cancers," said Dr. Jonathan Cheng, Vice President, Oncology Clinical Research, Merck & Co., Inc., Kenilworth, N.J., U.S.A. Research Laboratories. "We look forward to continuing our broad clinical research effort

in collaboration with Eisai to evaluate these two therapies in combination, with the goal of improving treatment outcomes for people living with cancer."

Trial Design and New Data for Study 111/KEYNOTE-146

Study 111/KEYNOTE-146 is a multi-center, open-label, single-arm, Phase 1b/2 basket trial (ClinicalTrials.gov, NCT02501096) evaluating the combination of LENVIMA (20 mg/day) with KEYTRUDA (200 mg intravenously every three weeks) in patients with selected solid tumors (metastatic endometrial cancer, metastatic head and neck cancer, metastatic melanoma, metastatic NSCLC, metastatic renal cell carcinoma and metastatic urothelial carcinoma). Patients were not preselected based on PD-L1 tumor expression status. The primary endpoint of the Phase 1b study was to determine the maximum tolerated dose of LENVIMA and KEYTRUDA in combination. The primary endpoint of the Phase 2 portion is investigator-assessed objective response rate (ORR) at week 24 based on immune-related RECIST (irRECIST). The secondary efficacy endpoints included ORR, progression-free survival (PFS) and duration of response (DOR) for patients with complete or partial responses. Data from Study 111/KEYNOTE-146 are being presented at SITC's 33rd Annual Meeting from the metastatic NSCLC, metastatic melanoma and metastatic urothelial carcinoma cohorts.

Phase 1b/2 trial of lenvatinib in combination with pembrolizumab in patients with NSCLC (Abstract #11147/Poster #P392)

As of data cutoff on March 1, 2018, 21 patients with metastatic NSCLC who either had no prior therapy or had received up to two prior lines of therapy were enrolled in this Phase 2 cohort. The primary endpoint of ORR at week 24 per irRECIST was 33.3% (95% CI: 14.6-57.0). For secondary endpoints, median PFS per irRECIST was 5.9 months (95% CI: 2.3-13.8), and the PFS rate at 12 months per irRECIST was 29.0% (95% CI: 10.2-51.0). Median DOR was 10.9 months (95% CI: 2.4-not estimable). Grade 3 treatment-related adverse events (TRAEs) occurred in 10 patients (48%), and Grade 4 TRAEs occurred in one patient (5%). The most common TRAEs (any grade) ≥30% were decreased appetite (67%), fatigue (62%), hypothyroidism (43%), diarrhea (43%), proteinuria (43%), arthralgia (33%) and hypertension (33%). There was one treatment-related death. The combination of LENVIMA and KEYTRUDA was generally well tolerated and demonstrated promising clinical activity regardless of PD-L1 status, supporting further evaluation of the combination in patients with metastatic NSCLC.

Phase 1b/2 trial of lenvatinib in combination with pembrolizumab in patients with advanced melanoma (Abstract #11187/Poster #P391)

As of March 1, 2018, 21 patients with metastatic melanoma who either had no prior therapy or had received up to two prior lines of therapy were enrolled in this cohort. The primary endpoint of ORR at week 24 per irRECIST was 47.6% (95% CI: 25.7-70.2). For secondary endpoints, median PFS was 5.5 months (95% CI: 2.6-15.8), and the PFS rate at 12 months was 34.7% (95% CI: 14.5-56.0). In addition, median DOR was 12.5 months (95% CI: 2.7-not estimable). All patients experienced at least one TRAE. Grade 3 or 4 TRAEs occurred in 14 patients (67%). The most common TRAEs (any grade) ≥30% were fatigue (52%), decreased appetite (48%), diarrhea (48%), hypertension (48%), dysphonia (43%), nausea (43%), arthralgia (33%) and proteinuria (33%). There were no treatment-related deaths. The LENVIMA and KEYTRUDA combination regimen was generally well tolerated and demonstrated encouraging clinical activity. These data support further evaluation of this regimen in patients with metastatic melanoma.

Phase 1b/2 trial of lenvatinib in combination with pembrolizumab in patients with urothelial cancer (Abstract #11201/Poster #P393)

As of March 1, 2018, 20 patients with metastatic urothelial cancer who either had no prior therapy or had received up to two prior lines of therapy were enrolled in this cohort. The primary endpoint of ORR at week 24 per irRECIST was 25% (95% CI: 9-49). For secondary endpoints, median PFS was 5.4 months (95% CI: 1.3-not estimable). Eighteen patients (90%) experienced TRAEs. Grade 3 or 4 TRAEs occurred in 10 patients (50%). The most common TRAEs (any grade) ≥30% were proteinuria (45%), diarrhea (40%), hypertension (35%), fatigue (30%) and hypothyroidism (30%). There was one treatment-related death. The LENVIMA and KEYTRUDA combination demonstrated encouraging anti-tumor activity, regardless of PD-L1 tumor expression status, and was generally well tolerated. These data support further evaluation of the combination in metastatic urothelial cancer.

Eisai Co., Ltd. Media Relations +81-(0)3-3817-5120 **Eisai Inc. Media Relations** Michele Randazzo: +1-(201) 746-2979 **Eisai Investor Relations** +81-(0)3-3817-3016	**Merck Media Relations** Pamela Eisele: +1-(267) 305-3558 Kristen Drake: +1-(908) 334-4688 **Merck Investor Relations** Teri Loxam: +1-(908) 740-1986 Michael DeCarbo: +1-(908) 740-1807

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About LENVIMA® (lenvatinib mesylate)

Discovered and developed in house by Eisai, LENVIMA is an orally administered kinase inhibitor with a novel binding mode that selectively inhibits the multi activities of vascular endothelial growth factor (VEGF) receptors (VEGFR1, VEGFR2 and VEGFR3) and fibroblast growth factor (FGF) receptors (FGFR1, FGFR2, FGFR3 and FGFR4) in addition to other pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRα; KIT; and RET) involved in tumor angiogenesis, tumor progression and modification of tumor immunity.

Currently, Eisai has obtained approval for LENVIMA as a treatment for refractory thyroid cancer in over 50 countries, including the United States, Japan, in Europe and Asia. Additionally, Eisai has obtained approval for the agent in combination with everolimus as a second-line treatment for renal cell carcinoma in over 45 countries, including the United States and in Europe. In Europe, the agent was launched under the brand name Kisplyx® for renal cell carcinoma.

In addition, LENVIMA has been approved as a treatment for hepatocellular carcinoma in Japan, the United States, Europe, China and other countries. Furthermore, Eisai has submitted applications for an indication covering hepatocellular carcinoma in Taiwan (December 2017) as well as in other countries.

About KEYTRUDA® (pembrolizumab)

KEYTRUDA is an anti-PD-1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

About the Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. Strategic Collaboration

In March 2018, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A., 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 LENVIMA. Under the agreement, the companies will jointly develop and commercialize LENVIMA, both as monotherapy and in combination with Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s anti-PD-1 therapy KEYTRUDA. In addition to ongoing clinical studies of the combination, the companies will jointly initiate new clinical studies evaluating the LENVIMA and KEYTRUDA combination to support 11 potential indications in six types of cancer (bladder cancer, endometrial cancer, head and neck cancer, hepatocellular carcinoma, melanoma and non-small cell lung cancer), as well as a basket trial targeting six additional cancer types. The LENVIMA and KEYTRUDA combination is not approved in any cancer types today.

Glossary of Terms

Progression-Free Survival (PFS): PFS is the objectively confirmed time from the commencement of treatment clinical trial to the date of disease progression, or date of death from any cause, whichever occurs first.

Objective Response Rate (ORR): ORR is the combined proportion of patients whose tumor was eliminated (complete response [CR]) and whose tumor was reduced by over 30% in size (partial response [PR]) during a specified period of time as verified by imaging assessment.

Duration of Response (DOR): The duration of overall response is measured from the time measurement criteria are met for CR or PR (whichever is first recorded) until the first date that disease progression is observed.