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Eisai Co., Ltd. and Merck & Co., Inc., Kenilworth, N.J., U.S.A. Enter Global Strategic Oncology Collaboration for LENVIMA® (lenvatinib mesylate)

Companies to Jointly Develop and Commercialize LENVIMA, as Monotherapy and in Combination with Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s KEYTRUDA® (pembrolizumab) for Multiple Cancer Types

Eisai Books LENVIMA Product Sales and Companies to Share Development and Marketing Costs Equally, as well as Gross Profits From LENVIMA

LENVIMA/KEYTRUDA Combination Already Granted U.S. FDA Breakthrough Therapy Designation for Renal Cell Carcinoma; Expanded Joint Development Program to Support 11 Additional Potential Indications Across Six Other Cancer Types

Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s Strong Commercial Footprint and Medical Expertise, Combined with Eisai's Extensive Real-World Evidence for LENVIMA, Will Expedite Patient Access Worldwide for Current and Future Potential Indications

TOKYO and KENILWORTH, N.J. Mar. 8, 2018 – Eisai Co., Ltd. (Headquarters: Tokyo, Representative Corporate Officer and 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 that the companies have agreed upon a strategic collaboration for the worldwide co-development and co-commercialization of LENVIMA® (lenvatinib mesylate), an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. will develop and commercialize LENVIMA jointly, both as monotherapy and in combination with Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab).

Eisai will book LENVIMA product sales globally, as monotherapy and in combination, and Merck & Co., Inc., Kenilworth, N.J., U.S.A. and Eisai will share gross profits equally. LENVIMA is currently approved as monotherapy for use in the treatment of thyroid cancer, as well as in combination with everolimus for the treatment of patients with renal cell carcinoma (RCC) who have failed previous therapy. Applications for regulatory approval of LENVIMA monotherapy for

the treatment of hepatocellular carcinoma have been submitted in Japan, the United States, Europe, China and other countries.

A Phase 3 study (Study 307), sponsored by Eisai, is ongoing to evaluate separate combinations of LENVIMA with KEYTRUDA (pembrolizumab) or LENVIMA with everolimus versus chemotherapy alone for the treatment of RCC. In January 2018, the companies announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for the LENVIMA/KEYTRUDA combination in advanced and/or metastatic RCC. This was based on interim results from an ongoing Phase 1b/2 trial (Study 111/KEYNOTE-146), evaluating the combination in select solid tumors (including RCC and endometrial cancer), which provided evidence for synergistic effects on the observed overall response rate, regardless of treatment experience or PD-L1 tumor expression.

Per the agreement, the companies will also jointly initiate new clinical studies evaluating the LENVIMA/KEYTRUDA combination to support 11 potential indications in six types of cancer (endometrial cancer, non-small cell lung cancer, hepatocellular carcinoma, head and neck cancer, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types.

“Aiming to maximize the potential of LENVIMA and expedite the creation of innovative treatments in this age of "Cancer Evolution," we have entered into this collaboration with Merck who developed the anti-PD-1 antibody KEYTRUDA,” commented Haruo Naito, Representative Corporate Officer and CEO of Eisai Co., Ltd. “By providing new treatment options including for refractory cancers with no hopes for a cure to date, we are striving to further contribute to increasing the benefits provided to patients and their families.”

“Together with Eisai, we aim to maximize the value of LENVIMA for its current indications while jointly pursuing additional approvals in combination with KEYTRUDA across a wide range of cancers,” said Dr. Roger M. Perlmutter, President, Merck Research Laboratories. “There is strong scientific evidence supporting synergistic effects of KEYTRUDA when used in combination with LENVIMA, and the companies have already received Breakthrough Therapy Designation from the U.S. FDA for the KEYTRUDA/LENVIMA combination in renal cell carcinoma. Through this collaboration, we will both broaden our oncology portfolio and have the opportunity to help even more cancer patients around the world.”

Financial Considerations

Gross profits from LENVIMA product sales globally will be shared equally by Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. Expenses incurred during co-development, including for studies evaluating LENVIMA as monotherapy, will be shared equally by the two companies.

Under the agreement, Merck & Co., Inc., Kenilworth, N.J., U.S.A. will pay Eisai an upfront payment of $300 million U.S. dollars and up to $650 million U.S. dollars for certain option rights through 2020 (Eisai's financial year: fiscal year ended March 2021), as well as $450 million U.S. dollars as reimbursement for research and development expenses. In addition, Eisai is eligible to receive up to $385 million U.S. dollars associated with the achievement of certain clinical and regulatory milestones and a maximum of up to $3.97 billion U.S. dollars for the achievement of milestones associated with sales of LENVIMA. Assuming the achievement of all development and commercial goals for all indications, the total amount of upfront, option and regulatory and sales milestone payments has the potential to reach up to $5.76 billion U.S. dollars.

The impact of this collaboration on Eisai's consolidated financial results has been incorporated into the Notification Regarding Revision of Consolidated Financial Results Forecasts (IFRS) for the Fiscal Year Ending March 31, 2018 announced on March 8 (Japan).

About the Phase 1b/2 Study (Study 111/KEYNOTE-146) that Supported Breakthrough Therapy Designation for the LENVIMA/KEYTRUDA Combination

Study 111/KEYNOTE-146 is a multicenter, open-label, Phase 1b/2 clinical study being carried out in the United States and the European Union to evaluate the efficacy and safety of LENVIMA in combination with KEYTRUDA. The primary objective of the Phase 1b portion of the study was to determine the maximum tolerated dose in patients with unresectable solid tumors (endometrial cancer, melanoma, non-small cell lung cancer, RCC, squamous cell carcinoma of the head and neck, and urothelial cancer) who had progressed after treatment with approved therapies or for which there are no standard effective therapies available. The initial part of Phase 2 enrolled patients with select solid tumors after previous treatment with 0-2 lines of systemic therapy (unless discussed with the sponsor) with a recommended dosage based on the results of the Phase 1b part. The primary endpoint of the initial part of Phase 2 was objective response rate (ORR) after 24 weeks of treatment, with select secondary endpoints including ORR, disease control rate, progression-free survival, and duration of response. The expansion part of Phase 2 is ongoing, and enrollment of patients is continuing in the endometrial cancer cohort.

From the results of the analysis (investigator review) of the RCC cohort 1 (n=30)[1] in Study 111/KEYNOTE-146 as of March 1, 2017, the primary endpoint of the Phase 2 portion, ORR after 24 weeks of treatment (ORR Week 24) was 63 percent (95% CI, 44-80), with tumor regression observed in 93 percent (28/30) of patients since the initiation of treatment (baseline). A tumor response was observed regardless of previous treatment experience or tumor PD-L1 expression. In this cohort, the most frequently observed adverse events (top six) were diarrhea, fatigue, hypothyroidism, stomatitis, hypertension, and nausea.

The results of the interim analysis (n=23)[2] of the endometrial cancer cohort in Study 111/KEYNOTE-146 as of December 1, 2016, indicated ORR Week 24 of 52.2 percent (95% CI, 30.6-73.2) based on independent radiologic review and 47.8 percent (95% CI, 26.8-69.4) based on investigator review. Additionally, tumor regression was observed regardless of the state of microsatellite instability (MSI). Anti-PD-1 antibodies are generally less effective in patients with low frequency of MSI, which is a biomarker for the inability to repair errors in the base sequence of DNA, or who are MSI negative.[3] In this cohort, the most frequently observed adverse events (top five) were hypertension, fatigue, arthralgia, diarrhea, and nausea.

Meanwhile, a similar Phase 1b clinical study (Study 115/KEYNOTE-523) in Japanese patients with unresectable solid tumors and a Phase 1b clinical study (Study 116/KEYNOTE-524) of the combination therapy in hepatocellular carcinoma in Japan and the United States are both underway.

About LENVIMA® (lenvatinib mesylate)

Discovered and developed in-house by Eisai, LENVIMA is an orally administered multiple receptor tyrosine kinase (RTK) inhibitor with a novel binding mode that selectively inhibits the kinase 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 RCC in over 40 countries, including the United States and in Europe. In Europe, the agent was launched under the brand name Kisplyx® for RCC.

Furthermore, Eisai has submitted applications for an indication covering hepatocellular carcinoma in Japan (June 2017), the United States and Europe (July 2017), China (October 2017), Taiwan (December 2017) and other countries.

The eight major clinical studies in progress on LENVIMA are as follows:

- A Phase 3 clinical study (Study 307) of separate combinations of LENVIMA with KEYTRUDA or LENVIMA with everolimus versus chemotherapy alone in RCC (first-line) conducted in Japan, the United States and Europe.
- A Phase 3 clinical study (Study 308) of LENVIMA in thyroid cancer being conducted in China.
- A Phase 2 clinical study (Study 215) of LENVIMA in biliary tract cancer being conducted in Japan.
- A Phase 2 clinical study (Study 209) of LENVIMA in non-small cell lung cancer with RET translocations being conducted in Japan, the United States, Europe and Asia.
- A Phase 1b/2 clinical study (Study 111/KEYNOTE-146) of LENVIMA in combination with KEYTRUDA (pembrolizumab) in select solid tumors (RCC, endometrial cancer, non-small cell lung cancer, urothelial cancer, squamous cell carcinoma of the head and neck, and melanoma) being conducted in the United States and European Union. Based on interim results, the combination treatment has been granted Breakthrough Therapy Designation by the U.S. FDA for the potential treatment of patients with advanced and/or metastatic RCC.
- A Phase 1b clinical study (Study 115/KEYNOTE-523) of LENVIMA in combination with KEYTRUDA in select solid tumors (RCC, endometrial cancer, non-small cell lung cancer, urothelial cancer, squamous cell carcinoma of the head and neck, and melanoma) being conducted in Japan.
- A Phase 1b clinical study (Study 116/KEYNOTE-524) of LENVIMA in combination with KEYTRUDA in hepatocellular carcinoma being conducted in Japan and the United States.
- A Phase 1b clinical study of LENVIMA in combination with nivolumab in hepatocellular carcinoma being conducted in Japan.

About Eisai Co., Ltd.

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as “giving first thought to patients and their families and to increasing the benefits health care provides,” which we call our *human health care* (*hhc*) philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products in various therapeutic areas with high unmet medical needs, including Oncology and Neurology.

As a global pharmaceutical company, our mission extends to patients around the world through our investment and participation in partnership-based initiatives to improve access to medicines in developing and emerging countries.

For more information about Eisai Co., Ltd., please visit www.eisai.com.

About Merck & Co., Inc., Kenilworth, N.J., U.S.A.

For more than a century, Merck & Co., Inc., Kenilworth, N.J., U.S.A., a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck & Co., Inc., Kenilworth, N.J., U.S.A. continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer’s disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., U.S.A.

This news release of Merck & Co., Inc., Kenilworth, N.J., U.S.A. (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. **There can be no guarantees with respect to pipeline products that the**

products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2017 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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1. Lee CH, et al. A Phase 1b/2 Trial of Lenvatinib + Pembrolizumab in Patients With Renal Cell Carcinoma. *ESMO Congress Abstract,* 2017; #847O
2. Makker V, et al. A phase Ib/II trial of lenvatinib (LEN) plus pembrolizumab (Pembro) in patients (Pts) with endometrial carcinoma. *ASCO Meeting Abstract*, 2017; #5598
3. Dung T. Le. et al, PD-1 Blockade in Tumors with Mismatch-Repair Deficiency, *The New England Journal of Medicine* 372:2509-2520, 2015.