FOR IMMEDIATE RELEASE

EISAI AND MERCK & CO., INC., KENILWORTH, N.J., U.S.A. ANNOUNCE CHINA NATIONAL MEDICAL PRODUCTS ADMINISTRATION (NMPA) APPROVAL OF LENVIMA® (LENVATINIB) FOR TREATMENT OF UNRESECTABLE HEPATOCELLULAR CARCINOMA (HCC)

First Approval for LENVIMA in China and First New Therapy for the First-line Treatment of Unresectable HCC Approved in China in a Decade

TOKYO and KENILWORTH, N.J. Sept. 5, 2018 – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Merck & Co., Inc., Kenilworth N.J., U.S.A., known as MSD outside of the United States and Canada, announced today that the China National Medical Products Administration (NMPA) approved the kinase inhibitor LENVIMA® (lenvatinib) as a single agent for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy. In China, the application of LENVIMA was submitted in October 2017, and was designated for Priority Review by the NMPA due to LENVIMA's significant clinical benefit compared to existing treatments, leading to approval in approximately 10 months. This approval marks the first for LENVIMA in China, where the incidence of HCC is high,[1] and the first new systemic therapy approved for the first-line treatment of unresectable HCC in China in ten years.[1]

The approval was based on results from the REFLECT study (Study 304),[2] an open-label, Phase 3 trial where LENVIMA demonstrated a treatment effect on overall survival (OS)*[1] by statistical confirmation of non-inferiority when compared with the standard of care, sorafenib, in 954 patients with previously untreated unresectable HCC. LENVIMA demonstrated statistically significant superiority and clinically meaningful improvements in progression-free survival (PFS)*[2], time to progression (TTP)*[3] and objective response rate (ORR)*[4]. In a subpopulation analysis of 288 patients in the study from the greater Chinese region (mainland China, Hong Kong and Taiwan), LENVIMA demonstrated efficacy based on non-inferiority of OS compared to sorafenib, with improvements also observed in PFS, TTP and ORR[3]. Approximately 80% of patients in the subpopulation were living with HCC resulting from chronic hepatitis B virus (HBV), which has high unmet medical need. For these patients, LENVIMA demonstrated non-inferiority based on OS compared with sorafenib, thereby demonstrating the effect of LENVIMA in patients with HCC resulting from HBV. (For the detailed data, please refer to "Notes for Editors" below.)

In the China package insert, the five most common adverse reactions observed in patients treated with LENVIMA were hypertension (45%), fatigue (44%), diarrhea (39%), decreased appetite (34%) and decreased weight (31%), which is consistent with the known side-effect profile of LENVIMA.

Liver cancer is the second leading cause of cancer-related deaths and is estimated to be responsible for approximately 750,000 deaths per year globally. Additionally, approximately 780,000 cases are newly diagnosed each year, about 80% of which occur in Asian regions. Specifically, in China, there are approximately 395,000 new cases and 380,000 deaths per year, accounting for approximately 50% of cases worldwide.[1] HCC accounts for 85% to 90% of primary liver cancer cases. Unresectable HCC, for which treatment options are limited, is extremely difficult to treat, and the development of new treatments is necessary.

Since the initial launch, more than 10,000 patients have been treated with LENVIMA. Today, LENVIMA is approved as a treatment for refractory thyroid cancer in over 50 countries including the United States, Japan, in Europe and Asia, and as combination with everolimus as a second-line treatment for renal cell carcinoma (RCC) in over 45 countries including the United States and in Europe. For HCC, LENVIMA was approved for use in Japan in March 2018, and in the United States and Europe in August 2018. In Japan, approximately 3,000 HCC patients have been treated with LENVIMA since approval of this indication.

*[1] Overall Survival (OS): The time period from the commencement of cancer treatment up until death by any cause. Whether the cause of death is cancer or not is not taken into consideration for this variable.

*[2] Progression Free Survival (PFS): PFS is the objectively confirmed time from the commencement of cancer treatment to the date of disease progression, or date of death from any cause, whichever occurs first.

*[3] Time To Progression: TTP is the objectively confirmed time from the commencement of cancer treatment to the date of disease progression. Unlike PFS, TTP does not consider death from any cause.

*[4] Objective Response Rate (ORR): ORR is the combined proportion of patients whose tumor was eliminated (complete response) and whose tumor was reduced by over 30% in size (partial response) as verified by imaging assessment.

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– Notes for Editors –

About the REFLECT Trial (Study 304) [2]

REFLECT was a large (n=954) Phase 3, randomized, multicenter, open-label trial conducted by Eisai to compare the efficacy and safety of LENVIMA versus sorafenib as a first-line systemic treatment in patients with unresectable HCC. Patients at 154 trial sites in 20 countries were randomized to receive LENVIMA 12 mg or 8 mg once a day depending on body weight (≥60 kg or <60 kg, respectively) (n=478) or sorafenib 400 mg twice a day (n=476). Treatment was continued until disease progression or unacceptable toxicity. The primary endpoint of this study was OS, tested first for non-inferiority to sorafenib, then for superiority. The key secondary efficacy endpoints of this study included PFS, TTP and ORR, tested for superiority to sorafenib.

In the China package insert, REFLECT showed that LENVIMA achieved the primary endpoint, demonstrating a treatment effect on OS by statistical confirmation of non-inferiority to sorafenib. Patients treated with LENVIMA experienced a median OS of 13.6 months compared to 12.3 months with sorafenib (Hazard Ratio [HR]: 0.92; 95% Confidence Interval [CI]: 0.79-1.06). Patients randomized to the LENVIMA arm did not have a statistically significant improvement in OS compared to those in the sorafenib arm. In addition, LENVIMA showed statistically significant superiority and clinically meaningful improvements in the secondary efficacy endpoints of PFS, TTP and ORR, as confirmed by a blinded independent imaging review:

- Median PFS was doubled with LENVIMA compared to sorafenib: 7.3 months versus 3.6 months (HR: 0.64; 95% CI: 0.55–0.75; p<0.00001) per blinded independent imaging review based on mRECIST criteria.
- Median TTP was doubled with LENVIMA compared to sorafenib: 7.4 months versus 3.7 months (HR: 0.60; 95% CI: 0.51–0.71; p<0.00001) per blinded independent imaging review based on mRECIST criteria.
- LENVIMA showed nearly 3.5 times the ORR of sorafenib: 40.6% (95% CI: 36.2-45.0) versus 12.4% (95% CI: 9.4-15.4) per blinded independent imaging review based on mRECIST criteria (odds ratio 5.01, 95% CI: 3.59-7.01; p<0.00001).

About the Subpopulation Analysis of Patients from the Greater Chinese Region[3]

The results of subpopulation analysis of patients from the greater Chinese region[3] were based on 288 patients out of the 954 HCC patients who participated in the REFLECT study. In this subpopulation analysis, median OS was 15.0 months for LENVIMA versus 10.2 months for sorafenib (HR: 0.73; 95% CI: 0.55-0.96; nominal p=0.02620). Independent imaging review based on mRECIST criteria revealed the following results: PFS (LENVIMA 8.4 months versus sorafenib 3.6 months in median [HR: 0.47; 95% CI: 0.35-0.64; nominal p<0.00001]), TTP (LENVIMA 9.2 months versus sorafenib 3.6 months in median [HR: 0.45; 95% CI: 0.33-0.62; nominal p<0.00001]) and ORR (LENVIMA 43.8% versus sorafenib 13.2% [odds ratio 5.14; 95% CI: 2.84-9.31; nominal p<0.00001]).

Additionally, of the 288 patients in the subpopulation, approximately 80% (n=242) were living with HCC resulting from HBV. An analysis of these patients revealed the following results for OS: LENVIMA (n=123) 14.9 months versus sorafenib (n=119) 9.9 months in median (HR: 0.72; 95% CI: 0.53-0.97).

About Unresectable Hepatocellular Carcinoma (HCC)

Liver cancer is the second leading cause of cancer-related deaths and is estimated to be responsible for 750,000 deaths per year globally. Additionally, 780,000 cases are newly diagnosed each year.[2] There is a large regional difference, with about 80% of new cases occurring in Asian regions, including China and Japan. HCC accounts for 85% to 90% of primary liver cancer cases. HCC is associated with chronic liver disease, in particular cirrhosis. Major causes of cirrhosis include hepatitis B virus and hepatitis C virus. However, according to a recent investigation, non-B/non-C HCC is on the rise. Surgery is the first option for treatment, but for patients with unresectable HCC who are not amenable for potentially curative therapeutic interventions, which include liver transplant, surgical resection and tumor ablation (typically radiofrequency ablation or cryotherapy), or who are not suitable for transarterial chemoembolization (TACE), treatment options are limited and the prognosis is very poor.

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 RCC in over 45 countries, including the United States and in Europe. In Europe, the agent was launched under the brand name Kisplyx® for RCC.

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

It is important to note that the dose for LENVIMA for patients with unresectable HCC is based on the patient's weight (12 mg for patients weighing 60 kilograms or more, 8 mg for patients weighing less than 60 kilograms); the recommended dosage and dose adjustments are described in the full prescribing information.

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, 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® (pembrolizumab). 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, as well as a basket trial targeting six additional cancer types. The LENVIMA and KEYTRUDA combination is not approved in any cancer types today.

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 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 human health care 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.

Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s Focus on Cancer

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck & Co., Inc., Kenilworth, N.J., U.S.A., the potential to bring new hope to people with cancer drives our purpose and supporting accessibility to our cancer medicines is our commitment.

As part of our focus on cancer, Merck & Co., Inc., Kenilworth, N.J., U.S.A. is committed to exploring the potential of immuno-oncology with one of the largest development programs in the industry across more than 30 tumor types. We also continue to strengthen our portfolio through strategic acquisitions and are prioritizing the development of several promising oncology candidates with the potential to improve the treatment of advanced cancers.

For more information about our oncology clinical trials, visit www.merck.com/clinicaltrials.

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).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., U.S.A.

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[1] GLOBOCAN2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012. http://globocan.iarc.fr/ .

[2] Kudo M et al., “Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomised phase 3 non-inferiority trial” *The Lancet* 2018, 391 (10126), 1163-1173

[3] The Package Insert of Lenvatinib Mesilate Capsules in China