NEWS RELEASE

Eisai and Merck Announce FDA Approval of LENVIMA® (lenvatinib) Capsules for First-line Treatment of Unresectable Hepatocellular Carcinoma (HCC)

8/16/2018

Approval was based on REFLECT, the first-ever positive Phase 3 trial against an active comparator in previously untreated patients with unresectable HCC

Marks second approval under Eisai-Merck global collaboration to co-develop and co-commercialize LENVIMA, following Japan in March 2018

Woodcliff Lake, NJ and Kenilworth, NJ, Aug. 16, 2018 – Eisai Inc. and Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) approved the kinase inhibitor LENVIMA® (lenvatinib) for the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC). This approval was based on results from REFLECT (Study 304), where LENVIMA demonstrated a proven treatment effect on overall survival (OS) by statistical confirmation of non-inferiority, as well as statistically significant superiority and clinically meaningful improvements in progression-free survival (PFS) and objective response rate (ORR) when compared with sorafenib in patients with previously untreated unresectable HCC.

“Unresectable hepatocellular carcinoma is an extremely difficult-to-treat cancer, with no new first-line systemic therapy options for more than a decade,” said Dr. Ghassan Abou-Alfa, medical oncologist, Memorial Sloan Kettering Cancer Center. “REFLECT is the first-ever positive Phase 3 trial against an active comparator in unresectable HCC.

The efficacy and safety data from REFLECT are important findings for oncologists and others in the multidisciplinary teams who treat liver cancer, as well as for our patients who are affected by it."

Adverse reactions, some of which can be serious or fatal, may occur with LENVIMA, including hypertension, cardiac dysfunction, arterial thromboembolic events, hepatotoxicity, renal failure or impairment, proteinuria, diarrhea, fistula formation and gastrointestinal perforation, QT interval prolongation, hypocalcemia, reversible posterior leukoencephalopathy syndrome, hemorrhagic events, impairment of thyroid stimulating hormone suppression/thyroid dysfunction, and wound healing complications. Based on the severity of the adverse reaction, LENVIMA should be monitored, withheld or discontinued. Based on its mechanism of action and data from animal reproduction studies, LENVIMA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception. For more information, see "Important Safety Information" below.

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 (HR: 0.92; 95% CI: 0.79–1.06). The OS analysis was conducted when 351 events had occurred in the LENVIMA arm and 350 events had occurred in the sorafenib arm, as prespecified in the statistical analysis plan. In addition, LENVIMA showed statistically significant superiority and clinically meaningful improvements in the secondary efficacy endpoints of PFS and ORR, as confirmed by a blinded independent imaging review (IIR):

- 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<0.001) per blinded independent imaging review based on mRECIST criteria, and 7.3 months with LENVIMA versus 3.6 months with sorafenib (HR: 0.65; 95% CI: 0.56–0.77) per RECIST 1.1.
- LENVIMA showed nearly 3.5 times the ORR of sorafenib: 41% (95% CI: 36-45%) vs. 12% (95% CI: 10-16%) per blinded independent imaging review based on mRECIST criteria, respectively (p<0.001), and 19% (95% CI: 15-22%) with LENVIMA versus 7% (95% CI: 4-9%) with sorafenib per RECIST 1.1.
    - Per mRECIST: Treatment with LENVIMA resulted in complete response (CR) = 2.1% (n=10) vs. 0.8% (n=4) with sorafenib; treatment with LENVIMA resulted in partial response (PR) = 38.5% (n=184) vs. 11.6% (n=55) with sorafenib
    - Per RECIST 1.1: Treatment with LENVIMA resulted in CR = 0.4% (n=2) vs. 0.2% (n=1) with sorafenib; treatment with LENVIMA resulted in PR = 18.4% (n=88) vs. 6.3% (n=30) with sorafenib

In addition, median time to progression (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<0.0001) per blinded independent imaging review based on mRECIST criteria, and 7.4 months with LENVIMA versus 3.7 months with sorafenib (HR: 0.61; 95% CI: 0.51–0.72; p<0.0001) per RECIST 1.1. Time to progression is defined as time from randomization to radiological progression.

Deaths during follow-up without evidence of radiological progression are censored. This differs from PFS and is less correlative to overall survival.

In REFLECT, the most common adverse reactions (≥20%) observed in patients treated with LENVIMA were hypertension, fatigue, diarrhea, decreased appetite, arthralgia/myalgia, decreased weight, abdominal pain, palmar-plantar erythrodysesthesia syndrome, proteinuria, dysphonia, hemorrhagic events, hypothyroidism and nausea. The most common serious adverse reactions (≥2%) reported in patients treated with LENVIMA were hepatic encephalopathy (5%), hepatic failure (3%), ascites (3%) and decreased appetite (2%).

The most common adverse reactions (≥20%) observed in patients who received sorafenib were palmar-plantar erythrodysesthesia syndrome, diarrhea, fatigue, hypertension, abdominal pain, decreased appetite, rash, decreased weight and arthralgia/myalgia. The most common serious adverse reactions (≥2%) reported in patients who received sorafenib were ascites (2%) and abdominal pain (2%).

It is also 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.

"Eisai strives to be a leading global R&D-based pharmaceutical company, driven by our human health care (hhc) mission to improve the lives of patients and their loved ones," said Shaji Procida, President and Chief Operating Officer, Eisai Inc., and Commercial Head of the Oncology Business Group, Americas at Eisai. "That purpose is what has propelled us toward this win for patients with unresectable hepatocellular carcinoma. Our goal is to bring monumental solutions to patients and health care providers, changing expectations for the oncology landscape, and we look forward to continuing this work in our ongoing collaboration with Merck."

"We are pleased by the FDA approval of LENVIMA as it marks an important advancement in the treatment of unresectable hepatocellular carcinoma," said Dr. Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, Merck Research Laboratories. "With our shared mission to find solutions for difficult-to-treat cancers, we look forward to working with Eisai to help bring this needed option to patients and physicians."

LENVIMA, a kinase inhibitor, was first approved in the U.S. in February 2015 for patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC). In May 2016, LENVIMA was approved in the U.S. in combination with everolimus, for patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. Under the collaboration, Eisai and Merck initiated co-commercialization activities for LENVIMA in the U.S. in June 2018. Since the initial launch, more than 10,000 patients were treated with LENVIMA, which is approved in more than 50 countries worldwide.

About the REFLECT Trial (Study 304)

REFLECT was a large (N=954) phase 3, randomized, multicenter, open-label trial conducted by Eisai to compare the efficacy and safety of lenvatinib versus sorafenib as a first-line systemic treatment in patients with unresectable hepatocellular carcinoma (HCC). Patients at 154 trial sites in 20 countries were randomized to receive lenvatinib 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 overall survival, tested first for non-inferiority to sorafenib, then for superiority. Patients randomized to the LENVIMA arm did not have a statistically significant improvement in OS compared to those in the sorafenib arm. The key secondary efficacy endpoints of this study included progression-free survival, time to progression and objective response rate, tested for superiority to sorafenib. The results of the REFLECT trial were published online in The Lancet (Vol 391(10126):1163-1173) on February 9, 2018.

About Unresectable Hepatocellular Carcinoma (HCC)

The prevalence and mortality rate of hepatocellular carcinoma have been rising steadily over the past decade. Hepatocellular carcinoma is the most common type of liver cancer, accounting for about 90% of cases of primary liver cancer. The stage of disease at diagnosis largely determines treatment approach, with potentially curative options, like resection or transplantation, only available for early stage HCC. Unresectable HCC, a type of liver cancer that cannot be removed by surgery, has a worse prognosis, with a median survival of less than one year. Unfortunately, approximately 70% of patients are diagnosed too late to be eligible for resection or transplantation, and there have been limited treatment options available for patients with unresectable disease.

About LENVIMA® (lenvatinib) capsules 10 mg and 4 mg

LENVIMA® (lenvatinib) is a kinase inhibitor that is indicated for the treatment of:

- For the treatment of patients with locally recurrent or metastatic, progressive radioactive iodine-refractory differentiated thyroid cancer (DTC)
- In combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy
- For the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)

LENVIMA, discovered and developed by Eisai, is a kinase inhibitor that inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors VEGFR1 (FLT1), VEGFR2 (KDR), and VEGFR3 (FLT4). LENVIMA inhibits other kinases that have been implicated in pathogenic angiogenesis, tumor growth, and cancer progression in

addition to their normal cellular functions, including fibroblast growth factor (FGF) receptors FGFR1-4; the platelet derived growth factor receptor alpha (PDGFRα), KIT, and RET. Lenvatinib also exhibited antiproliferative activity in hepatocellular carcinoma cell lines dependent on activated FGFR signaling with a concurrent inhibition of FGF-receptor substrate 2α (FRS2α) phosphorylation.

Important Safety Information

Warnings and Precautions

Hypertension. In DTC, hypertension occurred in 73% of patients on LENVIMA (44% grade 3-4). In RCC, hypertension occurred in 42% of patients on LENVIMA + everolimus (13% grade 3). Systolic blood pressure ≥160 mmHg occurred in 29% of patients, and 21% had diastolic blood pressure ≥100 mmHg. In HCC, hypertension occurred in 45% of LENVIMA-treated patients (24% grade 3). Grade 4 hypertension was not reported in HCC.

Serious complications of poorly controlled hypertension have been reported. Control blood pressure prior to initiation. Monitor blood pressure after 1 week, then every 2 weeks for the first 2 months, and then at least monthly thereafter during treatment. Withhold and resume at reduced dose when hypertension is controlled or permanently discontinue based on severity.

Cardiac Dysfunction. Serious and fatal cardiac dysfunction can occur with LENVIMA. Across clinical trials in 799 patients with DTC, RCC, and HCC, grade 3 or higher cardiac dysfunction occurred in 3% of LENVIMA-treated patients. Monitor for clinical symptoms or signs of cardiac dysfunction. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Arterial Thromboembolic Events. Among patients receiving LENVIMA or LENVIMA + everolimus, arterial thromboembolic events of any severity occurred in 2% of patients in RCC and HCC and 5% in DTC. Grade 3-5 arterial thromboembolic events ranged from 2% to 3% across all clinical trials.

Permanently discontinue following an arterial thrombotic event. The safety of resuming after an arterial thromboembolic event has not been established and LENVIMA has not been studied in patients who have had an arterial thromboembolic event within the previous 6 months.

Hepatotoxicity. Across clinical studies enrolling 1,327 LENVIMA-treated patients with malignancies other than HCC, serious hepatic adverse reactions occurred in 1.4% of patients. Fatal events, including hepatic failure, acute hepatitis and hepatorenal syndrome, occurred in 0.5% of patients. In HCC, hepatic encephalopathy occurred in 8% of LENVIMA-treated patients (5% grade 3-5). Grade 3-5 hepatic failure occurred in 3% of LENVIMA-treated patients. 2% of patients discontinued LENVIMA due to hepatic encephalopathy and 1% discontinued due to hepatic failure.

Monitor liver function prior to initiation, then every 2 weeks for the first 2 months, and at least monthly thereafter during treatment. Monitor patients with HCC closely for signs of hepatic failure, including hepatic encephalopathy. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Renal Failure or Impairment. Serious including fatal renal failure or impairment can occur with LENVIMA. Renal impairment was reported in 14% and 7% of LENVIMA-treated patients in DTC and HCC, respectively. Grade 3-5 renal failure or impairment occurred in 3% of patients with DTC and 2% of patients with HCC, including 1 fatal event in each study. In RCC, renal impairment or renal failure was reported in 18% of LENVIMA + everolimus–treated patients (10% grade 3).

Initiate prompt management of diarrhea or dehydration/hypovolemia. Withhold and resume at reduced dose upon recovery or permanently discontinue for renal failure or impairment based on severity.

Proteinuria. In DTC and HCC, proteinuria was reported in 34% and 26% of LENVIMA-treated patients, respectively. Grade 3 proteinuria occurred in 11% and 6% in DTC and HCC, respectively. In RCC, proteinuria occurred in 31% of patients receiving LENVIMA + everolimus (8% grade 3).

Monitor for proteinuria prior to initiation and periodically during treatment. If urine dipstick proteinuria ≥2+ is detected, obtain a 24-hour urine protein. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Diarrhea. Of the 737 LENVIMA-treated patients in DTC and HCC, diarrhea occurred in 49% (6% grade 3). In RCC, diarrhea occurred in 81% of LENVIMA + everolimus–treated patients (19% grade 3). Diarrhea was the most frequent cause of dose interruption/reduction, and diarrhea recurred despite dose reduction.

Promptly initiate management of diarrhea. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Fistula Formation and Gastrointestinal Perforation. Of the 799 patients treated with LENVIMA or LENVIMA + everolimus in DTC, RCC, and HCC, fistula or gastrointestinal perforation occurred in 2%. Fistulas and gastrointestinal perforations have also been reported in other lenvatinib clinical trials and in post-marketing experience. Pneumothorax has been reported with and without clear evidence of a bronchopleural fistula. Some reports of gastrointestinal perforation, fistula, and pneumothorax occurred in association with tumor regression or necrosis. In most cases of fistula formation or gastrointestinal perforation, risk factors such as prior surgery or radiotherapy were present.

Permanently discontinue in patients who develop gastrointestinal perforation of any severity or grade 3-4 fistula.

QT Interval Prolongation. In DTC, QT/QTc interval prolongation occurred in 9% of LENVIMA-treated patients and QT interval prolongation of >500 ms occurred in 2%. In RCC, QTc interval increases of >60 ms occurred in 11% of patients receiving LENVIMA + everolimus and QTc interval >500 ms occurred in 6%. In HCC, QTc interval increases of >60 ms occurred in 8% of LENVIMA-treated patients and QTc interval >500 ms occurred in 2%.

Monitor and correct electrolyte abnormalities at baseline and periodically during treatment. Monitor electrocardiograms in patients with congenital long QT syndrome, congestive heart failure, bradyarrhythmias, or those who are taking drugs known to prolong the QT interval, including Class Ia and III antiarrhythmics. Withhold and resume at reduced dose upon recovery based on severity.

Hypocalcemia. In DTC, grade 3-4 hypocalcemia occurred in 9% of LENVIMA-treated patients. In 65% of cases, hypocalcemia improved or resolved following calcium supplementation with or without dose interruption or dose reduction. In RCC, grade 3-4 hypocalcemia occurred in 6% of LENVIMA + everolimus–treated patients. In HCC, grade 3 hypocalcemia occurred in 0.8% of LENVIMA-treated patients.

Monitor blood calcium levels at least monthly and replace calcium as necessary during treatment. Withhold and resume at reduced dose upon recovery or permanently discontinue depending on severity.

Reversible Posterior Leukoencephalopathy Syndrome. Across clinical studies of 1,823 patients who received LENVIMA as a single agent, RPLS occurred in 0.3%. Confirm diagnosis of RPLS with MRI. Withhold and resume at reduced dose upon recovery or permanently discontinue depending on severity and persistence of neurologic symptoms.

Hemorrhagic Events. Serious including fatal hemorrhagic events can occur with LENVIMA. In DTC, RCC, and HCC clinical trials, hemorrhagic events, of any grade, occurred in 29% of the 799 patients treated with LENVIMA as a single agent or in combination with everolimus. The most frequently reported hemorrhagic events (all grades and occurring in at least 5% of patients) were epistaxis and hematuria. In DTC, grade 3-5 hemorrhage occurred in 2% of LENVIMA-treated patients, including 1 fatal intracranial hemorrhage among 16 patients who received LENVIMA and had CNS metastases at baseline. In RCC, grade 3-5 hemorrhage occurred in 8% of LENVIMA + everolimus–treated patients, including 1 fatal cerebral hemorrhage. In HCC, grade 3-5 hemorrhage occurred in 5% of LENVIMA-treated patients, including 7 fatal hemorrhagic events.

Serious tumor-related bleeds, including fatal hemorrhagic events, occurred in LENVIMA-treated patients in clinical trials and in the postmarketing setting. In postmarketing surveillance, serious and fatal carotid artery hemorrhages were seen more frequently in patients with anaplastic thyroid carcinoma (ATC) than other tumors. Safety and

effectiveness of LENVIMA in patients with ATC have not been demonstrated in clinical trials.

Consider the risk of severe or fatal hemorrhage associated with tumor invasion or infiltration of major blood vessels (eg, carotid artery). Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Impairment of Thyroid Stimulating Hormone Suppression/Thyroid Dysfunction. LENVIMA impairs exogenous thyroid suppression. In DTC, 88% of patients had baseline thyroid stimulating hormone (TSH) level ≤0.5 mU/L. In patients with normal TSH at baseline, elevation of TSH level >0.5 mU/L was observed post baseline in 57% of LENVIMA-treated patients. In RCC and HCC, grade 1 or 2 hypothyroidism occurred in 24% of LENVIMA + everolimus–treated patients and 21% of LENVIMA-treated patients, respectively. In patients with normal or low TSH at baseline, elevation of TSH was observed post baseline in 70% of LENVIMA-treated patients in HCC and 60% of LENVIMA + everolimus–treated patients in RCC.

Monitor thyroid function prior to initiation and at least monthly during treatment. Treat hypothyroidism according to standard medical practice.

Wound Healing Complications. Wound healing complications, including fistula formation and wound dehiscence, can occur with LENVIMA. Withhold for at least 6 days prior to scheduled surgery. Resume after surgery based on clinical judgment of adequate wound healing. Permanently discontinue in patients with wound healing complications.

Embryo-fetal Toxicity. Based on its mechanism of action and data from animal reproduction studies, LENVIMA can cause fetal harm when administered to pregnant women. In animal reproduction studies, oral administration of lenvatinib during organogenesis at doses below the recommended clinical doses resulted in embryotoxicity, fetotoxicity, and teratogenicity in rats and rabbits. Advise pregnant women of the potential risk to a fetus; and advise females of reproductive potential to use effective contraception during treatment with LENVIMA and for at least 30 days after the last dose.

Adverse Reactions

In DTC, the most common adverse reactions (≥30%) observed in LENVIMA-treated patients were hypertension (73%), fatigue (67%), diarrhea (67%), arthralgia/myalgia (62%), decreased appetite (54%), decreased weight (51%), nausea (47%), stomatitis (41%), headache (38%), vomiting (36%), proteinuria (34%), palmar-plantar erythrodysesthesia syndrome (32%), abdominal pain (31%), and dysphonia (31%). The most common serious adverse reactions (≥2%) were pneumonia (4%), hypertension (3%), and

dehydration (3%). Adverse reactions led to dose reductions in 68% of LENVIMA-treated patients; 18% discontinued LENVIMA. The most common adverse reactions (≥10%) resulting in dose reductions were hypertension (13%), proteinuria (11%), decreased appetite (10%), and diarrhea (10%); the most common adverse reactions (≥1%) resulting in discontinuation of LENVIMA were hypertension (1%) and asthenia (1%).

In RCC, the most common adverse reactions (≥30%) observed in LENVIMA + everolimus–treated patients were diarrhea (81%), fatigue (73%), arthralgia/myalgia (55%), decreased appetite (53%), vomiting (48%), nausea (45%), stomatitis (44%), hypertension (42%), peripheral edema (42%), cough (37%), abdominal pain (37%), dyspnea (35%), rash (35%), decreased weight (34%), hemorrhagic events (32%), and proteinuria (31%). The most common serious adverse reactions (≥5%) were renal failure (11%), dehydration (10%), anemia (6%), thrombocytopenia (5%), diarrhea (5%), vomiting (5%), and dyspnea (5%). Adverse reactions led to dose reductions or interruption in 89% of patients. The most common adverse reactions (≥5%) resulting in dose reductions were diarrhea (21%), fatigue (8%), thrombocytopenia (6%), vomiting (6%), nausea (5%), and proteinuria (5%). Treatment discontinuation due to an adverse reaction occurred in 29% of patients.

In HCC, the most common adverse reactions (≥20%) observed in LENVIMA-treated patients were hypertension (45%), fatigue (44%), diarrhea (39%), decreased appetite (34%), arthralgia/myalgia (31%), decreased weight (31%), abdominal pain (30%), palmar-plantar erythrodysesthesia syndrome (27%), proteinuria (26%), dysphonia (24%), hemorrhagic events (23%), hypothyroidism (21%), and nausea (20%). The most common serious adverse reactions (≥2%) were hepatic encephalopathy (5%), hepatic failure (3%), ascites (3%), and decreased appetite (2%). Adverse reactions led to dose reductions or interruption in 62% of patients. The most common adverse reactions (≥5%) resulting in dose reductions were fatigue (9%), decreased appetite (8%), diarrhea (8%), proteinuria (7%), hypertension (6%), and palmar-plantar erythrodysesthesia syndrome (5%). Treatment discontinuation due to an adverse reaction occurred in 20% of patients. The most common adverse reactions (≥1%) resulting in discontinuation of LENVIMA were fatigue (1%), hepatic encephalopathy (2%), hyperbilirubinemia (1%), and hepatic failure (1%).

Use in Specific Populations

Because of the potential for serious adverse reactions in breastfed infants, advise women to discontinue breastfeeding during treatment and for at least 1 week after last dose. LENVIMA may impair fertility in males and females of reproductive potential.

No dose adjustment is recommended for patients with mild (CLcr 60-89 mL/min) or moderate (CLcr 30-59 mL/min) renal impairment. LENVIMA concentrations may increase in patients with DTC or RCC and severe (CLcr 15-29 mL/min) renal impairment. Reduce the dose for patients with RCC or DTC and severe renal impairment. There is no recommended dose for patients with HCC and severe renal impairment. LENVIMA has not been studied in patients

with end stage renal disease.

No dose adjustment is recommended for patients with HCC and mild hepatic impairment (Child-Pugh A). There is no recommended dose for patients with HCC with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.

No dose adjustment is recommended for patients with DTC or RCC and mild or moderate hepatic impairment. LENVIMA concentrations may increase in patients with DTC or RCC and severe hepatic impairment. Reduce the dose for patients with DTC or RCC and severe hepatic impairment.

For more information about LENVIMA please see available full **Prescribing Information**.

About the Eisai and Merck Strategic Collaboration

In March 2018, Eisai and Merck, through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of LENVIMA® (lenvatinib). Under the agreement, the companies will jointly develop and commercialize LENVIMA, both as monotherapy and in combination with Merck'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/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/KEYTRUDA combination is not approved in any cancer types today.

About Eisai Inc.

At Eisai Inc., human health care (hhc) is our goal. We give our first thoughts to patients and their families, and helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we have a passionate commitment to patient care that is the driving force behind our efforts to discover and develop innovative therapies to help address unmet medical needs.

Eisai is a fully integrated pharmaceutical business that operates in two global business groups: oncology and neurology (dementia-related diseases and neurodegenerative diseases). Each group functions as an end-to-end global business with discovery, development, manufacturing and marketing capabilities. Our U.S. headquarters, commercial and clinical development organizations are located in New Jersey; our discovery labs are in Massachusetts and Pennsylvania; and our global demand chain organization resides in Maryland and North Carolina. To learn more about Eisai Inc., please visit us at **eisai.com/us** and follow us on **Twitter** and **LinkedIn**.

Merck's Focus on Cancer

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck, 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 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

For more than a century, Merck, 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 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., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (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**).

Merck Media Relations
Doris Li, (908) 246-5701
Ann Bush, (908) 740-6677
or
Merck Investor Relations
Teri Loxam, (908) 740-1986
Petter Dannenbaum, (908) 740-1037

Eisai Inc. Media Relations
Michele Randazzo, (201) 746-2979