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Eisai and Merck Enter Collaboration to Explore Novel Combination Regimens of Anti-PD-1 Therapy with Multi-targeting RTK Inhibitor and Microtubule Dynamics Inhibitor in Multiple Types of Cancer

Combination clinical studies of lenvatinib, eribulin and pembrolizumab to be explored

Tokyo, Japan and Kenilworth, NJ – March 4, 2015 – Eisai Co., Ltd. and Merck (NYSE:MRK), known as MSD outside the U.S. and Canada, through a subsidiary, announced today a clinical trial collaboration to evaluate the safety, tolerability and efficacy of Merck's anti-PD-1 therapy, pembrolizumab (marketed in the U.S. under the brand name KEYTRUDA®), in combination with Eisai oncology compounds lenvatinib mesylate (a multi-targeting RTK inhibitor marketed in the U.S. under the brand name LENVIMA™, "lenvatinib") and eribulin mesylate (a microtubule dynamics inhibitor marketed in nearly 60 countries including Japan, the U.S., and Europe under the brand name HALAVEN®, "eribulin") in multiple clinical trials.

The planned studies include a multicenter, open-label Phase 1b/2 study of lenvatinib plus pembrolizumab in select solid tumors and an open-label, single-arm, multicenter Phase 1b/2 study to evaluate the efficacy and safety of eribulin in combination with pembrolizumab in metastatic triple-negative breast cancer. Eisai and Merck will establish a Joint Development Committee to oversee clinical development activities. The studies are expected to begin in the second half of 2015. Financial terms of the agreement were not disclosed.

"This collaboration could be a major step in the direction of developing combination regimens in different types of cancer, potentially maximizing the value of eribulin and lenvatinib," said Kenichi Nomoto, PhD, president, oncology product creation unit, Eisai Product Creation Systems. "Together, Eisai and Merck seek to explore combination regimens that have the potential to create synergistic effects between lenvatinib and pembrolizumab as well as between eribulin and pembrolizumab. Our hope is that we will bring treatments to market that make a difference in the lives of people battling cancer."

"Cancer is a complex disease that often requires different approaches to help patients achieve the best possible outcome," said Dr. Eric Rubin, therapeutic area head, oncology early-stage development, Merck Research Laboratories. "The collaboration with Eisai exemplifies Merck's focus on advancing breakthrough science in immuno-oncology. We look forward to evaluating pembrolizumab in combination with eribulin and also with lenvatinib in different tumor types."

The combinations of lenvatinib and pembrolizumab, and eribulin and pembrolizumab, are investigational. The efficacy and safety of these combinations have not been established.

About LENVIMA™ (lenvatinib mesylate)
LENVIMA, discovered and developed by Eisai, is an oral molecular targeted agent that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors (VEGFR1 (FLT1), VEGFR2 (KDR) and VEGFR3 (FLT4)), and fibroblast growth factor (FGF) receptors FGFR1, 2, 3 and 4 in addition to other proangiogenic and oncogenic pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRα; KIT; and RET) involved in tumor proliferation. In particular, LENVIMA possesses a new binding mode (Type V) to VEGFR2, as confirmed through X-ray crystal structural analysis, and exhibits rapid and potent inhibition of kinase activity, according to kinetic analysis.

LENVIMA was approved on February 13, 2015 and launched on February 26, 2015 for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer in the United States, and is currently undergoing regulatory review for this indication in Japan, the EU, Switzerland, South Korea, Canada, Singapore, Russia, Australia and Brazil. Meanwhile, Eisai is currently conducting studies clinical studies of LENVIMA in several types of cancer including hepatocellular carcinoma (Phase III), renal cell carcinoma (Phase II), non-small cell lung cancer (Phase II) and endometrial cancer (Phase II). Furthermore, lenvatinib has been granted Orphan Drug Designation in Japan (for thyroid cancer), the United States (for the treatment of follicular, medullary, anaplastic, and metastatic or locally advanced papillary thyroid cancer), and Europe (for follicular and papillary thyroid cancer).

About HALAVEN® (eribulin mesylate)
HALAVEN, a halichondrin class microtubule dynamics inhibitor with a novel mechanism of action, belongs to a class of antineoplastic agents, the halichondrins, which are natural products isolated from the marine sponge *Halichondria okadai*. It is believed to work by inhibiting the growth phase of microtubule dynamics without affecting the shortening phase and sequestering tubulin into nonproductive aggregates.

HALAVEN was first approved as a treatment for metastatic breast cancer in the United States in November 2010, and is now approved in nearly 60 countries worldwide, including Japan and countries in the Americas, Europe and Asia. In the United States, HALAVEN Injection is indicated for patients with metastatic breast cancer who have received at least two chemotherapeutic regimens for the treatment of metastatic breast cancer. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. In Japan, HALAVEN has been approved to treat inoperable or recurrent breast cancer and was launched in the country in July 2011. Since June 2014, Eisai has been obtaining approval in countries in Europe and Asia for the indication expansion of HALAVEN to contribute to earlier treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting, unless patients were not suitable for these treatments. In addition, HALAVEN has been designated as an orphan drug for soft-tissue sarcoma in the United States and Japan.

About KEYTRUDA® (pembrolizumab)
KEYTRUDA (pembrolizumab) is a humanized monoclonal antibody that blocks the interaction between PD-1 (programmed death receptor-1) and its ligands, PD-L1 and PD-L2. KEYTRUDA is indicated in the United States at a dose of 2 mg/kg administered as an intravenous infusion over 30 minutes every three weeks for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Merck is advancing a broad and fast-growing clinical development program for KEYTRUDA with more than 70 clinical trials – across more than 30 tumor types and over 8,000 patients – both as a monotherapy and in combination with other therapies.

Important Safety Information for LENVIMA™ (U.S. labeling) Warnings and Precautions
Hypertension was reported in 73% of LENVIMA-treated patients (of which 44% were ≥ Grade 3) and 16% of patients in the placebo group. Control blood pressure prior to treatment and monitor blood pressure after 1 week, then every 2 weeks for the first 2 months, and then at least monthly during treatment. Withhold LENVIMA for Grade 3 hypertension; resume at a reduced dose when hypertension is controlled at ≤ Grade 2. Discontinue LENVIMA for life-threatening hypertension.

Cardiac dysfunction was reported in 7% of LENVIMA-treated patients (2% Grade 3 or greater.) Monitor patients for clinical symptoms or signs of cardiac decompensation. Withhold LENVIMA for development of Grade 3 cardiac dysfunction until improved to Grade 0 or 1 or baseline. Resume at a reduced dose or discontinue LENVIMA depending on the severity and persistence of cardiac dysfunction. Discontinue LENVIMA for Grade 4 cardiac dysfunction.

Arterial thromboembolic events were reported in 5% of LENVIMA-treated patients; events of Grade 3 or greater were 3%. Discontinue LENVIMA following an arterial thrombotic event. LENVIMA has not been studied in patients who have had an arterial thromboembolic event within the previous 6 months.

Four percent (4%) of LENVIMA-treated patients experienced an increase in ALT and 5% experienced an increase in AST that was Grade 3 or greater. Monitor liver function before initiation and during treatment with LENVIMA. Withhold LENVIMA for the development of ≥ Grade 3 liver impairment until resolved to Grade 0 to 1 or baseline. Resume at a reduced dose or discontinue LENVIMA depending on the severity and persistence of hepatotoxicity. Discontinue LENVIMA for hepatic failure.

Proteinuria was reported in 34% of LENVIMA-treated patients (of which 11% were Grade 3.) Monitor for proteinuria before initiation of, and periodically during treatment. Obtain a 24 hour urine protein if urine dipstick proteinuria ≥2+ is detected. Withhold LENVIMA for ≥ 2 grams of proteinuria/24 hours and resume at a reduced dose when proteinuria is <2 gm/24 hours. Discontinue LENVIMA for nephrotic syndrome.

Events of renal impairment were reported in 14% of LENVIMA-treated patients. Renal failure or impairment ≥ Grade 3 was 3% in LENVIMA-treated patients. Withhold LENVIMA for development of Grade 3 or 4 renal failure / impairment until resolved to Grade 0 to 1 or baseline. Resume at a reduced dose or discontinue LENVIMA depending on the severity and persistence of renal impairment.

Events of gastrointestinal perforation or fistula were reported in 2% of LENVIMA-treated patients. Discontinue LENVIMA in patients who develop gastrointestinal perforation or life-threatening fistula.

QT/QTc interval prolongation was reported in 9% of LENVIMA-treated patients (2% Grade 3 or greater). Monitor ECG in patients with congenital long QT syndrome, CHF, bradyarrhythmias, or patients taking drugs known to prolong the QT interval. Monitor and correct electrolyte abnormalities in all patients. Withhold LENVIMA for the development of ≥ Grade 3 QT interval prolongation. Resume LENVIMA at a reduced dose when QT prolongation resolves to Grade 0 or 1 or baseline.

Hypocalcemia ≥ Grade 3 was reported in 9% of LENVIMA-treated patients. Monitor blood calcium levels at least monthly and replace calcium as necessary during LENVIMA treatment. Interrupt and adjust LENVIMA dosing as necessary depending on severity, presence of ECG changes, and persistence of hypocalcemia.

Reversible posterior leukoencephalopathy syndrome (RPLS) was reported in 3 patients across clinical studies in which 1108 patients received LENVIMA. Confirm the diagnosis of RPLS with MRI. Withhold

LENMIVA for RPLS until fully resolved. Resume at a reduced dose or discontinue LENVIMA depending on the severity and persistence of neurologic symptoms.

Hemorrhagic events occurred in 35% of LENVIMA-treated patients and in 18% of the placebo group. The incidence of Grade 3-5 hemorrhage was similar between arms at 2% and 3%, respectively. The most frequently reported hemorrhagic event was epistaxis (11% Grade 1 and 1% Grade 2). Discontinuation due to hemorrhagic events occurred in 1% of LENVIMA-treated patients. There was one case of fatal intracranial hemorrhage among 16 patients who received LENVIMA and had CNS metastases at baseline. Withhold LENVIMA for the development of Grade 3 hemorrhage until resolved to Grade 0 to 1. Resume at a reduced dose or discontinue LENVIMA depending on the severity and persistence of hemorrhage. Discontinue LENVIMA in patients who experience Grade 4 hemorrhage.

LENVIMA impairs exogenous thyroid suppression. Elevation of TSH level above 0.5 mU/L was observed post baseline in 57% of LENVIMA-treated patients. Monitor TSH levels monthly and adjust thyroid replacement medication as needed.

LENVIMA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LENVIMA and for at least 2 weeks following completion of therapy.

Advise women not to breastfeed during treatment with LENVIMA.

Adverse Reactions
The most common adverse reactions observed in LENVIMA-treated patients vs. placebo treated patients respectively were hypertension (73% vs 16%), fatigue (67% vs 35%), diarrhea (67% vs 17%), arthralgia/myalgia (62% vs 28%), decreased appetite (54% vs 18%), weight decreased (51% vs 15%), nausea (47% vs 25%), stomatitis (41% vs 8%), headache (38% vs 11%), vomiting (36% vs 15%), proteinuria (34% vs 3%), palmar-plantar erythrodysesthesia syndrome (32% vs 1%), abdominal pain (31% vs 11%), and dysphonia (31% vs 5%).

For more information about LENVIMA™, please see the full product information or visit www.LENVIMA.com.

Important Safety Information for HALAVEN®

Neutropenia

- Monitor complete blood counts prior to each dose, and increase the frequency of monitoring in patients who develop Grade 3 or 4 cytopenias. Delay administration and reduce subsequent doses in patients who experience febrile neutropenia or Grade 4 neutropenia lasting longer than 7 days.
- Severe neutropenia (ANC <500/mm^3) lasting more than 1 week occurred in 12% (62/503) of patients. Patients with elevated liver enzymes >3 × ULN and bilirubin >1.5 × ULN experienced a higher incidence of Grade 4 neutropenia and febrile neutropenia than patients with normal levels.
- Grade 3 and Grade 4 neutropenia occurred in 28% and 29%, respectively, of patients who received HALAVEN. Febrile neutropenia occurred in 5% of patients and two patients (0.4%) died from complications.

Peripheral Neuropathy

- Patients should be monitored closely for signs of peripheral motor and sensory neuropathy.
- Grade 3 peripheral neuropathy occurred in 8% of patients, and Grade 4 in 0.4% of patients who received HALAVEN. Delay administration of HALAVEN until resolution to Grade 2 or less.
- Neuropathy lasting more than 1 year occurred in 5% of patients. Twenty-two percent of patients developed a new or worsening neuropathy that had not recovered within a median follow-up duration of 269 days (range 25-662 days).

- Peripheral neuropathy (5%) was the most common adverse reaction resulting in discontinuation.

Pregnancy Category D

- HALAVEN is expected to cause fetal harm when administered to a pregnant woman and patients should be advised of these risks.

QT Prolongation

- In an uncontrolled ECG study in 26 patients, QT prolongation was observed on Day 8, independent of eribulin concentration, with no prolongation on Day 1. ECG monitoring is recommended for patients with congestive heart failure; bradyarrhythmias; concomitant use of drugs that prolong QT interval, including Class Ia and III antiarrhythmics; and electrolyte abnormalities.
- Correct hypokalemia or hypomagnesemia prior to initiating HALAVEN and monitor electrolytes periodically during therapy. Avoid in patients with congenital long QT syndrome.

Hepatic and Renal Impairment

- For patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic and/or moderate or severe (CrCl 15-49 mL/min) renal impairment, a reduction in starting dose is recommended.

Most Common Adverse Reactions

- Most common adverse reactions (≥25%) reported in patients receiving HALAVEN were neutropenia (82%), anemia (58%), asthenia/fatigue (54%), alopecia (45%), peripheral neuropathy (35%), nausea (35%), and constipation (25%).
- The most common serious adverse reactions reported in patients receiving HALAVEN were febrile neutropenia (4%) and neutropenia (2%).

For more information about HALAVEN, please see the full product information or visit www.HALAVEN.com.

Selected Important Safety Information for KEYTRUDA®

Pneumonitis occurred in 12 (2.9%) of 411 patients with advanced melanoma receiving KEYTRUDA (the approved indication in the United States), including Grade 2 or 3 cases in 8 (1.9%) and 1 (0.2%) patients, respectively. Monitor patients for signs and symptoms of pneumonitis. Evaluate suspected pneumonitis with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold KEYTRUDA for Grade 2; permanently discontinue KEYTRUDA for Grade 3 or 4 pneumonitis.

Colitis (including microscopic colitis) occurred in 4 (1%) of 411 patients, including Grade 2 or 3 cases in 1 (0.2%) and 2 (0.5%) patients respectively, receiving KEYTRUDA. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold KEYTRUDA for Grade 2 or 3; permanently discontinue KEYTRUDA for Grade 4 colitis.

Hepatitis (including autoimmune hepatitis) occurred in 2 (0.5%) of 411 patients, including a Grade 4 case in 1 (0.2%) patient, receiving KEYTRUDA. Monitor patients for changes in liver function. Administer corticosteroids for Grade 2 or greater hepatitis and, based on severity of liver enzyme elevations, withhold or discontinue KEYTRUDA.

Hypophysitis occurred in 2 (0.5%) of 411 patients, including a Grade 2 case in 1 and a Grade 4 case in 1 (0.2% each) patient, receiving KEYTRUDA. Monitor for signs and symptoms of hypophysitis. Administer corticosteroids for Grade 2 or greater hypophysitis. Withhold KEYTRUDA for Grade 2; withhold or discontinue for Grade 3; and permanently discontinue KEYTRUDA for Grade 4 hypophysitis.

Nephritis occurred in 3 (0.7%) patients receiving KEYTRUDA, consisting of one case of Grade 2 autoimmune nephritis (0.2%) and two cases of interstitial nephritis with renal failure (0.5%), one Grade 3

and one Grade 4. Monitor patients for changes in renal function. Administer corticosteroids for Grade 2 or greater nephritis. Withhold KEYTRUDA for Grade 2; permanently discontinue KEYTRUDA for Grade 3 or 4 nephritis.

Hyperthyroidism occurred in 5 (1.2%) of 411 patients, including Grade 2 or 3 cases in 2 (0.5%) and 1 (0.2%) patients respectively, receiving KEYTRUDA. Hypothyroidism occurred in 34 (8.3%) of 411 patients, including a Grade 3 case in 1 (0.2%) patient, receiving KEYTRUDA. Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function (at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation) and for clinical signs and symptoms of thyroid disorders. Administer corticosteroids for Grade 3 or greater hyperthyroidism. Withhold KEYTRUDA for Grade 3; permanently discontinue KEYTRUDA for Grade 4 hyperthyroidism. Isolated hypothyroidism may be managed with replacement therapy without treatment interruption and without corticosteroids.

Other clinically important immune-mediated adverse reactions can occur. The following clinically significant, immune-mediated adverse reactions occurred in less than 1% of patients treated with KEYTRUDA: exfoliative dermatitis, uveitis, arthritis, myositis, pancreatitis, hemolytic anemia, partial seizures arising in a patient with inflammatory foci in brain parenchyma, adrenal insufficiency, myasthenic syndrome, optic neuritis, and rhabdomyolysis.

For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm etiology or exclude other causes. Based on the severity of the adverse reaction, withhold KEYTRUDA and administer corticosteroids. Upon improvement of the adverse reaction to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Restart KEYTRUDA if the adverse reaction remains at Grade 1 or less. Permanently discontinue KEYTRUDA for any severe or Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction.

Based on its mechanism of action, KEYTRUDA may cause fetal harm when administered to a pregnant woman. If used during pregnancy, or if the patient becomes pregnant during treatment, apprise the patient of the potential hazard to a fetus. Advise females of reproductive potential to use highly effective contraception during treatment and for 4 months after the last dose of KEYTRUDA.

For the treatment of advanced melanoma, KEYTRUDA was discontinued for adverse reactions in 6% of 89 patients who received the recommended dose of 2 mg/kg and 9% of 411 patients across all doses studied. Serious adverse reactions occurred in 36% of patients receiving KEYTRUDA. The most frequent serious adverse drug reactions reported in 2% or more of patients were renal failure, dyspnea, pneumonia, and cellulitis.

The most common adverse reactions (reported in ≥20% of patients) were fatigue (47%), cough (30%), nausea (30%), pruritus (30%), rash (29%), decreased appetite (26%), constipation (21%), arthralgia (20%), and diarrhea (20%).

The recommended dose of KEYTRUDA is 2 mg/kg administered as an intravenous infusion over 30 minutes every three weeks until disease progression or unacceptable toxicity. No formal pharmacokinetic drug interaction studies have been conducted with KEYTRUDA. It is not known whether KEYTRUDA is excreted in human milk. Because many drugs are excreted in human milk, instruct women to discontinue nursing during treatment with KEYTRUDA. Safety and effectiveness of KEYTRUDA have not been established in pediatric patients.

Please see Prescribing Information for KEYTRUDA (pembrolizumab) at http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf and the Medication Guide for KEYTRUDA at http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_mg.pdf

About Eisai in Oncology
Eisai is dedicated to discovering, developing and producing innovative oncology therapies that may make a difference and impact the lives of patients and their families. This passion for people is part of Eisai's *human health care* (*hhc*) mission, which strives for better understanding of the needs of patients and their families to help increase the benefits health care provides. Our commitment to meaningful progress in oncology research, built on scientific expertise, is supported by a global capability to conduct discovery and preclinical research, and develop small molecules and biologic agents across various types of cancer.

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 over 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.

Merck's Focus on Cancer
Our goal is to translate breakthrough science into biomedical innovations to help people with cancer worldwide. For Merck Oncology, helping people fight cancer is our passion, supporting accessibility to our cancer medicines is our commitment, and pursuing research in immuno-oncology and other areas of breakthrough science is our focus to potentially bring new hope to people with cancer. For more information about our oncology clinical trials, visit www.merck.com/clinicaltrials.

About Merck
Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. 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 healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

Merck Forward-Looking Statement
This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck'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 healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory

approval; Merck'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 Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck 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 Merck's 2014 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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