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Eisai Co., Ltd.

EISAI INC. ENTERS INTO COLLABORATION AGREEMENT TO CO-PROMOTE EISAI'S ANTICANCER AGENT LENVIMA® IN COMBINATION WITH EVEROLIMUS AS TREATMENT FOR ADVANCED RENAL CELL CARCINOMA IN THE UNITED STATES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its U.S. subsidiary Eisai Inc. has entered into an agreement with Novartis Pharmaceuticals Corporation (Novartis), a U.S. affiliate of Novartis AG (Headquarters: Basel, Switzerland, CEO: Joseph Jimenez), to collaborate on commercial and medical affairs activities (including the provision of scientific evidence to healthcare professionals) for Eisai's in-house developed novel anticancer agent Lenvima® (lenvatinib mesylate) and the anticancer agent everolimus in the United States.

On May 13, 2016, Eisai Inc. received approval from the U.S. Food and Drug Administration for an additional indication for Lenvima in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy. This is the only combination regimen approved in the United States to significantly prolong progression-free survival when compared with a standard of care in patients with advanced renal cell carcinoma following prior anti-angiogenic therapy. Under the terms of the collaboration agreement, Eisai and Novartis sales representatives will promote the availability of this combination regimen to healthcare professionals in the United States. The companies will also collaborate on medical affairs activities. Each company will continue to book sales of their respective product.

The number of patients with kidney cancer in the United States is estimated to be approximately 58,000[1] and renal cell carcinoma comprises more than 90% of all malignancies of the kidney.[2] For advanced or metastatic renal cell carcinoma that is difficult to treat with surgery, the standard treatment is molecular targeted drug therapy, however with low 5-year survival rates, this is a disease with significant unmet medical need.

Lenvima is approved for thyroid cancer in over 40 countries including the United States, Japan, in Europe, South Korea and Canada. Lenvima is also approved in combination with everolimus for patients with advanced renal cell carcinoma in the United States. A new drug application seeking approval for an indication covering advanced or metastatic renal cell carcinoma submitted in Europe in January 2016 is under review, and Eisai intends to discuss further steps regarding submission strategies for this potential indication with the regulatory authorities in Japan.

Through this agreement, Eisai is committed to maximizing the clinical value of Lenvima in order to address the diverse needs of, and further contribute to, patients with cancer, their families and healthcare professionals.

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[Notes to editors]

1. About Lenvima (lenvatinib mesylate)

Discovered and developed in-house, 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 proangiogenic and oncogenic pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRα; KIT; and RET) involved in tumor proliferation.

Currently, Eisai has obtained approval for Lenvima as a treatment for refractory thyroid cancer in over 40 countries including the United States, Japan, in Europe, Korea and Canada, and the agent is undergoing regulatory review throughout the world including in Asia, Russia, Australia, Brazil and Mexico. Specifically, Eisai has obtained approval for the agent indicated in the United States for treatment for locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, in Japan for the treatment of unresectable thyroid cancer, and in Europe for the treatment of adult patients with progressive, locally advanced or metastatic differentiated (papillary, follicular, Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine, respectively.

In May 2016, Lenvima was also approved for an additional indication in the United States in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy. A new drug application seeking approval for an indication covering advanced or metastatic renal cell carcinoma submitted in Europe in January 2016 is under review, and Eisai intends to discuss further steps regarding submission strategies for this potential indication with the regulatory authorities in Japan.

Meanwhile, Eisai is conducting clinical studies of Lenvima in several other tumor types such as hepatocellular carcinoma (Phase III), endometrial carcinoma (Phase II), biliary tract cancer (Phase II), and in combination with an immune checkpoint inhibitor (Phase Ib/II).

For further information on Lenvima in the United States, including Important Safety Information (ISI), please visit the Lenvima product website (http://www.lenvima.com).

2. About Afinitor® (everolimus) Tablets

Afinitor (everolimus) tablets is approved in 112 countries, including the United States and in the European Union, for locally advanced, metastatic or unresectable progressive neuroendocrine tumors (NET) of pancreatic origin. Afinitor is not indicated for the treatment of patients with functional carcinoid tumors in the United States. Afinitor is now approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with progressive, well-differentiated, nonfunctional NET of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic.

It is also approved in more than 120 countries including the United States and European Union for advanced renal cell carcinoma following progression on or after vascular endothelial growth factor (VEGF)-targeted therapy (in the United States, specifically following sunitinib and sorafenib).

Additionally, Afinitor is approved in more than 110 countries including the United States and European Union for advanced HR+/HER2- breast cancer in combination with exemestane, after prior endocrine therapy.

Everolimus is also available from Novartis for use in certain non-oncology patient populations under the brand names Afinitor or Votubia®, Certican® and Zortress® and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Indications vary by country and not all indications are available in every country. The safety and efficacy profile of everolimus has not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for additional indications anywhere else in the world.

Important Safety Information about Afinitor (everolimus) tablets

Afinitor/Votubia can cause serious side effects including lung or breathing problems, infections (including sepsis), and kidney failure, which can lead to death. Patients taking concomitant angiotensin-converting enzyme (ACE) inhibitors may be at an increased risk for angioedema. Mouth ulcers and mouth sores are common side effects. Afinitor/Votubia can affect blood cell counts, kidney and liver function, and blood sugar, cholesterol, and triglyceride levels. Afinitor/Votubia may cause fetal harm in pregnant women. Highly effective contraception is recommended for women

of child-bearing potential while receiving Afinitor/Votubia and for up to eight weeks after ending treatment. Women taking Afinitor/Votubia should not breast feed. Fertility in women and men may be affected by treatment with Afinitor/Votubia.

The most common adverse drug reactions (incidence ≥10 percent) are infections (including sore throat and runny nose, upper respiratory tract infection, pneumonia, sinusitis, and urinary tract infection), mouth ulcers, skin rash, feeling tired, diarrhea, fever, vomiting, nausea, cough, decreased appetite, low level of red blood cells, headache, abnormal taste, absence of menstrual periods, acne, inflammation of lung tissue, irregular menstrual periods, swelling of extremities or other parts of the body, high level of blood sugar, feeling weak, itching, weight loss, high levels of cholesterol, and nose bleeds. The most common Grade 3-4 adverse drug reactions (incidence ≥2 percent) are mouth ulcers, infections (including pneumonia), low level of red blood cells, high level of blood sugar, feeling tired, absence of menstrual periods, diarrhea, low white blood cells, inflammation of lung tissue, feeling weak, fever, and spontaneous bleeding or bruising. Cases of hepatitis B reactivation, blood clots in the lung or legs, and pneumocystis jirovecii pneumonia (PJP) have been reported. Abnormalities were observed in hematology and clinical chemistry laboratory tests.

3. About Study 205[3]

The U.S. Food and Drug Administration's approval of the additional indication for Lenvima in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy in the United States was based on the results of Study 205. Study 205 was a multicenter, randomized, open-label study of the combination of Lenvima (18 mg) plus everolimus (5 mg), Lenvima alone (24 mg), and everolimus alone (10 mg) in patients with unresectable advanced or metastatic renal cell carcinoma following one prior VEGF-targeted therapy, and was conducted in Europe and the United States. 153 patients were randomized in a 1:1:1 ratio to one of three treatment arms to compare the efficacy and safety of these three regimens.

From the results of the study, the combination of Lenvima plus everolimus group demonstrated a significant extension in the study's primary endpoint of progression free survival (PFS) compared to the everolimus alone group (median PFS for the Lenvima plus everolimus group: 14.6 months vs median PFS for the everolimus alone group: 5.5 months; Hazard Ratio (HR) 0.40 [95% CI: 0.24-0.68], p=0.0005). Additionally, median PFS for the Lenvima alone group was 7.4 months, demonstrating an extension in PFS compared to the everolimus alone group (HR: 0.61 [95% CI: 0.38-0.98]).

The study also assessed objective response rate (ORR) and overall survival (OS) as secondary endpoints. Regarding ORR, both the Lenvima plus everolimus group and the Lenvima alone group showed an improvement in ORR compared to the everolimus alone group (Lenvima plus everolimus: 43%, Lenvima alone: 27%, everolimus alone: 6%). Furthermore, regarding OS, an updated analysis carried out in December 2014 suggested that Lenvima plus everolimus extends OS compared to everolimus alone (HR 0.51 [95% CI=0.30-0.88]).

The most common treatment-emergent adverse events (TEAEs) reported in the lenvatinib plus everolimus group were diarrhea, decreased appetite and fatigue. The most common TEAEs of Grade 3 or higher were diarrhea, hypertension and fatigue.

4. About Renal Cell Carcinoma

The number of patients with renal cancer was estimated to be approximately 338,000 worldwide, including approximately 58,000 in the United States, 115,000 in Europe and 17,000 in Japan.[1] Renal cell carcinoma comprises more than 90% of all malignancies of the kidney,[2] and occurs when malignant cells are found in the lining of the tubules of the kidney. The incidence of renal cell carcinoma in people aged in their late 50s is rising, and is more likely to affect men than women. For advanced or metastatic renal cell carcinoma that is difficult to treat with surgery, the standard treatment method is molecular targeted drug therapy, however with low 5-year survival rates, this is a disease with significant unmet medical need.

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

2 Eble J.N, ed. Pathology and Genetics of Tumours of the Urinary System and Male Genital Organs. *World Health Organization Classification of Tumours, 3rd ed*. IARC*Press*, Lyon, 2004.

3 Motzer, R, et al. "Lenvatinib, everolimus, and the combination in patients with metastatic renal cell carcinoma: a randomised, phase 2, open-label, multicentre trial." *The Lancet Oncology*, 2015; 16, 1473-1482.