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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 N 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-

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

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.

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-