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Eisai Co., Ltd.

EISAI LAUNCHES IN-HOUSE DEVELOPED NOVEL ANTICANCER AGENT LENVIMA[®] IN MEXICO

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that its pharmaceutical sales subsidiary in Mexico, Eisai Laboratorios, S. de R.L. de C.V. (Location: Mexico City, "Eisai Mexico") has launched its in-house developed novel anticancer agent Lenvima[®] (lenvatinib mesylate) in Mexico.

Discovered at Eisai's Tsukuba Research Laboratories and developed in-house, Lenvima is a molecular targeted agent with a novel binding mode. Lenvima is approved as a treatment for refractory thyroid cancer in over 40 countries including the United States, Japan, in Europe, South Korea and Canada. In Mexico, Lenvima was approved for treatment of locally progressive or metastatic, recurrent, radioactive iodine-refractory differentiated thyroid cancer in May 2016.

In 2014, Mexico's pharmaceutical market was worth 11.3 billion U.S. dollars, making it the 16th biggest pharmaceutical market in the world, and the third biggest in Latin America after Brazil and Venezuela.¹ In 2019, Mexico's pharmaceutical market is expected to grow to a scale of 13.4 billion U.S. dollars.² In August 2011, Eisai established Eisai Mexico, which currently markets the anticancer agents Halaven[®] and Gliadel[®] in addition to Lenvima. Eisai Mexico has also received approval for the antiepileptic agent Inovelon[®] and submitted the antiepileptic agent Fycompa[®] as well as the antiobesity agent lorcaserin for regulatory review.

Eisai is committed to delivering innovative new treatments to patients in Mexico while enhancing its product lineup as it seeks to further increase the benefits it provides to patients and their families in the country.

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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 PDGFR α ; 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 in the United States, Japan, in Europe, South Korea and Canada, and is undergoing regulatory review in countries throughout the world including Brazil and South Africa. Specifically, Eisai has obtained approval for the agent indicated in the United States for treatment of 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.

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).

2. About the Mexican Health Insurance System

The Mexican health insurance system is built upon two main pillars, a public health insurance system and a national health insurance program. The public health insurance system consists of the Instituto Mexicano del Seguro Social (IMSS) which is social insurance for employees of private companies, and the Instituto de Seguridad y Servicios de los Trabajadores del Estado (ISSSTE) which is for employees of the public sector. Approximately half of the national population is covered by this system. The majority of people who are not enrolled in the public health insurance system and tend to have lower incomes are covered by a national health insurance program (Seguro Popular) which is funded by the federal and state governments.

3. About Eisai Mexico

Eisai established Eisai Laboratorios, S. de R.L. de C.V. (Eisai Mexico) in August 2011 in Mexico City as a direct subsidiary of Eisai's U.S. subsidiary Eisai Inc.

Mexico is ranked as the fifth largest pharmaceutical market in the Americas behind the United States, Canada, Brazil and Venezuela and the 16th largest in the world.¹

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