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Eisai Co., Ltd.

EISAI LAUNCHES LENVIMA® (LENVATINIB) IN CHINA

COMMENCES PROVIDING THE FIRST NEW THERAPY FOR UNRESECTABLE HEPATOCELLULAR CARCINOMA IN CHINA IN ALMOST A DECADE

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced that its Chinese subsidiary Eisai China Inc. (ECI) has launched the kinase inhibitor LENVIMA® (product name in China: 乐卫玛®, generic name: lenvatinib mesylate) in China.

In China, LENVIMA was approved first as a single agent for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy in September 2018. Through this launch, LENVIMA is the first new systemic therapy in approximately ten years available for the first-line treatment of unresectable HCC in China,[1] where the incidence of HCC is the highest in the world.[1]

In March 2018, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. (known as MSD outside the United States and Canada), through an affiliate, entered into a strategic collaboration for the worldwide co-development and co-commercialization of LENVIMA, and collaboration between the companies is progressing around the world. Going forward, ECI and Merck & Co., Inc., Kenilworth, N.J., U.S.A.'s Chinese subsidiary MSD China will work to jointly provide information on LENVIMA in China as well.

Liver cancer is the second leading cause of cancer-related deaths and is estimated to be responsible for approximately 750,000 deaths per year globally. Additionally, approximately 780,000 cases are newly diagnosed each year, about 80% of which occur in Asian regions. Specifically, in China, there are approximately 395,000 new cases and 380,000 deaths per year, accounting for approximately 50% of cases worldwide.[1] HCC accounts for 85% to 90% of primary liver cancer cases. Unresectable HCC, for which treatment options are limited, is extremely difficult to treat, and the development of new treatments is necessary.

Today, LENVIMA is approved as a treatment for refractory thyroid cancer in over 50 countries including the United States, Japan and Europe, and in combination with everolimus as a second-line treatment for renal cell carcinoma in over 45 countries, including in the United States and Europe. In addition to China, LENVIMA is approved for use in the treatment of HCC in Japan, the United States, Europe, and other countries in Asia and around the world.

The Chinese pharmaceutical market is the second largest market in the world after the United States, and in 2017 was worth US$122.2 billion and growing at a rate of 4% on a local currency basis, maintaining growth.[2] Eisai considers China as a key region for driving its global business following after Japan and the United States, and with the launch of LENVIMA in China, seeks to contribute further to increasing the benefits provided to cancer patients and their families.

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[Notes to editors]

1. About LENVIMA® (lenvatinib mesylate)

Discovered and developed in-house by Eisai, LENVIMA is an orally administered kinase inhibitor with a novel binding mode that selectively inhibits the multi 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 pathway-related RTKs (including the platelet-derived growth factor (PDGF) receptor PDGFRα; KIT; and RET) involved in tumor angiogenesis, tumor progression and modification of tumor immunity.

Currently, Eisai has obtained approval for LENVIMA as a treatment for refractory thyroid cancer in over 50 countries, including the United States, Japan, in Europe and Asia. Additionally, Eisai has obtained approval for the agent in combination with everolimus as a second-line treatment for renal cell carcinoma in over 45 countries, including the United States and in Europe. In Europe, the agent was launched under the brand name Kisplyx® for renal cell carcinoma.

In addition, LENVIMA has been approved as a treatment for hepatocellular carcinoma in Japan, the United States, Europe, China and other countries. Furthermore, Eisai has submitted applications for an indication covering hepatocellular carcinoma in Taiwan (December 2017), Brazil (March 2018), Russia (August 2018) and as well as in other countries. In Japan, over 5,000 patients have been treated with LENVIMA since approval of the HCC indication. It is 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.

2. About the Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A. Strategic Collaboration

In March 2018, Eisai and Merck & Co., Inc., Kenilworth, N.J., U.S.A., known as MSD outside the United States and Canada, 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 & Co., Inc., Kenilworth, N.J., U.S.A.'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 and KEYTRUDA combination to support 11 potential indications in six types of cancer (bladder cancer, endometrial cancer, head and neck cancer, hepatocellular carcinoma, melanoma and non-small cell lung cancer), as well as a basket trial targeting six additional cancer types. The LENVIMA and KEYTRUDA combination is not approved in any cancer types today.

3. About Unresectable HCC

Liver cancer is the second leading cause of cancer-related deaths and is estimated to be responsible for 750,000 deaths per year globally. Additionally, 780,000 cases are newly diagnosed each year. There is a large regional difference, with about 80% of new cases occurring in Asian regions, including China and Japan.[1] HCC accounts for 85% to 90% of primary liver cancer cases. HCC is associated with chronic liver disease, in particular cirrhosis. Major causes of cirrhosis include hepatitis B virus and hepatitis C virus. However, according to a recent investigation, non-B/non-C HCC is on the rise. Surgery is the first option for treatment, but for patients with unresectable HCC who are

not amenable for potentially curative therapeutic interventions, which include liver transplant, surgical resection, and tumor ablation (typically radiofrequency ablation or cryotherapy), or who are not suitable for transarterial chemoembolization (TACE), treatment options are limited and the prognosis is very poor.

4. History of Eisai's Business in China

Eisai has been conducting business in China for over 25 years. Eisai expanded into the market in 1991 through a joint venture company, and in 1996, established Eisai China Inc. (Suzhou, Jiangsu Province), a 100% subsidiary with manufacturing / marketing capabilities. In 2010, Eisai (Suzhou) Trading Co., Ltd. was established for directly importing products and in December 2015, Eisai entered the generic pharmaceutical business in China by buying out Eisai (Liaoning) Pharmaceutical Co., Ltd. for the purpose of providing a stable supply of high-quality generic medicine to fulfil the medical needs of Chinese patients. These three companies were consolidated under Eisai China Holdings Ltd., which was established in December 2014.

In January 2018, construction of a new oral solid dose production facility and administration building was completed at the new Suzhou Plant within the Suzhou Industrial Park, and Eisai is working to establish the new Suzhou plant as the plant with the largest production capacity under the Eisai Group.

The core products of Eisai's Chinese business include peripheral neuropathy treatment Methycobal®, liver disease/allergic disease agents Stronger Neo-Minophagen® C / Glycyron® tablets, anti-Alzheimer's agent Aricept®, proton pump inhibitor Pariet®, gastritis/gastric ulcer treatment Selbex®, and Parkinson's disease treatments Comtan®, Stalevo® and Eldepryl® as well as the pipeline product branched-chain amino acid formula Livact® Granules.

[1] GLOBOCAN2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012. http://globocan.iarc.fr/

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