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China NMPA accepts Lenvima for Additional Indication of Thyroid Cancer

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Tokyo based Eisai Co., Ltd. has announced that LENVIMA (generic name: lenvatinib), the orally available kinase inhibitor discovered by Eisai, has been accepted by the National Medical Products Administration(NMPA) of China for an application for the additional indication of differentiated thyroid cancer. This application for additional indication marks the second in China following the indication for hepatocellular carcinoma, which was approved in September 2018.

This application was mainly based on the results of the SELECT Study (Study 303) conducted globally for patients with radioactive iodine-refractory differentiated thyroid cancer. In the SELECT study, LENVIMA demonstrated a statistically significant extension in progression-free survival (PFS), which is the primary endpoint, compared to placebo (median PFS in the LENVIMA group: 18.3 months, median PFS in the placebo group: 3.6 months; Hazard Ratio 0.21 [99% CI: 0.14-0.31]; $p<0.001$). Eisai could submit this application earlier by utilizing the results of SELECT study, while local Phase III clinical trial (Study 308) evaluating LENVIMA in patients with radioactive iodine-refractory differentiated thyroid cancer is ongoing in China.

In China, approximately 190,000 new cases of thyroid cancer are diagnosed each year, and approximately 8,600 are likely to die annually. Although treatment is possible for most types of thyroid cancer, there are few treatment options available once thyroid cancer has progressed, therefore it remains a disease with significant unmet medical needs.

Eisai positions oncology as a key therapeutic area, and is aiming to discover revolutionary new medicines with the potential to cure cancer. Eisai is committed to exploring the potential clinical benefits of LENVIMA, as it seeks to contribute further to addressing the diverse needs of, and increasing the benefits provided to, cancer patients, their families, and healthcare providers.