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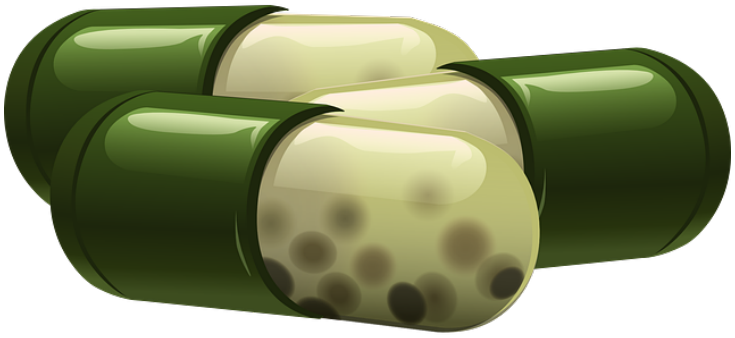

Japan's leading pharmaceutical company Eisai Co. Ltd. has launched its in-house developed novel anticancer agent Lenvima Capsule 4 mg and 10 mg (lenvatinib mesylate, Lenvima) as a treatment for unresectable thyroid cancer in Japan on May 20, 2015.

Lenvima is the first molecular targeted treatment in Japan approved with an indication for unresectable thyroid cancer which covers differentiated thyroid cancer as well as medullary thyroid carcinoma and anaplastic thyroid carcinoma.

Discovered at Eisai's Tsukuba Research Laboratories and developed in-house, Lenvima is an orally administered molecular targeted agent that selectively inhibits the activities of several different molecules including VEGFR, FGFR, RET, KIT and PDGFR. In particular, the agent simultaneously inhibits VEGFR, FGFR and also RET which are especially involved in tumor angiogenesis and proliferation of thyroid cancer.

Furthermore, Lenvima has been confirmed through X-ray co-crystal structural analysis to demonstrate a new binding mode (Type V) to VEGFR2, and exhibits rapid binding to the target molecule and potent inhibition of kinase activity, according to kinetic analysis.

Lenvima was launched in the United States in February 2015, and received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use in March 2015. In addition, the agent is currently undergoing regulatory review in Switzerland, South Korea, Canada, Singapore, Russia, Australia and Brazil.

Also, Eisai is conducting a global Phase III study of Lenvima in hepatocellular carcinoma as well as Phase II studies of Lenvima in several other tumor types such as renal cell carcinoma and non-small cell lung cancer.

In addition to providing Lenvima as a new treatment option for thyroid cancer, in accordance with the conditions of approval, Eisai will work after launch to carry out a special use investigation (all-case study) and promote the appropriate use of Lenvima. Eisai is committed to exploring the potential clinical benefits of Lenvima in order to further contribute to, and address the diverse needs of, patients with cancer, and their families.