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China approves anti-cancer agent by Eisai

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Halaven is a halichondrin class microtubule dynamics inhibitor with a distinct binding profile.

Japan based Eisai Co., Ltd. has received New Drug Approval for Eisai's in-house developed anticancer agent Halaven® (eribulin mesylate) for use in the treatment of patients with locally advanced or metastatic breast cancer, previously treated with at least two prior chemotherapy regimens, including an anthracycline and a taxane, from the China National Medical Products Administration (NMPA).

This approval is based on the results of Study 304, which was a multicenter, open-label, randomized, parallel group Phase III clinical study, to evaluate the efficacy and safety of Halaven and vinorelbine in 530 women with locally recurrent or metastatic breast cancer, previously treated with chemotherapy regimens, including an anthracycline and a taxane. Halaven demonstrated a statistically significant extension in the study's primary endpoint of progression-free survival (PFS) over the comparator treatment vinorelbine according to independent imaging review (Hazard Ratio: 0.80; 95% Confidence Interval: 0.65-0.98; p = 0.036).

The five most common adverse events observed in the Halaven arm of this study were white blood cell count decreased, neutrophil count decreased, increased aspartate aminotransferase, increased alanine aminotransferase, and anemia, which is consistent with the known side-effect profile of Halaven.

The number of women diagnosed with breast cancer in China has increased in recent years, with an estimated 368,000 new cases of breast cancer and approximately 98,000 related deaths in 2018. Breast cancer is now the most frequently diagnosed cancer in Chinese women.

Halaven is a halichondrin class microtubule dynamics inhibitor with a distinct binding profile. In addition to its mechanism of action of inhibiting the growth of microtubule dynamics, non-clinical studies showed Halaven's unique actions on the tumor microenvironment such as an increase in vascular perfusion and permeability in tumor cores, promotion of the epithelial state, decrease in the capacity of breast cancer cells to migrate, etc. For use in the treatment of breast cancer, Halaven is currently approved in over 65 countries worldwide, including the United States, Japan and countries in Europe and Asia.

Eisai positions oncology as a key therapeutic area, and is aiming to discover revolutionary new medicines with the potential to cure cancer. Lenvima® has been available as a treatment of patients with unresectable hepatocellular carcinoma who have not received prior systematic therapy in China since November 2018.* With this approval of Halaven, Eisai seeks to contribute

further to addressing the diverse needs of, and increasing the benefits provided to, patients with cancer, their families, and healthcare providers in China.