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Chugai seeks nod for breast cancer drug in Japan

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Chugai seeks approval for breast cancer treatment T-DM1



Singapore: Japanese multinational Chugai Pharmaceutical has filed a new drug application to the Ministry of Health, Labor and Welfare (MHLW) for antibody-drug conjugate trastuzumab emtansine (T-DM1) for the treatment of HER2-positive metastatic or recurrent breast cancer.

T-DM1 comprises the antibody trastuzumab and the chemotherapy DM1 attached together using a stable linker. T-DM1 is designed to target HER2, inhibit HER2 signalling, induce antibody-dependent cell mediated cytotoxicity, and deliver the chemotherapy DM1 directly inside HER2-positive cancer cells. Once trastuzumab emtansine is taken up by those cancer cells, it is designed to destroy them by releasing the DM1. The number of patients newly diagnosed with breast cancer in Japan is estimated at approximately 60,000 annual average in 2015-2019. And HER2 expression has been observed in approximately 20 percent of breast cancer patients.

Chugai filed the application with the ministry based on the results from an overseas phase III clinical trial and a domestic phase II clinical trial. The trial is an international phase III study comparing T-DM1 alone to lapatinib in combination with capecitabine in people with HER2-positive metastatic or unresectable locally advanced breast cancer who had previously been treated with trastuzumab and a taxane chemotherapy. Japanese patients were not included in the trial.

The trial had progression free survival as one of its primary endpoints, and patients who received T-DM1 experienced a 35 percent reduction in the risk of their disease worsening or death compared to those who received lapatinib plus capecitabine. Regarding safety, fewer patients who received T-DM1 experienced Grade 3 or higher AEs than those who received lapatinib plus capecitabine. The most common Grade 3 or higher AEs reported in patients receiving T-DM1, compared to those receiving lapatinib plus capecitabine, included low platelet count and increase of AST and ALT levels.
The phase II trial conducted in Japan confirmed the efficacy and the tolerability of T-DM1 in Japanese patients.