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Daiichi Sankyo Advances [Fam-] Trastuzumab in Japan

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Global regulatory submission for the antibody drug conjugate is based on the pivotal phase 2 DESTINY-Breast01 and phase 1 trials

Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) has announced the submission of a New Drug Application (NDA) to Japan's Ministry of Health, Labour and Welfare (MHLW) for the use of [fam-] trastuzumab deruxtecan (DS-8201), an investigational HER2 targeting antibody drug conjugate (ADC), for the treatment of patients with HER2 positive metastatic breast cancer.

The Japan NDA is primarily based on the positive results from the pivotal phase 2 DESTINY-Breast01 trial of [fam-] trastuzumab deruxtecan, an open-label, global, multicenter trial, which evaluated dosing, efficacy and safety in patients with HER2 positive metastatic breast cancer. The submission also includes data from the phase 1 trial published in The Lancet Oncology. The response rate observed in DESTINY-Breast01, as assessed by an independent review committee, confirmed the clinical activity observed in the phase 1 trial. Data from DESTINY-Breast01 will be presented at an upcoming medical meeting.

"We are proud to initiate this critical next step in the regulatory process in Japan and look forward to the presentation of the phase 2 DESTINY-Breast01 study of [fam-] trastuzumab deruxtecan to the scientific community," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "We look forward to working closely with the Japan Health Authority on our application for [fam-] trastuzumab deruxtecan in order to bring this important potential new treatment to patients in Japan."

[Fam-] trastuzumab deruxtecan is currently in development for the treatment of patients with a variety of HER2 expressing or HER2 mutant cancers, including gastric, colorectal and lung cancer, as well as in breast cancer with HER2 low expression.

The safety and tolerability profile of [fam-] trastuzumab deruxtecan in DESTINY-Breast01 was consistent with the phase 1 trial data published in The Lancet Oncology, in which the most common adverse events (?30 percent, any grade) included nausea, decreased appetite, vomiting, alopecia, fatigue, anemia, diarrhea and constipation. Cases of drug-related pneumonitis, including grade 5 events, have also been reported in the clinical development program.