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Daiichi Sankyo- AstraZeneca's breast cancer drug reveals positive response

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Pivotal phase 2 DESTINY-Breast01 trial met primary endpoint, supporting global regulatory submission plan to start in first half of fiscal year 2019



Daiichi Sankyo Company, Limited (Daiichi Sankyo) and AstraZeneca have announced positive topline results for the pivotal phase 2 DESTINY-Breast01 trial of [fam-] trastuzumab deruxtecan (DS-8201). The HER2 targeting antibody drug conjugate (ADC) was evaluated in patients with HER2 positive unresectable and/or metastatic breast cancer previously treated with trastuzumab emtansine (T-DM1).

The response rate in DESTINY-Breast01, as assessed by an independent review committee, confirms in a heavily-pretreated global patient population the unprecedented clinical activity in the recently published phase 1 trial. The safety and tolerability profile of [fam-] trastuzumab deruxtecan was also consistent with previous experience. These results are expected to support planned global regulatory submissions, including the Biologics License Application with the U.S. Food and Drug Administration (FDA) anticipated in the first half of fiscal year 2019.

DESTINY-Breast01 is a pivotal phase 2, open-label, global, multicenter, two-part trial of [fam-] trastuzumab deruxtecan. The optimal dose of 5.4 mg/kg was previously identified in part one of the trial. Today's results from part two evaluated the efficacy and safety of that dose in patients who have failed or discontinued previous treatment with T-DM1.

"These results confirm our commitment to pursue accelerated regulatory pathways in HER2 positive metastatic breast cancer with [fam-] trastuzumab deruxtecan," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "We are more dedicated than ever to our comprehensive and ambitious development strategy evaluating the potential across a spectrum of HER2 expressing cancers including breast, gastric, lung and colorectal."

"We are encouraged to see positive data from [fam-] trastuzumab deruxtecan, with the DESTINY-Breast01 trial now reinforcing what earlier data have shown," said José Baselga, Executive Vice President and President R&D Oncology, AstraZeneca. "We believe this antibody drug conjugate has the potential to redefine the treatment of patients with HER2 expressing cancers, and we are eager to bring it as quickly as possible to patients with refractory HER2 positive breast cancer who continue to have high unmet medical need."

[Fam-] trastuzumab deruxtecan has been granted U.S. FDA Breakthrough Therapy Designation and Fast Track Designation for HER2 positive patients in the advanced or refractory breast cancer setting. This investigational agent is currently in development for the treatment of multiple HER2 expressing cancers, including in patients with HER2 low expression.