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Trastuzumab deruxtecan gets FDA priority review to treat metastatic breast cancer

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“Trastuzumab deruxtecan has the potential to transform the treatment landscape for patients with HER2-positive metastatic breast cancer who have limited treatment options today.”

AstraZeneca and Daiichi Sankyo Company, Limited (Daiichi Sankyo) have announced that the US Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for [fam-] trastuzumab deruxtecan (DS-8201) and granted Priority Review.

The Prescription Drug User Fee Act (PDUFA) date for trastuzumab deruxtecan, a HER2-targeting antibody drug conjugate (ADC) and potential new medicine for the treatment of HER2-positive metastatic breast cancer, is set for the second quarter of 2020.

José Baselga, Executive Vice President, Oncology R&D, said: “Trastuzumab deruxtecan has the potential to transform the treatment landscape for patients with HER2-positive metastatic breast cancer who have limited treatment options today. This Priority Review draws on the strength and the consistency of results seen in the Phase I and Phase II trials and is a critical step on the journey to deliver this potential new medicine to patients.”

Antoine Yver, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo, said: “We are pleased that the FDA has accepted the application and granted Priority Review, as we believe trastuzumab deruxtecan has the potential to redefine the treatment of patients with HER2-positive metastatic breast cancer. Following the recent regulatory submission in Japan, we look forward to working closely with regulatory authorities to bring trastuzumab deruxtecan to patients in the US and Japan as soon as possible.”

Trastuzumab deruxtecan was previously granted US FDA Breakthrough Therapy Designation and Fast Track designation. The BLA is based on the combination of data from the Phase I trial and the pivotal Phase II DESTINY-Breast01 trial. The response rate observed in DESTINY-Breast01, as assessed by an independent review committee, validated the clinical activity observed in the Phase I trial.