**FDA accepts BLA from AstraZeneca and Daiichi for targeted chemotherapy**

AstraZeneca and Daiichi Sankyo have announced that the US Food and Drug Administration (FDA) has accepted their biologics license application for targeted cytotoxic chemotherapy trastuzumab deruxtecan. The FDA also granted the drug priority review and the regulator’s decision date will be the second quarter of 2020.

Trastuzumab deruxtecan is a HER2-targetting antibody drug conjugate (ADC); it is potential new medicine for treatment for HER2-positive metastatic breast cancer, where patients experience disease progression following treatment with currently available therapies.

It is the most advanced programme in AstraZeneca’s ADC platform and Daiichi’s lead ADC product.

The FDA’s decision was based upon results from a Phase I study published in *The Lancet* and pivotal, global Phase II data from the DESTINY-Breast01 trial, which will be presented at the San Antonio Breast Cancer Symposium.

AstraZeneca executive vice-president of oncology research and development José Baselga 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.”

Daiichi Sankyo global head of oncology research and development and executive vice-president Antoine Yver 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.”

AstraZeneca and Daiichi have been collaborating on development and commercialisation outside of Japan, where Daiichi will retain exclusive rights; it has recently made a regulatory submission to the Japanese Ministry of Health, Labour and Welfare.

**Sources:**

<https://www.astrazeneca.com/media-centre/press-releases/2019/trastuzumab-deruxtecan-granted-fda-priority-review-for-treatment-of-patients-with-her2-positive-metastatic-breast-cancer-17102019.html>