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Daiichi Sankyo shows updated Phase 1 Data for U3-1402 in cancer patient

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Preliminary efficacy data demonstrated a 42.9 percent confirmed overall response rate and a 90.5 percent disease control rate at a median follow-up time of 10.5 months

Daiichi Sankyo Company, Limited announced that updated efficacy and safety results from the ongoing phase 1/2 study of U3-1402, an investigational and potential first-in-class HER3-targeting antibody-drug conjugate (ADC), in 42 heavily pretreated patients with HER3-positive metastatic breast cancer were presented during a Spotlight Session at the 2018 San Antonio Breast Cancer Symposium (SABCS).

Updated efficacy data for 42 evaluable patients who received U3-1402 in dose levels between 1.6 mg/kg to 8.0 mg/kg in the dose escalation and dose-finding parts of the study showed a confirmed overall response rate of 42.9 percent (18/42 patients) and a disease control rate of 90.5 percent (38/42 patients) at a median follow-up time of 10.5 months. A median duration of response was not reached (range: 2.8, 13.8+). The median progression-free survival was 8.3 months (range: 1.2, 16.8+). Efficacy was observed in all molecular subtypes. A total of 21 patients remain on treatment at the time of data cut-off on November 6, 2018.

"These results offer preliminary evidence of U3-1402 activity in HER3-positive metastatic breast cancer and further study is warranted," said Norikazu Masuda, MD, PhD, National Hospital Organization, Osaka National Hospital, Osaka, Japan, and an investigator for the trial. "The initial efficacy and safety data suggest that a HER3-targeting agent such as U3-1402 could provide a new treatment approach for patients with HER3-expressing metastatic breast cancer, who are in need of additional options to manage their disease."

"We are encouraged by these preliminary findings with U3-1402, particularly because there are no therapies specifically approved for HER3-expressing breast cancer," said Kouichi Akahane, PhD, MBA, Executive Officer, Head of Oncology Function, R&D Division, Daiichi Sankyo. "Additionally, these findings continue to build evidence that supports the portability of Daiichi Sankyo's proprietary DXd and linker ADC technology to other targets such as HER3."