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AstraZeneca, Daiichi Sankyo's trastuzumab shows promise in Phase II Trial

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AstraZeneca and Daiichi Sankyo's trastuzumab deruxtecan demonstrated an impressive 14.8-month median duration of response and 16.4-month median progression-free survival

AstraZeneca and Daiichi Sankyo Company presented positive detailed data from the global pivotal Phase II single-arm DESTINY-Breast01 trial of trastuzumab deruxtecan (DS-8201), a HER2-targeting antibody drug conjugate (ADC) and potential new medicine, in patients with HER2-positive metastatic breast cancer who received two or more prior HER2-targeted regimens.

The primary endpoint of objective response rate (ORR), confirmed by independent central review, was 60.9% with trastuzumab deruxtecan monotherapy (5.4mg/kg). Patients had a median of six prior therapies for metastatic disease (2-27).

Patients achieved a disease control rate (DCR) of 97.3% with a median duration of response (DoR) of 14.8 months and median progression-free survival (PFS) of 16.4 months. The median overall survival (OS) has not yet been reached, with an estimated survival rate of 86% at one year. The results were consistent across subgroups of patients.

José Baselga, Executive Vice President, Oncology R&D, said: “The clinically meaningful and durable responses seen among these patients illustrate the potential of trastuzumab deruxtecan to establish a new standard of care. These results are impressive, as women with this advanced stage of breast cancer have already endured multiple prior therapies for HER2-positive metastatic breast cancer.”

Antoine Yver, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo, said: “The strength of the pivotal results and the consistency with previously reported trastuzumab deruxtecan data further underscore that this specifically engineered HER2-targeted antibody drug conjugate is delivering on its intent of enhancing efficacy for patients with HER2-positive metastatic breast cancer.”

Ian E. Krop, a principal investigator of the DESTINY-Breast01 trial and Associate Chief, Division of Breast Oncology, Susan F. Smith Center for Women's Cancers, Dana-Farber Cancer Institute, said: “These results are particularly striking as trastuzumab deruxtecan prompted a high level of durable tumour reduction among patients, the majority of whom had exhausted most if not all standard therapies for HER2-metastatic breast cancer. We are excited by these results and their

potential to help patients with this advanced stage of breast cancer.”