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Daiichi-Sankyo

Press Release

Daiichi Sankyo Highlights Progress in Creating New Standards of Care for Patients Across Multiple Cancers at ASCO

- ENHERTU® late-breaking data from DESTINY-Breast06 continues to redefine the classification and treatment of metastatic breast cancer with new data in patients with HER2 low and HER2 ultralow disease
- Updated survival results from DESTINY-Breast03 trial of ENHERTU in patients with previously treated HER2 positive metastatic breast cancer also to be presented
- Investor meeting to discuss ASCO presentations and oncology development updates

Basking Ridge, NJ – (May 21, 2024) – Daiichi Sankyo (TSE: 4568) will present new clinical research across its oncology portfolio with more than 45 abstracts in multiple cancers at the 2024 American Society of Clinical Oncology Scientific Program (#ASCO24).

Data at ASCO showcasing the company's progress in creating new standards of care for patients with cancer will include the late-breaking positive results of the DESTINY-Breast06 phase 3 trial (LBA #1000) evaluating ENHERTU® (trastuzumab deruxtecan) compared to standard of care chemotherapy in patients with HR positive, HER2 low (IHC 1+ or IHC 2+/ISH-) or HER2 ultralow [defined as IHC 0 with membrane staining; IHC >0 <1+] metastatic breast cancer following one or more lines of endocrine therapy. Data from DESTINY-Breast06 will be featured in an ASCO press briefing.

"Results to be shared at ASCO from DESTINY-Breast06 demonstrate how ENHERTU continues to challenge the traditional classification and treatment of breast cancer, building on the practice-changing results seen with DESTINY-Breast04," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "These significant data along with updated survival results from DESTINY-Breast03 highlight how ENHERTU is a transformative medicine for the treatment of certain patients with metastatic breast cancer."

Updated survival results from the DESTINY-Breast03 phase 3 trial (#1025) of ENHERTU versus trastuzumab emtansine (T-DM1) in patients with previously treated HER2 positive metastatic breast cancer along with interim results from the dose expansion portion of DESTINY-Breast07 phase 1b/2 trial (#1009) evaluating ENHERTU monotherapy as well as ENHERTU plus pertuzumab in patients with previously untreated HER2 positive metastatic breast cancer also will be presented.

Additional ENHERTU data at ASCO includes the final results of the DESTINY-Lung02 phase 2 trial (#8543) in patients with previously treated HER2 mutant non-small cell lung cancer (NSCLC) as well as three sub-analyses from the DESTINY-PanTumor02 phase 2 trial in patients with HER2 expressing metastatic biliary tract and pancreatic cancer (#4090), bladder cancer (#4565) and head and neck cancer (#6037). Data from DESTINY-PanTumor02 was one of three phase 2 trials that led to the recent accelerated approval in the U.S. of ENHERTU for a tumor agnostic indication in unresectable or metastatic HER2 positive (IHC 3+) solid tumors.

Additional Data and Trials-in-Progress Across Daiichi Sankyo's DXd ADC Portfolio at ASCO

Additional sub-analyses from the TROPION-Lung02 phase 1b trial (#8617) evaluating datopotamab deruxtecan (Dato-DXd) in combination with pembrolizumab with or without platinum chemotherapy as a first-line treatment for patients with advanced or metastatic NSCLC, the intracranial efficacy of datopotamab deruxtecan in patients with advanced or metastatic NSCLC with actionable genomic alterations from the TROPION-Lung05 phase 2 trial (#8593), and patient reported outcomes from the TROPION-Breast01 phase 3 trial (#1006) of datopotamab deruxtecan versus chemotherapy in patients with previously treated inoperable or metastatic hormone receptor positive, HER2 negative breast cancer will be presented.

Trials-in-progress presentations include the IDeate-Lung02 phase 3 trial (TPS8126) evaluating ifinatamab deruxtecan (I-DXd) in patients with relapsed small cell lung cancer, the REJOICE-Ovarian01 phase 2/3 trial (TPS5625) evaluating raludotatug deruxtecan (R-DXd) in patients with platinum-resistant ovarian cancer, the HERTHENA-PanTumor01 phase 2 trial (TPS3164) evaluating patritumab deruxtecan (HER3-DXd) in patients with locally advanced or metastatic solid tumors, and the first-in-human phase 1/2 trial (TPS3165) of DS-3939 in patients with advanced solid tumors.

Additional trials-in-progress featuring combinations of Daiichi Sankyo's DXd ADCs and a novel medicine in development include a phase 1b trial (TPS4180) evaluating valemetostat, a dual inhibitor of EZH1 and EZH2, in combination with ENHERTU or datopotamab deruxtecan in patients with solid tumors and a phase 1b trial (TPS1120) evaluating valemetostat in combination with ENHERTU in HER2 low, ultralow and null metastatic breast cancers.

Daiichi Sankyo will hold a virtual conference call for investors on Monday, June 3, 2024 from 6:00 to 7:00 pm CDT / Tuesday, June 4, 2024 from 8:00 to 9:00 am JST. Executives from Daiichi Sankyo will provide an overview of the ASCO research data and address questions.

Highlights of data from Daiichi Sankyo's oncology portfolio at ASCO 2024 include:

Presentation Title		Author	Abstract	Presentation (CDT)
ENHERTU (trastuzumab deruxtecan; T-DXd)				
Breast	Trastuzumab deruxtecan (T-DXd) vs physician's choice of chemotherapy (TPC) in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2) low or HER2 ultralow metastatic breast cancer (mBC) with prior endocrine therapy (ET): primary results from DESTINY-Breast06 (DB-06)	G. Curigliano	LBA1000	Oral Presentation Sunday, June 2 7:30 – 8:00 am
	Trastuzumab deruxtecan (T-DXd) vs trastuzumab emtansine (T-DM1) in patients with HER2+ mBC: updated survival results of DESTINY-Breast03	E. Hamilton	1025	Poster Session Sunday, June 2 9:00 am – 12:00 pm
	DESTINY-Breast07: dose-expansion interim analysis of T-DXd monotherapy and T-DXd + pertuzumab in patients with previously untreated HER2+ mBC	F. Andre	1009	Oral Presentation Saturday, June 1 3:00 – 6:00 pm
	Pooled analysis by best confirmed response to trastuzumab deruxtecan (T-DXd) in patients with HER2+ mBC from DESTINY-Breast-01, 02, and 03	C. Saura	1023	Poster Session Sunday, June 2 9:00 am – 12:00 pm
Lung	Trastuzumab deruxtecan in patients with HER2 mutant metastatic non-small cell lung cancer: final analysis results of DESTINY-Lung02	P. Janne	8543	Poster Session Monday, June 3 1:30 – 4:30 pm
Tumor Agnostic	Trastuzumab deruxtecan (T-DXd) in patients with HER2 expressing biliary tract cancer and pancreatic cancer: outcomes from DESTINY-PanTumor02	D. Oh	4090	Poster Session Saturday, June 1 1:30 – 4:30 pm
	Efficacy and safety of trastuzumab deruxtecan (T-DXd) in patients with HER2 expressing solid tumors: results from the bladder cohort of DESTINY-PanTumor02 study	P. Wysocki	4565	Poster Session Sunday, June 2 9:00 am – 12:00 pm
	Trastuzumab deruxtecan (T-DXd) in patients with HER2 expressing head and neck tumors: outcomes from DESTINY-PanTumor02	F. Meric-Bernstam	6037	Poster Session Monday, June 3 9:00 am – 12:00 pm
Datopotamab Deruxtecan (Dato-DXd)				
Breast	Datopotamab deruxtecan versus chemotherapy in previously-treated inoperable or metastatic hormone receptor positive, HER2 negative breast cancer: Patient-reported outcomes from the TROPION-Breast01 study	S. Pernas	1006	Oral Presentation Saturday, June 1 3:00 – 6:00 pm
Lung	Datopotamab deruxtecan plus pembrolizumab with or without platinum chemotherapy as first-line therapy for advanced non-small cell lung cancer: subgroup analysis from TROPION-Lung02	B. Levy	8617	Poster Session Monday, June 3 1:30 – 4:30 pm
	Intracranial efficacy of datopotamab deruxtecan in patients with previously treated advanced/metastatic non-small cell lung cancer with actionable genomic alterations: results from TROPION-Lung05	A. Lisberg	8593	Poster Session Monday, June 3 1:30 – 4:30 pm
Patritumab Deruxtecan (HER3-DXd)				
Pan-Tumor	HERTHENA-PanTumor01: a global, multicohort phase 2 trial of HER3-DXd in relapsed/refractory metastatic solid tumors	A. Bhatia	TPS3164	Poster Session Saturday, June 1 9:00 am -12:00 pm
	Patritumab deruxtecan (HER3-DXd) in active brain metastases from metastatic breast and non–small cell lung cancers, and leptomeningeal disease from advanced solid tumors: the TUXEDO-3 phase II trial	R. Bartsch	TPS2091	Poster Session Saturday, June 1 9:00 am -12:00 pm

Ifinatamab Deruxtecan (I-DXd)				
Lung	IDeate-Lung02: a phase 3, randomized, open-label study of ifinatamab deruxtecan (I-DXd) versus treatment of physician's choice in relapsed small cell lung cancer	T. Owonikoko	TPS8126	Poster Session Monday, June 3 1:30 – 4:30 pm
Raludotatug Deruxtecan (R-DXd)				
Ovarian	REJOICE-Ovarian01: a phase 2/3 study of raludotatug deruxtecan (R-DXd) in patients with platinum-resistant ovarian cancer	I. Ray-Coquard	TPS5625	Poster Session Monday, June 3 9:00 am –12:00 pm
DS-3939				
Pan-Tumor	A phase 1/2, first-in-human study of DS-3939 in patients with advanced solid tumors: a new DXd ADC targeting TA-MUC1	N. Yamamoto	TPS3165	Poster Session Saturday, June 1 9:00 am – 12:00 pm
Valemetostat with DXd ADCs				
Breast	Phase 1b study of EZH1/2 inhibitor valemetostat in combination with trastuzumab deruxtecan in patients with HER2 low/ultra low/null metastatic breast cancer	T. Iwase	TPS1120	Poster Session Sunday, June 2 9:00 am – 12:00 pm
Pan-Tumor	A phase 1b, multicenter, open-label study of valemetostat in combination with DXd antibody drug conjugates, trastuzumab deruxtecan (T-DXd) or datopotamab deruxtecan (Dato-DXd), in patients with solid tumors	J. Sands	TPS4180	Poster Session Saturday, June 1 1:30 – 4:30 pm

About the DXd ADC Portfolio of Daiichi Sankyo

The DXd ADC portfolio of Daiichi Sankyo currently consists of six ADCs in clinical development across multiple types of cancer. ENHERTU, a HER2 directed ADC, and datopotamab deruxtecan (Dato-DXd), a TROP2 directed ADC, are being jointly developed and commercialized globally with AstraZeneca. Patritumab deruxtecan (HER3-DXd), a HER3 directed ADC, ifinatamab deruxtecan (I-DXd), a B7-H3 directed ADC, and raludotatug deruxtecan (R-DXd), a CDH6 directed ADC, are being jointly developed and commercialized globally with Merck. DS-3939, a TA-MUC1 directed ADC, is being developed by Daiichi Sankyo.

Designed using Daiichi Sankyo's proprietary DXd ADC Technology to target and deliver a cytotoxic payload inside cancer cells that express a specific cell surface antigen, each ADC consists of a monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

Datopotamab deruxtecan, ifinatamab deruxtecan, patritumab deruxtecan, raludotatug deruxtecan and DS-3939 are investigational medicines that have not been approved for any indication in any country. Safety and efficacy have not been established.

About Daiichi Sankyo

Daiichi Sankyo is an innovative global healthcare company contributing to the sustainable development of society that discovers, develops and delivers new standards of care to enrich the quality of life around the world. With more than 125 years of experience, Daiichi Sankyo leverages its world-class science and technology to create new modalities and innovative medicines for people with cancer, cardiovascular and other diseases with high unmet medical needs. For more information, please visit www.daiichisankyo.com.

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