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Daiichi-Sankyo

Press Release

Daiichi Sankyo Showcases Progress in Developing New Standards of Care for Patients with Industry-Leading DXd ADC Portfolio Across Multiple Cancers at ESMO

- Three late-breaking abstracts, including two Presidential Symposia presentations, showcase datopotamab deruxtecan data from TROPION-Breast01 and TROPION-Lung01 phase 3 trials
- New data featuring first progression-free and overall survival results from DESTINY-PanTumor02 phase 2 trial of ENHERTU® to be highlighted
- Additional analysis from HERTHENA-Lung01 phase 2 trial of patritumab deruxtecan and updates from early phase trials of raludotatug deruxtecan in ovarian cancer and ifinatamab deruxtecan across several tumor types to be presented
- Investor conference call to discuss ESMO presentations across five DXd ADCs in Daiichi Sankyo's oncology portfolio

Basking Ridge, NJ – (October 16, 2023) – Daiichi Sankyo (TSE: 4568) will present new clinical research across its DXd antibody drug conjugate (ADC) portfolio in multiple types of cancer at the 2023 European Society for Medical Oncology (#ESMO23) Congress to be held October 20 - 24, 2023. Three late-breaking abstracts, including two Presidential Symposia presentations, are among the more than 20 abstracts showcasing Daiichi Sankyo's leadership and progress in developing new standards of care for patients with cancer.

Data at ESMO will highlight results from the TROPION-Breast01 and TROPION-Lung01 phase 3 trials (LBA11 and LBA12) evaluating datopotamab deruxtecan (Dato-DXd) versus chemotherapy in patients with HR positive, HER2 low or negative metastatic breast cancer and advanced non-small cell lung cancer (NSCLC) during back-to-back presentations at the Presidential Symposium 3. These data will be featured in an ESMO press briefing.

Other late-breaking data includes a mini-oral session featuring the first presentation of progression-free and overall survival results from the DESTINY-PanTumor02 phase 2 trial (#LBA34) evaluating ENHERTU® (trastuzumab deruxtecan) across multiple HER2 expressing solid tumors, including biliary tract, bladder, cervical, endometrial, ovarian, pancreatic and other cancers.

Updates from other trials across Daiichi Sankyo's DXd ADC portfolio include mini-oral sessions presenting an exploratory analysis of the intracranial efficacy of patritumab deruxtecan (HER3-DXd) in patients with EGFR-mutated metastatic NSCLC from the HERTHENA-Lung01 phase 2 trial, and updated data from an ongoing first-in-human phase 1 trial of raludotatug deruxtecan (R-DXd) in patients with previously treated ovarian cancer. A poster

presentation also will feature updated clinical and biomarker results of ifinatamab deruxtecan (I-DXd) in patients with advanced solid tumors from an ongoing phase 1/2 trial.

"We continue to bring forward new research that demonstrates how our industry-leading DXd antibody drug conjugate portfolio has the potential to transform the current standards of care for patients across multiple tumor types and treatment settings. Data from TROPION-Breast01 and TROPION-Lung01, the first two pivotal trials from our datopotamab deruxtecan clinical development program, underscore the potential to change the way certain patients with HR positive, HER2 low or negative metastatic breast cancer as well as advanced non-small lung cancer are treated," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "Additionally, data from our other ongoing trials of ENHERTU, patritumab deruxtecan, raludotatug deruxtecan and ifinatamab deruxtecan showcase our continued efforts to apply our DXd antibody drug conjugate technology to different targets and types of cancer with the goal of bringing new treatments to patients."

Additional datopotamab deruxtecan data at ESMO includes the first presentation from the TROPION-Lung05 phase 2 trial in patients with previously treated NSCLC with actionable genomic alterations and updated data from the BEGONIA phase 1b/2 trial in patients with previously untreated advanced/metastatic triple negative breast cancer during two mini-oral sessions.

Other ENHERTU data to be highlighted in proffered paper or mini-oral sessions include the primary results from the DESTINY-PanTumor01 phase 2 trial in patients with solid tumors with HER2 activating mutations and a pooled analysis from the DESTINY-Lung01 and DESTINY-Lung02 phase 2 trials in patients with HER2 mutant metastatic NSCLC with and without brain metastases. A proffered paper session also will include updated survival results from the DESTINY-Breast04 phase 3 trial in patients with HER2 low metastatic breast cancer as well as pooled exploratory efficacy and safety analysis from the DESTINY-Breast01, DESTINY-Breast02 and DESTINY-Breast03 trials in patients with HER2 positive metastatic breast cancer with brain metastases.

Daiichi Sankyo will hold a virtual conference call for investors on Tuesday, October 24, 2023 at 8:00-9:30 am ET / 9:00-10:30 pm JST. Executives from Daiichi Sankyo will provide an overview of the ESMO research data and address questions.

Highlights of late-breaking data across Daiichi Sankyo's DXd ADC portfolio at 2023 ESMO include:

Presentation Title		Lead Author	Abstract	Presentation
Datopotamab deruxtecan (Dato-DXd)				
Breast	Datopotamab deruxtecan (Dato-DXd) vs chemotherapy in previously-treated inoperable or metastatic hormone receptor-positive, HER2 negative breast cancer: primary results from the randomized phase 3 TROPION-Breast01 trial	A. Bardia	LBA11	Presidential 3 Monday, October 23 4:30 – 4:42 pm CEST
Lung	Datopotamab deruxtecan (Dato-DXd) vs docetaxel in previously treated advanced/metastatic non-small cell lung cancer (NSCLC): results of the randomized phase 3 study TROPION-Lung01	M. Ahn (presented by A. Lisberg)	LBA12	Presidential 3 Monday, October 23 4:42 – 4:54 pm CEST
ENHERTU (trastuzumab deruxtecan; T-DXd)				
Pan-Tumor	Trastuzumab deruxtecan (T-DXd) for pretreated patients with HER2 expressing solid tumors: primary efficacy analysis from the DESTINY-PanTumor02 study	F. Meric-Bernstam	LBA34	Mini-Oral Session Monday, October 23 4:40 – 4:45 pm CEST

Additional highlights of data to be presented at 2023 ESMO include:

Presentation Title		Lead Author	Abstract	Presentation
Datopotamab deruxtecan (Dato-DXd)				
Breast	Datopotamab deruxtecan (Dato-DXd) + durvalumab as first-line treatment for unresectable locally advanced/metastatic triple-negative breast cancer: updated results from BEGONIA, a phase 1b/2 study	P. Schmid	379MO	Mini-Oral Session Sunday, October 22 8:30 – 8:35 pm CEST
Lung	TROPION-Lung05: datopotamab deruxtecan (Dato-DXd) in previously treated non-small cell lung cancer with actionable genomic alterations	L. Paz-Ares	1314MO	Mini-Oral Session Saturday, October 21 9:30 – 9:35 am CEST
	TROPION-Lung07: a phase 3 trial of datopotamab deruxtecan (Dato-DXd) plus pembrolizumab with or without platinum chemotherapy as first-line therapy in advanced/metastatic non-small cell lung cancer with PD-L1 expression	I. Okamoto	1505TiP	Poster Presentation Monday, October 23
ENHERTU (trastuzumab deruxtecan; T-DXd)				
Breast	Trastuzumab deruxtecan vs treatment of physician's choice in patients with HER2 low unresectable and/or metastatic breast cancer: updated survival results of the randomized, phase 3 DESTINY-Breast04 study	S. Modi	376O	Proferred Paper Session Saturday, October 21 10:25 – 10:35 pm CEST
	A pooled analysis of trastuzumab deruxtecan in patients with HER2 positive metastatic breast cancer with brain metastases from DESTINY-Breast-01, -02, -03	S. Hurvitz	377O	Proferred Paper Session Saturday, October 21 10:55 – 11:05 pm CEST
Lung	Trastuzumab deruxtecan in patients with HER2 (*ERBB2*)-mutant metastatic non-small cell lung cancer with and without brain metastases: pooled analyses from DESTINY-Lung01 and DESTINY-Lung02	D. Planchard	1321MO	Mini-Oral Presentation Sunday, October 22 9:05 – 9:10 am CEST
	Phase 1b multicenter study of trastuzumab deruxtecan and immunotherapy with or without chemotherapy in first-line treatment of patients with advanced or metastatic non squamous non-small cell lung cancer and HER2 overexpression: DESTINY-Lung03	D. Planchard	1507TiP	Poster Presentation Monday, October 23
Pan-Tumor	DESTINY-PanTumor02 study of trastuzumab deruxtecan in patients with HER2 expressing solid tumors: exploratory biomarker analyses of HER2 expression and gene amplification in tissue and plasma	V. Makker	148P	Poster Presentation Saturday, October 21

	Efficacy and safety of trastuzumab deruxtecan (T-DXd) in patients with solid tumors harboring specific HER2 activating mutations: primary results from the international phase 2 DESTINY-PanTumor01 study	B. Li	654O	Proffered Paper Session Sunday, October 22 9:20 – 9:30 am CEST
Patritumab Deruxtecan (HER3-DXd)				
Lung	Intracranial efficacy of HER3-DXd in patients with previously treated advanced EGFR-mutated NSCLC: results from HERTHENA-Lung01	M. Johnson	1319MO	Mini-Oral Session Sunday, October 22 9:00 – 9:05 am CEST
Raludotatug Deruxtecan (R-DXd)				
Ovarian	Raludotatug deruxtecan (R-DXd; DS-6000) monotherapy in patients with previously treated ovarian cancer: subgroup analysis of a first-in-human phase 1 study	K. Moore	745MO	Mini-Oral Session Sunday, October 22 11:35 – 11:40 am CEST
Ifinatamab Deruxtecan (I-DXd)				
Pan-Tumor	Ifinatamab deruxtecan (I-DXd; DS-7300) in patients with advanced solid tumors: updated clinical and biomarker results from a phase 1/2 study	M. Patel	690P	Poster Presentation Monday, October 23

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. Four additional Daiichi Sankyo DXd ADCs include patritumab deruxtecan (HER3-DXd), a HER3 directed ADC, ifinatamab deruxtecan (I-DXd), a B7-H3 directed ADC, raludotatug deruxtecan (R-DXd), a CDH6 directed ADC, and DS-3939, a TA-MUC1 directed ADC.

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 120 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 need. For more information, please visit www.daiichisankyo.com.

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