Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

Daiichi Sankyo Demonstrates Breadth and Depth of Oncology Portfolio Across Multiple Cancers with New Data at ESMO Asia, SABCS and ASH

- Annual R&D Day to provide overview of data and updated strategy across Daiichi Sankyo R&D pipeline

Basking Ridge, NJ – (December 1, 2023) – Daiichi Sankyo (TSE: 4568) will present new clinical research across its oncology portfolio in multiple types of solid and blood cancers at the 2023 ESMO Asia Congress (#ESMOAsia23), San Antonio Breast Cancer Symposium (#SABCS23) and American Society of Hematology (#ASH23) Annual Meeting prior to its annual R&D Day.

Presentation highlights include the first presentation of results from three trials from Daiichi Sankyo's DXd ADC and hematology portfolio, which include the DESTINY-Gastric06 phase 2 trial of ENHERTU® (trastuzumab deruxtecan) in Chinese patients with previously treated HER2 positive locally advanced/metastatic gastric cancer or gastroesophageal junction adenocarcinoma at ESMO Asia, the DESTINY-Breast08 phase 1b trial of ENHERTU in combination with anastrozole or fulvestrant in patients with HER2 low metastatic breast cancer at SABCS and the VALENTINE-PTCL01 phase 2 trial of valemetostat in patients with relapsed/refractory peripheral T-cell lymphoma (PTCL) at ASH.

"Our goal is to push the boundaries of science to change the way cancer is treated," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "These data reinforce the breadth and depth of our oncology pipeline and the important progress we are making in developing innovative medicines and exploring combination strategies for patients across a wide range of cancers, including breast, lung, gastric, acute myeloid leukemia and peripheral T-cell lymphoma."

Subgroup analyses of the TROPION-Lung05 phase 2 trial of datopotamab deruxtecan (Dato-DXd) in Asian patients with non-small cell lung cancer (NSCLC) with actionable genomic alterations and the DESTINY-Lung02 phase 2 trial of ENHERTU in Asian patients with *HER2* mutant NSCLC will be presented at ESMO Asia. Additional subgroup analyses of the QuANTUM-First phase 3 trial in patients with newly diagnosed *FLT3*-ITD positive acute myeloid leukemia (AML), which formed the basis of recent approvals of VANFLYTA® (quizartinib) in the EU, Japan and U.S. will be presented at ASH.

Daiichi Sankyo will hold its annual R&D Day for investors, analysts and media on Monday, December 11 at 5:30 - 7:00 pm EST/Tuesday, December 12 at 7:30 - 9:00 am JST. Company executives will provide highlights of Daiichi Sankyo's research data presented at SABCS and ASH as well as updates on the company's R&D strategy.

ESMO Asia Data

Encore presentations of the TROPION-Lung01 phase 3 trial and TROPION-Lung05 phase 2 trial of datopotamab deruxtecan (Dato-DXd) as well as the DESTINY-PanTumor02 phase 2 trial of ENHERTU will be presented at ESMO Asia from December 1 - 3 in Singapore, along with other data, including:

Presentation Title		Presenter	Abstract	Presentation
ENHERTU (trastuzumab deruxtecan; T-DXd)				
Lung	Trastuzumab deruxtecan (T-DXd) in Asian patients with human epidermal growth factor receptor 2 (*HER2*; *ERBB2*) mutant (*HER2*m) metastatic non–small cell lung cancer: subgroup analysis of DESTINY-Lung02	Y. Goto	510MO	Mini-Oral Session December 2, 2023 9:00 – 10:30 am SGT
Pan-Tumor	Trastuzumab deruxtecan (T-DXd) for pretreated patients with HER2 expressing solid tumors: primary analysis from the DESTINY-PanTumor02 study	D. Oh	74MO	Mini-Oral Session December 1, 2023 10:45 am – 12 :15 pm SGT
Gastric	Trastuzumab deruxtecan (T-DXd) in Chinese patients with previously treated HER2 positive locally advanced/ metastatic gastric cancer or gastroesophageal junction adenocarcinoma: primary efficacy and safety from the phase 2 single-arm DESTINY-Gastric06 trial	L. Shen	172P	Poster Presentation December 2, 2023
Datopotamab deruxtecan (Dato-DXd)				
Lung	Datopotamab deruxtecan (Dato-DXd) vs docetaxel in previously treated advanced/metastatic non-small cell lung cancer: results of the randomized phase 3 study TROPION-Lung01	M. Ahn	509MO	Mini-Oral Session December 2, 2023 9:00 – 10:30 SGT
	TROPION-Lung05: datopotamab deruxtecan (Dato-DXd) in previously treated non-small cell lung cancer with actionable genomic alterations	S. Kitazono	518MO	Mini-Oral Session Sunday, December 3 9:00 – 10:30 am SGT
	TROPION-Lung05: datopotamab deruxtecan (Dato-DXd) in Asian patients with previously treated non-small cell lung cancer with actionable genomic alterations	Y. Goto	552P	Poster Presentation December 2, 2023

SABCS Data

Highlights of Daiichi Sankyo data across several subtypes of breast cancer to be presented at SABCS from December 5 - 9 in San Antonio, Texas, include:

Presentation Title		Author	Abstract	Presentation
ENHERTU (trastuzumab deruxtecan; T-DXd)				
HER2 Low Breast	Trastuzumab deruxtecan (T-DXd) in combination with anastrozole or fulvestrant in patients with HER2 low HR+ advanced/metastatic breast cancer: a phase 1b, open-label, multicenter, dose-expansion study (DESTINY-Breast08)	K. Jhaveri	RF02-03	Rapid-Fire Mini-Oral December 7, 2023 12:00 – 12:45 pm CST

	An open-label, interventional multicenter study of trastuzumab deruxtecan monotherapy in patients with unresectable and/or metastatic HER2 low or HER2 immunohistochemistry 0 breast cancer: DESTINY-Breast15	S. Modi	PO2-19-06	Poster Presentation December 6, 2023 5:00 – 7:00 pm CST
HER2 Positive Breast	European real-world experience of patients with HER2+ advanced/metastatic breast cancer accessing trastuzumab deruxtecan through a named patient program: first interim analysis of EUROPA T-DXd	M. De Laurentiis	PO3-16-12	Poster Presentation December 7, 2023 12:00 – 2:00 pm CST
	Real-world experience with trastuzumab deruxtecan in patients with breast cancer: 6 month interim analysis of an all patient post marketing surveillance in Japan	J. Tsurutani	PO3-17-07	Poster Presentation December 7, 2023 12:00 – 2:00 pm CST
	Population pharmacokinetics of trastuzumab deruxtecan (T-DXd) in HER2 positive breast cancer subjects: analyses across 12 Phase 1-3 studies	C. Li	PO3-04-01	Poster Presentation December 7, 2023 12:00 – 2:00 pm CST
	Exposure-efficacy and exposure-safety analysis of trastuzumab deruxtecan in patients with advanced metastatic HER2+ breast cancer: analyses from phase 3 studies DESTINY-Breast02 and DESTINY-Breast03	C. Li	PO3-04-02	Poster Presentation December 7, 2023 12:00 – 2:00 pm CST
Datopotamab deruxtecan (Dato-DXd)				
HR Positive Breast	Randomized phase 3 study of datopotamab deruxtecan vs chemotherapy for patients with previously treated inoperable or metastatic hormone receptor positive, HER2 negative breast cancer: results from TROPION-Breast01	A. Bardia	GS02-01	Oral Presentation December 7, 2023 8:15 - 8:30 am CST
TNBC	Durvalumab + datopotamab deruxtecan in patients with PD-L1 positive advanced/metastatic triple negative breast cancer: arm 8 of the phase 1b/2, open label, platform BEGONIA study	P. Schmid	PO1-19-10	Poster Presentation December 6, 2023 12:00 - 2:00 pm CST

ASH Data

Highlights of Daiichi Sankyo data from its hematology portfolio to be presented at ASH from December 9 - 12 in San Diego, California, include:

Presentation Title		Presenter	Abstract	Presentation
Valemetostat (EZHARMIA in Japan only)				
T-cell Lymphoma	Efficacy and safety of valemetostat monotherapy in patients with relapsed or refractory peripheral T-cell lymphomas: primary results of the phase 2 VALENTINE-PTCL01 study	S. Horwitz	302	Oral Presentation December 9, 2023 4:15 pm PST
	Valemetostat for relapsed or refractory peripheral T-cell lymphomas: primary results from a phase 1 trial	E. Jacobsen	303	Oral Presentation December 9, 2023 4:30 pm PST
B-cell Lymphoma	Valemetostat for relapsed or refractory B-cell lymphomas: primary results from a phase 1 trial	K. Izutsu	1731	Poster Presentation December 9, 2023 5:30 - 7:30 pm PST

VANFLYTA (quizartinib)				
***FLT3*-ITD AML**	QuANTUM-First: FMS-like tyrosine kinase 3-internal tandem duplication (*FLT3*-ITD)-specific measurable residual disease (MRD) clearance assessed through induction and consolidation is associated with improved overall survival in newly diagnosed *FLT3*-ITD+ AML patients	A. Perl	832	Oral Presentation December 11, 2023 3:30 pm PST
	QuANTUM-First: safety by treatment phase and by age in newly diagnosed patients with FMS-like tyrosine kinase 3-internal tandem duplication (*FLT3*-ITD) positive acute myeloid leukemia (AML)	H. Erba	972	Oral Presentation December 11, 2023 5:45 pm PST
	Patient-reported outcomes in acute myeloid leukemia patients with *FLT3*-ITD mutation receiving quizartinib vs. standard chemotherapy: results from the QuANTUM-First trial	E. Oliva	918	Oral Presentation December 11, 2023 4:00 pm PST
	QuANTUM-First: clinical bridging study for FMS-like tyrosine kinase 3-internal tandem duplication (*FLT3*-ITD) companion diagnostic development	J. Rohrbach	4260	Poster Presentation December 11, 2023 6:00 - 8:00 pm PST
	Kinetics of complete remission (CR) and CR duration and its impact on overall survival (OS) and event-free survival (EFS) in QuANTUM-First	P. Montesinos	4254	Poster Presentation December 11, 2023 6:00 - 8:00 pm PST

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 & Co., Inc., Rahway, NJ. U.S.A. 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 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.

Media Contacts:

Global/US:
Jennifer Brennan
Daiichi Sankyo, Inc.
jbrennan2@dsi.com
+ 1 908 900 3183 (mobile)

Japan:
Koji Ogiwara
Daiichi Sankyo Co., Ltd.
ogiwara.koji.ay@daiichisankyo.co.jp
+81 3 6225 1126 (office)

Investor Relations Contact:
DaiichiSankyoIR@daiichisankyo.co.jp