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Daiichi-Sankyo

Press Release

Daiichi Sankyo Advances Science Across Three Lead DXd ADCs with New Data in Multiple Cancers at 2021 ASCO Virtual Meeting

- Data to highlight promising early efficacy of patritumab deruxtecan in patients with TKI-resistant, EGFR-mutated locally advanced or metastatic non-small cell lung cancer
- Final results from DESTINY-Gastric01 and DESTINY-CRC01 trials continue to demonstrate potential of ENHERTU® across multiple HER2 targetable cancers
- Investor conference calls to discuss ASCO presentations and provide oncology development updates

Munich and Basking Ridge, NJ – (May 19, 2021) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) will present new research data for its three lead DXd antibody drug conjugates (ADCs) in multiple types of cancer at the 2021 American Society of Clinical Oncology (#ASCO21) Virtual Scientific Program to be held June 4 to 8, 2021.

Presentations will highlight the company's growing leadership in developing multiple potential treatment approaches for cancer including an oral presentation featuring extended follow-up data from a phase 1 trial of patritumab deruxtecan (HER3-DXd) in patients with locally advanced or metastatic TKI-resistant, EGFR-mutated non-small cell lung cancer (NSCLC). Preliminary data from this trial informed the recently initiated pivotal HERTHENA-Lung01 phase 2 trial. Additionally, a dose analysis from the NSCLC cohort of the TROPION-PanTumor01 trial, which formed the basis of the datopotamab deruxtecan (Dato-DXd) dose being evaluated in the pivotal TROPION-Lung01 phase 3 trial, will be presented.

Final overall survival results from the pivotal DESTINY-Gastric01 phase 2 trial and final results from the DESTINY-CRC01 phase 2 trial of ENHERTU® (trastuzumab deruxtecan) also will be featured. ENHERTU was recently highlighted in the Clinical Cancer Advances 2021 report as one of two significant advancements in the "ASCO Clinical Advance of the Year: Molecular Profiling Driving Progress in GI Cancers," based on data from both DESTINY-Gastric01 and DESTINY-CRC01.

"The data being presented at ASCO showcase Daiichi Sankyo's sustained progress in advancing our three lead DXd ADCs across multiple cancers including lung, breast, gastric and colorectal cancers," said Ken Takeshita, MD, Global Head, Research and Development, Daiichi Sankyo. "All of these new data, biomarker research and trial-in-progress updates demonstrate our commitment to translating our innovative science and technology into potential treatment options for patients with cancer."

Additional ENHERTU data to be highlighted at ASCO includes updated subgroup analysis of the pivotal DESTINY-Breast01 trial in patients with metastatic HER2 positive breast cancer and brain metastases, initial

results from the ENHERTU arm of the BEGONIA phase 1b/2 durvalumab combination trial in patients with triple negative breast cancer (TNBC), and pooled subgroup analysis across two phase 1 studies of patients with HER2 expressing salivary gland cancer.

Daiichi Sankyo will hold two ASCO conference calls for investors and analysts on Monday, June 7, 2021 from 6:30 PM-8:00 PM EDT (investors located in Japan) and on Tuesday, June 8, 2021 from 7:00 AM-8:30 AM EDT (investors located outside of Japan). Company executives will provide an overview of the ASCO research data, updates for the oncology portfolio and address questions from investors and analysts.

Following is an overview of the research data from the oncology portfolio of Daiichi Sankyo to be presented at ASCO 2021:

Presentation Title		Author	Abstract	Presentation Details
Patritumab deruxtecan (HER3-DXd)				
NSCLC	Efficacy and safety of patritumab deruxtecan (HER3-DXd) in EGFR inhibitor–resistant, EGFR-mutated non-small cell lung cancer (NSCLC)	P. Jänne	9007	Oral Presentation Lung Cancer – Non-Small Cell Metastatic: Friday, June 4, 2021; 1:00 – 4:00 PM EDT
	A randomized phase 2 study of patritumab deruxtecan (U3-1402) in patients with previously treated metastatic or locally advanced EGFR-mutated NSCLC	P. Jänne	TPS9139	Poster Presentation
Datopotamab deruxtecan (Dato-DXd)				
NSCLC	TROPION-PanTumor01: dose analysis of the TROP2 directed antibody-drug conjugate (ADC) datopotamab deruxtecan (Dato-DXd; DS-1062) for the treatment of advanced or metastatic non-small cell lung cancer	F. Meric-Bernstam	9058	Poster Presentation
	A randomized, phase 3 study of datopotamab deruxtecan (Dato-DXd; DS-1062) vs docetaxel in previously treated advanced or metastatic non-small cell lung cancer (NSCLC) without actionable genomic alterations (TROPION-Lung01)	K. Yoh	TPS9127	Poster Presentation
Breast	BEGONIA: phase 1b/2, open-label, platform study of the safety and efficacy of durvalumab (D) ± paclitaxel (P) with novel oncology therapies for first-line metastatic triple-negative breast cancer (mTNBC): addition of Arm 7, D + datopotamab deruxtecan (Dato-DXd; DS-1062)	P. Schmid	TPS1105	Poster Presentation
ENHERTU (trastuzumab deruxtecan; T-DXd)				
Colorectal	Trastuzumab deruxtecan (T-DXd; DS-8201) in patients with HER2 expressing metastatic colorectal cancer (mCRC): final results from a phase 2, multicenter, open-label study (DESTINY-CRC01)	T. Yoshino	3505	Oral Presentation Gastrointestinal Cancer – Colorecal and Anal: Monday, June 7; 1:15 – 4:15 PM EDT
	Trastuzumab deruxtecan in patients with HER2 overexpressing locally advanced, unresectable, or metastatic colorectal cancer (mCRC): a randomized, multicenter, phase 2 study (DESTINY-CRC02)	K. Raghav	TPS3620	Poster Presentation
Gastric	Trastuzumab deruxtecan (T-DXd; DS-8201) in patients with HER2 positive advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma: final overall survival (OS) results from a randomized, multicenter, open-label, phase 2 study (DESTINY-Gastric01)	K. Yamaguchi	4048	Poster Presentation

	Quality-adjusted time without symptoms or toxicity (Q-TWiST) of trastuzumab deruxtecan (T-DXd) versus chemotherapy in patients with advanced gastric cancer from the DESTINY-Gastric01trial	D. Cella	4057	Poster Presentation
Breast	Trastuzumab deruxtecan (T-DXd) in patients with HER2+ metastatic breast cancer with brain metastases: a subgroup analysis of the DESTINY-Breast01 trial	G. Jerusalem	526	Poster Presentation
	BEGONIA: phase 1b/2 study of durvalumab (D) combinations in locally advanced/metastatic triple negative breast cancer (TNBC): Initial results from Arm 1, D+paclitaxel (P), and Arm 6, D+trastuzumab deruxtecan	P. Schmid	1023	Poster Discussion Session
	Trastuzumab deruxtecan (T-DXd) combinations in patients with HER2 positive advanced or metastatic breast cancer: a phase 1b/2, open-label, multicenter, dose-finding and dose-expansion study (DESTINY-Breast07)	F. Andre	TPS1096	Poster Presentation
	Prevalence of HER2 low in breast cancer subtypes using the VENTANA anti- HER2/neu (4B5) assay	M. Scott	1021	Poster Discussion Session
	Machine learning models to quantify HER2 for real-time tissue image analysis in prospective clinical trials	B.Glass	3061	Poster Presentation
Pan Tumor	Trastuzumab deruxtecan (T-DXd) in patients with human epidermal growth factor receptor 2 (HER2)-expressing salivary duct carcinoma: Subgroup analysis of two phase 1 studies	H. Bando	6079	Poster Presentation
	A phase 2, multicenter, open-label study evaluating trastuzumab deruxtecan (T-DXd) for the treatment of solid tumors harboring specific HER2 activating mutations (DESTINY-PanTumor01)	B.Li	TPS3162	Poster Presentation

About the DXd ADC Portfolio of Daiichi Sankyo

The DXd ADC portfolio of Daiichi Sankyo currently consists of seven ADCs with six in clinical development across multiple types of cancer. The company's three lead ADCs include ENHERTU, a HER2 directed ADC, and datopotamab deruxtecan (Dato-DXd), a TROP2 directed ADC, which are being jointly developed and commercialized globally with AstraZeneca; and patritumab deruxtecan (HER3-DXd), a HER3 directed ADC. Three additional ADCs including DS-7300 (B7-H3), DS-6157 (GPR20) and DS-6000 (CDH6) are being developed through a strategic research collaboration with Sarah Cannon Research Institute.

Each ADC is designed using Daiichi Sankyo's proprietary DXd ADC technology to target and deliver chemotherapy inside cancer cells that express a specific cell surface antigen. Each ADC consists of a monoclonal antibody attached to a topoisomerase I inhibitor payload, an exatecan derivative, via a stable tetrapeptide-based cleavable linker.

ENHERTU (5.4 mg/kg) is approved under accelerated approval in the U.S, under conditional marketing authorization in the EU and the UK, and under the conditional early approval system in Japan for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting based on the results from the DESTINY-Breast01 trial.

ENHERTU (6.4 mg/kg) is also approved in the U.S. and Japan for the treatment of adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen based on the results from the DESTINY-Gastric01 trial.

ENHERTU is approved in the U.S. with Boxed WARNINGS for Interstitial Lung Disease and Embryo-Fetal Toxicity. For more information, please see accompanying full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Patritumab deruxtecan, datopotamab deruxtecan, DS-7300, DS-6157 and DS-6000 are investigational medicines that have not been approved for any indication in any country. Safety and efficacy have not been established.

U.S. Important Safety Information for ENHERTU

Indications
ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- Unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

  This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

- Locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.

WARNING: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY

- **Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Advise patients of the risk and to immediately report symptoms.**
- **Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. Advise patients of these risks and the need for effective contraception.**

Contraindications
None.

Warnings and Precautions
Interstitial Lung Disease / Pneumonitis
Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ENHERTU. Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD. Promptly investigate evidence of ILD. Evaluate patients with suspected ILD by radiographic imaging. Consider consultation with a pulmonologist. For asymptomatic ILD/pneumonitis (Grade 1), interrupt ENHERTU until resolved to Grade 0, then if resolved in ≤28 days from date of onset, maintain dose. If resolved in >28 days from date of onset,

reduce dose one level. Consider corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥0.5 mg/kg/day prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), permanently discontinue ENHERTU. Promptly initiate systemic corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥1 mg/kg/day prednisolone or equivalent) and continue for at least 14 days followed by gradual taper for at least 4 weeks.

Metastatic Breast Cancer
In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, ILD occurred in 9% of patients. Fatal outcomes due to ILD and/or pneumonitis occurred in 2.6% of patients treated with ENHERTU. Median time to first onset was 4.1 months (range: 1.2 to 8.3).

Locally Advanced or Metastatic Gastric Cancer
In DESTINY-Gastric01, of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg, ILD occurred in 10% of patients. Median time to first onset was 2.8 months (range: 1.2 to 21.0).

Neutropenia
Severe neutropenia, including febrile neutropenia, can occur in patients treated with ENHERTU. Monitor complete blood counts prior to initiation of ENHERTU and prior to each dose, and as clinically indicated. For Grade 3 neutropenia (Absolute Neutrophil Count [ANC] <1.0 to 0.5 x 10^9/L) interrupt ENHERTU until resolved to Grade 2 or less, then maintain dose. For Grade 4 neutropenia (ANC <0.5 x 10^9/L) interrupt ENHERTU until resolved to Grade 2 or less. Reduce dose by one level. For febrile neutropenia (ANC <1.0 x 10^9/L and temperature >38.3ºC or a sustained temperature of ≥38ºC for more than 1 hour), interrupt ENHERTU until resolved. Reduce dose by one level.

Metastatic Breast Cancer
In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU 5.4mg/kg, a decrease in neutrophil count was reported in 62% of patients. Sixteen percent had Grade 3 or 4 decrease in neutrophil count. Median time to first onset of decreased neutrophil count was 23 days (range: 6 to 547). Febrile neutropenia was reported in 1.7% of patients.

Locally Advanced or Metastatic Gastric Cancer
In DESTINY-Gastric01, of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg, a decrease in neutrophil count was reported in 72% of patients. Fifty-one percent had Grade 3 or 4 decreased neutrophil count. Median time to first onset of decreased neutrophil count was 16 days (range: 4 to 187). Febrile neutropenia was reported in 4.8% of patients.

Left Ventricular Dysfunction
Patients treated with ENHERTU may be at increased risk of developing left ventricular dysfunction. Left ventricular ejection fraction (LVEF) decrease has been observed with anti-HER2 therapies, including ENHERTU. In the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, two cases (0.9%) of asymptomatic LVEF decrease were reported. In DESTINY-Gastric01, of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg, no clinical adverse events of heart failure were reported; however, on echocardiography, 8% were found to have asymptomatic Grade 2 decrease in LVEF. Treatment with ENHERTU has not been studied in patients with a history of clinically significant cardiac disease or LVEF <50% prior to initiation of treatment.

Assess LVEF prior to initiation of ENHERTU and at regular intervals during treatment as clinically indicated. When LVEF is >45% and absolute decrease from baseline is 10-20%, continue treatment with ENHERTU. When LVEF is 40-45% and absolute decrease from baseline is <10%, continue treatment with ENHERTU and repeat LVEF assessment within 3 weeks. When LVEF is 40-45% and absolute decrease from baseline is 10-20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF has not recovered to within 10% from baseline, permanently discontinue ENHERTU. If LVEF recovers to within 10% from baseline, resume treatment with ENHERTU at the same dose. When LVEF is <40% or absolute decrease from baseline is

>20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF of <40% or absolute decrease from baseline of >20% is confirmed, permanently discontinue ENHERTU. Permanently discontinue ENHERTU in patients with symptomatic congestive heart failure.

Embryo-Fetal Toxicity

ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. Verify the pregnancy status of females of reproductive potential prior to the initiation of ENHERTU. Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of ENHERTU. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months after the last dose of ENHERTU.

Additional Dose Modifications

Thrombocytopenia

For Grade 3 thrombocytopenia (platelets <50 to 25 x 10^9/L) interrupt ENHERTU until resolved to Grade 1 or less, then maintain dose. For Grade 4 thrombocytopenia (platelets <25 x 10^9/L) interrupt ENHERTU until resolved to Grade 1 or less. Reduce dose by one level.

Adverse Reactions

Metastatic Breast Cancer

The safety of ENHERTU was evaluated in a pooled analysis of 234 patients with unresectable or metastatic HER2-positive breast cancer who received at least one dose of ENHERTU 5.4 mg/kg in DESTINY-Breast01 and Study DS8201-A-J101. ENHERTU was administered by intravenous infusion once every three weeks. The median duration of treatment was 7 months (range: 0.7 to 31).

Serious adverse reactions occurred in 20% of patients receiving ENHERTU. Serious adverse reactions in >1% of patients who received ENHERTU were interstitial lung disease, pneumonia, vomiting, nausea, cellulitis, hypokalemia, and intestinal obstruction. Fatalities due to adverse reactions occurred in 4.3% of patients including interstitial lung disease (2.6%), and the following events occurred in one patient each (0.4%): acute hepatic failure/acute kidney injury, general physical health deterioration, pneumonia, and hemorrhagic shock.

ENHERTU was permanently discontinued in 9% of patients, of which ILD accounted for 6%. Dose interruptions due to adverse reactions occurred in 33% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose interruption were neutropenia, anemia, thrombocytopenia, leukopenia, upper respiratory tract infection, fatigue, nausea, and ILD. Dose reductions occurred in 18% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose reduction were fatigue, nausea, and neutropenia.

The most common (≥20%) adverse reactions, including laboratory abnormalities, were nausea (79%), white blood cell count decreased (70%), hemoglobin decreased (70%), neutrophil count decreased (62%), fatigue (59%), vomiting (47%), alopecia (46%), aspartate aminotransferase increased (41%), alanine aminotransferase increased (38%), platelet count decreased (37%), constipation (35%), decreased appetite (32%), anemia (31%), diarrhea (29%), hypokalemia (26%), and cough (20%).

Locally Advanced or Metastatic Gastric Cancer

The safety of ENHERTU was evaluated in 187 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma in DESTINY-Gastric01. Patients intravenously received at least one dose of either ENHERTU (N=125) 6.4 mg/kg once every three weeks or either irinotecan (N=55) 150 mg/m^2 biweekly or paclitaxel (N=7) 80 mg/m^2 weekly for 3 weeks. The median duration of treatment was 4.6 months (range: 0.7 to 22.3) in the ENHERTU group and 2.8 months (range: 0.5 to 13.1) in the irinotecan/paclitaxel group.

Serious adverse reactions occurred in 44% of patients receiving ENHERTU 6.4 mg/kg. Serious adverse reactions in >2% of patients who received ENHERTU were decreased appetite, ILD, anemia, dehydration, pneumonia, cholestatic jaundice, pyrexia, and tumor hemorrhage. Fatalities due to adverse reactions occurred in 2.4% of

patients: disseminated intravascular coagulation, large intestine perforation, and pneumonia occurred in one patient each (0.8%).

ENHERTU was permanently discontinued in 15% of patients, of which ILD accounted for 6%. Dose interruptions due to adverse reactions occurred in 62% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose interruption were neutropenia, anemia, decreased appetite, leukopenia, fatigue, thrombocytopenia, ILD, pneumonia, lymphopenia, upper respiratory tract infection, diarrhea, and hypokalemia. Dose reductions occurred in 32% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose reduction were neutropenia, decreased appetite, fatigue, nausea, and febrile neutropenia.

The most common (≥20%) adverse reactions, including laboratory abnormalities, were hemoglobin decreased (75%), white blood cell count decreased (74%), neutrophil count decreased (72%), lymphocyte count decreased (70%), platelet count decreased (68%), nausea (63%), decreased appetite (60%), anemia (58%), aspartate aminotransferase increased (58%), fatigue (55%), blood alkaline phosphatase increased (54%), alanine aminotransferase increased (47%), diarrhea (32%), hypokalemia (30%), vomiting (26%), constipation (24%), blood bilirubin increased (24%), pyrexia (24%), and alopecia (22%).

Use in Specific Populations

- **Pregnancy:** ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. There are clinical considerations if ENHERTU is used in pregnant women, or if a patient becomes pregnant within 7 months following the last dose of ENHERTU.
- **Lactation:** There are no data regarding the presence of ENHERTU in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ENHERTU and for 7 months after the last dose.
- **Females and Males of Reproductive Potential:** Pregnancy testing: Verify pregnancy status of females of reproductive potential prior to initiation of ENHERTU. Contraception: *Females*: ENHERTU can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 7 months following the last dose. *Males*: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months following the last dose. Infertility: ENHERTU may impair male reproductive function and fertility.
- **Pediatric Use:** Safety and effectiveness of ENHERTU have not been established in pediatric patients.
- **Geriatric Use:** Of the 234 patients with HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, 26% were ≥65 years and 5% were ≥75 years. No overall differences in efficacy were observed between patients ≥65 years of age compared to younger patients. There was a higher incidence of Grade 3-4 adverse reactions observed in patients aged ≥65 years (53%) as compared to younger patients (42%). Of the 125 patients with locally advanced or metastatic HER2-positive gastric or GEJ adenocarcinoma treated with ENHERTU 6.4 mg/kg in DESTINY-Gastric01, 56% were ≥65 years and 14% were ≥75 years. No overall differences in efficacy or safety were observed between patients ≥65 years of age compared to younger patients.
- **Hepatic Impairment:** In patients with moderate hepatic impairment, due to potentially increased exposure, closely monitor for increased toxicities related to the topoisomerase inhibitor.

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc. at 1-877-437-7763 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see accompanying full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

About Daiichi Sankyo

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit www.daiichisankyo.com.

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