

## Press Release

# Daiichi Sankyo Advances Leadership in Oncology with Potentially Practice Changing Data at 2021 ESMO Congress

- Four late-breaking presentations, including one Presidential Symposium, showcase ENHERTU data from DESTINY-Breast03, DESTINY-Lung01 and DESTINY-Gastric02 trials along with promising data from TROPION-PanTumor01 trial of datopotamab deruxtecan
- First preliminary results of fourth DXd ADC in clinical development, DS-7300, further demonstrates the strength of Daiichi Sankyo's DXd ADC technology in creating transformative medicines for patients with cancer
- Investor conference call to discuss ESMO presentations and provide oncology development updates

**Munich and Basking Ridge, NJ – (September 7, 2021)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) will present new research data across its antibody drug conjugate (ADC) portfolio in a broad range of cancers at the 2021 European Society for Medical Oncology (#ESMO21) Virtual Congress to be held September 16 to 21, 2021. Four late-breaking presentations, including a Presidential Symposium, showcase Daiichi Sankyo's growing leadership in creating transformative medicines for patients with cancer.

Data demonstrating superior progression-free survival results in a head-to-head comparison of ENHERTU® (trastuzumab deruxtecan) versus trastuzumab emtansine (T-DM1) in patients with previously treated HER2 positive metastatic breast cancer from the [DESTINY-Breast03](#) phase 3 trial will be highlighted during a Presidential Symposium.

Other late-breaking ENHERTU data at ESMO includes primary data from the HER2 mutated metastatic non-small cell lung cancer (NSCLC) cohort of the [DESTINY-Lung01](#) phase 2 trial and the first results from the [DESTINY-Gastric02](#) phase 2 trial in patients with HER2 positive unresectable gastric or gastroesophageal junction (GEJ) adenocarcinoma. Updated overall survival data from the [DESTINY-Breast01](#) phase 2 trial also will be presented.

“At this year's ESMO, Daiichi Sankyo's growing leadership in oncology will be demonstrated through the potentially practice-changing results from the DESTINY-Breast03 and DESTINY-Lung01 trials, which showcase the transformative nature of ENHERTU in HER2 positive metastatic breast cancer and HER2 mutated metastatic non-small cell lung cancer,” said Ken Takeshita, MD, Global Head, Research and Development, Daiichi Sankyo. “Other impressive data across our ADC portfolio, including datopotamab deruxtecan and DS-7300, continue to demonstrate the strength of Daiichi Sankyo's ADC technology across multiple cancers.”

The fourth late-breaking presentation will highlight promising results from a sub-group analysis of the patients with advanced/metastatic NSCLC and actionable genomic alterations from the [TROPION-PanTumor01](#) phase 1 trial of datopotamab deruxtecan (Dato-DXd) in solid tumors.

Preliminary results from the [phase 1/2 clinical trial of DS-7300](#), a B7-H3 directed ADC, in patients with advanced solid tumors will be featured as a Proffered Paper presentation. Preclinical research on DS-6000, a CDH6 directed ADC, also will be presented during the meeting.

Daiichi Sankyo will hold a conference call for investors and analysts on Tuesday, September 21, 2021 at 6:30 pm EDT. Ken Takeshita, MD, Global Head, Research and Development, Daiichi Sankyo, will provide an overview of the ESMO and World Conference on Lung Cancer (WCLC) research data and address questions from investors and analysts.

Following is an overview of the late-breaking research data from the oncology portfolio of Daiichi Sankyo to be presented at ESMO 2021:

Presentation Title		Author	Abstract ID	Presentation Details	
<b>Late-Breaking Presentations</b>					
<b>ENHERTU</b>	<b>Breast</b>	Trastuzumab Deruxtecan (T-DXd) vs. Trastuzumab Emtansine (T-DM1) in Patients With HER2+ Metastatic Breast Cancer (mBC): Results of the Randomized Phase 3 DESTINY-Breast03 Study	J. Cortés	# LBA1	Presidential Symposium Saturday, September 18 15:05 – 15:20 CEST
	<b>Lung</b>	Primary Data from DESTINY-Lung01: A Phase 2 Trial of Trastuzumab Deruxtecan (T-DXd) in Patients With HER2 Mutated (HER2m) Metastatic Non–Small Cell Lung Cancer (NSCLC)	B. Li	#LBA45	Proffered Paper Session NSCLC, Metastatic Saturday, September 18 14:10 – 14:20 CEST
	<b>Gastric</b>	Primary Analysis of a Phase 2 Single-Arm Trial of Trastuzumab Deruxtecan (T-DXd) in Western Patients With HER2 Positive (HER2+) Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Cancer Who Progressed on or After a Trastuzumab-containing Regimen	E. Van Cutsem	#LBA55	Mini Oral Session Gastrointestinal Tumors, Non-colorectal Friday, September 17 17:45 – 17:50 CEST
<b>Dato-DXd</b>	<b>Lung</b>	Efficacy of Datopotamab Deruxtecan (Dato-DXd) in Patients With Advanced/Metastatic Non-Small Cell Lung Cancer (NSCLC) and Actionable Genomic Alterations (AGAs): Preliminary Results from the Phase 1 TROPION-PanTumor01 Study	E. Garon	#LBA49	Mini Oral Session NSCLC, Metastatic Sunday, September 19 17:30 – 17:35 CEST

Other data presentations from the oncology portfolio of Daiichi Sankyo to be presented include:

Presentation Title		Author	Abstract ID	Presentation Details
<b>DS-7300</b>				
<b>Solid Tumors</b>	A Phase 1/2 Multicenter, First-in-Human Study of DS-7300 (B7-H3 DXd-ADC) in Patients With Advanced Solid Tumors	M. Johnson	Presentation #5130	Proffered Paper Session Developmental Therapeutics Friday, September 17 14:10 – 14:20 CEST
<b>ENHERTU</b>				
<b>Breast</b>	Trastuzumab Deruxtecan (T-DXd) in Patients With HER2 Positive Metastatic Breast Cancer (MBC): Updated Survival Results from a Phase 2 Trial (DESTINY-Breast01)	C. Saura	#279P	ePoster
	Phase 3 Study of Trastuzumab Deruxtecan (T-DXd) With or Without Pertuzumab vs a Taxane, Trastuzumab and Pertuzumab in First Line (1L), Human Epidermal Growth Factor Receptor 2–positive (HER2+) Metastatic Breast Cancer (mBC): DESTINY-Breast09	S. Tolaney	#328TiP	ePoster
	Open-label, Multinational, Multicenter, Phase 3b/4 Study of Trastuzumab Deruxtecan (T-DXd) in Patients With or Without Baseline Brain Metastasis With Previously Treated Advanced/Metastatic Human Epidermal Growth Factor Receptor 2–positive Breast Cancer (HER2+ BC): DESTINY-Breast12	N. Lin	#335TiP	ePoster
	A Retrospective Population-based Observational Study in Metastatic HER2 Positive Breast Cancer Patients in Denmark Previously Treated With T-DM1	A. Due	#289P	ePoster
	Burden of Illness of HER2+ in Metastatic Breast Cancer (MBC) Patients: A Systematic Literature Review (SLR)	G. Vondeling	#287P	ePoster
<b>NSCLC</b>	Trastuzumab Deruxtecan (T-DXd) in Patients with HER2 Mutated (HER2m) Metastatic Non-Small Cell Lung Cancer (NSCLC): A Phase 2 Study (DESTINY-Lung02)	E. Smit	#1361TiP	ePoster
<b>Gastric</b>	Trastuzumab Deruxtecan (T-DXd) in Patients With HER2 Positive Gastric Cancer (GC) or Gastroesophageal Junction (GEJ) Adenocarcinoma Who Have Progressed On or After a Trastuzumab-Containing Regimen (DESTINY-Gastric04, DG-04): A Randomized Phase 3 Study	K. Shitara	#1436TiP	ePoster
<b>Colorectal</b>	Exploratory Biomarker Analysis of DESTINY-CRC01, a Phase 2, Multicenter, Open-Label Study of Trastuzumab Deruxtecan (T-DXd, DS-8201) in Patients With HER2-Expressing Metastatic Colorectal Cancer (mCRC)	S. Siena	#386O	Proffered Paper Session Gastrointestinal Tumors, Colorectal Saturday, September 18 13:40 – 13:50 CEST

<b>Pan-Tumor</b>	A Phase 2, Multicenter, Open-label Study Evaluating Trastuzumab Deruxtecan (T-DXd) For the Treatment of Select HER2 Expressing Solid Tumors (DESTINY-PanTumor02)	F. Meric-Bernstam	#1869TiP	ePoster
<b>DS-6000</b>				
<b>Pre-Clinical</b>	DS-6000a, a Novel CDH6-targeting Antibody-Drug Conjugate With a Novel DNA Topoisomerase I Inhibitor DXd, Demonstrates Potent Antitumor Activity in Preclinical Models	H. Suzuki	#10P	ePoster

### 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 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 in Canada, EU, Israel, Japan, UK and U.S. 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 Israel, Japan and U.S. 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 the accompanying full [Prescribing Information](#), including Boxed WARNINGS, and [Medication Guide](#).

Datopotamab deruxtecan, patritumab 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  $\leq 28$  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.,  $\geq 0.5$  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.,  $\geq 1$  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  $0.5 \times 10^9/L$ ) interrupt ENHERTU until resolved to Grade 2 or less, then maintain dose. For Grade 4 neutropenia (ANC  $<0.5 \times 10^9/L$ ) interrupt ENHERTU until resolved to Grade 2 or less. Reduce dose by one level. For febrile neutropenia (ANC  $<1.0 \times 10^9/L$  and temperature  $>38.3^\circ C$  or a sustained temperature of  $\geq 38^\circ C$  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  $25 \times 10^9/L$ ) interrupt ENHERTU until resolved to Grade 1 or less, then maintain dose. For Grade 4 thrombocytopenia (platelets  $<25 \times 10^9/L$ ) 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 ( $\geq 20\%$ ) 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<sup>2</sup> biweekly or paclitaxel (N=7) 80 mg/m<sup>2</sup> 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 ( $\geq 20\%$ ) 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  $\geq 65$  years and 5% were  $\geq 75$  years. No overall differences in efficacy were observed between patients  $\geq 65$  years of age compared to younger patients. There was a higher incidence of Grade 3-4 adverse reactions observed in patients aged  $\geq 65$  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  $\geq 65$  years and 14% were  $\geq 75$  years. No overall differences in efficacy or safety were observed between patients  $\geq 65$  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](http://fda.gov/medwatch).

Please see accompanying full [Prescribing Information](#), including **Boxed WARNINGS**, and [Medication Guide](#).

### About Daiichi Sankyo in Oncology

The oncology portfolio of Daiichi Sankyo is powered by our team of world-class scientists that push beyond traditional thinking to create transformative medicines for people with cancer. Anchored by our DXd antibody drug conjugate (ADC) technology, our research engines include biologics, medicinal chemistry, modality and other research laboratories in Japan, and [Plexxikon](#), our small molecule structure-guided R&D center in the U.S. We also work alongside leading academic and business collaborators to further advance the understanding of cancer as Daiichi Sankyo builds towards our ambitious goal of becoming a global leader in oncology by 2025.

### 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](http://www.daiichisankyo.com).

**Media Contacts:**

**Global/US:**

Jennifer Brennan  
Daiichi Sankyo, Inc.  
[jbrennan2@dsi.com](mailto:jbrennan2@dsi.com)  
+1 908 992 6631 (office)  
+1 908 900 3183 (mobile)

**Japan:**

Masashi Kawase  
Daiichi Sankyo Co., Ltd.  
[kawase.masashi.a2@daiichisankyo.co.jp](mailto:kawase.masashi.a2@daiichisankyo.co.jp)  
+81 3 6225 1126 (office)

**EU:**

Lydia Worms  
Daiichi Sankyo Europe GmbH  
[lydia.worms@daiichi-sankyo.eu](mailto:lydia.worms@daiichi-sankyo.eu)  
+49 (89) 7808751 (office)  
+49 176 11780861 (mobile)

**Investor Relations Contact:**

[DaiichiSankyoIR@daiichisankyo.co.jp](mailto:DaiichiSankyoIR@daiichisankyo.co.jp)