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Press Release

Daiichi Sankyo to Present New Research Data Across DXd ADC Portfolio at 2020 ASCO Annual Meeting

- Research data from the pivotal phase 2 DESTINY-Gastric01 trial of ENHERTU® to be presented along with phase 2 DESTINY-Lung01 and DESTINY-CRC01 research data
- Updated phase 1 data for DS-1062 in patients with unresectable advanced non-small cell lung cancer will be reported
- Investor conference calls to be hosted by Daiichi Sankyo to discuss ASCO presentations and provide oncology development updates

Basking Ridge, NJ and Munich – (May 13, 2020) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it will present new research data across its DXd antibody drug conjugate (ADC) portfolio at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program to be held May 29 to May 31 (#ASCO20).

Highlights include research data presentations from four trials in the DESTINY program of ENHERTU® (fam-trastuzumab deruxtecan-nxki), a HER2 directed ADC, in several types of HER2 expressing cancers. Results will be reported from the pivotal phase 2 DESTINY-Gastric01 trial, which demonstrated a statistically significant and clinically meaningful improvement in objective response rate (ORR) and overall survival (OS) for patients with HER2 positive metastatic gastric cancer who progressed after two previous regimens treated with ENHERTU compared to investigator's choice of chemotherapy (irinotecan or paclitaxel monotherapy). ENHERTU was recently granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for patients in this setting.

Interim phase 2 data from the DESTINY-Lung01 trial in patients with HER2 mutant metastatic non-small cell lung cancer (NSCLC) and the DESTINY-CRC01 trial in patients with HER2 expressing advanced colorectal cancer will be presented during two oral presentations. Research data including objective response rate (ORR), duration of response (DOR), disease control rate (DCR), progression-free survival (PFS) as well as safety and tolerability from each of these trials will be reported. Findings from DESTINY-Breast01 evaluating clinical and molecular variables as possible predictors of efficacy also will be shared.

Updated phase 1 results with DS-1062, a TROP2 directed DXd ADC, will be presented in patients with advanced NSCLC who are refractory to or have relapsed following standard treatment or for whom no

standard treatment is available, including research data for additional patients enrolled into both the dose escalation and dose expansion parts of the trial.

"We look forward to sharing updates from the DESTINY development program including pivotal data from DESTINY-Gastric01, which represent the first research data from a randomized controlled trial evaluating tumor response and overall survival for ENHERTU compared to investigator's choice of chemotherapy," said Antoine Yver, MD, MSc, EVP and Global Head, Oncology Research and Development, Daiichi Sankyo. "The body of research data to be presented at ASCO demonstrates significant development progress for two of our lead ADCs, as we remain committed to translating our DXd ADC technology into new treatment options for as many appropriate patients as possible."

The overall safety and tolerability profile of ENHERTU in DESTINY-Gastric01 was consistent with that seen in the phase 1 trial in which the most common adverse events (≥30 percent, any grade) were hematologic and gastrointestinal including neutrophil count decrease, anemia, nausea and decreased appetite. There were cases of drug-related interstitial lung disease (ILD) and pneumonitis, the majority of which were grade 1 and 2 with two grade 3 and one grade 4. No ILD-related deaths (grade 5) occurred in patients with gastric cancer in the phase 1 trial or in the DESTINY-Gastric01 trial.

Daiichi Sankyo will hold two ASCO conference calls for investors and analysts: on Sunday, May 31, 2020 from 6:30 PM-8:00 PM EDT (in Japanese/English) and on Tuesday, June 2, 2020 from 8:00 AM-9:30 AM EDT (in English). 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 2020:

ASCO Virtual Scientific Program Abstract Title	**Presentation Details**
ENHERTU (HER2 ADC)	
Trastuzumab deruxtecan (T-DXd; DS-8201) in patients with HER2-expressing advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma: A randomized, phase 2, multicenter, open-label study (DESTINY-Gastric01)	Poster Discussion (Abstract 4513): K. Shitara, et al. Gastrointestinal Cancer: Gastroesophageal, Pancreatic, and Hepatobillary; May 29 at 8:00 AM ET
Trastuzumab deruxtecan (T-DXd; DS-8201) in patients with HER2-mutated metastatic non-small cell lung cancer (NSCLC): Interim results of DESTINY-Lung01	Oral Presentation (Abstract 9504): E. Smit, et al. Lung Cancer: Non-Small Cell Metastatic; May 29 at 8:00 AM ET
A phase 2, multicenter, open-label study of trastuzumab deruxtecan (T-DXd; DS-8201) in patients with HER2-expressing metastatic colorectal cancer (mCRC) (DESTINY-CRC01)	Oral Presentation (Abstract 4000): S. Siena, et al. Gastrointestinal Cancer: Colorectal and Anal; May 29 at 8:00 AM ET

Trastuzumab deruxtecan for HER2-positive metastatic breast cancer: DESTINY-Breast01 subgroup analysis	Poster Presentation (Abstract 1036): S. Modi, et al. Breast Cancer – Metastatic; May 29 at 8:00 AM ET
Trastuzumab deruxtecan (T-DXd; DS-8201) in combination with pembrolizumab in patients with advanced/metastatic breast or non-small cell lung cancer (NSCLC): A phase 1b, multicenter, study	Poster Presentation (Abstract TPS1100 – Trial in Progress): H. Borghaei, et al. Breast Cancer – Metastatic; May 29 at 8:00 AM ET
Multicenter phase II study of trastuzumab deruxtecan (DS-8201) for HER2 positive unresectable or recurrent biliary tract cancer: HERB trial	Poster Presentation (Abstract TPS4654 – Trial in Progress): A. Ohba, et al. Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary; May 29 at 8:00 AM ET
A basket trial of trastuzumab deruxtecan, a HER2-targeted antibody-drug conjugate, for HER2 amplified solid tumors identified by circulating tumor DNA analysis (HERALD trial)	Poster Presentation (Abstract TSP3650 – Trial in Progress): M. Yagisawa, et al. Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology; May 29 at 8:00 AM ET
Real-world effectiveness of post–T-DM1 treatments in HER2-positive metastatic breast cancer: KBCSG-TR1917 observational study	Online Publication (Abstract #e13020): S. Masuda, et al; May 13 at 5:00 PM ET
Real-world study of the treatments following trastuzumab-emtansine for HER2-positive metastatic breast cancer: A multi-central cohort study (WJOG12519B)	Online Publication (Abstract #e13019): S. Kurozumi, et al; May 13 at 5:00 PM ET
DS-1062 (TROP2 ADC)	
Updated results from the phase 1 study of DS-1062, a trophoblast cell-surface antigen 2 (TROP-2) antibody-drug conjugate (ADC), in patients (pts) with advanced non-small cell lung cancer (NSCLC)	Visual Presentation in Poster Session (Abstract 9619): A.E. Lisberg, et al. Lung Cancer—Non-Small Cell Metastatic; May 29 at 8:00 AM ET
DS-7300 (B7-H3 ADC)	
A phase I/II, two-part, multicenter first-in-human study of DS-7300a in patients with advanced solid malignant tumors (Trial-in-Progress)	Visual Presentation in Poster session (Abstract TPS3636 – Trial in Progress): J.C. Bendell, et al. Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology; May 29 at 8:00 AM ET
TURALIO® (CSF1R inhibitor)	
Patient journey and quality of life among diffuse-type TGCT in the U.S.	Online Publication (Abstract e23565): N. Bernthal, et al. May 13 at 5:00 PM ET
Evaluation of Patient and Healthcare Provider (HCP) Knowledge, Attitudes, and Behavior for Safety and Use of Pexidartinib	Online Publication (Abstract e23580): M. Salas, et al. May 13 at 5:00 PM ET

About the DXd ADC Portfolio of Daiichi Sankyo

The DXd ADC portfolio of Daiichi Sankyo currently consists of seven novel antibody drug conjugates (ADCs) with four in clinical development across multiple types of cancer. These include ENHERTU, a HER2 directed ADC, which is being jointly developed and commercialized globally with AstraZeneca; DS-1062 (TROP2); U3-1402 (HER3); and DS-7300 (B7-H3). Each ADC is engineered using Daiichi Sankyo's proprietary and portable 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 by a tetrapeptide-based linker to a novel topoisomerase I inhibitor payload (chemotherapy) with a customized drug to antibody ratio (DAR) to optimize the risk-benefit ratio for the intended patient population.

ENHERTU (formerly known as DS-8201; trastuzumab deruxtecan outside the U.S.; fam-trastuzumab deruxtecan-nxki in the U.S. only) has been approved for use only in the U.S. and Japan. ENHERTU has not been approved in the EU, or countries outside of the U.S. and Japan for any indication. It is an investigational agent globally for various indications. Safety and effectiveness have not been established for the subject proposed uses. TURALIO (pexidartinib) has been approved for use only in the U.S. TURALIO has not been approved in the EU or Japan, or countries outside of the U.S. for any indication. DS-1062 and DS-7300 are investigational agents that have not been approved for any indication in any country. Safety and efficacy have not been established.

U.S. FDA-Approved Indication for ENHERTU
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.

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. In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer treated with ENHERTU, 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).

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 prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), permanently discontinue ENHERTU. Promptly initiate corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥1 mg/kg prednisolone or equivalent). Upon improvement, follow by gradual taper (e.g., 4 weeks).

Neutropenia
Severe neutropenia, including febrile neutropenia, can occur in patients treated with ENHERTU. Of the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, a decrease in neutrophil count was reported in 30% of patients and 16% had Grade 3 or 4 events. Median time to first onset was 1.4 months (range: 0.3 to 18.2). Febrile neutropenia was reported in 1.7% of patients.

Monitor complete blood counts prior to initiation of ENHERTU and prior to each dose, and as clinically indicated. Based on the severity of neutropenia, ENHERTU may require dose interruption or reduction. 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.

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. 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. Manage LVEF decrease through treatment interruption. Permanently discontinue ENHERTU if LVEF of <40% or absolute decrease from baseline of >20% is confirmed. 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.

Adverse Reactions
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 adverse reactions (frequency ≥20%) were nausea (79%), fatigue (59%), vomiting (47%), alopecia (46%), constipation (35%), decreased appetite (32%), anemia (31%), neutropenia (29%), diarrhea (29%), leukopenia (22%), cough (20%), and thrombocytopenia (20%).

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%).
- **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 WARNING, and Medication Guide.

U.S. FDA-Approved Indication for TURALIO

TURALIO (pexidartinib) is indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

WARNING: HEPATOTOXICITY

- **TURALIO can cause serious and potentially fatal liver injury.**
- **Monitor liver tests prior to initiation of TURALIO and at specified intervals during treatment. Withhold and dose reduce or permanently discontinue TURALIO based on severity of hepatotoxicity.**
- **TURALIO is available only through a restricted program called the TURALIO Risk Evaluation and Mitigation Strategy (REMS) Program.**

Contraindications
None.

Warnings and Precautions

Hepatotoxicity
TURALIO can cause serious and potentially fatal liver injury and is available only through a restricted program called the TURALIO REMS. Hepatotoxicity with ductopenia and cholestasis has occurred in patients treated with TURALIO. Across 768 patients who received TURALIO in clinical trials, there were 2 irreversible cases of cholestatic liver injury. One patient with advanced cancer and ongoing liver toxicity died and one patient required a liver transplant.

In ENLIVEN, 3 of 61 (5%) patients who received TURALIO developed signs of serious liver injury, defined as ALT or AST ≥3 × ULN with total bilirubin ≥2 × ULN. ALT, AST and total bilirubin improved to <2 × ULN in these patients 1 to 7 months after discontinuing TURALIO.

The mechanism of cholestatic hepatotoxicity is unknown and its occurrence cannot be predicted. It is unknown whether liver injury occurs in the absence of increased transaminases. Please see Adverse Reactions.

Avoid TURALIO in patients with preexisting increased serum transaminases, total bilirubin, or direct bilirubin (>upper limit of normal [ULN]) or patients with active liver or biliary tract disease including increased alkaline phosphatase (ALP). Taking TURALIO with food increases drug exposure by 100% and may increase the risk of hepatotoxicity. Administer TURALIO on an empty stomach, either 1 hour before or 2 hours after a meal or snack. Monitor liver tests, including aspartate aminotransferase (AST), alanine aminotransferase (ALT), total bilirubin, direct bilirubin, ALP, and gamma-glutamyl transferase (GGT), prior to initiation of TURALIO, weekly for the first 8 weeks, every 2 weeks for the next month, and every 3 months thereafter. Withhold and dose reduce, or permanently discontinue TURALIO based on the severity of the hepatotoxicity. Rechallenging with a reduced dose of TURALIO may result in a recurrence of increased serum transaminases, bilirubin, or ALP. Monitor liver tests weekly for the first month after rechallenge.

TURALIO REMS
TURALIO is available only through a restricted program under a REMS, because of the risk of hepatotoxicity. Notable requirements of the TURALIO REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Patients must complete and sign an enrollment form for inclusion in a patient registry.
- Pharmacies must be certified with the program and must dispense only to patients who are authorized (enrolled in the REMS patient registry) to receive TURALIO.

Further information is available at turalioREMS.com or by calling 1-833-887-2546.

Embryo-fetal toxicity
Based on animal studies and its mechanism of action, TURALIO may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective nonhormonal method of contraception, since TURALIO can render hormonal contraceptives ineffective, during treatment with TURALIO and for 1 month after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TURALIO and for 1 week after the final dose.

Adverse Reactions
The safety of TURALIO was evaluated in ENLIVEN, in which patients received TURALIO without food at a dose of 400 mg in the morning and 600 mg in the evening orally for 2 weeks followed by 400 mg orally twice daily until disease progression or unacceptable toxicity.

Serious adverse reactions were reported in 13% of patients who received TURALIO. The most frequent serious adverse reactions (occurring in >1 patient) included abnormal liver tests (3.3%) and hepatotoxicity (3.3%).

Permanent discontinuation due to adverse reactions occurred in 13% of patients who received TURALIO. The most frequent adverse reactions (occurring in >1 patient) requiring permanent discontinuation included increased ALT (4.9%), increased AST (4.9%), and hepatotoxicity (3.3%).

Dose reductions or interruptions occurred in 38% of patients who received TURALIO. The most frequent adverse reactions (occurring in >1 patient) requiring a dosage reduction or interruption were increased ALT (13%), increased AST (13%), nausea (8%), increased ALP (7%), vomiting (4.9%), increased bilirubin (3.3%), increased GGT (3.3%), dizziness (3.3%), and abdominal pain (3.3%).

The most common adverse reactions for all grades (>20%) were increased lactate dehydrogenase (92%), increased AST (88%), hair color changes (67%), fatigue (64%), increased ALT (64%), decreased neutrophils (44%), increased cholesterol (44%), increased ALP (39%), decreased lymphocytes (38%), eye edema (30%), decreased hemoglobin (30%), rash (28%), dysgeusia (26%), and decreased phosphate (25%).

Clinically relevant adverse reactions occurring in <10% of patients were blurred vision, photophobia, diplopia, reduced visual acuity, dry mouth, stomatitis, mouth ulceration, pyrexia, cholangitis, hepatotoxicity, liver disorder, cognitive disorders (memory impairment, amnesia, confusional state, disturbance in attention, and attention deficit/hyperactivity disorder), alopecia, and skin pigment changes (hypopigmentation, depigmentation, discoloration, and hyperpigmentation).

Drug Interactions

- Use with hepatotoxic products: TURALIO can cause hepatotoxicity. In patients with increased serum transaminases, total bilirubin, or direct bilirubin (>ULN) or active liver or biliary tract disease, avoid coadministration of TURALIO with other products known to cause hepatotoxicity.
- Moderate or strong CYP3A inhibitors: Concomitant use of a moderate or strong CYP3A inhibitor may increase pexidartinib concentrations. Reduce TURALIO dosage if concomitant use of moderate or strong CYP3A inhibitors cannot be avoided.
- Strong CYP3A inducers: Concomitant use of a strong CYP3A inducer decreases pexidartinib concentrations. Avoid concomitant use of strong CYP3A inducers.
- Uridine diphosphate glucuronosyltransferase (UGT) inhibitors: Concomitant use of a UGT inhibitor increases pexidartinib concentrations. Reduce TURALIO dosage if concomitant use of UGT inhibitors cannot be avoided.
- Acid-reducing agents: Concomitant use of a proton pump inhibitor (PPI) decreases pexidartinib concentrations. Avoid concomitant use of PPIs. Use histamine-2 receptor antagonists or antacids if needed.
- CYP3A substrates: TURALIO is a moderate CYP3A inducer. Concomitant use of TURALIO decreases concentrations of CYP3A substrates. Avoid coadministration of TURALIO with hormonal contraceptives and other CYP3A substrates where minimal concentration changes may lead to serious therapeutic failure. Increase the CYP3A substrate dosage in accordance with approved product labeling if concomitant use is unavoidable.

Use in Specific Populations

- **Pregnancy:** TURALIO may cause embryo-fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus.
- **Lactation:** Because of the potential for serious adverse reactions in the breastfed child, advise women to not breastfeed during treatment with TURALIO and for at least 1 week after the final dose.
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to the initiation of TURALIO. Advise females of reproductive potential to use an effective nonhormonal method of contraception, since TURALIO can render hormonal contraceptives ineffective,

during treatment with TURALIO and for 1 month after the final dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TURALIO and for 1 week after the final dose.
- **Renal impairment:** Reduce the dose when administering TURALIO to patients with mild to severe renal impairment (CLcr 15 to 89 mL/min, estimated by Cockcroft-Gault [C-G] using actual body weight).

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 WARNING**, and **Medication Guide.**

About Daiichi Sankyo Cancer Enterprise

The mission of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do. Anchored by our DXd antibody drug conjugate (ADC) technology, our powerful research engines include biologics, medicinal chemistry, modality and other research laboratories in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. For more information, please visit: www.DSCancerEnterprise.com.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com.

Media Contacts:

Global/US:
Jennifer Brennan
Daiichi Sankyo, Inc.
jbrennan2@dsi.com
+1 908 992 6631 (office)
+1 201 709 9309 (mobile)

EU:
Lydia Worms
Daiichi Sankyo Europe GmbH
lydia.worms@daiichi-sankyo.eu
+49 (89) 7808751

Investor Relations Contact:
DaiichiSankyoIR@daiichisankyo.co.jp