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Daiichi-Sankyo

Press Release

Daiichi Sankyo Continues to Transform Standards of Care for Patients with Three Landmark Breast Cancer Trials and Additional Data Across Industry-Leading ADC Portfolio at ESMO

- Back-to-back Presidential Symposium presentations of ENHERTU from DESTINY-Breast11 and DESTINY-Breast05 demonstrate its potential to become a foundational treatment in curative-intent settings of HER2 positive early breast cancer
- Late-breaking data from TROPION-Breast02 showcase that DATROWAY is the first and only therapy to significantly improve overall survival versus chemotherapy as first-line treatment for patients with first-line metastatic triple negative breast cancer for whom immunotherapy is not an option
- Data from eight additional trials – DESTINY-Breast09, REJOICE-Ovarian01, IDeate-Lung01, TROPION-PanTumor03, DESTINY-Gastric04, DESTINY-CRC02, DESTINY-PanTumor02 and DS-3939 – further support the strength of the DXd ADC portfolio of Daiichi Sankyo across multiple types of cancer
- Investor conference call to discuss ESMO

Tokyo and Basking Ridge, NJ – (October 13, 2025) – Daiichi Sankyo (TSE: 4568) will present new clinical research across its DXd antibody drug conjugate (ADC) portfolio with four late-breaking presentations from more than 20 abstracts at the 2025 European Society for Medical Oncology (#ESMO25) Congress.

Data at ESMO will spotlight the company's advances towards creating new standards of care for patients with breast cancer, including back-to-back presentations during Presidential Symposium I featuring data from the DESTINY-Breast11 (291O) and DESTINY-Breast05 (LBA1) phase 3 trials. Results of these two landmark trials will showcase the potential of ENHERTU® (trastuzumab deruxtecan) to become a foundational treatment in curative-intent settings of HER2 positive early breast cancer.

Late-breaking DATROWAY® (datopotamab deruxtecan) data from the TROPION-Breast02 phase 3 trial (LBA21), representing the first trial ever to demonstrate a significant improvement in overall survival compared to chemotherapy as first-line treatment for patients with locally recurrent inoperable or metastatic triple negative breast cancer (TNBC) for whom immunotherapy is not an option, will be featured in a proffered paper session.

"Data from these three landmark trials demonstrate how the DXd ADC portfolio of Daiichi Sankyo continues to transform standards of care for patients with breast cancer. The findings from DESTINY-Breast11 and DESTINY-Breast05 highlight the potential of ENHERTU to become a foundational treatment in the curative-intent settings of HER2 positive early breast cancer," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "Additionally, the DATROWAY results from TROPION-Breast02 represent the first time ever that an

overall survival benefit has been demonstrated in the first-line setting of patients with metastatic triple negative breast cancer for whom immunotherapy is not an option. Couple these impressive results for DATROWAY with previous results seen with ENHERTU in the HER2 positive, HER2 low and HER2 ultralow disease settings, Daiichi Sankyo will now have two medicines with the potential to treat approximately 90 percent of patients with metastatic breast cancer."

Additional breast cancer data at ESMO includes a mini oral presentation of data from Arm 7 and Arm 8 of the BEGONIA phase 1/2 trial (555MO) evaluating DATROWAY plus durvalumab in patients with first-line metastatic TNBC. The efficacy and safety of this combination strategy is being further investigated in three phase 3 trials – TROPION-Breast03, TROPION-Breast04 and TROPION-Breast05 – across stages and treatment settings of TNBC.

Trials Supporting Three Recent Breakthrough Therapy Designations Showcased

Data from additional late-stage trials – DESTINY-Breast09, REJOICE-Ovarian01 and IDeate-Lung01 – that supported three recent Breakthrough Therapy Designations (BTD) in the U.S. for ENHERTU, raludotatug deruxtecan (R-DXd) and ifinatamab deruxtecan (I-DXd) will be showcased at ESMO.

Two late-breaking proffered paper sessions will highlight the primary analysis from the phase 2 part of the REJOICE-Ovarian01 phase 2/3 trial (LBA42) of raludotatug deruxtecan in patients with previously treated platinum-resistant ovarian cancer, and additional analyses of key subgroups of interest from the DESTINY-Breast09 phase 3 trial (LBA18) evaluating ENHERTU plus pertuzumab versus THP (taxane, trastuzumab, pertuzumab) for the first-line treatment of patients with HER2 positive metastatic breast cancer. Results of DESTINY-Breast09 formed the basis for a supplemental Biologic License Application in the U.S. for ENHERTU, which was recently granted Priority Review under the Real-Time Oncology Review program.

Detailed results highlighting the intracranial activity of ifinatamab deruxtecan from the IDeate-Lung01 phase 2 trial (2760MO) in patients with previously treated extensive-stage small cell lung cancer (ES-SCLC) and baseline brain metastases will be highlighted during a mini oral session. The primary results of IDeate-Lung01 were presented last month at the 2025 World Conference on Lung Cancer (#WCLC25).

Progress Continues in Multiple Cancers Across the DXd ADC Portfolio of Daiichi Sankyo

Additional mini oral sessions at ESMO will feature the first presentation of data from two early phase trials from the DXd ADC portfolio of Daiichi Sankyo. These include preliminary results from the first-in-human phase 1/2 trial of DS-3939 (917O), the sixth DXd ADC in clinical development, in patients with previously treated

advanced solid tumors refractory to standard treatment, as well as initial results from a sub-study of the TROPION-PanTumor03 phase 2 trial (3072MO) evaluating DATROWAY plus rilvegostomig, AstraZeneca's PD-1/TIGIT bispecific antibody, in patients as first-line or second-line locally advanced or metastatic urothelial carcinoma.

Final analyses from two trials – DESTINY-CRC02 and DESTINY-PanTumor02 – that supported the tumor agnostic indication of ENHERTU, which is now approved in more than 10 countries/regions worldwide, will be presented. A mini oral session will feature the final analysis from the DESTINY-CRC02 phase 2 trial (737MO) of ENHERTU in patients with previously treated HER2 positive metastatic colorectal cancer while two poster presentations will highlight the final results (957P) and an exploratory biomarker analysis (145P) from part 1 of the DESTINY-PanTumor02 phase 2 trial in patients with previously treated HER2 expressing solid tumors. Additional regulatory submissions seeking a tumor agnostic approval in patients with HER2 positive metastatic solid tumors currently are under review in the EU and Japan.

Further sub-analyses from the DESTINY-Gastric04 phase 3 trial of ENHERTU versus ramucirumab plus paclitaxel in the second-line treatment of patients with HER2 positive metastatic gastric cancer or gastroesophageal junction (GEJ) adenocarcinoma will be presented as a poster presentation (2099P) reporting the concordance of central HER2 testing with local HER2 testing along with additional efficacy and safety analyses. Data from DESTINY-Gastric06, a phase 2 trial in patients from China with HER2 expressing advanced gastric or GEJ adenocarcinoma who have received at least two prior regimens including a fluoropyrimidine agent and a platinum agent, will be presented in two poster presentations. The first poster (2105P) will feature an analysis of patients that received prior anti-HER2 treatment other than or in addition to trastuzumab. The second poster (2175P) will report the risk of hepatitis B virus reactivation in patients with past or resolved HBV or inactive chronic HBV infection treated with ENHERTU.

Updates of progress in lung cancer include a mini oral session reporting updated results from a phase 1/2 trial of gocatamig (2758MO), a DLL3 targeting T-cell engager being jointly developed by Merck, in patients with small cell lung cancer and other neuroendocrine cancers, as well as a poster presentation that will highlight the initial safety results from a phase 1b trial of valemetostat (2023P), a dual EZH1 and EZH2 inhibitor, in combination with DATROWAY in patients with previously treated advanced non-squamous non-small cell lung cancer (NSCLC).

Trials-in-Progress Across Daiichi Sankyo's Oncology Portfolio

Several trials-in-progress poster presentations at ESMO further highlight the Daiichi Sankyo R&D strategy of continuing to expand the DXd ADC portfolio to address a broad spectrum of unmet needs for patients with cancer.

A trial-in-progress poster will highlight the design of the DESTINY-Endometrial01 phase 3 trial (1223TiP) evaluating ENHERTU in combination with rilvegostomig or pembrolizumab versus platinum-based chemotherapy (carboplatin and paclitaxel) in combination with pembrolizumab as a first-line therapy in patients with HER2 expressing (IHC 3+/ 2+), mismatch repair proficient (pMMR) primary advanced or recurrent endometrial cancer.

Three phase 2 trials-in-progress will include the HERTHENA-Breast03 trial (463eTiP) evaluating neoadjuvant patritumab deruxtecan (HER3-DXd) plus pembrolizumab before or after pembrolizumab plus chemotherapy in patients with high-risk early-stage TNBC or HR low positive/HER2 negative breast cancer; the REJOICE-GI01 trial (1001TiP) evaluating the efficacy and safety of raludotatug deruxtecan in patients with gastrointestinal cancers, including pancreatic ductal adenocarcinoma, gastroesophageal adenocarcinoma, biliary tract and colorectal cancer; and, the KEYMAKER-U01 sub-studies 01H/01I (2081eTiP) evaluating ifinatamab deruxtecan, raludotatug deruxtecan or docetaxel in patients with stage IV NSCLC.

The design of two additional early phase trials will be shared, including the phase 1/2 trial (2792TiP) evaluating ifinatamab deruxtecan and gocatamig in patients with relapsed/refractory ES-SCLC and a phase 1b trial (977P) of valemetostat in combination with ipilimumab in patients with refractory genitourinary tumors, including prostate cancer, urothelial carcinomas and renal clear cell carcinoma.

Investor Briefing During ESMO

Daiichi Sankyo will hold a virtual conference call for investors on Tuesday, October 21, 2025 from 8:00 to 9:30 am EDT / 9:00 to 10:30 pm JST. Executives from Daiichi Sankyo will provide an overview of the ESMO data.

Daiichi Sankyo Oral Presentations at ESMO

	Presentation Title	Author	Abstract	Presentation (CEST)
Breast	Trastuzumab deruxtecan (T-DXd) vs trastuzumab emtansine (T-DM1) in patients with high-risk human epidermal growth factor receptor 2-positive (HER2+) primary breast cancer with residual invasive disease after neoadjuvant therapy: interim analysis of DESTINY-Breast05	C. Geyer	LBA1	Presidential Symposium I Saturday, October 18 4:30 – 6:15 pm

	DESTINY-Breast11: neoadjuvant trastuzumab deruxtecan alone (T-DXd) or followed by paclitaxel + trastuzumab + pertuzumab (T-DXd-THP) vs SOC for high-risk HER2+ early breast cancer	N. Harbeck	291O	Presidential Symposium I Saturday, October 18 4:30 – 6:15 pm
	Trastuzumab deruxtecan (T-DXd) + pertuzumab vs taxane + trastuzumab + pertuzumab (THP) for patients with HER2+ advanced/metastatic breast cancer: additional analyses of DESTINY-Breast09 in key subgroups of interest	S. Loibl	LBA18	Proffered Paper Session Sunday, October 19 8:30 – 10:00 am
	First-line datopotamab deruxtecan (Dato-DXd) vs chemotherapy in patients with locally recurrent inoperable or metastatic triple negative breast cancer for whom immunotherapy was not an option: primary results from the randomized, phase 3 TROPION-Breast02 trial	R. Dent	LBA21	Proffered Paper Session Sunday, October 19 8:30 – 10:00 am
	Datopotamab deruxtecan (Dato-DXd) + durvalumab as first-line treatment for unresectable locally advanced/ metastatic triple negative breast cancer: final results from the phase 1b/2 BEGONIA study	P. Schmid	555MO	Mini Oral Session Monday, October 20 10:15 – 11:45 am
Lung	Intracranial activity of ifinatamab deruxtecan (I-DXd) in patients with extensive-stage small cell lung cancer and baseline brain metastases: primary analysis of IDeate-Lung01	P. Rocha	2760MO	Mini Oral Session Saturday, October 18 4:30 – 6:00 pm
	Updated results from a phase 1/2 study of gocatamig for small cell lung cancer and other neuroendocrine cancers	H. Beltran	2758MO	Mini Oral Session Saturday, October 18 4:30 – 6:00 pm
Ovarian	Raludotatug deruxtecan (R-DXd) in patients with platinum-resistant ovarian cancer: primary analysis of the phase 2 dose-optimization part of the REJOICE-Ovarian01 study	I. Ray-Coquard	LBA42	Proffered Paper Session Sunday, October 19 2:45 – 4:15 pm
Bladder	Datopotamab deruxtecan (Dato-DXd) + rilvegostomig in patients with locally advanced or metastatic urothelial cancer: results from the phase 2 TROPION-PanTumor03 study	S. Rha	3072MO	Mini Oral Session Friday, October 17 4:00 – 5:30 pm
CRC	Trastuzumab deruxtecan (T-DXd) in patients with HER2 positive (HER2+) metastatic colorectal cancer: final analysis of DESTINY-CRC02, a randomized, phase 2 trial	K. Raghav	737MO	Mini Oral Session Sunday, October 19 2:45 – 4:15 pm
PanTumor	DS-3939, a tumor-associated mucin 1 (TA-MUC1)-directed antibody drug conjugate (ADC), in patients with advanced/metastatic solid tumors: initial results from a first-in-human study	M. Patel	917O	Proffered Paper Session Sunday, October 19 2:45 – 4:20 pm

Daiichi Sankyo Poster Presentations at ESMO

Presentation Title		Author	Abstract	Presentation (CDT)
Breast	Final real-world safety and effectiveness results of REALITY-01 study: trastuzumab deruxtecan (T-DXd) in patients received ≥2 prior treatment lines for HER2+ metastatic or unresectable breast cancer	J. Pierga	539P	Poster Session
	The effectiveness of post-trastuzumab deruxtecan (T-DXd) treatment regimens and the incidence of recurrent interstitial lung disease (ILD) in patients with HER2+ metastatic breast cancer who discontinued T-DXd due to ILD	J. Tsurutani	540P	Poster Session

	HERTHENA-Breast03: a phase 2, randomized, open-label study evaluating neoadjuvant patritumab deruxtecan + pembrolizumab before or after pembrolizumab + chemotherapy for early-stage TNBC or HR low+/HER2− breast cancer	M. Danso	463eTiP	ePoster
Lung	Phase 1b study of valemetostat in combination with datopotamab deruxtecan (Dato-DXd) in advanced non-squamous non-small cell lung cancer: initial safety results	A. Spira	2023P	Poster Session
	A phase 1b/2 study of gocatamig (MK-6070; HPN328) and ifinatamab deruxtecan for relapsed/refractory extensive-stage small cell lung cancer	J. Sun	2792TiP	Poster Session
	KEYMAKER-U01 phase 2 substudies 01H/01I: ifinatamab deruxtecan (I-DXd), raludotatug deruxtecan (R-DXd) or docetaxel in stage IV non-small cell lung cancer	E. Nadal	2081eTiP	ePoster
Gastrointestinal	Trastuzumab deruxtecan (T-DXd) vs ramucirumab plus paclitaxel in second-line treatment of patients with HER2+ unresectable/metastatic gastric cancer/gastroesophageal junction adenocarcinoma: additional data from DESTINY-Gastric04	F. Pietrantonio	2099P	Poster Session
	Trastuzumab deruxtecan (T-DXd) in patients with HER2+ gastric cancer or gastroesophageal junction adenocarcinoma who received prior anti-HER2 treatment other than/in addition to trastuzumab in DESTINY-Gastric06	Z. Peng	2105P	Poster Session
	Risk of hepatitis B virus reactivation in patients with past or resolved HBV or inactive chronic HBV infection treated with trastuzumab deruxtecan (T-DXd) in the DESTINY-Gastric06	L. Shen	2175P	Poster Session
	Raludotatug deruxtecan in participants with gastrointestinal cancers: phase 2 REJOICE-GI01 trial	M. Ueno	1001TiP	Poster Session
Endometrial	A randomized phase 3 study of first-line trastuzumab deruxtecan (T-DXd) with rilvegostomig or pembrolizumab in patients with HER2 expressing, mismatch repair-proficient, primary advanced or recurrent endometrial cancer: DESTINY-Endometrial01/GOG-3098/ENGOT-EN24	B. Slomovitz	1223TiP	Poster Session
PanTumor	Trastuzumab deruxtecan (T-DXd) for pretreated patients with HER2 expressing solid tumors: DESTINY-PanTumor02 part 1 final analysis	V. Makker	957P	Poster Session
	Trastuzumab deruxtecan (T-DXd) in pretreated patients with HER2 expressing solid tumors: exploratory biomarker analysis of DESTINY-PanTumor02 part 1	D. Oh	145P	Poster Session
	DS3201 (valemetostat), an EZH1/2 inhibitor, with ipilimumab in patients with refractory genitourinary tumors	S. Goswami	977P	Poster Session

About the ADC Portfolio of Daiichi Sankyo

The Daiichi Sankyo ADC portfolio consists of seven ADCs in clinical development crafted from two distinct ADC technology platforms discovered in-house by Daiichi Sankyo.

The ADC platform furthest in clinical development is Daiichi Sankyo's DXd ADC Technology where 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. The DXd ADC portfolio currently

consists of ENHERTU, a HER2 directed ADC, and DATROWAY, a TROP2 directed ADC, which 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, USA. DS-3939, a TA-MUC1 directed ADC, is being developed by Daiichi Sankyo.

The second Daiichi Sankyo ADC platform consists of a monoclonal antibody attached to a modified pyrrolobenzodiazepine (PBD) payload. DS-9606, a CLDN6 directed PBD ADC, is the first of several planned ADCs in clinical development utilizing this platform.

Ifinatamab deruxtecan, patritumab deruxtecan, raludotatug deruxtecan, DS-3939 and DS-9606 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 needs. For more information, please visit www.daiichisankyo.com.

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