Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

# Press Release

## Daiichi Sankyo Continues to Transform Treatment Landscape for Patients with Cancer with Practice-Changing Data at ASCO

- Late-breaking data from DESTINY-Breast09 and DESTINY-Gastric04 phase 3 trials showcase how ENHERTU will potentially redefine standard of care for first-line HER2 positive metastatic breast cancer and second-line HER2 positive metastatic gastric cancer
- Investor meeting to discuss ASCO presentations and oncology development updates

**Basking Ridge, NJ – (May 22, 2025)** – Daiichi Sankyo (TSE: 4568) will present new clinical research across its oncology portfolio with more than 20 abstracts in multiple cancers at the 2025 American Society of Clinical Oncology Scientific Program (#ASCO25).

Data at ASCO showcasing the company's progress towards creating new standards of care for patients with cancer will include two late-breaking oral presentations. The first will feature results of the DESTINY-Breast09 phase 3 trial (LBA #1008) where ENHERTU® (trastuzumab deruxtecan) in combination with pertuzumab demonstrated superior progression-free survival compared to taxane, trastuzumab and pertuzumab (THP) as a first-line treatment in patients with HER2 positive metastatic breast cancer. The second will highlight results of the DESTINY-Gastric04 phase 3 trial (LBA #4002) where ENHERTU demonstrated superior overall survival compared to ramucirumab and paclitaxel as a second-line treatment in patients with HER2 positive metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma. Data from DESTINY-Breast09 and DESTINY-Gastric04 will be featured in ASCO press briefings.

"This year's ASCO marks the fourth in a row where potential practice-changing ENHERTU data will be showcased," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "With the results of DESTINY-Breast09 and DESTINY-Gastric04, we now have six breast and two gastric cancer randomized trials that have demonstrated significant survival improvements with ENHERTU. These data, along with other updates across our industry-leading oncology portfolio, underscore our commitment to pushing the boundaries of science to create new medicines or combination strategies that improve outcomes for patients with cancer."

Other ENHERTU data at ASCO will include an oral presentation featuring an exploratory circulating tumor DNA analysis of the DESTINY-Breast06 phase 3 trial (#1013) evaluating ENHERTU compared to physician's choice of chemotherapy in hormone receptor (HR) positive, HER2 low (IHC 1+ or IHC 2+/ISH-) or HER2 ultralow (IHC 0 with membrane staining) metastatic breast cancer. Updated results from the PRO-DUCE study (#1545)

examining vital sign monitoring compared to usual care in patients with metastatic breast cancer receiving ENHERTU also will be highlighted as a poster presentation.

A trials-in-progress poster presentation will feature the DESTINY-Gastric05 phase 3 trial (TPS4207) evaluating ENHERTU in combination with a fluoropyrimidine-based chemotherapy and pembrolizumab compared to trastuzumab in combination with platinum-based chemotherapy and pembrolizumab in previously untreated patients with unresectable, locally advanced or metastatic HER2 positive (IHC 3+ or IHC 2+/ISH+) gastric or GEJ cancer.

**Progress in Lung Cancer Across Daiichi Sankyo's DXd ADC Portfolio**

Updated DATROWAY® (datopotamab deruxtecan) combination data across three early-phase trials will be highlighted in patients with early or advanced non-small cell lung cancer (NSCLC).

Updated results from the TROPION-Lung02 phase 1b trial (#8501) evaluating DATROWAY plus pembrolizumab with or without platinum-based chemotherapy in patients with previously untreated advanced NSCLC without actionable genomic alterations will be featured as an oral presentation. This will include results from an exploratory analysis using quantitative continuous scoring (QCS), AstraZeneca's proprietary computational pathology platform.

Poster sessions will highlight the first presentation of data of DATROWAY and rilvegostomig, AstraZeneca's PD-1/TIGIT bispecific antibody, from the TROPION-Lung04 phase 1b trial (#8521) cohort evaluating the combination in patients without actionable genomic alterations who have advanced or metastatic NSCLC, and the final pathologic complete response and major pathologic response data from the NeoCOAST-2 phase 2 trial (#8046) evaluating DATROWAY with durvalumab, AstraZeneca's anti-PD-L1 therapy, and chemotherapy as neoadjuvant treatment followed by adjuvant treatment with durvalumab in patients with resectable early-stage (IIA to IIIB) NSCLC.

Additional lung cancer data at ASCO will include an oral presentation of the HERTHENA-Lung02 phase 3 trial (#8506) of patritumab deruxtecan (HER3-DXd) versus platinum doublet chemotherapy in patients with locally advanced or metastatic EGFR-mutated NSCLC with disease progression following the use of an EGFR tyrosine kinase inhibitor (TKI).

Trials-in-progress poster presentations in lung cancer across the DXd ADC portfolio will include the TROPION-Lung14 phase 3 trial (TPS8647) evaluating DATROWAY combined with osimertinib, AstraZeneca's EGFR TKI,

compared to osimertinib alone in the first-line setting of patients with locally advanced or metastatic EGFR-mutated NSCLC and a substudy of KEYMAKER-U01, a phase 1/2 trial (TPS8652), evaluating pembrolizumab plus ifinatamab deruxtecan (I-DXd) or patritumab deruxtecan with or without chemotherapy in patients with untreated advanced NSCLC.

**Additional Data and Trials-in-Progress Across Daiichi Sankyo's Oncology Portfolio at ASCO**

Oral presentations also will highlight initial results from the TUXEDO-3 phase 2 trial (#2005) evaluating patritumab deruxtecan in patients with metastatic breast cancer or advanced NSCLC and active brain metastases and in patients with leptomeningeal carcinomatosis/disease from advanced solid tumors, as well as results from a phase 1 trial (#10003) evaluating valemetostat, a dual EZH1 and EZH2 inhibitor, in pediatric patients with malignant solid tumors.

Additional DXd ADC trials-in-progress poster presentations include the REJOICE-PanTumor01 phase 2 trial (TPS3158) evaluating raludotatug deruxtecan (R-DXd) in patients with locally advanced or metastatic gynecologic or genitourinary cancers, IDeate-PanTumor02 phase 1b/2 trial (TPS3157) evaluating ifinatamab deruxtecan in patients with recurrent or metastatic solid tumors and a substudy of KEYMAKER-U06, a phase 1/2 trial (TPS4209) evaluating ifinatamab deruxtecan in combination with pembrolizumab with or without chemotherapy in patients with advanced esophageal squamous cell carcinoma. Other trials-in-progress posters include the QuANTUM-Wild phase 3 trial (TPS6580) evaluating VANFLYTA® (quizartinib) in combination with chemotherapy in patients with *FLT3*-ITD negative acute myeloid leukemia and a first-in-human phase 1 trial of DS-2243 (TPS2668), a potential first-in-class bispecific T-cell engager targeting HLA-A*02/NY-ESO in patients with advanced solid tumors.

Daiichi Sankyo will hold a virtual conference call for investors on Monday, June 2, 2025 from 6:00 to 7:15 pm CDT / Tuesday, June 3, 2025 from 8:00 to 9:15 am JST. Executives from Daiichi Sankyo will provide an overview of the ASCO research data and address questions.

Details of the two late-breaking ENHERTU oral presentations at ASCO 2025 include:

| | Presentation Title | Author | Abstract | Presentation (CDT) |
|---|---|---|---|---|
| **LBAs** | Trastuzumab deruxtecan (T-DXd) + pertuzumab vs taxane + trastuzumab + pertuzumab (THP) for first-line treatment of patients with human epidermal growth factor receptor 2 positive (HER2+) advanced/metastatic breast cancer: interim results from DESTINY-Breast09 | S. Tolaney | LBA1008 | Special LBA Session<br>Oral Presentation<br>Monday, June 2<br>7:30 – 8:00 am |

| | | | | |
|---|---|---|---|---|
| | Trastuzumab deruxtecan (T-DXd) vs ramucirumab plus paclitaxel in second-line treatment of patients with human epidermal growth factor receptor 2 positive (HER2+) unresectable/metastatic gastric cancer or gastroesophageal junction adenocarcinoma: primary analysis of the randomized, phase 3 DESTINY-Gastric04 study | K. Shitara | LBA4002 | Oral Presentation<br>Saturday, May 31<br>3:00 – 6:00 pm |

Highlights of additional clinical data and trials-in-progress from Daiichi Sankyo's oncology pipeline include:

| Presentation Title | | Author | Abstract | Presentation (CDT) |
|---|---|---|---|---|
| **Breast** | Exploratory biomarker analysis of trastuzumab deruxtecan (T-DXd) vs physician's choice of chemotherapy in HER2 low/ultralow, hormone receptor-positive (HR+) metastatic breast cancer in DESTINY-Breast06 | R. Dent | 1013 | Oral Presentation<br>Saturday, May 31<br>1:15 – 4:15 pm |
| | 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 | J. O'Shaughnessy | TPS629 | Poster Session<br>Monday, June 2<br>9:00 am – 12:00 pm |
| | Electronic patient-reported outcomes with vital sign monitoring versus usual care during trastuzumab deruxtecan treatment for metastatic breast cancer: updated results from the PRO-DUCE study | Y. Kikawa | 1545 | Poster Session<br>Sunday, June 1<br>9:00 am – 12:00 pm |
| **Lung** | TROPION-Lung02: datopotamab deruxtecan (Dato-DXd) plus pembrolizumab with or without platinum chemotherapy as first-line therapy for advanced non-small cell lung cancer | B. Levy | 8501 | Oral Presentation<br>Sunday, June 1<br>8:00 – 11:00 am |
| | Patritumab deruxtecan (HER3-DXd) in resistant EGFR-mutated advanced non-small cell lung cancer after a third-generation EGFR TKI: the phase 3 HERTHENA-Lung02 study | T. Mok | 8506 | Oral Presentation<br>Sunday, June 1<br>8:00 – 11:00 am |
| | First-line datopotamab deruxtecan (Dato-DXd) + rilvegostomig in advanced or metastatic non-small cell lung cancer: results from TROPION-Lung04 (cohort 5) | S. Waqar | 8521 | Poster Session<br>Saturday, May 31<br>1:30 – 4:30 pm |
| | TROPION-Lung14: a phase 3 study of osimertinib ± datopotamab deruxtecan (Dato-DXd) as first-line treatment for patients with EGFR-mutated locally advanced or metastatic non-small cell lung cancer | S. Lu | TPS8647 | Poster Session<br>Saturday, May 31<br>1:30 – 4:30 pm |
| | Neoadjuvant durvalumab + chemotherapy + novel anticancer agents and adjuvant durvalumab ± novel agents in resectable non-small cell lung cancer: updated outcomes from NeoCOAST-2 | T. Cascone | 8046 | Poster Session<br>Saturday, May 31<br>1:30 – 4:30 pm |
| | KEYMAKER-U01 substudy 01A: phase 1/2 study of pembrolizumab plus ifinatamab deruxtecan (I-DXd) or patritumab deruxtecan (HER3-DXd) with or without chemotherapy in untreated stage IV non-small cell lung cancer | C. Aggarwal | TPS8652 | Poster Session<br>Saturday, May 31<br>1:30 – 4:30 pm |
| **Gastric** | An open-label, randomized, multicenter, phase 3 study of trastuzumab deruxtecan (T-DXd) + chemotherapy ± pembrolizumab versus chemo + trastuzumab ± pembro in first-line metastatic HER2+ gastric or gastroesophageal junction cancer: DESTINY-Gastric05 | K. Shitara | TPS4207 | Poster Session<br>Saturday, May 31<br>9:00 am – 12:00 pm |

| | | | | |
|---|---|---|---|---|
| **Esophageal** | KEYMAKER-U06 substudy 06E: phase 1/2 open-label, umbrella platform study of ifinatamab deruxtecan in combination with pembrolizumab with or without chemotherapy for first-line treatment of advanced esophageal squamous cell carcinoma | K. Kato | TPS4209 | Poster Session<br>Saturday, May 31<br>9:00 am – 12:00 pm |
| **AML** | QuANTUM-Wild: a phase 3, randomized, double-blind, placebo-controlled trial of quizartinib in combination with chemotherapy and as single-agent maintenance in *FLT3*-ITD negative acute myeloid leukemia | P. Montesinos | TPS6580 | Poster Session<br>Sunday, June 1<br>9:00 am – 12:00 pm |
| **Pan-Tumor** | Patritumab deruxtecan (HER3-DXd) in active brain metastases from metastatic breast and non-small cell lung cancers, and leptomeningeal disease from advanced solid tumors: results from the TUXEDO-3 phase 2 trial | M. Preusser | 2005 | Oral Presentation<br>Friday, May 30<br>2:45 – 5:45 pm |
| | IDeate-PanTumor02: a phase 1b/2 study to evaluate the efficacy and safety of ifinatamab deruxtecan (I-DXd) in patients with recurrent or metastatic solid tumors | T. Kogawa | TPS3157 | Poster Session<br>Monday, June 2<br>1:30 – 4:30 pm |
| | REJOICE- PanTumor01: a phase 2 signal-seeking study of raludotatug deruxtecan (R-DXd) in patients with advanced or metastatic gynecologic or genitourinary tumors | L. Albiges | TPS3158 | Poster Session<br>Monday, June 2<br>1:30 – 4:30 pm |
| | A phase 1, first-in-human study of DS-2243, an HLA-A*02/NY-ESO directed bispecific T-cell engager, in patients with advanced solid tumors | S. D'Angelo | TPS2668 | Poster Session<br>Monday, June 2<br>1:30 – 4:30 pm |
| **Pediatric** | Safety and efficacy of the EZH1/2 inhibitor valemetostat tosylate (DS-3201b) in pediatric patients with malignant solid tumors (NCCH1904): a multicenter phase 1 trial | A. Arakawa | 10003 | Oral Presentation<br>Saturday, May 31<br>3:00 – 6:00 pm |

**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 125 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.

**Media Contacts:**

**Global/US Media:**
Jennifer Brennan
Daiichi Sankyo, Inc.
jennifer.brennan@daiichisankyo.com
+ 1 908 900 3183 (mobile)

**Japan:**
Daiichi Sankyo Co., Ltd.
DS-PR_jp@daiichisankyo.com

**Investor Relations Contact:**
DaiichiSankyoIR_jp@daiichisankyo.com