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Daiichi-Sankyo

# Press Release

## Daiichi Sankyo Unveils New Research Across Industry-Leading ADC Portfolio in Multiple Cancers at WCLC and ESMO

- Six late-breaking presentations across lung and breast cancer trials of DXd ADCs, including two Presidential Symposia at WCLC featuring datopotamab deruxtecan data
- First ever clinical data from Daiichi Sankyo's second ADC platform to be presented at ESMO
- Investor meeting to discuss WCLC and ESMO presentations

**Basking Ridge, NJ – (September 4, 2024)** – Daiichi Sankyo (TSE: 4568) will present new clinical research across its antibody drug conjugate (ADC) portfolio with more than 25 abstracts across multiple types of cancer at the IASLC 2024 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (#WCLC24) and the 2024 European Society for Medical Oncology (#ESMO24).

Data at WCLC and ESMO showcasing Daiichi Sankyo's progress towards its goal of creating new standards of care for patients with cancer will include six late-breaking presentations, including two back-to-back presentations during Presidential Symposium 1 featuring datopotamab deruxtecan (Dato-DXd) data at WCLC, and the first presentation of clinical data of DS-9606, a CLDN6 directed modified pyrrolobenzodiazepine (PBD) ADC from Daiichi Sankyo's second ADC platform, at ESMO.

"New data in lung, breast, gastric, ovarian, endometrial and other cancers from several of our DXd antibody drug conjugates demonstrates how we are making substantial progress toward creating new standards of care for patients with cancer," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "We look forward to presenting initial clinical data from our second antibody drug conjugate platform at ESMO, which underscores how Daiichi Sankyo is applying our expertise in this technology to craft new innovation for patients."

**Progress in Lung Cancer at WCLC and ESMO**

Late-breaking data at WCLC to be reported during back-to-back presentations at Presidential Symposium 1 will highlight the first interim results from the NeoCOAST-2 phase 2 platform trial evaluating novel perioperative treatment combinations including one arm studying datopotamab deruxtecan with durvalumab and chemotherapy as neoadjuvant treatment followed by adjuvant treatment with durvalumab in patients with resectable early-stage (IIA to IIIB) non-small cell lung cancer (NSCLC).

The second Presidential Symposium 1 presentation will feature results from the application of quantitative continuous scoring (QCS), AstraZeneca's proprietary computational pathology platform, to measure TROP2 in tissue samples collected in the TROPION-Lung01 phase 3 trial that evaluated datopotamab deruxtecan versus docetaxel in patients with locally advanced or metastatic NSCLC treated with at least one prior line of therapy. Overall survival results from TROPION-Lung01 also will be presented as a late-breaking oral presentation.

Other data at WCLC include two oral presentations featuring the interim results from the dose optimization part of the IDeate-Lung01 phase 2 trial of ifinatamab deruxtecan (I-DXd) in patients with pretreated extensive-stage small cell lung cancer and results from the ENHERTU® (trastuzumab deruxtecan) monotherapy arm of the DESTINY-Lung03 phase 1b trial in patients with previously treated HER2 overexpressing unresectable, locally advanced or metastatic NSCLC. A trial-in-progress poster from the NSCLC cohort of a phase 1b trial evaluating the combination of datopotamab deruxtecan and valemetostat, a dual inhibitor of EZH1 and EZH2, in previously treated locally advanced, unresectable or metastatic nonsquamous NSCLC with or without actionable genomic alterations also will be highlighted.

At ESMO, additional data in lung cancer being reported include poster presentations featuring a post-hoc analysis of patients with nonsquamous NSCLC by baseline brain metastases status in the TROPION-Lung01 phase 3 trial of datopotamab deruxtecan and intracranial responses seen in the IDeate-Lung01 phase 2 trial of ifinatamab deruxtecan, as well as a trial-in-progress poster featuring the design of the IDeate-Lung03 phase 1b/2 trial of ifinatamab deruxtecan in combination with atezolizumab with or without carboplatin as first-line induction or maintenance therapy in patients with extensive-stage small cell lung cancer.

**Continued Innovation in Breast Cancer at ESMO**

Late-breaking presentations in breast cancer at ESMO will include a proffered paper session featuring the primary results of the DESTINY-Breast12 phase 3b/4 trial evaluating ENHERTU in patients with HER2 positive advanced or metastatic breast cancer with or without brain metastases, and two mini oral sessions highlighting patient reported outcomes and determination of the HER2 low and HER2 ultralow status of tumors from the DESTINY-Breast06 phase 3 trial in patients with HR positive, HER2 low and HER2 ultralow metastatic breast cancer.

Two proffered paper sessions will highlight results from the ICARUS-BREAST01 phase 2 study of patritumab deruxtecan (HER3-DXd) in patients with HR positive, HER2 negative advanced breast cancer with disease progression following two or more treatments and the investigator-initiated ERICA phase 2 trial evaluating olanzapine-based triplet antiemetic therapy for prevention of nausea and vomiting in combination with

ENHERTU in patients with metastatic breast cancer. A mini oral session will feature a supplementary biomarker analysis from the DAISY phase 2 trial evaluating ENHERTU in three cohorts of patients with HER2 expressing metastatic breast cancer and a poster presentation will report on an exploratory biomarker analysis of ENHERTU in patients with HR positive, HER2 low metastatic breast cancer from the DESTINY-Breast04 phase 3 trial. A poster reporting on exposure-adjusted incidence rates of adverse events from the TROPION-Breast01 phase 3 trial of datopotamab deruxtecan versus chemotherapy in patients with previously treated HR positive, HER2 negative metastatic breast cancer also will be featured.

**Data from Daiichi Sankyo's Second ADC Platform and DXd ADC Data in Multiple Additional Cancers at ESMO**

At ESMO, a proffered paper session will highlight preliminary results from a phase 1 trial of DS-9606, a CLDN6 directed modified PBD ADC from Daiichi Sankyo's second ADC platform, in patients with solid tumors known to express CLDN6. Results from the DESTINY-Gastric03 phase 1b/2 trial evaluating ENHERTU monotherapy or ENHERTU combinations with chemotherapy and/or immunotherapy in patients with HER2 expressing advanced/metastatic gastric or gastroesophageal junction carcinoma also will be presented at a proffered paper session.

A mini oral session will feature results from the TROPION-PanTumor03 phase 2 trial of datopotamab deruxtecan in patients with previously treated recurrent endometrial or ovarian cancer. Trial-in-progress poster presentations will highlight the HERTHENA-PanTumor01 phase 2 trial evaluating patritumab deruxtecan in patients with a broad range of solid tumors including bladder, cervical, endometrial, esophageal, gastric, head and neck, melanoma, ovarian, pancreatic and prostate and a phase 1 trial of DS-1471, a CD147 monoclonal antibody, in patients with locally advanced or metastatic solid cancers.

**Investor Conference Call Following ESMO**

Daiichi Sankyo will hold a virtual conference call for investors on Tuesday, September 17, 2024 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 WCLC and ESMO research data and address questions.

**WCLC and ESMO Data Highlights**

Highlights of data from Daiichi Sankyo's ADC portfolio at WCLC 2024 include:

| | Presentation Title | Author | Abstract | Presentation (PDT) |
|---|---|---|---|---|
| NSCLC | NeoCOAST-2: efficacy and safety of neoadjuvant durvalumab (D) + novel anticancer agents + CT and adjuvant D ± novel agents in resectable NSCLC | T. Cascone | PL02.07 | Presidential Symposium 1<br>Sunday, September 8<br>8:30 - 10:00 am |
| | Normalized membrane ratio of TROP2 by quantitative continuous scoring is predictive of clinical outcomes in TROPION-Lung01 | M.C. Garassino | PL02.11 | Presidential Symposium 1<br>Sunday, September 8<br>8:30 - 10:00 am |
| | Datopotamab deruxtecan vs docetaxel in patients with non-small cell lung cancer: final overall survival from TROPION-Lung01 | J. Sands | OA08.03 | Oral Presentation<br>Monday, September 9<br>10:45 - 12:00 pm |
| | Trastuzumab deruxtecan monotherapy in pretreated HER2 overexpressing nonsquamous non-small cell lung cancer: DESTINY-Lung03 part 1 | D. Planchard | OA16.05 | Oral Presentation<br>Tuesday, September 10<br>1:30 - 2:45 pm |
| | Valemetostat and datopotamab deruxtecan in previously treated, advanced, unresectable, or metastatic non-squamous NSCLC | A. Spira | P2.10A.04 | Poster Session<br>Sunday, September 8<br>6:15 - 7:45 pm |
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| SCLC | Ifinatamab deruxtecan (I-DXd) in extensive-stage small cell lung cancer (ES-SCLC): interim analysis of IDeate-Lung01 | C. Rudin | OA04.03 | Oral Presentation<br>Sunday, September 8<br>2:00 - 3:15 pm |
| | Exposure-response analyses to support phase 3 dose selection for I-DXd (ifinatamab deruxtecan) in extensive stage SCLC patients | N. Midde | P1.13A.12 | Poster Session<br>Sunday, September 8<br>12:00 - 2:00 pm |

Highlights of data from Daiichi Sankyo's ADC portfolio at ESMO 2024 include:

| | Presentation Title | Author | Abstract | Presentation (CEST) |
|---|---|---|---|---|
| NSCLC | Datopotamab deruxtecan (Dato-DXd) vs docetaxel in patients with advanced nonsquamous non-small cell lung cancer with brain metastases: results from TROPION-Lung01 | E. Pons-Tostivint | 1312P | Poster Session<br>Saturday, September 14 |
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| SCLC | Intracranial response in patients with baseline brain metastases and extensive-stage small cell lung cancer treated with ifinatamab deruxtecan (I-DXd) in the IDeate-Lung01 study | M. Johnson | 1787P | Poster Session<br>Saturday, September 14 |
| | IDeate-Lung03: a phase 1b/2 study of ifinatamab deruxtecan (I-DXd) plus atezolizumab with or without carboplatin as first line induction or maintenance in patients with extensive stage small cell lung cancer | C. Rudin | 1812TiP | Poster Session<br>Saturday, September 14 |
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| BREAST | Trastuzumab deruxtecan (T-DXd) in patients with HER2+ advanced/metastatic breast cancer with or without brain metastases: primary results from DESTINY-Breast12 | N. Lin | LBA18 | Proffered Paper Session<br>Friday, September 13<br>4:00 – 5:30 pm |
| | HER2 low and HER2 ultralow status determination in tumors of patients with HR+ mBC in DESTINY-Breast06 | G. Viale | LBA 21 | Mini Oral Session<br>Sunday, September 15<br>8:30 – 10:00 am |
| | Effects of trastuzumab deruxtecan (T-DXd) vs treatment of physician's choice on patient-reported outcomes in hormone receptor-positive (HR+), human epidermal | X. Hu | LBA22 | Mini Oral Session<br>Sunday, September 15<br>8:30 – 10:00 am |

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| | growth factor receptor 2 (HER2) low/ultralow metastatic breast cancer: results from DESTINY-Breast06 | | | |
| | Efficacy, safety and biomarker analysis of ICARUS-BREAST01: a phase 2 study of patritumab deruxtecan (HER3-DXd) in patients with HR+/HER2- advanced breast cancer | B. Pistilli | 340O | Proffered Paper Session<br>Friday, September 13<br>4:00 - 5:30 pm |
| | A multicenter, randomized, double-blind, placebo-controlled study of olanzapine-based triplet antiemetic therapy for prevention of delayed and persistent nausea and vomiting induced by trastuzumab deruxtecan in patients with metastatic breast cancer: ERICA study | H. Sakai | 1816O | Proffered Paper Session<br>Saturday, September 14<br>2:45 - 4:25 pm |
| | Unraveling the mechanisms of action and resistance to trastuzumab deruxtecan (T-DXd): supplementary biomarker analyses from DAISY trial | F. Mosele | 343MO | Mini Oral Session<br>Sunday, September 15<br>8:30 - 10:00 am |
| | Exploratory biomarker analysis of trastuzumab deruxtecan versus treatment of physician's choice in HER2-low, hormone receptor-positive metastatic breast cancer in DESTINY-Breast04 | N. Ueno | 432P | Poster Session<br>Monday, September 16 |
| | Exposure-adjusted incidence rates of adverse events from the TROPION-Breast01 study of datopotamab deruxtecan (Dato-DXd) vs investigator's choice of chemotherapy in patients with pretreated, inoperable/ metastatic HR+/HER2- breast cancer | H. Rugo | 431P | Poster Session<br>Monday, September 16 |
| | Treatment patterns and outcomes in HER2 low, HR+ metastatic breast cancer patients previously treated with endocrine therapy in the United States | S. Modi | 399P | Poster Session<br>Monday, September 16 |
| **OTHER SOLID TUMORS** | Preliminary results from a phase 1, first-in-human study of DS-9606a, a Claudin 6 (CLDN6) directed antibody drug conjugate, in patients with tumor types known to express CLDN6 | M. Patel | 610O | Proffered Paper Session<br>Sunday, September 15<br>2:45 - 4:15 pm |
| | Trastuzumab deruxtecan (T-DXd) monotherapy and combinations in patients with advanced/metastatic HER2 positive esophageal, gastric or gastroesophageal junction adenocarcinoma: DESTINY-Gastric03 | Y. Janjigian | 1401O | Proffered Paper Session<br>Saturday, September 14<br>8:30 - 10:00 am |
| | Datopotamab deruxtecan (Dato-DXd) monotherapy in patients with endometrial or ovarian cancer: results from the phase 2 TROPION-PanTumor03 study | A. Oaknin | 714MO | Mini Oral Session<br>Sunday, September 15<br>2:45 – 4:15 pm |
| | HERTHENA-PanTumor01: A global phase 2 trial of HER3-DXd in metastatic solid tumors | T. Powles | 690TiP | Poster Session<br>Saturday, September 14 |
| | A phase 1, first-in-human study of DS-1471 in patients with advanced/metastatic solid tumors | S. Koganemaru | 682TiP | Poster Session<br>Saturday, September 14 |
| | Claudin-6 expression in primary and recurrent epithelial ovarian cancer: a potential therapeutic target for high-grade serous ovarian cancer | D. Shintani | 771P | Poster Session<br>Saturday, September 14 |

**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 datopotamab deruxtecan (Dato-DXd), 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. 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 PBD payload. DS-9606, a CLDN6 directed PBD ADC, is the first of several planned ADCs in clinical development utilizing this platform.

Datopotamab deruxtecan, 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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