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Daiichi-Sankyo

Press Release

Ifinatamab Deruxtecan Granted Breakthrough Therapy Designation by U.S. FDA for Patients with Pretreated Extensive-Stage Small Cell Lung Cancer

- Data from IDeate-Lung01 trial will be presented at upcoming IASLC 2025 World Conference on Lung Cancer
- First Breakthrough Therapy Designation for Daiichi Sankyo and Merck's ifinatamab deruxtecan based on IDeate-Lung01 phase 2 trial, with support from IDeate-PanTumor01 phase 1/2 trial
- Fourteenth Breakthrough Therapy Designation granted by FDA across the oncology portfolio of Daiichi Sankyo

Tokyo and Rahway, NJ – (August 18, 2025) – Ifinatamab deruxtecan (I-DXd) has been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with extensive-stage small cell lung cancer with disease progression on or after platinum-based chemotherapy.

Ifinatamab deruxtecan is a specifically engineered, potential first-in-class B7-H3 directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo (TSE: 4568) and being jointly developed by Daiichi Sankyo and Merck & Co., Inc., Rahway, N.J., USA, known as MSD outside of the United States and Canada.

The FDA BTD is designed to accelerate the development and regulatory review of potential new medicines that are intended to treat a serious condition and address a significant unmet medical need. The medicine is required to have shown encouraging preliminary clinical results that demonstrate substantial improvement on a clinically significant endpoint over currently available medicines.

The FDA granted the BTD based on data from the IDeate-Lung01 phase 2 trial, with support from the IDeate-PanTumor01 phase 1/2 trial. Results from the primary analysis of IDeate-Lung01 will be presented in a late-breaking oral presentation at the IASLC 2025 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (#WCLC25). This is the first BTD for ifinatamab deruxtecan and represents the first BTD since the start of the Daiichi Sankyo and Merck collaboration.

"This Breakthrough Therapy Designation granted by the FDA to ifinatamab deruxtecan highlights the urgent need for new treatment options for patients with pretreated extensive-stage small cell lung cancer," said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. "We are committed to

advancing this medicine with the goal of bringing the first B7-H3 directed antibody drug conjugate to patients in order to transform the outcomes of those facing this aggressive disease."

"Patients living with extensive-stage small cell lung cancer often have limited therapeutic options following disease progression after standard of care treatments," said Eliav Barr, MD, Senior Vice President, Head of Global Clinical Development and Chief Medical Officer, MSD Research Laboratories. "This Breakthrough Therapy Designation reinforces our confidence in the promise of ifinatamab deruxtecan to play an important role in the treatment of extensive-stage small cell lung cancer, and we are looking forward to sharing data at the upcoming IASLC 2025 World Conference on Lung Cancer that show the potential of this novel option."

About IDeate-Lung01

IDeate-Lung01 is a global, multicenter, randomized, open-label, two-part phase 2 trial evaluating the safety and efficacy of ifinatamab deruxtecan in patients with extensive-stage small cell lung cancer who were previously treated with at least one prior line of platinum-based chemotherapy and a maximum of three prior lines of therapy. Patients with asymptomatic brain metastases (untreated or previously treated) were eligible.

In the first part of the trial (dose optimization), patients were randomized 1:1 to receive ifinatamab deruxtecan 8 or 12 mg/kg intravenously Q3W. In the second part of the trial (dose expansion), patients received ifinatamab deruxtecan 12 mg/kg intravenously Q3W.

The primary endpoint is objective response rate (ORR) as assessed by blinded independent central review (BICR) per RECIST v1.1. Secondary endpoints included duration of response, progression-free survival, disease control rate, time to response, overall survival, pharmacokinetics and safety. Intracranial ORR was assessed by BICR as an exploratory analysis.

IDeate-Lung01 enrolled 187 patients in Asia, Europe and North America. For more information about the trial, visit ClinicalTrials.gov.

About IDeate-PanTumor01

IDeate-PanTumor01 is a global, multicenter, first-in-human, open-label phase 1/2 trial evaluating the safety and efficacy of ifinatamab deruxtecan in patients with advanced/unresectable or metastatic solid tumors that are refractory or intolerable to standard treatment or for whom no standard treatment exists.

The phase 1 part of the trial (dose escalation) is assessing the safety and tolerability of increasing doses of ifinatamab deruxtecan to determine the maximum tolerated dose and recommended dose for expansion (RDE). The phase 2 part of the trial (dose expansion) is evaluating the safety and efficacy of ifinatamab deruxtecan at the RDE of 12 mg/kg in patients with squamous non-small cell lung cancer, metastatic castration-resistance prostate cancer or esophageal squamous cell carcinoma.

The dose escalation part of the trial is evaluating dose-limiting toxicity and safety. The dose expansion part of the trial is evaluating overall response rate, duration of response, disease control rate, progression-free survival, overall survival and safety. Pharmacokinetic endpoints, exploratory biomarker and immunogenicity endpoints will also be assessed.

IDeate-PanTumor01 enrolled approximately 250 patients in Asia and North America. For more information about the trial, visit ClinicalTrials.gov.

About Small Cell Lung Cancer

More than 2.48 million lung cancer cases were diagnosed globally in 2022.[1] Small cell lung cancer (SCLC) is the second most common type of lung cancer, accounting for approximately 15% of cases.[2] SCLC is aggressive and progresses rapidly to the distant metastatic stage, which has a low five-year survival rate [3,4] While conventional standard of care treatments for patients with advanced SCLC may help improve outcomes, there is a need for additional subsequent treatment approaches.[5,6,7,8]

About B7-H3

B7-H3 is a transmembrane protein that belongs to the B7 family of proteins, which bind to the CD28 family of receptors that includes PD-1.[9,10] B7-H3 is overexpressed in a wide range of cancer types, including SCLC, and its overexpression has been shown to correlate with poor prognosis, making B7-H3 a promising therapeutic target.[11,12,13, 14] There are currently no B7-H3 directed medicines approved for the treatment of any cancer.

About Ifinatamab Deruxtecan

Ifinatamab deruxtecan (I-DXd) is an investigational potential first-in-class B7-H3 directed ADC. Designed using Daiichi Sankyo's proprietary DXd ADC Technology, ifinatamab deruxtecan is comprised of a humanized anti-B7-H3 IgG1 monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers.

Ifinatamab deruxtecan has been granted orphan drug designation by the U.S. FDA, European Commission, Japan Ministry of Health, Labour and Welfare and Taiwan Food and Drug Administration for the treatment of SCLC.

About the Ifinatamab Deruxtecan Clinical Development Program

A comprehensive global clinical development program is underway evaluating the efficacy and safety of ifinatamab deruxtecan monotherapy and in combination with other anticancer medicines across multiple cancers.

About the Daiichi Sankyo and Merck & Co., Inc., Rahway, N.J., USA's Collaboration

Merck & Co., Inc., Rahway, N.J., USA (known as MSD outside of the United States and Canada) entered into a global collaboration in October 2023 to jointly develop and commercialize patritumab deruxtecan (HER3-DXd), ifinatamab deruxtecan (I-DXd) and raludotatug deruxtecan (R-DXd), except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply. In August 2024, the global co-development and co-commercialization agreement was expanded to include gocatamig (MK-6070/DS3280), which the companies will jointly develop and commercialize worldwide, except in Japan where Merck & Co., Inc., Rahway, N.J., USA will maintain exclusive rights. Merck & Co., Inc., Rahway, N.J., USA will be solely responsible for manufacturing and supply for gocatamig.

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, N.J., 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.

Merck & Co., Inc., Rahway, N.J., USA's Focus on Cancer

Every day, we follow the science as we work to discover innovations that can help patients, no matter what stage of cancer they have. As a leading oncology company, we are pursuing research where scientific opportunity and medical need converge, underpinned by our diverse pipeline of more than 25 novel mechanisms. With one of the largest clinical development programs across more than 30 tumor types, we strive to advance breakthrough science that will shape the future of oncology. By addressing barriers to clinical trial participation, screening and treatment, we work with urgency to reduce disparities and help ensure patients have access to high-quality cancer care. Our unwavering commitment is what will bring us closer to our goal of bringing life to more patients with cancer. For more information, visit www.msd.com/research/oncology.

About Merck & Co., Inc., Rahway, N.J., USA

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.msd.com and connect with us on X (formerly Twitter), LinkedIn and YouTube.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2024, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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References:

1. World Health Organization. International Agency for Research on Cancer. U.S. Cancer Fact Sheet. Accessed June 2025.
2. Schabath MB, et al. *Cancer Epidemiol Biomarkers Prev*. 2019 Oct;28(10):1563-1579.
3. Rudin CM, et al. *Nat Rev Dis Primers*. 2021;7(1):3.
4. National Cancer Institute. SEER Explorer. Small cell carcinoma of the Lung and Bronchus: 5-year Relative Survival. Accessed June 2025.
5. American Cancer Society. Treatment Choices for Small Cell Lung Cancer, by Stage. Accessed June 2025.
6. Liu SV, et al. *J Clin Oncol*. 2021;39(6):619-30.
7. Paz-Ares L, et al. *ESMO Open*. 2022;7(2):100408.
8. von Pawel J, et al. *J Clin Oncol*. 2014; 32:4012-4019.
9. Zhao B, et al. *J Hematol Oncol*. 2022;15(1):153.
10. Janakiram M, et al. *Immunol Rev*. 2017;276(1):26-39.
11. Qiu M-j, et al. *Front. Oncol*. 2021;11:600238.
12. Picarda E, et al. *Clin Cancer Res.* 2016;22(14):3425-3431.
13. Bendell JC, et al. *J Clin Oncol.* 2020;39(15 suppl 1). Abstract TPS3646.
14. Kontos F, et al. *Clin Cancer Res.* 2021;27(5):1227-1235.