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Press Release

Ifinatamab Deruxtecan Demonstrated Clinically Meaningful Response Rates in Patients with Extensive-Stage Small Cell Lung Cancer in IDeate-Lung01 Phase 2 Trial

- An objective response rate of 48.2% was observed with ifinatamab deruxtecan in these previously treated patients
- Discussions with global regulatory authorities underway

Tokyo and Rahway, NJ – (September 7, 2025) – Results from the IDeate-Lung01 phase 2 trial showed that ifinatamab deruxtecan (I-DXd) demonstrated clinically meaningful response rates in patients with previously treated extensive-stage small cell lung cancer (ES-SCLC). These data were presented today during a late-breaking presentation (OA06.03) and included as part of the press program at the 2025 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (#WCLC25).

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.

SCLC is aggressive and progresses rapidly to the distant metastatic stage, which has a low five-year survival rate.[1,2] While conventional standard of care treatments for patients with advanced SCLC may help improve outcomes, there is a need for additional subsequent treatment approaches.[3,4,5,6]

In August 2025, ifinatamab deruxtecan was granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy.

Response was assessed in patients who received ifinatamab deruxtecan (12 mg/kg) in both the dose optimization and single-arm expansion parts of the trial. A confirmed objective response rate (ORR) of 48.2% (95% confidence interval [CI]: 39.6–56.9) was observed with ifinatamab deruxtecan in 137 patients with previously treated ES-SCLC as assessed by blinded independent central review (BICR). Three complete responses (CRs), 63 partial responses (PRs) and 54 cases of stable disease (SD) were seen. A median duration of response (DOR) of 5.3 months (95% CI: 4.0–6.5) and a disease control

rate (DCR) of 87.6% (95% CI: 80.9–92.6) were observed. Median progression-free survival (PFS) was 4.9 months (95% CI: 4.2–5.5) and median overall survival (OS) was 10.3 months (95% CI: 9.1–13.3). Disease progression and time-to-event results support further randomized, controlled assessment.

In a subset of patients (n=32) receiving ifinatamab deruxtecan as a second-line treatment, a confirmed ORR of 56.3% (95% CI: 37.7–73.6) was observed as assessed by BICR. Eighteen PRs and 13 cases of SD were seen in this subset of patients. A median DOR of 7.2 months (95% CI: 3.6–NE) and a DCR of 96.9% (95% CI: 83.8–99.9) were observed. Median PFS of 5.6 months (95% CI: 3.9–8.1) and median OS of 12.0 months (95% CI: 7.3–19.1) were seen.

In a subset of patients (n=105) receiving ifinatamab deruxtecan in a third-line and beyond setting, a confirmed ORR of 45.7% (95% CI: 36.0–55.7) with three CRs, 45 PRs and 41 cases of SD were seen. A DCR of 84.8% (95% CI: 76.4–91.0) was observed in these patients.

In an exploratory analysis, an intracranial ORR of 46.2% (95% CI: 33.7–59.0) was observed by CNS RECIST v1.1 in a subset of patients (n=65) with brain metastases at baseline. A full subgroup analysis (2760MO) will be presented at 2025 European Society for Medical Oncology (#ESMO25).

“Patients with extensive-stage small cell lung cancer have an extremely poor prognosis despite current standard of care treatment options,” said Myung-Ju Ahn, MD, PhD, Professor, Department of Hematology & Oncology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea. “The impressive response rates observed in IDeate-Lung01 provide further evidence of the potential role that ifinatamab deruxtecan could play in treating this aggressive form of lung cancer.”

The safety profile observed in IDeate-Lung01 was consistent with that seen for ifinatamab deruxtecan in the phase 1 trial with no new safety signals identified. Grade 3 or higher treatment-related adverse events (TRAEs) occurred in 36.5% of patients. The most common (≥10%) grade 3 or higher TRAEs were neutropenia (13.9%), lymphopenia (12.4%), and anemia (10.2%). Seventeen patients (12.4%) had confirmed treatment-related interstitial lung disease (ILD)/pneumonitis as determined by an independent adjudication committee. The majority of ILD/pneumonitis events were low grade, with 11 grade 1 or 2 (8.0%), four grade 3 (2.9%), and two grade 5 (1.5%) ILD/pneumonitis events observed as of the data cutoff of March 3, 2025.

“In these primary results from IDeate-Lung01, ifinatamab deruxtecan produced clinically meaningful responses in patients with previously treated extensive-stage small cell lung cancer,” said Ken

Takeshita, MD, Global Head, R&D, Daiichi Sankyo. “These data reinforce the potential benefit of this B7-H3 directed antibody drug conjugate in patients who have received one or more lines of platinum-based chemotherapy and will support our ongoing discussions with global regulatory authorities.”

“Small cell lung cancer is the second most common type of lung cancer globally, with 15 percent of patients impacted by this particularly devastating form of the disease,” said Eliav Barr, MD, Senior Vice President, Head of Global Clinical Development and Chief Medical Officer, MSD Research Laboratories. “With limited advances over the last 30 years, there is a high unmet need for new medicines and novel mechanisms of action that could provide additional options to patients with extensive-stage small cell lung cancer.”

A majority of patients (54.7%) in IDeate-Lung01 received a median of two prior lines of treatment, including immunotherapy (81%), topoisomerase I inhibitor (32.1%), lurbinectedin (21.2%), amrubicin (8.8%) and DLL3-targeting T-cell engager (8.0%). As of the data cutoff, the median treatment duration was 4.8 months (range: 0.7–22.7) and 14 patients remain on treatment.

Summary of IDeate-Lung01 Results

Efficacy Measure	**Ifinatamab Deruxtecan 12 mg/kg**		
	Total Population (N=137)	**Second-Line Subset (n=32)**	**Third-Line Plus and Beyond Subset (n=105)**
Confirmed ORR, % (95% CI)	48.2% (39.6–56.9)	56.3% (37.7–73.6)	45.7% (36.0–55.7)
CR, n (%)	3 (2.2%)	0	3 (2.9%)
PR, n (%)	63 (46.0%)	18 (56.3%)	45 (42.9%)
SD, n (%)	54 (39.4%)	13 (40.6%)	41 (39.0%)
DCR (95% CI), %	87.6% (80.9–92.6)	96.9% (83.8–99.9)	84.8% (76.4–91.0)
DOR, median (95% CI), months	5.3 months (4.0–6.5)	7.2 months (3.6–NE)	4.3 months (3.7–5.8)
TTR, median (95% CI), months	1.4 months (1.0–8.1)	1.4 months (1.2–4.0)	N/A
PFS, median (95% CI), months	4.9 months (4.2-5.5)	5.6 months (3.9–8.1)	N/A
OS, median (95% CI), months	10.3 months (9.1-13.3)	12.0 months (7.3–19.1)	N/A

CR, complete response; DCR, disease control rate; DOR, duration of response; N/A, not available; NE, not evaluable; ORR, objective response rate; OS, overall survival; PR, partial response; PFS, progression-free survival; SD, stable disease; TTR, time to response

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 ES-SCLC 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 to participate.

In the first part of the trial (dose optimization), patients were randomized 1:1 to receive ifinatamab deruxtecan (8 or 12 mg/kg) given intravenously once every three weeks. In the second part of the trial (dose expansion), patients received ifinatamab deruxtecan (12 mg/kg) intravenously at the same dosing interval.

The primary endpoint is ORR as assessed by BICR per RECIST v1.1. Secondary endpoints included DOR, PFS, DCR, TTR, OS, 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 Small Cell Lung Cancer

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

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 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 was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with extensive-stage SCLC with disease progression on or after platinum-based chemotherapy.

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 cancer medicines across multiple cancers.

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

Daiichi Sankyo and 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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