NEWS RELEASE

Ifinatamab Deruxtecan Granted Priority Review in the U.S. for Adult Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer who Experienced Disease Progression on or After Platinum-Based Chemotherapy

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Based on results from IDeate-Lung01 Phase 2 trial, with support from IDeate-PanTumor01 Phase 1/2 trial

If approved, ifinatamab deruxtecan would be a first-in-class B7-H3 directed DXd antibody drug conjugate for these patients

RAHWAY, N.J.--(BUSINESS WIRE)-- Daiichi Sankyo (TSE: 4568) and Merck's (NYSE: MRK), known as MSD outside of the United States and Canada, Biologics License Application (BLA) for ifinatamab deruxtecan (I-DXd) has been accepted and granted Priority Review by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. The Prescription Drug User Fee Act (PDUFA) date, the FDA action date for its regulatory decision, is October 10, 2026.

Ifinatamab deruxtecan is a specifically engineered, potential first-in-class B7-H3 directed DXd antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed by Daiichi Sankyo and Merck.

The FDA grants Priority Review to applications for medicines that, if approved, would offer significant improvements

over available treatment options by demonstrating safety or efficacy improvements, preventing serious conditions or enhancing patient compliance. The FDA is also reviewing the BLA under the Real-Time Oncology Review (RTOR) program and Project Orbis, two initiatives of the FDA which are designed to bring safe and effective cancer treatments to patients as early as possible. RTOR allows the FDA to review components of an application before submission of the complete application. Project Orbis provides a framework for concurrent submission and review of oncology medicines among participating international partners.

The BLA is based on results 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 were **presented** at the 2025 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (#WCLC25) and published in the **Journal of Clinical Oncology**. Ifinatamab deruxtecan also was previously **granted** Breakthrough Therapy Designation by the FDA in August 2025 for the treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy.

“The FDA’s granting of Priority Review for ifinatamab deruxtecan marks a significant milestone in our effort to provide new and innovative treatment options for patients with extensive-stage small cell lung cancer,” said John Tsai, MD, global head, R&D, Daiichi Sankyo. “We look forward to continuing to work with the FDA to bring this potential first-in-class B7-H3 directed DXd antibody drug conjugate to patients as quickly as possible.”

“Small cell lung cancer remains one of the toughest cancers to treat, with few options if the disease progresses after standard of care treatments,” said Eliav Barr, MD, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “The FDA’s acceptance of the BLA reinforces the important role that ifinatamab deruxtecan could play in helping to address the needs of patients with extensive-stage small cell lung cancer.”

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 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 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 objective response rate (ORR) as assessed by blinded independent central review (BICR)

per RECIST v1.1. Secondary endpoints included duration of response (DOR), progression-free survival (PFS), disease control rate (DCR), time to response (TTR), overall survival (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 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-resistant 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 ORR, DOR, DCR, PFS, OS and safety. Pharmacokinetic endpoints, exploratory biomarker and immunogenicity endpoints also will be assessed.

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

About small cell lung cancer

Approximately 250,000 patients are diagnosed with small cell lung cancer (SCLC) each year globally. There were approximately 27,000 new cases of SCLC in the U.S. in 2025, accounting for about 12% of all lung cancer cases. SCLC is aggressive and progresses rapidly to the distant metastatic stage, which has a low five-year survival rate. While conventional standard of care treatments for patients with advanced SCLC may help improve outcomes, there is a need for additional subsequent treatment approaches.

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. 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. There are currently no B7-H3 directed medicines approved for the treatment of 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 FDA for the treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy.

Ifinatamab deruxtecan has been granted Orphan Drug Designation (ODD) 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. Ifinatamab deruxtecan also was granted ODD for the treatment of esophageal cancer by the FDA.

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. The program is currently comprised of three Phase 3 trials in advanced/metastatic disease, including SCLC (**IDeate-Lung02**), castration-resistant prostate cancer (**IDeate-Prostate01**) and esophageal squamous cell carcinoma (**IDeate-Esophageal01**).

About the Daiichi Sankyo and Merck collaboration

Daiichi Sankyo and Merck entered into a global collaboration in **October 2023** to jointly develop and commercialize ifinatamab deruxtecan (I-DXd), raludotatug deruxtecan (R-DXd) and patritumab deruxtecan (HER3-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 will maintain exclusive rights. Merck will be solely responsible for manufacturing and supply for gocatamig.

About the ADC portfolio of Daiichi Sankyo

The Daiichi Sankyo ADC portfolio consists of eight ADCs in clinical development crafted from ADC technology discovered in-house by Daiichi Sankyo.

The DXd ADC Technology platform of Daiichi Sankyo consists of seven ADCs in clinical development where each ADC is comprised of a monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers. The DXd ADCs include ENHERTU® and DATROWAY®, which are being jointly developed and commercialized globally with AstraZeneca, and ifinatamab deruxtecan (I-DXd), raludotatug deruxtecan (R-DXd) and patritumab deruxtecan (HER3-DXd), which are being jointly developed and commercialized globally with Merck. DS-3939 and DS3790 are being developed by Daiichi Sankyo.

An additional ADC being developed by Daiichi Sankyo is DS3610, which consists of an antibody attached to a novel payload that acts as an agonist of STING.

Ifinatamab deruxtecan, raludotatug deruxtecan, patritumab deruxtecan, DS-3939, DS3610 and DS3790 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’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 20 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.merck.com/research/oncology**.

About Merck

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.merck.com** and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

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, 2025 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

Media Contacts:

Daiichi Sankyo

Global/US:

Jennifer Brennan

Daiichi Sankyo

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

Merck

Media:

Julie Cunningham

julie.cunningham@merck.com

Michael McArdle

michael.mcardle@merck.com

Investors:

Peter Dannenbaum

(732) 594-1579

Steven Graziano

(732) 594-1583

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