NEWS RELEASE

Ifinatamab Deruxtecan Biologics License Application for Certain Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer Voluntarily Withdrawn

2026-09-25

RAHWAY, N.J.--(BUSINESS WIRE)-- The Biologics License Application (BLA) seeking accelerated approval in the U.S. for Daiichi Sankyo (TSE: 4568) and Merck's (NYSE: MRK), known as MSD outside of the United States and Canada, ifinatamab deruxtecan (I-DXd) for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy has been voluntarily withdrawn.

The decision to withdraw the BLA is based on discussions with the U.S. Food and Drug Administration (FDA) that data supporting the application, including from the **IDeate-Lung01** Phase 2 trial, do not satisfy requirements needed to support an accelerated approval for the proposed indication.

Patient enrollment continues in the **IDeate-Lung02** Phase 3 trial evaluating the efficacy and safety of ifinatamab deruxtecan versus treatment of physician's choice of chemotherapy (amrubicin, lurbinectedin or topotecan) in patients with relapsed ES-SCLC following disease progression with only one prior line of platinum-based chemotherapy.

"Extensive-stage small cell lung cancer is a challenging disease to treat, leaving patients in need of new options," said Abderrahmane Laadem, MD, head, therapeutic area oncology development, Daiichi Sankyo. "Enrollment into the IDeate-Lung02 Phase 3 trial is near completion and we look forward to assessing the potential for a future filing of ifinatamab deruxtecan with the FDA and other global regulatory authorities based on those results."

“While we are disappointed that the current dataset are not supportive of an approval at this time, we are continuing to evaluate the role of ifinatamab deruxtecan in patients with extensive-stage small cell lung cancer and other types of difficult-to-treat cancer,” said Marjorie Green, MD, senior vice president and head of oncology, global clinical development, Merck Research Laboratories. “We would like to thank the patients, their families and investigators who have participated or continue to participate in these studies.”

In addition to the IDeate-Lung02 Phase 3 trial, there are two additional Phase 3 trials underway with ifinatamab deruxtecan in advanced/metastatic disease, including **IDeate-Prostate01** for castration-resistant prostate cancer (CRPC) and **IDeate-Esophageal01** for esophageal squamous cell carcinoma (ESCC).

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 has been granted orphan drug designation (ODD) by the U.S. FDA, European Commission, Japan Ministry of Health, Labor 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.

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**), CRPC (**IDeate-Prostate01**) and ESCC (**IDeate-Esophageal01**).

About IDeate-Lung01

IDeate-Lung01 (ClinicalTrials.gov, **NCT05280470**) is a Phase 2 global, multicenter, randomized, open-label, two-part 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. IDeate-Lung01 enrolled 187 patients in Asia, Europe and North America. Patients with asymptomatic brain metastases (untreated or previously treated) were eligible to participate. Patients with a history of ILD/pneumonitis requiring treatment with steroids or current ILD/pneumonitis at screening, clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses, were not eligible.

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 include 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.

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 highly expressed 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 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.

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 25 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:

Julie Cunningham
Julie.cunningham@merck.com

Justine Moore
(347) 281-3754

Investor Contacts:

Peter Dannenbaum
(732) 594-1579

Steven Graziano
(732) 594-1583

Source: Merck & Co., Inc.