Press Release

Daiichi-Sankyo

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License Application for Certain Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer Voluntarily Withdrawn

Tokyo – (September 25, 2026) – The Biologics License Application (BLA) seeking accelerated approval in the U.S. for Daiichi Sankyo (TSE: 4568) and MSD's, known as Merck & Co., Inc., Rahway, N.J., USA in 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small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy has been voluntarily withdrawn.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. The accelerated approval pathway in the U.S. allows for earlier approval of medicines based on surrogate endpoints to treat serious conditions where there is an unmet medical need.

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.

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 MSD.

"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, Head of Oncology Global Clinical Development, MSD 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 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. Patients with a history of interstitial lung disease (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.

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

Approximately 250,000 patients are diagnosed with small cell lung cancer (SCLC) each year globally.[1] There were approximately 27,000 new cases of SCLC in the U.S. in 2025, accounting for about 12% of all lung cancer cases.[2,3] SCLC is aggressive and progresses rapidly to the distant metastatic stage, which has a low five-year survival rate.[4,5] While conventional standard of care treatments for patients with advanced SCLC may help improve outcomes, there is a need for additional subsequent treatment approaches.[6,7,8,9]

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.[10,11] B7-H3 is overexpressed in a wide range of cancer types, including SCLC, CRPC and ESCC, and its overexpression has been shown to correlate with poor prognosis, making B7-H3 a promising therapeutic target.[12,13,14,15]

About Ifinatamab Deruxtecan

Ifinatamab deruxtecan is an investigational potential first-in-class B7-H3 directed ADC. Designed using the proprietary DXd ADC Technology of Daiichi Sankyo, 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, Labour and Welfare, South Korea Ministry of Food and Drug Safety 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), CRPC (IDeate-Prostate01) and ESCC (IDeate-Esophageal01).

About the Daiichi Sankyo and MSD Collaboration

Daiichi Sankyo and MSD, known as Merck & Co., Inc., Rahway, N.J., USA in the United States and Canada, 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 MSD will maintain exclusive rights. MSD will be solely responsible for manufacturing and supply for gocatamig.

About the ADC Portfolio of Daiichi Sankyo

The Daiichi Sankyo ADC portfolio consists of nine 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 MSD. DS-3939 and DS3790 are being developed by Daiichi Sankyo.

Additional ADCs being developed by Daiichi Sankyo include DS3610, which consists of an antibody attached to a novel payload that acts as an agonist of STING, and DS1025, which consists of a CD25 directed antibody attached to an immuno-oncology optimized cytotoxic payload.

Ifinatamab deruxtecan, raludotatug deruxtecan, patritumab deruxtecan, DS-3939, DS3610, DS3790 and DS1025 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 (TSE: 4568) is a global healthcare company committed to becoming a trusted healthcare innovator, transforming the lives of people through its strength in science and technology. The company discovers and develops new standards of care to address diverse medical needs to fulfill its purpose of contributing to the enrichment of quality of life around the world. With a strategic focus on oncology, Daiichi Sankyo is advancing an industry-leading antibody drug conjugate portfolio along with identifying new breakthrough generating technologies to deliver practice-changing medicines to patients, healthcare professionals and society. For more information, please visit www.daiichisankyo.com.

MEDIA CONTACTS:

Global:
Jennifer Brennan
jennifer.brennan@daiichisankyo.com
+1 908 900 3183 (mobile)

Japan:
DS-PR_jp@daiichisankyo.com

INVESTOR RELATIONS CONTACT:
DaiichiSankyoIR_jp@daiichisankyo.com

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