

DS1025 Enters Clinical Development in Patients with Advanced Solid Tumors as Novel CD25 Directed ADC in Industry-Leading ADC Portfolio of Daiichi Sankyo

Tokyo – (August 27, 2026) – The first patient has been dosed in a first-in-human [phase 1 trial](#) evaluating DS1025 in adult patients with advanced or metastatic solid tumors with disease progression on or after at least one prior line of standard therapy.

DS1025 is a specifically engineered, investigational, potential first-in-class CD25 directed antibody drug conjugate (ADC) containing an immuno-oncology optimized cytotoxic payload discovered by Daiichi Sankyo (TSE:4568).

CD25 is a cell surface protein that is highly expressed on regulatory T cells (Treg cells) which suppresses the response of the immune system against cancer,¹ making it a promising therapeutic target. Currently, there are no CD25 directed ADCs approved for any type of cancer.

“While immunotherapies have transformed cancer treatment, continued innovation in leveraging pathways that can activate the immune system is needed,” said John Tsai, MD, Global Head, R&D, Daiichi Sankyo. “The initiation of this trial evaluating DS1025 reflects continued progress in advancing our pipeline through the development of novel antibody drug conjugates in order to deliver medicines that improve outcomes for patients with cancer.”

About the Phase 1 Trial

The multicenter, open-label, first-in-human, dose escalation [phase 1 trial](#) will assess the safety, tolerability, pharmacokinetics and preliminary efficacy of DS1025 in patients with advanced or metastatic solid tumors with disease progression on or after at least one prior line of standard therapy.

The trial will evaluate primary endpoints of safety and tolerability, including dose-limiting toxicities and adverse events. Secondary endpoints include pharmacokinetics and immunogenicity. Exploratory endpoints include overall response rate, duration of response and time to response.

The trial is expected to enroll up to 45 patients across multiple sites in Asia and Europe. For more information, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About CD25

CD25 is a cell surface protein that is highly expressed on regulatory T cells (Treg cells). Treg cells work to suppress the immune system, helping tumors evade the body's natural ability to destroy abnormal cells and are thought to be a key contributor to resistance that develops with currently available immunotherapies.²

About DS1025

DS1025 is an investigational, potential first-in-class CD25 directed ADC that builds on the DXd ADC Technology of Daiichi Sankyo by delivering an immuno-oncology optimized cytotoxic payload that works to deplete immunosuppressive T cells (Treg cells) in the tumor microenvironment and activate the immune system to detect and destroy cancer cells.

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 Merck & Co., Inc, Rahway, NJ, USA. DS3939 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, DS3939, 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.

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¹ Sureka N, et al. *Cell Biol Int*. 2025;49(8):897-928.

² Fares C, et al. *Am Soc Clin Oncol Educ Book*. 2019 Jan;39:147-164.