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Daiichi-Sankyo

Press Release

IDeate-Prostate01 Phase 3 Trial of Ifinatamab Deruxtecan Initiated in Patients with Pretreated Metastatic Castration-Resistant Prostate Cancer

Tokyo and Basking Ridge, NJ – (June 18, 2025) – The first patient has been dosed in the IDeate-Prostate01 phase 3 trial evaluating the efficacy and safety of investigational ifinatamab deruxtecan (I-DXd) versus docetaxel in patients with metastatic castration-resistant prostate cancer (mCRPC) with disease progression during or after treatment with an androgen receptor pathway inhibitor.

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, NJ, USA.

While localized prostate cancer has a five-year survival rate of more than 90%, survival decreases to 31% in the advanced or metastatic stage.[1] Current standard of care for patients with mCRPC includes treatment with androgen receptor pathway inhibitors followed by taxane-based chemotherapy.[2-5] However, due to poor prognosis associated with previously treated mCRPC, many patients do not receive subsequent therapy, reinforcing the need for new approaches to improve outcomes.[6]

“Despite the emergence of new therapies, the current treatment landscape for patients with metastatic castration-resistant prostate cancer is challenging, and there is a need for new treatments,” said Mark Rutstein, MD, Head, Therapeutic Area Oncology Development, Daiichi Sankyo. “Following the promising results seen in our earlier phase trial, IDeate-Prostate01 has been initiated to evaluate whether ifinatamab deruxtecan may replace standard taxane-based chemotherapy as a potential treatment strategy in patients with metastatic castration-resistant prostate cancer with disease progression during or after treatment with androgen receptor pathway inhibitors.”

“IDeate-Prostate01 marks the initiation of the third pivotal trial in the ifinatamab deruxtecan development program and reinforces our commitment to addressing critical unmet needs for patients,” said Marjorie Green, MD, Senior Vice President and Head of Oncology, Global Clinical Development, MSD Research Laboratories. “Our continued progress in the exploration of this potential first-in-class B7-H3 antibody drug conjugate in collaboration with Daiichi Sankyo, speaks to our pursuit of novel science in the hopes of making a difference for patients in need of new options.”

The initiation of IDeate-Prostate01 is based on results from the IDeate-PanTumor01 phase 1/2 trial previously presented at the 2022 and 2023 European Society of Medical Oncology (ESMO) Congresses where ifinatamab deruxtecan showed promising responses in heavily pretreated patients with mCRPC.

About the IDeate-Prostate01 Trial

IDeate-Prostate01 is a multicenter, open-label, randomized phase 3 trial evaluating the safety and efficacy of ifinatamab deruxtecan (12 mg/kg) versus docetaxel (75 mg/m^2) plus corticosteroid in patients with mCRPC. Eligible patients must have received prior treatment with one or two androgen receptor pathway inhibitors and experienced disease progression during or after at least eight weeks of treatment.

The dual primary endpoints of IDeate-Prostate01 are overall survival and radiographic progression-free survival. Secondary endpoints include objective response rate, time to first subsequent therapy, duration of response, time to pain progression, time to prostate-specific antigen (PSA) progression, PSA response, time to first symptomatic skeletal-related event and safety.

IDeate-Prostate01 will enroll approximately 1,440 patients across Asia, Europe, North America and Oceania. For more information, please visit ClinicalTrials.gov.

About Metastatic Castration-Resistant Prostate Cancer

Prostate cancer is the second most common cancer in men, and the fifth leading cause of cancer death in men worldwide.[7] Nearly 1.5 million prostate cancer cases were diagnosed in 2022, with approximately 400,000 deaths globally.[7]

While localized prostate cancer has a five-year survival rate of more than 90%, survival decreases to 31% in advanced or metastatic stage.[1] Approximately 10% to 20% of early-stage prostate cancer cases progress to metastatic disease within five years of treatment on hormonal therapies such as androgen deprivation therapy.[8,9] Current standard of care for patients with mCRPC includes treatment with androgen receptor pathway inhibitors followed by taxane-based chemotherapy. However, due to poor prognosis associated with previously treated mCRPC, many patients do not receive subsequent therapy, reinforcing the need for new approaches to improve outcomes.[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.[10,11] B7-H3 is overexpressed in a wide range of cancer types,

including mCRPC and its overexpression has been shown to correlate with poor prognosis, making B7-H3 a promising therapeutic target.[12-15] There are currently no B7-H3 directed medicines approved for the treatment of any cancer.

About Ifinatamab Deruxtecan

Ifinatamab deruxtecan (I-DXd) 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 by the U.S. Food and Drug Administration, European Commission, Japan Ministry of Health, Labour and Welfare and Taiwan Food and Drug Administration for the treatment of small cell lung cancer.

About the Ifinatamab Deruxtecan Clinical Development Program

A comprehensive global clinical development program is underway evaluating the efficacy and safety of ifinatamab deruxtecan across multiple B7-H3 targetable cancers. Trials in combination with other anticancer treatments also are underway.

About the Daiichi Sankyo and Merck & Co., Inc., Rahway, N.J., USA 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, NJ, USA. DS-3939, a TA-MUC1 directed ADC, is being developed by Daiichi Sankyo.

The second 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 https://www.merck.com/research/oncology.

About Merck & Co., Inc., Rahway, N.J., USA

At Merck & Co., Inc., Rahway, N.J., USA, 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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References:
1. Ferretti S, et al. *Res Rep Urol*. 2023;15:243-259.
2. Nuhn P, et al. *Eur Urol.* 2019;75(1):88-99.
3. Leaning D, et al. *Front Oncol.* 2023;13:1240864.
4. Hwang C. *Ther Adv Med Oncol.* 2012;4(6):329-40.
5. Kreis K, et al. *BJU Int.* 2022;129(4):470-479.
6. Muniz M, et al *J Nucl Med*. 2024;65(12):1932–1938.
7. Bray F, et al. *CA Cancer J Clin.* 2024;74:229-263.
8. Kirby M, et al. *Int J Clin Pract*. 2011;65(11):1180-1192.
9. Čapoun O, et al. *Anticancer Res*. 2016;36(4):2019-2026.
10. Zhao B, et al. *J Hematol Oncol*. 2022;15(1):153.
11. Janakiram M, et al. *Immunol Rev*. 2017;276(1):26-39.
12. Qiu M-j, et al. *Front. Oncol*. 2021;11:600238.
13. Picarda E, et al. *Clin Cancer Res.* 2016;22(14):3425-3431.
14. Bendell JC, et al. *J Clin Oncol.* 2020;39(15 suppl 1). Abstract TPS3646.
15. Kontos F, et al. *Clin Cancer Res.* 2021;27(5):1227-1235.