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Daiichi Sankyo and Merck & Co., Inc., Rahway, N.J., USA Announce Global Development and Commercialization Collaboration for Three Daiichi Sankyo DXd ADCs

- Collaboration combines Daiichi Sankyo's proven ADC expertise and DXd technology with Merck & Co., Inc., Rahway, N.J., USA's deep experience in oncology and clinical development capabilities to advance and expand the reach of ADCs for patients across multiple types of cancer
- Daiichi Sankyo and Merck & Co., Inc., Rahway, N.J., USA to co-develop and co-commercialize patritumab deruxtecan, ifinatamab deruxtecan and raludotatug deruxtecan worldwide except for Japan where Daiichi Sankyo retains exclusive rights
- Merck & Co., Inc., Rahway, N.J., USA to pay Daiichi Sankyo a \$4 billion upfront payment in addition to \$1.5 billion in continuation payments over the next 24 months, and may make additional payments of up to \$16.5 billion contingent upon the achievement of future sales milestones, for a total potential consideration of up to \$22 billion
- Daiichi Sankyo investor conference call scheduled for Friday, October 20 at 6 am EST / 7 pm JST

Tokyo and Basking Ridge, N.J. – (October 20, 2023) – Daiichi Sankyo (TSE: 4568) and Merck & Co., Inc., Rahway, N.J., USA (known as MSD outside of the United States and Canada) (NYSE: MRK) have entered into a global development and commercialization agreement for three of Daiichi Sankyo's DXd antibody drug conjugate (ADC) candidates: patritumab deruxtecan (HER3-DXd), ifinatamab deruxtecan (I-DXd) and raludotatug deruxtecan (R-DXd). The companies will jointly develop and potentially commercialize these ADC candidates worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply.

All three potentially first-in-class DXd ADCs are in various stages of clinical development for the treatment of multiple solid tumors both as monotherapy and/or in combination with other treatments. Patritumab deruxtecan was granted [Breakthrough Therapy Designation](#) by the U.S. Food and Drug Administration in December 2021 for the treatment of patients with EGFR-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after treatment with a third-generation tyrosine kinase inhibitor (TKI) and platinum-based therapies. The submission of a biologics license application (BLA) in the U.S. is planned by the end of March 2024 for patritumab deruxtecan, which is based on data from the [HERTHENA-Lung01](#) phase 2 trial recently [presented](#) at the IASLC 2023 World Conference on Lung Cancer and simultaneously published in the [Journal of Clinical Oncology](#).

Ifinatamab deruxtecan is currently being evaluated as monotherapy in [IDeate-01](#), a phase 2 clinical trial in patients with previously treated extensive-stage small cell lung cancer (SCLC). Updated results from a subgroup analysis of a [phase 1/2 trial](#) of ifinatamab deruxtecan in SCLC were recently [presented](#) at the IASLC 2023 World Conference on Lung Cancer. Raludotatug deruxtecan is currently being evaluated in a first-in-human [phase 1 clinical trial](#) and updated results in patients with advanced ovarian cancer will be presented at the upcoming European Society for Medical Oncology (ESMO) Congress 2023.

Designed using Daiichi Sankyo's proprietary DXd ADC technology to target and deliver a cytotoxic payload inside cancer cells that express a specific cell surface antigen, 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 promising results from clinical trials of patritumab deruxtecan, ifinatamab deruxtecan and raludotatug deruxtecan continue to demonstrate the broad applicability of Daiichi Sankyo's DXd ADC technology across multiple targets, with each of these medicines having the potential to change clinical practice as has been already seen with ENHERTU[®],” said Sunao Manabe, Representative Director, Executive Chairperson and CEO, Daiichi Sankyo Company, Limited. “As Daiichi Sankyo continues its transformation into a global oncology leader by increasingly building our infrastructure and talent, we recognize that a collaboration with Merck & Co., Inc., Rahway, N.J., USA, a company with remarkable oncology experience and strong in-house development capabilities and resources, will help us deliver on our obligation to deliver these potential new DXd ADCs to more patients as quickly as possible.”

“At Merck & Co., Inc., Rahway, N.J., USA, we continue to augment and diversify our oncology pipeline while building on our immuno-oncology foundation,” said Robert M. Davis, Chairman and Chief Executive Officer, Merck & Co., Inc., Rahway, N.J., USA. “The pioneering work by Daiichi Sankyo scientists has highlighted the far-reaching potential of ADCs to provide meaningful new options for patients with cancer. We look forward to forging this collaboration to deliver the next generation of precision cancer medicines, driven by our mutual compassion for patients around the world.”

Financial Highlights

Under the terms of the agreement, Merck & Co., Inc., Rahway, N.J., USA will pay Daiichi Sankyo upfront payments of \$1.5 billion for ifinatamab deruxtecan due upon execution; \$1.5 billion for patritumab deruxtecan, where \$750 million is due upon execution and \$750 million is due after 12 months; and \$1.5 billion for raludotatug deruxtecan, where \$750 million is due upon execution and \$750 million is due after 24 months. Merck & Co., Inc., Rahway, N.J., USA also will pay Daiichi Sankyo up to an additional \$5.5 billion for each DXd ADC contingent upon the achievement of certain sales milestones. When combined with the additional refundable upfront payment of \$1 billion described below, total potential consideration across the three programs is up to \$22 billion.

Merck & Co., Inc., Rahway, N.J., USA may opt out of the collaboration for patritumab deruxtecan and raludotatug deruxtecan and elect not to pay the two continuation payments of \$750 million each that are due after 12 months and 24 months, respectively. If Merck & Co., Inc., Rahway, N.J., USA opts out of patritumab deruxtecan and/or raludotatug deruxtecan, the upfront payments already paid will be retained by Daiichi Sankyo and rights related to such DXd ADCs will be returned to Daiichi Sankyo.

As referenced above, Merck & Co., Inc., Rahway, N.J., USA will pay an additional upfront payment of \$1 billion (\$500 million each for patritumab deruxtecan and ifinatamab deruxtecan), a pro-rated portion of which may be refundable in the event of early termination of development with respect to each program. For raludotatug deruxtecan, Merck & Co., Inc., Rahway, N.J., USA will be responsible for 75% of the first \$2 billion of R&D expenses. Except as outlined above with respect to R&D expenses, the companies will equally share expenses as well as profits worldwide, except for Japan where Daiichi Sankyo retains exclusive rights and Merck & Co., Inc., Rahway, N.J., USA receives a royalty based on sales revenue. Daiichi Sankyo will generally book sales worldwide.

In aggregate, the three programs have multi-billion dollar worldwide commercial revenue potential for each company approaching the mid-2030s.

The impact on Daiichi Sankyo's consolidated results for the fiscal year ending March 31, 2024 will be announced at an appropriate time in the future. The collaboration is expected to contribute to enhancing the corporate and shareholder value of Daiichi Sankyo over the medium to long term.

In conjunction with this transaction, Merck & Co., Inc., Rahway, N.J., USA will record an aggregate pretax charge of \$5.5 billion, or approximately \$1.70 per share, reflecting the \$4 billion upfront payment and the \$1.5 billion in continuation payments. The impact of this charge will result in a reduction in both fourth-quarter and full-year 2023 GAAP and non-GAAP results. In addition, Merck & Co., Inc., Rahway, N.J., USA will invest in the pipeline assets and incur costs to finance the transaction, resulting in a negative impact to EPS of approximately \$0.25 in the first 12 months following the close of the transaction.

About the DXd ADC Portfolio of Daiichi Sankyo

The DXd ADC portfolio of Daiichi Sankyo currently consists of six ADCs in clinical development across multiple types of cancer. ENHERTU, a HER2 directed ADC, and datopotamab deruxtecan (Dato-DXd), a TROP2 directed ADC, 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, raludotatug deruxtecan (R-DXd), a CDH6 directed ADC, are being jointly developed and commercialized globally with Merck & Co., Inc., Rahway, N.J., USA. DS-3939, a TA-MUC1 directed ADC, is being developed by Daiichi Sankyo.

Designed using Daiichi Sankyo's proprietary DXd ADC technology to target and deliver a cytotoxic payload inside cancer cells that express a specific cell surface antigen, 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.

Datopotamab deruxtecan, ifinatamab deruxtecan, patritumab deruxtecan, raludotatug deruxtecan and DS-3939 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 need. For more information, please visit www.daiichisankyo.com.

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 [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 the global outbreak of novel coronavirus disease (COVID-19); 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, 2022 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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