



Press Release

Daiichi Sankyo and Merck & Co., Inc., Rahway, NJ, USA Enter into Global Development and Commercialization Agreement for MK-6070

- Agreement builds on and complements Daiichi Sankyo and Merck & Co., Inc., Rahway, NJ, USA's shared commitment to develop novel medicines for patients with cancer
- Daiichi Sankyo and Merck & Co., Inc., Rahway, NJ, USA to co-develop and co-commercialize MK-6070, an investigational delta-like ligand 3 (DLL3) targeting T-cell engager, worldwide except for Japan where Merck & Co., Inc., Rahway, NJ, USA retains exclusive rights

Tokyo and Rahway, NJ – (August 6, 2024) – Daiichi Sankyo (TSE: 4568) and Merck & Co., Inc., Rahway, NJ, USA (NYSE: MRK) (known as MSD outside of the United States and Canada) have expanded their existing global co-development and co-commercialization agreement for three investigational DXd antibody drug conjugates to include Merck & Co., Inc., Rahway, NJ, USA's MK-6070, an investigational delta-like ligand 3 (DLL3) targeting T-cell engager. The companies will jointly develop and commercialize MK-6070 worldwide, except in Japan where Merck & Co., Inc., Rahway, NJ, USA will maintain exclusive rights. Merck & Co., Inc., Rahway, NJ, USA will be solely responsible for manufacturing and supply for MK-6070.

MK-6070 is a T-cell engager targeting DLL3, an inhibitory canonical Notch ligand that is expressed at high levels in small cell lung cancer (SCLC) and neuroendocrine tumors, currently being evaluated in a [phase 1/2 clinical trial](#). The companies are planning to evaluate MK-6070 in combination with ifinatamab deruxtecan in certain patients with SCLC, as well as other potential combinations. Merck & Co., Inc., Rahway, NJ, USA obtained MK-6070 through its [acquisition](#) of Harpoon Therapeutics.

“Expanding our oncology pipeline with a DLL3 T-cell engager further supports Daiichi Sankyo's strategy to create new standards of care for patients with cancer worldwide,” said Ken Takeshita, MD, Global Head, R&D, Daiichi Sankyo. “We look forward to continuing our relationship with MSD with the addition of MK-6070 as it provides potential synergies with our established antibody drug conjugate collaboration, particularly ifinatamab deruxtecan, and demonstrates our shared commitment to advancing new medicines for patients.”

“Small cell lung cancer is an aggressive, fast-growing form of lung cancer and new treatment approaches are urgently needed,” said Dean Y. Li, MD, PhD, President, MSD Research Laboratories. “We are pleased to build upon our collaboration with Daiichi Sankyo and look forward to evaluating the combination of MK-6070 and ifinatamab deruxtecan as a novel two-pronged approach targeting the underlying biology of small cell lung cancer along with other forms of cancer.”

Financial Highlights

Under the terms of the agreement, Merck & Co., Inc., Rahway, NJ, USA will receive an upfront cash payment of \$170 million and has also satisfied a contingent quid obligation from the original collaboration agreement. The companies will share R&D and commercialization expenses as well as profits worldwide, except for Japan where Merck & Co., Inc., Rahway, NJ, USA retains exclusive rights and Daiichi Sankyo receives a royalty based on sales. R&D expenses related to MK-6070 in combination with ifinatamab deruxtecan will be shared in a manner consistent with the original agreement for ifinatamab deruxtecan. Merck & Co., Inc., Rahway, NJ, USA will generally record sales for MK-6070 worldwide.

About DLL3

Delta-like ligand 3 (DLL3), a Notch inhibitory ligand, is highly expressed on small cell lung cancer and other neuroendocrine tumors such as melanoma, small cell bladder cancer and metastatic castration resistant prostate cancer and is minimally expressed in normal tissues.¹ DLL3 is a promising therapeutic target where multiple treatment approaches are being explored.^{1, 2}

About MK-6070

MK-6070 is an investigational DLL3 directed tri-specific T-cell engager currently being evaluated in a phase 1/2 clinical trial as a monotherapy in certain patients with advanced cancers associated with expression of DLL3 and in combination with atezolizumab in certain patients with SCLC. The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to MK-6070 for the treatment of SCLC in March 2022.

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 is solely responsible for manufacturing and supply.

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.msd.com/research/oncology/>.

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

At MSD, known as Merck & Co., Inc., Rahway, N.J., USA in 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, 2023 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 Owen D, et al. *Journal of Hematology & Oncology*. 2019; 12,61

² Rudin C, et al. *Journal of Hematology & Oncology*. 2023; 16,66