

## Press Release

# Daiichi Sankyo Announces 15 Billion Yen Manufacturing Investment to Support Acceleration of Antibody Drug Conjugate Portfolio

- Significant investment in antibody drug conjugate (ADC) manufacturing capabilities will improve research productivity and accelerate clinical development of novel Daiichi Sankyo Cancer Enterprise ADC candidates including HER2-targeting DS-8201 and HER3-targeting U3-1402
- Investment reflects company commitment to the potential of its proprietary ADC technology and delivering on its vision to create meaningful treatments for patients with cancer

**Tokyo, Japan, Parsippany, NJ, and Munich, Germany – (April 27, 2017)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced it is making an initial 15 billion yen investment to optimize and enhance its manufacturing capabilities to support its growing antibody drug conjugate (ADC) pipeline.

“This strategic investment will bolster our leadership and expertise in ADC manufacturing, as we apply our proprietary ADC technology to more than two dozen biologics in preclinical or early stage development,” said Katsumi Fujimoto, Ph.D., Senior Executive Officer, Head of Supply Chain Division, Daiichi Sankyo. “Our manufacturing capacities will more than triple by 2021, affording us greater flexibility for research and development, and strengthening our anticipated future commercial production.”

The company’s investment will build new and refurbish manufacturing lines at three of the company’s manufacturing plants in Japan. These improvements will optimize and expand the production of fully synthesized ADCs and ensure a stable supply for future investigational and commercial use.

“We are committed to the continued advancement and acceleration of our ADC franchise, and expanding our manufacturing capabilities will allow us to hone and drive our institutional ADC expertise as we progress development and investigation of these complex medicines,” said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. “We believe that our researchers have systemically addressed several critical limitations of current ADC technology, so we want to ensure this expertise is carried over to the clinic.”

Antibody drug conjugates (ADCs) are a type of targeted cancer medicine that deliver cytotoxic chemotherapy (“payload”) directly to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells. Daiichi Sankyo’s proprietary ADC technology, which has broad application across multiple types of cancer, is designed to deliver enhanced cancer cell destruction with less systemic exposure to the cytotoxic payload.

The ADC Franchise of Daiichi Sankyo Cancer Enterprise currently consists of six novel ADCs including DS-8201 and U3-1402 in phase 1 clinical development as well as DS-7300, DS-1062 and two other ADCs with undisclosed targets in pre-clinical development.

DS-8201 is an investigational HER2-targeting ADC currently in phase 1 clinical development for HER2-positive advanced or metastatic breast or gastric cancer, HER2-low-expressing breast cancer and other HER2-expressing solid cancers. The U.S. Food and Drug Administration (FDA) granted Fast Track designation to DS-8201 for the treatment of HER2-positive unresectable and/or metastatic breast cancer in patients who have progressed after prior treatment with HER2-targeted therapies including ado-trastuzumab emtansine (T-DM1). U3-1402 is an investigational and potential first-in-class HER3-targeting ADC currently in phase 1 clinical development for HER3-positive metastatic or unresectable breast cancer. DS-8201 and U3-1402 have not been approved for any indication in any country.

### **About Daiichi Sankyo Cancer Enterprise**

The vision of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking in order to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do. Anchored by our Antibody Drug Conjugate (ADC) and Acute Myeloid Leukemia (AML) Franchises, our cancer pipeline includes more than 20 small molecules, monoclonal antibodies and ADCs stemming from our powerful research engines: our two laboratories for biologic/immuno-oncology and small molecules in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. Compounds in development include: quizartinib, an oral FLT3 inhibitor, for FLT3-ITD+ AML; DS-8201, a HER2-targeting ADC, for HER2-expressing breast or gastric cancer or other HER2-expressing solid tumors; and pexidartinib, an oral CSF-1R inhibitor, for tenosynovial giant cell tumor (TGCT), which is also being explored in a range of solid tumors in combination with the anti-PD1 immunotherapy pembrolizumab. For more information, please visit: [www.DSCancerEnterprise.com](http://www.DSCancerEnterprise.com).

### **About Daiichi Sankyo**

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with a Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other

rare diseases. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com). Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: [www.dsi.com](http://www.dsi.com).

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