

## Press Release

# **Daiichi Sankyo and AstraZeneca Announce Global Development and Commercialization Collaboration for Daiichi Sankyo's HER2 Targeting Antibody Drug Conjugate [Fam-] Trastuzumab Deruxtecan (DS-8201)**

April 03, 2019

### [Company](#)

- Collaboration combines Daiichi Sankyo's scientific and technological excellence with AstraZeneca's global experience and resources in oncology to accelerate and expand the potential of [fam-] trastuzumab deruxtecan as monotherapy and combination therapy across a spectrum of HER2 expressing cancers
- AstraZeneca to pay Daiichi Sankyo up to \$6.90 billion in total consideration, including \$1.35 billion upfront payment and up to an additional \$5.55 billion contingent upon achievement of future regulatory and sales milestones as well as other contingencies
- Companies to share equally development and commercialization costs as well as profits worldwide from [fam-] trastuzumab deruxtecan with Daiichi Sankyo maintaining exclusive rights in Japan
- Daiichi Sankyo is expected to book sales in U.S., certain countries in Europe, and certain other markets where Daiichi Sankyo has affiliates; AstraZeneca is expected to book sales in all other markets worldwide, including China, Australia, Canada and Russia

**Tokyo, Munich and Basking Ridge, NJ - (March 28, 2019)** - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that it has entered into a global development and commercialization

agreement with AstraZeneca for Daiichi Sankyo's lead antibody drug conjugate (ADC), [fam-] trastuzumab deruxtecan (DS-8201), currently in pivotal development for multiple HER2 expressing cancers including breast and gastric cancer, and additional development in non-small cell lung and colorectal cancer.

Daiichi Sankyo and AstraZeneca will jointly develop and commercialize [fam-] trastuzumab deruxtecan as a monotherapy or a combination therapy worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and the supply of [fam-] trastuzumab deruxtecan.

As announced separately by Daiichi Sankyo, a Biologics License Application (BLA) submission to U.S. FDA for [fam-] trastuzumab deruxtecan in HER2 positive metastatic breast cancer previously treated with ado trastuzumab emtansine (T-DM1) will be accelerated to the first half of fiscal year 2019.

Designed using Daiichi Sankyo's DXd proprietary ADC technology, [fam-] trastuzumab deruxtecan is comprised of a humanized HER2 antibody attached to a novel topoisomerase I inhibitor payload by a tetrapeptide-based linker. It is designed to target and deliver chemotherapy inside cancer cells and reduce systemic exposure to the cytotoxic payload compared to the way chemotherapy is commonly delivered.

"[Fam-] trastuzumab deruxtecan is the flagship asset in our oncology pipeline created by our relentless pursuit of science and technology, the most important strengths of our company," said George Nakayama, Representative Director, Chairman and CEO of Daiichi Sankyo Company, Limited. "Through the strategic collaboration with AstraZeneca, a company with a wealth of global experience and expertise in oncology, we will combine our respective skill sets to maximize the value of [fam-] trastuzumab deruxtecan, and accelerate the establishment of our global oncology business. By aiming to provide new treatment options across a wide range of cancers as soon as possible, we will maximize our contribution to patients with cancer and their families around the world."

"We believe that [fam-] trastuzumab deruxtecan could become a transformative new medicine for the treatment of HER2 positive breast and gastric cancers," said Pascal Soriot, Chief Executive Officer, AstraZeneca. "In addition, [fam-] trastuzumab deruxtecan has the potential to redefine breast cancer treatment as the first therapy for HER2 low expressing tumors. It also has the potential to treat other HER2 mutated or HER2 overexpressing tumors, including lung and colorectal cancers. We are proud to be working with Daiichi Sankyo, a long-term collaborator of AstraZeneca in other disease areas."

## Financial Terms

Under the terms of the agreement, AstraZeneca will pay Daiichi Sankyo an upfront payment of \$1.35 billion. Contingent payments of up to \$5.55 billion include \$3.8 billion for achievement of future regulatory milestones and other contingencies, as well as sales-related milestones of up to \$1.75 billion. Total payments under the agreement have the potential to reach up to \$6.90 billion.

Daiichi Sankyo and AstraZeneca will share equally development and commercialization costs as well as profits from [fam-] trastuzumab deruxtecan worldwide, except for Japan. Daiichi Sankyo is expected to book sales in U.S., certain countries in Europe, and certain other markets where Daiichi Sankyo has affiliates. AstraZeneca is expected to book sales in all other markets worldwide, including China, Australia, Canada and Russia.

The impact on Daiichi Sankyo's consolidated results for the fiscal year ending March 31, 2019 is immaterial because the upfront payment will be booked in revenue over the period in which Daiichi Sankyo has contractual performance obligations under this collaboration. The collaboration is expected to contribute to enhancing the corporate and shareholder value of Daiichi Sankyo over the medium to long term.

## About [Fam-] Trastuzumab Deruxtecan

[Fam-] trastuzumab deruxtecan (DS-8201; [fam-] trastuzumab deruxtecan in U.S. only; trastuzumab deruxtecan in other regions of world) is the lead product in the investigational ADC Franchise of the Daiichi Sankyo Cancer Enterprise. ADCs are targeted cancer medicines that deliver cytotoxic chemotherapy ("payload") to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells.

A broad and comprehensive development program with [fam-] trastuzumab deruxtecan is underway in North America, Europe and Asia including five pivotal studies. [Fam-] trastuzumab deruxtecan is in pivotal phase 3 development in previously treated HER2 low expressing metastatic breast cancer versus investigator's choice (DESTINY-Breast04); phase 3 development in HER2 positive metastatic breast cancer versus ado-trastuzumab emtansine (T-DM1) (DESTINY-Breast03); and phase 3 development in HER2 positive metastatic breast cancer versus investigator's choice post T-DM1 (DESTINY-Breast02). [Fam-] trastuzumab deruxtecan also is in pivotal phase 2 clinical development for HER2 positive metastatic breast cancer resistant or refractory to T-DM1 (DESTINY-Breast01); pivotal phase 2 development for HER2 positive advanced gastric cancer resistant or refractory to trastuzumab (DESTINY-Gastric01); phase 2 development for HER2 expressing advanced colorectal cancer; phase 2 development for metastatic non-squamous HER2 overexpressing or HER2 mutated NSCLC; and, phase 1 development in combination with nivolumab for HER2 expressing metastatic breast and bladder cancer.

[Fam-] trastuzumab deruxtecan has been granted Breakthrough Therapy designation for the treatment of patients with HER2 positive, locally advanced or metastatic breast cancer who have been treated with trastuzumab and pertuzumab and have disease progression after T-DM1, and Fast Track designation 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 T-DM1 by the U.S. Food and Drug Administration (FDA). [Fam-] trastuzumab deruxtecan has received SAKIGAKE Designation for the treatment of HER2 positive advanced gastric or gastroesophageal junction cancer by the Japan Ministry of Health, Labour and Welfare (MHLW).

[Fam-] trastuzumab deruxtecan is an investigational agent that has not been approved for any indication in any country. Safety and efficacy have not been established.

## About Daiichi Sankyo Cancer Enterprise

The mission of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking 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 three pillars including our investigational Antibody Drug Conjugate Franchise, Acute Myeloid Leukemia Franchise and Breakthrough Science, we aim to deliver seven distinct new molecular entities over eight years during 2018 to 2025. Our powerful research engines include two laboratories for biologic/ immuno-oncology and small molecules in Japan, and Plexikon Inc., our small molecule structure-guided R&D center in Berkeley, CA. Compounds in pivotal stage development include: [fam-] trastuzumab deruxtecan, an antibody drug conjugate (ADC) for HER2 expressing breast, gastric and other cancers; quizartinib, an oral selective FLT3 inhibitor, for newly-diagnosed and relapsed/refractory FLT3-ITD acute myeloid leukemia (AML); and pexidartinib, an oral CSF1R inhibitor, for tenosynovial giant cell tumor (TGCT). 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 15,000 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 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 Basking Ridge, 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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