Press Release

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Daiichi Sankyo Launches Antitumor Agent Trastuzumab Biosimilar for Intravenous Drip Infusions "Daiichi Sankyo" in Japan

Tokyo, Japan (November 28, 2018) - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced that it launched the antitumor agent trastuzumab BS for intravenous drip infusions 60 mg and 150 mg "Daiichi Sankyo" (generic name: trastuzumab (genetical recombination)[trastuzumab biosimilar 2], hereafter, "the product") in Japan today.

The product is a pharmaceutical agent developed by Amgen Inc. (Headquarters: Thousand Oaks, CA, U.S.A; hereafter, "Amgen") as a biosimilar product to the anti-HER2 antibody, trastuzumab. The product was approved on September 21, 2018, and indicated for breast cancer with HER2 overexpression (Dosage A), and unresectable advanced or relapsed gastric cancer with HER2 overexpression (Dosage B).

Based on the exclusive agreement on the commercialization of biosimilars concluded with Amgen in July 2016, Daiichi Sankyo is responsible for the distribution and commercialization of the product in Japan, while Amgen is responsible for its manufacture.

The product is the first biosimilar product launched by Daiichi Sankyo, and the company expects that the product will provide patients and medical professionals with various options for cancer treatment, thereby further contributing to medical treatment.

<Product Outline>

Product name	Trastuzumab BS for intravenous drip infusions 60 mg and 150 mg “Daiichi Sankyo”
Generic name	Trastuzumab (Genetical Recombination)[Trastuzumab Biosimilar 2]
Indications	Breast cancer with HER2 overexpression Unresectable advanced or recurrent gastric cancer with HER2 overexpression
Dosage and administration	・Dosage A is applied for breast cancer with HER2 overexpression. ・Dosage B in combination with other antineoplastic agents is applied for unresectable advanced or recurrent gastric cancer with HER2 overexpression. Dosage A: In adults 4 mg/kg (body weight) trastuzumab (recombinant) [biosimilar 2 of trastuzumab] is intravenously infused once daily at the first administration, and 2 mg/kg for 90 minutes or longer at one-week intervals for the second and subsequent treatments. Dosage B: In adults 8 mg/kg (body weight) trastuzumab (recombinant) [generic product 2 of trastuzumab] is intravenously infused once daily at the first administration, and 6 mg/kg for 90 minutes or longer at three-week intervals for the second and subsequent treatments. If the initial dose is well tolerated, the administration time can be shortened up to 30 minutes for the second and subsequent treatments.
Date of approval for manufacturing and marketing	September 21, 2018
Date of listing in the NHI reimbursement	November 28, 2018
Day of launch	November 28, 2018
Marketing authorization holder	DAIICHI SANKYO COMPANY, LIMITED
Partner	Amgen Inc.