



MSD and Taiho Enter into Co-Promotion Agreement in Japan for Pembrolizumab, MSD's Immune Checkpoint Inhibitor (Anti-PD-1 Therapy)

TOKYO, April 11, 2016 – MSD K.K. also known as Merck in the US and Canada (MSD; President and Representative Director: Tony Alvarez) and Taiho Pharmaceutical Co., Ltd. (Taiho; President and Representative Director: Masayuki Kobayashi) announced today that they have entered into a co-promotion agreement in Japan for pembrolizumab (generic name; development code: MK-3475), an immune checkpoint inhibitor (anti-PD-1 therapy) of which MSD has filed an application for approval in Japan.

Under the agreement, Taiho will co-promote pembrolizumab with MSD while MSD will manufacture and distribute it.

Pembrolizumab, an immune checkpoint inhibitor (anti-PD-1 therapy), is a humanized monoclonal antibody that blocks the interaction between PD-1 mainly expressed on activated lymphocytes with anti-tumor activity, and its ligands, PD-L1 and PD-L2 expressed mainly on tumor cells. By binding to the PD-1 receptor and blocking the interaction with the receptor ligands, pembrolizumab releases the PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.

In Japan, an application for marketing approval was submitted for the anti-PD-1 antibody pembrolizumab (genetic recombination), for the treatment of patients with unresectable or metastatic melanoma on December 22, 2015, and for the treatment of patients with unresectable advanced or recurrent non-small cell lung cancer on February 29, 2016. The ongoing clinical programs are for bladder cancer, lung cancer, breast cancer, gastric cancer, head and neck cancer, multiple myeloma, esophageal cancer, colorectal cancer, Hodgkin's lymphoma, and advanced solid tumor. Pembrolizumab is one of the first medicines included in the Ministry of Health, Labor and Welfare's Sakigake Fast-Track Review, for the treatment of unresectable advanced or recurrent gastric cancer on October 27, 2015.

MSD and Taiho will further contribute to patients and healthcare providers in the oncology area by establishing a close partnership with co-promotion of pembrolizumab, a promising new option for cancer treatment.

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