Mitsubishi Tanabe Pharma Corporation Daiichi Sankyo Co., Ltd.

Japan's First DPP-4 Inhibitor / SGLT2 Inhibitor Combination Drug
Application approved in Japan for CANALIA® Combination Tablets, a
type 2 diabetes mellitus treatment agent
-Combination of selective DPP-4 inhibitor TENELIA® Tablets and
SGLT2 inhibitor CANAGLU® Tablets-

Osaka and Tokyo, Japan (July 3, 2017) - Mitsubishi Tanabe Pharma Corporation (hereafter Mitsubishi Tanabe Pharma; Head Office: Chuo-ku, Osaka; President & Representative Director, CEO: Masayuki Mitsuka) and Daiichi Sankyo Co., Ltd. (hereafter Daiichi Sankyo; Head Office: Chuo-ku, Tokyo; Representative Director, President & COO: Sunao Manabe) announced today that on July 3, 2017, Mitsubishi Tanabe Pharma received manufacturing and sales approval for CANALIA® Combination Tablets, a type 2 diabetes mellitus treatment agent that combines selective DPP-4 inhibitor TENELIA® Tablets (generic name: teneligliptin) and SGLT2 inhibitor CANAGLU® Tablets (generic name: canagliflozin), from the Japanese Ministry of Health, Labour and Welfare. The approval is for an indication of type 2 diabetes mellitus.

Approved for the first time in Japan, CANALIA® Combination Tablets is a combination drug that contains two ingredients, a DPP-4 inhibitor and a SGLT2 inhibitor. Both TENELIA® Tablets and CANAGLU® Tablets are type 2 diabetes mellitus treatment agents originally discovered by Mitsubishi Tanabe Pharma in Japan. CANALIA® Combination Tablets, a combination drug incorporating the above two constituents, is an orally-administered (once daily) agent that lowers blood-glucose levels based on two different mechanisms of action: inhibiting DPP-4 and thereby increasing insulin release according to blood glucose levels; and inhibiting SGLT2 and thereby promoting excretion of glucose into urine. Results of clinical trials conducted in Japanese T2DM patients who have inadequate glycemic control to TENELIA® Tablets or CANAGLU® Tablets demonstrated efficacy, safety and good tolerability.

Use of CANALIA® Combination Tablets by patients with type 2 diabetes mellitus whose blood glucose levels are stably controlled by concomitant treatment with TENELIA® Tablets and CANAGLU® Tablets will enhance convenience and improve medication adherence. Use of CANALIA® Combination Tablets by type 2 diabetes mellitus patients who have inadequate glycemic control to monotherapy with TENELIA® Tablets or CANAGLU® Tablets is also expected to result in improved blood glucose control.

Currently, marketing of TENELIA® Tablets is conducted by Daiichi Sankyo, whereas marketing of CANAGLU® Tablets is carried out by Mitsubishi Tanabe Pharma.

Marketing of CANALIA® Combination Tablets will be conducted by Daiichi Sankyo, and both companies will co-promote the product, as is the case with TENELIA® Tablets and CANAGLU® Tablets.

Mitsubishi Tanabe Pharma and Daiichi Sankyo aim to contribute to the treatment of patients with diabetes by maximizing the product values of the above three agents in the diabetes treatment drug markets as well as by engaging in prompt and appropriate promotion activities through the alliance between both companies.

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