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Mitsubishi Tanabe files NDA for Canagliflozin

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Singapore: Mitsubishi Tanabe Pharma announced that the company has submitted an application for the manufacturing and marketing approval of TA-7284 (Canagliflozin), a sodium glucose co-transporter 2 (SGLT2) inhibitor, for the treatment of patients with type 2 diabetes, to the Ministry of Health, Labor and Welfare in Japan.

Canagliflozin, discovered by Mitsubishi Tanabe Pharma, is an oral type 2 diabetes treatment with a novel mechanism of action. The kidneys play an important role in the homeostasis of blood glucose levels in the body and it is known that reabsorption of glucose in the kidneys is increased in patients with type 2 diabetes which leads to maintain and progress hyperglycemia.

Canagliflozin inhibits sodium glucose co-transporter 2 (SGLT2), a transporter involved in the reabsorption of glucose in the renal tubule of the kidneys, suppresses reabsorption of glucose, promotes the loss of excessive glucose into the urine, and as a result, improves glycemic control.

More than 11,000 patients with type 2 diabetes were enrolled in the phase III programs in and outside Japan, which assessed the efficacy and safety of canagliflozin. The development program included mono-therapy adjunct to diet and exercise, combination therapies with other anti-hyperglycemic agents such as DPP-4 inhibitors, insulin and also involved type 2 diabetes patients with impaired renal function, those who have or are at high risk of developing cardiovascular disease and elderly patients.

In March, 2013, Janssen Pharmaceuticals, licensee, obtained the new drug application (NDA) approval for canagliflozin (Invokana) in the US for the treatment of adult patients with type 2 diabetes mellitus. Also, the marketing authorization application has been filed in Europe.