New Drug Application Filed in Japan for TA-7284 (Canagliflozin)

To Treat Patients with Type 2 Diabetes

Osaka, Japan, May 27, 2013---Mitsubishi Tanabe Pharma Corporation (President Representative Director: Michihiro Tsuchiya) announced that the Company has submitted to the Ministry of Health, Labor and Welfare in Japan an application for the manufacturing and marketing approval of TA-7284 (generic name: canagliflozin), a sodium glucose co-transporter 2 (SGLT2) inhibitor, for the treatment of patients with type 2 diabetes.

Canagliflozin, which has been 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 3 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, Inc. (Raritan, NJ, US), licensee, obtained the NDA approval for canagliflozin (Product Name: INVOKANA™) in the United States for the treatment of adult patients with type 2 diabetes mellitus, and the marketing authorization application has been filed in Europe.

By providing this new treatment option for type 2 diabetes mellitus, Mitsubishi Tanabe Pharma hopes to support patients, who are combating this disease.

<Media enquiry>
Corporate Communications Department
Phone: +81 6-6205-5211