August 4, 2021

# Application for approval of CANAGLU® Tablets 100mg for the indication of chronic kidney disease with type 2 diabetes mellitus in Japan

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Hiroaki Ueno) submitted an application for partial changes to CANAGLU® Tablets 100mg (CANAGLU)(INN: canagliflozin) for the additional indication of chronic kidney disease associated with type 2 diabetes mellitus on August 4.

Chronic kidney disease (CKD) is a condition in which the function of the kidney deteriorates due to some cause, and the number of patients with CKD in Japan is estimated to be 1 in 8, or approximately 13.3 million, adults *, and it is a very common disease. Type 2 diabetes is a major risk factor for the development and progression of CKD, and measures against CKD associated with type 2 diabetes have become an important issue from the viewpoints of quality of life (QOL) of patients and health economics.

Canagliflozin promotes the excretion of excessive glucose into the urine, and as a result, lowers the blood glucose level. In addition, Canagliflozin is presumed to exhibit a renoprotective effect by reducing glomerular pressure in the kidney, etc.

CANAGLU is a treatment agent for type 2 diabetes mellitus discovered by MTPC. CANAGLU was approved in July 2014 in Japan and has been marketed since September 2014.
For the indication of diabetic nephropathy, CANAGLU was approved in February 2021 in Taiwan.

By providing new options for the treatment of CKD with type 2 diabetes mellitus to a growing number of patients in the world, MTPC group show its continued resolve to improve their QOL.

*Japanese Society of Nephrology Clinical Practice Guidebook for Diagnosis and Treatment of Chronic Kidney Disease 2021

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<Reference>

## ■canagliflozin (Japan names: CANAGLU® Tablets 100mg)

Canagliflozin (INN: canagliflozin; Japan names: CANAGLU® Tablets 100mg) is an SGLT2 inhibitor that originated in Japan. It is a treatment for type 2 diabetes mellitus which was discovered by Mitsubishi Tanabe Pharma and has its research roots in T-1095, the world's first orally bioavailable sodium glucose co-transporter inhibitor. CANAGLU® inhibits SGLT2, a transporter involved in the reabsorption of glucose in the renal tubules of the kidneys, suppresses the reabsorption of glucose, promotes the excretion of excessive glucose into the urine, and as a result, lowers the blood glucose level. Canagliflozin was approved in Japan, July 2014 followed by Taiwan in March 2017. In Taiwan, the additional indication for diabetic nephropathy was approved in February 2021.