



October 8, 2020

Canagliflozin (TA-7284) has been approved in Indonesia for Type2 Diabetes Mellitus

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Hiroaki Ueno), announced today that PT Mitsubishi Tanabe Pharma Indonesia (MTID), MTPC's subsidiary in Indonesia obtained the regulatory approval of CANAGLU[®] (generic name: canagliflozin hydrate; Japan names: CANAGLU[®] Tablets 100mg) for a treatment agent for type 2 diabetes mellitus from Indonesia FDA on September 18, 2020.

Canagliflozin is a treatment agent for type 2 diabetes mellitus discovered by MTPC and was approved in Japan in July 2014. In 88 countries including the US and Europe, licensee Janssen Pharmaceuticals, Inc. has received approval of Canagliflozin under the brand name INVOKANA

In Indonesia, the number of patients with type 2 diabetes has been increasing in recent years, and it is estimated that this trend will continue. MTID was established in July 1970 and has supplied numerous products for lifestyle-related diseases in Indonesia for 50 years. MTID will utilize the business foundation it has built through the sale of these products, and with the sale of CANAGLU[®] as an opportunity, will contribute to the treatment of patients with type 2 diabetes in Indonesia.

By providing a new option for the treatment of diabetes to a growing number of patients in the world, MTPC shows its continued resolve to improve their quality of life (QOL).

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

Canagliflozin (generic name: canagliflozin hydrate; 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 2015 followed by Taiwan in March 2017.

More than 11,000 patients with type 2 diabetes were enrolled in global Phase 3 programs, including in Japan, which assessed the efficacy and safety of CANAGLU[®]. The development program included a mono-therapy, dual and triple combination therapies with other anti-hyperglycemic agents and also involved type 2 diabetes patients with impaired renal function, patients who have or are at high risk of developing cardiovascular diseases and elderly patients.

■ PT Mitsubishi Tanabe Pharma Indonesia

PT Mitsubishi Tanabe Pharma Indonesia (MTID) was established in July 1970 and is manufacturing and sales subsidiary of MTPC. Its Headquarters is in Jakarta, sales bases in 13 locations throughout Indonesia, and production bases in Bandung in Indonesia.

MTID has been operating in Indonesia for 50 years and has marketed a number of lifestyle-related disease products including Herbesser[®], Tanapress[®] (Japan name: Tanatril[®]) and LIVALO[®]. MTID will utilize the business foundation established through the sales of these products, and through the sales of CANAGLU[®] will contribute to the treatment of patients with type 2 diabetes in Indonesia. In addition to the ASEAN countries, MTID supplies products to Hong Kong, Sri Lanka, Brazil, Pakistan, and other countries. With the objective of increasing production capacity and further improving quality, MTID constructed a new formulation building in Bandung, which began operating in January 2015.