

Astellas Pharma Inc.: Submits Application for Marketing Approval of Ipragliflozin (ASP1941), SGLT2 Inhibitor for Treatment of Type 2 Diabetes, in Japan

TOKYO, March 13, 2013 - [Astellas Pharma Inc.](#) (“Astellas”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced today that it has submitted a market authorization application for a SGLT2 inhibitor ipragliflozin (generic name; development code: ASP1941) to the Ministry of Health, Labour and Welfare in Japan seeking an approval for the indication of type 2 diabetes .

Ipragliflozin is a selective SGLT2 (sodium-glucose co-transporter 2) inhibitor discovered through research collaboration with Kotobuki Pharmaceutical Co., Ltd. SGLTs are membrane proteins that exist on the cell surface and transfer glucose into cells. SGLT2 is a subtype of the sodium-glucose co-transporters and plays a key role in the reuptake of glucose in the proximal tubule of the kidneys. Ipragliflozin reduces blood glucose levels by inhibiting the reuptake of glucose.

In the Phase III pivotal study in monotherapy for type 2 diabetes in Japan, ipragliflozin demonstrated significant decreases of HbA1c, an index of glycemic control, in change from baseline compared to placebo. Based on the safety results in this study, ipragliflozin was safe and well tolerated. Patients with type 2 diabetes generally need combination therapy, so it is important for a novel oral hypoglycemic agent to be safe to use with existing diabetes therapies. In this regard, Astellas has conducted six Phase III studies to investigate the safety and efficacy of ipragliflozin used in combination with other hypoglycemic agents for a long term period. In these Phase III studies, effectiveness and favorable safety of ipragliflozin was confirmed even in combination with other hypoglycemic agents.

Astellas expects to provide an additional therapeutic option and further contribute to the treatment of type 2 diabetes by introducing ipragliflozin, an oral hypoglycemic agent with a novel mechanism of action, into the Japanese market.

About Type 2 Diabetes

Diabetes (medically known as diabetes mellitus) is a disorder in which the body has difficulty regulating its blood glucose (sugar) level. There are two major types of diabetes: type 1 and type 2. Type 2 diabetes (formerly called non-insulin-dependent diabetes mellitus or adult-onset diabetes) is a disorder that is characterized by high blood glucose in the context of insulin resistance and relative insulin deficiency. Patients are instructed to increase exercise and diet restrictions, but most require treatment with an anti-diabetic agent to control blood glucose.

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