

Astellas Pharma Inc.: Approval of Suglat[®] Tablets, a Selective SGLT2 Inhibitor for Treatment of Type 2 Diabetes, in Japan

TOKYO, January 17, 2014 - [Astellas Pharma Inc.](#) (“Astellas”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced today that it has obtained the marketing approval of selective SGLT2 inhibitor Suglat[®] 25mg and 50mg tablets (generic name Ipragliflozin L-Proline; development code: ASP1941, “Suglat”) for the treatment of type 2 diabetes in Japan. Astellas filed an application for approval in March 2013.

Suglat is a selective SGLT2 (Sodium-Glucose Co-Transporter 2) inhibitor discovered through a research collaboration and is being jointly developed with Kotobuki Pharmaceutical Co., Ltd.. SGLTs are membrane proteins that exist on the cell surface and transfer glucose into cells. SGLT2 is one subtype of SGLTs and plays a key role in the reuptake of glucose in the proximal tubule of the kidneys. Suglat reduces blood glucose levels by inhibiting the reuptake of glucose by selectively inhibiting SGLT2. Suglat is the first SGLT2 inhibitor approved as a treatment for type 2 diabetes in Japan.

The efficacy and safety of Suglat were observed in a Phase III pivotal study in monotherapy and clinical studies used in combination with other hypoglycemic agents (6 types) in Japan..

Astellas will manufacture and sell Suglat and co-promote it with Kotobuki Pharmaceutical Co., Ltd. and MSD K.K..

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

Summary of Approval

Brand name:	Suglat [®] tablets 25mg and 50mg
Generic name:	Ipragliflozin L-Proline
Indication:	Type 2 Diabetes
Dosage regimen:	Usually, adults are orally administered 50mg once a day before or after breakfast. If the effects are insufficient, dosage may be increased up to 100mg once a day while carefully monitoring the progress of the disease.

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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For inquiries or additional information

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