

**For Immediate Release**

## **Astellas Announces Oral Presentation of SGLT2 Inhibitor Detailing Safety and Efficacy in Patients with Type 2 Diabetes at the European Association for the Study of Diabetes Meeting**

**TOKYO, September 16, 2011** – Astellas Pharma Inc. (Tokyo: 4503, "[Astellas](#)") announced that it presented results from a Japanese Phase 3 study conducted with ipragliflozin (development code: ASP1941), a selective SGLT2 inhibitor, at the 47th Annual Meeting of the European Association for the Study of Diabetes ("EASD") in Lisbon on September 15, 2011 (local time). ASP1941 is designed to block the re-absorption of glucose in the kidney and excrete glucose in the urine. The oral presentation was conducted, along with the two poster presentations, on clinical pharmacokinetics/pharmacodynamics on renal impairment patients and clinical safety/pharmacokinetics/pharmacodynamics in combination with treatment by metformin.

During the presentation (No. 149), entitled "Ipragliflozin improved glycaemic control with additional benefits of reductions of body weight and blood pressure in Japanese patients with type 2 diabetes mellitus: BRIGHTEN Study," Dr. Atsunori Kashiwagi from Shiga University of Medical Science presented data from a double-blind, placebo-controlled trial (dose: 50mg, treatment period: 16 weeks) in 129 Japanese patients with type 2 diabetes mellitus. This study showed statistically significant decreases in HbA1c compared to baseline and against placebo (primary endpoint) of up to 1.23% ( $p<0.001$ ). Ipragliflozin reduced body weight statistically significant against placebo of up to 1.47kg ( $p<0.001$ ). Also, the study demonstrated ipragliflozin was safe and well tolerated.

In addition to the oral presentation, the posters that were presented are as follows:

<b>No.</b>	<b>Title</b>	<b>Date/Time (local)</b>
847	The effect of renal impairment on the pharmacokinetics and urinary glucose excretion of the SGLT2 inhibitor ipragliflozin (ASP1941) in Japanese type 2 diabetes mellitus patients	September 14 at 1:30 – 2:30 p.m.
849	Combination treatment with ipragliflozin (ASP1941) and metformin in type 2 diabetes patients: a safety, pharmacokinetic and pharmacodynamic interaction study	September 15 at 12:30 – 1:30 p.m.

Through further development of ipragliflozin, Astellas expects to provide an additional option to the current type 2 diabetes mellitus therapy.

**About SGLT2 Inhibitor and ASP1941**

SGLT (sodium-glucose co-transporters) 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.

ASP1941 reduces blood glucose level by inhibiting the reuptake of glucose.

ASP1941 is being co-developed with Kotobuki Pharmaceutical Co., Ltd. and is also in clinical development in the U.S. (Phase 2) and the EU (Phase 2).

**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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