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News Release

For Immediate Release

Astellas Announces Poster Presentation of SGLT2 Inhibitor (Ipragliflozin) Detailing Efficacy and Safety in Combination with Other Hypoglycemic Agents in Patients with Type 2 Diabetes at the European Association for the Study of Diabetes Meeting

TOKYO, October 3, 2012 – Astellas Pharma Inc. (Tokyo: 4503, "Astellas") announced that it presented results from two Japanese Phase 3 studies conducted on the selective SGLT2 inhibitor ipragliflozin (generic name, development code: ASP1941) in combination with other hypoglycemic agents, at the 48th Annual Meeting of the European Association for the Study of Diabetes ("EASD") in Berlin on October 2, 2012 (local time). Ipragliflozin is designed to block the re-absorption of glucose in the kidney and excrete glucose in the urine.

In the poster (Presentation No. 739) entitled "Ipragliflozin Reduced HbA_{1c} and Body Weight in Japanese Type 2 Diabetes Mellitus Patients Who Have Inadequate Glycaemic Control on Sulfonylurea or Pioglitazone Alone," Dr. Atsunori Kashiwagi from Shiga University of Medical Science presented data from two double-blind, placebo-controlled, parallel group studies in combination with sulfonylurea or pioglitazone (hereafter, "SU study" or "PIO study", respectively) in Japanese patients with type 2 diabetes mellitus. In patients with type 2 diabetes mellitus with inadequate glycaemic control while on a sulfonylurea or pioglitazone alone, 242 patients in the SU study and 151 patients in the PIO study received 50 mg of ipragliflozin or placebo once daily for a 24 week period in combination with either sulfonylurea or pioglitazone, and the safety and efficacy of ipragliflozin used in combination with each hypoglycemic agent was evaluated.

After 24 weeks, the studies showed statistically significant decreases in HbA_{1c} compared to baseline and against placebo (primary endpoint) of up to 1.14% in the SU study and up to 0.88% in the PIO study ($p<0.001$). Moreover, ipragliflozin reduced body weight statistically significant against placebo of up to 1.32kg in the SU study and up to 2.79kg in the PIO study ($p<0.001$). Both the SU and PIO studies demonstrated ipragliflozin was safe and well tolerated.

The poster that was presented is as follows:

No.	Title	Date/Time (local)
739	Ipragliflozin Reduced HbA_{1c} and Body Weight in Japanese Type 2 Diabetes Mellitus Patients Who Have Inadequate Glycaemic Control on Sulfonylurea or Pioglitazone Alone	October 2 from 1:45 – 2:45 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 ipragliflozin
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. Ipragliflozin reduces blood glucose level by inhibiting the reuptake of glucose. Ipragliflozin is being co-developed with Kotobuki Pharmaceutical Co., Ltd..

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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