

## **News Release**

#### For Immediate Release

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

TOKYO, JAPAN, June 28, 2010 – Astellas Pharma Inc. (Headquarters: Tokyo, President & CEO: Masafumi Nogimori, "Astellas") announced that the company presented results from a Japanese Phase 2 study conducted with ASP1941, a selective SGLT2 inhibitor, at the 70th Scientific Sessions of the American Diabetes Association (ADA) on June 26, 2010 (EST). ASP1941 is designed to block the re-absorption of glucose in the kidney and excrete glucose in the urine. The oral presentation, along with the four poster presentations, on non-clinical pharmacology, clinical pharmacokinetics/pharmacodynamics and a U.S. Phase 2a study, marks Astellas' first appearance at the ADA meeting and demonstrates the company's commitment to find treatments for diabetes.

During the presentation (75-OR), entitled "ASP1941, a Novel, Selective SGLT2 Inhibitor, Was Effective and Safe in Japanese Healthy Volunteers and Patients with Type 2 Diabetes Mellitus," Dr. Atsunori Kashiwagi from Shiga University of Medical Science presented data from a 12-week dose finding study (12.5, 25, 50, 100 mg and placebo) in 361 Japanese patients with Type 2 diabetes mellitus. This study showed dose related and statistically significant decreases in HbA1c compared to baseline and against placebo of up to 1.3% reaching a maximum at the 50 mg dose. ASP1941 reduced body weight dose-dependently and statistically significant by up to 2 kg in the 100 mg group after 12 weeks. All dosages were well tolerated. Based on the results of this dose-finding study, 50 mg has been selected as the dose for the ongoing Phase 3 program in Japan.

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

Date/Time: Location: Titles: June 28, 2010 at 12:00 – 2:00 p.m. EST Orange County Convention Center, Orlando, Florida

- In Vitro and In Vivo Pharmacological Properties of ASP1941, a Novel, Potent and Selective SGLT2 Inhibitor (Poster # 570-P)
- ASP1941, a Novel, Potent and Selective SGLT2 Inhibitor, Improves Hemoglobin A1c and Symptoms of Diabetes in Animal Models (Poster # 562-P)
- ASP1941, a Novel and Selective SGLT2 Inhibitor, Stimulates Urinary Glucose Excretion in Healthy Subjects (Poster # 565-P)
- ASP1941, a Novel and Selective Inhibitor of Sodium-Glucose Co-Transporter 2 (SGLT2), Reduces Fasting Plasma Glucose in Type 2 Diabetes Mellitus Patients Over 28 Days (Poster # 566-P)



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#### **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 co-developed with Kotobuki Pharmaceutical Co., Ltd. and is in clinical development in Japan (Phase 3), 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.

#### **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 15,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. For more information on Astellas Pharma Inc., please visit our website at <a href="http://www.astellas.com/en">http://www.astellas.com/en</a>.

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