Summary of Results for Laypersons

What was the Study Called?

A Phase 2a, Randomized, Double-Blind, Placebo Controlled, Multiple Dose Study to Assess the Safety and Tolerability of ASP1941 in Adult Patients with Type 2 Diabetes Mellitus

Why was this Study Needed?

Type 2 diabetes is a disease which is characterized by too much glucose or sugar in the blood. Medicines to help type 2 diabetes patients regulate their blood sugar are already available, but some of them may cause unwanted effects and some do not work in all patients. Ipragliflozin (also known as ASP1941 and Suglat®) is a medicine that is being developed to treat type 2 diabetes.

The main question this study helped answer was if patients with type 2 diabetes could tolerate 28 days of taking ipragliflozin and whether there were any related safety issues.

This study for ipragliflozin took place at 1 clinic in the United States between October 2008 and March 2009. When the study ended, the sponsor (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

What Kind of Study was This and Who Took Part in it?

This was a "blinded" study. In this study, the patients and the researchers did not know who took which of the treatments (ipragliflozin or placebo).

A "placebo" is a dummy treatment such as a tablet or capsule that looks like a medicine, but does not have any medicine in it. Using a placebo helps make study results fair and unbiased, because researchers and patients cannot tell who is taking a placebo, and who is taking the real medicine. Patients were picked for each treatment by chance alone.

Both men and women took part in the study. They were all over 18 years old. They had type 2 diabetes for at least 3 months before the study. Patients could not take part in this study if they had any of the following conditions:

- Blood vessel disease caused by their type 2 diabetes
- Took insulin to manage their blood sugar within 3 months prior to the start of the study
- Took high doses of oral combination therapy to treat diabetes
- Increased blood levels of certain proteins that indicate kidney or liver issues
- Protein in their urine
- Infection of structures carrying urine within 4 weeks prior to the start of the study
- Continuous, uncontrolled high blood pressure
- Evidence of kidney disease
- Significant heart disease
- Hepatitis
- History of drug or alcohol abuse

The treatment period for this study was 4 weeks. Some patients who were enrolled in the study were taking an oral medicine for their diabetes. These patients went off their oral diabetes medicine for 2 weeks before starting the 4 week treatment period. Patients remained in the clinic during the treatment period. While in the clinic, patients ate a standardized, weight maintenance diet which was adjusted to meet each patient's calorie needs. All patients were followed for 2 weeks after the treatment period ended.

All of the 61 patients who were enrolled in the study completed the 4 week treatment period. The patients took the following once per day before breakfast:

- 12 patients took ipragliflozin 50 mg
- 12 patients took ipragliflozin 100 mg
- 12 patients took ipragliflozin 200 mg
- 12 patients took ipragliflozin 300 mg
- 13 patients took placebo

	Number of Patients
Age Group Aged 18 years and older	 61
Men Women	35 26
EU Countries Outside EU	0 61

What Were the Study Results?

Ipragliflozin was safe and well tolerated compared with placebo at all treatment levels. No safety concerns were noticed at the higher ipragliflozin doses.

What Adverse Reactions did Patients Have?

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

The table below shows the most common adverse reactions experienced by patients while taking part in this study.

Adverse Reaction	Number of Placebo Patients (out of 13)	Number of Ipragliflozin Patients			
		50 mg (out of 12)	100 mg (out of 12)	200 mg (out of 12)	300 mg (out of 12)
Constipation	2	3	3	5	3
Nausea or urge to vomit	2	0	1	1	1
Abnormally dry skin	2	1	1	1	1
Headache or head pain	2	0	1	0	0
Sleepiness	2	0	0	0	0

An adverse reaction is considered "serious" when it is life threatening, causes lasting problems, or needs hospital care. Two patients had serious adverse reactions: 1 patient in the placebo group and 1 patient in the ipragliflozin 100 mg group.

Where Can I Learn More About This Study?

Astellas may perform additional studies to better understand ipragliflozin.

This summary of the clinical study results is available online at http://www.astellasclinicalstudyresults.com. Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. If you have questions about ipragliflozin, please discuss these with your doctor.

Sponsor Contact Details:

Astellas Pharma Global Development, Inc.
1 Astellas Way
Northbrook, IL 60062
USA