Summary of Results for Laypersons

What was the Study Called?

A Phase 2, Double-blind, Randomized, Placebo and Active-controlled, Dose-finding Study to Assess the Efficacy, Safety and Tolerability of Multiple Oral Doses of ASP1941 in 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 help control blood sugar in patients with type 2 diabetes.

The main question this study helped answer was if ipragliflozin was better than no medicine at all in controlling blood sugar in patients with type 2 diabetes.

This study for ipragliflozin took place at 59 clinics in the United States, Mexico, Columbia, India and the Philippines between March 2010 and April 2011. 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, placebo, or metformin).

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. Metformin is an approved medicine to treat patients with type 2 diabetes. Metformin was used in the study as the "active-comparator."

Both men and women took part in the study. They were all over 18 years old. They were all diagnosed with type 2 diabetes. They all had type 2 diabetes for at least 6 weeks before the study.

The treatment period for this study was 12 weeks. Patients were picked for each treatment group by chance alone. Before the treatment period, all patients entered a 2-week placebo "run-in" period. Patients who were taking medicine for their diabetes went off their medicine for 6 weeks before the 2-week placebo "run-in" period. During this placebo "run-in" period patients took placebo once daily for 2 weeks and had baseline laboratory tests performed. After the "run-in" period, patients entered the 12-week treatment period and took one of the following treatments:

- Ipragliflozin 12.5 mg once daily for 12 weeks
- Ipragliflozin 50 mg once daily for 12 weeks

- Ipragliflozin 150 mg once daily for 12 weeks
- Ipragliflozin 300 mg once daily for 12 weeks
- Placebo once daily for 12 weeks
  Metformin 500 mg twice daily for 2 weeks followed by 500 mg in the morning and 1000 mg in the evening for 10 weeks

Patients had their blood sugar levels tested periodically during the study. All patients were followed for 4 weeks after the 12-week treatment period ended.

A total of 412 patients were enrolled in the study. A total of 411 patients received at least 1 dose of study medicine during the 12-week treatment period and are listed below by treatment group.

- 70 patients took ipragliflozin 12.5 mg
- 67 patients took ipragliflozin 50 mg
- 68 patients took ipragliflozin 150 mg
- 68 patients took ipragliflozin 300 mg
- 69 patients took placebo
- 69 patients took metformin 500 mg twice daily for 2 weeks followed by 500 mg in the morning and 1000 mg in the evening for 10 weeks

Additional information regarding the 411 patients who received at least 1 dose of study medicine are listed in the table below.

	Number of Patients
Age Group	
Aged between 18 and 64 years	345
Aged 65 years and older	66
Men	211
Women	200
EU Countries	0
Outside EU	411

What Were the Study Results?

Results from the study showed that ipragliflozin was better than placebo in controlling blood sugar levels in patients with type 2 diabetes. Ipragliflozin was also safe and well tolerated at all doses given to patients. 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 the 411 patients while taking part in this study.

Adverse Reaction	Number of Placebo Patients (out of 69)	Number of Ipragliflozin Patients				Number of Metformin Patients (out of 69)
		12.5 mg (out of 70)	50 mg (out of 67)	150 mg (out of 68)	300 mg (out of 68)	
Diarrhea	1	0	1	1	0	4
Swelling or feeling of fullness and tightness in the abdomen (belly)	2	0	1	1	0	2
Constipation	1	0	2	1	2	0
Urinary tract infection	2	1	3	0	1	2
Blood in the urine	1	0	3	1	0	0
A frequent urge to urinate	0	0	2	1	0	0
Itchy skin	0	1	0	0	2	0
Fatigue or tiredness	2	0	1	0	0	1
Inflammation or swelling of the head and foreskin of the penis	0	0	2	0	0	1
Increased blood level of enzyme (creatine phosphokinase) from muscle	1	0	2	0	0	0
Headache or head pain	0	0	0	0	2	0

An adverse reaction is considered “serious” when it is life threatening, causes lasting problems, or needs hospital care. There were no serious adverse reactions reported in this study and no patients died during the study.

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