Summary of Results for Laypersons

What was the Study Called?

An Open-label, Parallel Group Study to Assess the Effect of Different Grades of Renal Impairment in Patients With Type 2 Diabetes Mellitus on the Pharmacokinetics, Pharmacodynamics and Safety & Tolerability of ASP1941 Relative to Type 2 Diabetes Mellitus With Normal Renal Function and Healthy Volunteers

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 patients with type 2 diabetes 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 purpose of this study was to see if ipragliflozin had any affect in patients with type 2 diabetes who have renal impairment (patients that have kidneys that do not work well). The kidney is an organ that filters out waste products from the blood. When kidneys are impaired, they do not work as well as normal kidneys to remove waste products from the body. Ipragliflozin works to control blood glucose levels in the kidney. Therefore, a decrease in clinical benefit (i.e., efficacy) is anticipated in patients with renal impairment considering the mechanism of action of ipragliflozin. In this study, ipragliflozin was administered to healthy subjects and to patients with type 2 diabetes who had kidney impairment and to patients with type 2 diabetes who did not have kidney impairment.

The main question this study helped answer was if ipragliflozin 100 mg once daily could be safely given to patients with renal impairment.

This study took place at multiple clinics in Europe (Poland, Slovakia, Hungary, and the Czech Republic) from January 2010 to June 2010. 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 an "open-label" study. All patients knew that they were receiving ipragliflozin.

This study enrolled healthy subjects and patients with type 2 diabetes that were 45 to 80 years old. Patients with type 2 diabetes were divided into 4 groups. Patients with normal kidney function were in one group. Patients with kidney impairment were divided into 3 groups according to the severity (mild, moderate, severe) of their kidney impairment. Patients with type 2 diabetes continued to take medicine to control their blood sugar as long as the dose was stable (had not been changed in the month before the study).

All healthy subjects and patients with type 2 diabetes stayed overnight at the study clinic for 6 nights. On study day 1 they received one dose of ipragliflozin. During the remaining days

in the clinic, all patients (including the healthy subjects) had blood and urine samples collected to see how well their kidneys were working and to measure the level of study medicine in their body. All patients were discharged from the clinic on day 6. Study staff continued to monitor patients after they left the clinic for up to 14 days for any adverse reactions (side effects) from the study medicine.

A total of 91 men and women volunteered for the study. A total of 40 men and women met the entry criteria and were enrolled in the study. The 40 men and women included 8 healthy subjects and 32 patients with type 2 diabetes. They all received one dose of ipragliflozin and were assigned to one of 5 groups as follow:

- 8 healthy volunteers
- 8 patients with type 2 diabetes with normal kidney function
- 8 patients with type 2 diabetes with mild kidney impairment
- 8 patients with type 2 diabetes with moderate kidney impairment
- 8 patients with type 2 diabetes with severe kidney impairment

Additional information regarding the 40 men and women enrolled in the study is listed in the table below.

	Number of Patients
Age Group Between 45 and 80 years old	 40
Men Women	23 17
EU Countries Outside EU	40 0

What Were the Study Results?

In this study, a single 100-mg dose of ipragliflozin was well tolerated in healthy subjects and patients with type 2 diabetes. The process by which the study medicine is absorbed, distributed, metabolized and eliminated by the body was similar in patients with type 2 diabetes who had normal kidney function and in patients who had moderate to severe impairment in kidney function. The study also showed that patients with type 2 diabetes who had severe kidney impairment (the group of patients with the worst kidney function) were not able to eliminate sugar from their body as well patients with normal kidney function.

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.

There were no adverse reactions reported by healthy volunteers or patients with type 2 diabetes during the study.

An adverse reaction is considered "serious" when it is life threatening, causes lasting problems, or needs hospital care. There were no serious adverse reactions or deaths reported 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.

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