Summary of Results for Laypersons

Astellas is grateful to the patients who took part in this clinical study. Thank you.

What was the Study Called?

A Phase 3, Double-blind, Randomized, Active-controlled, Monotherapy Study to Assess the Efficacy and Safety of ASP1941 in Asian Patients with Type 2 Diabetes Mellitus

Why was this Study Needed?

Diabetes is a disease in which the blood sugar level is too high. Insulin is a hormone that helps transport the sugar from the blood into the cells. The sugar then becomes energy for the cells. In type 2 diabetes, the body does not use insulin properly. People with diabetes need to manage their disease to stay healthy. Diabetes can cause problems that may be disabling or even life-threatening. Acarbose is an oral medicine (taken by mouth) for the treatment of type 2 diabetes. But it may not control blood sugar levels well in some patients. Therefore, there was a need to study a new treatment for type 2 diabetes. Ipragliflozin (also known as ASP1941 and Suglat®) is a new oral medicine for the treatment of type 2 diabetes. Ipragliflozin works in the kidneys to reduce the reabsorption of sugar into the blood. This lowers blood sugar levels and increases the amount of sugar in the urine.

This study was conducted in patients who had type 2 diabetes. Patients took ipragliflozin and placebo or acarbose and placebo. (The section below describes what placebo tablets and capsules are.) The main question this study helped answer was if ipragliflozin was not worse in decreasing blood sugar compared to acarbose in Asian patients with type 2 diabetes. It was also important to find out what unwanted effects these patients had from the study medicines.

The study started in April 2012. The sponsor of this study (Astellas) stopped this study in October 2012. This was done earlier than planned for business reasons that were not related to the study medicine. When the study was stopped, 46 patients had taken study medicine. 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 study had 2 parts or periods: a “run-in period,” followed by a “double-blinded period.”

“Run-in period”: The study doctors, but not the patients, knew that all patients took placebo during the 4-week run-in period”

“Double-blinded period”: The patients and the study doctors did not know who took which of the study medicines (ipragliflozin and placebo or acarbose and placebo) during the double-blinded period. 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 that way all patients took 1 tablet (ipraglifozin or

placebo) and 3 capsules (placebo or acarbose) each day. The study doctors and patients could not tell who was taking ipragliflozin and who was taking acarbose.

This study included Asian adult women and men aged 20 years or older. They had type 2 diabetes for at least 3 months before the first study visit. They had an HbA1c level between 7.0% and 10.0% at the second visit. The HbA1c level is a measure of a patient's average level of blood sugar over the past 3 months. Their body mass index (BMI) at the second visit was between 20 and 45. BMI is a measure of body fat in adults that is based on height and weight. An adult with a BMI of 25 or higher is overweight.

During the study, the study doctor did a check-up of the patients at several study visits. At the first visit, patients were checked to see if they could be in the study. Starting at the second visit, all patients who could be in the study took placebo for 4 weeks. Thereafter, they were picked for 1 of 2 treatments by chance alone.

- Ipragliflozin and placebo: Patients took 1 ipragliflozin tablet (50 mg) once a day and 1 placebo capsule 3 times a day. They were to take these study medicines for 6 months.
- Acarbose and placebo: Patients took 1 acarbose capsule (50 mg) 3 times a day and 1 placebo tablet once a day for the first month. Thereafter, they took 1 acarbose capsule (100 mg) 3 times a day and 1 placebo tablet once a day. They were to take those study medicines for 5 months.

Because the study was stopped, patients took their study medicines for fewer than 3.5 months.

This study took place at 31 clinics in Korea and Taiwan. When this study was stopped, 46 patients were in the study. All 46 patients took at least 1 dose of study medicine.

	Number of Patients
Age Group	
Aged less than 65 years	30
Aged 65 years or older	16
Sex	
Men	21
Women	25
Clinic Location	
Outside European Union	46
Korea	40
Taiwan	6

What Were the Study Results?

The main question this study was meant to answer was if ipragliflozin was not worse in decreasing blood sugar compared to acarbose in Asian patients with type 2 diabetes.

When this study was stopped, there were not enough patients in the study to answer the study's main question. This is a summary of study results for the patients in the study.

From the start of treatment until the end, the average HbA1c level decreased 0.51% in the ipragliflozin group. It decreased 0.53% in the acarbose group.

	HbA1c Level	
Visit	**Ipragliflozin (out of 10 patients)**	**Acarbose (out of 10 patients)**
Start of treatment	7.40%	7.70%
End of treatment	6.89%	7.17%

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, study doctors 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.

One patient in the ipraglifozin group and 1 patient in the acarbose group experienced the adverse reaction of upper belly pain.

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care.

No patients experienced serious adverse reactions during this study.

Where Can I Learn More About This Study?

This document is a short summary of the main results from this study and reflects the information available as of March 2014. You can find this summary and more information about this study 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. This summary only shows the results of this 1 study. Your doctor may help you understand more about the results of this study.

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