# Summary of Results for Laypersons

## What was the Study Called?

A Phase 1, Double-blind, Randomized, Placebo-controlled, Parallel Design Study, in Patients with Type 2 Diabetes Mellitus, to Investigate the Safety, Pharmacokinetic and Pharmacodynamic Interactions of Multiple Oral Doses of ASP1941 and Metformin

## 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. Metformin is an approved medicine to treat patients with type 2 diabetes.

The main question this study helped answer was if patients could tolerate 14 days of taking ipragliflozin at a dose of 300 mg with their daily dose of metformin.

This study took place at 4 clinics in the Netherlands, Poland, Hungary and Slovakia (one clinic in each country) between February 2009 and December 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 group by chance alone.

This was also a "drug-drug interaction" study. A drug-drug interaction study is used to determine if a medicine influences how the body breaks down another medicine that is in the body at the same time.

Both men and women took part in the study. They were all between 18 and 75 years old and diagnosed with type 2 diabetes. All patients were taking either metformin alone or metformin in combination with another diabetes medicine to control their blood sugar. Patients had to be taking the same dose of metformin for at least 3 months before the study. The dose of metformin patients were currently taking had to be between 850 and 1500 mg taken twice daily. During the study, patients received ipragliflozin once daily in addition to metformin twice daily for 14 days.

The treatment period for this study was 14 days. Before the treatment period, patients received metformin (850 mg to 1500 mg taken twice daily) for 2 weeks. Following this

2-week period, patients were assigned to take ipragliflozin 300 mg or placebo once daily in addition to metformin twice daily. Blood samples were taken periodically to check drug levels and blood sugar levels. All patients were followed for 2 weeks after the treatment period ended.

A total of 128 patients volunteered for the study. A total of 36 patients met the entry criteria and were enrolled in the study.

All of the 36 patients received at least 1 dose of study medicine. The number of patients assigned to each treatment group is listed below.

- 18 patients took 300 mg ipragliflozin
- 18 patients took placebo

Additional information regarding the 36 patients is listed in the table below.

| | **Number of Patients** |
|---|---|
| **Age Group**<br>Between 18 and 75 years old | 36 |
| Men<br>Women | 25<br>11 |
| EU Countries<br>Outside EU | 36<br>0 |

**What Were the Study Results?**

Ipragliflozin was well tolerated compared with placebo when taken with metformin. There were no safety concerns observed in patients who took either study medicine (ipragliflozin or placebo).

**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 chart below shows the most common adverse reactions experienced by the 36 patients while taking part in this study.

| **Adverse Reaction** | **Number of Placebo Patients (out of 18)** | **Number of Ipragliflozin 300 mg Patients (out of 18)** |
|---|---|---|
| Increased appetite | 1 | 0 |
| An increase in the amount of a waste product called creatinine removed from the blood by the kidneys | 1 | 0 |
| *Table continued on next page* | | |

| Adverse Reaction | Number of Placebo Patients (out of 18) | Number of Ipragliflozin 300 mg Patients (out of 18) |
|---|---|---|
| Diarrhea | 1 | 1 |
| Dry mouth | 0 | 1 |
| Excess passing of gas | 1 | 0 |
| Headache or head pain | 0 | 1 |
| Excess sweating | 1 | 0 |
| High blood pressure | 0 | 1 |
| Nausea or urge to vomit | 0 | 1 |
| A frequent urge to urinate | 1 | 0 |
| Fast heartbeat; regular rhythm | 0 | 1 |
| Sleepiness, the state of feeling drowsy, ready to fall asleep | 1 | 0 |
| Blurred vision | 1 | 0 |
| Vomiting | 0 | 1 |

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 during the study. There were no 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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