# Summary of Results for Laypersons

## What was the Study Called?

A Randomized, Double-blind, Placebo-controlled Parallel-group and Phase IV study on the Efficacy and Safety of Solifenacin Succinate in Patients with an Overactive Bladder after TURP or PVP.

## Why was this Study Needed?

People with overactive bladder have symptoms such as:

- Sudden need to urinate which is difficult to delay (called urinary urgency).
- Having to empty the bladder more often than usual (called increased urinary frequency).
- Not being able to control the emptying of the bladder and lose urine involuntarily (called urge incontinence).

There are medicines for adults with overactive bladder. These include solifenacin succinate (also known as YM905 and Vesicare®). The prostate is a gland that surrounds the tube carrying urine from the bladder (urethra). The prostate can grow larger (called benign prostate hyperplasia) in older men and block the urine flow. Following surgery to remove the excess prostate tissue, some patients may still experience overactive bladder symptoms. There was a need to study solifenacin succinate in these patients.

This study was conducted in patients who had overactive bladder following surgery for their enlarged prostate. These patients had a surgery called transurethral resection of the prostate ("TURP"). To remove the enlarged prostate, a scope was inserted via the tip of the penis into the urethra. Or the patients had a surgery called photoselective vaporization of the prostate ("PVP"). A laser was used to destroy or remove excess prostate tissue.

This study looked at the number of times per day that patients had a sudden need to urinate that was difficult to delay (called urinary urgency). This study helped find out if 2 weeks of solifenacin succinate was better than placebo at decreasing that need. It was also important to find out what unwanted effects these patients had from the study treatments.

This study for solifenacin succinate took place at 1 clinic in South Korea. The study took place from December 2012 to October 2013. 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 (solifenacin succinate 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 test medicine.

Men could take part in the study if:

- They were 50 years or older.
- They were able to fill out a diary and questionnaires about their bladder problem symptoms.
- They were scheduled to undergo surgery for their enlarged prostate. The surgery was either TURP or PVP of the prostate.

Patients could not take part in this study if:

- They had prostate or bladder cancer, or a cancer in their pelvis at the start of the study.
- The cause of their bladder problems were problems with the wiring of the nerves controlling the bladder.
- They were allergic to drugs such as solifenacin succinate.
- They had a blockage of the digestive tract.

During this study, the study doctor did a check-up of the patients at 5 study visits. At visit 1, patients were checked to see if they could be in the study. Patients had surgery for their enlarged prostate between visits 1 and 2. At visit 2 (about 5 days later), catheters (tubes for draining urine) were removed from the patients. Next, the patients were released from the hospital. Patients kept a diary of their bladder symptoms during the 3 days before visit 3. At visit 3, their diaries were checked to see if they could remain in the study. Patients could remain in the study if their diaries showed that by visit 3:

- They had urinary urgency on at least 3 occasions.
- They had to urinate 8 or more times per day.
- They had a study protocol-specified score on questionnaires.

Patients could not remain in the study if:

- They had a blockage of the bladder preventing urine flowing out of the bladder properly.
- The amount of urine left in their bladder after urination was more than 100 mL.

Patients who could remain in the study were picked for 1 of the following treatments by chance alone:

- Placebo
- Solifenacin succinate 5 mg once daily

Patients took study treatment once a day for 4 weeks. Two weeks after the start of study treatment, the patients returned to the clinic for a check-up (visit 4). Two weeks after visit 4, patients returned to the clinic for the final check-up (visit 5).

A total of 68 patients were in this study and took at least 1 dose of study treatment.

- 34 patients took placebo.
- 34 patients took solifenacin succinate.

| | Number of Patients (out of 68 patients) |
|---|---|
| **Age Group** | |
| Aged between 56 and 88 years | 68 |
| **Sex** | |
| Men | 68 |
| **Clinic Location** | |
| European Union Countries | 0 |
| Outside European Union | 68 |
| South Korea | 68 |

**What Were the Study Results?**

This study was conducted in patients who had overactive bladder following surgery for their enlarged prostate. The study compared solifenacin succinate to placebo tablets. This study looked at the number of times per day that patients had urinary urgency. It compared that number at study start and after patients took study treatment for 2 weeks.

After 2 weeks of treatment, the study found no difference between the study treatments in decreasing the average daily urinary urgency. On average, there was a decrease of 3.81 urinary urgency episodes from the start of treatment in the placebo group compared to the decrease of 3.77 urinary urgency episodes in the solifenacin succinate group.

**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 who took at least 1 dose of study treatment.

Two patients who took placebo had blood in urine. None of the patients who took solifenacin succinate had blood in urine. Each of the other adverse reactions occurred in 1 patient.

| Adverse Reaction | Placebo (out of 34 patients) | Solifenacin succinate (out of 34 patients) |
|---|---|---|
| Blood in the urine | 2 (5.88%) | 0 |
| Pain or discomfort when urinating | 1 (2.94%) | 0 |
| Stomach pain or belly ache | 0 | 1 (2.94%) |
| Constipation | 0 | 1 (2.94%) |
| Hives | 0 | 1 (2.94%) |
| Difficulty sleeping or falling asleep | 1 (2.94%) | 0 |

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

One patient had a serious adverse reaction after he took placebo. He had blood in the urine.

**Where Can I Learn More About This Study?**

Astellas may perform additional studies to better understand solifenacin succinate.

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 solifenacin succinate, please discuss these with your doctor.

**Sponsor contact details:**

Astellas Pharma Korea, Inc.
Kumha Building, 6th Floor
41-2 Chungdam-dong,
Gangnam-gu
Seoul, 135 766
South Korea