Summary of Results for Laypersons

What was the Study Called?

A Randomized, Double-blind, Placebo-controlled, Parallel-group Fixed-dose, Multicenter Study to Assess Efficacy and Safety of Daily Oral Administration of 10 mg YM905 (Solifenacin Succinate) Versus Placebo in Male and Female Patients with Overactive Bladder.

Why was this Study Needed?

People suffering from overactive bladder with symptoms such as an increase in the number of times a day they urinate and a greater urgency to urinate, with or without episodes of leaking before reaching the toilet may benefit from medicines. Medicines are already available, but some of them may cause unwanted effects and some do not work in all patients.

This study was done to find out how well solifenacin succinate worked in treating patients with overactive bladder. Solifenacin succinate (also known as YM905 and VESIcare®) is a medicine that is being evaluated for treatment of 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).
- Any loss of urine due to not being able to control when to empty the bladder (called urinary incontinence).

The main question this study helped answer was if solifenacin succinate (10 mg taken once daily) was better than placebo to treat patients with overactive bladder. The study helped answer if solifenacin succinate was well tolerated. Also, it was important to find out what unwanted effects solifenacin succinate might cause.

This study took place at 33 clinics in the US. The study took place from February 2001 to October 2001. 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 medicines (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 study medicine.

In this study patients were given 1 of the following treatments:

- 10 mg of solifenacin succinate once daily for up to 12 weeks
- placebo once daily for up to 12 weeks

Patients were picked for each treatment by chance alone.

Both men and women took part in the study. They were all over 18 years old. They had symptoms of overactive bladder problems such as:

- Urinary urgency
- Increased urinary frequency
- Urinary incontinence

Patients could not take part in this study if they had any of the following conditions:

- Leakage of urine under stress conditions such as coughing, sneezing or other movements that put pressure on the bladder (called stress incontinence).
- The combination of urgency incontinence and stress incontinence (called mixed incontinence) with a predominant stress component.
- A neurological cause for uncontrolled muscle contractions of the bladder. A neurological cause means a disorder of the brain. Uncontrolled muscle contractions of the bladder result in not being able to control when to urinate.

During this study, patients made 6 visits to the clinic. During the first visit, patients were asked to keep a diary of their symptoms for 3 days. During the second visit, patients were selected to stay in the study if their diaries showed that during the previous 3 days:

- They had urinary incontinence or urinary urgency at least 1 time each day.
- They urinated at least 8 times each day.

A total of 672 patients volunteered for the study:

- 340 patients received solifenacin succinate 10 mg once daily.
- 332 patients received placebo once daily.

All patients received at least 1 dose of study medicine and participated in the study for up to 12 weeks.

	Total (out of 672 patients)
Age Group	
Aged less than18 years	0
Aged between 18 and 64 years	444
Aged 65 years and older	228
Men	123
Women	549
EU Countries	0
Outside EU	672

What Were the Study Results?

The results of the study showed that solifenacin succinate 10 mg taken once daily reduced the number of times a patient urinated in a 24-hour period. The medicine also improved other symptoms of overactive bladder including urinary incontinence. Taking 10 mg of solifenacin succinate once daily was well tolerated.

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 while taking part in this study. Information on all patients who received at least 1 dose of study medicine is included in the table below.

Adverse Reactions	Placebo (out of 332 patients)	Solifenacin Succinate 10 mg (out of 340 patients)	Total (out of 672 patients)
Dizziness	3	7	10
Dry mouth	12	87	99
Constipation	11	55	66
Headache or head pain	13	9	22
Nausea or urge to vomit	6	11	17
Blurred vision	4	11	15
Heartburn	1	13	14
Diarrhea	8	4	12

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care. Some patients had serious adverse reactions: 3 patients in the placebo group and 5 patients in the solifenacin succinate 10 mg dose group.

One patient in the placebo group died during the study. The death was not because of the study medicine.

Where Can I Learn More About This Study?

Astellas might perform additional trials 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.

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