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 Randomized, Double-Blind, Double-Dummy, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Solifenacin Succinate (5 and 10 mg Once Daily) Against Placebo and Oxybutynin Hydrochloride (5 mg Three Times Daily) in the Treatment of Subjects with Neurogenic Detrusor Overactivity. This is also known as the SONIC study.

Why was this Study Needed?

The central nervous system consists of the brain and the spinal cord. The spinal cord contains the nerves that run down the middle of the back. It carries the signals between the brain and the rest of the body. Damage to the nervous system because of a spinal injury or MS can result in neurogenic detrusor overactivity (or NDO for short). (MS, short for multiple sclerosis, is a disease of the brain and the spinal cord.) People with NDO have poor bladder control because of permanent problems with the wiring of the nerves to the bladder. They can have periods of high pressure in their bladder. This is potentially dangerous for the kidneys. It can also cause other problems like losing urine involuntarily (incontinence). People with NDO often need to use a clean tube (catheter) to help empty their bladder. Oxybutynin is an oral prescription medicine (taken by mouth) for the treatment of NDO. It may cause unwanted effects in some patients. Therefore, there was a need to study new treatments for NDO. At the time of this study, solifenacin succinate (also known as YM905 and VESIcare®) was an oral experimental medicine for NDO.

This study was conducted in patients who had NDO. Patients took solifenacin, oxybutynin or placebo. (The section below describes what placebo tablets and capsules are.) This study looked at how much urine the bladder can hold before urine starts to leak or the patient feels pain or discomfort. This is called the maximum bladder capacity. This study compared the change in maximum bladder capacity after patients took study medicines for 4 weeks. It was also important to find out what unwanted effects these patients had from the study medicines.

The study started in March 2008 and ended in January 2011. When the study ended, the sponsor of this study (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 "double-blinded" study. That means that the patients and the study doctors did not know who took which of the study medicines (solifenacin and placebo, oxybutynin and placebo or placebo alone). 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 study doctors and patients cannot tell who is taking a placebo, and who is taking the test medicine. All patients in this study took the same number of tablets and capsules each day.

This study included adult women and men who had NDO. Their NDO was caused by their MS or their spinal cord injury. Their symptoms for NDO and their MS or spinal cord injury were stable for at least 6 months before the start of the study. If needed, they were able to use a catheter (they put it in and took it out) for emptying the bladder several times a day.

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. Patients who could be in the study took placebo for 2 weeks. Next, the study doctor checked what their maximum bladder capacity was. If it was less than 400 mL, the patients could remain in the study.

Patients who could remain in the study were picked for 1 of 4 treatments by chance alone.

- Solifenacin 5 mg: Patients took 1 solifenacin tablet (5 mg), 1 placebo tablet and 3 placebo capsules each day.
- Solifenacin 10 mg: Patients took 2 solifenacin tablets (10 mg total) and 3 placebo capsules each day.
- Oxybutynin: Patients took 2 placebo tablets and 3 oxybutynin capsules (15 mg total) each day.
- Placebo: Patients took 2 placebo tablets and 3 placebo capsules each day.

Patients took study medicine for 4 weeks.

This study took place at 45 clinics in several countries. 194 patients were in the study. Out of these patients, 189 patients took at least 1 dose of study medicine.

	Number of Patients
Age Group	
Aged less than 65 years	185
Aged 65 years or older	4
Sex	
Men	95
Women	94
Clinic Location	
European Union Countries (*at the time of the study*)	164
Belgium	1
Czech Republic	59
France	39
Germany	12
Hungary	9
Italy	17
The Netherlands	3
Spain	14
The UK	10
Outside European Union	25
Australia	11
Russia	14

What Were the Study Results?

This study in patients who had NDO because of their MS or spinal injury looked at the maximum bladder capacity.

The maximum bladder capacity increased in all patients after they took study medicines for 4 weeks. The average increase was 5.4 mL after patients took placebo for 4 weeks. And it was 134.2 mL after patients took solifenacin 10 mg for 4 weeks. A statistical test showed that the difference in increase between placebo and solifenacin was not likely to be due to chance. It is considered to be an effect of the treatment with solifenacin 10 mg.

Study Results After Treatment for 4 Weeks	Placebo (out of 40 patients)	Solifenacin 5 mg (out of 46 patients)	Solifenacin 10 mg (out of 51 patients)	Oxybutynin 15 mg (out of 39 patients)
Average increase in maximum bladder capacity (mL)	5.4	77.8	134.2	165.4

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 medicine in this study.

Adverse Reaction	Placebo (out of 43 patients	Oxybutynin (out of 47 patients)	Solifenacin (out of 99 patients)
Any adverse reaction	4 (9.3%)	10 (21.3%)	12 (12.1%)
Rash	2 (4.7%)	0	0
Dry mouth	1 (2.3%)	8 (17.0%)	6 (6.1%)
Blurred vision	0	3 (6.4%)	5 (5.1%)
Constipation	0	2 (4.3%)	4 (4.0%)

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

None of the patients experienced serious adverse reactions in 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 January 2012. 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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