Summary of Results for Laypersons

What was the Study Called?

A Multicenter, Open-label, Single-dose Study to Evaluate Pharmacokinetics, Safety and Tolerability of Solifenacin Succinate Suspension in Pediatric Subjects from 5 to less than 18 Years of Age with Neurogenic Detrusor Overactivity (NDO)

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).
- Any loss of urine due to not being able to control when to empty the bladder (called urinary incontinence).

Neurogenic detrusor overactivity (called NDO) describes a problem where bladder control is poor due to problems with nerves to the bladder. The condition is different from overactive bladder.

NDO can be found frequently in conditions called spina bifida (SB) and cerebral palsy (CP). In SB the bones and nerves of the spine, and sometimes the brain, do not form correctly. In CP the nerves and brain develop correctly but are permanently damaged usually at the time of birth. Both SB and CP can cause the permanent nerve wiring problems that disturb bladder function – called NDO. Patients with NDO may benefit from medicines.

There are medicines for adults with overactive bladder. These include solifenacin succinate (also known as YM905 and VESIcare®). It comes in tablets. It is not approved to treat NDO. Tablets can be difficult to swallow for children. A liquid form of solifenacin succinate was made for children to take by mouth.

This study tested the liquid form (called solifenacin succinate suspension) in children and teenagers with NDO. This study helped answer how well the liquid form is absorbed into the body and how long it stays in the body. It was also important to find out what unwanted effects these patients had from the study medicine. This study was not designed to test whether the study medicine was useful or effective.

This study took place at 4 clinics in Belgium, Denmark, Poland and the UK. The study took place from March 2012 to August 2012. 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 an “open-label” study. All patients knew that they took solifenacin succinate suspension.

All patients took the same dose of solifenacin succinate suspension. This dose was comparable to 5 mg of solifenacin succinate tablets taken once daily in adults. The amount of solifenacin succinate suspension was based on body weight.

Children and teenagers with NDO could take part in the study if:

- The children were 5 to less than 12 years old and the teenagers were 12 to less than 18 years old.
- They had a normal weight and height for their age.
- They had regular bowel movements.
- They could swallow the study medicine.
- Patients who were having sex used reliable birth control methods.

Patients could not take part in this study if:

- They were pregnant or were breastfeeding their baby.
- They had bowel problems such as partial or complete blockage of the bowel or slow bowel movement. Or they were at risk of problems with stomach emptying.
- They had dry stool that could not pass out of the body.
- They had irregular heart rhythms.
- They had serious heart abnormalities.

On the morning of the treatment day (day 1), the patients arrived at the clinic. Patients were checked to see if they could be in the study. Patients who could be in the study took a single dose of solifenacin succinate suspension. Blood samples were taken from all patients after they took study medicine. Patients returned to the clinic for blood samples on days 3, 5 and 7.

A total of 15 patients were in this study. A total of 14 patients took study medicine.

	Number of Patients (out of 14 patients)
Age Group	
Aged 5 to 11 years	7
Aged 12 to 17 years	7
Gender	
Girls	7
Boys	7
Clinic Location	
EU Countries	
Belgium	0
Denmark	3
Poland	11
The UK	0
Outside EU	0

What Were the Study Results?

This study was conducted in children and teenagers with NDO. They took solifenacin succinate suspension by mouth. The study looked at how well the study medicine was absorbed into the body and how long it stayed in the body. The study results were comparable to what was seen in the past in children and teenagers with overactive bladder.

The study showed that children and teenagers with NDO who took solifenacin succinate suspension did not have a lot of unwanted effects.

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.

None of the patients had an adverse reaction.

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care. None of the patients had a serious adverse reaction.

None of the patients died during the study.

Where Can I Learn More About This Study?

Astellas might 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 Europe B.V.
Sylviusweg 62
2333 BE Leiden
The Netherlands