Summary of Results for Laypersons

What was the Study Called?

An Open-label, Long-term Extension, Multicenter, Sequential Dose Titration Study to Assess Safety and Efficacy of Solifenacin Succinate Suspension in Pediatric Subjects with Overactive Bladder

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).

There are medicines for adults with overactive bladder. These include solifenacin succinate (also known as YM905 and VESIcare®). It comes in tablets. 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 overactive bladder. The study helped answer was whether the liquid form improved bladder function in these patients. It was also important to find out what unwanted effects these patients had from the study medicine.

This study took place at 39 clinics in Belgium, Brazil, Canada, Denmark, Mexico, Norway, Philippines, Poland, Serbia, Sweden, South Africa, South Korea, Turkey, Ukraine, the UK and the US. The study took place from October 2012 to October 2014. 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.

Patients took solifenacin succinate suspension once daily for 40 weeks. The best dose was determined for each patient during the first 12 weeks. The possible doses of solifenacin succinate suspension were:

- Dose "2.5," which was comparable to 2.5 mg of solifenacin succinate tablets taken once daily in adults,
- Dose "5," which was comparable to 5 mg of solifenacin succinate tablets taken once daily in adults, and
- Dose "10," which was comparable to 10 mg of solifenacin succinate tablets taken once daily in adults.

Children and teenagers with bladder problems 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 finished Study 905-CL-076.
- Female patients were not pregnant.
- 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 were allergic to the study medicine.
- The study doctor thought that they would not finish the study.
- They used medications that were not allowed.
- They had a serious condition that was not treated well.

The study had 7 visits. The first study visit was on the same day as the last visit of Study 905-CL-076. Patients were checked to see if they could be in the study. Patients who could be in the study took study medicine the next day. Patients returned to the clinic for 3 visits. At these visits, their dose could be changed to determine the best dose for them. Patients then took the same dose for 31 weeks. In that time, patients returned to the clinic for 3 more visits.

A total of 119 children and 29 teenagers were in this study. All patients took at least 1 dose of study medicine.

	Number of Children (out of 119 patients)	**Number of Teenagers (out of 29 patients)**
Age Group		
Aged 5 to less than 12 years	119	0
Aged 12 to less than 18 years	0	29
Gender		
Girls	61	24
Boys	57	5
Clinic Location		
EU Countries	76	9
Belgium	31	3
Denmark	17	3
Poland	19	2
Sweden	7	1
The UK	2	0
Outside EU	43	20

What Were the Study Results?

This study was conducted in children and teenagers with overactive bladder. They took solifenacin succinate suspension by mouth. The study showed that treatment with study medicine improved their bladder function. The improvements started after 3 weeks of treatment. The improvements lasted up to 52 weeks.

The study showed that children and teenagers with overactive bladder who took study medicine for up to 52 weeks 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.

The table below shows the most common adverse reactions experienced by patients who took at least 1 dose of study medicine. Abnormal electrical conduction within the heart was common in children and teenagers. Constipation was common in children but not in teenagers. Nausea or the urge to vomit was common in teenagers but did not happen in children.

Adverse Reaction	Number of children (out of 119 patients)	Number of teenagers (out of 29 patients)
Constipation	14 (11.9%)	1 (3.4%)
Abnormal electrical conduction within the heart	10 (8.5%)	4 (13.8%)
Nausea or the urge to vomit	0	2 (6.9%)

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 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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