Summary of Results for Laypersons

Astellas is grateful to the men who took part in this clinical study. Thank you.

What was the Study Called?

A Randomized, Double-blind, Parallel, Placebo-controlled, Phase 4, Multicenter Study to Assess Efficacy and Safety of VESIcare® (Solifenacin Succinate) to Improve Urinary Continence of Subjects after Robotic Assisted Radical Prostatectomy

Why was this Study Needed?

The prostate is a gland in men that surrounds the tube carrying urine from the bladder (urethra). Men diagnosed with prostate cancer may choose to have their prostate removed. This surgery can be done with robotic assistance. After prostate surgery, some men may not be able to control when their bladder empties. They may lose urine involuntarily (this is called incontinence). They may be required to wear pads under their clothing for several weeks. This affects their quality of life. Therefore, there was a need to study new treatments for these men. VESIcare (also known as YM905) is an oral (taken by mouth) prescription medicine. It is for relief of symptoms of overactive bladder. One of the symptoms of overactive bladder is incontinence.

This study was conducted in men who had their prostate removed. The men took either VESIcare or placebo tablets. (The section below describes what placebo tablets are). The study looked at how much time it took from first dose of study medicine until the men stopped being incontinent. It was also important to find out what unwanted effects these men had from the study medicines.

The study started in August 2011 and ended in October 2013. 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-blind study. That means that the patients and the study doctors did not know who took which of the study medicines (VESIcare 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 study doctors and patients cannot tell who is taking a placebo, and who is taking the test medicine.

This study included men aged 18 years and older with prostate cancer. Their cancer was treated by removing their prostate using robotic assistance. They were incontinent for 1 week after their catheter was removed. A catheter is a clean tube that helps empty the bladder. They were using 2 to 10 pads under their clothing per day for 7 days in a row.

During the study, the study doctor did a check-up of the men at several study visits. At the first visit, the men were checked to see if they could be in the study. If men who could be in

the study were taking medicine for their incontinence they stopped taking it for 2 weeks. This allowed that medicine to leave their body.

During the following week men who could be in the study kept a diary on how many pads they used under their clothing each day. Next, the study doctor checked the diaries to see if the men could remain in the study.

Men who could remain in the study were picked for a treatment group (VESIcare or placebo) by chance alone. The men took either 1 tablet of 5 mg VESIcare or 1 tablet of placebo each day. They took their study medicine for up to 12 weeks. After 4 weeks of treatment, the study doctor could decide to increase the dose to 2 tablets each day.

This study took place at 70 clinics in the US and Canada. 640 men were in the study. Out of these, 623 men took at least 1 dose of study medicine.

	Number of Men
Age Group	
Aged less than 65 years	407
Aged 65 years or older	216
Clinic Location	
Outside European Union	623
Canada	6
The US	617

What Were the Study Results?

The study looked at how much time it took from first dose of study medicine until the men stopped being incontinent for 3 days in a row.

66 out of 309 (21.4%) men in the placebo group became continent during the study. And 91 out of 313 (29.1%) men in the VESIcare group became continent during the study. From the date of the first dose, it took 91 days for 25% of men in the placebo group to become continent. It took 72 days from the date of the first dose for 25% of men in the VESIcare group to become continent. A statistical test showed the difference between the treatment groups was likely due to chance.

Study Results during 12 week treatment		**Placebo (out of 309 men)**	**VESIcare (out of 313 men)**
Urinary Continence During 12-week Treatment Period	Yes (number of men (%)	66 (21.4%)	91 (29.1%)
Time from First Dose to Urinary Continence	25 Percentile	91 days	72 days

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 the men who took at least 1 dose of study medicine in this study.

Adverse Reaction	**Placebo (out of 310 men)**	**VESIcare (out of 313 men)**
Any adverse reaction	18 (5.8%)	38 (12.1%)
Dry mouth	2 (0.6%)	19 (6.1%)
Constipation	7 (2.3%)	8 (2.6%)

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

One man (0.2%, or 1 out of 623 men) experienced a serious adverse reaction in this study. This man was in the placebo treatment group.

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 March 2014. 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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