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, Placebo-controlled, Multicenter, Phase 2a, Proof-of-Concept Study of ASP8302 in Subjects with Underactive Bladder.

Why was this Study Needed?

Underactive bladder is a bothersome and largely underdiagnosed but significant global health issue, particularly in elderly patients. Patients with underactive bladder are unable to empty their bladder properly and/or completely, often leading to distressing lower urinary tract symptoms, increased postvoid residual volumes (which is the amount of urine remaining in the bladder after voiding has occurred) and recurrent urinary tract infections that can significantly impact quality of life. In addition, if large postvoid residual volumes and urinary tract infections are not properly treated, this may result in more serious complications such as kidney failure or acute urinary retention. Therefore, there was a need to study new treatments for underactive bladder. ASP8302 was expected to improve voiding dysfunction by enhancing bladder contraction during voiding (not when the bladder is filling).

This study looked at how well ASP8302 worked to treat underactive bladder. This was done by measuring a decrease in postvoid residual volume after patients took study medicine for 4 weeks. Patients took ASP8302 or placebo (see below). It was also important to find out what unwanted effects these patients had from the study medicines.

The study started in November 2018 and ended in April 2020. 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 (ASP8302 or placebo). A "placebo" is a dummy treatment 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 adult women and men who were diagnosed with underactive bladder. They were able to void spontaneously, did not have significant obstruction or overactive bladder, and were allowed to continue self-catheterization if they were doing that for 1 month or longer.

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 were randomly assigned to take either ASP8302 or placebo. About half of the patients received placebo.

- ASP8302: Patients took ASP8302 capsules (100 mg) once a day.
- Placebo: Patients took placebo capsules once a day.

All patients took placebo for 2 weeks before taking the randomly assigned study medicine for 4 weeks.

This study took place at 29 clinics in several countries. A total of 135 patients participated in the study. Out of these patients, 133 patients took at least 1 dose of study medicine.

	Number of Patients
Age Group	
Aged less than 65 years	64
Aged 65 years or older	69
Sex	
Men	78
Women	55
Clinic Location	
Germany	12
The UK	1
Japan	59
The Netherlands	12
Poland	38
Slovakia	11

What Were the Study Results?

This study in patients with underactive bladder looked to see if there was a decrease in postvoid residual volume after patients took study medicine for 4 weeks. After voiding as much as they could on their own, the remaining urine in the patient's bladder was removed through a catheter and its volume was measured in order to get the postvoid residual volume.

A total of 124 patients were included for efficacy analysis. Postvoid residual volume measurements were taken 2 to 4 hours after study medicine intake on the day of week 4 visit. This value was compared to that at the start of the study. For patients who took ASP8302, the median change in postvoid residual volume was a decrease of 40.0 mL. In contrast, for patients who took placebo, the median change in postvoid residual volume was a decrease of 35.0 mL. The difference between ASP8302 and placebo was so small that it was due to chance; therefore, compared to placebo, ASP8302 did not decrease the postvoid residual volume in underactive bladder patients.

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 adverse reactions experienced by patients who took at least 1 dose of study medicine in this study.

Adverse Reaction	**ASP8302 (out of 63 patients)**	**Placebo (out of 70 patients)**
Any adverse reaction	6 (9.5%)	3 (4.3%)
Abnormal excessive sweating	2 (3.2%)	0
Diarrhea	1 (1.6%)	0
Discomfort in the upper belly	1 (1.6%)	0
Headache	1 (1.6%)	0
Nausea or urge to vomit	1 (1.6%)	0
Skin rash like acne	1 (1.6%)	0
Urge to urinate	1 (1.6%)	0
Failure of the blood circulation	0	1 (1.4%)
Fatigue or tiredness	0	1 (1.4%)
Increased blood level of bilirubin	0	1 (1.4%)

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

None of the patients who received ASP8302 experienced serious adverse reactions or died.

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 December 2020. 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.

Sponsor contact details:

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