Summary of Results for Laypersons

What was the Study Called?

A Prospective, Double-blind, Randomized, Two-period Crossover, Multi-center Study to Evaluate the Tolerability and Patient Preference Between Myrbetriq® and Detrol® LA in Subjects with Overactive Bladder (OAB). This is also known as the PREFER study.

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).
- Not being able to control when to empty the bladder (called urgency incontinence).

There are several medicines for overactive bladder in adults. They include mirabegron and tolterodine (also known as Detrol LA).

The main question this study helped answer was if patients with these bladder problems tolerated mirabegron better than tolterodine. The study assessed the patient preference for each study medicine. It was also important to find out what unwanted effects these patients had from the study medicines.

This study for mirabegron (also known by its brand names Betmiga®, Myrbetriq® and Betanis®) took place at 36 clinics in Canada and the US. The study took place from July 2014 to November 2015. 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 a "blinded" study. In this study the patients and the researchers did not know who took which of the medicines (mirabegron or tolterodine).

Both men and women could take part in the study if:

- They were 18 years or older.
- They were able to fill out a diary and questionnaires about their bladder problem symptoms.
- They had bladder problems for at least 3 months before the start of the study.
- They had not taken medicines for their bladder problems in the past.
- Patients who were having sex used reliable birth control methods.

Patients could not take part in this study if:

- Female patients were breastfeeding their baby.
- They had a blockage of the bladder. This blockage reduced or prevented the urine flow into the tube that carries urine out of the body.
- They had leakage of urine under stress conditions (exercise, laughing).
- They had infections of the structures that carry urine.

- The cause of their bladder problems was not overactive bladder.
- They had catheters (tube for draining urine) inserted in their bladders.

The study had 8 visits. At visit 1, patients were checked to see if they could be in the study. If patients could be in the study, they kept a diary of their bladder symptoms for 3 days. At visit 2, the diaries were checked to see if patients could remain in the study. Patients could remain in the study if their diaries showed that during the previous 3 days:

- They had a sudden need to urinate that was difficult to delay on at least 3 occasions.
- They had urinated at least 8 times a day.

If patients could remain in the study, they took study medicine during periods 1 and 2. Each period lasted 8 weeks. Between periods 1 and 2 patients did not take any study medicine for 2 weeks. Patients were picked for 1 of the following treatments by chance alone.

- Mirabegron in period 1 and tolterodine in period 2
- Tolterodine in period 1 and mirabegron in period 2
- Mirabegron in both periods 1 and 2
- Tolterodine in both periods 1 and 2

The dose of mirabegron was 25 mg once daily for 4 weeks and then was increased to 50 mg once daily. The dose of tolterodine was 4 mg once daily.

A total of 376 patients were in this study and took study medicine.

- A total of 319 patients took mirabegron once daily.
- A total of 325 patients took tolterodine once daily.

	Number (out of 376 patients)
Age Group	
Aged between 18 and 64 years	291
Aged 65 years and older	85
Gender	
Men	99
Women	277
Clinic Location	
EU Countries	0
Outside EU	376

What Were the Study Results?

Patients with overactive bladder tolerated treatment with mirabegron better than they did treatment with tolterodine. There was less bother from certain unwanted effects (such as dry mouth) with mirabegron. It did not matter in what order the patients took the study medicines.

The patient preference for the 2 study medicines was not different.

The study showed that the patients did not have a lot of unwanted effects while taking either study medicine.

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.

More patients had dry mouth while they took tolterodine than while they took mirabegron. The number of patients who had constipation was the same for mirabegron and tolterodine. The table below shows the most common adverse reactions experienced by patients who took at least 1 dose of study medicine.

	Number of Patients	
Adverse Reaction	**Mirabegron (out of 319 patients)**	**Tolterodine (out of 325 patients)**
Dry mouth	29 (9.1%)	53 (16.3%)
Constipation	17 (5.3%)	17 (5.2%)

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems or needs hospital care. Two patients had serious adverse reactions while they took mirabegron. None of the patients had serious adverse reactions while they took tolterodine.

None of the patients died during the study.

Where Can I Learn More About This Study?

Astellas may perform additional studies to better understand mirabegron.

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 mirabegron, please discuss these with your doctor.

Sponsor Contact Details:

Development US
1 Astellas Way
Northbrook, IL 60062
US