COVER PAGE

NCT number: 02916693

Official Title: Mirabegron for Erectile Dysfunction

Document date: March 12, 2018

Principal Investigator: Arthur L. Burnett

Participating Site: Johns Hopkins University, Baltimore, MD, USA

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Mirabegron for Erectile Dysfunction**

Application No.: **IRB00097439**

Sponsor: **Astellas Pharma Global Development, Inc.**

Principal Investigator (P.I.): **Arthur L. Burnett II M.D., M.B.A.**
P.I. Address: **The James Buchanan Brady Urological Institute**
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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens (urine) will be collected in this study. Most biospecimens contain DNA, which is the genetic code for each person.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to discover if the study drug, Mirabegron is effective in improving symptoms of Erectile Dysfunction (ED) and Overactive Bladder Disease (OAB) in adult men.

Mirabegron is approved by the Food and Drug Administration (FDA) for the treatment of Overactive Bladder Disease. It is not approved for use in Erectile Dysfunction and its use in the study is considered investigational. The FDA is allowing the use of Mirabegron in this research study.

- Standard care for ED usually involves taking medication by mouth. However, these medications do not always work for everyone. If the oral medication does not produce results, the patient can take other medications that are either injected into the penis or inserted as a suppository. Some men find these medications uncomfortable to take. Vacuum pump devices and penile prostheses are also alternative treatments for ED.

Mirabegron can be taken by mouth. In this study, we would like to evaluate if taking Mirabegron is helpful for men with ED symptoms.

Men may join the study if:

- Are between the ages of 18 and 70
- Have mild to moderate erectile dysfunction
- Are not taking any drugs for erectile dysfunction
- Have had overactive bladder disease symptoms for at least 3 months
- Has never had pelvic surgery including on the penis
- Do not have high blood pressure, stage 4 or 5 kidney disease or moderate to severe liver disease
- Are not using certain drugs
- Do not have a urinary tract infection

How many people will be in this study?

About 20 participants will be enrolled in this study at Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

1. Come to the clinic of the study doctor where he, another study doctor or a study nurse will conduct the initial clinic visit.
    - You will be asked about your medical history which includes any drugs (prescribed, over-the-counter and recreational) you are currently taking or have taken in the past. You will be asked about surgeries you may have had, any other illnesses you may have or had in the past and the treatment for those illnesses. You will also be asked if any diseases run in your family including cancer.
    - Your blood pressure and heart rate will be measured.
    - You will be asked to provide a urine sample so that it can be checked for signs of infection.
    - After you have provided your sample, the amount of urine left in your bladder (the post void residual) will be measured using a small ultrasound machine while you are laying down.

- You will also be asked to complete 2 questionnaires.
- You will be provided with daily study drug tablets, enough for 14 days (2 weeks) but by the end of the study you would have taken the study drug for 12 weeks.

2. Take one tablet daily for 2 weeks and call any member of the study team at any time if you experience any side effects, for example headache or abdominal pain.
3. After 14 days, return to the clinic for re-evaluation which involves:
    - Have your blood pressure, heart rate and post void residual re-measured.
    - Fill out the same 2 questionnaires from the initial visit again
    - Let a study team member know if you have experienced any side effects
    - You will be given enough daily study drug for 2 weeks
4. After taking the study drug for 14 more days (2 weeks), return to the clinic for re-evaluation and you will be given enough daily study drug for 28 days
5. After taking the study drug for 28 days (4 weeks) since you last came to the clinic, you will be asked to return for re-evaluation and given enough study drug for a final 28 days (4 weeks).
6. After taking the drug for the last 4 weeks, you will be asked to return to the clinic for the final evaluation. You will be encouraged to call any of the study team members after the completion of the study if you have any concerns about side effects

How long will you be in the study?

You will be in this study for 12 weeks.

Incidental Findings

The ultrasound you are having as part of this research study will be reviewed by a qualified person just as it would be if you were having the ultrasound as part of your routine medical care.

There is a possibility that while reviewing your ultrasound we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know ultrasound if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

4. What are the risks or discomforts of the study?

The study drug, Mirabegron, may cause:

- An increase in blood pressure or make blood pressure worse if there is a history of high blood pressure
- Inability to empty the bladder or cause a weak urine stream

- Symptoms similar to the common cold
- Urinary tract infection
- Headache
- An allergic reaction that may be serious

If any of these or any other side effect occurs, please contact any member of the study team as soon as possible.

There are no known harmful effects from the ultrasound used for medical testing.

There is the risk that information about you may become known to people outside this study. To protect against this, the study information will be kept in password-protected computers in locked rooms accessible only to study staff.

5. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

- Alternative erectile dysfunction and overactive bladder disease treatments are available but are being withheld in this study so that the study team can properly evaluate the effect of Mirabegron alone on ED and OAB.
- If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments for erectile dysfunction include: Tadalafil, Sildenafil and Vardenafil which can be taken by mouth. Alprostadil is another treatment that can either be injected into the penis or inserted as a suppository. Vacuum pump devices and penile prostheses are also alternative treatments for ED.
- Other oral treatments for overactive bladder disease include: Oxybutynin, Tolterodine, Darifenacin, Solifenacin and Fesoterodine.
- You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

8. Will you be paid if you join this study?

No. Parking will be provided for visits 2 through 5

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.

- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by

phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The study sponsor, Astellas Pharma Global Development, Inc., has agreed to pay the usual and standard costs of treatment or hospital care you receive as a direct result of a study-related injury that are not covered by a health insurer (provided the costs are not the result of care required to treat your underlying disease or condition).

Any costs that are not covered by the study sponsor or a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Burnett at 410-614-3986. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call the Principal Investigator, Dr. Arthur Burnett at 410-614-3986 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Arthur Burnett at **410-614-3986** during regular office hours and at **410-614-3986** after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

14. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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