

Elagolix (ABT-620)  
Study M14-702 Informed Consent  
09 Jun 2017

## Research Subject Information and Consent Form

**Study Title:** A Phase 3 Study to Evaluate the Safety and Efficacy of Elagolix in Combination with Estradiol/Norethindrone Acetate in Subjects with Moderate to Severe Endometriosis-Associated Pain

**Protocol Number:** M14-702

**Sponsor:** AbbVie  
1 North Waukegan Road  
North Chicago, IL 60064

**Study Doctor:** Michael L. Twede, MD, FACOG

**Telephone:** (385) 695-2300 Or (801) 576-2050

**After Hours:** (801) 576-2050

Before you can make an informed decision to participate in this research study, you should understand the possible risks and benefits of this study. This process is known as informed consent. The Institutional Review Board (IRB)/Ethics Committee (EC) has approved the information in this consent and has given approval for the study doctor to do the study. An Institutional Review Board (IRB)/Ethics Committee (EC) is an independent committee made up of a group of independent experts and lay persons set up to help protect the rights of research subjects. This does not mean the IRB/EC has approved your participation in the study. It also does not mean the study is without risk. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family, friends or anyone you choose before making your decision. If you decide to participate in this study, you will be asked to read and sign this consent form to confirm that you have had the study explained to you, and you have agreed to participate. You will receive a copy of the signed consent form.

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## **Introduction**

You have been asked to participate in a research study of an investigational drug called elagolix (a drug that is not approved by the FDA) because you are an 18 to 49 year old, premenopausal woman with moderate to severe pain associated with endometriosis (for example, painful menstruation, non-menstrual pelvic pain, and painful sexual intercourse). In addition to elagolix, you may also receive a small amount of estrogen/progestin medication to decrease some of the side effects from elagolix treatment, called add-back therapy. E2/NETA has been approved by the regulatory authorities in countries, including by the United States (US) FDA, to treat specific medical conditions in postmenopausal women. The E2/NETA is being studied with elagolix in this study to see if it will reduce the occurrence of symptoms associated with low estradiol levels such as hot flashes, and to prevent potential bone loss which may occur in women who take elagolix. Therefore, the use of E2/NETA is investigational (experimental) for the purposes of this study. AbbVie is paying the doctor to perform this study.

Elagolix (or ABT-620) is a new oral GnRH antagonist that is being developed for the treatment of the symptoms of endometriosis and uterine fibroids. Elagolix inhibits the secretion of the hormones called gonadotropins from brain cells (pituitary gland). As a result, elagolix reduces the production of the sex hormone estrogen by the ovaries in women. The level of estrogen suppression is dependent on the dose of elagolix. Because elagolix can reduce the normal level, it is being tested for the treatment of the symptoms of endometriosis and uterine fibroids, two conditions that are hormone dependent. To date, approximately over 3,700 women, including healthy women and patients with endometriosis and uterine fibroids, have received at least one dose of elagolix. Doses and duration of dosing has varied across the various studies conducted to date. Being in this study does not replace your regular medical care.

## **Purpose of the Study**

The purpose of this research study is to look at the safety and effectiveness of elagolix with E2/NETA compared to placebo and elagolix alone in managing moderate to severe endometriosis-associated pain and effects on bone mineral density after 24 months of treatment.

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### **Study Information**

This study is being conducted at approximately 200 research centers in the United States, Puerto Rico and Canada. Approximately 700 subjects with moderate to severe endometriosis-associated pain will participate in this study.

There are 4 study periods:

- Washout Period - up to 10 months prior to Screening (this will only apply if you are taking medications that need to be stopped before you can begin the study; the length of Washout depends on the type of medication being taken)
- Screening-approximately 1 ½ - 4 months
- Treatment-24 months
- Follow-Up -12 months

Your participation in this study will last approximately 27-50 months and include approximately 19 study visits to the research center and approximately 11 visits that will be conducted over the phone (including all study periods).

This study was designed to enroll 700 subjects for scientific, regulatory and ethical reasons; therefore, if the target number of subjects has been enrolled, and you are in screening, there is a possibility that you will not be enrolled.

If you qualify for the study, you will be randomly assigned by chance (like the flip of a coin) on Study Day 1 to 1 of the following 3 groups for Treatment Period:

- elagolix 200 mg twice a day plus standard dose E2/NETA (add-back) once a day (4 out of 7 chance)
- elagolix 200 mg twice a day alone (1 out of 7 chance)
- placebo (inactive substance that looks like elagolix or E2/NETA (2 out of 7 chance)

Neither you nor your study doctor will be able to pick which group you will be assigned to or which study drug you will receive. This is a double-blind study, which means neither you nor your study doctor will know which study group you were assigned to during the first 12 months. In case of an emergency, your study doctor can find out this information.

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However, at Month 6 of the Treatment Period, if you were randomly assigned to elagolix 200 mg twice a day, you will start receiving elagolix plus standard dose E2/NETA for the duration of the Treatment Period. Regardless of which group you were assigned to on Day 1, during the last the last 12 months of the Treatment Period (Months 13-24) all subjects will receive elagolix 200 mg twice a day plus standard dose E2/NETA once a day.

You will receive the elagolix tablets, E2/NETA capsules or matching placebo tablets or capsules (for the first 12 months) with instructions to take the study drug by mouth for 96 weeks (24 28-day months) during this study. You will take elagolix twice a day (1 tablet in the morning, 1 tablet in the evening, approximately 12 hours apart) and E2/NETA once a day (1 capsule in the morning) with approximately 8 oz (240 mL) of water. You should take the study drug at about the same time every morning and evening.

## **Procedures**

### **Study Procedures**

If you agree to be in this research study, you will undergo one or more of the study procedures, tests and evaluations described below during study visits and outlined in this form:

- *Vital Signs:* Check your blood pressure (BP) by putting a band around your arm (this will squeeze your arm for about a minute), count the number of heartbeats over time, counting the number of times you breathe in and out over a period of time, and take your temperature.
- *Physical Exam:* You should ask the study doctor or study staff about what will happen during this exam.
- *Questionnaires:* You will answer questions about your endometriosis, your health, your diet, work and activity level, your quality of life, and the study drug.
- *Medical/Social History:* A complete medical history, including documentation of any clinically significant medical conditions and medications, and history of tobacco and alcohol use, and licit/illicit drug abuse.
- *e-Diary:* You will be given a handheld electronic diary to take home. You will need to log into the diary every day to answer questions about your endometriosis pain, your period, your pain during sexual intercourse (if applicable) and how many pills of the study allowed pain rescue medication you may have taken in a 24 hour period. It is very important that you answer the eDiary questions every day that you are in the study. You will return the eDiary at your Month 12 study visit.
- *Gynecological Exam:* includes examination of external genitalia, breasts and pelvis (abdomen).

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- *Pap Smear*: A test used to detect pre-cancerous cells in the cervix.
- *Electrocardiogram (screening only)*: A harmless test which records the electrical activity of your heart.
- *Blood Sample*: About 20 teaspoons of blood total will be taken throughout all study periods for all labs. Some of your blood will be used to test for Hepatitis and HIV. The study doctor or study staff will tell you if the test results are positive. If required by state law, the study doctor or study staff may report a positive test result to the local health department. You may have to sign a separate consent form before this testing can be done. The results of these tests must be negative in order for you to be in the study.
- *Pharmacokinetic (PK) Blood Testing*: PK testing is the study of how the body absorbs, distributes, breaks down and eliminates a drug.
- *Pharmacodynamic (PD) Blood Testing*: PD testing for this study will look at how the study drug affects hormones, like estrogen, in the body.
- *Pregnancy Testing*: Test your blood or urine to see if you are pregnant. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study. For study visits conducted by phone, you will be given an at-home urine pregnancy test to perform.
- *Dual Energy X-ray Absorptiometry (DXA)*: A special x-ray to measure your bone mineral density in your hip and spine.
- *Transvaginal Ultrasound (TVU)*: A transvaginal ultrasound involves inserting a gel-covered probe (like a tampon), into the vagina. By sending high frequency sound waves from the probe and measuring the waves as they are reflected back, images of the uterus and ovaries are seen on a screen.
- *Endometrial Biopsy*: The doctor takes a small sample of the endometrium (tissue lining of the uterus). The tissue is sent to a lab for evaluation.

You may or may not have the procedures listed below performed during the study:

- *Pharmacogenetic (PG) Blood and Endometrial Tissue Testing (optional)*: PG testing may improve our understanding of how patients like you respond to drugs and our ability to predict, detect, and monitor diseases and their progression. If you choose to participate in the PG testing portion of the study, more information will be provided to you in a separate consent form.
- *Mammogram*: A mammogram is an x-ray used to examine the breast to screen for any abnormalities or changes in the breast.
- *Optional urine testing for Gonorrhea and Chlamydia*: A urine sample may be taken to test for Gonorrhea and Chlamydia if the study doctor feels it is necessary. Positive test results may be reportable to authorities according to local laws.

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- Colposcopy: *If your Pap smear results show abnormal changes, the study doctor may request that you undergo a colposcopy with biopsy. A colposcopy is a procedure that uses an instrument that looks like binoculars with a bright light that allows the doctor to get a magnified view of the cervix, vagina or vulva for signs of cervical abnormalities. The doctor will also take a sample of cervical tissue (biopsy).*
- Saline Infusion Sonography (SIS): *An SIS is a transvaginal ultrasound test in which a small amount of saline (water with a small amount of salt) is inserted into the uterus through the cervix using a tiny catheter (a thin tube). This allows the lining of the uterus to be clearly seen on an ultrasound scan.*
- Office Hysteroscopy: *A thin lighted tube (hysteroscope) with a camera is inserted into the vagina that allows the doctor to look inside your uterus and see it on a video screen.*

### **Washout Period**

You will be asked to stop taking hormonal contraception (e.g., birth control pills), other hormonal therapies or other medications for an amount of time depending on which medication you are taking before you begin screening for the study. This is called a Washout Period, during which time the effects of these medications leave your body.

You will remain in the Washout Period until the medication being washed out leaves your body. If you stop your regular hormonal contraception, then your endometriosis symptoms may get worse. Also, when you stop your regular hormonal contraception, you will be required to use other non-hormonal contraception (e.g., condoms with spermicide) during the washout period and for the duration of the study.

### **Screening Period**

After Washout, or if you are not taking exclusionary medications, you will enter the Screening Period (about 1.5 to 4 months) and will undergo some activities, tests and evaluations to determine if you are eligible for this study.

Tests and procedures to be performed during the Screening Period to determine if you qualify to participate in this study are listed in Table 1. Please note that you may be asked to repeat a procedure or test if your study doctor feels it is needed to evaluate your condition.

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It is important that you are not intending to become pregnant and will take precautions not to become pregnant during the study.

You will be given your e-Diary and be instructed on how to complete it and make daily entries throughout the Screening and Treatment Periods. You will begin daily e-Diary entries during the Screening Period.

**Table 1. Washout and Screening Period**

<b>Activity</b>	<b>Washout</b>	<b>Screening</b>
Informed Consent	X	X
Medical/Gynecological/ Endometriosis History (includes smoking and alcohol use, family history and documentation of your endometriosis diagnosis)	X	X
Physical Exam	X	X
Gynecological Exam and Pap Test		X
Electrocardiogram (ECG)		X
TVU, DXA		X
Vital Signs	X	X
Endometrial Biopsy (including <i>Optional</i> Pharmacogenetic Endometrial Tissue Sample)		X
Pregnancy Tests (urine and/or blood)	X	X
Collect blood and urine for routine safety , Hepatitis and HIV, Hormone and Lipids Tests, and Vitamin D (about 11 tsp of blood for all tests)		X
e-Diary dispensed Begin Daily e-Diary Entry (minimum of 45 days of entry needed)		X
Health and Medication Updates	X	X
Contraception Counseling/Dispense Contraceptives and Birth Control Attestation (as applicable)	X	X
Mammogram (if you're $\geq$ 39 years old at the time of screening, unless you have had a mammogram within 3 months prior to Screening)		X

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### **Treatment Period**

The Study Treatment Period will last approximately 24 months (1 month=28 days). The Day 1 Visit will take place on days 1 – 10 of your next menstrual cycle after meeting all of the qualifications for the study during the Screening Period. The study staff will discuss with you the scheduling of this visit, based upon your menstrual cycle. Tests and procedures to be performed prior to and after your first dose of study drug are listed in Table 2. Please note that you may be asked to repeat a procedure or test if your study doctor feels it is needed to evaluate your condition.

#### **Study Treatment Period:**

After the Day 1 Visit, you will come to the study site for regularly scheduled visits, or have phone visits. The tests and procedures to be performed at the regularly scheduled visits are listed in Table 2.

#### **Study Treatment Period: Month 6**

For the Treatment Month 6 visit, a DXA will be completed. It is recommended to complete the DXA within approximately 15 days prior to your Treatment Month 6 visit to ensure results are received in time for your visit. The results of these tests will be reviewed by your study doctor to see if it is safe for you to continue in the Treatment Period. If the study doctor decides you may continue, if you were previously receiving elagolix alone, you will be assigned to the elagolix 200mg twice a day plus standard dose E2/NETA treatment group for the remainder of the Treatment Period. You and the study doctor will remain blinded; that is, you will still not know which treatment group you are in.

#### **Study Treatment Period: Month 12**

At the Treatment Month 12 visit, a TVU, DXA, and endometrial biopsy will be completed. It is recommended that these procedures are completed approximately 15 days prior to your Treatment Month 12 visit to ensure results are received in time for your visit. The results of these tests will be reviewed by your study doctor to see if it is safe for you to continue in the Treatment Period.

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You will return the eDiary at this visit. If the study doctor decides you may continue, if you were previously receiving placebo (inactive substance), you will be assigned to the elagolix 200 mg twice a day plus standard dose E2/NETA treatment group for the remainder of the Treatment Period.

**Study Treatment Period: Premature Discontinuation**

If you discontinue study drug early (premature discontinuation [PD]), you will be asked to return all used/unused study drug cartons and blister cards to the study site and complete a PD visit. If you discontinue the study before Month 12, you will return the e-Diary to the study site. Tests and procedures to be performed are listed in Table 2. If you PD, you will be asked to remain in the study and continue to follow the scheduled study visits and procedures in the Follow-Up Period. Some procedures may not be necessary depending on when you PD from the study.

**Table 2: Treatment Period**

Activity- Treatment Period	Day 1	Months 1, 2,4,5	Month 3	Month 6	Months 7, 9, 11 Phone Contact Only	Month 8, 10	Month 12
Medical/Gynecological/ Endometriosis History (updated, if needed)	X						
BMD Risk Factors Questionnaires	X			X			X
Physical Exam	X						X
Gynecological Exam							X
Vital Signs	X	X	X	X		X	X
DXA				X			X
TVU							X
Endometrial Biopsy (including <i>Optional</i> Pharmacogenetic Endometrial Tissue Sample)							X
Pregnancy tests (urine and/or blood)	X	X	X	X	X	X	X
Collect blood & urine for routine safety testing	X		X	X		X (month 8 only)	X

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<b>Activity- Treatment Period</b>	<b>Day 1</b>	<b>Months 1, 2,4,5</b>	<b>Month 3</b>	<b>Month 6</b>	<b>Months 7, 9, 11 Phone Contact Only</b>	<b>Month 8, 10</b>	<b>Month 12</b>
Collect blood for Pharmacokinetic (PK) Tests			X	X		X (month 10 only)	X
Collect blood for Pharmacodynamic (PD) Tests	X	X	X	X		X	X
Collect blood for <i>Optional</i> Pharmacogenetic (PG) Blood Samples	X			X			X
<b>Daily</b> e-Diary Entry	X	X	X	X	X	X	X
Applicable Quality of Life Questionnaires	X	X	X	X	X	X	X
Overall Health and Medication Review	X	X	X	X	X	X	X
Contraception Counseling/Dispensing Contraceptives and Birth Control Attestation (as applicable)	X	X	X	X	X	X	X
Study Drug Dispensed and Returned Day 1 = Dispensed only	X	X	X	X		X	X

<b>Activity- Treatment Period</b>	<b>Months 13, 14, 16, 17 Phone Contact Only</b>	<b>Month 15</b>	<b>Month 18</b>	<b>Months 19, 20, 22, 23 Phone Contact Only</b>	<b>Month 21</b>	<b>Month 24</b>	<b>PD</b>
BMD Risk Factors Questionnaires			X			X	X
Physical Exam						X	X
Gynecological Exam						X	X
Vital Signs		X	X		X	X	X
DXA			X			X	X
TVU						X	X
Endometrial Biopsy						X	X
PAP smear						X	X

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Activity- Treatment Period	Months 13, 14, 16, 17 Phone Contact Only	Month 15	Month 18	Months 19, 20, 22, 23 Phone Contact Only	Month 21	Month 24	PD
	Pregnancy tests (urine and/or blood)	X	X	X	X	X	X
Collect blood & urine for routine safety testing		X	X			X	X
Collect blood for Pharmacokinetic (PK) Tests			X			X	X
Collect blood for Pharmacodynamic (PD) Tests		X	X		X	X	X
Applicable Quality of Life Questionnaires	X	X	X	X	X	X	X
Overall Health and Medication Review	X	X	X	X	X	X	X
Contraception Counseling/Dispensing Contraceptives and Birth Control Attestation (as applicable)	X	X	X	X	X	X	X
Study Drug Dispensed and Returned (Month 24/PD = returned only)		X	X		X	X	X

**Follow-Up Period**

When you complete the Month 24 visit or if you prematurely discontinue from the Treatment Period after Month 6, you will enter into the Follow-up Period for up to 12 months.

Tests and procedures to be performed during Follow-Up are listed in Table 3. Please note that you may be asked to repeat a procedure or test if your study doctor feels it is needed to evaluate your condition.

**Table 3: Follow-Up Period**

Activity- Follow-Up Period	Month 1	Month 6	Month 12
	DXA		X
Brief Physical Exam	X		
Collect Blood for Hormone Testing	X	X	X
Pregnancy Test (urine and/or blood)	X	X	X
Overall Health and Medication Review about Your Menstrual Period	X	X	X

**Subject Responsibilities**

In order for this study to provide good information about how the study drug(s) work(s) in subjects with moderate to severe endometriosis-associated pain, you will be expected to do the following:

- Follow the directions of the investigator and research team, *including requirements to use an appropriate birth control method.*
- Refrain from participation in other research studies while you are a subject in this study.
- Fill out your e-Diary daily. Complete the e-Diary and questionnaires completely, honestly and as instructed by study staff. Return the e-Diary when you are asked to.
- Come to all your scheduled study visits and procedures e.g. endometrial biopsies, DXAs, ultrasounds and collect urine pregnancy tests at home, as required.
- You may be required to stop certain medications and supplements you are currently taking. Certain medications you are taking or have taken in the past may keep you from being in this study. Please review all of your medications with your study doctor.

- Some procedures/conditions you may have had in the past may keep you from being in this study. Be sure to tell your study doctor everything you recall about your medical and surgical history.
- Do not change any of your medications or start any new medications (including medications for endometriosis) without checking with your study doctor.
- Use only the protocol specified rescue medications for endometriosis pain. You should contact your study doctor if you feel a change in your rescue medication is needed. Taking these medications on a standing basis for prevention of endometriosis pain is not allowed.
- Take and store your study drug as instructed and return the unused study drug and/or empty containers to the study doctor's office at each visit.
- Do not share your study drug with anyone. You are the only person allowed to take the study drug.
- Keep the study drug and study supplies out of the reach of children and persons of limited ability to read or understand.
- Tell the study staff about any health problems you are having even if you don't think they are important.
- Tell the study staff if you wish to stop being in the study.
- Follow contraception counseling and be willing to consistently use 2 methods of non-hormonal birth control (as applicable) to prevent pregnancy while you are in this study.
- Tell the study staff about the types of birth control methods used and if you had any problems with them.
- For the at home urine pregnancy tests, you will need to report the pregnancy test results to the study staff

In the event of an emergency, dial your local emergency phone number immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

SCHULMAN APPROVED  
IRB #201604190  
DATE: August 4, 2017

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If you have questions about your participation in this study or if you think you have had a study-related injury or reaction to the study drug, or if you have any concerns or complaints about your participation in this study, contact the study doctor at the phone numbers listed on Page 1 of this Informed Consent Form.

If you have questions concerning your rights as a research subject, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you may contact: Schulman Institutional Review Board

4445 Lake Forest Drive - Suite 300  
Cincinnati, Ohio 45242

Or, call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST.

## **Birth Control Counseling**

You will be tested regularly throughout the study for pregnancy. You must have a negative pregnancy test result at all times during the study, starting with your first visit. In addition, you will be counseled at every visit throughout the study on the importance of pregnancy prevention and the use of appropriate and effective methods of birth control.

You must agree to use 2 forms of non-hormonal birth control during the Washout (if applicable), Screening and Treatment Periods, and Follow-up Period Month 1. Contraceptive supplies (listed below) will be provided to you by the study site. Below is a list of acceptable methods of 2 forms of birth control:

- Condom with spermicide (cream, spray, foam, gel, suppository or polymer film)
- Diaphragm with spermicide (condom may or may not be used)
- Cervical cap with spermicide (condom may or may not be used)
- Vaginal sponge impregnated with spermicide used with a condom

You are not required to use 2 forms of birth control methods if:

- Your sexual partner(s) is vasectomized (a procedure where the vas deferens [a tube that carries sperm out of the testicles] was cut or tied off) at least 6 months prior to Screening.
- You have had a bilateral tubal occlusion (including tubal ligation which is a procedure where the fallopian tubes are either cut or clamped to prevent the release of eggs) or had a blockage method (you must have had prior confirmation of tubal occlusion confirmation test) at least 4 months prior to Screening.

- You are not sexually active with men.
- You practice abstinence from sexual intercourse as the preferred lifestyle. Periodic abstinence is not acceptable and requires use of dual contraception.
- You are using hormonal contraception after the Follow-Up Month 1 visit.

Occasional sexual relationship(s) with men requires the use of non-hormonal contraception throughout the Screening, Treatment and Follow-Up Periods of the study.

You will confirm (attest) at each study visit that you continue to agree to use 2 forms of non-hormonal contraception throughout the study (if you have had a tubal ligation or blockage, you will only need to attest once when you consent).

After the Follow-Up Period Month 1 visit if you have returned to 1 menstrual cycle/period, if you choose to, you may begin to use hormonal contraception, such as birth control pills.

If, during the study, you become pregnant, think you might be pregnant, or if you decide to become pregnant, it is important that you tell the study doctor as soon as possible. If you become pregnant, you must stop the study drug and you will not be allowed to continue in the study.

## **Risks and Discomforts**

### **Study Drug Risks**

Your study doctor will be monitoring you for side effects from elagolix and E2/NETA. It is important that you report any side effects you have had to your study doctor right away. Your study doctor may give you other drugs to help with side effects. If you or your study doctor thinks that you cannot tolerate the side effects, the study drug may be stopped altogether and you will be withdrawn from the study.

### **Safety Information from Animal Studies**

Based on animal studies (mouse, rat, dog and monkey) of up to 6-9 months duration, elagolix was not associated with adverse effects at animal blood levels of elagolix of up to nearly 4 times higher than those expected in humans. This includes doses of up to 600 mg per day for an extended duration. At higher elagolix doses in animals, the main adverse effect included a mild increase in liver function tests in some of the animals. This effect was not observed up to approximately 8 times the blood levels of elagolix expected in humans. Animal studies suggest that elagolix is not associated with an increased risk of tumors or teratogenicity (fetal abnormalities). However, in animals, decreased maternal body weight gain, decreased fetal body weight and lower birth weights were seen. It is unknown if decreased fetal body weight was due to the direct effect of elagolix on the fetuses or on the pregnant animal. Miscarriages were also seen in animal studies at very high doses.

### **Common Side Effects Associated with Elagolix During Clinical Studies**

The very common side effects of elagolix observed in women include:

- hot flashes
- headache
- feeling sick to one's stomach (nausea)

Common side effects include:

- abdominal pain or distention
- acne
- changes in mood including depression and anxiety
- changes in sexual arousal
- diarrhea
- difficulty falling asleep or staying asleep (insomnia)
- dizziness or lightheadedness (vertigo)
- feeling tired (fatigue, somnolence)

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- hair loss
- increased or abnormal lipids
- migraine headache
- pelvic pain
- sweating
- vaginal bleeding, pain, itching, or dryness
- vomiting
- weight gain

There is always a possibility of an allergic reaction to any medication. Some cases of allergic reaction including rash have been reported in women taking elagolix. Some people who experienced these reactions required treatment and, in some cases, stopped the study drug. One allergic reaction was considered serious. The woman stopped study drug and the symptoms resolved without any further treatment.

Some allergic reactions to drugs could become severe or life-threatening. Symptoms of a severe or life-threatening allergic reaction include: difficulty breathing, fast pulse, rash, sudden drop in blood pressure causing dizziness or fainting, sweating, swelling around the mouth, tongue, lips, throat, or eyes, wheezing when you take a breath.

If you have any of the above symptoms, contact your study doctor immediately or go to the emergency department. Inform the study doctor if you have had any allergic reaction to drugs in the past or if you know that you have an allergy or are sensitive to any other drugs like elagolix (e.g., GnRH agonists such as leuprolide acetate [Lupron®], nafarelin acetate [Synarel®], goserelin acetate [Zoladex®] or GnRH antagonists cetrorelix or ganirelix) or estrogen/progestin drugs like E2/NETA.

### **Mood Change**

Some subjects experienced mood changes, including mood swing, depression, depressed mood and anxiety, during elagolix treatment. In all elagolix studies, depression was reported in 1.9% subjects and depressed mood was reported in 0.8% subjects. A number of subjects who reported depression had history of depression. Four cases of suicidal thought, and one case with a history of depression reported suicidal thought while on elagolix treatment. One case of depression with suicidal thought was reported while on placebo. There was one case of completed suicide which was considered by the study doctor not related to study drug rather related to potential life stress.

If you have history of depression, other psychiatric related conditions or taking an anti-depressant, please let your study doctor know. If you have any of the above symptoms, please contact your study doctor immediately.

### **Effects on Ovulation**

Elagolix is not a contraceptive, that is, it does not prevent pregnancy. Although elagolix does prevent ovulation in some women, especially with higher doses, in other women data show that ovulation may still occur while taking elagolix, indicating that women may still become pregnant. You must not become pregnant while you are taking elagolix. In clinical trials of up to 6 months in duration, there is evidence that ovulation starts again soon after elagolix is stopped. The long term effects on ovulation and the ability to become pregnant are not known at this time.

### **Risk of Pregnancy**

**ELAGOLIX IS NOT A BIRTH CONTROL PILL.** You must use birth control as instructed by your study doctor. Unplanned pregnancies have been reported during elagolix studies. If you decide to participate in this study, you must use birth control measures as instructed by your study doctor during the entire duration of the study including the post-treatment follow-up period and take every precaution to avoid becoming pregnant.

If you think that you may be pregnant, decide to become pregnant, or have a positive pregnancy test at any time while you are in the study, including the post-treatment follow up period, it is important that you tell the study doctor immediately. If you become pregnant, you must stop study drug and you will not be allowed to continue in the study.

During early pregnancy, an ultrasound may be done to confirm pregnancy, better estimate timing of pregnancy (date of conception), and assess the status of the fetus. You may request to know exactly what study drug treatment you were assigned to during the study (also known as un-blinding). Your study doctor will discuss your options and next steps with you. You will be asked to provide information about your pregnancy, your delivery, and about your baby (for example, sex, birth weight, and if there were any birth defects).

#### **Pregnancy Outcomes: Birth Defects and Miscarriage**

Among women who decided to carry the pregnancy to term, 2 babies exposed to elagolix in the womb were born with birth defects. One baby was born with a cleft palate (an opening in the roof of the mouth). Another baby was born with a connection between the esophagus (the tube that carries food from the mouth to the stomach) and the trachea (wind pipe), and an abnormal heart. These abnormalities can sometimes be corrected with surgery. It is not known if elagolix caused these birth defects.

There is also a possible risk of miscarriage if you become pregnant at any time during the study or the follow-up period because of the possible effects of elagolix on the levels of hormones in your body that are important for pregnancy.

#### **Effects on Menstrual Bleeding**

While you are on treatment with elagolix you may experience changes in your menstrual cycle and bleeding pattern. Your menstrual bleeding may be more or less or occur for fewer days or no days. The time between each period may also be longer and your periods may not be predictable. At higher doses, elagolix may completely suppress your periods. This effect is reversible after stopping treatment.

**Bone Mineral Density and the Risk of Fractures:**

Similar to other medications that reduce female hormone levels in the body, particularly estrogen levels, elagolix treatment has been shown to reduce bone mineral density and affect laboratory values that measure bone health and strength. The data suggest that higher doses and longer exposure to elagolix result in greater bone loss. Bone loss can place a woman at risk for osteoporosis (softening of the bones) and fractures (broken bones). Inform the study doctor if you or family members have been diagnosed with osteoporosis, if your mother had a hip fracture, if you are a smoker, if you have used or are now using drugs such as corticosteroids or drugs to treat epilepsy (convulsions or seizures) and if you have ever had any fractures. Because the risk of fractures depends on many factors (including your age, overall health status, overall bone strength), you should discuss the possible risk of fractures specific to you with your study doctor. There is evidence that the bone loss associated with the use of elagolix is reversible. However, in some patients, in particular very young women, elagolix may reduce the maximum bone growth, and this may be associated with an increased risk of osteoporosis and fracture later in life.

**Effects on Lipids:**

Lipid changes, such as increases in total cholesterol, triglycerides, and LDL cholesterol are associated with lower levels of estrogen, whether this occurs naturally at menopause, surgically (with removal of the ovaries) or medically-induced (varying prescription and over the counter drugs). Similar changes in serum lipids have occurred in clinical studies with elagolix. Mean percent increases of 5 to 20% in total cholesterol, LDL cholesterol, and triglycerides have been seen over a 6-month period. While the significance of these lipid changes in healthy young women is unknown, your levels will be closely monitored during this study.

### **Drug Interaction Risks**

To date, important drug interactions have not been identified. However, it is very important that you tell the study doctor about any other medicines (either prescription or over the counter) or supplements such as vitamins or herbs that you are taking.

### **Unknown Side Effects**

Elagolix is an experimental drug that is being developed for the treatment of women with endometriosis-associated pain and heavy menstrual bleeding associated with uterine fibroids. Not all of the side effects are known at this time. For this reason, you will be watched closely for known and other unknown, possibly serious side effects. You will be told if there is new drug safety information that may change your willingness to stay in this study, as it becomes available.

Please tell the study doctor or study staff right away if you have any symptoms or side effects. Failure to report symptoms may be harmful to your health. Also, tell them if you have any other problems with your health, the way you feel during the study, if you are hospitalized for any reason during the study, or if you stop taking the study drug, even if you do not think the problems are caused by the study drug.

### **Estradiol and Norethindrone Acetate (E2/NETA) Drug Risks**

In postmenopausal (after menopause) women, the following side effects were reported in women who received E2/NETA to treat menopausal symptoms:

Serious, but less common side effects include heart attack, stroke, blood clots, dementia, breast cancer, cancer of the lining of the uterus (womb), cancer of the ovary, high blood pressure, high blood sugar, gallbladder disease, liver problems, changes in your thyroid hormone levels, and enlargement of benign tumors (“fibroids”).

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Less serious, but common side effects include: headache, breast pain, irregular vaginal bleeding or spotting, stomach or abdominal cramps, bloating, nausea and vomiting, hair loss, fluid retention and vaginal yeast infection. Call the study doctor and study staff right away if you get any of the following warning signs or any other unusual symptoms that concern you such as new breast lumps, unusual vaginal bleeding, changes in vision or speech, sudden new severe headaches, severe pains in your chest or legs with or without shortness of breath, weakness and fatigue.

### **Unknown Side Effects**

The effects of E2/NETA in premenopausal women have not been evaluated, especially in combination with elagolix.

Not all of the side effects are known at this time. For this reason, you will be watched closely for known and other unknown, possibly serious side effects. You will be told if there is new information that may change your willingness to stay in this study, as it becomes available.

E2/NETA is not birth control, and should not be used during pregnancy. There appears to be little or no increased risk of birth defects in children born to women who have used estrogens and progestins from oral contraceptives inadvertently during early pregnancy.

Your study doctor may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), diabetes, migraine, endometriosis, lupus, angioedema (swelling of face and tongue), hypertriglyceridemia (elevated levels of triglycerides in your blood), problems with your heart, liver, thyroid, kidneys, have high calcium levels in your blood, or if you are planning to have surgery or will be on bed rest during the study.

### **Pregnancy and Breastfeeding Risks**

The safety of elagolix and E2/NETA during pregnancy has not been determined. Taking the study drug may involve unknown risks to a pregnant woman, an embryo, fetus or nursing infant. If you become pregnant, information regarding the pregnancy and its outcome must be provided to the investigator.

### **Risks Associated with Placebo**

Some people in the study will get placebo instead of elagolix during the first 12 months of treatment. If you use placebo during the study, it is possible that your endometriosis pain may get worse. Please ask the study doctor or study staff if you have any questions about placebo.

### **Risks Related to Study Procedures**

- **Physical Exam:** there are no special risks with an exam. It will be similar to examinations you have had in your doctor's office in the past.
- **Questionnaires:** Filling out the questionnaires could lead you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while filling out a questionnaire. You have the right to refuse to answer any questions.
- **Gynecological Examinations (External Genitalia, Breast and Pelvic Examination/Pap Smear):** There may be mild discomfort or pain associated with the gynecologic examinations. Some women experience discomfort from the pressure applied on the breast and when the speculum (instrument that helps the doctor see) is inserted into the vagina or when the cervix is scraped to take a Pap smear. There may be temporary spotting or bleeding afterward. You may experience discomfort from the pressure applied during a manual pelvic examination.
- **TVU:** Ultrasounds are usually a painless procedure, however, there may be varying degrees of pressure as the probe is inserted and often moved around to allow for the uterus and ovaries to be examined until desired pictures are captured. The transvaginal ultrasound may cause mild uterine spotting. Ultrasounds do not use x-rays.

- Endometrial Biopsy: You may briefly experience pelvic pain, cramps or uterine bleeding or spotting after the biopsy. The risks of endometrial biopsy include bleeding, infection, minor discomfort, and rarely the risk of uterine perforation (tearing or making a hole). Perforation may require hospitalization, antibiotic therapy, or additional procedures necessary to repair the perforation site. If a sedative, analgesic, or local anesthetic is used during the biopsy, the study doctor will describe its risks to you.
- Dual Energy X-Ray Absorptiometry (DXA): DXA is a simple, quick and noninvasive procedure. The amount of radiation used is extremely small – less than one-tenth the dose of a standard chest x-ray, and less than a day's exposure to natural radiation. Women should always inform their physician or x-ray technologist if there is any possibility that they are pregnant.
- Blood Sample Collection: You may experience some pain and/or bruising and increased risk of bleeding at the site on your arm where the blood is taken. In some instances, a localized (confined to an area) blood clot may form or an infection may occur. Some people experience faintness during or shortly after having blood drawn. If you feel like you may faint, you should notify the study staff and lie down immediately to avoid a possible injury caused by falling. Although one attempt at drawing blood is usually all that is necessary, additional attempts may be needed if the first attempt is unsuccessful.
  - You may be asked to fast (nothing to eat or drink) for 8 hours before some of the blood sample collections. Fasting for 8 hours could cause dizziness, headache, stomach discomfort, or fainting.
- Pharmacogenetic (PGt), Pharmacogenomic (PGx), Pharmacokinetic (PK): the risks are similar to any blood test.
- Pregnancy Testing: the risks are similar to any urine or blood test.
- Electrocardiogram: Patches from the ECG leads may cause a skin reaction, such as redness or itching. You may also experience localized (confined to an area) skin discomfort and/or hair loss where the ECG leads were placed.
- Mammogram: Obtaining a mammogram may be painful to some women when the breasts are compressed between 2 plates of the x-ray machine, but this pain will go away. Mammography exposes you to low-dose radiation.

The dose is very low, though, and for most women the benefits of regular mammography outweigh the risks posed by this amount of radiation.

- Colposcopy: You may have a colposcopy if your doctor requests further evaluation if your pap smear shows abnormal changes. Significant complications from a colposcopy are not common, but may include bleeding, infection, and failure to identify abnormal cells. Some patients experience discomfort if a biopsy sample is obtained during the colposcopy.
- Saline Infusion Sonography (SIS): During a SIS, you may feel occasional cramping as a result of the introduction of the saline. You may have vaginal spotting for a few days after the procedure, which is normal. There is a possibility of infection.
- Office Hysteroscopy: May cause mild bleeding, infection, injury to the cervix, uterus, bowel or bladder, intrauterine scarring, and a reaction to the substance used to expand the uterus. Be sure to call your doctor if you experience any fever, severe abdominal pain or heavy vaginal bleeding or discharge.

### **Risks Related to Analgesic Rescue Medication:**

Your study doctor will be monitoring you for side effects from analgesic rescue medications. Ask your study doctor about the risks of your analgesic medication(s). The rescue medication you take may cause side effects.

- Naproxen: Some common and important adverse effects are: abdominal pain, constipation, heartburn (burning sensation in the chest), nausea/vomiting, headache, dizziness, drowsiness, diarrhea, skin reaction (rash and blisters), increase risk of serious GI adverse events (including bleeding ulcers and perforation [forming of a hole]) and may have an increased risk of cardiovascular thrombotic events (heart attack and stroke).
- Ibuprofen: Some common and important adverse effects are: upset stomach, mild heartburn, nausea, vomiting; bloating, gas, diarrhea, constipation; dizziness, headache, nervousness; mild itching or rash; or ringing in your ears.

- Diclofenac: Some common and important adverse effects are: headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence (gas), anorexia, transaminases increased (elevated liver enzymes) and rash.
- Celecoxib: Some common and important adverse effects are: headache, abdominal pain, indigestion, diarrhea, nausea, upset stomach, bloating, gas, dizziness, nervousness, headache, runny or stuffy nose, sore throat, skin rash, and insomnia.

NSAIDs (non-steroidal anti-inflammatory drugs such as naproxen, ibuprofen, diclofenac, celecoxib) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

- Acetaminophen: Some additional important adverse effects associated are: rash/urticaria, allergic reactions (including anaphylaxis – *very serious allergic reactions are rare*), bone marrow suppression (thrombocytopenia, leukopenia), hepatotoxicity (and acute liver failure – *may cause serious or fatal liver disease*) and serious skin reactions (reddening of the skin, rash, blisters and peeling of the skin – *serious skin reactions are rare*).
- Hydrocodone with acetaminophen: Some common and important adverse effects are: lightheadedness, dizziness, nausea/vomiting, constipation, mental clouding/impairment of your thinking and drowsiness/sedation (avoid driving or operating machinery until you know how this drug will affect you).
- Codeine phosphate with acetaminophen: Some common and important adverse effects are: drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, sweating, and constipation. Other adverse reactions include allergic reactions, euphoria (feeling very happy), dysphoria (feeling very bad), abdominal pain, pruritus (itching), rash, thrombocytopenia (severe decrease in cells that aid in clotting), and agranulocytosis (severe decrease in cells that help fight infections).

## **Costs**

You will not be charged for the required study drug(s) or procedures during the study. Contraceptives will be provided to you at no cost during the study. You are responsible for the cost of your regular medical care. Before you agree to be in this study, you should contact your health-care payer/insurance company to see if your plan will cover the costs required as part of your participation. You can ask the study doctor or study staff to find out more about costs.

## **Compensation for Participation**

The IRB agreed that for your time and inconvenience related to your participation in this study and to cover the costs of travel and your rescue medications as required by the Protocol, you will be paid for the study site visits you complete according to the following schedule:

**SCHULMAN APPROVED**  
**IRB #201604190**  
**DATE: August 4, 2017**

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M14-702: Subject Stipend for Participation																
Washout and Screening			Treatment Period													PD
US Dollars	Wash-out Period (if appl.)	Screening Visit	Day 1	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	PD
Stipend Per Visit	50	100-Visit 25-DXA 25-TVU 25-PAP 25-Biopsy 25-Mammogram (if needed)	150	125	125	125	125	125	125-Visit 25-DXA	25	125	25	125	25	150-Visit 25-DXA 25-TVU 25-Biopsy	50 25-DXA 25-TVU 25-PAP 25-Biopsy (if needed)
<b>Treatment Period Year 2</b>				<b>Month 13</b>	<b>Month 14</b>	<b>Month 15</b>	<b>Month 16</b>	<b>Month 17</b>	<b>Month 18</b>	<b>Month 19</b>	<b>Month 20</b>	<b>Month 21</b>	<b>Month 22</b>	<b>Month 23</b>	<b>Month 24</b>	
<b>Unscheduled Visits during the Treatment Period (up to 10)</b>		50	25	25	100	25	25	100 25-DXA	25	25	100	25	25	100 25-DXA 25-TVU 25-PAP 25-Biopsy		
<b>Follow-Up Period</b>																
	Month 1	Month 6	Month 12													
<b>Procedure</b>	50	50 25-DXA	50 25-DXA													
Unscheduled Visits during Follow-Up Period (Up to 2)	50															

If you do not complete the study for any reason, you will be paid for each study visit you do complete according to the schedule above. You will be paid *[depending on site submission form – ‘after each visit’, ‘annually’, ‘bi-weekly’, etc.]*. If you have any questions regarding your compensation for participation, please contact the study doctor at the telephone number listed on page one of this consent document.

### **ClinCard Program**

GreenPhire is a company AbbVie is using to manage subject compensation (payment for participation) for this study. You will be issued a ClinCard by GreenPhire, which is a debit card that your funds are loaded onto. When a study visit is completed, funds will be approved and loaded onto your ClinCard. The funds will be available within approximately 2-5 business days following each completed visit and can be used as outlined in the Compensation for Participation section.

In order for GreenPhire to be able to compensate you via the ClinCard system, GreenPhire needs to collect certain information about you, including:

Name  
Address  
Date of birth

GreenPhire will also request that you provide a Social Security Number (SSN) or Individual Taxpayer Identification Number (ITIN).

Payment received as compensation for participation in research is considered taxable income. No deductions for any state or federal withholding or any other similar taxes will be made and you are solely responsible for reporting such payments on your state and federal income tax returns for paying any tax due on your study payments. If study payments equal or exceed \$600 in any one calendar year, where required, GreenPhire will file a Form 1099 (Miscellaneous Income) with the Internal Revenue Service (IRS) for you on behalf of AbbVie. You will be provided you with a copy of that form.

This information will be collected from you by the study staff during your screening visit and shared with GreenPhire. This information will not be shared with AbbVie or sold, used or distributed for any purpose other than as required to support the compensation process and will be kept completely confidential. Such use, communication, and transfer of your information shall be in accordance with all applicable laws. This information is stored securely and will be deleted from the GreenPhire system up to one year after the study has been completed. After that, data is encrypted and stored on a secure server for seven years.

You will be issued one card for the duration of your participation in the study. If your card is lost, you need to let the study staff know as soon as possible. Your site can replace it for you. You may contact Greenphire directly or your study site with any other questions.

## **Benefits**

The information that is obtained during this study may be useful scientifically and thus be helpful to others with the same condition in the future. You may or may not receive any direct medical benefit from being in this study. Your condition may get better, it may get worse, or it may stay the same.

## **Alternatives to Participation**

You do not have to participate in this study to receive treatment for your condition. Your study doctor can discuss the risks and advantages of these alternative treatment methods with you. In addition, you may discuss our options with your regular health care provider. Alternative treatments include:

- Non-steroidal anti-inflammatory drugs (NSAIDS) (such as Ibuprofen or Naproxen) with or without hormonal therapy (such as oral contraceptive pills): the potential benefit is relief of pain; risks of NSAIDS include stomach upset, inflammation or ulcers; the potential risks of hormonal therapy include irregular menstrual bleeding, nausea, and rarely blood clots or heart attacks.

- Surgery (such as laparoscopy) may be necessary to confirm the diagnosis of endometriosis and remove any visible endometriosis lesions prior to treatment with more aggressive therapies. Following a laparoscopy surgery, more aggressive therapies such as high-dose progestins or GnRH agonists can be used: the potential benefits include pain relief; risks of these medications include hot flashes and bone loss; the potential risks of laparoscopy surgery include complications from having the procedure performed, such as infection, bleeding, and scar tissue formation, possibly requiring treatment.
- Definitive therapy (hysterectomy with oophorectomy – removal of the uterus and ovaries) may be performed if the above treatment options are unsuccessful: the potential benefit is treatment of endometriosis lesions; the potential risks include complications from having a surgical procedure performed such as infection, bleeding, and scar tissue formation, possibly requiring treatment; in addition, hysterectomy with oophorectomy removes the option for future pregnancy.

### **New Information**

You will be informed in writing in a timely manner and will be asked to sign a new (revised) informed consent if new information that could affect your willingness to continue participation in this study becomes available.

### **HIV/AIDS Testing**

Depending on the local laws, you may have to sign a separate consent form before HIV testing can start. The study doctor or study staff will tell you if the results are positive. If required, the study doctor or study staff may report a positive test result to the local health department. The tests are confidential, and the study doctor or study staff will not share your results outside this study unless local law requires it.

### **In Case of Research Related Injuries**

Treatment for injuries that result from the study drug or study procedures is available. Your study doctor will discuss with you the available medical treatment options. You may arrange to have treatment performed by the study doctor or a licensed doctor selected by you.

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If you experience any injuries that result from the study drug or study procedures, the sponsor will provide reimbursement for reasonable medical expenses that are a direct result of such injuries.

AbbVie makes no commitment to provide compensation except as described above. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

In the event of an emergency, seek immediate medical attention.

### **INFORMATION ABOUT CONFIDENTIALITY AND HIPAA AUTHORIZATION**

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

#### **Why is access to my health information being requested?**

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

#### **What information will be collected and used?**

When you are a subject, we will collect health information about you that also includes your name, address, or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law.

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The following are examples of personal health information that may be collected for this study:

- results of tests and procedures such as physical examinations and blood and tissue testing
- your biological samples
- information about your medical conditions and history

**Who will see my protected health information?**

The study doctor and the research team will use your personal health information to carry out this study. By signing this consent, you allow access to your personal health information (including direct access to your medical records at the study site or any other facility where the study is conducted) to the following:

<b>Who may have access:</b>	<b>Purpose:</b>
The sponsor and its representatives	To oversee the study and make sure the information is correct
The study doctor and the research team	To conduct the study and make sure the study information is correct
The FDA and government agencies that regulate research in the US and other countries	To make sure applicable laws are being followed
IRB	To protect the rights and safety of subjects and make sure applicable laws are followed

After the study has been completed, it is possible that your coded data will be used for future research relating to the study drug, your disease, or similar diseases and medical conditions.

**Will you keep my health information confidential?**

We will keep your personal health information as confidential as possible. While it is unlikely that your personal information will be given to others without your permission, we can't control how it is used once it leaves the study site, and it will no longer be covered by the HIPAA Privacy Rule.

Your study records and biological samples will receive a unique code in place of information that can be used to identify you (such as your name or address). The sponsor and the people and companies that it works with on the study will have access to and use these coded records and samples and accompanying data to conduct the research described in this form. However, they will not be able to see the key that links the code to you.

**How long will my personal health information be used?**

Access to your personal health information begins as soon as you sign this form. This authorization expires fifty years after the date that you sign this form, unless you revoke it sooner.

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. There will not be any penalty or loss of benefits to which you are otherwise entitled, but you will not be able to continue in the research study. We will stop collecting information from you, but will still use, analyze, and disclose any information that we gathered before you revoked your permission.

**Can I see my study records?**

You may have the right to see and get a copy of your medical records. However, by signing this informed consent, you agree that you may not get to see your records relating to the study until after the study is over.

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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.

### **Withdrawal/Voluntary Participation**

You do not have to be in this study. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care. If you start the study, you may stop at any time by notifying the study doctor without penalty or loss of benefits. If you want to stop participating in the study for any reason, you must let the investigator know in writing.

The study may be stopped early by AbbVie, the investigator, the IRB or the FDA. You could be withdrawn from the study without your consent, at any time and for any reason.

If you have questions, concerns, information, or complaints about this research study, you may contact the study doctor or the IRB at the phone numbers listed on Page 1 of this Informed Consent Form. The IRB can also provide more information regarding your rights as a research subject.

If you are harmed by the research, or if you have any questions or concerns about the investigational product, contact the study doctor immediately for further instructions.

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When you withdraw from the study for any reason, all study drug(s) and study drug cartons and blister cards, including those unused and empty cartons and blister must be returned to the study site. You will also be asked to return to the study site so that the study doctor may perform a final evaluation, which may include a physical examination and/or laboratory tests.

### **Primary Care Physician / Specialist Notification**

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

\_\_\_\_\_ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

\_\_\_\_\_ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

\_\_\_\_\_ I do not have a primary care physician/specialist.

\_\_\_\_\_ The study doctor is my primary care physician/specialist.

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## Consent

I have read and understand this consent form and its contents were explained. My questions have been answered to my satisfaction. I consent voluntarily to participate in this research study and I will receive a signed and dated copy of this consent form for my records.

I understand that the potential risks of study drug (elagolix) on the unborn child are unknown and therefore I must not get pregnant during the entire time of my study participation, including the Follow-up Period.

I agree to consistently use contraception as described within this consent throughout the Washout (if applicable), Screening and Treatment Periods and through at least the first month of the Follow-up Period of the study.

By signing this consent form, I am not giving up any of my legal rights.

By signing this informed consent form, I am authorizing access, use and transfer of my personal data as described in this informed consent.

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Name of Subject (Printed)

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Signature of Subject

---

Date

I attest that the subject named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

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Name of Person Conducting Informed Consent Discussion (Printed)

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Signature of Person Conducting Informed Consent Discussion

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Date