**ADULT CONSENT / SUBJECT INFORMATION SHEET
TO PARTICIPATE IN A RESEARCH STUDY**

STUDY TITLE: Oral budesonide suspension (OBS) in Adolescent and Adult Subjects (11 to 55 years of age, inclusive) with Eosinophilic Esophagitis: A Phase 3 Randomized, Double-blind, Placebo-Controlled Study

SHORT STUDY TITLE: N/A

PROTOCOL NUMBER: SHP621 - 301

STUDY DRUG: Oral budesonide suspension (OBS)

SPONSOR: Shire ViroPharma, Incorporated (Shire)
300 Shire Way
Lexington, MA 02421 USA

INVESTIGATOR (STUDY DOCTOR): Satinder Gill, MD

CENTER/SITE NAME and NUMBER: Emeritas Research Group, LLC
19455 Deerfield Ave., Suite 201
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1. INTRODUCTION

Before you decide if you want to take part in this research study, it is important for you to understand why the research is being done and what it will involve. Please take time to read this form carefully and discuss the information with friends and family if you wish. Your study doctor or a member of the study team will explain the study to you. Please ask your study doctor or a member of the study team if there is anything that is not clear, or if you would like any more information.

This form describes the purpose, procedures, benefits, risks, and discomforts of the study. It also describes treatments that may be available to you (if applicable) and your right to withdraw from the study at any time.

Before the study starts, you will be asked to talk to the study doctor about your health and family history. It is important for your safety that you answer all questions honestly and completely. You must also tell your study doctor if anything changes during the study.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

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2. PURPOSE

You are being invited to take part in a research study for an investigational drug called oral budesonide suspension (OBS) because you have a condition called Eosinophilic Esophagitis (EoE). In EoE, the esophagus, the tube that connects your mouth to the stomach, contains a type of white cell called an eosinophil which is normally not found there. It is believed that EoE is caused by an allergic reaction to something that is eaten or breathed in. The eosinophils damage the lining of the esophagus and cause it to be inflamed. The inflammation of the esophagus may result in symptoms such as difficulty swallowing or cause food to get caught when you swallow. There are other symptoms that you may experience with EoE such as chest pain. Investigational in this study means that the drug has not been approved by the United States Food and Drug Administration (FDA) for the treatment of EoE.

Budesonide is already approved and used for children and adults in inhaled (breathed in) forms for asthma and in a nasal (nose) spray for hay fever. Children as young as 12 months are treated with inhaled budesonide for asthma. The FDA has also approved a budesonide capsule in adults with lower intestinal diseases (Inflammatory bowel disease). OBS is different from approved budesonide inhaled and capsule form in that it is in liquid form.

The purpose of this study is to help answer the following question(s):

- Can taking OBS decrease the inflammation in my esophagus?
- Can taking OBS help improve my difficulty swallowing? How safe is OBS and what are the side effects that might be related to it?
- How does OBS compare to placebo? A placebo looks like OBS but has no active drug in it.

3. NUMBER OF SUBJECTS / LENGTH OF TIME IN STUDY

You will be in the study about 26 weeks. This study will involve 6 study visits and one follow-up telephone call. About 228 people, aged 11 through 55, at about 60 sites are expected to take part in this study. To date, approximately 148 subjects have received OBS in clinical studies.

4. VOLUNTARY PARTICIPATION

Taking part in the study is entirely voluntary. It is up to you whether or not you want to take part.

If you decide to take part, you must sign and date the consent at the end of this form. Even after signing the consent, you are free to leave the study at any time without giving a reason.

There may be reasons why it would not be good for you to be in the study. The study doctor will ask you about your health and your family history. This information, along with the results of screening tests, will help him/her decide whether or not you can take part in the study.

If you decide not to take part or if you withdraw from the study at a later time, there will be no penalty or loss of benefits to which you are otherwise entitled. The consequences of stopping OBS could lead to a relapse of symptoms of dysphagia (difficulty swallowing) or the increase in eosinophils in the esophagus.

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5. STUDY DRUGS

The study drug(s) used in this study are OBS and placebo. A placebo is a look-alike substance that has no active drug in it. Both OBS and the placebo will be called "the study drug." The study drug will be given to you in the form of a liquid that you will take twice a day, once in the morning after breakfast and once in the evening at bedtime every night for 16 weeks.

Sometimes in a research study, people are put into groups that will receive a different treatment. The results are compared to see if one is better. To keep things fair, each subject is put into a group randomly (like pulling a name from a hat). The chance that you will receive OBS is **2** in **1**. Neither you nor your study doctor will know which study drug you are taking during this part of the research study. If your study doctor needs to know because of a medical emergency, he/she can find out.

At some point during the study, all subjects will receive placebo. Your study doctor will know that you are taking placebo, but you will not be told this information.

6. STUDY PROCEDURES

Study procedures will be performed according to the following visit schedule:

Screening Visit

If you decide to take part in this research study, the study doctor and research team will first need to determine if you are eligible to join the study. This will be done during the Screening Visit and starts when you sign and date this informed consent. The Screening Period may occur over 3-6 weeks and may take place across several days to allow an appropriate time frame in which to complete all procedures and confirm study eligibility. The following procedures will be performed:

- You will be asked for written permission to participate in the study.
- You will be asked specific questions if you are qualified for the study.
- You will be asked questions about your medical history.
- Your blood pressure, heart rate, respirations, and temperature will be taken.
- Your height and weight will be measured.
- You will be scheduled for a test called an esophagogastroduodenoscopy (EGD) or upper endoscopy; using a flexible tube with a camera at the end to look at your esophagus, stomach and part of your small intestine. During this test a doctor will take samples of tissue to examine the lining of your esophagus, stomach and small intestine, also called biopsies. The tissue will be sent to a special doctor to examine under a microscope to determine if you further qualify to continue to the next part of the study.
- You will be given a special device to record your symptoms of dysphagia (difficulty swallowing) and other related symptoms as part of the Dysphagia Symptom Questionnaire (DSQ). You will be trained on how to complete the questionnaire, which will be done every night to determine how your swallowing was for that day. It is very important to complete this recording every night.

- A physical examination will be performed.
- A blood sample for routine blood tests will be taken; about 2.5 teaspoons and you must not eat the night before the sample is collected (for at least 8 hours before the blood sample is taken)
- A urine sample will be collected for routine laboratory tests
- A blood sample for a pregnancy test will be taken if you are a female.
- You will be asked about current use of prescription and non-prescription medications and procedures, including medications taken and procedures done within 3 months prior to the endoscopy for entrance into this study. Note: if you are taking a medication called a Proton Pump Inhibitor (PPI), you must remain on the same dose of the PPI throughout the study, and if you are not taking a PPI, then you must remain off of any PPIs for the duration of the study.

Visit 0

You must not eat the night before this visit (for at least 8 hours prior to the visit)

If you complete the Screening Period and are found eligible to participate in the next part of the study, you will return to the clinic for Visit 0.

- You will be asked how you have been feeling since the last study visit
- You will be asked about any changes to medicines you have been taking
- Your blood pressure, heart rate, respirations, and temperature will be taken.
- Your weight will be taken.
- The study doctor or research staff will check your DSQ dysphagia episodes on your DSQ device and how well you have been following instructions to record this information; the study doctor or his staff will give you back the DSQ device with instructions to continue completion of the DSQ nightly.
- A physical examination will be performed to check if there were any changes from the last visit.
- A blood sample for routine blood tests will be taken; about 2.5 teaspoons and you must not eat the night before the sample is collected (for at least 8 hours before the blood sample is taken)
- A urine sample will be collected for routine laboratory tests
- A urine sample for a pregnancy test will be taken if you are a female
- The study doctor or research staff will give out your study drug and review with you instructions for taking the study drug. Your first dose of study drug will be administered in the clinic during this visit, after you are given breakfast. Beginning before bedtime after this visit, you will take your first dose at home and continue with the twice daily (once in the morning, after breakfast and once at bedtime) dosing schedule.
- You will bring back all bottles of study drug that were given to you at this visit, even if empty at the next visit.

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Visit 1 (Week 4)

You must not eat anything the night before (for at least 8 hours prior to the visit) and do not take your morning dose before this visit.

- This visit must occur between 6:00 AM and 9:00 AM.
- You will be asked about how you have been feeling since the last visit.
- You will be asked about any changes to the medicines you have been taking.
- Your blood pressure, heart rate, respirations, and temperature will be taken.
- Your weight will be taken.
- The study doctor or research staff will check your DSQ dysphagia episodes on the DSQ device and how well you have been following instructions to record this information; the study doctor or his staff will give you back the DSQ device with instructions to continue completion of the DSQ nightly.
- You will be asked to complete two questionnaires regarding your health status and symptoms, and to rate the severity of your dysphagia over the last 7 days.
- A physical examination will be performed to check if there were any changes from the last visit
- A blood sample for routine blood tests will be taken; about 2.5 teaspoons and you must not eat the night before the sample is collected (for at least 8 hours before the blood sample is taken)
- A urine sample will be collected for routine laboratory tests
- A urine sample for a pregnancy test will be taken if you are a female
- A blood sample; about ½ teaspoon will be taken between 6:00 - 9:00 am to check levels of a hormone called cortisol. You cannot take the morning dose of study drug until after this test has been performed.
- You will be given an injection of an artificial form of hormone called ACTH in what is called an ACTH stimulation test. A blood sample will be taken, approximately ½ a teaspoon, at approximately 30 minutes and then at 60 minutes to look at the levels of cortisol found in your body after stimulation with ACTH.
- The study doctor or research staff will give out your study drug and review with you instructions for taking the medication. The next dose of study drug will be given in the clinic during this visit after you are given breakfast. Beginning on the evening of this visit, you will take your next dose at home and continue with the twice daily (once in the morning, after breakfast and once at bedtime) dosing routine.
- You will bring back all bottles of study drug at this visit, even if the bottles are empty, and they will be checked to see how well you have been taking your study drug.

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Visits 2 and 3: **(Weeks 8 and 12)**

You must not eat the night before (for at least 8 hours prior to the visit) and do not take your morning dose before this visit

- These visits must occur between 6:00 AM and 9:00 AM.
- Your blood pressure, heart rate, respirations, and temperature will be taken.
- Your weight will be taken.
- You will be asked about how you have been feeling since the last visit
- You will be asked about any changes to the medicines you have been taking
- The study doctor or research staff will check your DSQ dysphagia episodes on the DSQ device and how well you have been following instructions to record this information; the study doctor or his staff will give you back the DSQ device with instructions to continue completion of the DSQ nightly
- You will be asked to complete a questionnaire and rate how your dysphagia symptom was over the last 7 days.
- A physical examination will be performed to check if there were any changes from the last visits.
- A blood sample for routine blood tests will be taken; about 2.5 teaspoons and you must not eat the night before the sample is collected (for at least 8 hours before the blood sample is taken)
- A urine sample will be collected for routine laboratory tests
- A urine sample for a pregnancy test will be taken if you are a female
- A blood sample; about ½ a teaspoon, will be taken between 6:00 - 9:00 am to check levels of a hormone called cortisol. You cannot take the morning dose of study drug until after this test has been performed.
- If you choose to participate, you will be asked to stay at the clinic one time for a series of blood samples. Samples can be collected on any day between Week 5 (Visit 1 plus 7 days) and Week 16 (Visit 4). Blood samples will be taken at different times of the day up to 12 hours after your morning dose to see how much of the study drug is in your blood and to see how fast the study drug is used by your body; this blood sampling is also called pharmacokinetic sampling. You will be asked to give blood samples; ideally, just before your morning dose and at 30 minutes and 1 hour after your dose. If you can remain in the clinic or return to the clinic, additional samples will be taken at 2, 3, 4, 6, 8, and 12 hours after your morning dose. You may choose to give samples at some of these times after your morning dose but not all times, as your schedule permits. If you provide all of these samples it will be about 9 teaspoons. You will be required to eat a moderate-fat breakfast at the clinic prior to your morning dose. You will not be discontinued from the study if you do not participate in pharmacokinetic sampling.

- The study doctor or research staff will give out your study drug and review with you instructions for taking the study drug. The next dose of study drug will be given in the clinic during this visit after you are given breakfast. Beginning on the evening of this visit, you will take your next dose at home and continue with the twice daily (once in the morning, after breakfast and once at bedtime) dosing routine.
- You will bring back all bottles of study drug at this visit, even if the bottles are empty and the study doctor or research staff will check to see how well you have been taking your study drug.

Visit 4: (Week 16)
You must not eat the night before (for at least 8 hours prior to the visit) and do not take your morning dose before this visit

- This visit must occur between 6:00 AM and 9:00 AM.
- Your blood pressure, heart rate, respirations, and temperature will be taken.
- Your height and weight will be measured.
- You will be asked about how you have been feeling since the last visit
- You will be asked about any changes to the medicines you have been taking
- You will be scheduled for a test called an esophagogastroduodenoscopy (EGD) or upper endoscopy; using a flexible tube with a camera at the end to look at your esophagus, stomach and part of your small intestine. During this test a doctor will take samples of tissue to examine the lining of your esophagus, stomach and small intestine, also called biopsies. The tissue will be sent to a special doctor to examine under a microscope.
- Your DSQ device will be collected and will be checked to see how well you have been following DSQ entry instructions.
- You will be asked to complete two questionnaires which ask about your health status and symptoms, and to rate the severity of your dysphagia in the last 7 days.
- A physical examination will be performed to check if there were any changes since the last visit.
- A blood sample for routine blood tests will be taken; about 2.5 teaspoons and you must not eat the night before the sample is collected (for at least 8 hours before the blood sample is taken)
- A urine sample will be collected for routine laboratory tests
- A blood sample for a pregnancy test will be taken if you are a female
- A blood sample will be taken between 6:00 - 9:00 am to check levels of a hormone called cortisol. You cannot take the morning dose of study drug until after this test has been performed.
- You will be given an injection of an artificial form of hormone called ACTH in what is called an ACTH stimulation test. A blood sample will be taken, approximately ½ a teaspoon, at approximately 30 minutes and then at 60 minutes to look at the levels of cortisol found in your body after stimulation

with ACTH. If this ACTH test is abnormal at the visit, you will be asked to come back to the clinic 6 weeks later for another ACTH test.

- If you want to take part in giving pharmacokinetic samples and did not do this at earlier visit (as detailed above), you may provide these samples at Visit 4 after a dose of study drug in the clinic.
- You will bring back the DSQ device at this visit
- You will bring back all study drug at this visit, even if the bottles are empty and the study doctor or research staff will check to see how well you have been taking your study drug.

Treatment Extension Study

- You will be asked to provide a signed and dated informed consent if you are continuing onto the treatment extension study. Information about this study will be contained in the consent for the treatment extension study and study staff will provide this to you before the extension study will begin.

Visit 5 Follow-up Contact (Week 20)

The Safety Follow Up Contact will only be done if you do not enroll in the Treatment Extension study or if you discontinue at any time during this research study. You will receive a follow-up phone call 4 weeks following your last dose of study drug.

- You will be asked about any changes to the medicines you have been taking and if you have had any new procedures since your last visit.
- You will be asked how you have been feeling since the last study visit.

If an unexpected medical event happens during the study, some tests or procedures may have to be repeated. You may also be asked for additional information, and have additional tests or procedures performed at that time. All pregnancies are to be reported from the time informed consent is signed until 4 weeks after your last dose.

7. STUDY SAMPLES

Blood will be drawn a total of 6 times. The volume of blood that will be taken each time will vary from 2 mL (0.2 teaspoons) to 6 mL (1.2 teaspoons). The total amount of blood drawn in this 22-week study will be about 64 mL (about 13 teaspoons).

If you elect to participate in additional Pharmacokinetic blood sampling at either Visit 2 or Visit 3:
Blood will be drawn a total of 9 times. The volume of blood that will be taken each time will be approximately 5 mL (1 teaspoon). The total amount of blood drawn in this study for Pharmacokinetic sampling will be about 45 mL (about 9 teaspoons)

Your blood and urine samples will be shipped to a central laboratory in the United States and will be stored there until they are tested.

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Your blood and urine samples will be stored for as long as is required to:

- Complete the study
- Publish data related to the study
- Support any regulatory applications for the study drug

This could be for up to about 15 years. Your samples will then be destroyed. The samples you provide will not be used for genetic or DNA testing or for any purpose other than those outlined in this form without informing you first and asking for your permission. You have the right to refuse further testing.

8. YOUR RESPONSIBILITIES

- Visit the study doctor about 6 times over about 22 weeks.
- Take the study drug as instructed by the study doctor and staff
- Bring any unused study drug and the empty containers to each visit, or bring them if you withdraw from the study.
- Keep the study drug out of the reach of children and store the study drug in a safe location in the refrigerator (36-46ºF).
- Supply the names of any medicines you are taking, including vitamins, herbal treatments, and over the counter medicines (such as, cough or cold medicines). The study doctor will let you know which medicines to avoid during the study.
- Bring your DSQ handset with you to every study visit.
- Carry a small card (about the size of a credit card) that lists the study you are taking part in. The card also lists a 24-hour contact telephone number for advice about the study and your treatment.
- Agree to not donate blood products during this study and for 4 weeks after your last dose of study drug.
- Arrange for non-study related medical and mental health care with your primary care doctor.
- Inform the study doctor or staff if you decide to withdraw from the study. You will then be asked to return to your study doctor for a final visit. It is important for your health and safety to have this final visit.
- Use medically acceptable birth control if you are a sexually active female (or become sexually active during the study) and are able to have children. You are considered able to have children if you:
  Have started your period
  AND
  Have not completed menopause and have not had a hysterectomy

  Acceptable birth control for this study includes:
  - Abstinence
  - Surgically sterile male partner
  - Stable oral contraceptives
  - Condoms plus:
    - Intrauterine devices (IUDs),
    - Hormonal contraceptives (oral, depot, patch, injectable, or vaginal ring)

- Double barrier methods (e.g., condoms and diaphragms with spermicidal gel or foam).
- Continue to use birth control for 30 days after your last dose of study drug.
- If you become pregnant during the study or within 30 days after your last dose of study drug, your study doctor will keep in touch with you until the end of the pregnancy. Your study doctor will ask you to provide information about the outcome of the pregnancy. If you have a baby, the study doctor will ask about the health of the baby.

Other Restrictions

You must adhere to the following restrictions for the duration of the study:

- No change in exercise (other than seasonal changes in sports or activities). Intense exercise should be avoided unless part of an established exercise routine.
- No change in diet (liquid diet for 3 days or less are acceptable)
- Short course of systemic steroids (no more than 7 days) are permitted to treat, for example, exacerbation of asthma but cannot be used 4 weeks prior to the final EGD (endoscopy)
- No change in dosing of nasal or inhaled steroids unless your study doctor permits. Seasonal changes in dosing of nasal steroids are permitted for seasonal allergic rhinitis (seasonal hay fever) but should not occur in the 4 weeks prior to study EGDs (endoscopies).
- No change in Proton Pump Inhibitor use
- No use of CYP450 3A4 inhibitors (for example, grapefruit juice and ketoconazole). Your study doctor will be able to give other examples.
- An esophageal dilatation (a medical procedure that enlarges the inside space of the esophagus) during the trial.
- No use of sucralfate since the medication may interfere with how study medication coats the esophagus

Tell your study doctor or nurse right away if you:

- Have any accident or injury
- Have any medical treatment including surgeries, hospitalizations, or emergency hospital visits
- Become pregnant during the study and for 4 weeks after your last dose of study drug.
- Notice any symptoms or illnesses that are new or different
- Notice that your EoE symptoms become worse. If you add or change any medicines you are taking, including vitamins, herbal treatments, or over-the-counter medicines (such as, cough or cold medicines)

9. RISKS AND DISCOMFORTS

Certain side effects have been seen in patients who have taken budesonide in ongoing and previous clinical studies. Some of these side effects include the following:

- Headache
- Diarrhea

- Sinusitis (infection of the sinuses)
- Cough
- Rash
- Constipation
- Nasopharyngitis (stuffy nose)
- Flu
- Sore Throat
- Fever
- Adrenal suppression (abnormal cortisol or ACTH blood tests)

The most common side effect seen with swallowing budesonide is:

- Oropharyngeal candidiasis (also called thrush). This is a yeast infection which causes white patches in the mouth and throat. The mouth and throat may be sore. You should call the study doctor if you have this so you can be treated with the appropriate medicine.
- Esophageal candidiasis is a yeast infection of the esophagus that your study doctor may see when performing the upper endoscopy. If you have this, your study doctor will treat you with the appropriate medicine.

OBS is a corticosteroid. In general, corticosteroids may cause several different side effects, including those in the list below.

- Adrenal suppression or adrenal insufficiency may occur when budesonide gets into your system and turns off the body's usual production of cortisol. Cortisol helps the body maintain a balance and respond to stress. The study doctor will check your adrenal system with the cortisol blood test throughout the study.
- Signs and symptoms of adrenal steroid excess, including:
    - Slowed growth (height)
    - Increased appetite, fluid retention, weight gain
    - Increased blood glucose (sugar) level
    - Skin (hirsutism or abnormal hair growth, acne), muscle, bone, neurologic, blood pressure, lipid (cholesterol), or stomach problems
    - Fat deposits in the face (called "moon face")
    - Mood or energy level changes, feeling anxious, irritability, trouble sleeping
    - Immune system effects such as greater susceptibility to infection or more severe infection

If you develop a significant medical condition or illness, you may need to be treated with an additional corticosteroid temporarily and may result in you being withdrawn from study participation.
Grapefruit juice, as well as several medications, may affect how budesonide is broken down in the body and how much budesonide gets into your body. For this reason, grapefruit juice should be avoided throughout study participation. The study doctor will tell you which medications must be avoided.

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Many patients with EoE have other diseases that require treatment with inhaled, nasal, or skin corticosteroids, such as asthma, allergic rhinitis (stuffy or runny nose), or eczema (itchy red skin rash). If you are taking corticosteroids for another condition, there may be an added risk of corticosteroid side effects with the use of the study drug. It is important that you discuss all medications and nutritional supplements you are taking with the study doctor.

Endoscopy and biopsy are the best methods for monitoring EoE disease activity. Patients with EoE may normally need repeated endoscopies every year. There is a small chance of infection, bleeding, tears, ruptures, or perforations (holes) in your esophagus, stomach, or small intestine. These risks may be increased if you have more severe disease. You may experience mild discomfort due to gagging while the tube is passed down your throat. Aspiration (inhaling of fluid or stomach contents into the lungs) is also a rare complication.

You could also have an adverse reaction to the anesthetic, medication, or tranquilizer used for the endoscopy. These reactions may require treatment. There may be inflammation of the vein through which medication is given. If you have asthma, you may have an increased risk for problems with the anesthesia. An adverse reaction to the medications used for the endoscopy can include:

- Difficulty breathing, respiratory depression
- Low blood pressure
- Slow heart rate
- Excessive sweating
- Spasms in the larynx (voice box)
- An allergic reaction, such as hives and itching or anaphylaxis (a severe allergic reaction). Serious allergic reactions can be life threatening.

After the endoscopy, you may experience pain in your throat or neck, vomiting, black or bloody stools, pain in the chest or abdomen, or fever. You should call the study doctor if you have any problems after the endoscopy.

When blood is drawn, you may feel some discomfort or pain. Possible side effects include pain, bruising, bleeding, inflammation, a blood clot, or infection at the site of the needle stick where blood is drawn. Some people feel lightheaded or may faint when blood is drawn. Precautions will be taken to minimize these difficulties. If numbing cream is used for blood draws, you may have skin irritation or the skin may temporarily turn red, white, or develop a rash. Your study doctor may choose to place a temporary needle into your vein. This decreases the amount of times your veins will need to be punctured during some portions of the study

Other risks in this study include the following:

- The blood pressure cuff may cause discomfort or bruising to the upper arm.
- There may still be risks of using the test and marketed drugs in combination which are unknown at this time.
- There may be a risk to you if you stop taking study drug without notifying the study doctor

There may be other side effects or risks that are not known at this time.

There is a chance you may experience these or other side effects. If you experience any side effects, contact your study doctor.

You could experience an allergic reaction with the use of OBS or other medicines to treat EoE and dysphagia. Allergic reactions are serious and could be life threatening if not treated promptly.

Other medicines you may be taking could have a negative effect with OBS.

There is a chance that the study drug may not help your EOE or that your dysphagia might worsen.

If you receive placebo, your EoE will not be treated for 16 weeks, so it may stay the same or become worse. Your condition may also stay the same or worsen if you receive OBS.

Fasting for 8 hours could cause dizziness, headache, stomach discomfort, or fainting.

The procedures in this study may have risks that are not known at this time.

It is not known whether the study drugs affect pregnant women, unborn children or children of nursing women. Because of these unknown risks, you may not enter the study if you are pregnant, breastfeeding, or trying to become pregnant. A pregnancy test will be done before you enroll in the study. During the study, you should not become pregnant, and you should not nurse a baby. Let your study doctor know right away if you become pregnant

10. BENEFITS

There may be a direct benefit to you if you are taking the active (OBS) study drug and it works as it is intended or your EoE may get better, stay the same, or get worse.Your biopsy results of EoE and symptoms of dysphagia may improve while taking study drug**.** However, if you are on placebo or the study drug does not work, you may not benefit. The results of this study may provide information that could help improve available treatment in the future.

11. ALTERNATIVE TREATMENT

You do not have to take part in this study to receive treatment for your EoE and dysphagia. There may be other alternatives such as being treated with diets that eliminate foods that you are or may be allergic to. Some subjects are treated with corticosteroids or other medications. The study doctor will discuss these options with you.

There are benefits and risks related to these medicines that the study doctor will discuss with you.

Your other option is to not take part in the study.

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12. NEW INFORMATION

New information about the study or OBS that might affect your decision to stay in the study may become available during the study. If this happens, your study doctor will tell you about it in a timely manner and ask you whether you want to continue in the study. You may decide to stop taking part in the study at that time. If you stop taking part, your study doctor will discuss the steps you should follow. If you decide to continue in the study, you may be asked to read and sign a revised consent form containing the new information.

13. COMPENSATION FOR INJURY

If you require immediate medical treatment for an illness or injury that is determined to be a direct result of either taking the study drug or undergoing study-related procedures according to the study plan, reimbursement for medical care will be available. If applicable, you should first submit a request for coverage to your health insurance, government health program, or others providing coverage for health care for the reasonable and customary costs of such treatments. In the event insurance coverage is not available, the study Sponsor will reimburse the treatment provider for the reasonable costs of this treatment.

There are no plans to provide other compensation beyond that which is listed in this informed consent document. 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.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

14. COSTS

You will not be charged for your study drug(s), visits to your study doctor, study-related exams, tests, or procedures.

15. COMPENSATION FOR PARTICIPATION

For your participation in this study, you will be paid for the study visits you complete according to the following schedule: $42.00 per visit. If you elect to participate in the additional Pharmacokinetic blood sampling at either Visit 2 or Visit 3, you will be additionally compensated the following:

2 hours or less, you will be paid $46
4 hours or less, you will be paid $92
8 hours or less, you will be paid $138
12 hours, you will be paid $184

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 not be compensated for telephone visits.

You will be paid after each visit.

**ADULT CONSENT / SUBJECT INFORMATION SHEET
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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.

16. WITHDRAWAL FROM STUDY / END OF STUDY

Your study doctor may decide that it is best for you to stop taking part in the study. If so, he or she will discuss with you the reasons why you may have to leave the study. For example, you may have to leave the study without your consent if you need other treatment, do not follow the study plan, have a study-related injury, or for any other reason. The Sponsor may also end the study at any time.

If you stop taking part in the study or are withdrawn from the study, you will be asked to have medical tests and follow-up to check your health and safety. You will not be able to continue taking the study drug. Your study doctor will talk to you about any medical problems that may happen if you stop taking part in the study.

Any data about you (including your personal health information) that has already been collected will remain part of the study database and may not be removed. This is in order to maintain the reliability of the study's results and to satisfy legal and regulatory requirements.

At the end of the study your study doctor or primary care doctor will discuss with you the options for your continued care.

You may decide to stop taking study drug as part of the study, but still allow the study doctors and study staff to contact you by telephone to find out how you are feeling and if there have been any changes in your health approximately 4 weeks after your last dose.

17. CONFIDENTIALITY AND PRIVACY

If you decide to be in this study, the study doctor and research team will collect, retain, and use personal health information about you to conduct the study. This may include your initials date of birth, medical history, and information from your study visits. This information helps the Sponsor ensure the study data are correct. It will be collected from the time you sign this form until 4 weeks after your last dose of study drug. Information about the results of the study procedures described in this document will also be collected. To protect your identity, the study staff will assign a unique, confidential code number to you. This number helps the study staff identify your research records for this study.

All reasonable steps will be taken to make sure that the personal information in your medical record is kept confidential. However, total privacy cannot be guaranteed. Your personal information may be shared with others if required by applicable law or regulation. In addition, study information collected about you and your medical record (which may include your name) may be directly accessed and copied by the following people:

- The Sponsor and those working for the Sponsor
- Government health and regulatory agencies, such as the FDA
- Independent ethics committees, such as the IRB

**ADULT CONSENT / SUBJECT INFORMATION SHEET
TO PARTICIPATE IN A RESEARCH STUDY**

By signing this consent form you are giving your permission for this to happen.
To the extent permitted by law and regulation, all information that is collected about you and leaves the clinic will have your name, address, contact details, and any other information that could identify you removed so that you cannot be recognized by it.

The Sponsor and those working for the Sponsor will use the results of this study and health information collected during this study. This information will be used to evaluate OBS / EoE and its treatment, to publish or present the study results, and to submit to regulatory or health authorities. The Sponsor may also use the information about the results of this study for other research purposes which may include:

- Reviewing the safety or effectiveness of OBS;
- Conducting performance reviews of OBS or retrospective reviews of the study or the study data;
- Evaluating other products or therapies for patients;
- Developing a better understanding of the disease; or
- Improving the design and efficiency of future clinical trials

This information will not reveal your identity. The study data may be transferred to other countries for processing, including countries not covered by data protection legislation. The laws of your state may provide further protection.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your personal data, including any sensitive personal data, will be retained for as long as is required to:

- Complete the study,
- Publish data related to the study,
- Support any regulatory applications for the study drug.

You may cancel your permission for the researchers to collect or use your personal health information. This can be done at any time by writing to the study doctor. If you cancel your permission, you will not be able to stay in the study. The study staff will stop collecting medical information about you. You have the right to require that any previously retained samples are destroyed. They will continue to use the information already collected in order to maintain the reliability of the study's results and to satisfy legal and regulatory requirements. However, the law does require that any side effects you may suffer are documented and reported.

Regulations may allow you to have access to your study-related personal health information. You have the right to ask your study doctor for updated information on what data he/she has recorded for you and you can request corrections of any errors in the recorded data. However, you will not have access to your study-related personal health information until the study is complete.

Your primary care doctor should be informed of your involvement in this study. If you do not wish your primary care doctor to be informed of this, please notify the study staff or your study doctor.

**ADULT CONSENT / SUBJECT INFORMATION SHEET
TO PARTICIPATE IN A RESEARCH STUDY**

Results of the study may be provided to the study doctor at the end of the study.
A more detailed explanation of how health data about you will be used and shared is included in a separate form. If you decide not to sign this separate form, you will not be able to participate in the study.

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.

18. SOURCE OF FUNDING

The study is being conducted by the Sponsor, Shire ViroPharma Inc. Your study doctor (or his/her institution) is being paid by the Sponsor to cover expenses and professional services to conduct this study.

19. CONTACTS FOR QUESTIONS

If you have questions about the research study, contact the study doctor at the telephone number listed on page one.

If you have questions about a research-related injury or medical issues, please contact the 24-hour number listed on page one.

If you need emergency medical treatment, contact the nearest available emergency medical center.

If you have any questions relating to privacy, ethical issues, potential conflicts of interest of the study doctor, or your rights as a research subject, you should write to 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.

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.

**ADULT CONSENT / SUBJECT INFORMATION SHEET
TO PARTICIPATE IN A RESEARCH STUDY**

CONSENT

I understand that responsible individuals from the Sponsor, those working for the Sponsor, study staff, ethics committees, and health and regulatory authorities, may review sections of any of my medical notes and data collected during the study where it is relevant to my taking part in this research. I permit these individuals to have access to my records.

I understand that my taking part in this study is voluntary. I am free to withdraw at any time, without giving a reason. This will not affect my medical care or legal rights.

I understand that I may have to leave the study without my consent if I need other treatment, do not follow the study plan, have a study-related injury, or for any other reason.

I have read and understand the adult consent/subject information for the above study and have had time to consider the information. I have had the chance to ask questions and have had these questions answered to my satisfaction. I understand that I will receive a signed and dated copy of this consent form.

I agree to take part in the above study.

I hereby consent to participate in this study:

_____
Name of Subject (Print)

_____ _____
Signature of Subject Date

_____
Name of Person Conducting Consent Discussion (Print)

_____ _____
Signature of Person Conducting Consent Discussion Date

_____
Name of Witness* (Print)

_____ _____
Signature of Witness* Date

***If the subject is unable to read or write, an impartial witness is required to document that the participant understands the study and the consent process, and has consented to participate. A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" (fingerprint or X where legally accepted) on the consent document, as long as there is an impartial witness.**