

# **ALISTA™ Clinical Study**

## ***Fact Sheet***

A clinical study is a research method used to test a drug or medical device in humans after it has demonstrated a positive result in the laboratory and/or in animal studies. The U.S. Food and Drug Administration (FDA), which oversees human drug testing to protect the public, closely monitors studies. The goal of each study is to answer scientific questions and to find better ways to prevent, diagnose and treat disease. Clinical studies are the safest and quickest way to find new drugs/treatments that are safe and effective.

New clinical studies are being conducted throughout the U.S. to evaluate the safety and efficacy of ALISTA, a topically applied product for the treatment of women with female sexual arousal disorder (FSAD) as a result of undergoing a hysterectomy. As there are no medications currently approved by the FDA for the treatment of diminished sexual arousal, these clinical studies are an important step in the development of new therapeutic options.

### **About this trial:**

#### **What criteria must a woman meet to be considered for enrollment in this trial?**

Women may be able to participate if they meet the following criteria:

- ✓ Are 21 to 60 years of age
- ✓ Have undergone a hysterectomy (with or without oophorectomy)
- ✓ Have a primary diagnosis of FSAD
- ✓ Are in a stable, monogamous, heterosexual relationship

#### **What criteria must the woman's partner meet to be included in this trial?**

Sexual partners of study subjects must:

- ✓ Be males who are 21 years of age or older
- ✓ Provide written informed consent
- ✓ Agree to a private screening interview with study staff
- ✓ Desire treatment of their partners' FSAD
- ✓ Be sexually functional or only minimally impotent

#### **How many sites will be conducting this study?**

Women will be enrolled at approximately 40 study sites in the U.S.

#### **How long will the trial last?**

Each subject will participate in this trial for approximately eight months.

## **What are the clinical endpoints of this study?**

A clinical endpoint, or data measurement tool, determines if the study treatment is effective. The primary clinical endpoints in this study are changes in the percentage of sexual encounters that are satisfying to patients and changes in the number of satisfying encounters that patients experience over time. These outcomes are recorded by patients in diaries during their study participation.

## **How is the investigational treatment administered?**

The investigational treatment consists of a liquid solution that is applied to the genitalia prior to sexual activity using a sponge type applicator. The active ingredient in the treatment is alprostadil, a synthetic version of prostaglandin E1 (a dosage of 400 mcg is administered).

## **What is alprostadil?**

Alprostadil is a synthetic version of prostaglandin E1 (PGE1), a naturally occurring chemical compound that dilates blood vessels. When applied directly to the genitals, this agent works by increasing blood flow to the genital tissues, allowing for greater sensitivity and sexual arousal. Prostaglandin E1 is found in high concentrations in male semen and is well tolerated by women. The safety profile of this compound is well established having been first approved for the treatment of blue baby syndrome and for the treatment of erectile dysfunction in men.

## **What is the benefit of participating in this trial?**

Participants in this study will receive a medical evaluation and the investigational medication free of charge. In addition, participants may also help to make this medication available to women in the future for the treatment of FSAD. Although treatments may improve the ability to become sexually aroused, not all patients participating in this study will receive active drug, and the active drug may not be effective for all who do receive it.

## **About clinical studies:**

### **Phases**

When a drug/treatment enters clinical studies, it progresses through three phases before becoming eligible for FDA approval:

- PHASE I:** The drug is tested in a small group of (usually) healthy subjects to determine safety, appropriate dosage and route of administration (i.e. by mouth, injected into the blood or applied topically)
- PHASE II:** A larger group of patients is tested to determine the drug's safety and whether it has a positive effect in treating the targeted disease or medical condition
- PHASE III:** The drug is tested in a large group of people to confirm its safety and effectiveness

## **Placebo-Controlled Study**

- A placebo is a treatment that does not contain the active drug ingredient
- Placebos are used in clinical studies to provide a control group to compare the active treatment's safety and effectiveness
- One group of patients will be given the active medication while the control group will be given a placebo; neither the participants nor trial staff will know who is receiving which treatment. This is referred to as a "double-blind" trial
- Double-blind studies are performed so neither the patients' nor the doctors' expectations about the experimental drug can influence the outcome of the study

## **Institutional Review Board (IRB) and Study Participant Protection**

- An IRB is an independent committee of scientists, physicians, community advocates and others from a community that meet to review and monitor a hospital's or research institution's clinical studies to ensure participant safety
- The IRB ensures that volunteers are exposed to the minimum possible risk and that the risks associated with the trial are reasonable in relation to the expected benefits
- Any institution conducting research involving human subjects is required by federal regulations to have IRB review and approval of the research activity
- If participants experience unexpected/severe side effects or if evidence exists that the patient risks are outweighing the benefits, the trial will be stopped and no one else will receive the medication

## **Informed Consent**

- A process required by the FDA that ensures complete information about a clinical study is provided to and acknowledged by the participant
- The FDA requires that all trial volunteers be told:
  - That the trial involves research of an unapproved drug or device
  - The purpose of the trial
  - The procedures involved and expected length of the trial
  - What happens during the trial and which parts are experimental
  - Any possible risks and benefits of the trial
  - Other treatments that might be considered
  - Assurance that their identity will remain confidential
  - Patients have the right to discontinue participation in the clinical trial at any time, without the loss of any benefits that they would otherwise receive