skylight™

HOT FLASHES NIGHT SWEATS

These clinical studies are evaluating a non-hormonal investigational drug for moderate to severe hot flashes.

Advancing Treatment Options Through Research

Hot flashes and night sweats (also called vasomotor symptoms or VMS) are one of the most common complaints among women experiencing menopause. These symptoms can be disruptive and have a negative effect on your quality of life.

While current treatment options, such as hormone replacement therapy or selective serotonin reuptake inhibitors (SSRIs) may offer some relief, they can also be associated with unpleasant side effects and long-term safety concerns.

Now, a different approach to managing these unpleasant symptoms is being investigated. New research suggests that menopause-related hormone decreases may increase the brain's sensitivity to a specific peptide, which is thought to trigger hot flashes. The investigational drug – fezolinetant – was developed in response to this scientific research.

Fezolinetant is designed to work in a way that is different from other currently approved medications, such as hormone replacement therapies and SSRIs, by targeting the signals that affect the way your body regulates temperature. By blocking a specific peptide, fezolinetant can potentially reduce the frequency and severity of hot flashes associated with menopause.

Introducing the Skylight Studies

The Skylight Studies are evaluating the effectiveness and safety of fezolinetant, an oral, non-hormonal investigational drug designed to potentially reduce the frequency and severity of hot flashes associated with menopause.

If you are experiencing moderate to severe hot flashes and choose to take part, your study participation will last 52 weeks. Each study consists of four parts:

- → Screening Visit
- → 12-Week Double-Blind, Placebo-Controlled Study Treatment Period
- → 40-Week Non-Controlled Extension Study Treatment Period
- → Safety Follow-up Visit

Who can take part in the Skylight Studies?

Only a study doctor can determine if you meet all eligibility criteria. To learn more or to schedule a Screening Visit to see if you can take part, please contact the study doctor who provided this information to you.

Consider Participating in the Skylight Studies

We are currently enrolling women in the Skylight Studies. The study team is available to answer any questions you may have about the study or what your participation involves. To see if you can take part, please schedule a screening visit.

FREQUENTLY ASKED QUESTIONS

What is a clinical study?

Clinical studies such as these play an important role in discovering potential new treatment options. By choosing to participate in the Skylight Studies, you are helping to advance scientific knowledge of an investigational drug for moderate to severe hot flashes associated with menopause.

Clinical studies are designed to test the safety and effectiveness of investigational drugs and must follow rules and guidelines. Clinical studies are necessary to determine whether or not potential treatments will be approved for future use.

All clinical studies must be approved and monitored by an Institutional Review Board or Ethics Committee; whose role is to protect study participants. All personal information provided is kept entirely confidential.

As with all clinical research, your participation in the Skylight Studies is voluntary and you may leave at any time. There are risks and potential benefits involved that will be explained to you in more detail if you choose to participate. Your decision to participate (or not) in this study will in no way affect the medical care that you receive now or in the future.

What is informed consent?

Every eligible study participant takes part in the informed consent process, which will explain the following in detail: the purpose of the study, the study design and procedures, what is expected of a study participant, the possible benefits and risks of participation, and how your personal information is used and protected.

This process ensures that potential participants can have their questions answered and understand everything involved in the study to help them make an informed decision about participation. Participation in any clinical study is completely voluntary, and you may stop at any time and for any reason.

If you choose to participate, all study-related information will be clarified in the Informed Consent Form (ICF), which the study doctor will provide and explain to you. You will be asked to review and sign the ICF to indicate that you are willing to take part in the study.

Who is conducting this clinical research study?

The Skylight Studies are sponsored by Astellas Pharma Global Development, Inc. (APGD) and is being conducted by doctors and medical specialists at study locations across North America, the United Kingdom, and Europe.

What is the investigational drug?

The study drug being investigated is called fezolinetant. It is designed to determine whether it helps reduce the frequency and severity of hot flashes associated with menopause by targeting the signals that affect the way your body regulates temperature.

What are the risks involved in participating in this study?

As with any medication, there may be side effects associated with the investigational drug (fezolinetant), and it is possible that it may not work for some participants. If you are eligible and decide to participate, the study staff will discuss the risks and potential benefits with you in full detail.

Why would someone consider participating in this clinical study?

Clinical studies are essential to the development of new treatment options for women experiencing moderate to severe hot flashes associated with menopause. By choosing to participate in the Skylight Studies, you are assisting the medical community in researching the safety and effectiveness of fezolinetant, which may provide relief for hot flashes associated with menopause.

Throughout the Skylight Studies, eligible participants will receive the following at no cost:

- All study-related drugs.
- Close care and monitoring from a team of medical professionals.
- An electronic diary to track the frequency and severity of your hot flashes.

Depending on the policies of your study site, reimbursement for your time and travel costs may also be available

Consider Participating in the Skylight Studies

We are currently enrolling women to take part in the Skylight Studies. The study team in your area is available to answer any questions you may have about participation in this clinical study. To learn more or to schedule a Screening Visit to determine study eligibility, please contact the study doctor who provided you this information.