Why is this study important?

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COPERNICUS GROUP IRB

Considering alternative treatment options for your **Glaucoma** or **Ocular Hypertension?**

Due to the impact vision loss has on a person's quality of life and how common glaucoma and ocular hypertension are, it is important to find more treatment options for these conditions. This study is evaluating how the investigational drug trabodenoson combines with latanoprost to provide additional lowering over latanoprost alone.

Studies like this one are used by pharmaceutical industries to learn more about investigational drugs before they are made available to the public. The results of this study will provide them with more information about the investigational drug and how it may be combined with the most common drug latanoprost. By taking part in this study, you will be making an important contribution to ocular hypertension and primary open angle glaucoma treatment research.

To learn more about this study, please contact:

<<Contact Name>>
<<Contact Number>>

INOTEK PHARMACEUTICALS

Learn more about this study of an investigational eye medication being evaluated for its ability to lower pressure in the eye.

Are you or someone you care about being treated for **ocular hypertension** or **primary open-angle glaucoma**?

A contributing factor in both conditions is elevated intraocular pressure (IOP). When abnormally high IOP occurs inside the eye, it may eventually damage the optic nerve and reduce a person's vision potentially leading to blindness in severe cases. Therefore, it's important for patients to keep their IOP under control. Doing so, doctors believe, aids in the treatment of ocular hypertension and primary open-angle glaucoma by slowing down the damage to the optic nerve and vision.

While there are approved medications available to help reduce elevated IOP, there is no single IOP medication that works well for every patient, and having more options is important to treating patients.

As a result, doctors are looking for alternative treatment options for lowering the pressure and new drugs that can be combined with other established drugs.

In this clinical research study, fixed dose combinations of trabodenoson and latanaprost are being evaluated.

Trabodenoson is an investigational eye drop, which was found to increase the outflow of fluid from the eye and lower intraocular pressure in a phase 2 study in patients with OHT or POAG.

Latanoprost is an approved medication for the treatment of glaucoma and ocular hypertension.

Who is eligible to participate in this study?

To pre-qualify for this study, you must be:

- 18 years of age or older
- Diagnosed with ocular hypertension or primary open angle glaucoma

All study-related visits, tests, and drugs will be provided to you at no cost. In addition, reimbursement for study-related travel may be provided.

What will happen during this study?

Before you join the study, you will be screened for eligibility. If you are found to be eligible, and you agree to participate, you will be asked to stop taking certain eye medications.

Based on the eye medications you may be taking, you could enter a Washout Period, which is used to allow all traces of your eye medications to be eliminated from the body. The Washout Period may last between 4 and 39 days.

After the Washout Period, you will begin a Placebo Run-in Period that will last 5 to 9 days. The purpose of this period is to prepare you and your eyes for the required eye drop dosing during the study and to collect information on your eyes prior to receiving one of the study drugs. The eye drops used during the Run-in Period are placebo drops (like salt water) which do not contain any active drug.

If you complete the Run-in Period, you will begin the Treatment Period. You will be randomly assigned (like the flip of a coin) to receive 1 of 5 study treatments, which are all eye drops that will be taken twice per day. The study treatments are either a combination of the investigational drug trabodenoson and latanoprost or latanoprost alone.

You, your study doctor, and the study staff will not know which study treatment you are receiving. This is to prevent any opinions about the study drugs from affecting the results of the study (also known as bias). However, in the event of an emergency, this information can be provided.

No matter which study treatment you receive, you will put one drop in both eyes in the morning and evening. The study treatment will last a total of 8 weeks.

Throughout the study, you will be asked to visit the study center 8 times so that doctors and study staff members can evaluate your health and progress. Your maximum total participation will last 128 days.

What are the risks and benefits related to this study?

As with any clinical research study, your condition may not improve. The investigational drug has been studied before and was generally safe and tolerable, but it is possible you could experience a side effect during this study.

You will be closely monitored during this study. Researchers for this study designed a protocol (study plan), which explains all of the study procedures in detail. An independent review board (IRB) responsible for participant safety reviewed and approved this protocol.

What if I have questions?

The study staff is always available to answer any questions or concerns about the study or the study drugs.