If you are interested in learning more about an investigational treatment option, talk to your study doctor about the VISTAS Study.

Am I Eligible?

To participate in this clinical research study, you must meet a set of qualifying criteria. Some are listed here. A study representative will be able to give you more information to see if you or your loved one qualifies.

You or a loved one may qualify if you:

- ARE 18 OR OLDER IN AGE
- HAVE A CONFIRMED DIAGNOSIS OF LARGE DUCT OR SMALL DUCT PSC
- ARE CURRENTLY AFFECTED BY CHOLESTATIC ITCH CAUSED BY PSC

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Frequently asked questions.

WHY IS THIS CLINICAL RESEARCH STUDY BEING CONDUCTED?

The VISTAS Study is seeking adults with PSC to learn if volixibat might be a safe and effective treatment option for cholestatic itch, and whether volixibat may improve markers associated with PSC disease progression.

WILL COMPENSATION BE PROVIDED?

No, unless specified by your study site. However, you may be reimbursed for study-related expenses, such as travel for study participants. All study-related treatments, medications, office visits, procedures and examinations are provided at no cost to participants or their families.

IS STUDY PARTICIPATION VOLUNTARY?

Yes! While it is important to remain in a clinical research study after enrollment, you have the right to cease your participation at any time for any reason. If you do decide to leave the study, speak with the study doctor first to discuss how leaving the clinical research study may affect your health, along with other treatment options.

HOW CAN I LEARN MORE?

To learn more, please talk to your study doctor for more information. You can also visit www.clinicaltrials.gov using the study ID, VLX-301, and/or the study name, VISTAS.

vistas

A Clinical Research Study for Primary Sclerosing Cholangitis (PSC)

Thank you for considering enrolling in the VISTAS Study, a clinical research study for adults with PSC.

What are clinical research studies?

Through clinical research, scientists and doctors are able to determine whether a new medical strategy, drug, or device is safe and effective for people. New treatments are only discovered through clinical research studies, which rely on potential study participants, like you, to evaluate their safety and efficacy. Participation in clinical research studies is voluntary. If you take part, you may withdraw from the study at any time.

What is investigational medication?

Investigational medications are not yet approved for sale by any government health authorities such as the FDA, EMA, MHRA, TGA or Medsafe. A clinical research study is used to test the safety and efficacy (or effectiveness) of an investigational medication.

What are the stages of development for a new medication?

Clinical trials are important to help determine if new medications are both safe and effective. Typically, investigational medications must pass through three stages or phases of development in clinical trials, called Phase 1, Phase 2, and Phase 3. Results from each phase must be properly assessed before medications can be approved for use in the general public. The VISTAS Study is a Phase 2 study, which focuses on learning more about the use of the study medicine, volixibat, for the treatment of cholestatic pruritus (itching) associated with PSC. Information from VISTAS may also help scientists understand whether volixibat may also help improve markers of PSC disease progression, when given long term during the OLE portion. Volixibat has already been studied in >400 patients in earlier Phase 1 and Phase 2 studies, in patients with other conditions other than PSC.

What will happen during this study?

The study consists of a screening period, a "Core Study" treatment period, and a follow-up period. The study will last at least 32 weeks with the potential option to participate in an open-label extension (OLE) study, in which participants are guaranteed to receive volixibat.

screening period

First, you must be evaluated to determine if you meet the criteria for entry into the study. During the screening period, study staff will assess your itch and your health and determine if you are eligible for the VISTAS Study. Upon entering the screening period, you will be asked to complete an eDiary once each day for the duration of your participation in the study.

treatment period

If you qualify for the study, you will enter the treatment period. During this time, you will take study treatment as instructed and will have appointments where the study team will perform study-related tests and procedures and ask questions about your health. During the treatment period, you will be asked to continue completing the eDiary once each day.

Whether you are treated with the investigational medicine will be determined randomly. You will receive standard medical care for PSC from an experienced medical team, plus oral, twice-daily dosing with the investigational medicine (volixibat) or placebo.

extension period

After successful completion of the study treatment period, you will be able to continue participation, if eligible, in an extension period called the Open-Label Extension (OLE) study, where you will be guaranteed to receive volixibat and continue to be closely monitored by your doctor for up to 2 years (or the duration of the OLE that has been planned). If you choose not to participate in the OLE study, you will have a follow-up visit 4 weeks after completing the study treatment period to close out your participation in the VISTAS Study. If you are a part of the OLE study, your follow-up will be four weeks after the completion of the OLE study treatment period.