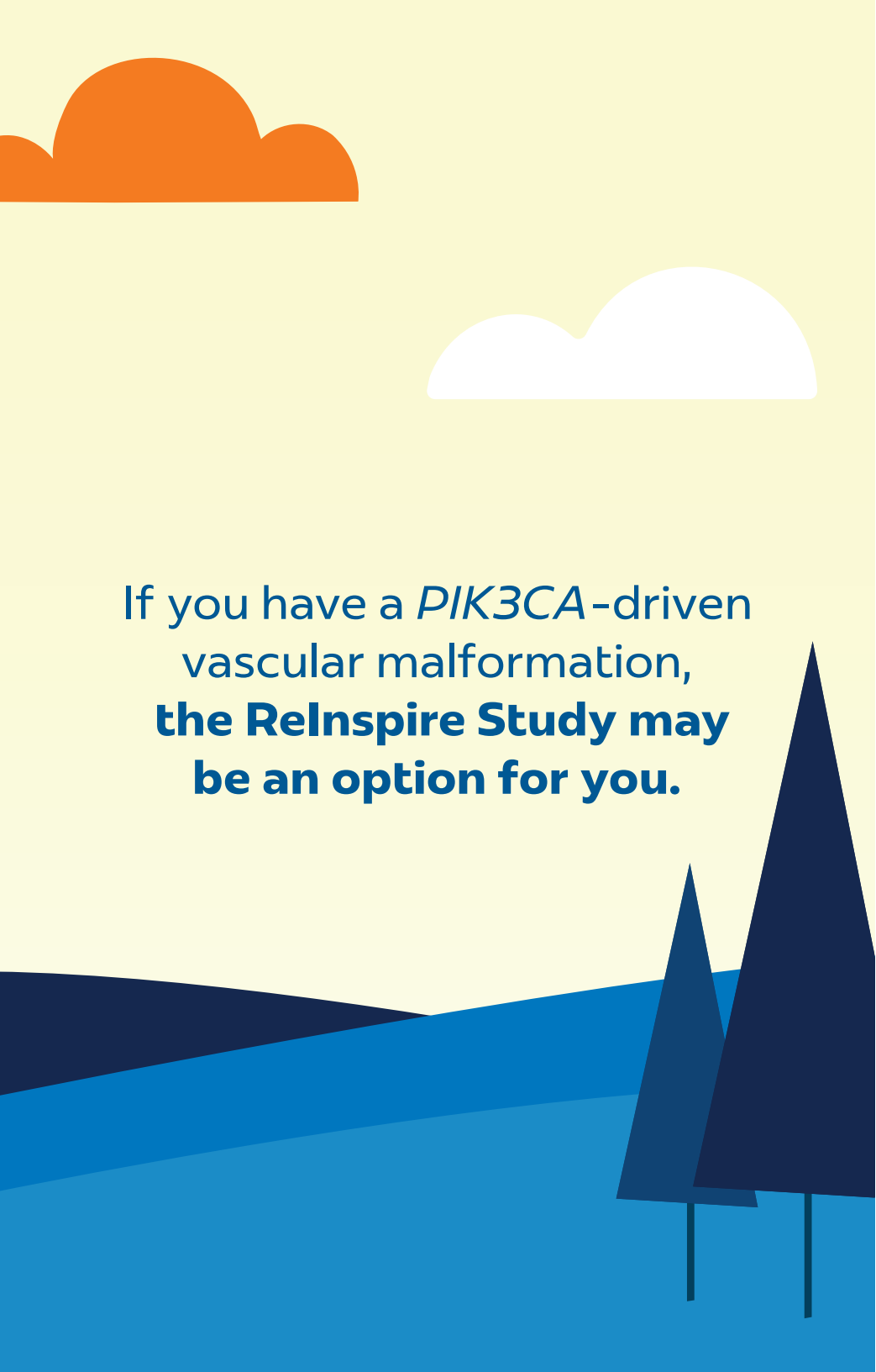




Could a more
selective treatment
mean brighter days?

Consider clinical research for individuals with *PIK3CA*-driven vascular malformations including Lymphatic Malformations and *PIK3CA*-Related Overgrowth Spectrum (PROS).



If you have a *PIK3CA*-driven
vascular malformation,
**the ReInspire Study may
be an option for you.**

What Are *PIK3CA*-Driven Vascular Malformations?

PIK3CA-driven vascular malformations may include lymphatic malformations and *PIK3CA*-related overgrowth spectrum (PROS). PROS consists of syndromes such as Klippel-Trenaunay, CLOVES, FAVA, MCAP, and more.

This clinical research study is designed to learn about a potential new treatment option for *PIK3CA*-driven vascular malformations. These types of malformations are caused by mutations or changes in the *PIK3CA* gene, which create a malfunctioning form of the protein PI3K α . When mutated, PI3K α can cause vascular malformations and/or overgrowths throughout the body, along with other symptoms. Although everyone has a unique experience, common symptoms include pain, swelling, infections, and impaired physical functioning, which can significantly impact quality of life.

About the ReInspire Study

The ReInspire Study is evaluating an investigational study drug for the treatment of *PIK3CA*-driven vascular malformations. "Investigational" means that the study drug has not yet been approved by the US Food and Drug Administration (FDA) or any other regulatory agency, such as the European Commission in the EU, and is not available outside of a clinical research study.



About the Investigational Study Drug

The study drug being evaluated is called RLY-2608. It is a drug taken orally that is designed to specifically hinder the mutated PI3K α protein that can cause *PIK3CA*-driven vascular malformations. By selectively targeting the mutated proteins and limiting impact on the non-mutated proteins, the study drug aims to reduce side effects and provide more effective treatment over non-mutant-selective therapies.

Study Parts

The ReInspire Study is made up of three parts. Participants will only be enrolled in one part.




Part 1 will determine the dose(s) of RLY-2608 that provides the most benefit with the least side effects.

Part 2 will continue to collect data on the safety and effectiveness of the recommended dose(s) found during Part 1.

Part 3 will open after Parts 1 and 2 and will further confirm the treatment effect of the drug.

Study Design

To enter the study, you will first need to give your consent, or permission, by reviewing and signing an informed consent form. No matter what part of the ReInspire Study you are enrolled in, your participation will consist of three periods:

-  **Screening:** A study doctor will evaluate you to see if the study is a good match.
 - During this period, you will have a single or multiple screening visits to complete the tests or procedures such as a physical exam, routine labs, MRI, and others, to determine if you meet the requirements to participate.
-  **Treatment:** If the study is a good match for you and you agree to take part, you will begin taking the study drug and attend monthly study site visits. Your treatment period will last as long as you and your doctor determine it is in your best interest, or until the study ends.
-  **Follow-up:** If you stop taking the study drug, your study doctor will continue to monitor your health for a period of time.

Who Can Participate?

To participate in this study, you must:

- Have a diagnosis of a *PIK3CA*-driven vascular malformation, such as lymphatic malformation or PROS (includes syndromes such as Klippel-Trenaunay, CLOVES, FAVA, MCAP, and more)
- NOT have another genetic driver that is known to cause your disease

Additional requirements will apply. Ask your doctor if the ReInspire Study is right for you.

To learn more, visit ReInspireStudy.com or email clinicaltrials@relaytx.com.



What You Should Know About Clinical Research Studies

Clinical research studies, also called clinical trials, aim to answer specific questions about how drugs work in the participants who take them. You should feel fully informed about what to expect from your participation in a clinical research study.

Researchers use clinical research studies to:

- Learn about the safety and effects of investigational medicines
- Help find new ways of using certain medications
- Identify new treatment options
- Answer specific health questions

Participation in any clinical research study is voluntary (your choice). The clinical research study team will inform you of the potential risks and benefits of participation, as well as possible side effects. To make an informed decision, talk to your healthcare providers about any questions you may have.

All clinical research studies are:

- Developed to protect the rights, safety, and well-being of participants
- Conducted according to strict scientific and ethical principles
- Reviewed and approved by an institutional review board (IRB) or ethics committee (EC)