

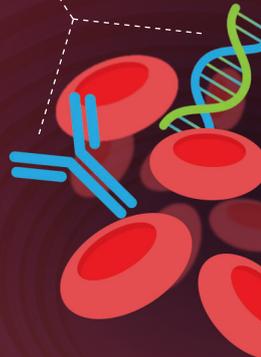
WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to learn more about the effects of an experimental combination treatment of **pozelimab** and **cemdisiran**, to see how well-tolerated and effective they are compared to an already approved treatment, ravulizumab. These study drugs are known as “complement inhibitors.”

Pozelimab and **cemdisiran**

may work together to reduce the levels and activity of C5, a protein involved in the destruction of red blood cells in people with PNH.

Ravulizumab is a drug that blocks the activity of C5 and is approved for the treatment of PNH in some countries.



WHO IS THE STUDY FOR?

This study is for adults 18 years of age or older who:

- Have a confirmed diagnosis of PNH.
- Have active disease (≥ 1 sign or symptom of PNH or history of blood transfusion due to PNH within the last 3 months).
- Are new to treatment with a complement inhibitor or have not received complement inhibitor treatment of eculizumab in the last 3 months or ravulizumab in the last 6 months.
- NOTE: Additional study criteria apply.

THANK YOU FOR CONSIDERING THE ACCESS-1 STUDY.

Clinical studies are research studies done to learn more about how the body responds to a certain treatment and whether that treatment works for a specific disease or medical condition.

You may or may not directly benefit from being in this study, but information learned may help others with PNH in the future.

Being in a clinical study is voluntary and you can stop participating at any time.



REGN - ACCESS-1 Study - Trifold - 16-Aug-2022 - English (Master) - V2.0

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UNDERSTANDING THE



For adults with Paroxysmal Nocturnal Hemoglobinuria (PNH) who are new to treatment* or have not received complement inhibitor treatment of eculizumab in the last 3 months or ravulizumab in the last 6 months.

*Treatment with a complement inhibitor.

REGENERON

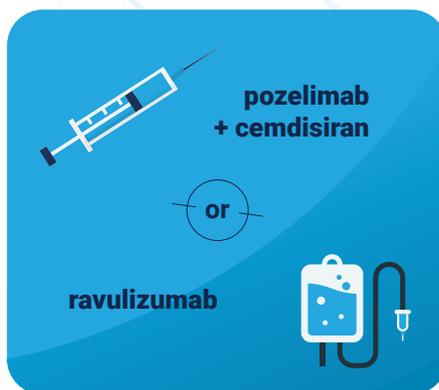
WHAT HAPPENS DURING THE STUDY?

If you agree to join the study, you will first have some tests and health checks to see if you are eligible (**Screening Period**). You will also be required to be up to date with certain vaccinations in order to lower your risk of infection.

If eligible, you will enter the **Treatment Period**, which lasts 26 weeks. During this period, you will have study visits to check on your health. Home healthcare or virtual visits may be available for certain visits.

WHAT STUDY TREATMENT WILL I RECEIVE?

You will be randomly assigned to receive either the study drug combination (pozelimab + cemdisiran) or another treatment called ravulizumab.



HOW ARE THE STUDY DRUGS GIVEN?

Ravulizumab is given as an infusion, which means slowly through a needle into a vein in the arm.

Pozelimab + cemdisiran are injected under the skin.*

(The study staff may be able to train you or a caregiver on how to give your injections at home).

You may also take **antibiotics** every day while receiving the study drug combination and for 1 year after your final dose to help lower the risk of infection (based on the advice of your doctor).

**The first dose of pozelimab is given as an infusion.*

WHAT KIND OF TESTS AND HEALTH CHECKS WILL I HAVE?



Blood tests



Heart activity (electrocardiogram)



Physical exam



Questionnaires



Urine test



Vital signs



Weight

You will not have all of these tests at each visit. There may also be some additional tests. Talk to the study doctor for more information.

More information about this study can be found in the full Informed Consent Form. Please ask your doctor if you have any questions.

To learn more about the ACCESS-1 Study, contact

at _____