Do You Have Wet Age-Related Macular Degeneration?

ATMOSPHERE™

AAV Gene Therapy Clinical Trial with RGX-314

ATMOSPHERE Study. Please refer to the Information and Consent Form document for full details.

REGENXBIO®

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What is RGX-314?

REGENXBIO's gene therapy product candidate, RGX-314, is designed to deliver a gene to the cells of the retina.

RGX-314 contains a gene that may tell the body to make a protein that blocks the eye from releasing VEGF (the protein is an anti-VEGF) and stops fluid from building up.

It may potentially allow the cells in your retina to make their own anti-VEGF.

This treatment may decrease the need for future treatment of wet AMD and help prevent further vision loss.

Safety

This clinical trial is a Phase 2b/3 study, meaning REGENXBIO's AAV gene therapy, RGX-314, has been tested in earlier studies in humans and animals.

RGX-314 is an investigational drug, and has not yet been approved by the FDA. This study is designed to test the safety and tolerability of AAV gene therapy for treatment of wet AMD.

What is a clinical study?

A clinical study is carefully conducted research that helps us find potential new treatments, new versions or new uses of approved treatments.

Thousands of people all around the world take part in clinical studies every year. Without them, new treatments simply cannot be developed.

All collected results are submitted to various regulatory bodies who evaluate whether the potential treatments are both safe and effective.

In this particular clinical study, the purpose is to evaluate whether two different doses of RGX-314 help improve or preserve vision compared to Lucentis®.

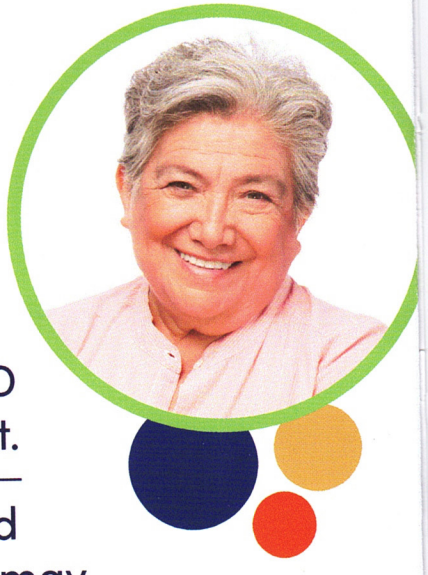
This study is important as it may provide valuable information to researchers and help others with wet AMD.

Who can participate?*

Females or Males between the ages of 50-89 years old, diagnosed with **neovascular (wet) Age-related Macular Degeneration (AMD).**

People previously treated with anti-VEGF injections for wet AMD with good response to treatment.

If you meet the study criteria and choose to participate, the study may last up to 98 weeks (about 2 years).



** This is a brief overview. Your doctor will discuss the full scope of the study and inclusion criteria with you.*

What will happen during the study?*

You will come to the clinic for up to three screening visits and have several tests done to determine if you are eligible to participate.

If you are eligible, you will be randomized (like drawing straws) to see if you will receive the gene therapy treatment with RGX-314 or Lucentis®.
If you are not initially randomized in the RGX-314 gene therapy group, you will be offered the choice to receive RGX-314 after one year if you are deemed eligible by your study doctor.

If you receive gene therapy treatment with RGX-314 in the study, RGX-314 will be surgically injected into your eye underneath your retina through a subretinal injection. This procedure will be done in an operating room by your doctor under local and monitored anesthesia where your eye will be numbed and you will be awake, but groggy.

You will attend follow-up visits with your doctor for up to 2 years. At these visits you will have your vision tested, imaging of your eyes and other assessments.

There is no cost to you for participating in the study. The study sponsor will pay for all medical visits and study related procedures provided during this study.

When your participation in this study has ended, if you received RGX-314, you will be asked to participate in a long-term follow-up study.

** This is a brief overview. Your doctor will discuss the full scope of the study and inclusion criteria with you.*

What is AAV gene therapy?

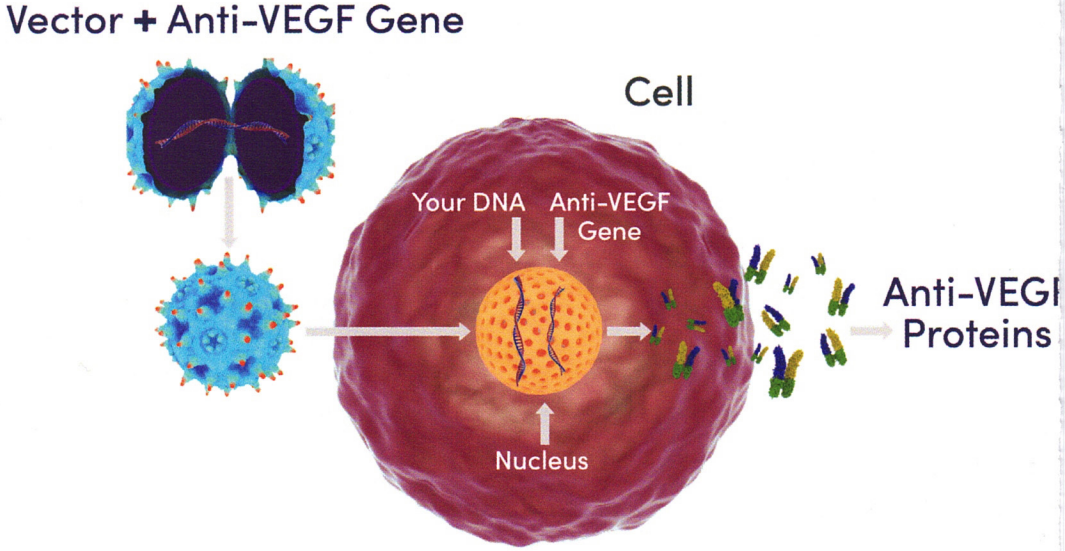
Gene therapy is a way of placing copies of a gene into cells in order to allow the cells to produce proteins that may treat a disease.

Genes are part of your genetic material that instructs the body to make certain proteins.

The gene is transferred to the cells using a modified virus, or vector, that has been used previously in humans and is not known to cause disease in humans.

The vector is designed to deliver the gene to specific cells in the body.

RGX-314 gene therapy may potentially produce long lasting results and could replace frequent anti-VEGF injections.



If you would like more information about AAV gene therapy for retinal disease, or if you or a loved one would be interested in participating in this study, or future clinical trials, please speak with your Doctor.

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