Do you have hearing loss caused by vestibular schwannoma (also known as acoustic neuroma)?

If so, you may be eligible for a clinical trial. Learn more and find out if you might qualify.

What is the purpose of the trial?

The purpose of this trial is to evaluate whether the study drug, administered once using the study device, is safe at different dose levels. Researchers in this trial will also evaluate whether the study drug is able to stabilize or improve hearing and/or shrink the size of the tumor in individuals affected by unilateral vestibular schwannoma.

Who may be eligible to join the trial?

You may be eligible for the trial if the following apply to you:

- ☑ You are at least 18 years old.
- ☑ You have significant hearing loss in one ear caused by vestibular schwannoma.
- ☑ You have had an MRI scan of the head in the past two years.
- ☑ You have not received surgery or radiation to treat the vestibular schwannoma.
- ☑ You do not have vestibular schwannoma on both sides.

Other eligibility criteria will also apply. Talk to your doctor to learn more!

What are the study drug and the study device?

The study drug is a type of *gene therapy*. It is designed to deliver a sequence of DNA to the cells of the inner ear. This sequence may enable the cells of your inner ear to produce and then release a protein referred to as anti-VEGF into the fluid of your inner ear. The anti-VEGF protein may then travel to the vestibular schwannoma, where it may block a growth factor called VEGF that is made by the tumor. By blocking VEGF, the study drug may help to slow or reverse the growth of the vestibular schwannoma and may also help to improve or stabilize your hearing.

The study drug will be administered to the inner ear during a surgical procedure, using the study device.

Both the study drug and the study device are *investigational*. This means they can only be used in clinical trials and have not been approved for sale by any regulatory authorities, such as the U.S. FDA. This is the first time the study drug is being used in humans. The study device has been used in another trial (unrelated to vestibular schwannoma), which is currently ongoing.

Continued on next page

What will happen during the trial?

Trial participants can expect the following:

1. **Informed consent:** Review and sign the Informed Consent Form.
2. **Screening:** Receive trial assessments, including an MRI scan of the head, blood tests, and hearing tests to determine if you are eligible for the trial.
3. **Study drug administration:** If you are eligible for the trial, you will have surgery to receive one dose of the study drug (using the study device) in the ear next to the vestibular schwannoma. You will stay overnight at the trial site after the surgery, so the trial staff can monitor your health.
4. **Follow-up:** If you receive the study drug, you will visit the trial site approximately nine times over the next year for follow-up visits. After one year, you will be expected to join a separate long term follow-up study that will last an additional four years (for a total of five years of follow-up after receiving the study drug).

What is a vestibular schwannoma (also known as an acoustic neuroma)?

A vestibular schwannoma is a non-cancerous tumor. It forms along the nerve that runs from the inner ear to the brain. A vestibular schwannoma can affect the body's ability to send nerve signals from the ear to the brain. This may lead to symptoms such as hearing loss and balance issues.

What is a clinical trial?

Clinical trials help scientists and doctors explore whether a medical strategy, drug, and/or device is safe and effective for people.

Before a new study drug and/or study device can be approved for sale and made available to the public, it must go through several phases of clinical research. Each phase helps researchers, regulators, and patients learn more about the medical strategy, drug, and/or device. Clinical research relies on volunteer participants.

For more information about the AK-antiVEGF-101 trial, visit www.VSclinicaltrial.com or email clinicaltrials@akouos.com, or scan the QR code.

V1 | 11OCT2024 | AK-antiVEGF-101

AKOUOS-GL-0054 10/2024