

FIRST PATIENT TREATED WITH VANEXIN FOLLOWING ANTI-VEGF INJECTION IN THE NEXUS STUDY

Annexin Pharmaceuticals AB announces that the first patient in the expanded patient cohort of the NEXUS study has now been treated according to the new study design. The patient, diagnosed with retinal vein occlusion (RVO), received an initial anti-VEGF injection followed by treatment with the drug candidate vanexin (formerly ANXV). To date, no limiting safety or tolerability findings have been reported. The patient is also the first to be treated in Germany at the STZ eyetrial clinic at University Hospital Tübingen.

In August, Annexin announced that the NEXUS study would be expanded to include, in addition to vanexin monotherapy, patients with RVO who have received initial treatment with anti-VEGF, the current standard of care for RVO. The purpose is to evaluate safety, tolerability and signals of effect. The design is a preparatory step ahead of the planned Phase 2b study, in which an anti-VEGF injection is intended to be administered initially to reduce retinal swelling, followed closely by treatment with vanexin to improve retinal blood supply over the longer term, reduce inflammation and increase cell survival. This approach is therefore expected to provide both short- and long-term benefits and enable maintenance of visual function with a significantly reduced subsequent need for anti-VEGF treatment.

The first patient in this expanded cohort has now been enrolled and initially treated with an anti-VEGF injection, followed shortly thereafter by treatment with vanexin. The patient has completed the Day 15 follow-up visit after vanexin treatment, and no adverse events have been observed to date. The company plans to include up to three patients in the cohort, depending on the safety and signals-of-effect data generated on an ongoing basis.

"We are pleased to report that the first patient in the expanded cohort has now been treated in Germany, with no adverse events observed following vanexin treatment. This is an important step towards the planned Phase 2b study," says Anna Frostegård, Chief Scientific and Medical Officer at Annexin Pharmaceuticals.

About the NEXUS study

Annexin's Phase 2a/proof of concept study NEXUS has an adaptive design and includes patients with diabetic retinopathy (DR), where there is a clear impact on retinal blood vessels and blood supply, as well as newly diagnosed RVO patients. It is an open-label study without a placebo group or comparison with another treatment. The study is being conducted at The Retina Clinic London, UK, with Professor Paulo-Eduardo Stanga as Principal Investigator, and from May 2026 also at STZ eye trial, Department for Ophthalmology, University Hospital Tübingen, Germany, with Dr Immanuel P. Seitz as Principal Investigator.

The study is adaptive and initially planned to include three patients with DR and RVO respectively, followed by a data analysis. After this data analysis, safety, tolerability and effect signals supported a reduction from 5 to 3 days of vanexin treatments and as recently amended, also including patients who have received an initial anti-VEGF treatment. Patients are treated with vanexin and followed up with detailed assessments up to 30 days and thereafter followed less frequently up to 120 days after the first vanexin treatment.

Both standard and high-advanced image analyses, functional and anatomical ophthalmological assessments, are performed at least monthly for four months following ANXV treatment. Evaluation is made of safety, tolerability and any signals of effect that may be related to vanexin. In addition to standardized tests of best corrected visual acuity (BCVA), the degree of diabetes-caused retinal damage, swelling of the retina and the need for anti-VEGF injections, objective functional tests and analyses of blood flow and vascular changes are performed. Initially, up to 12 patients in total are planned to be included in the study and the regulatory approvals allow for enrolment of up to 18 patients.

About diabetic retinopathy (DR)

DR is a serious eye disease and one of the leading causes of vision loss and blindness in people with diabetes. A significant proportion of patients suffer from vision loss during their working life. The disease occurs when high blood sugar levels damage the small blood vessels in the retina, leading to leakage, lack of oxygen and the formation of new, fragile blood vessels. Today's treatments include anti-VEGF injections, laser treatment, and surgery, but these are often costly, require repeated interventions, and do not always provide sufficient effect as they do not target the loss of blood flow in the retina. Therefore, there is a great need for new, more effective and long-term effective treatment options. Globally, it is estimated that over 100 million people are living with DR, and with an increasing prevalence of diabetes, the number of people affected is expected to rise sharply.

About Retinal Vein Occlusion (RVO)

RVO is a vascular disease of the eye in which blood flow in the retinal veins is acutely blocked. The disease often leads to severe visual impairment or blindness and the need for long-term treatment. Today's standard treatment for RVO consists of injections directly into the eye, usually once every 4 to 8 weeks, to treat swelling of the macula, the central area of the retina that we use to see details and distinguish between faces, but has no effect on the actual blockage of blood vessels that is the cause of RVO. Sources put the prevalence of RVO in the world at between 16 and 28 million people being affected. Most patients only have one eye affected. However, some patients may have a second occlusion in the same eye or an occlusion in the other eye.

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About Annexin Pharmaceuticals AB

Annexin Pharmaceuticals is a clinical stage biotechnology company active in the therapeutic areas ophthalmology and oncology. The company develops vanexin (previously ANXV), a recombinant human Annexin A5 protein, as a first-in-class biologic with potentially disease-modifying mechanisms of action. The vanexin program is currently in Phase 2 in ophthalmology for retinal vein occlusion (RVO) and diabetic retinopathy (DR) and in pre-clinical stage in oncology.

The company is based in Stockholm and listed on Nasdaq First North Growth Market Sweden under the ticker ANNX. Redeye Nordic Growth AB is the company's Certified Adviser.

Attachments

First patient treated with vanexin following anti-VEGF injection in the NEXUS study