

ANNEXIN UPDATES ON CONTINUOUS PROMISING DATA FROM THE NEXUS STUDY – DEMONSTRATING IMPROVEMENT OF RETINAL PERFUSION IN BOTH DR AND RVO

Annexin Pharmaceuticals AB announces an update on the NEXUS study key preliminary clinical findings. To date, treatment with the drug candidate ANXV has not been associated with limiting safety or tolerability findings. Improvements of retinal capillary perfusion have been observed after ANXV treatment, not only in patients with retinal vein occlusion (RVO), but for the first time ever also in patients with diabetic retinopathy (DR). The clinical data were presented by Principal Investigator Professor Paulo-Eduardo Stanga at the Clinical Trials at the Summit meeting in Las Vegas, USA. The results thus far support further clinical development of ANXV in RVO and DR.

The ongoing Phase 2a/Proof of Concept study NEXUS study evaluates the investigational new drug candidate ANXV in the two retinal vascular diseases - RVO and DR - for safety, tolerability and signals of effect. The study is an integral part of Annexin's clinical development strategy for ANXV in ophthalmology. It is intended to provide results that guide the design of a Ph2b study in RVO and establish Proof of Concept of ANXV's potential to improve, or stop deterioration of retinal function and vision in DR.

Summary of NEXUS data to date:

- In total, eight patients have been treated: six with RVO and two with DR. Three patients with RVO were treated for three days. The preliminary evaluation of data includes results obtained from seven patients' follow-up visits after ANXV treatment ranging from Day 15 to Day 120 (end of the study).
- ANXV was well tolerated by all evaluated patients and there were no limiting safety related findings.
- Following ANXV treatment, objective evidence of rapid and in many cases sustained improvement in retinal capillary perfusion was observed in all patients evaluated at 15 days or longer.
- In several patients increased retinal capillary perfusion was associated with anatomical and functional signs of improvement, evident within one week after ANXV infusions.
- One patient with non-proliferative DR (NPDR) has remained stable in ophthalmic parameters until Day 120 and self-reported a significant improvement in disabling diabetes-related pain and abnormal sensations in the feet, an improvement occurring shortly after receiving ANXV.
- In RVO, all five patients evaluated had significant retinal swelling at baseline and four patients received a standard of care single anti-VEGF injection by Day 30. One patient received an additional anti-VEGF injection at Day 120.
- One patient with proliferative DR (PDR) has during the study undergone laser coagulation treatment for vascular abnormalities present at inclusion in the study.

- The update is preliminary, pending full data quality assurance and control, which will be performed as the data is complete.

"We are excited with the progress in the NEXUS study. The findings in RVO patients are in line with our expectations and support our design for an upcoming Phase 2b study. In terms of shortening the treatment with ANXV from five to three days, we need to follow all the patients treated for three days longer in order to assess if this treatment regimen could be optimal for Phase 2b. We are looking forward to discussing the clinical path forward with the regulatory authorities in the next few months," says Anna Frostegård, Chief Scientific and Medical Officer of Annexin Pharmaceuticals. "Further, the requirement for an anti-VEGF in patients with significant macular edema before being treated with ANXV was anticipated. The mechanism of action of ANXV is such that it is not expected to neutralize pre-existing VEGF and reduce swelling in the acute phase but to prevent subsequent VEGF generation by e. g. improving retinal blood supply. Overall, we are very satisfied with what we have seen so far and look forward to completing the study."

"The presentation by Professor Stanga at a highly prestigious international meeting such as CTS in Las Vegas is an important scientific milestone, and the significance was acknowledged by retinal experts present. It is regarded as the first ever study that demonstrates an objective improvement of retinal blood flow in DR. The findings are clearly differentiating ANXV from current treatments and almost all other drug candidates in development for RVO and DR," says Anders Haegerstrand, CEO of Annexin Pharmaceuticals. "In addition, the diabetic patient's report on a significant improvement of painful sensations in the feet, which is a disabling complication for millions of patients with diabetes, is also very intriguing since it might point to beneficial systemic effects of ANXV in diabetes. The results so far strengthen the clinical and commercial potential of ANXV and support our ongoing partnering discussions."

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 planned to initially include three patients with DR, as well as three patients with newly diagnosed RVO. Patients are treated with ANXV for five days and followed up with detailed tests for 30 days, after which decisions are made regarding further patient recruitment. If the results are deemed promising, the intention within DR is to increase the number of patients and within RVO to study whether the treatment time can be shortened to three days, which was initiated in May 2026.

All patients are followed less intensively for an additional 90 days to evaluate whether any effects persist. Both standard and high-advanced image analyses, functional and anatomical ophthalmological assessments, are performed monthly for four months following ANXV treatment. Evaluation is made of safety, tolerability and any signals of effect that may be related to ANXV. 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 twelve patients in total are planned to be included in the study.

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 ANXV, a recombinant human Annexin A5 protein, as a first-in-class biologic with potentially disease-modifying mechanisms of action. The ANXV 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.



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Attachments

Annexin updates on continuous promising data from the NEXUS study – demonstrating improvement of retinal perfusion in both DR and RVO