

ANNEXIN COMPLETES PATIENT ENROLMENT IN THE NEXUS STUDY – MULTIPLE KEY CLINICAL AND REGULATORY MILESTONES AHEAD

Annexin Pharmaceuticals AB today announces that the final planned patient in its Phase 2a NEXUS study is receiving treatment, marking the completion of patient enrolment. The patient is the last to be enrolled in the expanded cohort in which vanexin is administered following an initial anti-VEGF injection, the treatment strategy the company intends to advance into Phase 2b. The vanexin development program is now entering an important phase, with several clinical and regulatory milestones expected over the coming months.

All 12 planned patients have now been enrolled, including nine patients with retinal vein occlusion (RVO) and three with diabetic retinopathy (DR). Enrolment in the NEXUS study is therefore considered complete. The study is expected to be completed, with topline data reported, by the end of the first quarter of 2027.

"Enrolling the final patient in the NEXUS study represents an important milestone for Annexin. Over the past year, we have generated promising clinical data, developed a treatment strategy that is well aligned with clinical practice, and taken important steps toward the next phase of development. We are now entering a particularly active period, with several significant clinical and regulatory milestones expected over the coming months. Our objective is to establish the best possible foundation for the continued development of vanexin and a future licensing agreement," says Anders Haegerstrand, CEO of Annexin Pharmaceuticals.

The third and final RVO patient has now been enrolled in the expanded cohort, which involves an initial anti-VEGF injection followed by treatment with vanexin. The expanded cohort represents an important step toward developing a treatment strategy that reflects how vanexin could be used in future clinical practice.

Anti-VEGF therapies are currently used to rapidly reduce retinal swelling in patients with RVO, while vanexin has a different mechanism of action and is being developed to improve blood flow in the retinal, reduce inflammation, and protect cells from damage. This sequential treatment strategy has the potential to deliver more sustained treatment benefits and reduce the need for repeated anti-VEGF injections. The approach is also expected to facilitate patient recruitment in the planned Phase 2b study and strengthen vanexin's commercial potential.

Multiple key milestones expected over the next six months

With patient enrolment in the NEXUS study now complete, Annexin is entering a phase focused on clinical results, regulatory preparations for a planned Phase 2b study in RVO and business development. The company anticipates the following near- to medium-term milestones:

- **120-day follow-up data in DR (November 2026)**

Reporting of results from all three DR patients at 120 days after initial treatment, focusing on safety, tolerability, and signals of effect.

- **30-day follow-up data in RVO following initial anti-VEGF treatment (December 2026)**
Reporting of initial results from all three RVO patients in the expanded cohort at 30 days after initial treatment, focusing on safety, tolerability and signals of effect.
- **Regulatory preparations for Phase 2b (Q4 2026/Q1 2027)**
Submission of a request for a Type C meeting with the FDA to discuss the continued clinical development program, including study design and treatment strategy for Phase 2b and Phase 3. The meeting is expected to take place in early 2027.
- **Completion of the NEXUS study (LPO) (Q1 2027)**
The final patient completes the 120-day follow-up period (last patient out, LPO), after which the final study analysis will begin. Topline data are expected to be reported by the end of the first quarter.

In parallel, Annexin continues to actively pursue business development opportunities, with the objective of securing a global or regional licensing agreements for vanexin. The company believes that the clinical results achieved thus far and regulatory interactions with the FDA will significantly strengthen the basis for discussions with potential partners. The ambition is to conduct the planned Phase 2b study in collaboration with a partner. The timepoint for a potential agreement cannot yet be estimated.

"We have a clear plan for the next steps. The analysed clinical findings from NEXUS and our dialogue with the FDA will provide the information needed to optimize the Phase 2b program. These are also important milestones that certain potential partners are awaiting. Our ambition is to advance development as efficiently as possible and realize vanexin's significant medical and commercial potential," concludes Anders Haegerstrand.

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, 12 patients in total were planned to be included in the study, although 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

Annexin completes patient enrolment in the NEXUS study – multiple key clinical and regulatory milestones ahead