

## **ANNEXIN RECEIVES CLINICAL TRIAL APPROVAL IN GERMANY, WIDENING PATIENT RECRUITMENT IN THE NEXUS STUDY**

**Annexin Pharmaceuticals AB today announces that the company has received an approval for a clinical trial with the drug candidate ANXV by the German Medicines Agency Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). The approval enables the ongoing Phase 2a/Proof of Concept study NEXUS to expand into Germany, which geographically broadens and accelerates patient recruitment in both retinal vein occlusion (RVO) and diabetic retinopathy (DR).**

The NEXUS study evaluates safety, tolerability and signals of effect of the drug candidate ANXV in the two retinal vascular diseases RVO and DR. The study is an important part of Annexin's clinical strategy for ANXV in ophthalmology. By broadening the study geographically to include Germany in addition to the UK, the company improves conditions for accelerated patient recruitment. Initially, the STZ Eyetrial at the Department of Ophthalmology, University Hospital Tuebingen with Dr Immanuel P. Seitz as the principal investigator will be activated. The addition of the clinic in Tuebingen site is expected to be cost-neutral for the company.

"The expansion to Germany is part of our work to further accelerate patient recruitment," says Anders Haegerstrand, CEO Annexin Pharmaceuticals. "Additional clinical data in RVO and a broadening to DR have been asked for by some potential licensees, and we are now strengthening our ability to meet this demand. With the NEXUS study, we aim to generate data that brings us closer to a treatment that addresses the underlying causes of these serious eye diseases, such as the poor blood perfusion of the retina, rather than merely alleviating the symptoms."

### **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 patients with newly diagnosed retinal vein occlusion (RVO). 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 eyetrial, 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. 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. 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. 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.

**For further information, please contact:**

Anders Haegerstrand, CEO

Phone: +46 (0)70 575 50 37

Mail: [anders.haegerstrand@annexinpharma.com](mailto:anders.haegerstrand@annexinpharma.com)

**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 receives clinical trial approval in Germany, widening patient recruitment in the NEXUS study**