

## **FIRST PATIENTS TREATED IN ANNEXIN'S PHASE 2A STUDY IN DIABETIC RETINOPATHY AND RVO**

**Annexin Pharmaceuticals AB today announces that the first two patients have been dosed in the company's Proof of Concept Phase 2a study with the drug candidate ANXV in diabetic retinopathy (DR) and retinal vein occlusion (RVO). The initial inclusion criteria have been modified during the autumn to support efficient patient recruitment. Safety and signals of effect data from the study will be reported on an ongoing basis once verified as relevant.**

The Phase 2a study is being conducted at The Retina Clinic in London with Professor Paulo-Eduardo Stanga as Principal Investigator and includes patients with DR and newly diagnosed RVO. The first patients are treated for five days with ANXV. Based on results at approximately one month after the first three patients in each indication have been treated, a decision is made on the inclusion of additional patients. If the results are deemed promising, the intention is to increase the number of patients in DR, while in RVO it is 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. This adaptive study design, with evaluation of two indications in parallel at a single clinic, enables the study to be conducted in a time- and cost-effective manner. The study will also provide the company with important information for the preparation of a Phase 2b study, which is primarily expected to be conducted by or in collaboration with an industrial partner.

"It is very gratifying that we have now successfully dosed the first patients in this study and with slightly broader inclusion criteria, we look forward to a more efficient recruitment rate when we evaluate ANXV as a new treatment for the serious eye disease diabetic retinopathy for the first time. With this study design, we will also obtain additional data within RVO, something that has been requested by potential licensees. Potential signals of effects in both indications will be reported after an evaluation together with the principal investigator," says Anders Haegerstrand, CEO of Annexin Pharmaceuticals.

### **About the Phase 2a study**

Annexin's phase 2a/proof of concept study has a so-called adaptive design and includes patients with diabetic retinopathy, 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 drug. The study is being conducted at The Retina Clinic in London, UK, with Professor Paulo-Eduardo Stanga as Principal Investigator and is planned to initially include three patients with diabetic retinopathy, as well as three patients with newly diagnosed RVO. Patients are treated with ANXV for five days and followed up with detailed tests during 30 days, after which decisions are made regarding further patient recruitment. All patients are followed less intensively for an additional 90 days to study whether any effects persist. Evaluation is made of safety, tolerability and any effect signals that may be related to ANXV. In addition to standardized tests of best corrected visual acuity (BCVA), the degree of diabetes-related 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.

**About diabetic retinopathy (DR)**

Diabetic retinopathy is a serious eye disease and one of the leading causes of vision loss and blindness in people with diabetes. 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. There is therefore 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 diabetic retinopathy, and with an increasing prevalence of diabetes, the number of sufferers 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 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 a month, but has no effect on the 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.

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**About Annexin Pharmaceuticals AB**

Annexin Pharmaceuticals AB is a leading biotechnology company in the Annexin A5 field for the treatment of various diseases. The company's biological drug candidate ANXV – a human recombinant protein, Annexin A5 – is primarily intended for treatment of patients with injuries and inflammation of the blood vessels, but also for cancer. The company has an extensive patent portfolio for the treatment of diseases with Annexin A5 and for production of Annexin A5. The Company is based in Stockholm, Sweden and listed on Nasdaq First North Growth Market, under the ticker ANNX. Redeye is the company's Certified Adviser.

**Attachments**

**First patients treated in Annexin's Phase 2a study in diabetic retinopathy and RVO**