PRESS RELEASE
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FAVOURABLE FINDINGS IN ANNEXIN'S ONGOING PHASE 2A STUDY IN DIABETIC RETINOPATHY AND RETINAL VEIN OCCLUSION

Annexin Pharmaceuticals AB today announces favourable findings in the company's ongoing Proof of Concept Phase 2a study with the drug candidate ANXV in Diabetic Retinopathy (DR) and Retinal Vein Occlusion (RVO). The first two patients have been evaluated up to one month after the treatment with ANXV. No safety-related findings have been identified and signals of effect in support of ANXV as a drug candidate in both diseases have been reported so far. The study is a part of the preparation work for an upcoming Phase 2b study in RVO and as an initial investigation in a new patient population with DR.

In the study, named NEXUS, to date two patients, one with DR and one with RVO, have been treated and evaluated up to one month after the ANXV treatment. No safety-related findings have been reported so far.

"The findings in the first two patients are very encouraging. In RVO the results are in line what had been observed previously. Importantly, the study includes for the first-time patients with DR. In addition to the absence of ANXV related toxicity, the rapid improvements in multiple highly relevant parameters that we observe a month after ANXV treatment in these patients are very promising. We can see increased retinal capillary density and increased retinal vascular perfusion in both of these vision threatening conditions. A novel drug such as ANXV with a differentiated mechanism of action has a potential to change the way we treat these patients," says Professor Paulo-Eduardo Stanga at The Retina Clinic London, in London, UK, and Principal Investigator.

"The findings so far reported by a renowned principal investigator supports our hypothesis about ANXV´s potential in both ophthalmic diseases. The first ever patient with DR treated with ANXV has responded with both functional and anatomical improvements which aligns with the mechanism of action and our expectations. To the best of our knowledge such findings are not expected in response to for example anti-VEGF or cortisone. We are committed to advance this programme further," says Anna Frostegård, Chief Scientific and Medical Officer at Annexin Pharmaceuticals.

RVO and DR share disease pathways, with long-term need and mostly short-lasting treatments available to patients today. Currently available treatments target macular oedema and retinal neovascularisation, but no treatment so far has been able to target the actual cause of the disease, that is, the vascular occlusion or the loss of retinal vascular perfusion that leads to retinal ischaemia.

“While still in a single DR patient, these findings in an additional medically important and commercially attractive ophthalmic indication provides further strength to our ANXV program. It provides strong motivation to move forward forcefully to develop ANXV towards the market. We are expecting to treat two more patients with DR during this quarter and are working to increase the recruitment of RVO patients. We trust that the results so far will solidify and improve the interest from potential licensing partners as well as support financing of our continued efforts,” says Anders Haegerstrand, CEO of Annexin Pharmaceuticals.

About the results
The patient diagnosed with DR had moderate retinal swelling, minimal visual impairment and multiple functional and anatomical changes in the retina common in DR. Thirty days after a course of ANXV treatment, improvements in relevant clinical parameters regarding both function and anatomical structure of retina were noted. There was a significant improvement of retinal perfusion/retinal capillary density on OCT Angiography (OCTA). The retinal response to light and electrical conduction of sensory input were improved as determined by microperimetry and electroretinogram, respectively. The macular swelling (intraretinal fluid) was decreased, and vascular anatomy was improved (less microaneurysms and less haemorrhages). It is considered very unlikely that these improvements are spontaneous. Visual acuity measured by the visual chart and the assessment of the degree of diabetic retinopathy remained stable at Day 30.

The second study patient diagnosed with central RVO had retinal swelling but minimal visual impairment at the time of diagnosis. In connection with ANXV treatment, rapid improvements in perfusion in the retina were observed similar to that of the healthier eye, not affected by RVO. Although somewhat reduced, the retinal swelling persisted and an injection of anti-VEGF was performed on Day 30. The observations in this patient are of the same character as previously reported in the concluded US Phase 2a study in RVO.

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 (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 drug. The study is being conducted at The Retina Clinic London, in London, UK, with Professor Paulo-Eduardo Stanga as Principal Investigator and 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 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. Standard type, as well as highly advanced imaging, functional and anatomical ophthalmic, assessments are performed monthly for 4 months following ANXV treatment. 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. 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.

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 are affected by loss of vision 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 retinal vascular perfusion. 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 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 the swelling of the macula, the central area of the retina we use to see details with and discriminate 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 get only one eye affected. However, some patients can get a second occlusion in the same eye or an occlusion in the fellow 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 is the company's Certified Adviser.

Attachments
Favourable findings in Annexin’s ongoing Phase 2a study in Diabetic Retinopathy and Retinal Vein Occlusion