PRESS RELEASE
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UPDATE ON ANNEXIN´S RVO STUDY CONFIRMS PROMISING SIGNALS OF EFFECT

Annexin Pharmaceuticals AB today announces that 6 out of 8 patients with the eye disease retinal vein occlusion (RVO) receiving the investigational drug candidate ANXV in the Phase 2a/proof-of-concept study and who have been followed for 3 months or longer show durable benefits while not requiring multiple anti-VEGF injections. To date, a total of 11 patients with newly diagnosed RVO have been treated with ANXV at three different dose levels and no limiting adverse events have been reported.

In august 2023, Annexin reported about 2 out of 4 treated patients showing promising signals of effect according to an independent analysis. These two patients have remained stable in visual acuity and treated with only one anti-VEGF injection during at least 12 months. The company now reports that an additional 4 patients who have been followed for at least 3 months after the ANXV treatment show an improvement, or no worsening, of their visual acuity (BCVA) and in several cases a reduced swelling of the retina. These patients have been deemed to require no or a single injection of anti-VEGF and this includes 2 patients with central retinal vein occlusion (CRVO) who would typically require more frequent treatments. The decision to administer anti-VEGF is based on the presence of swelling of the retina and poor visual acuity and is taken by the patient's treating ophthalmologist. The follow-up period for three additional patients is not yet over three months and therefore they have not yet been evaluated for visual acuity and retinal swelling.

"We have every reason to be optimistic as we observe signals of effect and limited need for the standard anti-VEGF treatments in 6 out of 8 ANXV-treated patients followed for several months, especially as RVO patients typically need at least four intra-ocular injections of anti-VEGF within the first six months of diagnosis. It is encouraging that a patient with CRVO, and associated visual impairment and retinal swelling who would typically need multiple injections of anti-VEGF, experiences significant improvement for more than three months after being treated with ANXV alone. It is also important to emphasize that the study is not designed to show statistical significance regarding either safety or efficacy, but to provide information and guidance for an upcoming phase 2b study," says Dr. Anna Frostegård, Chief Scientific and Medical Officer at Annexin Pharmaceuticals.

Since the placebo group in the study was removed, the patient recruitment rate has increased and so far 11 patients have been enrolled, 10 have been fully treated and 8 have been evaluated for 3 months or longer. If the safety and signal of effect data do not motivate further patient enrolments in the study, the company expects to have evaluated the data from the study´s last patient by mid-2024.

"We are very pleased with these new observations that confirm our previously reported findings and our expectation that ANXV can have clinically meaningful and lasting effects on visual acuity and reduce the need for unwanted drug injections directly into the eye. We are approaching the timepoint where we can plan for further clinical studies based on additional promising clinical data. Activities to find a license partner are ongoing and I am convinced that today's update will generate increased interest" says Anders Haegerstrand, CEO of Annexin Pharmaceuticals.

About the study
Annexin's phase 2a/proof-of-concept study includes patients who have recently suffered RVO, but have not been treated with the standard anti-VEGF therapy. After the protocol update, the study is an open-label study where patients receive the investigational new drug ANXV followed by anti-VEGF (as needed) and are followed up to four months with examinations to assess safety, tolerability and any signals of effect that may be related to ANXV. The company plans to include up to 16 patients at three different dose levels. The study is conducted at 7 different eye clinics in the US.

About retinal vein occlusion (RVO)
RVO is a vascular disease of the eye in which blood flow in the veins of the retina is blocked. The disease often leads to severe visual impairment or blindness and the need for long-term treatment. The treatments for RVO that are available today are injected directly into the eye, usually monthly, and have no effect on the blockage of blood vessels that causes RVO. According to a 2021 report by Transparency Market Research, the value of the RVO market in 2025 is estimated to reach approximately USD 20 billion, and it is expected to grow by approximately 7 percent annually over the next 10 years.

Every care has been taken in the translation of this document. In the event of discrepancies, the Swedish original will supersede the English translation.

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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.

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Attachments

Update on Annexin´s RVO study confirms promising signals of effect