PRESS RELEASE
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LAST PATIENT TREATED IN ANNEXIN'S RVO STUDY - PROMISING SIGNALS OF EFFECT AND NO SAFETY CONCERNS

Annexin Pharmaceuticals AB today announces that the last patient has been treated with the investigational new drug ANXV in the Phase 2a study that included a total of 15 patients with the eye disease retinal vein occlusion (RVO). Top-line data is planned to be presented in the summer of 2024. In terms of signals of effect and based on currently available information, 8 out of 10 patients followed for three months have shown improvement or no worsening of the disease, and they have either required no, or only one anti-VEGF injection (standard therapy). No limiting safety or tolerability events associated with the ANXV treatment have been reported at any investigated dose level to date.

A total of 15 patients have received ANXV, of which 6 patients have been administered 2 mg, 3 patients 4mg and 6 patients 6 mg. A recent review of available safety and tolerability data from the 6 patients who received 6 mg ANXV and were followed 10 days after receiving the last dose of ANXV did not reveal any findings of concern.

In terms of signals of effect 8 out of 10 patients, where information is available for at least three months after the treatment, data have shown an improvement or no worsening of their visual acuity (BCVA) and in several cases a reduced swelling of the retina with no or only one dose of anti-VEGF. Similarly, 10 of 12 patients, based on information available after two months have been deemed not to require any or only one anti-VEGF treatment. 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.

Based on the favorable safety profile and promising signals of effect at all dose levels Annexin has decided to stop patient recruitment.

"We are very happy to see the continued favorable safety and tolerability profile for ANXV. This is the first study with ANXV in a patient population and it is incredibly important for an investigational new drug to demonstrate a safety profile that allows further development," said Dr. Anna Frostegård, Chief Scientific and Medical Officer at Annexin Pharmaceuticals.

"We are also observing potential positive effects on the disease course accompanied by lower than typical anti-VEGF requirements. This Proof of Concept study has an open-label design, i.e. without a placebo- or other control-group which limits the interpretation of the effect signals and does not allow for statistical analysis. While we cannot exclude some level of recovery without or after only one anti-VEGF treatment, we consider the overall result in line with our highest expectations. We are now looking forward to in-depth analysis of all the parameters we have been following in these patients," Dr Anna Frostegård concluded.

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"We will reach a very important milestone in the summer of 2024 when presenting top-line data from the first study with ANXV in patients. Future and larger randomised studies will hopefully confirm the effect on the disease course and reduced need of anti-VEGFs. If so, we believe ANXV can become an important addition to the current standard of care to ease the burden on patients and society. We will present our study update during upcoming ophthalmology meetings in Seattle in May. We look forward to getting feedback on our data from ophthalmologists and potential licensing partners during the coming months," said Anders Haegerstrand, CEO at Annexin Pharmaceuticals.

About the study
Annexin's phase 2a/Proof of Concept study includes patients who have recently suffered from 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, administered intravenously for 5 days followed by anti-VEGF (if 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 study is ongoing at 7 eye clinics in the US and has included 15 patients treated with ANXV.

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

Last patient treated in Annexin's RVO study - promising signals of effect and no safety concerns