Annexin Pharmaceuticals

Empowering the body to fight disease

PRESS RELEASE

STOCKHOLM, August 11, 2023

Promising signals of effect in Annexin's RVO-study

Annexin Pharmaceuticals AB today announces that an independent evaluation of potential signals of effect has been carried out in the company's Phase 2-study in retinal vein occlusion with the investigational new drug ANXV. Positive findings justify an extended follow-up period.

A group of leading independent US ophthalmologists has conducted an evaluation of the available information from patients treated so far in the placebo-controlled study. The evaluation confirmed an unexpectedly long duration of effect with a single dose of standard of care anti-VEGF treatment in two of five treated patients. These two patients also had some positive effects on visual acuity and the retina already during the four weeks before standard of care treatment was used. The expert group recommended unmasking the treatment to clarify whether the treated patients received placebo or ANXV. The unmasking showed that the two patients with potential signals of effect had received ANXV. No clear signals of effect were observed in the other patients in the study where two had received ANXV and one had received placebo. The experts also recommended that the study should continue with a longer follow-up time and without a placebo group, since ANXV treatment has not raised safety concerns.

"The observations are interesting and indicate that ANXV may have a positive effect on the course of the disease in RVO, which is in line with our hypothesis. It is not possible to draw any firm conclusions from two patients, but it is unusual for such patients to respond to just a single anti-VEGF injection in the first six months after diagnosis. We intend to recruit and treat two more patients at the current dose and up to ten patients at a higher dose to gather more safety and tolerability data and to possibly confirm signals of effect", says Dr Anna Frostegård, Chief Scientific and Medical Officer at Annexin.

"With these early signals in the RVO study, a favorable safety profile and the imaging data that we reported last spring, we have several interesting clinical findings. In the simplified

study design we are removing the placebo group and altogether we believe the changes will accelerate patient enrolment", says Anders Haegerstrand, CEO in a comment.

About the study

Annexin's phase 2 study includes patients who have recently received their RVO diagnosis, but have not been treated with the standard anti-VEGF therapy. After the protocol update, the study will be an open-label study where patients receive the investigational new drug ANXV followed by anti-VEGF (as needed) and will be followed up to four months with examinations to evaluate safety, tolerability and any signals of effect that may be related to ANXV. The company plans to include up to sixteen patients treated with ANXV, including the four already treated patients.

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 of RVO 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 report by Transparency Market Research in 2021, the value of the RVO market in 2025 is estimated to reach about USD 20 billion, and it is expected to grow by about 7 percent annually for the next 10 years.

For further information, please contact:
Anders Haegerstrand, CEO, tel +4670 - 575 50 37

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.