

DATABASE LOCK COMPLETED IN ANNEXIN'S PHASE 2A STUDY IN RVO. DATA CONFIRMS PROMISING RESULTS – PROVIDING STRONG SUPPORT FOR CONTINUED DEVELOPMENT OF THE DRUG CANDIDATE ANXV

Annexin Pharmaceuticals AB today announces that the database has been locked and that the analysis of the results from the proof-of-concept phase 2a study, which evaluated the drug candidate ANXV for treatment in patients with retinal vein occlusion (RVO), has been completed. ANXV has demonstrated clinically relevant signals of effect and a continued favorable safety profile with no limiting treatment-related adverse events. Levels of ANXV and its target molecule have been measured in patients' blood. A decrease in levels of the target molecule confirms the expected mechanism of action as well as confirms the clinical results shown. The study's main objectives have thus been achieved and the results support continued clinical development of ANXV.

An analysis of the complete dataset from all participating patients shows that the results are consistent with, and strengthen, previously reported top-line data in August 2024. A total of 15 patients were treated with ANXV intravenously, of which 14 patients were available for follow-up for four months. The safety profile is reported unchanged as good, with no safety or tolerability issues or demonstrated immune reaction to ANXV. Based on visual acuity and retinal macular swelling, 12 of the 14 patients show an improved or a stable disease. Of these, 7 have not received any injection, and 5 patients have received only one injection of standard anti-VEGF treatment directly into the eye, as compared with about 5 injections over 6 months from diagnosis, anticipated in the United States. The main objectives of the study have thus been achieved. The levels of ANXV in patients' blood are as expected and in addition, a reduction in ANXV's target molecule, phosphatidylserine, has been observed in connection with treatment.

"We are very pleased with the results, which continue to confirm ANXV's potential. The fact that the database is now locked, significantly facilitates discussions with potential licensing partners as some have been waiting for complete dataset before the final evaluation of the project", says Anders Haegerstrand, CEO of Annexin Pharmaceuticals. "In January, we also visited San Francisco during the JP Morgan Annual Healthcare Conference, where we deepened our dialogues with several major players in the field. We continue to meet great interest and our goal is still to conclude a license agreement that both enables further development of ANXV and is advantageous from an ownership perspective."

"In addition to the signals of effect and the absence of adverse reactions to our drug candidate ANXV, the measured levels of ANXV and the reduction of phosphatidylserine in plasma, confirm that ANXV can exert the desired effect in the eye. It also provides further support for its potential in other diseases such as diabetes-induced vision impairment, cancer and sickle cell anemia," says Anna Frostegård, Chief Scientific and Medical Officer at Annexin Pharmaceuticals.

About the study

Annexin's Phase 2a/proof of concept study includes patients who have recently suffered RVO, but who have not been treated with the standard anti-VEGF treatment. After protocol update, the study became an open-label study without placebo in which patients received the new investigational drug ANXV (a recombinant human Annexin A5 protein), at doses of 2, 4 or 6 mg intravenously for five days early after RVO diagnosis, followed by anti-VEGF if needed, and then followed up to four months with studies to assess safety, tolerability and any signals of effect that may be related to ANXV. The study was conducted at 7 retinal specialist clinics in the US and has included 16 patients, of which 15 were treated with ANXV. Topline results were reported in August 2024 and the database lock was announced in February 2025. The parameters reported consist of the standardized measurements of best corrected visual acuity (BCVA) and swelling of the retina (central subretinal thickness, CST) along with the need for anti-VEGF injections, the latter a decision made by the patient's treating ophthalmologist.

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. 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 is projected to reach around USD 20 billion by 2025, and it is expected to grow by around 7 percent annually over the next 10 years.

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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

Database lock completed in Annexin's Phase 2a study in RVO. Data confirms promising results – providing strong support for continued development of the drug candidate ANXV