Annexin Pharmaceuticals

Empowering the body to fight disease

PRESS RELEASE

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First patient treated in the second dose group in Annexin's RVO study

Annexin Pharmaceuticals announces that all patients in the first dose group with the lowest dose have now completed treatment in the company's clinical phase 2 study in patients with retinal vein occlusion (RVO) with the investigational drug candidate ANXV. No limiting treatment-related side effects have been reported and the company has received recommendation to proceed with treatment of patients in the next dose group. An expected accelerated recruitment rate means that last patient in is planned to the first quarter of 2024.

"It is very gratifying that we see continued progress in this important study. Five out of seven dedicated eye clinics have now treated patients with good experiences, which bodes well for continued recruitment. With more patients treated, we now hope to be able to confirm the promising effect signals, and with an increased dose, hopefully also strengthened", says Anders Haegerstrand, CEO of Annexin Pharmaceuticals.

All six planned patients have now completed treatment in the phase 2 study's first patient group (cohort) where the patients were treated at the lowest dose level, 2 mg/day, for five days. No limiting side effects have been observed in the first cohort and after the recommendation by an independent Safety Review Committee, which evaluates the study based on safety, among other things, the first patient has now been treated in the second cohort of the study, where up to ten patients are planned to be treated with the higher dose, 4 mg/day, for five days. After two patients have been treated with the higher dose, a safety evaluation will be performed before the remaining patients can be enrolled. The company intends to continuously update the market on any efficacy signals, or any treatment-related side effects, as clinical data and other patient information have been verified and assessed by experts.

"During the autumn, we have visited several of our active eye clinics in the US and we are experiencing great enthusiasm after the promising signals of effect. We also see an increase

in recruitment rates after we changed the study protocol and removed the placebo group. We remain committed to our plan to have all patients included in the study during the first quarter of next year and to be able to report 4-month follow-up data thereafter", says Dr. Anna Frostegård, Chief Scientific and Medical Officer at Annexin Pharmaceuticals.

In August 2023, Annexin reported promising efficacy signals in two out of four patients treated with ANXV in the ongoing Phase 2 study. The positive findings warranted, among other things, extended patient follow-up and removal of the placebo group in the study as the ANXV treatment did not give rise to any serious treatment-related side effects.

About the Phase 2 study

Annexin's Phase 2 clinical trial includes patients who have recently received their RVO diagnosis, but who have not been treated with the standard anti-VEGF therapy. It is an open-label study in which patients receive ANXV followed by anti-VEGF (if needed) and followed for up to four months with examinations to evaluate safety, tolerability and any signals of efficacy related to ANXV. The company plans to include up to 16 patients, of which six patients have been treated at the lower dose level, 2 mg/day, and up to ten patients are intended to be treated at the higher dose level, 4 mg/day.

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 a 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 estimated to reach approximately USD 20 billion by 2025, and it is expected to grow by approximately 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.