

FIRST PATIENTS TREATED WITH HIGHER DOSE WITHOUT ADVERSE EVENTS IN ANNEXIN'S RVO STUDY

Annexin Pharmaceuticals today announces that the first two patients who received the higher dose of 4 mg of the drug candidate ANXV in the company's clinical phase 2 study in patients with retinal vein occlusion (RVO) are now fully treated. The safety profile remains good and no limiting treatment-related adverse events have been reported. The company now intends to apply for permission to test higher doses within the framework of the study. The last patient is still expected to be recruited during the first quarter of 2024.

"It is positive that even the higher dose was well tolerated by the treated patients. After the planned safety evaluation, we are now proceeding with the study and, provided that the safety profile continues to be good, we intend to apply for permission to go up further in dose(s). However, the total number of patients in the study - up to 16 patients - will not increase unless there are clinical results that justify it", says Anna Frostegård, Chief Scientific and Medical Officer at Annexin Pharmaceuticals. "Possible efficacy signals in the patients treated after we removed the placebo group and extended the follow-up period to four months will be reported as soon as such data are compiled and reviewed."

To date, eight patients have completed the treatment, of which six patients have been treated with the lower dose level of 2 mg/day and two patients with the higher dose of 4 mg/day during five days.

In August 2023, Annexin reported promising efficacy signals in two out of four patients treated with the lower dose of 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 adverse events.

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 levels.

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.

Attachments

First patients treated with higher dose without adverse events in Annexin's RVO study