Annexin Pharmaceuticals

Empowering the body to fight vascular diseases

PRESS RELEASE

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Annexin receives approval to start Phase 2 study in U.S.

Annexin Pharmaceuticals has been given the go-ahead by FDA to start the planned phase 2 clinical trial with the drug candidate ANXV in patients with retinal vein occlusion (RVO).

STOCKHOLM (5 April, 2022) - This first study with ANXV in patients aims to investigate safety, tolerability and efficacy related to vision and retinal function of RVO patients. The study is a placebo-controlled, multiple-dose trial involving approximately 20 patients at 6-8 eye clinics in the U.S. The overall results of the study are expected during the 4th quarter of 2022.

RVO is a vascular disease of the eye where blood flow in the retinal veins is blocked. The disease can affect anyone and can lead to acute or progressively increasing blindness. According to a report by Transparency Market Research 2021, the value of the market for RVO in 2025 is estimated to reach USD 20 billion, and is expected to grow by approximately 7 percent annually the next 10 years.

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. ANXV is considered to have the potential to be a real breakthrough in the treatment of the disease because the drug candidate has the potential to directly affect the blockage, the swelling of the retina and on the inflammatory reactions that make vision loss worse. ANXV is given intravenously for a short period of time.

"The approval to start the study in the United States is the most important milestone in Annexin Pharmaceuticals' history. We look forward to testing whether ANXV can offer patients a completely new type of treatment that is both medically important and commercially valuable. We have chosen to do the study in the US for several reasons, partly because the US represents over 50 percent of the RVO market but also to get the seal of quality that an FDA approval entails," says CEO Anders Haegerstrand.

About Annexin Pharmaceuticals AB (publ)

Annexin Pharmaceuticals AB is a world-leading biotechnology company in the Annexin A5 field for the treatment of various vascular diseases. The company's biological drug candidate ANXV – a human recombinant protein, Annexin A5 – is primarily intended for short term treatment of patients with injuries and inflammation of the blood vessels. The company has an extensive patent portfolio for the treatment of diseases that occur due to the damage and inflammation of the blood vessels. Annexin Pharmaceuticals has established and optimized a cell line for large-scale production of ANXV.

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, email certifiedadviser@redeye.se or phone +46 8 121 576 90.

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