

Annexin and Biovian have successfully completed ANXV manufacturing

Annexin Pharmaceuticals AB and CDMO Biovian Oy released the First-In-Class ANXV drug candidate for clinical trials. Following a clinical study in healthy subjects, clinical trials with the drug will target retinal vein occlusion, a condition causing blindness.

Annexin Pharmaceuticals drug candidate ANXV is a human recombinant Annexin A5. Annexin A5 is a naturally occurring protein that has shown to protect, repair and improve the body's own ability to fight against unwanted inflammation. The contract development and GMP manufacturing program started from the Drug Substance intermediate. Biovian provided Annexin Pharmaceuticals with the ANXV Drug Substance followed by Drug Product manufacturing including aseptic filling, quality control analyses and Qualified Person certified release for use in the clinical trial. Annexin Pharmaceuticals initiated the first clinical trial with ANXV in the Netherlands in late 2020, with the dosing of the first study participant on 21 December.

"I am very pleased that we selected Biovian as our CDMO partner for this program," says CEO Anders Haegerstrand at Annexin Pharmaceuticals. "Biovian successfully managed the final steps in the production of our first-in-class drug candidate for our first as well as upcoming clinical trials. We have established a good relationship and trust with Biovian. They met our expectations in quality and ambitious timeline and provided flexible and customer-oriented service from start to finish", he concludes.

Knut Ringbom, CEO at Biovian, comments: "For 18 years Biovian has been focusing on providing premium biopharmaceutical CDMO services. The project completed for Annexin Pharmaceuticals falls exactly into the key strengths of our comprehensive service offering for the microbially expressed recombinant proteins. The program was planned and executed from analytical technology transfer and method validation to finished Drug Product, being a model example of Biovian's One-Stop-Shop concept. This project was a great start to our hopefully long-term future partnership. We are proud that Annexin Pharmaceuticals trusted their valuable program in our hands."

About Annexin Pharmaceuticals:

Annexin Pharmaceuticals AB (publ) is a world-leading biotechnology company in the Annexin A5 field, for treatment of various cardiovascular diseases, which are currently the most common cause of death. The Company's biological drug candidate ANXV – a human recombinant protein, Annexin A5 – is intended primarily for the acute treatment of patients with cardiovascular diseases with vascular damages and inflammation. The Company also has a comprehensive patent portfolio for the treatment of diseases caused by vascular damage and inflammation. Annexin Pharmaceuticals has established and optimized a cell line for large-scale production of Annexin A5. The production process is patent pending. Additional information is available at <https://www.annexinpharma.com/sv/>

About Biovian:

Biovian is a Contract Development and Manufacturing Organization, CDMO that provides premium services to biotech companies developing innovative gene therapies or biopharmaceuticals. The goal of the company is to turn ideas into products by taking client projects from the laboratory bench to the clinic. Biovian offers its clients One-Stop-Shop GMP CDMO services, with modularity available from gene to finished vial. Biovian is especially focusing on Viral Vector production and microbial production of recombinant proteins and GMP plasmid DNA. Guided by its Nordic ethos Biovian has established a reputation for delivering high-quality work on time and within budget to a global client base. Additional information is available at <https://biovian.com/>