Pressmeddelande
Xintela AB (publ)
556780-3480
2021-04-12

Xintela GMP inspection for manufacturing license completed

Lund, Sweden, 12 April 2021 - Xintela announces today completion of the inspection by the Swedish Medical Products Agency for a license to produce cell therapy products, also known as Advanced Therapy Medicinal Products (ATMPs), for clinical studies.

Xintela has developed and patented the stem cell product platform XSTEM and built its own GMP (Good Manufacturing Practice) compliant facility for the production of ATMPs. As previously announced, the Company has applied for a license to produce ATMPs for clinical studies. The inspection was performed by the Swedish Medicinal Products Agency to ensure that the GMP facility, the production process and the cell therapy product meet the requirements of GMP and that the documentation requirements for an ATMP are followed. After a manufacturing license is granted, Xintela will produce XSTEM for the knee osteoarthritis clinical trial planned to start this year and for other clinical studies.

“We are really pleased with the inspection, which took three days to complete. We were well prepared and the team carried out the inspection in a very professional manner. The inspectors identified a few non-critical questions that we will respond to before the Medical Products Agency issues the manufacturing license. This is a hugely important step forward for Xintela and a fantastic achievement by our team,” says Xintela's CEO Evy Lundgren-Åkerlund.

Xintela AB (publ)
Evy Lundgren-Åkerlund, CEO
Tel: +46 46 275 65 00
Email: evy@xintela.se
Medicon Village
223 81 Lund, Sweden
www.xintela.se

About Xintela
Xintela develops innovative and patent protected cell therapies and targeted cancer therapies based on the marker technology platform XINMARK. The platform is built on specific cell surface proteins (integrins) and more than 25 years of research and development. Xintela uses the marker technology to select and quality assure stem cells (XSTEM) to develop stem cell therapies for diseases that today lack efficient treatment options, including the joint disease osteoarthritis (OA). Xintela has built an in-house GMP-facility for manufacturing of stem cell products and is preparing a First in Human clinical study on patients with knee OA. In the oncology program, Xintela develops antibody-based therapies for treatment of aggressive tumors including glioblastoma and triple-negative breast cancer. Xintela is listed on Nasdaq First North Growth Market Stockholm since 22 March 2016. Xintela's Certified Adviser at Nasdaq First North Growth Market is Erik Penser Bank AB, +46 8-463 80 00, certifiedadviser@penser.se.