



Xintela submits manufacturing license application

Lund, Sweden, 21 December 2020 - Xintela announces today that the company has submitted its application to 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. The company is now applying for a license to produce ATMPs for human clinical studies. This approval is issued by the Swedish Medical Products Agency, which is responsible for the inspection and approval of GMP facilities in Sweden. The inspection is performed to ensure that the GMP facility, the production process and the cell therapy product meet the requirements for Good Manufacturing Practise and safety and that the documentation requirements for an ATMP are followed.

“This is a huge and very important step forward for Xintela following a fantastic effort from our team. Once we have the license in place, we can start manufacturing for our clinical programmes. We plan to start our first study with XSTEM-OA in osteoarthritis patients in 2021 and then to test XSTEM in other indications as we move forward,” says Xintela's CEO Evy Lundgren-Åkerlund.

This information is such information that Xintela AB (publ) is obligated to publish in compliance with the EU market abuse regulation. The information was provided, through the below contact, for publication at 08:30 CET on the 21st of December, 2020.

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About Xintela

Xintela is an Advanced Therapy company developing regenerative stem cell therapies and targeted cancer therapies based on the patented 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 to develop stem cell therapies for diseases that today lack efficient treatment options, including osteoarthritis (OA). Studies on horses with OA have demonstrated that the stem cells are safe and that they have a positive effect on cartilage and bone. Xintela has established 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.