Press release
Xintela AB (publ)
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Xintela's GMP facility is completed and being prepared for production and clinical trials

Lund, Sweden, 26th of April 2018 - Xintela AB (publ) today announced that the GMP facility is completed and that the company has moved to offices and laboratories in direct conjunction with the GMP facility. It will now be equipped with instruments and prepared for inspection and approval by the Medical Products Agency for manufacturing licenses for clinical studies. The facility is expected to be ready for production by the end of 2018.

"The transition from our ordinary cell lab to the new GMP-qualified clean room will be smooth since we have already scaled up the methods for producing large amounts of stem cells in the so-called bioreactor," says Xintelas CEO Evy Lundgren-Åkerlund.

With its own GMP facility for manufacturing of stem cells, Xintela gains full control and flexibility over product development and a cost-effective production solution, even in the short term. In addition, Xintela is building a unique competence in GMP production, process development and quality systems that create significant value in the company, both for Xintela's own development, but also as a possible contract manufacturer for other stem cell companies.

"Our decision to produce stem cells in our own GMP facility is getting a lot of attention and increasing the interest of potential collaborating partners," says Evy Lundgren-Åkerlund.

In parallel with preparing GMP-grade production of stem cells, the Xintela team is working on an application to the Medical Products Agency (MPA) to initiate clinical studies on humans and animals. In line with this, Xintela will during the year perform a new study on horses with post-traumatic osteoarthritis to investigate the optimal dose of stem cells and obtain further information on mechanisms of action. These results, together with the results from the previous horse study, will form a critical part of the preclinical documentation that Xintela will present to the MPA.

"We have decided to start with the human clinical study for several reasons. Partly because the requirements for preclinical documentation were found to be similar between human and horse and partly because we can advance the start of a human study by our own GMP production. In addition, we have received great interest from potential partners for the human stem cell project for the treatment of osteoarthritis. If everything works as planned, we expect to be able to start clinical studies on humans in 2019," says Evy Lundgren-Åkerlund.

Xintela AB (publ)

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About Xintela

Xintela develops medical products within regenerative medicine and oncology based on its proprietary marker technology, XINMARK®. Xintela uses the technology to isolate and quality assure stem cells for the treatment of the joint disease osteoarthritis. Studies on horses have shown that the stem cells are safe and that they have a therapeutic effect on the articular cartilage and the underlying bone after an injury. Xintela has recently established its own GMP-facility to produce stem cells for clinical studies. In the oncology program, XINMARK® is used for the development of an antibody-based treatment (Antibody Drug Conjugate, ADC) against specific tumors with first focus on the aggressive brain tumor glioblastoma. Positive preclinical results from cell studies and animal model have shown that the ADC treatment has a targeting and killing effect on specific tumor cells supporting further development of the company's oncology business. Xintela is listed on Nasdaq First North Stockholm since 22 March 2016. Xintela's Certified Adviser at Nasdaq First North is Erik Penser Bank AB, +46 8-463 80 00.