Press release
Xintela AB (publ)
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XINTELA BUILDING OWN GMP-FACILITY FOR STEM CELL PRODUCTION

Lund, Sweden, September 11, 2017 - Xintela AB (publ) announces the company has decided to bring forward the construction of its own facility for production of equine and human stem cell-based ATMPs (Advanced Therapy Medicinal Products) at Medicon Village, Lund. Initially, stem cells will be produced for clinical studies in horses.

After careful evaluation of available options, Xintela has decided to initiate construction of its own facility for the GMP (Good Manufacturing Practice) production of stem cell-based ATMPs. A major reason is that available production units in Sweden cannot produce horse stem cells in parallel with their own production of human stem cells. In addition, Xintela now has the opportunity to build this custom-designed facility in close proximity to its own premises at Medicon Village.

"Compared to engaging an external contract manufacturer, the construction of our own production facility - in addition to increased flexibility and control - reduces costs, even in the short term. The decision means that we will invest time and resources earlier than planned in our own GMP-facility," says Xintela's CEO Evy Lundgren-Åkerlund.

With its own production unit, scheduled to be ready by the end of the year, Xintela can produce stem cells for both horses and humans. Before the production of stem cells can be initiated, the equipment, processes and quality systems need to be put in place, validated and inspected and manufacturing permits obtained from the Swedish MPA (Medical Products Agency). Clinical studies on horses will therefore start no earlier than by the end of 2018. However, clinical studies on humans can begin earlier than planned because the processes and quality systems for stem cell production will be developed in parallel for horses and humans.

"We have previously announced the recruitment of Liselotte Theorell, who is responsible for product development and quality management at Xintela. Her extensive experience in building clean rooms for GMP production and establishing processes and quality systems for cell therapy makes me very confident in taking this important step for Xintela," says Evy Lundgren-Åkerlund.

Liselotte Theorell comments:

"The development of a GMP facility for the production of stem cells is very important when we now take the next steps towards clinical trials in both horses and humans. With our own manufacturing facility, we get full control of the process and can locate the unit near our research facilities in Lund for more efficient transfer of our research and development."

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About Xintela
Xintela develops medical products for regenerative medicine and cancer based on its proprietary marker technology, XINMARK®. Xintela uses the technology to select and assure the quality of mesenchymal stem cells for the treatment of cartilage damage and osteoarthritis. In a study on horses, the company has shown that stem cells are safe to use and that they have a positive effect on the articular cartilage and the underlying bone after an injury. XINMARK® is also used for the development of an antibody-based treatment (Antibody Drug Conjugate, ADC) against glioblastoma, the most common and aggressive form of brain tumors in adults. Positive preclinical results from cell studies and animal model have shown that the antibody has a killing effect on glioblastoma cells and thus has confirmed the concept. 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.

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