Press release
Xintela AB (publ)
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# Significant progress in Xintela

**Xintela today announces an update on the company's development programs. Xintela develops medical products based on its patented marker technology platform XINMARK® with a focus on cell therapy and oncology. All projects have made significant progress in terms of results, patents and financing solutions so far this year.**

**Stem cell therapy for humans and animals**
Xintela has developed unique methods to identify, purify and quality assure stem cells for medical use through its marker technology. By using its markers to select and quality assure stem cells, Xintela has created and patented a unique stem cell platform XSTEM® for the development of safe and effective stem cell products. Xintela's first focus is stem cell therapy for cartilage repair in osteoarthritis, an area with very high medical needs and large, growing markets. Positive preclinical studies in horses have shown that Xintela's selected stem cells are safe to use and that they protect both joint cartilage and the underlying bone after a joint cartilage injury. The study was performed in collaboration with Cornell University in the United States and the results have been submitted for publication in an international scientific journal.

The horse study will form part of the preclinical documentation that Xintela is compiling for its applications to start clinical trials in humans and animals. A new preclinical horse study will begin this fall to study the mechanism of action of stem cells. Xintela's first clinical study will be performed on humans and is expected to start at the end of 2019.

**Negotiations with CO.DON on joint development of stem cells for osteoarthritis**
In July, Xintela signed a Letter of Intent with CO.DON AG and has initiated discussions to jointly develop Xintela's selected stem cells for the treatment of joint cartilage disorders, including osteoarthritis, in the European and North American markets. The plan is to form a new joint venture that will remain co-owned (50:50) throughout the development phase and into commercialization. Xintela will provide its marker and stem cell technology and stem cell competence. CO.DON will provide all the funding needed to develop and take the stem cell product to the market and provide expertise in clinical development and commercialization. The joint venture will also utilize Xintela's GMP facility to produce stem cells.

CO.DON develops, produces and markets autologous cell therapies for the minimally-invasive repair of cartilage damage in the knee joint following traumatic or degenerative defects. Spherox is a cell therapy product that uses only the patient's own cartilage cells ("autologous chondrocytes"). The company received EU marketing authorisation for Spherox in July 2017. The shares of CO.DON are listed on the Frankfurt Stock Exchange.

"Collaboration with CO.DON means that the stem cell project, aiming for osteoarthritis therapy, has full funding right from the preclinical stage and is thus a very interesting financing solution for Xintela's first stem cell product. By working with an established cell therapy company like CO.DON, we can reduce risks and shorten the time to market. It also gives Xintela more space to develop the XSTEM® platform for other indications," says Xintela's CEO Evy Lundgren-Åkerlund.

**MUMS status facilitates development of Xintela's horse stem cell product**
In June, Xintela announced that the company has received MUMS status (Minor Use Minor Species) in Europe for its stem cell product EQSTEM™ for the treatment of degenerative joint disease, including osteoarthritis, in horses. MUMS status is the veterinary equivalent to Orphan Drug in human medicine. MUMS status for the horse product provides significant reduction in documentation requirements for registration of the drug. In addition, Xintela will receive administrative assistance from EMA for registration of the product within the EU.

"The MUMS status both facilitates and speeds up the development and gives Xintela an important competitive edge in developing a stem cell product for the treatment of degenerative joint disease in horses. Xintela's strategy is to conduct clinical studies in horses and other animals in collaboration with development partners," says Evy Lundgren-Åkerlund.

**Production of stem cells in own GMP facility builds value**
An important step for Xintela's development of stem cell-based products is the establishment of its GMP facility for own production of stem cells. Xintela announced in April that the GMP facility has been completed and the company has moved into new laboratory facilities and offices directly adjacent to the GMP unit. The furnishings and fittings and most instruments are now in place and the team is working on completing the facility for inspection by the Swedish Medical Products Agency for manufacturing permits for clinical trial production. The facility is expected to be ready for production by the end of this year. During the summer Xintela expanded the team with 2 new employees with experience from GMP production, clean rooms and process development to meet future needs. The GMP facility gives Xintela full control and flexibility over the production and reduces the risks associated with outsourcing. Xintela is also building unique expertise in GMP production, process development and quality systems, creating significant value in the company both for Xintela's own development of stem cell products and as a future possible contract manufacturer for other stem cell companies.

"Our investment in the production facility is strategically very important and makes Xintela even more attractive as a partner. It also reduces the company's production costs, even in the short term, as compared to production through a contract manufacturer, which would involve extensive and costly transfer of Xintela's technology," says Evy Lundgren-Åkerlund.

**Neural stem cells - a new cell therapy area with great business potential**
Xintela announced in April that the company has developed new methods to identify and purify neural stem cells from the brain. The new methods have opened up a whole new field for Xintela for the treatment of traumatic damages and diseases of the central nervous system (CNS) including stroke, Alzheimer's and Parkinson's disease, where the need for better treatments is very high.

"Stem cell therapies within the CNS have huge commercial potential and several global pharmaceutical companies have significant interest in this area. Our patented method to identify and quality assure neural stem cells for therapeutic use represents an innovative way to enhance product safety, effect and reproducibility. Furthermore, this expands our project portfolio in regenerative medicine and confirms that our marker technology can be used for additional, very interesting indications," says Evy Lundgren-Åkerlund.

Xintela is now working to set the strategy for continued development when resources are available. The company has already begun discussions with potential partners that can provide financial resources and additional research expertise within the CNS area.

**Development and broadening of the oncology business**
Xintela's first focus in oncology is to develop a treatment for the aggressive brain tumor glioblastoma. Xintela has previously shown that the company's antibody-based ADC (Antibody-Drug Conjugate) has a killing effect on tumor cells both in cell experiments and in an animal model, thus building the foundation for Xintela's commitment to oncology. These results will now be submitted for publication in an international scientific journal. Xintela intends to further develop the project together with a partner with experience in ADC development, and discussions with potential partners are progressing well.

"Since we focus on developing an ADC, we are looking for a partner with extensive experience in this area. Xintela offers unique targets as well as specific antibodies to direct an ADC treatment to the

tumor cells. Our co-development partner will provide co-financing, facilitate the development and reduce risk in the project," says Evy Lundgren-Åkerlund.

Xintela has also identified additional oncology indications where the company's marker technology has great potential in both diagnostics and therapy.

"We are evaluating other tumor types with significantly larger markets than glioblastoma and which will add significant value to our oncology business. We are currently working on patent applications to protect our new discoveries," says Evy Lundgren-Åkerlund.

**Spin-out of oncology business to new company**
In March, Xintela announced that the company is investigating a possible spin-out of the oncology business into a separate company to provide the oncology projects the best possible conditions to continue developing internally and through collaborations. This will facilitate future partnerships and financing, thus allowing the separate oncology company to focus on activities that create maximum value for our shareholders.

"With the important milestones achieved in the glioblastoma project combined with new and exciting results in other oncology indications, the time is right for the oncology business to grow and develop as a separate company. This will clearly accelerate the development of our oncology projects. Xintela has recently formed a subsidiary, Targinta AB, and is currently working on the details of the spin-out," says Evy Lundgren-Åkerlund.

**XACT in Japanese collaboration**
During the year, Xintela has collaborated with the Japanese company CellSeed on Xintela's quality test XACT (Xintela Assay for Cell Therapy). CellSeed develops, among other things, a cartilage cell-based product for repair of cartilage injuries in the knee joint. In this collaboration, Xintela's integrin markers and XACT are evaluated for quality assurance of cartilage cells that CellSeed uses in the product development. The goal is to move into a long-term collaboration and licensing of Xintela's marker technology.

"Our collaboration with CellSeed has developed in a very positive way and generated revenue for Xintela. Discussions on the continued collaboration are ongoing. Development of cell therapy in Japan is very interesting because the regulatory system in Japan allows for market approval of a cell-based product already after clinical phase II," says Evy Lundgren-Åkerlund.

**Strategic development of the patent portfolio**
Xintela works proactively with its strong patent portfolio, covering all essential aspects of the marker technology platform XINMARK® to protect new, commercially and clinically relevant, discoveries arising from the company's development projects. Within the Integrin α10 patent family, the U.S. Patent Office (USPTO) recently issued a Notice of Allowance (NoA) for the patent application protecting integrin α10 cDNA as a product. This application is a follow-up application of previously granted patents in the same patent family. In Xintela's patent family protecting the monoclonal antibody mAb365, the USPTO has also issued a NoA for the follow-up application, that broadens the protection conferred by previously granted patents. Issue of the two patents is expected shortly.
In April, Xintela's patent application protecting integrin α10 as a marker for neural stem cells was published. The neural stem cell technology protected by this patent application can be used for treating patients suffering from cerebral and spinal cord injuries, after stroke or trauma.
Xintela recently announced that the company's patent application which protects the use of integrin α10 for the prevention and treatment of degenerative joint diseases including osteoarthritis and bone sclerosis using stem cells has been published.
Xintela has also recently filed a PCT application that extends patent protection for XACT and quality assurance of chondrocyte products.

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"The creative and innovative environment at Xintela continues to generate commercially and clinically relevant patentable inventions that create great value for its shareholders," said Peter Holm, Country Manager Sweden, Partner and European Patent Attorney, HØIBERG.

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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.