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Update on status and strategy for Xintela and Targinta

Xintela develops stem cell-based treatments with a focus on osteoarthritis and difficult-to-heal leg ulcers and, through its wholly owned subsidiary Targinta, targeted antibody-based treatments for aggressive cancers. We are focused on diseases where there is a high medical need and where effective treatments are lacking today. Solid preclinical R&D has laid the foundation for Xintela's and Targinta's continued progress toward clinical studies and commercialisation. A summary of each company's development pipeline, the status of each of these projects, and future strategy and priorities, is presented below.

Xintela's stem cell product XSTEM®
Xintela uses a proprietary stem cell marker, integrin α10β1, to select and quality assure homogeneous and reproducible stem cell products, XSTEM, from donated healthy adipose tissue. XSTEM is patent protected as a product including its therapeutic use for all indications. This, in combination with our in-house GMP manufacturing facility, creates an unrivalled position for developing safe and effective stem cell-based treatments for a number of different diseases. XSTEM's unique properties, providing both functional and regulatory benefits over other stem cell technologies, receive considerable attention from pharmaceutical companies with an interest in stem cell-based therapies.

Clinical studies with XSTEM for the treatment of osteoarthritis
Our first clinical study (Phase I/IIa) is planned to start at the end of this year (2021) in patients with grade II-III knee osteoarthritis (moderate osteoarthritis). The primary goal is to demonstrate that our product is safe but also to obtain preliminary results showing that XSTEM has DMOAD (Disease Modifying Osteoarthritis Drug) properties, i.e., can slow down cartilage and joint degradation and regenerate damaged cartilage and thereby improve joint function. Three different doses will be assessed in up to 54 patients and each patient will be followed for 18 months with continuous safety and efficacy evaluation every 6 months, which gives us the opportunity to look at effects throughout the course of the study. Our preclinical results provide strong evidence that XSTEM has DMOAD effects and has the potential to become a breakthrough treatment for osteoarthritis. Today there is no DMOAD on the market.

Clinical studies with XSTEM for the treatment of difficult-to-heal leg ulcers
Our second clinical study (Phase I/IIa), in patients with difficult-to-heal (chronic) leg ulcers, is planned to start in mid-2022. The study will be carried out in collaboration with Professor Folke Sjöberg and his team at the University Hospital in Linköping. Safety and efficacy will be evaluated over a period of 10 weeks allowing the study readout to be completed earlier than that expected for the osteoarthritis clinical study.
Difficult-to-heal leg ulcers constitute a very large under-served medical problem, which can be illustrated by the fact that wound care is estimated to account for 2-4 percent of the total healthcare budget in Western countries. We have demonstrated excellent wound healing capability with XSTEM in a preclinical wound healing model which provide support for XSTEM in the clinical treatment of difficult-to-heal leg ulcers in humans.
The project is partly financed by Vinnova through a government initiative to support development of cell and gene therapies (CAMP, Centre for Advanced Medical Products).

Future development of XSTEM for other indications
Xintela is preclinically evaluating future indications for XSTEM to further build our pipeline. The strategy includes seeking partners who are interested in licensing and developing XSTEM for disease areas where Xintela is not currently active.

A possible future indication for XSTEM is ARDS (Acute Respiratory Distress Syndrome), a very serious lung complication with high mortality (30-40 percent) which may be caused by Covid-19 and sepsis (blood poisoning). In a preclinical model of ARDS, XSTEM has demonstrated a positive therapeutic effect, including significantly reduced lung tissue damage and improved lung function. Xintela's strategy is to further develop XSTEM for the treatment for ARDS together with a partner.

Xintela's stem cell product EQSTEM® for osteoarthritis in horses
Xintela has developed the stem cell product EQSTEM for the treatment of horses, which is analogous to XSTEM for humans. Positive results from two osteoarthritis studies with EQSTEM in horses provide strong support for the development of stem cell products for horses and other animals. Xintela is now taking the next step towards the market with EQSTEM and will, in dialogue with EMA (European Medicines Agency), determine which additional studies are needed for an approval of EQSTEM. A major advantage of a veterinary stem cell product is that it can enter the market and generate revenues much earlier than the equivalent for humans due to shorter development timelines. There is substantial interest in stem cell-based therapies from animal owners and veterinary companies. Xintela has an ongoing dialogue with several companies in the animal health sector regarding the development and commercialisation of stem cell products.

In-house GMP facility and manufacturing
An important strategic and valuable asset in Xintela's operations is its GMP-approved manufacturing facility and the Company's broad competence in the manufacturing of cell therapy products, ATMPs (Advanced Therapy Medicinal Products). This gives Xintela full control and flexibility over the manufacturing process which significantly reduces production costs and risk of delays. In addition to producing XSTEM for in-house development, Xintela strategy is to become an established manufacturer of the Company's stem cell products developed together with partners. In longer term, Xintela's GMP facility and production operations may be used for contract manufacturing in the development and commercialisation of other ATMP products.

Xintela's commercialisation strategy
The overall commercialisation strategy is to develop our therapeutic pipeline to significant value inflection points and so optimise the companies' positions in partnership discussions and licensing deals. For the XSTEM projects, that value inflection point is after safety and proof-of-concept in humans, i.e., after clinical Phase I/IIa and for EQSTEM after proof-of-concept in horse patients. Xintela is active in partnering discussions and has built a large network of potential licensees within the pharmaceutical industry.

Targinta's antibody-based cancer therapies
Targinta is developing therapeutic antibodies specifically binding to the novel cancer target integrin α10β1, for the treatment of aggressive cancers such as triple-negative breast cancer and the brain tumor glioblastoma. Targinta is developing two different antibody modalities: function-blocking antibodies that can inhibit critical cancer cell functions such as proliferation (cell division) and migration (spreading), and antibody-drug conjugates (ADCs) that have a cytotoxin linked to the antibody that kills cancer cells. Targinta has previously reported inhibitory effects on proliferation and migration of cancer cells as well as reduced tumor growth in preclinical models.
The company has a patent portfolio that covers both the cancer target integrin α10β1 and the antibodies themselves. Targinta can thus block competitors from developing integrin α10β1-antibodies for aggressive cancers, which is a major upside and attracts attention from potential partners.

Selecting antibody drug candidates
An important step was recently taken when Targinta announced that the first function-blocking drug candidate has been selected, TARG10, for the treatment of triple-negative breast cancer. The company is now taking the next step in drug development, from preclinical research to preclinical development

including toxicology studies. The decision was made after extensive evaluation which confirmed the inhibitory effects on both tumor growth and tumor spreading in triple-negative breast cancer models. The company plans to select the first ADC drug candidate during the first quarter of 2022, for the treatment of aggressive cancers.

Targinta's commercialisation strategy
Targinta's strategy is to enter into commercial agreements already after completion of the preclinical development of selected drug candidates. Antibody-based drugs directed to new targets on cancer cells, known as First-in-Class products, are attractive to many drug companies due to the high need for new and more effective cancer treatments. Licensing deals with First-in-Class assets are frequently entered into at the preclinical stage. The fact that Targinta has patent protection for both its antibodies and target, further increases the attractiveness of the products.

Financing of Xintela's and Targinta's operations
The Board is actively working to ensure both companies' future financing needs and continuously evaluates various options such as partnerships generating income from development milestones, project financing, equity capital raising, grants or loans.

Spin-out of Targinta
We have come a long way in preparing the spin-out of our subsidiary Targinta. A new CEO, board and management team are in place and staff, premises and patent portfolios have been split out from Xintela. The Board of Directors of Xintela intends, subject to market conditions, to convene a general meeting before the end of the year for a decision on the dividend of Targinta in accordance with the Lex Asea rules. In the event of a dividend, Xintela's shareholders will receive shares in Targinta in proportion to their shareholding in Xintela. The ambition is to list Targinta shortly after the dividend.

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About Xintela
Xintela develops medical products in stem cell therapy and targeted cancer therapy based on the Company's cell surface marker integrin α10β1 which is found on mesenchymal stem cells and on certain aggressive cancer cells. The stem cell marker is used to select and quality-assure the patent-protected stem cell product XSTEM®, which is now entering a clinical development phase for treatment of knee osteoarthritis and difficult-to-heal leg ulcers. The company produces XSTEM for the clinical studies in its GMP-approved manufacturing facility. In cancer therapy, which is run by the wholly owned subsidiary Targinta AB, therapeutic antibodies, targeting integrin α10β1 (First-in-Class) are being developed for the treatment of triple-negative breast cancer and the brain tumor glioblastoma. Xintela conducts its business at Medicon Village in Lund, Sweden, and 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.