xintelling

Newsletter from Xintela AB No 5 2024

Dear shareholders,
First of all, I would like to thank you for your support and commitment during the past year and wish you all a Happy New Year. It has been an eventful year for our stem cell operations and I would like to take this opportunity to draw your attention to exciting milestones that we have ahead of us.

Paving the way for value inflection milestones in 2025

Interim analysis by Q1 2025

We are fully focused on our clinical study with our stem cell product XSTEM on osteoarthritis patients in Australia. Patients were treated with three different dose levels of XSTEM and have all now completed the 18-month follow-up. We are working to compile the results for an interim analysis of both safety and preliminary efficacy for all dose levels at 18 months, which we plan to report by the end of Q1 2025. All three dose levels have previously been judged safe three months after treatment and patients have reported reduced pain and improved joint function after 12 months. In the upcoming interim analysis, we will evaluate a number of different efficacy parameters including subjective analyses of pain and joint function and also objective analyses of the articular cartilage and other tissues in the joint, including results from magnetic resonance imaging. The patients at the highest dose level will continue the study for an additional 6 months for evaluation at 24 months after dosing, giving us additional important results to compare with previously reported studies. This is particularly relevant in our discussions with pharmaceutical companies.
In our earlier preclinical studies on horses with post-traumatic osteoarthritis, we have shown that the equine stem cell product EQSTEM has a disease modifying effect and although our study on knee osteoarthritis patients is first and foremost a safety study, we also investigate disease modifying effect by XSTEM.

Getting closer to commercialization

The results from the interim analysis will form the basis for planning the next step in the clinical development of XSTEM both for knee osteoarthritis and for other osteoarthritis indications going forward. As we approach the end of our knee osteoarthritis study, we are also getting closer to possible partnerships and commercialization of XSTEM. Our strategy is to enter into partnerships and out-license XSTEM once we have demonstrated proof of concept in osteoarthritis patients, which can happen when the ongoing study is completed.

In our clinical study on patients with difficult-to-heal leg ulcers, four patients have been dosed, of which three patients have completed the study after 4 months according to plan. The work to recruit additional patients to the study continues.

Recently, Dagens Medicin presented an article (December 13, 2024) about our study on patients with difficult-to-heal leg ulcers in Gothenburg, where doctors in charge of the study explained the great need for an effective treatment of difficult-to-heal leg ulcers and the potential of XSTEM.

Also in this study, the primary goal is to evaluate safety in treatment with XSTEM. So far, treatment with XSTEM has not shown any safety concerns, which we are already benefiting from when planning for the next step with XSTEM for the treatment of wounds including burns.

EQSTEM affects microRNA in cartilage cells

In our work of investigating mechanisms of action that contribute to the therapeutic effect of XSTEM, we have benefited greatly from our preclinical studies, including studies in horses, and the results have been published in several scientific journals. In an article published at the beginning of this year (https://www.frontiersin.org/journals/veterinary-science/articles/10.3389/fvets.2024.1374681/full), we, in collaboration with the University of Copenhagen, reported on the effect of our equine stem cell product EQSTEM, on the expression of microRNA in articular cartilage. MicroRNA are small RNA molecules that are important for the regulation of various cellular processes. Their effect has been associated with various diseases such as cancer, cardiovascular diseases and even osteoarthritis. MicroRNA have recently received extra attention in connection with the awarding of this year's Nobel Prize in Physiology or Medicine to the researchers who discovered MicroRNA.

At the 4th Regenerative Medicine Orthopedic Summit, held in Miami Beach on December 12-14, Xintela's CSO Lucienne Vonk was invited to give a presentation on microRNA and presented our results from the equine study. The results show, among other things, that when treating post-traumatic osteoarthritis in horses with our stem cell product EQSTEM, which reduced damage to the articular cartilage, the expression of certain microRNA in the cartilage cells was also reduced. A possible link between the change of microRNA in cartilage cells and reduced cartilage damage is discussed in the publication.

Licensing discussions with EQGen

Given that EQSTEM has demonstrated both safety and therapeutic efficacy in preclinical models of osteoarthritis in horses, it is very positive that we have ongoing collaboration and licensing discussions with the American company EQGen Biomedical for the continued development and commercialization of EQSTEM. Osteoarthritis is also very common in horses and the need for a treatment that can regenerate joint cartilage and restore joint function is very great, not least in competition horses.

Discussions with EQGen Biomedical are progressing while the team at EQGen Biomedical is working to secure financing from investors. We are really looking forward to finalizing the license agreement and getting started with the development work. The first planned assignment for Xintela will be to develop a GMP (Good Manufacturing Practice) process to produce EQSTEM for clinical studies.

GMP activities generate revenues

Xintela is also working on an assignment from Region Östergötland where our GMP team is developing a GMP process for the isolation and quality assurance of autologous (patient's own) skin cells for the treatment of patients with burns. The ongoing assignments for Region Östergötland and the planned one for EQGen are in line with Xintela's ambition to offer process development and production of advanced medicines, so-called ATMPs (Advanced Therapy Medicinal Products) and thereby generate revenues for the company.

Targinta looking for partner

In our subsidiary Targinta, we are continuing to look for financing and/or partners for the further development of Targinta's antibody-based drug candidates TARG9 and TARG10. We are receiving positive response to our unique cancer target and our first-in-class antibodies and ADCs, and continue, in parallel with our business development activities, to strengthen the preclinical documentation of our lead candidates. Our partner discussions have given us valuable information on complementary preclinical studies that can further strengthen our oncology program and provide support for our goal of landing a commercial deal for Targinta.

We very much look forward to 2025, which will be an exciting year with value-increasing milestones in sight.

With best regards,

Evy Lundgren-Åkerlund
CEO

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