# Newsletter from Xintela AB



# Breakthroughs for XSTEM and EQSTEM

In this newsletter, we highlight the recent successes of our stem cell products, where XSTEM shows excellent results in our knee osteoarthritis clinical study and EQSTEM has delivered our first licensing deal.

# Our excellent results with XSTEM in the osteoarthritis study provide great hope for osteoarthritis patients

On March 18, 2025, we reported positive interim data from our Phase I/IIa clinical study in knee osteoarthritis patients, evaluating three different dose levels of XSTEM (4, 8 and 16 million stem cells) in a total of 24 patients (8 patients/dose level). The results showed that all dose levels of XSTEM are safe and well tolerated and that no serious side effects related to the treatment have been reported, thus successfully achieving the primary goal of the study. The results also showed significant, clinically relevant, and sustained improvement in knee pain and knee joint function, as well as an improvement in bone structure and a trend to halt cartilage degradation, 18 months after treatment with XSTEM. These very good results achieve also the secondary goal of the study, to demonstrate the preliminary efficacy of XSTEM. The fact that the results also support the disease-modifying

potential of XSTEM in the treatment of osteoarthritis, confirms that our stem cell product has unique therapeutic properties and gives great hope to all osteoarthritis patients suffering from this painful and debilitating disease. Today, there is no disease-modifying treatment available for this very large patient group.

The evaluation of the efficacy of XSTEM in the study is performed both subjectively and objectively. In the subjective evaluation, using established and validated outcome measures, the patients report how XSTEM treatment affects pain in the knee joint (VAS, Visual Analogue Scale) and their opinion about their knee and associated functions (KOOS, Knee injury and Osteoarthritis Outcome Score). The KOOS uses a questionnaire with five separately scored subscales for pain, other symptoms, function in daily living, function in sport and recreation, and knee-related quality of life.

In the objective evaluation, X-ray and magnetic resonance imaging (MRI) is used to investigate the effect of XSTEM on the articular cartilage, the underlying bone and other tissues in the joint. By studying the structure of cartilage and bone tissue, we can see if XSTEM has a disease-modifying effect that halts the breakdown of cartilage and the progression of pathological changes of bone tissue, and regenerates and repairs joint tissues, thus restoring the function of the joint.

Interestingly, we see differences among the three tested dose levels which gives us important information for planning future clinical studies. The highest dose level clearly provided the best treatment effect and showed overall a better effect on pain and knee function compared

"The results of our osteoarthritis study confirm the strong results of our preclinical studies."

#### Comment from

Dr. Sven Kili, MD, specialist in orthopedics and cell & gene therapy, former consultant and board member of Xintela:

With these recent clinical results using XSTEM, the Xintela team has clearly shown the promise of a safe and effective cell therapy for Osteoarthritis (OA). The data from this phase I/IIa has met and exceeded its goal of demonstrating safety, but critically also demonstrating efficacy. We have previously seen clinical data from other MSC based therapies demonstrating safety, but durable efficacy has been very much missing, especially in OA. With this study, not only did Xintela demonstrate efficacy in the form of pain relief, but more importantly also demonstrated strong initial signs of a DMOAD (Disease modifying Osteoarthritis Drug) effect. This is truly the holy grail of OA research. Whilst we have previously seen therapies that deliver pain relief, often briefly, the ability to show an improvement in objective indicators of OA progression, including bone quality and maintenance of cartilage thickness is unique and extremely exciting. Naturally this effect will need to be replicated in additional studies towards approval. The addition of the 24-months follow-up in the current study will provide even a better indication on the duration of the improvement. I would like to congratulate Evy and the entire Xintela team on creating a product that is looking more and more like a potential blockbuster.

to the two lower doses. All the patients in the highest dose group showed a clinically meaningful improvement of knee function in daily living, 18 months after XSTEM treatment. In addition, pain (VAS) was reduced by 63% compared to before treatment. The highest dose also showed improvement of the bone tissue structure and a trend of stopping cartilage breakdown, which were not observed with the two lower doses.

The difference between dose levels also confirms that the effect comes from XSTEM treatment and is not a placebo effect, which is important information, even though a placebo effect typically lasts only 1 to 6 months.

To obtain further information about XSTEM's effect, we have chosen to evaluate the highest dose level for another 6 months, i.e. up to 24 months after treatment. This is an exploratory evaluation that will provide important information for the design of future studies and also give us the opportunity to compare XSTEM's results with 24-month published results from other clinical studies in knee OA. I would like to point out that this extension to 24 months of the highest dose level cannot change the positive results we already have achieved. Our results from the interim analysis of 18-month data will remain the main outcomes of the study when we issue the final report in September.

I would also like to highlight that the results of our osteoarthritis study confirm the strong results of our preclinical studies (publications on Xintela's website). With EQSTEM, our equine stem cell product, we demonstrated safety and disease-modifying effect on post-traumatic osteoarthritis in two preclinical horse studies. We also showed that XSTEM has the ability to home to damaged cartilage and produce new cartilage tissue in the knee joint in a preclinical animal model. Our preclinical and clinical results together, strongly demonstrate that XSTEM and EQSTEM, have a therapeutic effect that no other stem cell products has been able to show. The reason is that we have a unique stem cell technology based on Xintela's patented stem cell marker, integrin  $\alpha 10\beta 1$ . By way of a selection step in the production process, we can produce pure stem cell products that have high and reproducible guality and that differ from all other stem cell-based products. This gives Xintela and Xintela's partners a strong position in the development and commercialization of stem cell-based therapies.

xintela

"It is very exciting that EQSTEM will now be developed into a commercial product in veterinary medicine."

# EQSTEM, our stem cell product for horses, is now licensed to our partner EQGen Biomedical

On April 24, 2025, we reported that Xintela and EQGen Biomedical have signed a collaboration and license agreement for the development of stem cell products in veterinary medicine. This means that EQGen will have global rights to Xintela's stem cell product EQSTEM for the treatment of horses and stem cell products, based on Xintela's technology, for other animals including dogs, in musculoskeletal indications. EQGen also has an option to develop stem cell products for the treatment of other indications including tendon and ligament injuries.

EQGen is a US company founded by people with extensive experience in drug development for both humans and animals who saw the tremendous potential of our stem cell technology for the development of effective and disease-modifying veterinary treatments. Our discussions with EQGen's founders have been going on for almost a year, while they focused on establishing their team, their long-term business plan, and landing external financing for the start-up company. Initially, EQGen is being financed by the founders themselves.

To enable EQGen to get started as quickly as possible on clinical development in horses and to facilitate their work of raising external funding, we have now initiated the development of the GMP process for EQSTEM. The process is similar to the one we have developed to produce our human product XSTEM but will be optimized for the production of stem cells from horses. This work, which will be carried out this year, is fully financed by EQGen. Once the production process is established, further work related to the production of EQSTEM for clinical studies will be performed by Xintela.

The services Xintela will provide under the collaboration and license agreement with EQGen are an important part of our ambition that our GMP manufacturing facility becomes self-sustaining and, in the future, generates positive cashflow for the company. This, together with the work we have from Region Östergötland, already covers a significant part of our current GMP operating costs.

## xintela



### "Xintela: Promising data for XSTEM in OA"



Read the analysis here.



## "Xintela: Licensing deal with EQGen Biomedical"



Read the analysis here.



In addition to generating revenues for Xintela through process development and manufacturing of EQSTEM for clinical studies, there are several more upsides in our agreement with EQGen. When EOGen lands external financing, Xintela will receive a license fee of USD 1 million and shares in EQGen corresponding to USD 3 million at the same valuation as the external financing. In addition, Xintela will receive license payments when EQGen activates its option to develop other indications in addition to musculoskeletal indications. EQGen's first focus is to treat joint disease in horses. For the treatment of other animals, such as dogs, Xintela will carry out development work, funded by EQGen, to establish a stem cell product and a production process for each animal type. If EQGen sub-licenses parts of its business or is acquired, Xintela will receive additional compensation. Xintela will also receive variable royalties up to low double digits on EQGen's sales revenues.

It is really exciting that EQSTEM will now be developed into a commercial product in veterinary medicine. EQGen's team is very competent and enthusiastic, and we look forward to working together with them in the development of EQSTEM.

#### *Comment from* Dr. Willem Scheele, MD, EQGen Biomedical's founder and Chief Medical Officer:

"We are very impressed by Xintela's patented stem cell technology and preclinical studies that have shown that intra-articular treatment with *integrin* α10β1-selected mesenchymal stem cells protects against posttraumatic osteoarthritis in horses. The same technology has also shown statistically significant and clinically relevant reduced knee pain and improvement in knee joint function for patients with symptomatic knee osteoarthritis. Xintela's stem cell platform, with proven efficacy in several species, significantly increases the likelihood of technical and regulatory success for the development of an allogeneic stem cell therapy for osteoarthritis for both animals and humans. We are very pleased to continue working with the Xintela team and with EQSTEM for the treatment of inflammatory and degenerative joint disease in horses, and which has the potential to become a true disease modifying osteoarthritis drug.'

Finally, I would like to remind shareholders of the opportunity to exercise warrants during the period May 26 to June 5, 2025. In connection with the subscription of shares in the rights issue in July 2023, warrants were received with the right to subscribe for new shares on four occasions over two years at the same price, SEK 0.30. This is the fourth and last occasion. Further information about the terms and conditions of the warrants TO3 can be found on our website.



With best regards,

**Evy Lundgren-Åkerlund** CEO



## xintelo