Xintela's stem cell product XSTEM shows safety and positive efficacy results in knee osteoarthritis clinical study

Xintela's interim analysis of data from the knee osteoarthritis clinical study shows safety and positive efficacy results, 18 months after treatment with XSTEM. The results demonstrate statistically significant and clinically meaningful improvements in knee pain and knee function. In addition, the results of XSTEM treatment show an improvement in bone structure and also a trend of stopping cartilage breakdown, supporting a disease-modifying potential of XSTEM in the treatment of osteoarthritis. The highest dose of the three dose levels tested showed the best therapeutic effect.
XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and manufactured by Xintela.

Xintela is conducting a first-in-human study (Phase I/IIa) for the treatment of knee osteoarthritis, where three dose levels (4, 8 and 16 million stem cells) of the stem cell product XSTEM are being evaluated (8 patients/dose level). A total of 24 patients (41-75 years) with symptomatic moderate knee osteoarthritis (KL grade II-III) have received one injection of XSTEM into the knee joint. The primary goal of the study is to assess safety and tolerability of XSTEM. In addition, preliminary efficacy signals, such as reduced pain and improved joint function, as well as reduced degeneration of cartilage and other joint tissues, are being investigated every six months.
An interim analysis of study data up to 18 months after treatment with XSTEM, has now been performed. In summary, the results showed safety and sustained efficacy on pain, knee function and cartilage and bone structure. The major findings are described below:

* XSTEM treatment, at all dose levels, was safe and well tolerated. No serious adverse events related to the treatment have been reported.
* The highest dose of XSTEM showed overall a better effect on pain, knee function and bone and cartilage structure, compared to the two lower doses.
* The highest dose demonstrated statistically significant, clinically meaningful and sustained improvements in all pain and knee function assessments (VAS and KOOS) up to 18 months after XSTEM treatment as compared to before treatment.
* The highest dose reduced pain by 63% (VAS) and all patients in this group showed clinically meaningful improvements in activities of daily living (KOOS-ADL) at 18 months as compared to before XSTEM treatment.
* The highest dose also improved subchondral bone structure (reverse in osteoarthritis related changes) and showed a trend of stopping cartilage breakdown, which was not observed with the lower doses.

The study will be completed after the 24-month follow-up of the highest dose level of XSTEM and the final results are planned to be reported in September 2025. Patients at the lowest and mid dose levels have completed the study, 18 months after dosing.

Comment from Xintela's CEO, Evy Lundgren-Åkerlund:
"The therapeutic effect of XSTEM in this osteoarthritis study is very promising for all patients suffering from this progressive, painful and debilitating disease. It is very encouraging that XSTEM, in addition to a strong and sustained effect on knee pain and knee function, also showed a treatment effect on bone and cartilage tissues. This demonstrates XSTEM's potential to be a disease-modifying treatment for osteoarthritis, which is very much needed for this large patient group. Interestingly, we found a difference between the three doses and that the highest dose clearly showed the best effect. This demonstrates that the treatment effect comes from XSTEM and is not a placebo effect from the injection. We now look forward to completing the study with 24-month data from the highest dose level. Our results give strong support for the next clinical step with XSTEM which we plan to do together with a partner to accelerate the development of XSTEM to reach the market and patients worldwide."

Abbreviations:
VAS, Visual Analogue Scale
KOOS, Knee injury and Osteoarthritis Outcome Score
ADL, Activities of Daily Living

This information is information that Xintela AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-03-18 13:00 CET.

Contacts

Xintela AB (publ)
Evy Lundgren-Åkerlund, CEO
Tel: +46 46 275 65 00
Email: evy@xintela.se
Medicon Village
223 81 Lund, Sweden
www.xintela.se

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 in clinical development 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 is Carnegie Investment Bank AB (publ).

Attachments

Xintela's stem cell product XSTEM shows safety and positive efficacy results in knee osteoarthritis clinical study