Xintela's stem cell product XSTEM shows safety and sustained positive efficacy results two years after treatment in knee osteoarthritis clinical study

The final analysis including the 24-month evaluation of Xintela's (XINT) clinical study on XSTEM for knee osteoarthritis has now been completed. The results show continued safety, reduction of knee pain, improved joint function, and improvements in bone and cartilage structure. This confirms a sustained treatment effect in knee osteoarthritis and supports a disease-modifying effect of XSTEM. Xintela has previously communicated positive interim results up to 18 months after treatment of knee osteoarthritis patients with three dose levels of XSTEM. The highest dose level, which showed the best results after 18 months, has now shown sustained positive treatment effects two years after XSTEM treatment. XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and manufactured by Xintela.

Comment from Xintela's Chief Scientific Officer, Lucienne Vonk:
"We are very excited about the duration of the therapeutic effects of XSTEM. Patients in the study continued to experience relief from their symptoms for at least two years after a single XSTEM injection, which is notably longer that what is seen with other commonly used injection treatments, such as corticosteroids and hyaluronic acid, where effects often last between six weeks and six months. This beneficial effect of XSTEM could represent a meaningful improvement in the quality of life of osteoarthritis patients who are seriously affected by pain and immobility.
On top of this, we also see a disease-modifying potential of XSTEM. This means that XSTEM could halt and even reverse the disease by stopping the degradation of cartilage and other joint tissues, and by regenerating and repairing the damaged joint tissues. This could lead to a delay in and even reduced need for joint replacement surgery. The disease-modifying potential of XSTEM is especially promising for a large group of patients that are hampered in their daily lives by osteoarthritis but are still too young for a joint replacement and currently rely on therapies that manage their symptoms".

The now completed clinical study is a first-in-human (Phase I/IIa) study for the treatment of knee osteoarthritis and was carried out at sites in Australia. Three dose levels (4, 8 and 16 million stem cells) of Xintela's stem cell product XSTEM were evaluated with 8 patients per dose level. A total of 24 patients (ages ranging from 41 to 75 years) with symptomatic

moderate knee osteoarthritis (KL grade II-III) received one injection of XSTEM into the knee joint. Patients in the lowest and mid-range dose cohorts completed the study 18 months after XSTEM treatment while patients in the highest dose cohort were evaluated for an additional 6 months.

The primary goal of the study was to assess safety and tolerability of XSTEM. The secondary goal was to examine preliminary efficacy signals, including pain reduction and joint function improvement by patient reported outcomes as well as a reduction or reversal of degradation of cartilage and other joint tissues by X-ray and MRI.

An interim analysis of study data of all three dose levels up to 18 months after XSTEM treatment was performed and communicated in Q1 2025. The major findings from the final analysis of study data are presented below:

· XSTEM treatment, at all dose levels, was safe and well tolerated. No serious adverse events related to the treatment have been reported.
· Statistically significant and clinically meaningful improvements in knee pain and knee function 18 months after treatment with XSTEM were seen at all dose levels. The highest dose of XSTEM showed overall a better effect compared to the two lower doses.
· The highest dose demonstrated statistically significant and clinically meaningful improvements in all pain and knee function assessments (VAS and KOOS) from 1 month up to 24 months after XSTEM treatment. At 24 months after XSTEM treatment, the highest dose reduced pain by 57% (VAS) 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. This effect was sustained 24 months after treatment.
· In summary, XSTEM treatment was safe and well tolerated and showed sustained improvement on pain, knee function and cartilage and bone structure up to 24 months after treatment, demonstrating a long-lasting therapeutic effect and supporting a disease-modifying effect of XSTEM in the treatment of osteoarthritis.

Comment from Xintela's Chief Executive Officer, Evy Lundgren-Åkerlund:
"These positive final results from our osteoarthritis clinical study are a huge milestone for Xintela. We have demonstrated that one injection of XSTEM in an osteoarthritic knee has a strong therapeutic effect, that lasts for at least two years. Our results also support a disease-modifying effect of XSTEM which gives XSTEM a great competitive advantage compared to other treatment options. With positive phase I/IIa results we are now looking forward to partnering XSTEM for further clinical studies and commercialization, which has been our ambition from the start. I want to emphasize that there are no disease-modifying osteoarthritis treatments available today, which makes XSTEM extra attractive in partnering and licensing discussions. I am very proud of what we have accomplished, taking our stem cell product from an early idea through preclinical and clinical studies to results that indicate blockbuster potential for XSTEM".

About XSTEM

XSTEM is a proprietary, Best-in-Class stem cell product consisting of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells of superior purity and quality. XSTEM was investigated in a completed clinical Phase I/IIa study in osteoarthritis (OA) showing safety and positive efficacy results two years after treatment. OA is a leading cause of pain and immobility in adults, significantly impacting quality of life. Globally, over 550 million people are estimated to suffer from OA.
XSTEM is currently also investigated in a Phase I/IIa clinical study in difficult-to-heal venous leg ulcers, which are estimated to affect over 4% of individuals over 65 years.
XSTEM is manufactured in-house in Xintela's GMP facility.
Xintela is dedicated to making XSTEM the leading stem cell therapy platform for osteoarthritis and other indications through partnering and licensing.

Abbreviations:
VAS, Visual Analogue Scale
KOOS, Knee injury and Osteoarthritis Outcome Score
MRI, Magnetic Resonance Imaging
GMP, Good Manufacturing Practice

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 2025-09-22 23:15 CEST.

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About Xintela

Xintela (XINT) is a publicly-traded clinical-stage biopharma company, that develops cutting edge medical products in stem cell therapy and targeted cancer therapy. Xintela's proprietary technology uses the stem cell marker integrin α10β1 to select and quality-assure the stem cell product XSTEM®, which is in clinical development for the treatment of knee osteoarthritis and difficult-to-heal leg ulcers. Xintela's in-house GMP-facility manufactures XSTEM and generates revenues by providing process development and manufacturing of other cell therapies. Xintela's wholly owned subsidiary Targinta AB, develops First-in-Class therapeutic antibodies targeting integrin α10β1. TARG9, an Antibody-Drug Conjugate (ADC), and TARG10, a function blocking antibody, are in preclinical development for the treatment of aggressive, difficult to treat cancers including triple-negative breast cancer and brain tumor glioblastoma. Xintela conducts its business at Medicon Village in Lund, Sweden, and is listed on Nasdaq First North Growth Market Stockholm. Xintela's Certified Adviser is Tapper Partners AB.

Attachments

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