Xintela completes clinical study with XSTEM in knee osteoarthritis

Xintela's clinical study with XSTEM in knee osteoarthritis has been completed with the last follow-up visit for the last patient. Xintela previously communicated positive interim results up to 18 months after treatment and now completed the collection of 24-months data for the highest dose level. The final results of the study are planned to be reported at the end of September. XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and manufactured by Xintela (XINT).

"We are very excited to have this significant milestone behind us. Both for people with osteoarthritis and for our shareholders", highlighted Evy Lundgren-Åkerlund, CEO of Xintela. "We anticipate positive outcomes from the final report, and as a result, we are now planning the next clinical study to be performed either together with a partner or by Xintela".

The 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. Altogether, three dose levels (4, 8 and 16 million stem cells) of Xintela's stem cell product XSTEM are being 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) have received one injection of XSTEM into the knee joint.
Patients in the lowest and mid-range dose cohorts completed the study 18 months after treatment while patients in the highest dose cohort were evaluated for an additional 6 months.
The primary goal of the study is to assess safety and tolerability of XSTEM. The secondary goal is to examine preliminary efficacy signals, including pain reduction, joint function improvement as well as reduced degradation of cartilage and other joint tissues.

Interim Analysis

Interim analysis of study data of all three doses up to 18 months after XSTEM treatment was performed in Q1 2025. The results showed safety and statistically significant and clinically meaningful improvements in knee pain and knee function. In addition, the results showed an improvement in bone structure and a trend of stopping cartilage breakdown, supporting the disease-modifying potential of XSTEM in the treatment of osteoarthritis.

Analysis of the 24-months data for the highest dose level is now ongoing and the final

results of the study are planned to be reported at the end of September 2025.

“The positive 18-months results from the interim analysis will be the main outcome in our final report. In addition, the 24-month data from the highest dose level will give us important additional insight into the sustainability of the XSTEM effect for our planning of the next clinical study”, highlighted Evy Lundgren-Åkerlund.

About XSTEM
XSTEM is a proprietary, Best-in-Class stem cell product consisting of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells of high purity and quality. XSTEM is currently being explored for the treatment of knee osteoarthritis, which 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 osteoarthritis.
XSTEM cells are uniquely proven to home and adhere to sites of cartilage damage where they differentiate into cartilage cells and produce new cartilage tissue. Treatment with XSTEM reduces pain and improves joint function. 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.

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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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