Press Release
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Xintela reports safety results from the XSTEM clinical study in difficult-to-heal venous leg ulcers

Xintela announces that the XSTEM® treatment in the clinical Phase I/IIa study on patients with difficult-to-heal venous leg ulcers was considered safe and well tolerated and thus achieved the primary objective of the study. XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and manufactured by Xintela.

Xintela's completed Phase I/IIa clinical study in patients with difficult-to-heal venous leg ulcers is a placebo-controlled, randomized study. The patients in the study have received one dose of XSTEM (100,000 cells/cm^2, 4 patients) or placebo (2 patients) applied to the wound and then followed weekly for 10 weeks and after 4 months. Xintela has previously communicated that the number of patients enrolled was reduced from 12 to 6 due to slow recruitment and that the final results will focus on safety and tolerability which is the primary objective of the study.

The study has now been analysed and the results showed that XSTEM administered as a single dose was safe and well tolerated and thus achieved the primary objective of the study. The majority of the adverse events reported in the study were assessed as mild and unlikely to be related to the study treatment or study procedure. No serious adverse events were reported.

"This is an important clinical milestone for Xintela. Based on these positive safety results from the difficult-to-heal venous leg ulcer study, the effect of XSTEM can be evaluated on other wound indications going forward", says Evy Lundgren-Åkerlund, Xintela's CEO.

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About Xintela

Xintela (XINT) is a publicly-traded clinical-stage biopharma company developing 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 stem cells in the product XSTEM®, which has shown safety and positive efficacy in a clinical study on knee osteoarthritis and has completed a clinical study on difficult-to-heal leg ulcers. Xintela's in-house GMP-facility manufactures XSTEM and provides 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 glioblastoma, triple-negative breast cancer and sarcoma. 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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