Xintela decreases patient number in XSTEM clinical study in difficult-to-heal venous leg ulcers

Xintela has amended the study protocol in the clinical phase I/IIa study with XSTEM on patients with difficult-to-heal venous leg ulcers to complete the study earlier. The number of patients to be enrolled in the study has been reduced from 12 to 6. The primary goal of the study, to investigate safety and tolerability, will be achieved even with the reduced number of patients. XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and manufactured by Xintela.

The Phase I/IIa clinical study in patients with difficult-to-heal venous leg ulcers is a placebo-controlled, randomized study. Patients receive one dose of XSTEM or placebo applied to the wound and are assessed weekly for 10 weeks and after 4 months. The primary goal of the study is to show safety and tolerability and, also to investigate the preliminary effect of XSTEM in wound healing.

The number of patients to be enrolled in the study has been reduced from 12 to 6 due to slow recruitment. To date 5 patients have been dosed of which 4 have completed the study. The amended clinical study protocol has received regulatory approval.

“Due to the slow recruitment to this study, we have decided to reduce the number of patients to allow us to complete the study earlier. We have not seen any safety issues in the study, and we will now focus on the next step for XSTEM in wound healing, including burn patients, in collaboration with the Burn Centre in Linköping”, says Camilla Wennersten, Xintela’s Clinical Development Director.

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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

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