Xintela starts next dose level of XSTEM in knee osteoarthritis clinical study

Xintela's first-in-human study (Phase I/IIa) for the treatment of knee osteoarthritis, being conducted in Australia, is testing 3 different dose levels of the stem cell product XSTEM®. The Safety Review Committee for the clinical study assessed the treatment of the eight patients on the lowest XSTEM dose level at the one-month follow-up, concluded the dose is safe, and approved the continuation to dosing of patients at the second dose level. XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and manufactured by Xintela.

Patients with moderate knee osteoarthritis (grade II-III) receive one injection of XSTEM into the knee joint. Three different dose levels are being evaluated in up to 54 patients and each patient will be followed for 18 months with an efficacy reading every 6 months. The primary goal is to show that XSTEM is safe, and also to investigate preliminary efficacy signals, such as reduced breakdown of joint cartilage, regeneration of damaged cartilage, and improved joint function. Safety data from all dose levels and early efficacy results are expected in 2023.

"Completion of the safety evaluation for the lowest dose of XSTEM in the treatment of knee osteoarthritis and the decision to proceed with the inclusion of patients at the next dose level is an important milestone. To accelerate patient recruitment, we are now adding another clinical site to the study. We look forward to establishing the safety for all dose levels and to start evaluating the effect of the treatment," says Camilla Wennersten, Director Clinical Development.

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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 at Nasdaq First North Growth Market is Erik Penser Bank AB, +46 8-463 80 00, certifiedadviser@penser.se.

Attachments

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