Press Release
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Xintela's clinical study with XSTEM for knee osteoarthritis makes good progress

Xintela is conducting a first-in-human study (Phase I/IIa) for the treatment of knee osteoarthritis in Australia where three different dose levels of the stem cell product XSTEM® are being tested. The primary goal of the study is to show that XSTEM is safe but also to investigate preliminary efficacy signals. The treatment of 16 patients on the first and second dose levels with XSTEM has been assessed as safe at a one-month follow-up by the Safety Review Committee. The first efficacy results from the lowest dose show that patients experience reduced pain and improved joint function in the knee six months after the injection of XSTEM.

XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and produced by Xintela. Patients with moderate knee osteoarthritis (grades II-III) receive one injection of XSTEM into the knee joint. Three different dose levels are being evaluated in a total of 24 patients with the possibility to increase the number up to 54 patients. The first two dose levels have been considered safe and 6 out of 8 patients have been dosed at the third and final dose level. Xintela has now started to evaluate the first efficacy results for patients at the lowest dose level and can see an early trend showing that patients experience reduced pain and improved joint function in the knee six months after the injection with XSTEM.

Each patient will be followed for 18 months with efficacy readings every six months. The primary goal is to show that XSTEM is safe, but also to investigate preliminary efficacy signals, such as reduced pain, reduced degradation of articular cartilage, regeneration of damaged cartilage and improved joint function. Safety data from all dose levels and up to 12 months efficacy data from the lowest dose level are expected in 2023.

"We are pleased that the study with XSTEM for the treatment of knee osteoarthritis is progressing so well and that we are seeing indications of the effect of the treatment, although we are still at an early stage. We now look forward to establishing the safety from all dose levels and continuing to evaluate the effect of the treatment", says Camilla Wennersten, Director Clinical Development for Xintela.

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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.

Attachments

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