Xintela extends clinical study with XSTEM on knee osteoarthritis patients

Xintela has implemented a change to the clinical study protocol where the follow-up time for the patients at the highest dose level has been extended by 6 months to obtain additional efficacy data for XSTEM® 24 months after dosing. An interim analysis of study data up to 18 months post dosing for all dose levels has been added to the study and will be performed in Q1 2025. XSTEM, which consists of allogeneic (donated) integrin α10β1-selected mesenchymal stem cells, is developed and manufactured by Xintela.

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 evaluated (8 patients/dose level). Patients with moderate knee osteoarthritis (grade II-III) have received one injection of XSTEM into the knee joint. The primary goal of the study is to show that XSTEM is safe. In addition, preliminary efficacy signals, such as reduced pain and improved joint function, as well as reduced breakdown of joint cartilage and regeneration of damaged cartilage, are being investigated every six months.

The patients at the low and mid dose levels have completed, or will shortly complete the study, 18 months after dosing, as planned. The patients at the highest dose level will continue in the study to be evaluated after 24 months as well. The option to expand the study with an additional 30 patients has not yet been activated. The Safety Review Committee for the study has previously assessed all three dose levels as safe at the three-month follow-up, and patients at all dose levels have reported reduced pain and improved joint function after 12 months.

"The main reason for extending the follow-up period for the highest dose level by an additional 6 months is that 24 months is a common time point used for investigation of early regenerative effects on cartilage and other joint tissues. It is thus a good time point to compare our results with published results from other clinical trials. In order not to delay the planned analysis of primary and secondary endpoints, an interim analysis has been added in Q1 2025, following completion of the last patient's 18-month follow-up visit by end of December 2024. We are very much looking forward to the analysed results of the study and to plan for the next steps in the development of XSTEM", says Camilla Wennersten, Director Clinical Development.

Contacts

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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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