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Xintela's GMP facility approved for manufacturing of cell therapy products

Xintela announces today that the company has received permission from the Medical Products Agency to produce cell therapy products, so-called advanced therapy drugs (ATMPs), in its own GMP facility.

– It is a key achievement from the team that the manufacturing permit is now in place. This means we can now start to manufacture our stem cell product, XSTEM®, for clinical studies. We will initiate clinical studies on knee osteoarthritis patients during the year and plan for other indications going forward. To have full control and flexibility in the manufacturing of our own cell therapy products also brings financial and business advantages, says Xintela's CEO Evy Lundgren-Åkerlund.

Liselotte Theorell, Quality Management Director at Xintela, who played a key role in building the GMP facility and its associated production processes and quality system, says:

– This has been a major project and substantial investment for Xintela and I am really proud of what we have achieved through the fantastic effort of our team. That a company as small as Xintela chooses to produce its own cell therapy products is very unusual, but is clearly a winning strategy. Most cell therapy peer companies rely on contracting-out production of their products and have far less control over cost and scheduling. There is a recognized worldwide shortage of contract manufacturing for cell therapies, which is creating development bottlenecks for many companies. With our own production facility, Xintela has none of these worries. We are now really looking forward to starting XSTEM production for the coming clinical trials.

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About Xintela
Xintela develops innovative and patent protected cell therapies and targeted cancer therapies based on the marker technology platform XINMARK. The platform is built on specific cell surface proteins (integrins) and more than 25 years of research and development. Xintela uses the marker technology to select and quality assure stem cells (XSTEM) to develop stem cell therapies for diseases that today lack efficient treatment options, including the joint disease osteoarthritis (OA). Xintela has built an in-house GMP-facility for manufacturing of stem cell products and is preparing a First in Human clinical study on patients with knee OA. In the oncology program, Xintela develops antibody-based therapies for treatment of aggressive tumors including glioblastoma and triple-negative breast cancer. Xintela 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.