xintelling

Newsletter from Xintela AB No 4 2024

In this edition of Xintelling we focus on the ongoing clinical study with our stem cell product XSTEM for the treatment of difficult-to-heal venous leg ulcers (VLU). We have asked Professor Folke Sjöberg to comment on the study and the potential of XSTEM to treat VLU and other skin diseases and skin complications. We also give short updates on our clinical study with XSTEM in osteoarthritis patients and our licensing discussions with EQGen Biomedical.

Treatment of difficult-to-heal venous leg ulcers with XSTEM

Patients with very high medical need

Difficult-to-heal leg ulcers in the elderly, including VLU, are a major medical problem that results in chronic pain and reduced quality of life for the patient, as well as large costs for healthcare systems. The incidence increases with age and is estimated to be about four percent among individuals over 65 years of age [Global Data 2018; Markets and Markets 2020]. Today's treatments for difficult-to-heal venous leg ulcers include compression therapy and various surgical techniques, but there is a lack of effective healing treatments.

Ongoing clinical study with XSTEM

Our clinical study with XSTEM in patients with difficult-to-heal VLU is ongoing at clinics in Sweden. The study includes twelve patients who receive either XSTEM or placebo applied to the wound bed and thereafter safety and efficacy are evaluated weekly for ten weeks and at four months after treatment. Currently, four patients have been dosed and three patients have completed the study.

Xintela has previously reported that the recruitment of patients has been very slow, due to unexpectedly difficulties to recruit this patient group. Nevertheless, we continue to actively work with the clinics to get the remaining patients in as soon as possible and to finalize the study. The primary readout from the study is safety but we are also analyzing efficacy, such as pain and wound healing. The results from this study will form an important foundation for future clinical studies, also in other skin diseases and skin complications. The study has, to this point, been partly financed by a grant from Vinnova, the Swedish innovation fund, of 4.8 million SEK.

XSTEM shows disease modifying effect in preclinical studies

We have, in collaboration with Linköping University Hospital, performed two preclinical wound healing studies in pigs and have shown that XSTEM has excellent wound healing capacity and that the newly formed skin tissue closely resembles normal skin. The XSTEM treatment also showed less scarring (fibrosis) compared to control. Our results also demonstrated that XSTEM could be detected in the newly formed skin tissue after two weeks and that XSTEM differentiated into skin cells, keratinocytes, in cell cultures which further supports the regenerative capacity of XSTEM. The results will be submitted for publication in a scientific journal.


Foto: Emma Busk Winquist

Interview with Professor Folke Sjöberg, MD, PhD, Director at The Burn Center, Linköping University Hospital, Sweden

We asked Prof. Sjöberg, to give his view on the collaboration with Xintela, the therapeutic potential of XSTEM and the need for new treatments for difficult-to-heal venous leg ulcers and other skin diseases and skin complications such as burns. We also asked him to comment on the treatment of burns with Xintela's stem cells in comparison with the burn patients own skin cells, keratinocytes.

First of all, tell us why you started a collaboration with Xintela?

– For years, we have been seeking a viable cell therapy for burn-injured patients. The current standard involves the culture and expansion of autologous (patient's-own) keratinocytes, a complex and costly process that has shown limited impact on survival over the past 30 years. In Xintela we found a stem cell-based alternative with strong regenerative potential that can be stored frozen and applied immediately to patients. The Xintela product XSTEM stands out as it can be used as an allogeneic (donated) transplant, produced under GMP standards, making it a unique and promising option with immense clinical potential once approved.

Our collaboration with Xintela started with preclinical wound healing studies in pigs with XSTEM. From the results, we could conclude that XSTEM has remarkable healing capabilities in this advanced preclinical wound healing model and that this innovative stem cell product holds the potential to significantly alleviate suffering and enhance the quality of life for many individuals. This successful preclinical study then led to the clinical study application to the Swedish Medical Products Agency and our clinical study on patients with difficult-to-heal venous leg ulcers.

Why did you choose difficult-to-heal venous leg ulcers as the first clinical indication for XSTEM?

– The patient group is well-defined and characterised by poor healing conditions. The wounds are typically limited in size, and the treatment procedures are manageable. Additionally, the prevalence of such patients is high, making the approach both relevant and potentially impactful for a significant number of individuals.

Can you comment on why it has been so difficult to recruit patients to the study?

– This is a phase I/IIa study on a cell therapy product (so called ATMP, Advanced Therapy Medicinal Product), and such studies are inherently challenging due to the safety concerns involved. In addition, the patients are elderly and the majority have several other diseases which hinders them from participating in the study. It has been much more difficult than we expected to get the patients in,

"In Xintela we found a stem cell-based alternative with strong regenerative potential that can be stored frozen and applied immediately to patients."

but the recruitment continues and I am helping in every way I can to comlete this important study.

What about XSTEMs potential in other skin wounds and skin complications?

– There is an urgent need for effective treatments that promote healing in patients with challenging leg ulcers, such as arterial and diabetic leg ulcers, as well as major skin defects, including burns. I am genuinely enthusiastic about the potential of XSTEM, Xintela's allogeneic stem cell product, to become available to all wound patients, especially burn victims. In my role as a doctor and chairman of the World Organization for Burns, I have not yet encountered a treatment as promising as XSTEM. I also wish to declare that I have no conflicts of interest regarding Xintela, as I receive no financial support nor hold any ownership in the company.

Finally, Xintela has recently signed an agreement with Region Östergötland to develop a GMP-process to isolate and quality assure autologous skin cells (keratinocytes) from tissue samples from patients for the treatment of burns. Can you comment on this collaboration in relation to the ongoing collaboration with XSTEM therapies.

– The production team at Xintela has demonstrated their capability in producing successful cell therapies. As a result, we have requested their assistance in producing our autologous keratinocyte-based therapies under GMP standards, a quality level we have previously been unable to achieve or source within Europe. We utilize these therapies for skin grafting in the treatment of severe burn injuries at the national burn centre in Linköping, Sweden. Xintela's competence provides us with a valuable resource for advancing our treatment protocols. We see autologous keratinocytes as an important bridge in therapy of burn patients until XSTEM is available in the clinics.

Update on our clinical osteoarthritis study with XSTEM and our licensing discussions with EQGen Biomedical

The XSTEM-study in OA patients is nearing the end of the 18-month follow-up

Our knee osteoarthritis (OA) study with XSTEM progresses very well and as planned. In total, 24 patients have been dosed with three different dose levels of XSTEM (eight patients/dose level). The study's Safety Review Committee has previously assessed all three dose levels as safe at a three-month follow-up, and patients at all dose levels have reported reduced pain and improved joint function after twelve months. In December the last patient on the highest dose level will have the 18-month follow up. We have recently decided to extend the highest dose level by an additional six months for evaluation at 24 months after dosing. The reason for this is that 24 months is a common time point for investigating early regenerative effects on cartilage and other joint tissues and thus a good time point to use in comparing our results with published results from other clinical studies. This is especially relevant in our discussions with pharma companies. We will nevertheless perform an interim analysis in Q1 2025 of study data up to 18 months after dosing at all dose levels. The interim results will provide further support in our continuing business development and partnering discussions. The possibility to expand the study with an additional 30 patients has not yet been activated.

EQGen Biomedical makes great progress

Xintela has signed a non-binding term sheet with the US company EQGen Biomedical for a global license of our equine stem cell product EQSTEM. Xintela and EQGen Biomedical will collaborate on clinical development and commercialization of EQSTEM, initially in the US for the treatment of joint diseases in horses. Xintela will actively participate in the development of EQSTEM, including process development and production of EQSTEM, in an arrangement that is fully financed by EQGen Biomedical. The license agreement is subject to, among other things, EQGen Biomedical securing financing from its extensive, qualified investor network.

EQGen Biomedical has made great progress in building a strong team and is very active in discussions with potential investors. In parallel, Xintela and EQGen Biomedical are working together to plan the coming process development, manufacturing and clinical development of EQSTEM. We are also working on the license agreement and hope to be in a position to sign the agreement in the near future.

With best regards,

Evy Lundgren-Åkerlund
CEO

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