



For immediate release

October 19th, 2016

New clinical trial to evaluate LeucoPatch® in the treatment of malleoli ulcers

Birkerød, Denmark, October 19th, 2016 ... Reapplix today announced that it is funding a new clinical study for LeucoPatch®, on the healing of ulcers on the malleoli, a bony prominence on the ankle, which are often very hard-to-heal, due to the thin layer of tissue over this area.

LeucoPatch® improves wound healing by concentrating cells and growth factors from the patient's own blood and applying them to their wounds. Through this, LeucoPatch® is able to accelerate healing and improve clinical outcomes.

The LiDMUS (LeucoPatch® in Diabetic Malleoli Ulcer Study) study will evaluate both the effect of LeucoPatch® on wound healing and the effect on the local wound environment.

Following encouraging results from a continuing case series by Dr Magnus Löndahl in Lund, Sweden, Reapplix will fund this new 36 patient LiDMUS Randomized Controlled Trial to assess multiple endpoints, including ulcer healing frequency, time to healing and area reduction. Wound and blood samples collected as part of the study will be analysed to confirm the mode-of-action of LeucoPatch® and further advance the scientific documentation.

The trial will be run independently by the Sponsor, Dr Magnus Löndahl, from Skåne University Hospital, Lund, Sweden and will recruit patients at centres in both Sweden and Denmark. Norddjsjællands Hospital Department of Clinical Research will be the CRO for the study.

This new study is in addition to the 250 patient diabetic foot ulcer Randomized Controlled Trial that is being conducted in UK, Sweden and Denmark, which expects to report results in 2017.

Rasmus Lundquist (CSO) commented: *"A key goal of Reapplix is to add to the understanding of wound healing in general and the effects of LeucoPatch® on chronic wounds specifically. Analysis of patient derived LeucoPatches and wound samples will give us great insights into the involvement of the applied leucocytes and cytokines in the transition of these very chronic wounds into healing ones. Key features are believed*

to be the transition of macrophages from the pro-inflammatory M1 type to the tissue-healing M2 phenotype and the involvement of LeucoPatch® derived stem cells in the healing process.”

Graeme Brookes, Chief Executive Officer at Reaplix, added: *“Malleoli ulcers are difficult to treat and to heal, therefore we welcome the opportunity to test LeucoPatch® on these hard-to-heal wounds to prove that we can provide an efficacious treatment that can both reduce healthcare costs and improve patient outcomes.”*

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- Notes to editors -

Reaplix have developed a unique device technology for tissue regeneration, which is currently being focused on wound care. In Europe, this technology is known as the LeucoPatch® System and is undergoing both clinical evaluation and commercial market testing. In the LeucoPatch® System, blood is collected from the patient in a single use LeucoPatch® Device, which is a precision engineered mini cell processor. The LeucoPatch® Device, in combination with the LeucoPatch 3CP™ Centrifuge, uses the patent protected 3CP™ Technology to produce each autologous LeucoPatch® on demand using a simple to use process, with no reagents, which fits in well with existing clinical work flow.

LeucoPatch® is currently being used at selected centres across Europe to treat a variety of hard to heal wounds. In addition to this, LeucoPatch® is being evaluated for the treatment of diabetic foot ulcers in a 250 patient randomized controlled clinical study that is expected to be completed in 2017. Diabetic foot ulcers are associated with high morbidity and substantial health care costs as up to 40% of diabetic foot ulcer wounds remain unhealed after one year using current standards of care. Given these market dynamics, there is a clear need for a cost-effective and efficacious treatment option.

In February 2016, Reaplix’s unique technology - a single use medical device used to prepare an autologous platelet-rich plasma (PRP) gel from the patient’s peripheral blood by centrifugation, without the addition of any reagents - received US FDA 510(k) clearance to be put on market in the US as the 3C Patch System™, with the indication for use that under the supervision of a healthcare professional, the PRP gel produced by the 3C Patch System™ is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds.

Reapplix ApS is a privately-held wound care company backed by three leading Danish investors, Seed Capital, Novo SEEDS and Vækstfonden (The Danish Growth Fund).

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