For immediate release
April 13th, 2016

LeucoPatch® Trial to continue following Interim Analysis

Birkerød, Denmark, April 13th, 2016 … Reapplix today announced that it has been informed by the Trial Steering Committee for the ongoing LeucoPatch® Randomized Controlled Trial (ClinicalTrials.gov NCT02224742) that a planned interim analysis has been performed. The purpose of the planned interim analysis was to re-estimate the sample size (up to 352 patients if needed) or to stop for futility. Following the planned interim analysis, Reapplix has been informed that the trial will continue to the originally estimated sample size of 250 participants.

This large scale Randomized Controlled Trial is being conducted in up to 35 centres in UK, Sweden and Denmark. The aim of the Trial is to demonstrate whether the application of LeucoPatch® when used in addition to usual care in a multidisciplinary diabetes foot clinic setting, is superior to usual care alone with regard to complete healing of hard-to-heal diabetic foot ulcers. The study will also provide information on reduction in pain, decrease in ulcer area, amputations, well-being, costs and other clinical outcomes.

Reapplix are providing funding for this trial, which is being run independently by the Sponsors, Nottingham University Hospitals NHS Trust.

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- Notes to editors -

Reapplix have developed a unique device technology for 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 effectively 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 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, Reapplix'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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