



Positive outcome data of large Randomized Controlled Trial presented at American Diabetes Association Scientific Sessions

Reapplix business update

- Application of Reapplix's LeucoPatch® results in significantly higher incidence of healing
- Business update:
 - Established Reapplix Inc in the US and appointed James G Wetrich as President, Reapplix Inc
 - Appointment of Morten Have-Rasmussen as Chief Financial Officer

Birkerød, Denmark, 26 June, 2018 – Reapplix ApS, the regenerative medicine company, initially focussed on chronic wounds, announces that positive outcome data of an independent Randomized Controlled Trial (RCT) of its LeucoPatch® wound healing platform was presented at the American Diabetes Association 78th Scientific Sessions meeting in Orlando, Florida. The Company has also provided an update on the Company's progress.

Positive outcome data

LeucoPatch®, marketed in the US as 3CPatch®, is a novel platform technology which provides cells and growth factors concentrated from a small sample of the patients' own blood to produce a small 'patch' at the point of care, with no reagents or additives. This is applied topically for the management of exuding cutaneous wounds.

The multicentre, multinational, observer-blinded RCT, ([ClinicalTrials.gov NCT02224742](https://clinicaltrials.gov/ct2/show/study/NCT02224742)) was undertaken at 32 specialist diabetic foot clinics in the UK, Denmark and Sweden. The aim of the trial was to determine 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.

269 people were randomized to either usual care or care supplemented by weekly application of LeucoPatch®. The primary outcome measure for the trial was healing within 20 weeks of randomization and the trial found a significantly higher incidence ($p=0.0235$) of healing (Odds Ratio 1:58, a 58% increased chance of healing) in those receiving LeucoPatch®.

This investigator driven trial was run independently by the sponsors, Nottingham University Hospitals NHS Trust. Reapplix involvement was limited to funding the study.

Niels Erik Holm, Chief Operating Officer and Rasmus Lundquist, Chief Scientific Officer at Reapplix, jointly commented:

“This data is an important validation of LeucoPatch® and the positive outcomes it can bring to patients. We are grateful to the investigators, wound care professionals and patients who have taken part in this trial and look forward to bringing our treatment to market enabling those in need to benefit.”

Under the current standard of care, up to 40% of diabetic foot ulcer wounds remain unhealed after one year, meaning that there is a clear need for an efficacious and cost-effective treatment option.

Business update

Based on this strong clinical evidence, Reapplix has moved forward with key corporate activities and formed Reapplix Inc, based in Texas to bring the 3CPatch® System to the market in the US.

James G Wetrich has been appointed as President of Reapplix Inc, responsible for building sales in the US market. He brings a wealth of experience in wound care and corporate strategy, having been President and GM USA & LATAM for Mölnlycke Health Care from 2006 to 2014, where he oversaw the creation of its large and successful wound care business. He also ran his own consulting business having had previous roles in corporate and strategic planning at Abbott and VP roles in various US hospital groups.

Additionally, Morten Have-Rasmussen has been appointed as Chief Financial Officer. Morten previously held Finance Director roles at Qiagen and at Exiqon in Denmark.

Graeme Brookes, Chief Executive Officer at Reapplix, commented on the news:

“Diabetic foot ulcers are associated with high morbidity and substantial health care costs. Following the positive results of the LeucoPatch® trial, we are moving forward with our plans to build and strengthen Reapplix.

“With the key appointments of Jim Wetrich as President of Reapplix US and Morten Have-Rasmussen as CFO, we are investing for the future. Non-healing wounds are life threatening and we are excited at the potential for our LeucoPatch® technology to help more patients.”

-Ends-

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Notes to editors

About Reapplix ApS

Reapplix has developed a novel platform technology for regenerative medicine which provides cells and growth factors concentrated from a small sample of the patient's own blood and addresses unmet needs in tissue healing.

Reapplix's unique technology, including the automated 3CP® centrifuge, received US FDA 510(k) clearance in 2017 to be put on the market in the US as the 3C Patch System®. The indication for use is topical application, under the supervision of a healthcare professional, for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers, and mechanically or surgically-debrided wounds. In Europe, this technology has so far been made available under the name, LeucoPatch®.

Using a disposable procedure pack and the proprietary simple to use 3CP® process, a small 'patch' is produced at the point of care from the patient's blood with no reagents or additives. The technology is currently being used at selected centres across Europe and has been evaluated for the treatment of non-healing diabetic foot ulcers in large a randomized controlled clinical study, that has now reported and confirmed significantly improved healing versus usual care.

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 an efficacious and cost-effective treatment option.

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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