CUTISS AG receives Swissmedic approval to commence phase II denovoSkin™ trial for reconstructive surgery in adults and children.

Zurich, February, 2018 CUTISS AG announced that it has received approval from Swissmedic to commence a Phase II trial using denovoSkin™ in the treatment of reconstructive skin defects in adults and children. In Switzerland, these Trials will be recruiting patients at two centers, the University Children's Hospital Zurich where Phase I was recently completed, and the University Hospital Zurich. This Trial will expand to other two centers, The VUmc in The Netherlands, and the University Hospital in Birmingham in UK, subject to approval by the National Authorities. The trial is designed to treat up to 20 patients.

„The aim of these Phase II trial is to validate the efficacy of denovoSkin™ against standard of care in patients with large full-thickness skin defects that require coverage after excision of scar, giant nevus and benign skin tumors, plastic surgery etc., " said Dr. Fabienne Hartmann, CTO.

„We are also delighted to continue the trials where they originated, at University Children's Hospital Zurich". We want to thank the patients and their families who have taken part in the trials so far and those that will support our future efforts." Said Dr. Daniela Marino, CEO.

About full-thickness skin defects
Every year in the world, millions of people need autografting to restore skin function after e.g. scar, gian nevus and tumor excision, or plastic surgeries. In many cases, donor site shortage and morbidity, distress, and poor cosmetic/functional outcome represent a real problem. denovoSkin™ could significantly improve the life quality of patients worldwide by drastically overcoming donor site shortage, reducing distress and improving the functional and aesthetic outcome.

About CUTISS AG
CUTISS is a Swiss biotech company, spin-off of the UZH, developing personalized skin graft technologies for the treatment of a large spectrum of skin defects. Its first in line product denovoSkin™ has been tested in a phase I clinical trial on pediatric patients at the University Children's Hospital in Zurich. EU phase II studies are funded by Wyss Zurich. denovoSkin™ has received Orphan Drug Designation for the treatment of burns by Swissmedic, EMA and FDA. In addition, denovoSkin™ promises to improve life quality of elective (reconstructive) patients as well and it can further be developed in terms of complexity by adding pigmentation.

For Patients
Would you be willing to participate to our trials?
Please write to clinicaltrials@cutiss.swiss. Thanks!
Sponsor of the trials is the University of Zurich, Switzerland.

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