Media Release

CUTISS AG receives Swissmedic approval to commence Pivotal Phase II denovoSkin™ trials in burns

Zurich, November 03, 2017  CUTISS AG today announced that it has received approval from Swissmedic to commence two Pivotal Phase II trials using denovoSkin™ in the treatment of burns in adults and children, respectively. 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. The trials will expand to other two centers, The Dutch Burn Center in The Netherlands, and the University Hospital in Birmingham in UK, subject to approval by the National Authorities. The trials are designed to treat up to 15 burn patients each.

"The aim of these Pivotal Phase II trials is to validate the efficacy of denovoSkin™ against standard of care in burns” said Dr. Fabienne Hartmann, CTO at CUTISS AG. "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 at CUTISS AG.

About Burns
Every year in the world, more than 11 millions of people burn large areas of their bodies and need surgical intervention to restore skin function. In many cases, standard of care leaves patients with discomforting and debilitating scars. denovoSkin™ could significantly improve the life quality of patients worldwide by drastically reducing scarring after transplantation.

About CUTISS AG
CUTISS AG 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.

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