

PRESS RELEASE

CUTISS completes recruitment for denovoSkin™ Phase 2 clinical trial in adult and adolescent burn patients

Switzerland, 7 September 2022 – CUTISS AG, a Swiss clinical-stage life sciences company focused on skin regenerative medicine and tissue engineering, has announced the completion of recruitment for the Phase 2 clinical trial of its lead product denovoSkin™ in adult and adolescent burn patients. The entire study lasts about 12 months per patient with yearly follow-up visits 2 and 3 years after transplantation. Clinical outcome data from ongoing patient follow-ups are expected to become available in Q1 2023.

This Phase 2 clinical trial evaluates the safety and efficacy of denovoSkin™, a personalized, bio-engineered dermo-epidermal skin substitute (NCT03227146). The trial is conducted in hospitals across Switzerland, Italy, and the Netherlands in patients 12 years of age and older who require a skin graft due to a major burn. A total of 12 patients are included in this trial. Since the protocol allows up to 15 patients, 2 additional patients have been enrolled and treated in August.

Dr. Fabienne Hartmann-Fritsch, Clinical Study Advisor and co-founder at CUTISS, stated: *“We are very pleased to have completed the recruitment of patients for this ground-breaking clinical trial, a true milestone for the continued development of our lead product denovoSkin™. We now look forward to analyzing the clinical outcome data during 2023.”*

The personalized human skin graft denovoSkin™ that is bio-engineered in large quantities starting from a small, post stamp-sized piece of healthy skin of the patient, could take skin surgery to the next level and revolutionize current treatments. It promises to grow with the patient, limit scarring and drastically reduce the number of follow up corrective surgeries required.

Dr. Daniela Marino, Chief Executive Officer and co-founder at CUTISS, commented: *“In Switzerland and across Europe, this year’s particularly hot and dry summer resulted in several fire-related accidents and patients admitted to burn centers requiring skin surgery. After completing the technology transfer from Wyss Zurich, our new on-site manufacturing facility started activities in March 2022 which significantly increased our agility and capacity to produce denovoSkin™ for clinical trials as well as for patients on a compassionate use basis.”*

CUTISS is also conducting two other denovoSkin™ Phase 2 clinical trials in Switzerland, Italy, and the Netherlands: one for pediatric burns (under 12 years of age, NCT03229564), and one for reconstructive surgery of skin defects (from 1 years of age, NCT03394612). A clinical trial Phase 1 for denovoSkin™ involving children suffering from burns or skin defects requiring surgery was completed in 2021 with a 5 year follow up at the University Children’s Hospital in Zurich.

Further details of CUTISS’s clinical trials can be found on the company’s website [here](#).

To see how CUTISS bioengineers denovoSkin™, its pioneer automated manufacturing program, and the promising impact that CUTISS’s product has on patients, please visit the company’s YouTube channel [here](#).



About CUTISS AG

[CUTISS](#) is a Swiss clinical-stage life sciences company focused on regenerative medicine and skin tissue engineering. It is developing the first personalized and automated skin tissue therapy offering life-saving and life-changing medical treatments for patients with severe skin injuries.

The lead product denovoSkin™ promises to take skin surgery to the next level and revolutionize current treatments. It is a bio-engineered and personalized dermo-epidermal human skin graft, currently in Phase II clinical trials in Switzerland and the European Union, with Orphan Drug Designation for the treatment of burns from Swissmedic, EMA, and FDA.

CUTISS is also developing the world's first machines that can automate the entire production process of the personalized skin graft. The company's knowledge in skin bio-engineering and biology offers several growth opportunities in regenerative medicine.

Established in 2017, the company is a spin-off from University of Zurich (UZH) / University Children's Hospital and was a member of the accelerator Wyss Zurich until February 2022. Headquartered at the Bio-Technopark in Zurich-Schlieren, it won the Top 100 Swiss Startup Award 2020, and has raised over CHF 55 million from private investors, family offices and public bodies.

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