



PRESS RELEASE

Recruitment completed for denovoSkin™ Phase 2 clinical trial in reconstructive surgery

Switzerland, 07 November – CUTISS AG, a Swiss clinical-stage life sciences company focused on skin regenerative medicine and tissue engineering, has announced the successful completion of patient recruitment for the Phase 2 clinical trial of its lead product, denovoSkin™, in reconstructive surgery for both children and adults.

This Phase 2 clinical trial evaluates the safety and efficacy of denovoSkin™, a personalized, bio-engineered dermo-epidermal skin substitute in reconstructive surgery. The study has a follow-up period of a total of 3 years. Clinical outcome data are expected to become available in the next 12 months.

The trial is being conducted across multiple hospitals in Switzerland, Italy, and the Netherlands, encompassing patients from 1 year of age who require reconstructive skin surgery due to various conditions. A total of 20 patients were included in this trial.

Dr. Daniela Marino, Chief Executive Officer and co-founder at CUTISS, said: *“The end of recruitment for this pivotal clinical trial underscores our commitment to advancing the field of skin regenerative medicine beyond burns. We are eager to move to the next development phase and to analyze clinical outcome data during 2024.”*

The innovative denovoSkin™ graft, bio-engineered from a small sample of the patient's healthy skin, aims to transform the landscape of skin surgery. Its potential benefits include reduced scarring, a pivotal feature for reconstructive surgery.

Dr. Daniela Marino added: *“Our team has worked diligently to reach this stage, and we are grateful for the trust and collaboration of our clinical partners and patients. As we progress, we remain dedicated to our mission of offering advanced solutions for skin surgery.”*

In addition to this reconstructive surgery clinical trial, CUTISS has a Phase 2 study in recruitment for pediatric burns (under 12 years of age) with denovoSkin™, as well as an active Phase 2 study in burns for adult and adolescent patients (total follow-up period of 3 years). A Phase 3 clinical trial for denovoSkin™ in adult and adolescent burn patients is in the planning phase.

More details on CUTISS's clinical trials and other developments can be found on the website [here](#).

About denovoSkin™

Lead product denovoSkin™ is a personalized human skin graft that can be bio-engineered in large quantities, starting from a small, post stamp-sized piece of healthy skin. It promises to grow with the patient, limit scarring, and drastically reduce the number of follow up corrective surgeries required, particularly in children. The outcome is potentially life-saving and life-changing.

Following the completion of a safety clinical Phase 1 trial with a 5-year follow up, CUTISS [announced in April 2023 the positive results from the Phase 2 clinical trial](#) of denovoSkin™ in adult and adolescent burn patients. The efficacy endpoint was reached with high statistical significance.

It has Orphan Drug Designation for the treatment of burns from Swissmedic, EMA, and FDA.

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 transitioning towards phase III 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, aesthetic and other applications beyond 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 67 million from private investors, family offices and public bodies.

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