

PRESS RELEASE

**CUTISS announces results from Phase 2 clinical trials for denovoSkin™
in adolescent and adult burn patients, and Phase 1 in children**

- Phase 2 clinical trial reaches efficacy endpoint with high statistical significance for lead product denovoSkin™ in adult and adolescent burn patients.
- Phase 1 clinical trial of denovoSkin™ is completed with 5-year follow up demonstrating product safety in pediatric and adolescent patients in burn and reconstructive surgery.

Switzerland, 3 April 2023 – CUTISS AG, a Swiss clinical-stage life sciences company focused on skin regenerative medicine and tissue engineering, has announced positive results from the Phase 2 clinical trial of its lead product denovoSkin™, in adult and adolescent burn patients. The efficacy endpoint has been reached with high statistical significance, demonstrating efficacy of denovoSkin™ as a personalized, bio-engineered dermo-epidermal skin substitute for patients requiring a skin graft due to a major burn.

Furthermore, the Phase 1 clinical trial for denovoSkin™ completed the 5-year follow up period demonstrating the product's safety. The Phase 1 trial included pediatric and adolescent patients requiring a skin graft due to a burn injury or reconstructive surgery.

Dr. Daniela Marino, CEO of CUTISS, said: *"We are thrilled with the positive results from the Phase 2 and the completion of the Phase 1 clinical trial with five-year follow-up, which confirms the safety and efficacy of denovoSkin™ in adult and adolescent burn patients. We are proud of the progress made this far, and the hard work and dedication of the entire CUTISS team. We look forward to preparing for the next regulatory steps to bring this promising treatment to patients suffering from severe burns and skin injuries."*

The Phase 2 full data analysis with the three-year follow up will be available in 2025, with the last patient transplant having taken place in August 2022. A total of 15 patients are included in this trial.

Further details of CUTISS's clinical trials can be found on the company's website [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 65 million from private investors, family offices and public bodies.

Media contacts

Cabinet Privé de Conseils (Switzerland)

Toomas Kull kull@cpc-pr.com | +41 767 480 174