Press release

CUTISS announces positive one-year readout Phase 2 data for denovoSkin™ in adolescent and adult burn patients

Switzerland, 14 February 2024 – CUTISS AG, a Swiss clinical-stage life science company focused on skin regenerative medicine and tissue engineering, has announced positive one-year follow-up data from its Phase 2 clinical trial of the lead product denovoSkin™, in adult and adolescent severe burn patients. Following the announced positive primary endpoint in Q1 2023, the one-year readout evaluated long term safety and scar quality.

Dr Daniela Marino, CEO of CUTISS, commented: *"The latest data represent a pivotal moment in our mission. It reinforces the evidence we have gathered so far that denovoSkin™ can be life-saving and can become a transformative treatment option for patients suffering from severe burns by improving overall scar quality and relief post grafting."*

The Phase 2 data and results thus far demonstrate that denovoSkin™, a living, personalized bilayer (with epidermis and dermis) bioengineered skin graft, can safely cover severe burn wounds, significantly sparing patients' healthy donor sites while improving overall scar quality when compared to standard of care intra-patient.

Prof. Dr. MD, Martin Meuli, Chairman of CUTISS, added: *"The accomplishments of the past decade have placed us in the midst of an important paradigm shift in burn treatment: from mortality, that used to be the primary concern, to areas that focus on the quality of life of burn survivors. Conceptually understanding the epidermis as "life" whereas dermis as "quality of life" is maybe simplistic, but nonetheless useful to understand the impact that denovoSkin™ can potentially have in burn surgery."*

The current treatment in severe burns and reconstructive surgery – autografting – commonly results in permanent painful, debilitating, disfiguring scars that frequently require follow up corrective surgeries, psychosocial rehabilitation and intense home care. With denovoSkin™, CUTISS is seeking to revolutionize the treatment of severe burns. The Phase 2 clinical trial in adult and adolescent burns has a long-term follow-up of three years (data will be available in 2025). A total of 15 patients were included in this trial.

The company is preparing for the next regulatory steps, aiming to make denovoSkin™ available to patients suffering from severe burns and skin injuries worldwide.

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. 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.

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