CUTISS announces positive Phase 2 trial readout for long-term efficacy and safety of denovoSkin™ in reconstructive skin surgery and in burns

denovoSkin™ seeks to redefine skin surgery and significantly improve patient outcomes in burn treatment and reconstructive procedures.

Positive Phase 2 data from a 1-year follow-up in reconstructive skin surgery and a 2-year follow-up in severe burns treatment confirms safety and efficacy.

denovoSkin™ can significantly spare donor sites and improve scar quality when compared to standard of care treatment.

Switzerland – 12 February 2025 – CUTISS AG, a life sciences company at the forefront of tissue engineering therapy and regenerative medicine, announced positive long-term efficacy and safety readout in the Phase 2 clinical trials of denovoSkin™ in reconstructive surgery as well as in burns treatment.

The data reaffirm the role of denovoSkin™, an autologous, bio-engineered dermo-epidermal skin graft, in reducing the need for donor site harvesting and minimizing scarring, leading to improved patient outcomes following skin surgery compared to autografting which is today's standard of care.

"denovoSkin™ has the potential to revolutionize skin surgery beyond burns, and the latest data show that our product can also be used for elective reconstructive surgery indications," said **Dr. Daniela Marino, CEO of CUTISS**. *"The robust 1-year data in reconstructive procedures and the solid 2-year data in burns demonstrate denovoSkin™'s versatility and its ability to deliver superior outcomes, surpassing traditional methods."*

"The impact of living with scars is frequently underestimated. Patients often face limitations in movements because of a scar that doesn't stretch, requiring repeated surgeries that pose a constant burden for the patient and society," commented **Prof. Dr. Esther Middelkoop, Prof. of Skin Regeneration and Wound Healing at the Amsterdam University Medical Center**. *"Patients treated with denovoSkin™ for reconstruction perceived a remarkably fast maturation and good skin quality. The treated areas were particularly pliable, with texture and function comparable to normal skin. Unlike autografting, treatment with denovoSkin™ is less invasive and results in better skin quality. This could benefit many patients who are dealing with problematic wounds and scars today."*

Growing need in reconstructive skin surgery

Reconstructive skin surgery is needed for patients requiring scar revision, cancer resection, plastic and trauma surgery, as well as the removal of giant congenital nevi in children, for example.

Demand for plastic and reconstructive surgeries continues to grow, with 6.8 million reconstructive procedures performed in the U.S. in 2023, according to the American Society of Plastic Surgeons (ASPS).

denovoSkin™ promises improved patient outcomes and quality of life

The current standard in skin surgery – autografting – often faces donor site shortages[1] and results in scarring, which requires ongoing maintenance, limits mobility and growth, and may necessitate follow-up corrective surgeries, particularly in children.

[1] Donor site shortages refer to the limited availability of healthy skin for grafting, particularly in patients with extensive burns or insufficient viable tissue.

While denovoSkin™ clearly offers the key advantage of sparing donor sites and eliminating the need for large-scale skin harvesting, these Phase 2 data readouts also demonstrate that denovoSkin™ provides patients with significant improvements in terms of skin pliability, flexibility, relief, and overall scar quality when compared to standard of care in an intra-patient control setting.

Phase 2 clinical trials progressing, Phase 3 trial authorized and starting in the E.U.

The positive 1-year efficacy and safety data in the Phase 2 trial in **reconstructive skin** surgery in children and adults follows the announcement of a positive interim readout in July 2024, and the successful treatment of the first U.S. patient on a compassionate-use basis for complex post burn reconstructive procedures.

The positive 2-year long term follow-up data in **burns** follows the announcement of positive efficacy and safety readout in February 2024 in adolescent and adults, as well as several compassionate study reports.

denovoSkin™'s Phase 2 clinical trials have a total follow-up period of three years.

Meanwhile, CUTISS is advancing into **Phase 3 trials in the E.U. for burn patients**, having received authorization from the European Medicine's Agency (EMA) in December 2024.

With continued success, denovoSkin™ is set to redefine the future of skin surgery, offering advanced solutions that restore the skin's function and cosmesis[2] with minimal donor site harvesting.

The full clinical development program can be viewed online here.

About CUTISS

Established in 2017 as a spin-off of the Tissue Biology Research Unit of the University of Zurich, CUTISS is at the forefront of tissue engineering therapy and regenerative medicine. Our lead product, denovoSkin™, a bio-engineered, personalized skin graft, promises to transform skin surgery. Currently in phase III clinical trials in Europe, denovoSkin™ has received Orphan Drug Designation from Swissmedic, the European Medicines Agency (EMA), and the US FDA for the treatment of burns.

Moreover, CUTISS is pioneering the development of the world's first automated platform for large-scale skin tissue production, advancing breakthrough programs in skin pigmentation restoration and expanding the horizons of tissue engineering. For more information: www.cutiss.com.

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[2] Cosmesis refers to the aesthetic outcome of a medical procedure, particularly in minimizing visible scarring and improving skin appearance.