



PRESS RELEASE

## **CUTISS launches Series C financing round to advance the development of its personalized skin technology, paving the way towards commercialization**

- Round C to finance the continued development and path to commercialization of denovoSkin™ and Viticell®
- Phase 2 clinical trial results for lead product denovoSkin™ reached efficacy endpoint with high statistical significance
- VitiCell® is a CE marked medical device the treatment of skin pigmentation disorders

**Switzerland, 18 September 2023** – CUTISS AG, a Swiss clinical-stage life sciences company focused on skin regenerative medicine and tissue engineering, has announced the launch of its Series C for the next stage of the company's development.

CUTISS seeks to raise the Series C with the participation of existing and new investors to take its personalized skin therapy denovoSkin™ into the final stages of development, having recently completed the recruitment in Phase 2 clinical trials with positive results. The company will also proceed to industrialize and get to clinical readiness the automated machine that can bioengineer denovoSkin™. Furthermore, CUTISS will finalize the pre-launch activities for the commercialization of VitiCell®, the medical device for the treatment of Vitiligo which has been in-licensed from IBSA Pharma.

The Series C is co-led by the family office of Giammaria Giuliani (lead investor in CUTISS' previous rounds) and a US family (new investor) represented by Shiloh Advisors AG. The terms are set. Existing shareholders and new investors are called in to support CUTISS' journey in its final steps to commercialization.

**Dr Daniela Marino, CEO and co-founder of CUTISS**, commented: *“The opening of our Series C financing round is a significant step in our mission to develop and provide a life-saving and life-changing treatment for patients with severe skin injuries and defects. We are grateful for the continued support of our existing investors and the new investor from the US, and look forward to engaging with others. The recent positive Phase 2 clinical trial results for denovoSkin™ and the positive feedback from the medical community strongly motivate us to continue pushing the boundaries of innovation in the field of regenerative medicine.”*

CUTISS has so far raised a total of CHF 67 million from private investors, family offices, and public bodies, including Giammaria Giuliani (Giuliani Pharma, GiSev, Royalty Pharma and HBM), Zürcher Kantonalbank (ZKB), the Wyss Foundation, Yellowstone Holding, and Lichtsteiner Foundation. CUTISS has also received funds granted by the European Union, Innosuisse and Wyss Zurich.

### **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 the automation program**

CUTISS is working to scale-up the production of denovoSkin™ through automation. The company has developed its own unique approach to bioengineering human skin tissue composed of three modules: cell isolation, cell expansion, and skin tissue formation. Starting from a patient's biopsy and working in sequence, the modules produce the personalized dermo-epidermal skin graft denovoSkin™.

The denovoCast™ is the world's first machine that can bio-engineer large, personalized skin tissue grafts, in a fully closed way. The machine has undergone R&D testing at CUTISS and the company is ready to start the process of industrialization. In May 2023, CUTISS announced that Innosuisse, the Swiss Innovation Agency, [awarded a CHF 2.5 million grant to advance the pioneering automation program](#), and support the industrialization of the denovoCast™.

### **About VitiCell®**

VitiCell® is indicated for skin re-pigmentation, for example in the case of non-evolving Vitiligo or hypochromatic post traumatic scars. It is a medical device that makes autologous cellular grafting possible in an out-patient setting by a medical professional, be it at a hospital, private clinic or a dermatologist's cabinet. VitiCell® is a biotechnological product developed and patented by IBSA Pharma. In February 2022, CUTISS announced that it [received exclusive rights from IBSA Pharma to globally commercialize VitiCell®](#).

### **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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