

PRESS RELEASE

CUTISS starts onsite denovoSkin™ production and successfully exits Wyss Zurich accelerator

- CUTISS achieves full independence in its manufacturing capabilities with onsite facility.
- Increased agility and capacity in producing denovoSkin for current and future clinical trials and patients on compassionate basis.
- Successful transfer of technology and departure from Wyss Zurich Translational Center, a joint accelerator created by Hansjörg Wyss together with the University of Zurich and ETH Zurich (Swiss Federal Institute of Technology Zurich).

Zurich, Switzerland – 08 March 2022 – CUTISS AG, a Swiss clinical-stage life sciences company focused on regenerative medicine and skin tissue engineering, has announced the start of production at the company's new onsite manufacturing facility. This follows the certification of compliance for Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP)¹ from the regulator Swissmedic, the Swiss Agency for Therapeutic Products, in October 2021, and then the authorization to transfer the technology from Wyss Zurich to CUTISS.

Kathi Mujynya, Chief Operating Officer at CUTISS, said: *“This evolution represents a critical milestone for CUTISS. It centralizes our activities around the manufacturing of denovoSkin, increases our production capacities, and enables us to scale up the manufacturing process and take our automation program to the next level.”*

The CUTISS facility has commenced manufacturing and testing of tissue-engineered products, notably for the personalized human skin tissue therapy denovoSkin which is currently in Phase 2 clinical trials. The state-of-the-art facility, located at the company's headquarters at the Biotechnopark in Zurich-Schlieren, covers a surface area of 150 square meters and is comprised of several laboratories including a biobank and a histology lab.

Until now, CUTISS's products were manufactured at the GMP facility of Wyss Zurich Regenerative Medicine Technologies Platform, University of Zurich. Following the successful transfer of technology, CUTISS has become one of the first regenerative medicine companies to transfer out of this platform at Wyss Zurich.

Professor Simon P. Hoerstrup, Founding Co-Director of the Wyss Zurich Translational Center, stated: *“We are extremely pleased with the development of the project during its five years at Wyss Zurich, not least because it has all come out of our own development at the University of Zurich, our state-of-the-art technical and scientific platform facilities, and the Children's Hospital Zurich. Starting as a research project, moving to preclinical implementation, and finally to clinical trials in a highly regulated environment – this is one of Wyss Zurich's flagship projects. And finally, a successful technology transfer from Wyss Zurich's Regenerative Medicine Technologies Platform to the startup was achieved with the construction of its own facility by CUTISS.”*

Dr Daniela Marino, Chief Executive Officer at CUTISS, commented: *“We are very grateful to Wyss Zurich for their help and support throughout the last five years, enabling CUTISS to grow and arrive at this stage of development. Now, we are thrilled to have established and launched our own independent manufacturing capabilities, enabling us to scale up the development of our personalized skin tissue therapy and to meet the needs of patients with severe skin injuries.”*

Today's announcement coincides with CUTISS's five-year anniversary, having been established on 08 March 2017.

A video of the manufacturing facility can be viewed here: https://youtu.be/YDV2cvaXI_I

¹ Good Manufacturing Practice (GMP) standards and guidelines require that the manufactured medical products are of consistent high quality. Good Distribution Practice (GDP) refers to standards that ensure the quality and integrity of medicines throughout the supply chain.



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 IIb 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 machine 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 March 2022. Headquartered at the Bio-Technopark in Zurich, it won the Top 100 Swiss Startup Award 2020, and has raised about CHF 50 million from private investors, family offices and public bodies.

About Wyss Zurich

The [Wyss Zurich Translational Center](#) is a joint accelerator of the University of Zurich and ETH Zurich (Swiss Federal Institute of Technology Zurich), which was made possible by a generous donation from the Swiss entrepreneur and philanthropist Dr. h.c. mult. Hansjörg Wyss. It was established to foster translational research focused on developing treatment protocols and clinical therapies, as well as novel technologies and intelligent systems, in the emerging fields of Regenerative Medicine, Robotics, and hybrid technologies thereof. Wyss Zurich unites world-leading experts from both institutions in multidisciplinary teams, pooling their knowledge and expertise.

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