CUTISS receives Positive Opinion from the Paediatric Committee of the European Medicines Agency on the Company's proposed Paediatric Investigation Plan for denovoSkin™

Zurich, Switzerland, August 3, 2020 – CUTISS AG, an innovative Swiss Life Science Company aiming to provide patients that suffer from large and deep skin defects with an automatically produced, personalized skin tissue therapy, denovoSkin™, today announced that it received a positive opinion from the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) for its proposed Paediatric Investigation Plan (PIP) for denovoSkin™.

The positive opinion is based on the non-clinical program, as well as data from the phase I safety clinical trial and the plans for the current phase IIb efficacy trials running in children and adults. The PDCO's positive opinion on CUTISS' PIP endorsed the Company's program for denovoSkin™ as acceptable for assessment of safety and efficacy for the use in children from birth to less than 18 years of age.

Dr. Daniela Marino, Chief Executive Officer and Co-Founder of CUTISS AG, commented: "We are delighted having received a positive opinion from EMA's Paediatric Committee on our proposed Paediatric Investigation Plan for denovoSkin™, which is based on a comprehensive data package from our non-clinical and clinical development program. As planned, we will move forward with our clinical development of denovoSkin™ towards marketing application submission in Europe".

"In addition, we are very pleased with the outcome of our discussions with the Paediatric Committee. To our knowledge, it is the first time the PDCO has concluded that a clinical development program for a bio-engineered personalized skin tissue therapy is suitable for children suffering from burns", Daniela Marino added. This is of relevance as the Paediatric Committee (PDCO) is the European Medicines Agency's (EMA) scientific committee responsible for activities on medicines for children and to support the development of such medicines in the European Union by providing scientific expertise and defining paediatric needs.

The relevance of a Paediatric Investigation Plan (PIP)

A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorisation of a medicine for children. All applications for marketing authorisation for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when a marketing-authorisation holder wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorised and covered by intellectual property rights.

About CUTISS AG

CUTISS is a Swiss Life Science Company, spin-off of the University of Zurich, developing personalized skin graft technologies for the treatment of a large spectrum of skin defects. Its lead product candidate, denovoSkin™, has been tested in a phase I clinical trial on pediatric patients at the University Children's Hospital in Zurich; denovoSkin™ was well tolerated by all patients with no safety issue reported. Phase II studies are currently ongoing in Switzerland and the European Union and are partially funded by Wyss Zurich. denovoSkin™ has received Orphan Drug Designation for the treatment of burns by Swissmedic, EMA and FDA. In addition, denovoSkin™ aims to improve life quality of elective (reconstructive treatments) patients as well and it can further be developed in terms of complexity by adding pigmentation.

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