

## Poietis signs a clinical research collaboration contract with the Assistance Publique - Hôpitaux de Marseille (AP-HM) to prepare the first clinical trial of a bioprinted skin.

*This partnership with the AP-HM could lead to a world first and opens up important applications in the field of regenerative medicine.*

Pessac and Marseille, France – February 05<sup>th</sup>, 2020 - Poietis, leading bioprinting company, and the "Assistance Publique - Hôpitaux de Marseille" (AP-HM) announced today that they have entered into a partnership through the signature the 20<sup>th</sup> of January of a clinical research collaboration contract on a bioprinted tissue engineering product. The objective of this agreement is to carry out within two years a Phase I clinical trial of an Innovative Advanced Therapeutic Medicinal Product (ATMP) responding to wound skin healing issues.

The development of tissue engineering and the manufacture of implantable biological tissues represent major socio-economic challenges. The global market for tissue engineering and regeneration is expected to grow from \$24.7 billion in 2018 to \$109.9 billion by 2023 (*source: BCC Research*). As a result of longer life expectancy and the incidence of major pathologies such as cancer and diabetes, the number of people waiting for an organ transplant is constantly increasing: at the end of 2016 in the EU member countries more than 142,000 patients were waiting for a kidney, liver, heart, lung, pancreatic or intestinal transplant (*source: EDQM Council of Europe*).

Poietis is a biotechnology company specialized in the development and manufacturing of human tissues by bioprinting. Its main mission is to develop new therapeutic solutions based on its expertise in bioprinting technologies and in particular high-resolution laser assisted bioprinting. Poietis has developed the multimodal NGB ("Next Generation Bioprinting") bioprinting platform declined in two versions: one for *in vitro* tissue engineering research (NGB-R) and a clinical version (NGB-C) for the production of implantable bioprinted tissues. This multimodal, automated biomanufacturing platform enables tissue engineering researchers to achieve superior tissue engineering results through high resolution, and enables the fabrication of complex tissues with repeatability and reproducibility.

The AP-HM, and more particularly its "cell therapy unit » headed by Professor Florence Sabatier, has the manufacturing authorisation and expertise to manufacture, control and deliver cell therapy preparations (CTP) in the context of routine care, as well as expertise to manufacture, control and deliver innovative cell therapy medicinal products in the context of clinical trials conducted by the AP-HM (exploratory ATMPs and ATMPs punctually prepared).

AP-HM's Cell Culture and Therapy Laboratory (CCTL) is a platform, consisting of "controlled atmosphere manufacturing areas" in accordance with the requirements of the regulations dictated by the "Rules of Good Manufacturing Practice for Sterile Medicinal Products for Human Use (GMP 2019) and ATMP" and by the "Rules of Good Practice for the Preparation, Storage, Transport, Distribution and Disposal of Tissues, Cells and Cell Therapy Preparations".

The Department of Plastic and Restorative Surgery and the Interregional Centre for Major Burns of the AP-HM, directed by Pr Dominique Casanova, work in close collaboration with the Culture and Cellular Therapy Laboratory to develop innovative skin regeneration techniques. However, there is no technique available in daily practice that can effectively replace the skin graft taken from the patient himself.



"This collaboration is a further step for Poietis and its ambition to place a bio-printer in every hospital to enable the production of personalized tissues and improve the management of patients waiting for transplants," said Dr Fabien Guillemot, Founder and President of Poietis. "The successful completion of this project will pave the way for important applications of bioprinting in the medical field."

Bruno Brisson, co-founder and Business Development Director of Poietis added: "This agreement materializes all our efforts both on the development of a bio-rinted dermo-epidermal substitute and the transposition of our R&D bioprinting platform (NGB-R) to a clinical grade system (NGB-C). "We are delighted to enter into this partnership with the AP-HM teams, who have internationally recognized expertise in skin repair and in the conduct of clinical trials of Advanced Therapy Medicinal Products".

Dr. Bertrand, Plastic Surgeon at the AP-HM, commented: "Bioprinted skin prepared from a simple sample of the patient's own cells would greatly simplify the surgical procedure and avoid large skin samples. This therapeutic innovation "made in France" could be a real revolution in the treatment of patients requiring a skin graft, such as severe burns".

Dr. Magalon, pharmacist-biologist in the Cellular Therapy Unit continues: "This collaboration will bring together all the skills required to produce a bioprinted tissue that can be implanted in humans, in accordance with European regulations. But this is only one step. Tomorrow, the objective is to bioprint more complex tissues as close as possible to the patient. It is conceivable that all major hospitals will be equipped with bioprinters in the future. This reminds me of the success of surgical robotics: a breakthrough innovation that has become essential in daily practice ».

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**About Poietis:** Biotech company specialized in the development and manufacturing of human tissues by bioprinting, its main mission is the development of new therapeutic solutions based on its expertise in bioprinting technologies and in particular high-resolution laser assisted bioprinting. Poietis has developed the multimodal NGB ("Next Generation Bioprinting") bioprinting platform declined in two versions: one for *in vitro* tissue engineering research (NGB-R) and a clinical version (NGB-C) for the production of implantable bioprinted tissues. This multi-modal, automated biomanufacturing platform enables researchers to achieve superior tissue through high resolution, and enables the fabrication of complex tissues with repeatability and reproducibility. Poietis bioprinting technology is the result of innovative research carried out over ten years at Inserm and the University of Bordeaux. Poietis won the *iLab* competition in 2014, the *World Innovation Challenge Phase II* in 2017 and recently the *EY Disruptive Strategy Award*. The company currently employs 35 people. More information: [www.poietis.com](http://www.poietis.com)

**About Assistance Publique - Hôpitaux de Marseille (AP-HM):** AP-HM, the third largest medical research centre in France, is committed to research and the development of scientific knowledge with the aim of improving the quality of healthcare services, the state of health of the population and the performance of the healthcare system. Cellular biotherapies are undergoing considerable development, notably as a result of real progress in the knowledge of stem cells and the development of regenerative medicine. A speciality for which the teams of the culture and cell therapy laboratory (LCTC - Pr Florence SABATIER, Dr Jérémy MAGALON, Dr Julie VÉRAN and Dr. Fanny GRIMAUD) and hematology – vascular biology (Prof. Françoise DIGNAT-GEORGE) of the AP-HM are recognized worldwide. More information : <http://fr.ap-hm.fr/>

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