



 **PAT4CGT**



Media Release

PAT4CGT Consortium Announces Prestigious €4.7M Pathfinder Grant Awarded by European Innovation Council for the Development of Modular Cell & Gene Therapy Manufacturing Platform

- PAT4CGT project will develop a miniaturised analytical platform tailored for cell & gene therapy (CGT) manufacturing, enabling the automated and non-invasive monitoring of critical process parameters.
- By combining state-of-the-art sensors, a novel bioreactor design and predictive data intelligence, the innovative solution will provide actionable information, paving the way for in-process control to produce highly personalised cell therapy treatments.
- PAT4CGT consortium is composed of a multidisciplinary group of internationally recognized CGT experts and companies across 6 EU member states and Switzerland. The project will start in October 2022 and run for a period of 3 years.

Reugny (France) and Lausanne (Switzerland), 15 June 2022 – Partners involved in the international consortium PAT4CGT announced they received a highly competitive EIC Pathfinder grant following a positive evaluation of their project proposal entitled 'Closed and automated online monitoring towards process control and improved decision making in cell and gene therapy manufacturing'. PAT4CGT was recognized for its disruption potential and ranked amongst the 8 projects selected out of the 132 submissions to the 2021 EIC Pathfinder Challenge call for 'Emerging Technologies for Cell & Gene Therapies'. Together, the partners will receive €3.6M from the European Commission, with an additional €1.1M from the Swiss federal government's agency for education, research, and innovation (SERI).

Cell and gene therapies (CGT) represent a medical breakthrough in the treatment of a wide range of conditions. Highly personalised chimeric antigen receptor T-cell (CAR T) therapies were introduced in the clinic a decade ago, with spectacular results in patients suffering from previously incurable blood cancers. As more autologous CAR T-cell products enter clinical trials, there is a rapid increase in demand for clinical-grade cell products. However, current CGT manufacturing methods suffer from an important technological debt and still rely on semi-automated processes in centralised facilities. This lack of process scalability results in low throughput, high costs, and ultimately to limited global production capacity, preventing many patients from accessing this next generation of therapies.

In-process quality control monitoring of cell culture is one key bottleneck. It is open and manual, with a high risk of introducing human error and contamination. To address this issue, the PAT4CGT project will develop a miniaturised sensor platform that automatically collects critical process parameters data and build an 'intelligence' predictive tool, paving the way towards real-time monitoring and improvements of CGT manufacturing processes.

Luc Henry, co-founder, and CEO of Limula, explains: *"There is a clear need in the CGT industry for process analysis technologies tailored for the one patient-one batch character of highly personalised cell therapies. We wanted to identify the best possible partners to complement our bioreactor technology and deliver the best possible solution to our customers. With PAT4CGT, I believe we bring together the right team."*

The highly multidisciplinary collaboration will combine state-of-the-art sensors provided by Jobst Technologies, a novel bioreactor design developed by Limula, and predictive data intelligence in a closed and automated modular platform. The project will further leverage the academic expertise of Prof. Christoph Herwig at the Technische Universität Wien, contributing to the development of digital twins and predictive algorithms. End-user inputs and in-depth assessment of the resulting solution will be provided by Stematters and Exothera, two CDMOs offering services in CGT process development and cGMP manufacturing. This will result in high quality actionable information on the process status, supporting better batch documentation and improved decision making during the production of these complex therapies, with the potential to increase reproducibility.

Nadège Grabowski, Synthetic Biology Practice Leader, Da Vinci Labs, adds: *“By specifically addressing closed and automated online process monitoring towards improved decision making in cell and gene therapy manufacturing, the PAT4CGT consortium is an important addition to the EIC sub-portfolio of projects advancing cell therapy products to a clinical stage. This is the first time that the newly appointed EIC Programme Managers were directly involved in setting the challenges and selecting projects from among the best submissions to build a coherent portfolio of game-changing technologies.”*

The positive evaluation of the PAT4CGT proposal by the EIC is a strong validation of the mission of the consortium. The partners are brought together by a common vision to make CGT manufacturing more reliable by introducing automated, frequent, and non-invasive, monitoring of critical process parameters. With over 2500 cell therapies in the oncology pipeline, it is the right time to develop reliable and scalable processes, ultimately significantly improving access to these revolutionary treatments through increased global production capacity.

About PAT4CGT

The interdisciplinary consortium brings together internationally recognized experts across 6 EU countries and Switzerland. It is coordinated by Da Vinci Labs (France), an innovation hub supporting the development of breakthrough synthetic biology projects. The technical leader, Limula (Switzerland) develops a closed and automated bioreactor for cell and gene therapy manufacturing. Jobst Technologies (Germany), a spin-off of the University of Freiburg, brings expertise in miniature biosensors and micro control systems. The Bioprocess Technology research group led by Prof. Christoph Herwig at the Technische Universität Wien (Austria) focuses on the design of data analytics and control concepts for bioprocess characterisation. Exothera (Belgium) offers development and manufacturing services for viral vectors, using bioprocess approaches that leverage innovative technologies. Stematters (Portugal) designs and validates single use closed processes for products in non-clinical and clinical applications. Crowdhelix (IE) connects researchers with high tech companies & facilitates the planning and dissemination of collaborative projects.

About EIC

The European Innovation Council (EIC) is Europe's flagship innovation programme to identify, develop and scale up breakthrough technologies and game changing innovations. With a budget of €10.1 billion, it was introduced by the European Commission to support the commercialization of game changing innovations throughout the lifecycle, from early-stage research to proof of concept, technology transfer, and the financing and scale up of start-ups and SMEs.

About SERI

SERI is the federal government's specialised agency for national and international matters concerning education, research, and innovation (ERI) policy. Together with its partners, SERI ensures that Switzerland remains among the top countries in this area.

About Da Vinci Labs

Da Vinci Labs SAS is a deeptech accelerator based in the Touraine region of France and inspired by Leonardo da Vinci, putting artificial intelligence, synthetic biology and quantum computing at the service of our planet. The company is providing research and innovation support services to leading European innovators.

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About Limula SA

Limula SA is a Life Science start-up based in Lausanne, Switzerland. The company was established with the explicit mission to help bring the most personalized cancer treatments to the patients in need, at reasonable cost, wherever they are. To achieve this goal, our multidisciplinary team develops a modular platform with unique functionalities, enabling production of cell therapies at scale, through automation and standardisation.

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About Exothera

Exothera is a viral vector CDMO (contract manufacturing and development organization) using standard and innovative bioproduction platforms to rapidly deliver affordable viral vector-based vaccines and cell and gene therapies. As a Univercells company, Exothera capitalizes on novel manufacturing technologies and best-in-class bioprocessing expertise to provide custom-made process optimization and GMP clinical and commercial production of viral vectors. Based on its extensive technology expertise, Exothera selects technologies to optimally answer customer needs for cost-effective and agile viral vector manufacturing and provides QC services and analytical development.

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