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Smart Immune and CELLforCURE by SEQENS partner to industrialize SMART101 clinical batches manufacturing.

Smart Immune, a clinical-stage biotechnology company, and CELLforCURE by SEQENS, a Contract Development and Manufacturing Organization (CDMO) for Advanced Therapy Medical Products (ATMPs), announced today a strategic collaboration to expand SMART101 production capabilities. SMART101 is an innovative therapy in Phase I/II trials for patients with acute leukemia or primary immunodeficiencies (PID), in the EU and the US.

Enhanced Production Capacity

This partnership will complement Smart Immune's existing capabilities at the MEARY Center for Cell and Gene Therapy and Necker Children Hospital in Paris, supporting the company's expanding clinical development with patients' inclusions expected to rapidly increase in 2025.

The collaboration will enable the production of SMART101 for the ReSET trials in primary immune deficiencies and hematological malignancies post-transplant, as well as for new proof-of-concept trials in solid tumors. CELLforCURE brings a robust and strongly established commercial manufacturing experience, positioning itself as a highly reliable partner for Smart Immune at a critical development stage of its ProTcell platform.

Manufacturing Process Evolution

As part of this collaboration, the technology transfer will involve an intermediate manufacturing process, currently being set up at the MEARY Centre, which will bridge the gap between current clinical production methods and future fully automated steps.

This evolution includes cell selection, scale-up aligned with future v2.0 requirements, and semi-automation of key steps like the implementation of mini-bioreactor-based production.

Accelerating Patient Access

"This collaboration marks a significant step in our mission to bring innovative cell therapies to more patients," says Karine Rossignol, Co-Founder and Chief Executive Officer of Smart Immune. "By partnering with CELLforCURE, we're establishing a robust manufacturing framework to support our growing clinical programs and future commercialization needs."

"We are very proud to collaborate with Smart Immune and contribute to the ambition of bringing innovative cell therapies to more patients," says Pierre-Noël Lirsac, President of CELLforCURE. "CELLforCURE will leverage its historical expertise as a CDMO as well as its "real-life" experience to manufacture SMART101 clinical batches."

Pierre Heimendinger, Chief Technical Officer of Smart Immune, adds: *"The enhanced manufacturing process, featuring rapid sterility testing, will enable a vein-to-vein time of just two weeks. This is particularly*

crucial for patients receiving fresh allogeneic hematopoietic stem cell transplants within the European and Middle Eastern zones."

Strategic Choice of European Manufacturing

The choice of CELLforCURE, with its established track record in commercial cell therapy manufacturing, aligns with Smart Immune's commitment to maintaining production excellence in France and Europe. This decision builds upon the foundation established with the MEARY Center at Saint-Louis Hospital and Necker Children Hospital, reflecting the company's dedication to leveraging French and European expertise in advanced therapy manufacturing.

A commitment also shared by the SEQENS Group, who capitalized and invested in France and Europe to maintain and develop essential and strategic capabilities for the healthcare sector.

About CELLforCURE and SEQENS:

CELLforCURE SAS (commercial name: CELLforCURE by SEQENS) is a CDMO authorized by ANSM, dedicated to ATMPs production from concept to commercialization. With advanced technologies, extensive capabilities, and large scale capacity, CELLforCURE offers a seamless journey from early-stage development to commercial manufacturing of a wide range of cell therapies.

CELLforCURE is part of the SEQENS Group, a global partner in health, personal care and specialty ingredients, leveraging 3300 employees, 16 manufacturing sites and 9 R&D centers in 9 countries.

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About Smart Immune:

Smart Immune is a clinical-stage biotechnology company developing ProTcell, a thymus-empowered T-cell progenitor platform to rapidly re-arm the immune system against cancer and infection. The company aims to radically improve outcomes for patients in hematology and immuno-oncology. Its main asset SMART101 is in Phase I/II trials for patients with acute leukemia or primary immunodeficiencies (PID), in the EU and the US. Additional clinical applications are planned to be evaluated in combination with innovative cancer therapies.

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