



Smart Immune receives \$5 million investment to further its thymus-empowered ProTcell therapy platform

The new funding from the Gates Foundation will advance a Phase 1/2 clinical trial of an innovative T-cell therapy to treat cancer and infectious disease

PARIS, France, 17 April, 2023 – Smart Immune SAS, a clinical-stage biotechnology company developing ProTcell, a thymus-empowered T-cell therapy platform to fully and rapidly re-arm the immune system, announced today that it has received an equity investment of \$5 million from the Bill & Melinda Gates Foundation to accelerate the development of ProTcell, a proprietary T-cell therapy platform to treat cancer and infectious disease.

Smart Immune's ProTcell platform has been developed to ensure early immune reconstitution post allogeneic hematopoietic stem cell transplantation (allo-HSCT) and to reverse thymic involution through its proprietary T-cell progenitor-based therapy. Once infused to the patient, these T-cell progenitors migrate to the thymus, stimulate its activity, and are 'educated' to become a fully potent T-cell immune repertoire in fewer than 100 days, compared with the 18 months taken with today's standard of care.

The investment from the Gates Foundation will help advance a new Phase I/II clinical trial in adult acute leukemia patients of Smart Immune's lead asset, SMART 101, an allogeneic cell therapy product produced from healthy donor mobilized peripheral blood. This trial design has been developed to improve the capacity of leukemia patients to fight cancer and infection after standard of care haplo-identical stem cell transplantation. The study will provide insights into ways in which the T-cell deficiency associated with HIV may be reversed. Additionally, SMART 101 may provide a first step towards a universal HIV-resistant cell therapy product. This could benefit millions of people living with HIV, particularly in low- and middle-income countries where the burden is high.

Karine Rossignol, Pharm D, HEC, Chief Executive Officer and Co-founder of Smart Immune, said: *"We are delighted to be collaborating with the Gates Foundation to improve health outcomes for people around the world. Our work in rearming patients' immune system is particularly exciting for global health since this concept has applications beyond oncology and into infectious diseases such as HIV. This investment from the Gates Foundation is an important milestone for Smart Immune."*

Dr Robert J Soiffer, MD, Chief of the Division of Hematologic Malignancies, Dana Farber Cancer Institute and Chairman of Smart Immune's Clinical Advisory Board, commented: *"The new Phase I/II trial for adult acute leukemic patients is particularly promising. Patients undergoing allogeneic haploidentical hematopoietic stem cell transplants are often affected by delayed immune reconstitution. If Smart Immune's technology can provide a faster, polyclonal, naïve, host-thymus-educated T-cell compartment reconstitution for these patients, it will help them to better fight cancer and infection and will provide proof-of concept for potential applications in a number of other diseases."*

Sebastian Lombardo, Chairman of the Board of Smart Immune, added: *"I became involved with Smart Immune when the company was still at the research project stage with just two employees and to see it advance and achieve this milestone is incredibly rewarding. The science is ground-breaking, but it is the team driving Smart Immune, now 35 strong, that make it truly special. This investment from Gates*

is a testament to the hard work of everyone at Smart Immune as well as the broad potential of the ProTcell platform. I look forward to continuing to work with Karine, Marina, Isabelle and their team as they continue their mission to rearm the immune system of vulnerable patients."

About Smart Immune

Smart Immune is a clinical-stage biotechnology company developing ProTcell, a thymus-empowered T-cell therapy platform to fully and rapidly re-arm the immune system, enabling next-generation allogeneic T-cell therapies for all. The company, a spin-off from the Imagine Institute of Genetic Diseases, was founded in 2017 by Karine Rossignol, PharmD-HEC, Marina Cavazzana, MD-PhD and Isabelle André, PhD to help patients with life-threatening diseases such as high-risk blood cancers and primary immunodeficiencies.

Smart Immune's ProTcell platform, which is already in Phase I/II clinical trials, enables the recovery of a complete immune repertoire in patients fighting cancer and infection. ProTcell introduces potent, allogeneic T-cell progenitors which are then differentiated by the thymus into fully functional T-cells – an 'off the shelf' T-cell medicine.

Smart Immune's partners include Memorial Sloan Kettering Cancer Center in New York and Greater Paris University Hospitals (AP-HP). The company is headquartered in Paris, France.

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