



First US leukemia patient dosed with Smart Immune's investigational SMART101 cell therapy

Phase I/II trial will assess safety and efficacy of SMART101 in accelerating immune reconstitution to fight infection and relapse

PARIS, France, January 23, 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 the first adult leukemia patient has been dosed with SMART101, a T-cell progenitor cell injection derived from donor stem cells using ProTcell at Memorial Sloan Kettering Cancer Center (MSK).

The [Phase I/II trial \(NCT04959903\)](#) is a multicenter, open-label, first-in-human study expected to enrol up to 36 adult and pediatric patients with haematological malignancies, and has been designed to assess the safety and the potential of SMART101 to improve clinical outcomes of hematopoietic stem cell transplantation (HSCT).

The first enrolled patient received a SMART101 injection in December 2022; no related adverse events have been reported.

Dr Frédéric Lehmann, Chief Medical Officer of Smart Immune, said, “The infusion of the first patient is a significant milestone in our journey to address the challenge of slow immune reconstitution after allogeneic HSCT, using the power of the thymus. We are grateful to the dedicated investigators at MSK and look forward to continuing enrolment in this important trial.”

Karine Rossignol, Chief Executive Officer and Co-founder of Smart Immune, said: “We are excited to sponsor this pioneering trial. Accelerated reconstitution of a full polyclonal T-cell repertoire after stem cell transplantation could improve both quality of life and clinical outcomes for patients with acute leukemia, and we look forward to releasing more data as the trial progresses.”

About SMART101

SMART101 is generated *ex vivo* in 7 days from allogeneic blood stem cells, using Smart Immune's ProTcell T-cell therapy platform. Once injected into the patient, the SMART101 human T-cell progenitors travel to the thymus where they are educated to become fully functional and self-tolerant T-cells. Preclinical data suggest that the ProTcell platform could reconstitute the immune system in 100 days instead of the 12 to 18 months observed in physiology, thereby protecting patients from infection and relapse. SMART101 is produced by Smart Immune's Contract Development and Manufacturing Organization partner in France, the [MEARY Center](#) for Cell and Gene Therapy at Paris St Louis Hospital (Assistance Publique - Hôpitaux de Paris, AP-HP).

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 was founded in 2017 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 at Paris Biotech Santé, 29 rue du Faubourg St Jacques, France.

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