Smart Immune Doses First Leukemia Patients with ProTcell Therapy SMART101 in ReSET-02 Phase I/II Trial

- ***No safety concerns in first two patients treated***
- ***Designed to accelerate T-cell reconstitution following haploidentical Hematopoietic Stem Cell Transplantation (HSCT) with post-transplant cyclophosphamide to fight relapse and infection***

PARIS, France, 27 September 2023 – Smart Immune, a clinical-stage biotechnology company developing ProTcell, a thymus-empowered T-cell progenitor therapy platform to fully and rapidly re-arm the immune system, announced today that the first patients have been dosed in its ReSET-02 Phase I/II trial for adult acute leukemia and myelodysplasia syndrome patients.

Two patients have now received the first dose level of SMART101, an allogeneic cell therapy produced from donor mobilized peripheral blood stem cells and differentiated into T-cell progenitors through Smart Immune's ProTcell therapy platform. Early data show that SMART101 is being well tolerated and has a safety profile in line with that observed in patients enrolled in the ongoing ReSET-01 clinical trial in the T-cell-depleted allogeneic HSCT setting. Further patients are expected to be dosed over the next weeks, with 40 patients to be enrolled in total.

The ReSET-02 trial (NCT05768035) is an open-label, multi-center Phase I/II study to assess the safety and efficacy of SMART101 after standard-of-care HSCT with post-transplant cyclophosphamide, in adult patients with hematological malignancies (acute lymphoid leukemia, acute myeloid leukemia, and myelodysplasia syndrome). The trial is designed to accelerate T-cell reconstitution to fight relapse and infection and improve overall and disease-free survival post-transplant.

If successful, the trial will accelerate the validation of Smart Immune's ProTcell platform, which could have applications outside oncology such as in HIV.

SMART101 has been granted Orphan Drug Designation (ODD) by the European Medicines Agency and the US Food and Drug Administration (FDA), in addition to Fast Track Designation by the FDA, as a treatment to enhance cell engraftment in patients receiving HSCT. SMART101 is manufactured at the MEARY Center, AP-HP, in Paris.

Karine Rossignol, Chief Executive Officer of Smart Immune, said: *"We are excited to have begun our trial to evaluate SMART101 in the standard-of-care haploidentical setting. Our goal is to show that we can quickly and fully re-arm the immune system to improve survival rates in difficult-to-treat cancers, harnessing the thymus to provide a new immune system in a few months."*

Frédéric Lehmann, Chief Medical Officer of Smart Immune, added: *"There remains a significant need for a broadly available, well-tolerated therapy for immune-compromised patients with hematological malignancies post allogeneic transplant. The dosing of these two leukemia patients is the first step in potentially addressing this longstanding unmet medical need. Based on our preclinical data, we believe our thymus-empowered allogeneic cell therapy has the potential to shift the treatment paradigm and improve clinical outcomes of allogeneic HSCT. We warmly thank our participating patients, clinical sites, and our teams for their ongoing commitment."*

About Smart Immune

Smart Immune is a clinical-stage biotechnology company developing ProTcell, a thymus-empowered T-cell progenitor therapy platform to fully and rapidly re-arm the immune system, enabling next-generation allogeneic T-cell therapies for all. The company aims to radically improve outcomes for patients with life-threatening diseases such as high-risk blood cancers and primary immunodeficiencies. Smart Immune has ongoing collaborations with leading institutions in the US and Europe. SMART101 is already in Phase I/II clinical trials, in the EU and the US, looking at the acceleration of complete immune recovery in patients fighting cancer and infection and undergoing allogeneic hematopoietic stem cell transplantation. Smart Immune is also developing therapies using gene-modified T-cell progenitors through its ProTcell platform to provide targeted treatments against cancer or AIDS, like persistent off-the-shelf CAR T-cells or HIV-resistant T-cells. The company is headquartered in Paris, France, at Paris Biotech Santé.
https://www.smart-immune.com/
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About the ReSET-02 clinical trial

SMART101 is being evaluated in the ReSET-02 Phase I/II multi-center, open-label, dose-escalation study to evaluate the safety and activity of SMART101 after haploidentical peripheral blood stem cells transplantation with post-transplant cyclophosphamide, in patients with hematological malignancies. In the Phase II segment, patients will be enrolled in parallel into two cohorts according to the intensity of the conditioning chemotherapy and in two consecutive stages according to a Simon's 2-stage design. The trial is currently conducted at multiple sites in France and Italy. For more information, visit www.clinicaltrials.gov, study identifier number NCT05768035.

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