

Smart Immune to present details of the phase I/II studies of new T-cell therapy SMART101 at the European Hematology Association (EHA)

Two poster presentations at EHA showcase ProTcell, an innovative T-cell technology platform empowered by the thymus, for the treatment of cancers and infections

PARIS, France, 11 May, 2023 – Smart Immune, 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 will be presenting posters of two abstracts, detailing the phase I/II clinical trials of SMART101, at the 2023 European Hematology Association (EHA) Annual Meeting. The meeting takes place in Frankfurt, Germany from 8-11 June, and the abstracts are available on the <u>EHA website</u>.

The two trials are evaluating the safety and preliminary efficacy of increasing dose levels of SMART101, a cell therapy using allogeneic CD34-CD7+ T-lymphoid progenitors generated *ex vivo* in 7 days, from mobilized peripheral blood CD34+ cells from a donor via Smart Immune's ProTcell platform. Once infused to the patient, the SMART101 T-cell progenitors migrate to the thymus where they are educated to become fully functional T-cells. Preclinical data suggest that SMART101 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 CDMO partner in France, the MEARY Center for Cell and Gene Therapy at Paris St Louis Hospital (Assistance Publique - Hôpitaux de Paris, AP-HP).

Presentation details are as follows:

1) SI101-01 Phase I/II study evaluating safety and efficacy of allogeneic SMART101 T-lymphoid progenitor injection to accelerate immune reconstitution after T-cell depleted allogeneic HSCT

Presenter: Prof. Dr. Jaap Jan Boelens, Memorial Sloan Kettering Center Session date, time, and location: June 9th, 2023, 18:00-19:00 CEST, in the poster area [Link]

1) SMART101 donor T-lymphoid progenitors to accelerate immune reconstitution post-haploidentical peripheral blood stem cell transplantation with post-transplant cyclophosphamide: SI101-02 First-in-human Phase I/II

Presenter: Prof. Fabio Ciceri, San Raffaele Research Hospital Session date, time and location: June 9th, 2023, 18:00-19:00 CEST, in the poster area [Link]

Dr Jaap Jan Boelens, MD, PhD, Chief of the Pediatric Transplantation and Cellular Therapy Program and Director of the Immune Discovery & Modeling Service of the Memorial Sloan Kettering Center, commented: "This is an important study looking at accelerating immune reconstitution for vulnerable patients. Accelerated reconstitution of a full polyclonal T-cell repertoire after stem cell transplantation has the potential to improve quality of life and clinical outcomes for patients with acute leukemia."

Dr. Fabio Ciceri, MD, Head of the Hematology and Bone Marrow Transplantation Unit at San Raffaele Research Hospital, said: "I see great potential in the use of SMART101 in improving the outcome of allogeneic standard-of-care hematopoietic stem cell transplantation for adult patients with acute leukemia. A faster reconstitution of the polyclonal T-cell compartment will help these patients better fight cancer and infections."

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About the European Hematology Association

The European Hematology Association (EHA) is a non-governmental and not-for-profit membership organization officially established in 1992. Its aim is to promote excellence in patient care, research, and education in hematology, focusing on blood, blood cells, and blood disorders such as leukemia, lymphoma, hemophilia, anemia and thrombosis.

Among other missions, EHA organizes an annual congress attended by professionals from all over the world, provides an educational program based on the European Hematology Curriculum, publishes HemaSphere, an open access journal, and strengthens hematology's voice in Europe through lobbying.

https://ehaweb.org/

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 is a spin-off from the Imagine Institute of Genetic Diseases, and 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 has clinical partnerships with leading institutions in the US and Europe. The ProTcell platform, 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.

The company is headquartered in Paris, France, at Paris Biotech Santé.

https://www.smart-immune.com/

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