



Smart Immune Announces the Launch of its T Cell Progenitor-based Platform of Next-Generation Biotherapies for Severe Infections and Leukemia

PARIS, January 22, 2020 – 2.00 PM CET - **Smart Immune today announced the launch of its proprietary platform of T cell progenitor-based biotherapies intended for the treatment of severe infections and leukemia. Following a successful seed fundraising round of € 2.8 million completed with a € 1.88million grant of the French BPI Q4 2019, the Smart Immune team is advancing its lead cell therapy program T cell progenitors or ProTcells™ (CD7+/CD34- ; CD5- cells) which is currently being studied in three clinical trials, the first of which is currently recruiting children suffering from severe combined immunodeficiency (SCID) at Necker Children’s Hospital in Paris. Early evidence for the treatment’s safety and efficacy is expected by the beginning of 2021.**

Founded by three women Marina Cavazzana, Isabelle André and Karine Rossignol all highly expert on clinical development of immune-targeting biotherapies, Smart Immune is aiming to improve the prognosis of patients affected by severe diseases of the lympho-hematopoietic system. These diseases can be inherited such as SCID and sickle cell anemia, or acquired, such as leukemia. These patients are at risk for several major post-transplant complications, including toxicities, infections, immunological complications, and leukemic relapse, worsening short-, medium-, and long-term prognosis. Currently, these complications are responsible for 50% of mortality or morbidity within 3 years of the allogeneic stem cell transplant, both in children and adults.

More than 25,000 transplants are yearly performed in Europe and the USA, but it is estimated that more than 75,000 patients could benefit from this new generation of cell therapy based on ProTcells™. There are today 3 bottlenecks to lift to unlock the potential of the HSCT market i) Delayed efficacy and severe adverse events during post-transplant period, ii) Limited access to settings, graft preparation and patient monitoring competences and last but not least iii) Costly treatments, due to know-how and production constraints. With its proprietary T cell progenitors technology and its upstream integrated automation program, Smart Immune aims to i) change prognosis by shorten the immune vulnerability period hence drastically reducing adverse events, changing prognosis, ii) broaden access to the technology and iii) reduce COG to be in adequation with a sustainable health care available for all the patients.

“The fast reset of the immune system without adverse effects resulting from T cell progenitors technology, can change patient prognosis. The only way to significantly improve the survival curve of these patients is to help them to rebuild their T cell compartment as fast as possible, ideally in the first three months following the injection of ProTcells. Adverse effects could thus be reduced, and survival improved: these are Smart Immune’s objectives“. Pr Marina Cavazzana.

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The first cell therapy program, currently in clinical trials, is based on a new generation of cell therapies: T cell Progenitors.

Through a family of “*ex vivo* thymus” patents, Smart Immune is the first to deliver T cell progenitors or ProTcells™ (CD7+/CD34- ; CD5- cells) to patients. The progenitor cells begin their differentiation *in vitro* thanks to a process developed by Smart Immune, and finish differentiating very quickly *in vivo*, in the patient’s thymus. There, they are educated to become functional, polyvalent (polyclonal) T cells, capable of killing viruses and cancer cells without the usual side effects, thus completely changing life prognosis. This first group of “*ex vivo* thymus” patents has led to three clinical trials, the first of which is currently recruiting children suffering from severe combined immunodeficiency (SCID) at Necker Children’s Hospital in Paris. **Early evidence for the treatment’s safety and efficacy is expected by the beginning of 2021.**

About Us

Smart Immune is a clinical-stage biotechnology company incubated at Paris Biotech Santé, developing a new generation of cell and gene therapies. These treatments are based on the curative power of hematopoietic stem cells, without adverse effects, and aim to change care and prognosis for patients affected by inherited blood disorders and blood cancers. Its first program based on T cell Progenitors is actually in clinical stage in Europe.



Karine Rossignol

Co-founder and CEO

Karine is a Doctor of Pharmacy and HEC Business School graduate, with over 25 years’ experience as a manager in the biomedical research industry. She was CEO at the Foundation for Hearing for 3 years, co-Secretary General at Imagine Institute for genetic diseases for 10 years and worked in international marketing in the French cosmetics industry. Throughout her career, she showed her ability to develop, structure, and finance complex and ambitious projects

Pr Marina Cavazzana

Co-founder, acting CMO

Marina is an internationally recognized physician and researcher and pioneer in gene and cell therapy (6 first-in-man successful clinical trials and over 300 articles). The quality of her work has been awarded by numerous prizes and distinctions, including the Beutler ASH award, membership of the American National Academy of Medicine (NAM), the Irene Joliot Curie award, and the Grand prize of the French Academy of medicine. She is director of the Clinical Investigation Center for Biotherapy and director of the biotherapy department which ensures the continuity of the operating chain from the collection of cells to their infusion to the patients taken in charge at the Necker Enfants Malades Hospital. Marina is responsible for the clinical development of the technologies used by Smart Immune and co-chairs the scientific and medical advisory board.

Dr Isabelle André

Co-founder, acting CSO

Isabelle is a Ph D internationally recognized for the quality of her work on immunodeficiency (over 70 articles) and T cell differentiation. She heads the INSERM Human team working on human lympho-hematopoiesis at the Imagine Institute for genetic diseases.

She has extensive experience with T cell differentiation and is the inventor of the technology used by Smart Immune, carrying out all the pre-clinical studies and associated technological innovations. She co-chairs the scientific and medical advisory board

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