

PRESS RELEASE

Flash Therapeutics announces that the IRIS project, for which it is the industrial partner, has been accepted for the 4th solicitation of bids for RHU projects of the « Programme d'Investissements d'Avenir »

TOULOUSE, July 11, 2019 - Flash Therapeutics, a gene therapy company, announces that the "IRIS" project, for which it is the industrial partner, has been accepted for the solicitation of bids by the « Recherche Hospitalo-Universitaire en santé » (RHU) for the Programme d'Investissement d'Avenir, supporting innovative and large-scale projects in the health, and whose operator is the National Agency of Research in France.

The IRIS project (InheRited Immune diSorders) is a gene therapy project for monogenic inherited diseases of the immune system. Selected by an international committee of experts, this project is led by Pr. Marina CAVAZZANA, and the coordinating institution is Assistance Publique-Hôpitaux de Paris (AP-HP). This project will be financed with € 9.9 million. The selected consortium includes AP-HP, Imagine Institute, INSERM, Clinical Institute of Mice, and Flash Therapeutics.

The IRIS project aims to develop gene therapy products for severe hereditary immune deficiencies and thus, offer a refundable universal cure through our health system. This project has a strong international public-private partnership of recognized experts, integrating the most innovative technologies such as Flash Therapeutics, which will bring its expertise in the production of lentiviral vectors, including its proprietary non-integrative LentiFlash[®] technology.

The main challenges of this program are to involve industrial structures upstream of the clinical stages and to industrialize the manufacture of gene therapy products to allow all patients to access treatment. The goal for Flash Therapeutics is to demonstrate the therapeutic benefits of its LentiFlash[®] RNA transfer technology.

The expected impacts of IRIS are:

- Expand this gene therapy approach to other severe hereditary immune deficiencies
- Develop an economic model taking into account the cost/benefit ratio of the proposed therapy
- Serve as a reference to health authorities to set the refundable price for this therapy by the national health system.

The contribution of gene therapy

The IRIS project is part of a context where the bone marrow transplantation, of a compatible or partially compatible donor, is the reference treatment for inherited diseases affecting blood cells. In the absence of a compatible donor, the severity of the pathology requires the use of partially compatible family donors, such as one of the parents. In spite of recent progress, the results of partially compatible grafts remain unsatisfactory with a significant risk of death, severe complications of the immunological type and a high "societal" cost. In this context, gene therapy based on the autograft of genetically modified cells - stem cell transplants of the patient previously modified in the laboratory to restore a normal copy of the gene - presents itself as a solution to solve the problems raised by the absence of a compatible donor. This approach is particularly important for severe hereditary immunodeficiencies, given the vital prognosis that is initiated as soon as the diagnosis is made.

About Flash Therapeutics

Situated in Toulouse and Paris, Flash Therapeutics is a gene therapy company that develops gene and cell therapies using its own platform for the production of lentiviral tools and proprietary bioproduction technologies. The company is built around the lentiviral production platform, including non-integrative LentiFlash® technology, and lentiviral vector technology. By enabling efficient transient RNA transfer and short-term expression, LentiFlash® technology is ideally suited for gene-editing and antigen delivery in immunotherapy. When stable expression of DNA is required (CAR T-cell immunotherapies), integrative lentiviral vectors are advocated. These two technologies benefit from the production and purification processes developed and continuously optimized by Vectalys since 2005. Flash Therapeutics now combines two main activities: first, the development of clean therapeutic programs based on LentiFlash® technology; second, the development and manufacturing of customized tools for customers around the world who want to use lentiviral technologies in research and clinical programs. For more information, please visit www.flashtherapeutics.com.

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