



The OPTI-STEM consortium led by CDMO Cell-Easy receives €7M from the French government and Bpifrance and €800,000 from the Occitanie Region to democratize access to cell therapy in France and Europe

Toulouse, La Madeleine, Nancy, France – 28 February, 2022 – **The OPTI-STEM project aims to optimize the production of MSCs in order to democratize access to them and thus allow the diversification of therapeutic applications of this type of cells and their derivatives (exosomes, etc.). To achieve this objective, the R&D consortium led by Cell-Easy has obtained public funding of more than 7 million euros as part of the "Biotherapies and Bioproduction of Innovative Therapies" acceleration strategy, operated on behalf of the French government by Bpifrance.**

The development of innovative therapies based on mesenchymal stem cells (MSCs) is confronted with prohibitive production costs, limiting patient accessibility and discouraging reimbursement agencies in a context of budgetary constraints in many countries. The dilemma is important: deny innovation to millions of patients or develop a multi-speed elitist medicine. A significant improvement can only be achieved by a complete overhaul of these processes. The OPTI-STEM project, funded by the French government to the tune of 7 million euros, proposes to transpose to the production of MSCs for therapeutic purposes the systems biology methodology that has been successfully applied to microbial bioproduction, while integrating new components of non-animal origin into the culture media. Beyond the change of scale, it is also the management of the production parameters that will be improved thanks to the development of micro-sensors with "intelligent" monitoring.

OPTI-STEM aims to combine large-scale MSC production with on-board analytical monitoring. The goal is to monitor and control the industrialization of the production of large quantities of MSCs to facilitate therapeutic applications, reduce prices by a factor of 100 and reach a production capacity of more than 100,000 doses per year.

Upstream of the Opti-Stem2 project and in a complementary way, the funding from the Occitanie Region will allow the development of the preliminary phases of the process (2D and/or 3D), as well as the precise analytical characterization of the MSCs produced at 3 levels: their identity (Cell Identity®), their safety (Cell Secure®) and their therapeutic effectiveness (Cell Feature®).

Cell-Easy is a Young Innovative Company whose mission is to develop the production of stem cells on an industrial scale with the ambition to democratize access to them, by facilitating the implementation of numerous clinical trials in various fields of application, opening the way to new treatments for a greater number of patients in need, in particular for pathologies that currently have no therapeutic solution (critical ischemia of the lower limb, for example). As an indication, the current cost of a single dose of one of the few products currently on the market is €54,000.

The global approach of systems biology, directly inspired by the approach that has allowed the optimization of many microbial cultures, will lead to the removal of the empiricism that is still required in the field of cell cultures.

This observation led Cell-Easy to join a panel of partners - the Roquette Frères company, the RESTORE, TOXALIM, LAAS and LRGP-MTInov laboratories - mastering the production of innovative ingredients of vegetable origin, the knowledge of physiology metabolism and characterization of the properties of adipose tissue MSCs (ASC), the development of miniaturized sensors, the identification and modeling of metabolic pathways by bioinformatics analysis of metabolomics data and the culture of stem cells in 2D flasks.

This set of industrial and scientific skills perfectly complements the know-how developed by Cell-Easy for the production of MSCs and will allow a qualitative and quantitative leap in the mastery of the industrial production of this type of cells, which is essential both to succeed in a significant change of scale and to efficiently meet the quality, safety and efficacy constraints imposed by the regulatory agencies.

The consortium will conduct an original multidisciplinary approach around the following 5 axes:

- 1- Adequacy between culture conditions and cell phenotype
(RESTORE, TOXALIM, Cell-Easy)
- 2- Definition of culture and conservation media
(RESTORE, Cell-Easy, Roquette)
- 3- Quality control of cell productions
(RESTORE, LAAS, Cell-Easy)
- 4- Development of tools for real-time monitoring of MSC cultures in bioreactors
(LRGP, LAAS, Cell-Easy)
- 5- Data integration
(RESTORE, TOXALIM, Cell-Easy)

The joint financing of this new process by the State and the Occitanie Region will strengthen the development of the bioproduction of innovative therapy drugs (ITD) in France, and more particularly will contribute to facilitate the emergence of new therapeutic applications of mesenchymal stem cells over the next decade.

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