

GoLiver Therapeutics is the winner of the France 2030 “innovation in Biotherapies and Bioproduction” call for its GOCLINICALS project, dedicated to a novel stem cell-based liver therapy

GoLiver Therapeutics has been awarded €1.6m from France 2030 to progress its first biomedicine, developed from pluripotent stem cells, into the clinic for the treatment of severe liver failures.

Nantes, France, September 25th 2024 - GoLiver Therapeutics, a start-up focused on the development of advanced therapy medicinal products and the industrial processes necessary for their manufacturing, is pleased to announce that it has won the “Innovations in Biotherapies and Bioproduction” call for proposal launched by the French government to make France a European leader in the biotherapy sector. The start-up will receive a €1.6 million investment from France 2030.

Defeating the many severe liver diseases thanks to regenerative medicine

GoLiver Therapeutics aims to bring to market the first biomedicine to treat severe acute liver failure and, more broadly, chronic liver disease, without the need for liver transplantation, which is currently the only recognised curative treatment for end-stage liver disease.

The GOCLINICALS project is intended to provide the first clinical proof of tolerance, safety and efficacy of a new type of cellular biomedicine developed by GoLiver Therapeutics. This innovative therapy has both a unique therapeutic concept and an industrial bioproduction concept.

The young company from Nantes has developed GLTX-001, a biomedicine consisting of an injectable solution of frozen allogeneic liver cells that can be easily and rapidly prepared at the patient's bedside. GLTX-001 has been proven to be more effective than competing cells in a published preclinical study. It protects the liver from acute and massive destruction of hepatocytes and accelerates its natural capacity to regenerate. Furthermore, GoLiver Therapeutics has successfully solved the challenge of cell therapy, which requires the production of billions of drug cells, with its iMillenium™ manufacturing platform. Based on pluripotent stem cell technology combined with an innovative concept for liver cell production, iMillenium™ delivers unprecedented yield and cost-effectiveness. One additional asset is that the platform can be rapidly deployed on the market, as it uses bioreactors that are already marketed and used by Contract Development and Manufacturing Organizations (CDMOs) for advanced cell therapies.

*« We are very grateful to France 2030 for supporting us in reaching a major milestone for our first advanced cell drug candidate. The GOCLINICALS project will reveal our technological lead. **GoLiver Therapeutics will be the first company to conduct a clinical trial of liver regenerative medicine using pluripotent stem cells.** GLTX-001 will be a game-changer for patients suffering from liver disease. The preclinical data is impressive, and the fact that it can be made available immediately, in unlimited quantities and ready-to-use are already factors for its success in routine clinical use. I am confident that GOCLINICALS will demonstrate the incredible therapeutic potential of GLTX-001 in patients. I am really looking forward to seeing GOCLINICALS show the amazing potential of GLTX-*



001 for patients. *This is a federating project that we will involve our long-standing partners, the cell and gene therapy unit (UTCG) of Nantes University Hospital, with whom we have already produced a GMP pilot batch of 15 billion liver cells, and the Paul-Brousse Hospital of the AP-HP (Public Assistance - Paris Hospitals), France's first liver transplant centre. Our commitment is to start creating this new healthcare industry in France and to spread this medicine of tomorrow, which will be accessible to all, more affordable and more competitive. While we initially focused on liver disease, we will now be tackling other diseases to bring them the benefits of our advances. This will also be an opportunity to diversify our portfolio. We hope that this new recognition from the French government will bring us the support of investment funds to accelerate the scale-up of our company.* » said **Tuan Huy Nguyen, President of GoLiver Therapeutics.**

Today, around 800 million people suffer from chronic liver disease. Liver failure is responsible for over two million deaths, and only 30,000 liver transplants are performed each year worldwide. To overcome these challenges, GoLiver Therapeutics is harnessing the inherent ability of patient's own liver cells to regenerate into a new liver boosting by a cell drug whose pharmaceutical bioproduction is mastered in terms of quality and quantity on a large scale, which is currently a major gap.

About GoLiver Therapeutics - <https://golivertx.com/>

GoLiver Therapeutics is a spin-off from Inserm and the University of Nantes (now Nantes University), created in 2017. It is focused on the development of advanced therapy medicinal products to meet an urgent unmet medical need in transplantation. GoLiver Therapeutics aims to become a world leader in the field of regenerative medicine by tackling liver regeneration, by conducting the first clinical trials and bringing to market the first innovative cell-based drug for the treatment of liver disease without the need for transplantation, using the breakthrough technology of pluripotent stem cells.

Winner of France Relance in 2021, the start-up was awarded the the Seal of Excellence of the European Union in 2023, identified by Challenges magazine as one of the '100 start-ups to invest in' in 2019, GoLiver Therapeutics was awarded the France French Transfer Invest 2019, the i-LAB 2016 national Grand Prize in healthcare biotech and i-LAB 'Emergence' start-up contest 2015. Its R&D is supported by the European Regional Development Fund (ERDF) of the Région Pays de la Loire (2018, €400k), followed by a funding from the «Recovery plan for industry - strategic sectors» (2021, €1 million), aimed at implementing the first production line for its biomedicine in France.

About France 2030

✓ Reflects a dual ambition: to transform key sectors of our economy (health, energy, automotive, aeronautics and space) over the long term through technological innovation, and to establish France as a leading nation in the global economy of the future. From fundamental research, to the emergence of an idea, up to the production of a new product or service, France 2030 supports the entire life cycle of innovation, up to industrialisation.

✓ Is unprecedented in its scale: €54 billion will be invested to ensure that our businesses, universities and research bodies succeed in making the transition to these strategic sectors. The stake: Enable them to respond competitively to the ecological and attractiveness challenges of the world to come, and to develop the future leaders of our sectors of excellence. France 2030 is defined by two transversal objectives consisting in devoting 50% of its expenses to the decarbonisation of the economy, and 50% to emerging actors, drivers of innovation without expenses unfavourable to the environment (in the sense of the Do No Significant Harm principle).

✓ Will be implemented collectively: conceived and deployed in consultation with economic, academic, local and European actors to determine the strategic orientations and flagship actions. Project holders are invited to submit their applications via open, demanding and selective procedures in order to benefit from government support.

✓ Steered by the General Secretariat for Investment on behalf of the Prime Minister and implemented by the Agency for Ecological Transition (ADEME), the French National Research Agency (ANR), Bpifrance and the Territorial Bank (Banque des Territoires).

For more information: france2030.gouv.fr | @SGPI_avenir

About Bpifrance



Bpifrance is the French national investment bank : it finances businesses - at every stage of their development - through loans, guarantees and equity investments. Bpifrance supports them in their innovation and international projects. Bpifrance also supports their export activities with a wide range of products. Advice, universities, networking and acceleration programmes for start-ups, SMEs and ETIs are also part of the services offered to entrepreneurs. Thanks to Bpifrance and its 50 regional offices, entrepreneurs benefit from a single, close and efficient point of contact to support them and meet their challenges.

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