

OCTOBER 12, 2016

CarThera secures €5.7 million in funding for its DOME project from France's 'Investments for the Future Program', run by public investment bank Bpifrance



Paris, France, October 12, 2016 – CarThera, which designs and develops innovative medical devices to treat brain disorders, today announces it has received a grant of €5.7 million (\$6.4m) for its DOME project. The funding was awarded under the call for proposals 'Structuring R&D Projects for Competitiveness' from France's 'Investments for the Future Program', led by the General Investment Commission and run by Bpifrance.

The DOME project's aim is to support the development and market launch of implantable ultrasound devices that temporarily open the blood-brain barrier (BBB) in a controlled manner, in order to increase the efficacy of treatments for patients with brain tumors and neurodegenerative diseases.

The funding was granted following a comprehensive review of the proposal submitted by CarThera in its role as head of the consortium set up with *Assistance Publique-Hôpitaux de Paris* (the Greater Paris University Hospital) and in conjunction with a panel of expert subcontractors. It comes after the publication of preliminary findings from a Phase 1/2a study in glioblastoma (under Prof. Alexandre Carpentier at the Pitié-Salpêtrière Hospital in Paris) in the June edition of *Science*, which validated the concept of the SonoCloud intracranial ultrasound implant developed by CarThera.

The grant will finance a Phase 2b/3 study in glioblastoma, a large-scale clinical trial that will involve around 200 patients at centers in Europe and the United States. It will also fund a number of exploratory studies, including one on Alzheimer's disease, building on the findings from the Phase 1/2a study that paved the way for a broader array of clinical indications.

"Since it was founded in 2010 CarThera has received ongoing support from the public sector, with subsidies awarded by the Île-de-France regional authority and Bpifrance. Today, the substantial funding commitment from Bpifrance on behalf of the French government demonstrates significant confidence in our team and real interest in CarThera from industry professionals," said Frederic Sottolini, CEO of CarThera. *"Bpifrance's support for our project is an acknowledgment of our development potential. It allows us to pursue our ambitious goals. We can begin discussions with the FDA for Phase 2b/3 clinical trials, which will be conducted in both Europe and the US. We can also approach with confidence our next round of fundraising from institutional and corporate funds."*



CarThera's SonoCloud device temporarily opens the BBB, allowing for greater penetration of drug therapies to the brain. The BBB not only limits the efficacy of traditional chemotherapies, but also of new immunotherapies, which have shown significant clinical efficacy for a broad range of solid tumors such as breast cancer or melanoma. The impact of the BBB is reflected in a slowdown in the development of new drug therapies for the brain. Since 1998, nearly 75 molecules indicated for brain tumors have been abandoned in the absence of conclusive results. There is a substantial unmet need for solutions helping to overcome this barrier and providing brain tumor patients with new options.

Marie Zwarg, healthcare industry lead with Bpifrance, said: *"CarThera's latest development has been unanimously acclaimed as an innovative new solution for the treatment of brain disorders. With the funding awarded by Bpifrance under the 'Investments for the Future Program', this start-up can fast-track the development of its solutions and bring a disruptive innovation to a high-potential growth market."*

Bpifrance is the managing operator for research and development projects structuring competitiveness under the **'Investments for the Future' Program** led by the **General Investment Commission**. The goal of these projects is to frame and organize industry sectors or to generate new ones. They aim to strengthen the positions of French businesses in key markets by providing funding for ambitious programs. More broadly they aim to enhance the economic standing of a network of enterprises, by building or consolidating sustainable collaborative relationships between manufacturing, service industries and research organizations.

About SonoCloud

SonoCloud is an innovative medical device developed by CarThera. It is capable of emitting ultrasound to temporarily increase the permeability of the blood vessels in the brain, with the aim of increasing the delivery of therapeutic molecules. Created by Professor Alexandre Carpentier and developed in collaboration with the Laboratory of Therapeutic Applications of Ultrasound (Laboratoire Thérapie et Applications Ultrasonores, LabTAU) at INSERM, SonoCloud is an ultrasound implant inserted into the skull after a regular surgical procedure and activated prior to each round of chemotherapy. Two minutes of low intensity ultrasound emission is enough to open the blood brain barrier for six hours and to increase by five to seven times the concentration of therapeutic molecules delivered into the brain, with good tolerance.

About CarThera

CarThera designs and develops innovative therapeutic ultrasound-based medical devices for treating brain disorders. The company is a spin-off from AP-HP, Greater Paris University Hospitals, the largest hospital group in Europe, and Pierre and Marie Curie University (UPMC). CarThera leverages the inventions of Professor Alexandre Carpentier, a neurosurgeon at AP-HP who has achieved worldwide recognition for his innovative developments for treating brain disorders.

CarThera developed the SonoCloud[®], an intracranial ultrasound implant that temporarily opens the blood-brain barrier (BBB). By increasing the permeability of the cerebral blood vessels using low intensity pulsed ultrasound, the concentration of therapeutic molecules that reach the brain can be increased by five to seven times, with no increase in dose or toxicity. A Phase 1/2a clinical trial is underway in glioblastoma, for which treatment options are very limited. The initial results are supported by a paper published in Science Translational Medicine, which confirms the safety and therapeutic potential of the SonoCloud device. The ultrasound-induced disruption of the blood-brain barrier is a world first; it offers a new treatment option for a wide range of indications, including Alzheimer's disease.

Founded in 2010 by Professor Alexandre Carpentier, CarThera is based at the Brain and Spine Institute (Institut du Cerveau et de la Moelle épinière, ICM) in Paris, France, and has laboratories at the Bioparc Laënnec business incubator in Lyon, France. The company, led by Frederic Sottolini (CEO), works closely with the Laboratory of Therapeutic Applications of Ultrasound (Laboratoire Thérapie et Applications Ultrasonores, LabTAU, INSERM) in Lyon. Since its inception, the company has received support from



France's Ministry of Research, the Ile-de-France region, the Bpifrance public investment bank, Medicen Paris Region and Lyonbiopôle.

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About Bpifrance

Bpifrance, a subsidiary of Caisse des Dépôts and the French State, is a trusted partner of entrepreneurs which provides companies with credit, collateral and equity financing support from start up through to stock exchange listing. Bpifrance also provides guidance services and enhanced support for innovation, external growth and export, in partnership with Business France and Coface.

Bpifrance offers companies a continuum of financing for each key stage of their development and an offer adapted to specific regional features.

With 47 regional offices (90% of decisions are made regionally), Bpifrance offers entrepreneurs a tool for economic competitiveness. Bpifrance works in support of the public policies pursued nationally and regionally by the French government, to meet three objectives:

- support the growth of businesses;
- prepare for future competitiveness;
- contribute to the development of a favorable ecosystem for entrepreneurship.

With Bpifrance, companies have a strong and effective local contact to meet all their financial, innovation and investment needs.

For more information, please visit: www.bpifrance.fr – <http://investissementsdavenir.bpifrance.fr/> – Twitter: @bpifrance



Find out about the program 'Investing for the Future'

<http://www.gouvernement.fr/investissements-d-avenir-cgi>

Press contacts:

Bpifrance

Nicolas Jehly

Tel: +33 (0)1 41 79 95 12

nicolas.jehly@bpifrance.fr

CarThera/Andrew Lloyd & Associates

Agnes Stephens/Lise Beltzung

Tel: +44 1273 675 100

agnes@ala.com – lise@ala.com