

CarThera starts phase I/II trial in collaboration with Northwestern University to test SonoCloud-9 in patients with recurrent glioblastoma

NIH funded clinical trial explores combination of SonoCloud-9 device with Abraxane®; first patient treated and recruitment now on-going

Paris, France, December 16, 2020 – CarThera, a French company that designs and develops innovative ultrasound-based medical devices to treat brain disorders, today announces the launch of a new phase I/II clinical trial ([NCT04528680](https://clinicaltrials.gov/ct2/show/study/NCT04528680)) in collaboration with Northwestern University in Chicago. The trial will recruit up to 39 patients with recurrent glioblastoma (GBM) to test the SonoCloud-9 device in combination with Abraxane® - an albumin-bound formulation of paclitaxel. SonoCloud-9 is an implantable device with nine ultrasound emitters that are activated in conjunction with microbubbles to transiently open the blood-brain barrier. This allows the penetration of drugs such as Abraxane into the brain tissue. The first patient in this trial has been treated and further patient recruitment is now on-going.

The goal of the trial is to determine the safe dose of Abraxane to be used in combination with the SonoCloud-9 device in recurrent GBM patients (Phase I); then expand with the established safe dose in order to evaluate preliminary efficacy (Phase II).

This study, sponsored by Northwestern University, is being funded by the US National Cancer Institute (NCI) / National Institutes of Health (NIH) as an R01 (Research Project Grant) and led by investigators Dr. Adam Sonabend, neurosurgeon, and Dr. Roger Stupp, neuro-oncologist. Dr. Sonabend will also perform studies with an intraoperative component; measuring drug concentrations in patients' brain tissue to ensure that the drug is achieving cytotoxic concentrations after sonications to disrupt the BBB.

"This is a remarkable time. We are delighted that we have been awarded an R01 grant to fund this clinical trial that will explore alternative drugs in combination with the SonoCloud device. Paclitaxel is potentially one of the most potent drugs against GBM, yet its use in this indication has been limited because it does not cross the BBB," said Dr. Sonabend. "Over the last few years we have explored new therapies in preclinical glioma models in partnership with CarThera; the data with Abraxane look promising."

"Now, we are pleased to be able to offer this innovative technology and treatment to patients with recurrent glioblastoma. We have already treated the first patient, a second patient will be treated later this month," added Dr. Stupp.

Preclinical data obtained with the use of the SonoCloud in combination with Abraxane in animal models was published in early 2020 in [Clinical Cancer Research](#).

"CarThera has a strong collaboration with Northwestern. Together, we have been exploring a wide range of potential drug therapies in combination with the SonoCloud device in preclinical studies over the past several years," said Michael Canney, Scientific Director at CarThera. "This is the first clinical trial that has emerged from this multi-year collaboration. The SonoCloud-9 enables clinicians to use this promising drug for the first time and to ensure that it crosses into the brain."



Previously, Northwestern University has participated in CarThera's studies of the SonoCloud-9 in combination with carboplatin chemotherapy where it gained extensive experience with the device.

"This trial will extend the safety data for the use of the SonoCloud-9 with additional therapies. This means glioblastoma patients can be treated with a wider range of therapies using the device and, in the future, receive a therapy that is optimally selected for their particular tumor," said Frederic Sottolini, CEO at CarThera.

The first intraoperative results on drug enhancement are expected in mid-2021.

About glioblastoma

Each year 250,000 patients worldwide are diagnosed with a brain tumor, with about 17% of these diagnosed as glioblastoma (GBM). GBM is the second most common central nervous system cancer after meningioma, and one of the most aggressive, with less than 10% of patients currently surviving more than five years. The National Cancer Institute estimates that, this year alone, in the United States [close to 24,000 adults](#) have been diagnosed with brain and nervous system cancer, of which about 13,000 will be glioblastoma.

About SonoCloud

SonoCloud® is an innovative medical device developed by CarThera. It emits ultrasound to temporarily increase the permeability of the blood vessels in the brain. Invented by Pr. Alexandre Carpentier, SonoCloud is an implant inserted into the skull and activated prior to chemotherapy. Several minutes of low-intensity ultrasound opens the blood-brain barrier for six hours and increases the concentration of therapeutic molecules in the brain. The SonoCloud technology is appropriate for the treatment of brain diseases in general. Oncology indications are the company's primary target but investigations are ongoing in other conditions, including neurodegenerative diseases and Alzheimer's disease in particular.

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 Sorbonne University. CarThera leverages the inventions of Professor Alexandre Carpentier, a neurosurgeon at AP-HP who has achieved worldwide recognition for his innovative developments in treating brain disorders. CarThera developed SonoCloud, an intracranial ultrasound implant that temporarily opens the blood-brain barrier (BBB).

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, and has laboratories at the Bioparc Laënnec business incubator in Lyon. The company, led by Frederic Sottolini (CEO), works closely with the Laboratory of Therapeutic Applications in Ultrasound (Laboratoire Thérapie et Applications Ultrasonores, LabTAU, INSERM) in Lyon. Since its inception, the company has received support from the AP-HP, Sorbonne University, the ANR (National Research Agency), France's Ministry of Research, the Ile-de-France region, the Bpifrance public investment bank, the Medicen Paris Region and Lyonbiopôle clusters.

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