

CarThera receives FDA approval for Phase 1/2a trial in glioblastoma

SonoCloud ultrasound device for glioblastoma patients will be tested for first time at US clinical sites

Paris, France, July 9, 2019 - CarThera, a French company that designs and develops innovative ultrasound-based medical devices to treat brain disorders, today announces that the FDA has granted approval to launch a Phase 1/2a clinical trial in the US with its SonoCloud-9 ultrasound device in recurrent glioblastoma (GBM) patients treated with carboplatin.

CarThera's low-intensity pulsed ultrasound device, the SonoCloud, is designed to temporarily open the blood-brain barrier (BBB), potentially improving the penetration of therapeutic agents into the brain to increase efficacy. The company recently reported the results of a [Phase 1/2a glioblastoma trial](#) in France (Pitie Salpetriere Hospital at AP-HP) with its first generation device, the SonoCloud-1.

Its next-generation device, the SonoCloud-9, brings a nine-fold increase in coverage of the tumor and surrounding infiltrative areas. A phase 1/2a clinical trial aiming at measuring the safety, tolerance and efficacy of repeated openings of the BBB by SonoCloud-9, before infusion of carboplatin in 27 patients, has already started [in France](#) (Paris and Lyon) and will soon be up and running at the MD Anderson Cancer Center in Houston and at the Northwestern Memorial Hospital in Chicago.

"We are excited to initiate this clinical trial in the US to evaluate the potential of the SonoCloud-9 device for glioblastoma patients," said Professor Alexandre Carpentier, inventor of the technology and founder of CarThera. "Our first clinical study confirmed the safety and feasibility of this solution. We believe it represents a major step forward in the treatment of GBM."

This phase 1/2a study in France, conducted by Dr Ahmed Idhahbi, is a preliminary step in the development of the SonoCloud-9 for glioblastoma. A pivotal trial should start at the end of next year in Europe and in the US. This should lead to marketing approvals in these regions.

"We are delighted with the FDA approval of our SonoCloud-9 study in GBM patients and are looking forward to expanding our activities in the US," said Frederic Sottolini, CEO of CarThera. "The [appointment last month of Pascal E. R. Girin](#) as our US-based chairman of the board, our new subsidiary in Boston and a number of translational research programs with renowned US research institutes show our commitment to bringing our innovative technology to US patients with brain tumors."

According to the company's estimates, each year 250,000 patients worldwide are diagnosed with a brain tumor. Each year about 3 in 100,000 people develop glioblastoma. It is the second most common central nervous system cancer after meningioma. [In the US, the National Cancer Institute estimates that over 23,000 adults will be diagnosed in the United States with brain and nervous system cancer in 2019.](#)



The SonoCloud is the only tool capable of easily and repeatedly opening the BBB to allow for enhanced concentrations of therapeutics into the brain.

“Therapeutic ultrasound research has significantly increased in importance over the last decade. We are delighted that we can now introduce our ultrasound technology to US clinical and research centers. We believe that this is a significant step in developing this technology for use with a wide range of therapies for treatment of brain diseases,” said Michael Canney, scientific director at CarThera.

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 into 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. Since 2010, CarThera has been leveraging 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).

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 the AP-HP, Sorbonne University, the ANR (Nationale 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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Media and analysts contact
Andrew Lloyd & Associates
Juliette dos Santos – Agnes Stephens
juliette@ala.com – agnes@ala.com
Tel: +44 1273 675 100
[@ALA_Group](#)