Abstract #2016

ASCO 2018: CarThera presents promising preliminary efficacy data for treating recurrent glioblastoma

Preliminary data from the first clinical trial of the company’s intracranial ultrasound implant, SonoCloud®, show a good safety profile and promising trends in overall survival

Paris, France, June 03, 2018 – CarThera, a French company that designs and develops innovative ultrasound-based medical devices to treat brain disorders, today announced the preliminary data of its Phase I/IIa clinical trial (NCT02253212) on ultrasound induced blood-brain barrier (BBB) opening. Dr. Ahmed Idbaih, principal investigator and neuro-oncologist at AP-HP hospital in Paris, presented preliminary data from a trial involving 21 patients with recurrent glioblastoma (GBM), who were treated monthly with the SonoCloud device prior to carboplatin chemotherapy. The presentation took place at the McCormick Place Convention Center in Chicago, Illinois on June 2 during a session on Central Nervous System Tumors at the American Society of Clinical Oncology (ASCO).

The BBB prevents the passage of most drugs from the blood to the brain and may be responsible for the limited efficacy of current chemotherapies in GBM patients. To tackle this problem, Pr. Alexandre Carpentier, a French neurosurgeon at AP-HP and founder of CarThera, developed SonoCloud, a low-intensity pulsed ultrasound device that temporarily increases the permeability of the BBB and enhances the delivery of therapeutic molecules to the brain.

“Our mission is to improve the prognosis of patients with brain diseases by increasing the permeability of cerebral blood vessels to allow therapeutic molecules such as antibodies, pathway inhibitors, chemotherapies or enzymes to reach effective concentrations in the brain,” said Frederic Sottilini, CEO of CarThera.

In preliminary analysis of the data from 21 GBM patients who received 65 SonoCloud treatments, the investigators observed a good safety profile and trends in improvement of Progression Free and Overall Survival. OS was increased from 8.5 to 12.9 months in patients who had SonoCloud-induced BBB opening. The full abstract #2016 titled ‘Safety and preliminary efficacy data from a phase I study of an implantable low intensity pulsed ultrasound (LIPU) device for disrupting the blood-brain barrier (BBB) in patients treated by chemotherapy for recurrent glioblastoma (GBM)’ is available on https://meetinglibrary.asco.org/record/163756/abstract.

“We are excited to share promising preliminary data from our clinical trial at the ASCO annual meeting attended by more than 32,000 oncology professionals from around the world,” said Dr. Idbaih. “The sonication of larger volumes of brain in recurrent GBM will be investigated in a future trial and may further enhance the observed effectiveness of this new treatment modality.”

“Preliminary efficacy results presented by Dr. Idbaih at the annual ASCO meeting demonstrate the proof of concept of our first-in-class solution to enhance delivery of therapeutic agents in the brain. The increase in survival observed in GBM patients paves the way for the combination of the SonoCloud device with different agents for treating various brain disorders, such as cancers and neurodegenerative diseases,” said Frederic Sottilini.
According to the company’s estimates, each year 250,000 patients worldwide are diagnosed with brain tumors. The SonoCloud could benefit these patients as well as millions more with debilitating brain disorders.

**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 to increase the delivery of therapeutic molecules. Invented by Pr. Alexandre Carpentier and developed in collaboration with the Laboratory of Therapeutic Applications of Ultrasound (Laboratoire Thérapie et Applications Ultrasonores, LabTAU, INSERM) in Lyon, France, 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. This ultrasound-induced opening of the blood-brain barrier is a world first; it offers a new treatment option for a wide range of indications, including brain tumors and Alzheimer’s disease.

**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 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, France, and has laboratories at the Bioparc Laënnec business incubator in Lyon, France. The company, led by Frederic Sottilini (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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