CarThera announces enrollment of first melanoma patient in new clinical trial for SonoCloud technology

SoniMel study aims to demonstrate safety of SonoCloud procedure for patients with brain metastases from melanoma

Paris, France, June 8, 2020 – CarThera, a French company that designs and develops innovative ultrasound-based medical devices to treat brain disorders, today announces that the first patient has been enrolled and treated in a clinical trial evaluating the safety of using its SonoCloud® technology in combination with checkpoint inhibitors for the treatment of brain metastases from melanoma (NCT04021420).

CarThera has demonstrated the feasibility of its SonoCloud approach in previous glioblastoma studies and actively supports institutional research.[1] The SoniMel study – sponsored by Greater Paris University Hospitals and funded by the French National Cancer Institute – aims to demonstrate the safety of the procedure for patients with brain metastases from melanoma and to determine the optimal dose for further developments in this indication. The study is expected to finish in mid-2021.

"Enormous progress has been made in treating melanoma with new therapies, but despite progress in the treatment of brain metastases, therapeutic challenges are still high. In this respect, the SoniMel protocol is extremely important because of its technological innovation in opening the blood-brain barrier," said Professor Céleste Lebbé, principal investigator at Saint Louis Hospital, Paris.

In this trial, the checkpoint inhibitors (anti-PD1 alone or in combination with anti-CTLA4) are administered in metastatic melanoma patients before SonoCloud-mediated blood-brain barrier opening (BBB). BBB opening can help boost the brain's immunity and increase brain penetration of newly approved systemically delivered immunotherapies, such as checkpoint inhibitors. This could translate into controlling brain disease with the same magnitude as peripheral diseases, improving clinical outcomes for many patients worldwide.

"This study is of great interest for CarThera, as it targets a high unmet medical need, that of secondary tumors," said Frederic Sottilini, CEO at CarThera. "The incidence of brain metastases is high in patients with melanoma, lung or breast cancer. The functional and vital prognosis is severe. Opening the blood-brain barrier with the SonoCloud system in patients treated with immunotherapies for brain metastases is an interesting avenue to explore in improving the brain's immunological response."

Brain tumors are diagnosed in 10 to 40 percent of metastatic melanoma patients. Across all cancers, an estimated 100,000 to 170,000 new cases of brain metastasis are diagnosed annually.[2] With the brain metastases indication, CarThera anticipates it will considerably expand the market potential of its SonoCloud innovation.

"This is the fourth clinical trial to evaluate SonoCloud's technology for treatment of brain diseases," said Carole Desseaux, chief clinical officer at CarThera. "So far, a total of 45

[1] https://www.ncbi.nlm.nih.gov/pubmed/27306666
[2] https://www.sciencedaily.com/releases/2019/02/190220103405.htm

patients have been treated with the SonoCloud implantable ultrasound device, representing about 180 sonication sessions."

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 Sottilini (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 (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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