



Carthera announces positive outcome of End-of-Phase 2 meeting with FDA for SonoCloud-9 system for treatment of recurrent glioblastoma

Carthera and FDA aligned on key aspects of proposed pivotal trial design

Paris, France, March 13, 2023 – Carthera, a French company that designs and develops the SonoCloud[®], an innovative ultrasound-based medical device to treat a wide range of brain diseases, announces today the completion of its End-of-Phase 2 meeting with the US Food & Drug Administration (FDA).

The company presented preclinical and clinical data from its phase 1/2 trials and met support from the FDA to progress into the phase 3 step of the clinical program evaluating the SonoCloud-9[®] system for the treatment of recurrent glioblastoma (rGBM). This is another important milestone for the SonoCloud system that was recently granted Breakthrough Device Status by the FDA in 2022.

The SonoCloud device uses low intensity pulsed ultrasound to temporarily disrupt the Blood-Brain Barrier (BBB), to deliver higher brain exposure to therapeutic compounds. Carthera recently completed a phase 1/2 trial in rGBM with carboplatin in 33 patients and a phase 1 trial in rGBM with nab-paclitaxel in 17 patients. In total, over 60 patients have been treated to date with the SonoCloud-9 across trials in glioblastoma in over 250 treatment procedures.

“In these trials, to date, ultrasound-based blood-brain barrier opening using the SonoCloud-9 device has proven to be safe and effective at increasing drug levels in the human brain. Investigating the efficacy of this approach is the next step and we’re excited for this new phase of development,” said Michael Canney, chief scientific officer at Carthera.

“We had a very positive interaction with the FDA and its responses will now enable our team to finalize the design and to initiate the pivotal trial. The company is planning the phase 3 trial submission in Europe and the United States in the coming weeks,” said Sandra Thiollière, head of regulatory affairs at Carthera.

“We are convinced that by using SonoCloud, the therapeutic efficacy of drugs such as carboplatin and nab-paclitaxel will be unlocked and harnessed to improve the treatment of glioblastoma,” said Frederic Sottolini, CEO of Carthera. “The launch of our pivotal trial will pave the way for the first marketing approval of Carthera's SonoCloud technology in glioblastoma, as we continue to pursue a wide range of indications for our novel brain drug delivery platform.”

About SonoCloud-9

The SonoCloud-9 device is implanted in a skull window, below the skin; once in place it is invisible. When activated for a few minutes using a transdermal needle connection to an external control unit, the BBB is disrupted for several hours; a window during which drug therapies can be administered. When the BBB is disrupted, drugs can reach the brain in higher and more effective concentrations. This treatment can be repeated at each cycle of drug therapy.



The safety of the investigational use of SonoCloud-9 has not yet been determined, the device has not yet received EMA or FDA approval.

About Carthera

Carthera is a clinical-stage medtech company focused on developing innovative ultrasound-based medical devices to treat a wide range of brain disorders.

The company is a spin-off from AP-HP Paris and Sorbonne University. Carthera leverages the inventions of Pr. Alexandre Carpentier, head neurosurgeon at AP-HP Sorbonne university, who has achieved worldwide recognition for his innovative developments in treating brain disorders. Carthera is developing SonoCloud[®], an intracranial implant that temporarily opens the Blood-Brain Barrier (BBB). The device is currently in clinical trials in Europe and the United States.

Founded in 2010, Carthera has offices in France (Lyon and Paris) and a subsidiary in the United States. Since its inception, the technical and clinical development of SonoCloud has received support from the National Research Agency (ANR), the French public investment bank (Bpifrance), the National Institutes of Health (NIH) and the European Innovation Council (EIC).

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