

Carthera enrolls first patient in pivotal trial of SonoCloud-9® device for treatment of recurrent glioblastoma

Registrational study aims to enroll 560 US and EU patients over next two years, with view to obtaining marketing authorization

SONOBIRD trial will compare use of SonoCloud-9 ultrasound device combined with carboplatin vs standard of care therapies in patients with first recurrence of glioblastoma

Paris, France, February 5, 2024 - Carthera, a spin-off from Sorbonne University founded by Pr. Alexandre Carpentier, and developer of SonoCloud®, an innovative ultrasound-based medical device to treat a wide range of brain disorders, today announces the enrollment of the first patient in its SONOBIRD pivotal trial for the treatment of recurrent glioblastoma (rGBM). The trial ([NCT05902169](https://clinicaltrials.gov/ct2/show/study/NCT05902169)) aims to treat 560 patients across 40 sites in Europe and the US.

Prof. Dr. Johnny Duerinck, neurosurgeon at Universitair Ziekenhuis Brussel (Belgium), in the department of Prof. Dr. Michaël Bruneau and in close collaboration with the department of oncology of Prof. Dr. Bart Neyns, enrolled two patients earlier in January, marking the start of a two-year recruitment period for patients in the EU and the US. Eligibility criteria for the study include adult patients who have a first recurrence of their disease and who are eligible for a new tumor resection.

"We feel privileged to have enrolled the first patient in the SONOBIRD clinical trial. The development of effective treatments against glioblastoma is limited, due to the BBB preventing most systemic drugs from reaching the brain parenchyma. By utilizing Carthera's SonoCloud-9® device to temporarily open the BBB in the areas surrounding the tumor, we will be able to assess the effectiveness of carboplatin against existing treatments, with the aim of providing glioblastoma patients with better therapeutic options," said Prof. Dr. Duerinck.

This open-label, comparative, randomized, multicenter, two-arm clinical trial with a 1:1 ratio will evaluate overall survival in patients undergoing carboplatin chemotherapy and treated with the SonoCloud-9 system to open the Blood-Brain Barrier (BBB). This will be compared to the medical consensus recommended regimens (lomustine or temozolomide). The trial will also evaluate the effectiveness of the SonoCloud-9 and carboplatin treatment in delaying or slowing tumor growth.

The SONOBIRD trial follows on from the [SC9-GBM-01 trial](#) (full results expected to be published in Q2, 2024), which demonstrated the feasibility and the safety profile of the SonoCloud-9, as well as the potential of carboplatin tested as a monotherapy in combination with BBB opening.

"The launch of the SONOBIRD trial is a significant achievement in the clinical development of the SonoCloud-9 system. If the efficacy of carboplatin in combination with our device is proven, it will change the paradigm of how we treat glioblastoma," said Carole Desseaux, chief clinical officer at Carthera.

"We are proud to announce the enrollment of the first patient in our pivotal trial. This demonstrates our leadership in the development of therapeutic ultrasound for the treatment of neurological diseases," said Frederic Sottolini, CEO of Carthera.

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. It received [FDA Breakthrough Device Designation](#) in 2022.

Founded in 2010 by Pr. Alexandre Carpentier, run by CEO Frederic Sottolini and chaired by Oern Stuge MD, Carthera has offices in France (Lyon and Paris) and a subsidiary in Boston, Massachusetts, USA. 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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