

Carthera receives positive opinion from French High Authority for Health on Innovation Funding scheme to treat patients with recurrent glioblastoma

Following positive opinion, ultrasound-based medical device company will obtain temporary funding to conduct first registrational trial of SonoCloud® device in France

Paris, France, July 1, 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 that HAS, the French High Authority for Health, has issued a positive opinion on taking over the costs associated with the SonoCloud-9 system in the SONOBIRD study, within the framework of the *Forfait Innovation* (Innovation Funding) program.

Forfait Innovation provides exceptional funding for medical devices, in vitro diagnostic or medical procedures ahead of coverage by the mainstream health system, to give French patients early access to medical innovations. This funding is conditional on the completion of a prospective study demonstrating the technology's clinical potential.

Therefore, acceptance into the innovation funding scheme provides fast-track access to the market. Technology which is accepted into the innovation funding scheme is disseminated across the French market via the inclusion of patients in the study, with the assurance that there won't be any interruption in funding for patients between the clinical study and the request for coverage by the mainstream health system.

Since 2009, only [18 medical devices have been enrolled in the Forfait Innovation program](#).

The next step for Carthera is to enter budget discussions with the French Ministry of Solidarity and Health. Upon completion, *Forfait Innovation* will finance the SonoCloud products used for the conduct of the SONOBIRD international comparative trial at the French study sites.

The SONOBIRD 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 SonoCloud-9 and carboplatin treatment in delaying or slowing tumor growth.

"The positive opinion from the French High Authority for Health on *Forfait Innovation* is a recognition of the significant innovation likely to be delivered to glioblastoma patients by the SonoCloud device," said Professor Alexandre Carpentier, head of the neurosurgery department at AP-HP Sorbonne University, inventor of SonoCloud and founder of Carthera. "It also acknowledges that the proposed SONOBIRD study should be able to answer the primary endpoint question about the overall survival associated with administration of carboplatin chemotherapy after BBB opening using SonoCloud."

Carboplatin has been chosen for its proven anti-tumoral activity and has already been tested as a monotherapy in patients with glioblastoma. It shows limited Central Nervous System (CNS) toxicity at high doses or in direct exposure. However, it has limited penetration through the BBB when administered using standard intravenous (IV) routes.

Brain concentrations of carboplatin can be significantly enhanced when coupled with the SonoCloud-9 system to temporarily disrupt the BBB. Preliminary safety and efficacy results for combining SonoCloud-9 with carboplatin have already been published in [Nature Communications](#).

"We are delighted with this positive opinion from the HAS, which demonstrates real support in finding more effective treatments for glioblastoma patients in France. Following the Breakthrough Device Designation and Orphan Drug Designation from US and EU authorities for carboplatin when used with Carthera's SonoCloud technology, this is another important step in our project to rapidly make BBB opening with SonoCloud available to patients with glioblastoma and offer new therapeutic options," said Frédéric Sottolini, CEO of Carthera.

Glioblastoma (GBM) is one of the most complex, deadly and treatment-resistant cancers, with [more than 10,000 people in the US](#) and [15,000 in the EU](#) succumbing to the disease every year.

If confirmed by the SONOBIRD registrational study, SonoCloud has the potential to become a standard-of-care for patients with a first recurrence of glioblastoma.

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 to improve 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 injection of a therapeutic agent. 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.

SonoCloud is an investigational product, 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, and FDA/EMA Orphan Drug Designation in 2023 for carboplatin when used with SonoCloud.

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).

www.carthera.eu

Media and analysts contact

Andrew Lloyd & Associates

Saffiyah Khaliq- Juliette Schmitt

saffiyah@ala.associates – juliette@ala.associates

Tel: +44 1273 952 481
