Carthera receives EMA expert panel endorsement for Orphan Medical Device status of SonoCloud system

Following positive opinion, Carthera is one of the first companies to benefit from brand-new status - intended to support early access pathways for innovative devices targeting rare diseases

Paris, France, July 1, 2025 – 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 it has received EMA expert panel endorsement for Orphan Medical Device status of its SonoCloud system.

Carthera will be one of the first companies to benefit from EMA expert panel advice, supporting its clinical development strategy and clarifying the final steps before CE marking application. This advice, intended for medical device manufacturers and notified bodies, is part of the EU pilot program to support early access pathways for innovative devices targeting rare diseases. As part of the program, the EMA has prioritized certain types of orphan medical devices, such as those treating a medical condition that is life-threatening or that could cause permanent impairment of a body function, devices intended for children and novel devices with potential major clinical benefits.

"This is a very important step for the company, since it creates a unique forum for dialogue with the expert panel prior to submitting the technical documentation for conformity assessment," said Sandra Thiollière, director of regulatory affairs at Carthera. "In parallel, we are continuing our early-stage contacts with our notified body in order to prepare for CE marking submission."

SonoCloud was one of the very first projects selected for the Orphan Medical Device pilot program, launched in August 2024. After reviewing the information provided by Carthera, the expert panel has agreed that the SonoCloud system can be considered an orphan device. This positive opinion takes into account the estimated target patient population with recurrent glioblastoma in the EU, the expected clinical benefit of increasing permeability of the Blood Brain Barrier (BBB) and of enhancing the delivery of therapeutic agents directly to the tumor site in the brain with the potential expected improvements in clinical outcomes.

"In 2022, we obtained Breakthrough Device Designation from the FDA, and in 2024, the Forfait Innovation in France from the HAS. With this new status, we will be in the best position to put our highly promising technique on the market as early as possible and to bring its benefits to European patients," said Frédéric Sottilini, CEO of Carthera.

The next step for Carthera is to benefit from the free advice of the expert panel on the data needed to complete the clinical evaluation of the SonoCloud device, which should happen during Q3, 2025. The company is also continuing its early structured dialogue with its notified body to prepare for the submission of the technical documentation, with a view to applying for CE marking.

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 neurodegenerative diseases.

SonoCloud is an investigational product, the device has not yet received CE marking 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 Sottilini and chaired by Oern Stuge MD, Carthera has offices in France (Lyon) and a subsidiary in New York, 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
Carol Leslie– Juliette Schmitt
carol@ala.associates – juliette@ala.associates
Tel: +44 1273 952 481