Carthera receives FDA Breakthrough Device Designation for SonoCloud-9 system

Breakthrough Status allows for enhanced interaction with FDA and recognizes SonoCloud system as innovative and promising approach for treatment of recurrent glioblastoma

Paris, France, June 22, 2022 – Carthera, a French company that designs and develops SonoCloud, an innovative ultrasound-based medical device to treat a wide range of brain diseases, announces today that its SonoCloud-9® system has been listed as a Breakthrough Device by the Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA).

The SonoCloud device uses low intensity pulsed ultrasound to temporarily disrupt the Blood-Brain Barrier (BBB), to allow higher brain exposure to therapeutic compounds. By using SonoCloud, the therapeutic efficacy of new and existing therapies can be unlocked and harnessed to improve the treatment of a wide range of brain diseases, such as glioblastoma.

"There is a significant unmet need for new treatments for glioblastoma patients, who have very few available therapeutic options," said Michael Canney, chief scientific officer at Carthera. "We're excited that the FDA has acknowledged the innovative potential of the SonoCloud approach through the granting of this Breakthrough Designation."

The Breakthrough Devices Designation, intended to expedite the development and review of the medical device, was based on preliminary phase 1/2a clinical data that indicates substantial improvement over available second-line therapy (publication under preparation).

"The FDA Breakthrough Device Designation will help Carthera to efficiently advance to a pivotal trial and Premarket Approval (PMA)," said Sandra Thiollière, head of quality and regulatory affairs at Carthera. "We look forward to working closely with the FDA through this accelerated process to bring SonoCloud to patients with recurrent glioblastoma."

This designation will give Carthera access to priority review, more intensive FDA interaction to build an efficient device development program and commitment from experts and senior managers from the FDA, who will assist the company in addressing any potential challenges during the premarket review phase.

"Following the recent successful completion of our phase 1/2 trial in recurrent glioblastoma, this Breakthrough Device Designation is another important milestone supporting the potential of SonoCloud," said Frédéric Sottilini, CEO of Carthera. "This step forward is also a strong signal for investors who have joined our next round of financing and for those who are considering joining. I am confident that we will soon close our Series B round, which will allow us to start our pivotal clinical trial in early 2023."

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 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. By administering therapies 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.

About the FDA Breakthrough Device Program
The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to certain medical devices by speeding up their development, assessment and review, while preserving the statutory standards for Premarket Approval, 510(k) clearance and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

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 the 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 the 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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