



Press Release

ORIXHA obtains French Health Authority approval to initiate its feasibility clinical study in Post Cardiac Arrest Syndrome

The OverCool clinical trial will enroll post cardiac arrest patients treated with ultra-rapid therapeutic hypothermia by the Vent2Cool device, a world premiere for a Total Liquid Ventilation therapeutic solution.

Paris, September the 5th, 2024 – Orixha announced that it received the approval from the ANSM (French National Agency for the Safety of Medicines and Health Products) and the Ethics Committee for the OverCool study to be conducted at Hopital Cochin (APHP Paris). The OverCool study aims to achieve two major clinical breakthroughs. First, it will validate the ability to induce therapeutic hypothermia within 2 hours post resuscitation, in order to significantly improve survival and neurological outcomes for cardiac arrest patients. Secondly, the OverCool study will achieve a clinical world premiere for total liquid ventilation as Vent2Cool's ultra-rapid cooling performance is powered by Orixha's proprietary lung conservative liquid ventilation technology platform.

Answering the Need to Save more Lives from Post Cardiac Arrest Syndrome

One million cardiac arrests occur every year in Europe and the USA, most of them happening out of the hospital. In this case, about 30% of patients will be resuscitated by Emergency services and brought comatose in Intensive Care Units. Unfortunately, less than 10% will survive in good neurological condition. The majority – more than 150,000 patients every year - will succumb to Post Cardiac Arrest Syndrome (PCAS), for which there is no efficient therapeutic option.

PCAS occurs after prolonged cardiac arrest and causes an inflammatory storm that strikes the vital organs (brain, heart, liver and kidney).

Therapeutic hypothermia, lowering the body temperature to 33°C for 24 hours, is a well-known therapeutic modality against PCAS. Unfortunately, to date, cooling devices take hours to reach 33°C which is limiting their efficacy to blunt the PCAS cytokine storm.

« We recognize that the current therapeutic options for hypothermia are sub-optimal and therefore deliver a weak effect size in the general cardiac arrest population. The speed to cool the patient consistently is critical against PCAS. We welcome the opportunity to assess the potential added benefits of introducing ultra-rapid hypothermia induction in the protocol of care for cardiac arrest patients » explains Professor Alain Cariou, Principal Investigator of the OverCool study.

The OverCool Study – Pioneering a breakthrough in Therapeutic Hypothermia for Cardiac Arrest

OverCool is a First in Human Feasibility study for Orixha's Vent2Cool ultra-rapid cooling device to be held in a leading cardiac Arrest Centers, starting with Hospital Cochin in Paris. It should begin in the next few months, thanks to the approval of national health authorities and ethics committees.

OverCool is designed to demonstrate the feasibility and safety of a breakthrough approach to Hypothermic Targeted Temperature Management (TTM) in Post Cardiac Arrest Syndrome. This approach combines the Vent2Cool device, delivering unique ultra-rapid hypothermia induction and best in class TTM device for maintenance and rewarming.

OverCool will show that ultra-rapid therapeutic hypothermia at 33°C is safe and can be efficacious in humans, paving the way for future demonstration of superior efficacy of Hypothermic TTM vs. Normothermic TTM as seen in relevant cardiac arrest animal models.

« For the ORIXHA team and our partners, the green light to the OverCool study strengthens our commitment to make ultra-rapid therapeutic hypothermia an efficient and safe therapeutic modality for resuscitated cardiac arrest patients » stated Fabrice Paublant, Orixha's Chief Executive Officer.

For the OverCool study, the sponsor, Orixha, received financial support from the Programme d'Investissements d'Avenir PIA3 and the BD Foundation.

Powering a World Premiere in Total Liquid Ventilation

Vent2Cool is based on Orixha's lung conservative total liquid ventilation platform, also called LuncoLive. Vent2Cool delivers ultra-rapid cooling by using the lungs as highly potent thermal exchangers. The Vent2Cool procedure, liquid ventilation with a temperature controlled breathable, is restricted to adult comatose resuscitated cardiac arrest patients and lasts less than one hour.

« The disruptive LuncoLive technology which powers Vent2Cool is based on 10 years of academic research by Orixha's academic co-founders at Université de Sherbrooke and INSERM - Ecole Nationale Vétérinaire d'Alfort » added Pr Renaud Tissier, Orixha co-Founder, "OverCool will be a founding moment for Total Liquid Ventilation as it shows that it can be safely delivered to adult comatose patients for the first time in history. We are delighted to have obtained the authorizations to help our dream to save lives with Total Liquid Ventilation become a clinical reality".

About Orixha - <https://orixha.com>

Orixha is a DeepTech company whose mission is to become the world leader in Liquid Venting by demonstrating its life-saving clinical benefits for Critical Care patients.

Orixha is developing the Vent2Cool medical device to provide near-immediate protection for vital organs, particularly the brain and heart, in post-cardiac arrest resuscitation patients, thereby significantly reducing mortality and morbidity. Vent2Cool transforms the lungs into a heat exchanger with the blood compartment. This enables ultra-rapid therapeutic hypothermia to be induced, in the order of minutes, whereas current hypothermia solutions take hours to reach the target temperature of 33°C.

Orixha's proprietary LuncoLive for "Lung Conservative Liquid Ventilation" technology, once validated in therapeutic hypothermia, will be developed for other Critical Care conditions, including Acute Respiratory Distress Syndrome.

Young University compagnie spin-off from the Ecole Nationale Vétérinaire d'Alfort, the University of Sherbrooke and INSERM, Orixha is a winner of the i-LAB 2019 and i-NOV 2020 competitions. The company has received support from SATT Erganeo, WILCO, Agoranov, Bpifrance, France 2030, EIT Health and the European Innovation Council (EIC Accelerator).

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