CARDIAWAVE

PRESS RELEASE

CARDIAWAVE HAS BEEN GRANTED AUTHORIZATION BY THE ANSM

Paris, November 17th, 2020.

The French MedTech Cardiawave has been granted authorization by the Agence Nationale de Sécurité du Médicament et des produits de santé - ANSM (French National Agency for Health Products Safety) on October 20th to extend its clinical trial in France and treat patients with calcific aortic stenosis (AS).

CLINICAL TRIALS HAVE RESUMED IN THE NETHERLANDS

Cardiawave has continued to develop Valvosoft®, its non-invasive medical device to treat AS, despite the current COVID-19 pandemic. The company offers an unparalleled and fully non-invasive treatment which enables the heavily calcified aortic valve to open widely again by softening the tissus using high-intensity therapeutic ultrasound focused directly on the aortic valve from outside the body. As part of its first clinical trial investigating the safety and feasibility of the treatment, Cardiawave treated 10 patients in France and the Netherlands in 2019. The results were presented at several international conferences on cardiology. Last week, Pr. Emmanuel Messas, co-founder of Cardiawave, cardiologist at the Georges Pompidou European Hospital (HEGP-APHP) and principal investigator of this study, presented the interim results, with promising potential over 12 months, at the American Heart Association (AHA) Scientific Sessions which were held online. Through his perseverance, the start-up resumed its clinical trials in Europe in October 2020 after it was granted authorization to extend its clinical study in the Netherlands. Six patients with severe aortic stenosis were treated at the Amphia Hospital in Breda (The Netherlands) under the supervision of Dr. Sander IJsselmuiden, local investigator, and Pr. Emmanuel Messas. Furthermore, the start-up hopes to resume the ongoing clinical trials in Serbia, which were interrupted in March 2020 due to the pandemic.

NEW CLINICAL TRIAL IN FRANCE



Valvosoft® © Cardiawave

Following the authorization granted by the ANSM, French patients with severe symptomatic aortic stenosis, who are ineligible for valve replacement by surgery or by transcatheter aortic valve implantation (TAVI), can again be treated using Cardiawave's non-invasive therapy. In France, in 2018, about 13,000 people with severe symptomatic AS underwent TAVI. Unfortunately, around 1,500 people with severe symptomatic AS are not eligible for this procedure. These very sick patients are unable to make any effort and have a very short life expectancy. Up to 20 new patients are meant to be treated as part of the extended clinical trial. It aims to confirm the safety of the therapy and the procedure and to assess its performance by improving the quality of life of patients and their anatomical and hemodynamic parameters. Depending on the evolution of the health crisis, trials should resume at the beginning of 2021, with new clinical centers to be opened in France alongside the HEGP.

Image: Cardiawave

FUTURE PROSPECTS

Another study is being considered in Europe, in 2021, with the aim of obtaining the CE marking by 2023 at the latest. After that, Cardiawave will provide an ambulatory and essential treatment for patients who are ineligible for current medical solutions. At the end of the first quarter of 2021, the company will apply to the Haute Autorité de santé (French National Authority for Health) to try to benefit from the Innovation Pass. It is a temporary funding process aimed to facilitate early access to innovative technologies, conditioned by the establishment of a clinical study and possibly a medico-economic study to provide the missing data. The company also wishes to expand to the United States. A first clinical trial should be conducted in 2021 at the Mount Sinai Hospital under the supervision of Pr. Roxana Mehran. To pursue its development in 2022 and 2023, Cardiawave will carry out a capital increase with Life Sciences investors in the second half of 2021.

According to **Pr. Emmanuel Messas, principal investigator**: *"My team at the HEGP initiated the development of this new therapy working alongside the teams at the Physics for Medicine academic laboratory (UMR INSERM, ESPCI Paris, PSL, CNRS) and the Langevin Institute (UMR ESPCI Paris and CNRS). The extended clinical trial which will be conducted in France, with, hopefully, two new French centers, will allow us to treat patients who currently have no therapeutic solution. Our non-invasive therapy offers them tremendous hope. Our main objectif today is to make sure that our treatment is safe for the patients. The results of our first clinical trial are very promising."*

TO EXTEND ITS CLINICAL TRIAL IN FRANCE

ABOUT CARDIAWAVE



Based at the business incubator of Paris Biotech Santé in Cochin and member of the national research consortium RHU Stop-AS, with ISO 13485:2016 certification since 2019, Cardiawave has developed a non-invasive medical device for the treatment of valvular heart diseases, especially calcific aortic stenosis, the most prevalent heart valve disease in adults and one of the most common causes of cardiovascular mortality worldwide. Member of the competitiveness cluster MEDICEN Paris Région, Cardiawave employs 26 people and has secured over €22M in funding since its creation at the end of 2014.

This project was supported by the French program "Investissements d'Avenir" as part of the "Concours Mondial de l'Innovation". It is also supported by the French Government via the National Research Agency (ANR) under the program "Investissements d'Avenir" with the references ANR-16-RHUS-0003_STOP-AS andANR-17-CE19-0019-03.

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