CARDIAWAVE

CARDIAWAVE OBTAINS CLINICAL TRIAL AUTHORIZATION FOR THE WORLD'S FIRST NON-INVASIVE TREATMENT SOLUTION FOR AORTIC STENOSIS

Press release • Paris, 3 April 2019 • Cardiawave, the MedTech company created following research conducted by the Institut Langevin and the HEGP (Georges Pompidou European Hospital), announces that it has obtained the authorization to launch clinical trials for its non-invasive treatment solution for aortic stenosis. This announcement highlights the need for a solution to this unmet medical need which affects millions of patients.

A GROUND-BREAKING NEW THERAPY FOR CALCIFIC AORTIC STENOSIS

Cardiawave has developed a highly innovative technology, non-invasive therapy to treat Calcific Aortic Stenosis. It improves the opening of heavily calcified aortic valves by reducing the stiffness in the aortic valve tissue using high-energy, short pulses of ultrasound that are transmitted directly into the aortic valve from outside the body.

CLINICAL TRIALS: THE FIRST STEP TOWARDS A NEW TREATMENT FOR AORTIC STENOSIS

Authorization has now been granted by ethical committees and competent authorities (in France the Agency for the Safety of Medicines, ANSM) to begin clinical trials in France and the Netherlands, with imminent approval in Serbia as well. A trial in 10 patients will therefore commence shortly, with the patient inclusion process scheduled to end in the summer of this year. This multi-center, international study is a collaborative project between three renowned centers: the Georges Pompidou European Hospital (HEGP) in Paris, France; the Amphia Hospital in Breda, the Netherlands; the Clinical Center of Serbia in Belgrade, Serbia. The trial will be coordinated by Professor Emmanuel Messas, cardiologist at the HEGP.

According to Benjamin Bertrand, CEO of Cardiawave: "The granting of these authorizations in several countries is recognition for the hard work of our teams and partners over the last few years, and it paves the way for a completely non-invasive treatment for this disease which affects an increasing number of patients due to an aging population. We are delighted to participate in this study in France, because the project has been predominantly funded and supported by French stakeholders in both public and private sectors".

In practical terms, the multi-disciplinary cardiovascular team (the "Heart Team") within these three investigative centers will initially determine the eligibility of patients and obtain their informed consent; a Case Review Committee will then confirm this eligibility and the patient can proceed to the treatment stage. By performing an echocardiogram before, during and after the therapy, the movements of the valve can be monitored and the affected areas can be precisely targeted with the therapeutic ultrasound pulses. Finally, a post-treatment evaluation will be scheduled at 1, 3, 6, 12 and 24 months to ensure patient safety and the efficacy of the therapy. A central laboratory (Cardialysis BV, Rotterdam, The Netherlands), acting in the capacity of an independent competent third-party, will objectively assess the condition of the patients' aortic valves at each time point.

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AORTIC STENOSIS: THE CONTINUED SEARCH FOR OPTIMAL TREATMENT

There are two forms of treatment currently available for aortic stenosis: the Transcatheter Aortic Valve Replacement (TAVR) procedure and open-heart valve replacement surgery. However, these approaches are not suitable for all patients. Even though the development of the TAVR procedure has made treatment possible for some patients who are ineligible for aortic valve replacement surgery, it does not provide a solution for all patients as there is still some risk involved in this procedure. Simply put, elderly patients with multiple comorbidities may be deemed ineligible for surgery by the Heart Team.

As Professor Bernard Jung, cardiologist and specialist in valvular diseases at Bichat-Claude Bernard Hospital points out: "What we know for certain, is that between 10 and 20% of patients are not suitable for TAVR or surgery as the health risk outweighs the benefits. Many of these patients would therefore make excellent potential candidates for a palliative approach such as that of Cardiawave".

There are other advantages to the Cardiawave solution. As Prof. Emmanuel Messas explains: "The therapy that we have developed opens up new possibilities for patients who are currently awaiting treatment for this disease. We hope to improve the quality of life of these patients with this potentially ambulatory treatment. Lastly, in the not so distant future, we may be able to offer this treatment in a preventive capacity."

The clinical trials will determine whether the therapy developed by Cardiawave is effective and risk-free, or if further fine-tuning is required. Cardiawave will also be positioned as the new solution for aortic stenosis, a huge public health issue, for which the average age of onset is 65 years in Western countries, and where the number of cases is continuously on the rise.

ABOUT CARDIAWAVE

BASED AT THE BUSINESS INCUBATOR OF PARIS BIOTECH SANTE IN COCHIN AND MEMBER OF THE NATIONAL RESEARCH CONSORTIUM RHU STOP-AS, CARDIAWAVE HAS DEVELOPED A COMPLETELY NON-INVASIVE MEDICAL DEVICE FOR THE TREATMENT OF CARDIO-VALVULAR DISEASES, IN PARTICULAR AORTIC STENOSIS, THE PRIMARY VALVOPATHY IN ADULTS AND ONE OF THE LEADING CAUSES OF CARDIOVASCULAR DEATH WORLDWIDE. MEMBER OF THE COMPETITIVENESS CENTER MEDICEN, THE COMPANY EMPLOYS 20 STAFF AND HAS SECURED OVER 14M IN FUNDING SINCE ITS CREATION AT THE END OF 2014.

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