Press Release.

Deeptech - Aortic Stenosis - Heart Valve Disease

Cardiawave announces French National Agency for the Safety of Medicines and Health Products (ANSM) green light to launch VALVOSOFT® Pivotal Study in France

Paris, France, May 2, 2022 – Cardiawave SA, a deeptech medical device manufacturer that has developed VALVOSOFT® a revolutionary non-invasive medical device to treat aortic stenosis, the most prevalent heart valve disease in adults, today announced the authorization by the French National Agency for the Safety of Medicines and Health Products (ANSM) to proceed with a new clinical study in France.

"Following the recent announcement of positive results from our First In Human (FIH) clinical studies which validated the safety and feasibility of treating aortic stenosis with our non-invasive ultrasound therapy device on 34 patients, the ANSM approval confirms the successful progress of our clinical development. This announcement is a major milestone for Cardiawave, and we look forward to demonstrating through this new pivotal study the performance and efficacy of our non-invasive ultrasound therapy to treat a greater number of patients with aortic valve stenosis." said **Benjamin Bertrand, CEO of Cardiawave.**

France is the first country to authorize this European clinical study, which will also be rolled out in Germany and the Netherlands. Cardiawave will enroll c.60 patients with aortic stenosis in 11 hospitals between May and December 2022, with the aim of obtaining CE Marking. The clinical protocol involves patient follow up at 1, 6 and 12 months after treatment. The aim of this study is to ensure, on the one hand, the absence of serious adverse events related to the device or the procedure and, on the other hand, the efficacy of the treatment, which will be measured by the improvement of the patients' quality of life and an improved opening of the aortic valve after the treatment.

"VALVOSOFT® represents a breakthrough non-invasive therapeutic solution, complementary to TAVI, which will not only allow the treatment of the most fragile patients for whom TAVI is not an option, but also, in the longer term, open the way for new patients with calcified aortic stenosis. We are very pleased to be participating in the pivotal study and have the opportunity to treat patients with a very promising new French technology," said **Professor Hélène Eltchaninoff, Cardiologist at the Rouen University Hospital** and national coordinator of the pivotal study in France and the STOP-AS research program.

About VALVOSOFT®

VALVOSOFT® is a non-invasive ultrasound therapy medical device for the treatment of calcific aortic stenosis developed by Cardiawave. It is currently undergoing clinical investigations for safety and efficacy. It has not yet received CE Marking or marketing authorization and its use is limited to clinical investigations.

Cardiawave has developed its new breakthrough technology following the work of the prestigious French academic laboratories Institut Langevin (INSERM/CNRS/ESPCI) and Physics for Medicine Paris (INSERM/CNRS/ESPCI/PSL). This non-invasive treatment of aortic stenosis combines therapeutic ultrasound, robotics, and ultrasound imaging. All software and most hardware components have been developed in-house thanks to the unique know-how of Cardiawave and its academic partners. This device uses a new and unique ultrasound technology with a remote repair procedure on the aortic valve. Ultrasound softens the tissue, restores leaflet mobility, and enables a wider opening of the valve. This non-invasive therapeutic solution is less risky for elderly patients and less costly for the healthcare system. This device has very favorable environmental credentials, with very low electricity consumption (1kVA max), very little waste (60 g) and no use of chemicals products for the procedure.

About CALCIFIC AORTIC STENOSIS

Calcific aortic stenosis is a degenerative and potentially life-threatening condition, caused by calcium buildup which prevents the aortic valve from fully opening. Aortic Stenosis evolves over time leading to heart failure and increases the risk of sudden death during its final stage (severe & symptomatic stenosis). Aortic stenosis has become a public health issue as the pathology affects between 2 and 12% of subjects over 65 years old. With age, the aortic valve calcifies, becomes more rigid and narrow, and no longer opens properly leading to poor blood circulation.

Aortic Stenosis (AS) can be mild, moderate, and severe. 2 million people are estimated to suffer from severe AS in Europe and in the USA, of whom 500,000 benefit from Transcatheter Aortic Valve Replacement (TAVI) or open-heart surgery. 1.5 million patients remain untreated and face a low life expectancy of 2 to 5 years. Around 3 million further patients suffer from moderate AS for whom there is no early treatment.

About CARDIAWAVE

Cardiawave has developed a non-invasive ultrasound therapy medical device for the treatment of valvular heart diseases, and in particular, Aortic Stenosis, the most prevalent heart valve disease in adults and one of the most common causes of cardiovascular mortality worldwide. Based near Paris, Cardiawave is a member of the national research consortium RHU Stop-AS, and has EN ISO 13485:2016 certification since 2019. Cardiawave employs 28 people and has secured over €22M in funding since its creation in 2014. Learn more: www.cardiawave.com

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