CARDIAWAVE

Press Release.

Deeptech - Aortic Stenosis - Heart Valve Disease

Cardiawave confirms the safety of VALVOSOFT® its non-invasive ultrasound treatment for aortic stenosis

- ***No cerebrovascular event before and after treatment observed***
- ***Successful completion of the FIM II clinical study prior to the pivotal study, that will pave the way for CE marking***

Paris, France, June 14, 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 positive MRI scans before and after therapeutic ultrasound treatment to assess the risk of stroke.

This final phase of the clinical study "VALVOSOFT® FIM STUDY" (FIM II) showed no signs of any cerebral vascular anomaly in the 10 patients treated. This marks the completion of two successful First-In-Human clinical studies involving a total of 40 patients treated in France, the Netherlands and Serbia.

"This confirmation of the safety of VALVOSOFT® bodes well for the launch of patient recruitment for our European pivotal study which will commence shortly in France, and extended to Germany and the Netherlands, with the aim of obtaining CE Marking." said **Benjamin Bertrand, CEO of Cardiawave.**

VALVOSOFT®'s non-invasive treatment brings great hope for patients with aortic stenosis and for their families. Having the absence of any abnormality before and after treatment being confirmed by MRI scans is major clinical step forward" declared **Professeur Emmanuel Messas the Georges Pompidou European Hospital (AP-HP), in Paris.**

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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