Cardiawave is presenting the 30-day follow-up results from its "Valvosoft® Pivotal Study" on the treatment of severe symptomatic aortic valve stenosis

At the 73rd Annual Conference of the ACC

(American College of Cardiology)

April 6–8, 2024, Atlanta (GA)

Levallois-Perret, France, April 5th, 2024 – Cardiawave SA, a French medtech company that has developed an innovative Non-Invasive focused Ultrasound Therapy (NIUT) device for the treatment of severe symptomatic calcific aortic stenosis, will present the 30-day follow-up results for 60 patients enrolled in its European pivotal study to the 73rd annual conference of the American College of Cardiology in Atlanta, Georgia. This is a leading event in the cardiovascular medicine calendar, which brings together specialists from around the world to discuss the latest advances, research results and clinical innovations in the field of cardiology.

Prof. Eric Van Belle, cardiologist at Lille University Hospital, one of the principal investigators for the European pivotal study, commented: "*I'm very proud to present the excellent results obtained using Cardiawave's NIUT device to treat patients with severe symptomatic aortic valve stenosis, leading to a significant improvement in their condition and a better quality of life. This ACC.24 presentation represents a major contribution to the advance of science and will open up innovative therapeutic strategies for cardiology patients*."

A summary of the poster session will be published on the **Journal of the American College of Cardiology's website**.

Presentation title: QUALITY OF LIFE ASSESSMENT AT 30-DAYS FOLLOW-UP OF THE VALVOSOFT® PIVOTAL STUDY ON SEVERE AORTIC VALVE STENOSE PATIENTS" (control number 16930)

Time and date: April 8, 2024 - 9:32 a.m.–9:42 a.m. EDT

The results of the Cardiawave First-in-Human "Valvosoft® FIM Study" were published in The Lancet in November 2023:

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01518-0/fulltext

About CARDIAWAVE

Cardiawave has developed a Non-Invasive Ultrasound Therapy (NIUT) medical device for the treatment of valvular heart diseases, and in particular, CAS, 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 30 people and has secured over 29M€ in funding since its creation in 2014. This project was supported by the Program "Investissements d'Avenir" as part of the World Innovation Competition. It also benefited from state aid managed by the National Research Agency under the references ANR-16-RHUS-0003_STOP-AS and ANR-17-CE19-0019-03 and the Horizon 2020 SME instruments program of the European Commission (reference no. 829492). Cardiawave is a winner of the French Tech Health 20 programme, a member of La French Care since 2023, Medtech in France and France Biotech since 2024, and also a member of the competitiveness cluster Medicen.

Learn more: www.cardiawave.com

Winner 2023 French Tech Health 20

This program is funded by French National Research Agency

This program received funding from European Commission under SME-Instrument funding device

This program is funded by France 2030 (I-NOV & Innov'Up Leader PIA funding devices) & Investissements d'Avenir

Member of the competitiveness cluster Medicen

French Care Member since 2023

MedTech in France member since 2024

France Biotech member since 2024

About Valvosoft®

This is a non-invasive ultrasound therapy investigational medical device for the treatment of calcific aortic stenosis developed by Cardiawave. This device uses a new and unique non-invasive transthoracic ultrasound technology that delivers shockwaves on the aortic valve through the cavitation phenomenon. Ultrasound softens the tissue, restores leaflet mobility, and enables a wider opening of the valve. It is currently undergoing clinical investigations for safety and efficacy. It has not yet received any marketing authorization (e.g. CE Marking) and is intended exclusively for 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.

About CALCIFIC AORTIC STENOSIS

Calcific aortic stenosis (CAS) is a degenerative and potentially life-threatening condition, caused by calcium buildup which prevents the aortic valve from fully opening. Aortic Stenosis (AS) evolves over time leading to heart failure and increases the risk of sudden death during its final stage (severe & symptomatic stenosis). AS has become a public health issue as the pathology affects between 1,7 and 12,4% of subjects over 75 years old (sources: Durko AP, et al. Annual number of candidates for transcatheter aortic valve implantation per country: current estimates and future projections. European Heart Journal. July 01, 2018; 39(28):2635-2642. (DOI: 10.1093/eurheartj/ehy107); Lindman B, et al. Calcific Aortic Stenosis. Nature Reviews Disease Primers 2, Article number: 16006. March 03, 2016. (DOI: 10.1038/nrdp.2016.6); Osnabrugge R., et al. Aortic Stenosis in the Elderly: Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study. Journal of American College of Cardiology, Volume 62, Issue 11, Pages 1013-1014. September 2013. (DOI: 10.1016/j.jacc.2013.05.015). With age, the aortic valve calcifies, becomes more rigid and narrow, and no longer opens properly leading to poor blood circulation.

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 per year benefit from Transcatheter Aortic Valve Replacement (TAVR) 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.

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