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Cardiawave appoints Olivier Pierron as its Chief Executive Officer

Levallois-Perret, France, 15 April 2024 — Cardiawave SA, a French Medtech company that has developed an innovative Non-Invasive Ultrasound Therapy (NIUT) device for the treatment of severe symptomatic calcific aortic stenosis, is delighted to announce the appointment of Olivier Pierron as its new Chief Executive Officer. With more than 25 years of experience in cardiovascular therapies and a passion for innovation, Olivier Pierron brings to Cardiawave invaluable expertise in the development and international commercialization of new medical technologies at a crucial time in the company's growth, following the announcement of positive clinical trial results.

Before joining Cardiawave, Olivier Pierron held executive roles at some well-known companies in the sector, showing his capabilities as a manager and innovator in organizations at various stages of maturity. His international experience, combined with his involvement in development, acquisition and IPO transactions, makes him a sound strategic choice to lead Cardiawave towards new horizons.

Olivier Pierron, Cardiawave's new CEO, said: *"The approach developed by Cardiawave is unique and complements the existing range of cardiology treatments. Being entirely non-invasive, it expands the treatment options of patients suffering from severe symptomatic aortic valve stenosis. I am very honored to be joining this visionary team and to be working with them to bring this disruptive solution to market, in order to treat the largest number of people as quickly as possible. Cardiawave's technology represents a major step forward, one that is acknowledged by the international medical community, and our clinical results are very promising. I am determined to make this innovation a success in our various markets."*

As CEO, Olivier Pierron will take on several exciting challenges such as deploying Valvoflex[®] — Cardiawave's innovative non-invasive ultrasound therapy for the treatment of severe symptomatic calcific aortic stenosis — in the European market, starting clinical trials in the United States under premarket approval, strengthening strategic partnerships to bolster Cardiawave's international footprint, and leading its Series B funding in order to accelerate its development. Cardiawave has recently reached some key milestones, such as filing its CE Mark application and completing the enrollment of 60 patients in its Valvoflex[®] Pivotal Study, taking the total number of severe symptomatic calcific aortic stenosis patients being treated to 100, across 12 research centers in four European countries. The six-month results of FIH studies have been published in prestigious scientific journal *The Lancet*, strengthening Cardiawave's position as a leading innovator in the field of cardiology. Cardiawave is one of the companies supported by the French Tech Health 20 program, has been a member of La French Care healthcare industry association since 2023, and has been a member of the MEDICEN technology cluster, Medtech In France and France Biotech since 2024.

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. 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



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Member of the competitiveness cluster Medicen



Membre de la French Care depuis 2023



Membre de MedTech in France depuis 2024



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Membre de France Biotech depuis 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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