VALVOSOFT®, the first non-invasive treatment for severe Symptomatic Aortic Stenosis (sSAS) from Cardiawave receives CE Marking

Levallois-Perret, France – Dec. 4th, 2025 – Cardiawave, a pioneering medtech company developing non-invasive ultrasound therapy (NIUT) for aortic stenosis, has received CE Certificate for Valvosoft®, the world's first non-invasive therapeutic alternative to treat Severe Symptomatic Aortic Stenosis (sSAS), a serious, degenerative and fast-growing disease due to population aging, which remains without a solution for many patients around the world.

"*Innovating to address unmet patient needs is at the heart of Cardiawave's mission. We are therefore extremely proud to have received CE Certificate for our first-of-its-kind non-invasive ultrasound therapy (NIUT) for patients suffering from aortic valve stenosis who are not recommended for immediate valve replacement, or refusing such intervention*," said **Carine Schorochoff, Chief Executive Officer and Board Director at Cardiawave.** « *With CE Marking of our Valvosoft system, we can now provide a much-needed treatment option for patients*."

This approval follows the results from Cardiawave's **Valvosoft® FIM Study (24 months)** and **Valvosoft® Pivotal Study (12 months)** evaluating its innovative NIUT for the treatment of sSAS. Conducted in **100 elderly, highly comorbid patients across 12 European centers in 4 countries**, the studies demonstrated the feasibility, safety, and clinical benefits of the therapy. Durable improvements were observed one year after treatment, including enhanced cardiac function and significantly better patient quality of life.

Prof. Christian Spaulding, **Director of Interventional Cardiology, Hôpital Européen Georges Pompidou - AP-HP - Paris, France, and Coordinating Investigator for the Valvosoft® Pivotal Study**, stated: "*The Valvosoft® Pivotal Study has demonstrated a strong safety profile and has shown its ability to improve hemodynamic parameters in patients suffering from symptomatic severe aortic valve stenosis who are not eligible for immediate valve replacement. The improvements in patients' quality of life are now offering a therapy to many patients who previously had no treatment options*."

"*Valvosoft perfectly illustrates how ultrasound technology is now coming of age, both from a regulatory standpoint and in terms of patient access. The CE Marking validates the robustness of this non-invasive approach and paves the way for broader adoption in Europe and beyond. This major milestone introduces a new therapeutic option that could transform the treatment of aortic stenosis and, more broadly, cardiovascular diseases.*" said **Jonathan Freeman, Chairman of the Board of Directors.**

"*Valvosoft is one of the most promising innovations we have seen in the field of aortic stenosis in the past decade. Its CE Marking is a major achievement, supported by robust clinical data showing safety, feasibility, and substantial clinical improvement in elderly patients with severe aortic stenosis. A non-invasive therapy capable of improving valve function would represent a paradigm shift in how we manage aortic stenosis. The next clinical steps in North America will be crucial and potentially transformative for patient care*." comment **Prof. Josep Rodes-Cabau & Prof. Philippe Pibarot, from Laval University, Canada.**

"The CE Marking of Valvosoft confirms the clinical value of the approach: using therapeutic ultrasound to treat aortic stenosis in a non-invasive way. This important milestone is exciting and potentially marks the beginning of a new era in the management of valvular disease." stated **Dr Philippe Généreux**, **Interventional Cardiologist and Director of the Structural Heart Program at the Gagnon Cardiovascular Institute at Morristown Medical Center, Morristown NJ, USA.**

"*Given the growing burden of aortic stenosis, an increasingly prevalent disease driven by population aging, and the clear clinical benefit of intervening before irreversible cardiac damage occurs, Valvosoft introduces a novel and highly promising therapeutic approach that could redefine how we manage this disease*." said **Prof. Azeem Latib**, **Section Head And Director of Interventional Cardiology and Director of Structural Heart Interventions at Montefiore Health System, NYC and Cardiawave Medical Advisory Board Member.**

Regulatory Status

Valvosoft® is a CE Marked medical device in the EU and is an investigational medical device, not yet approved for commercial use in other countries or areas including the United States.

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