Cardiawave Announces Positive 12-Month Results from Its “Valvosoft® FIM Study” and "Valvosoft® Pivotal Study" for the Treatment of Severe Symptomatic Aortic Stenosis (sSAS)

At the EuroPCR 2025 Congress – Paris

Results confirm the promise of non-invasive ultrasound therapy (NIUT) previously observed in earlier clinical studies.

- **91%** of patients were free of major adverse cardiac events (MACE) at 30 days (achieving the primary endpoint objective MACE ≤ 25%).
- **85%** of patients experienced an improvement or stabilization in their NYHA class.
- **An average 9-point improvement** in the KCCQ (Kansas City Cardiomyopathy Questionnaire) score, indicating a significant gain **in quality of life.**
- **A 43% increase in aortic valve area (AVA)** at 12 months compared to the natural progression of the disease.

Levallois-Perret, France – May 22, 2025 — Cardiawave SA, medtech company specialized in valvular heart disease, presented today at the **EuroPCR** Congress the 12-month results from its "**Valvosoft® FIM Study**" and "**Valvosoft® Pivotal Study**" evaluating its innovative non-invasive ultrasound therapy (**NIUT**) device for the treatment of Severe Symptomatic Aortic Stenosis (**sSAS**).

Following two First-in-Human studies (40 patients) that demonstrated the safety and feasibility of the therapy, and a multicenter, prospective, single-arm pivotal study (60 patients), conducted in total on 100 elderly patients with multiple comorbidities treated across 12 European centers in 4 countries, **the treatment has shown feasibility, safety, and efficacy**. **Durable clinical benefits** were observed one year after treatment, including improved cardiac function and significantly enhanced patient quality of life.

“*These positive 12-month results confirm the ability of this innovative technology to significantly improve hemodynamics and patient quality of life in a completely non-invasive way. This device is emerging as a serious long-term therapeutic option for aortic stenosis. These results also open the door to additional indications, such as pre-TAVI preparation*,” said **Professor Hélène Eltchaninoff, Head of the Cardiology Department at Rouen University Hospital** and principal investigator of the study, during **her presentation at the EuroPCR Congress in Paris on May 22.**

A New Option for Patients Without Therapeutic Alternatives

In 2024, approximately 2.5 million people over the age of 75 suffer from sSAS in the EU and the USA[1] . This therapy could become **the first non-invasive therapeutic alternative** to treat sSAS—a serious, degenerative, and fast-growing disease due to population aging—which remains without a solution for many patients.

"*These results are very encouraging. They reinforce our determination to make this non-invasive therapy accessible to as many people as possible, including for complementary indications such as pre-TAVI preparation*," said **Cardiawave's leadership team**. "*We are excited to move forward with regulatory steps in Europe and the United States, aiming for a European market launch next year*."

Valvosoft® is an investigational medical device and is not yet approved for commercial use in the European Union or the United States.

Cardiawave Contact:

contact@cardiawave.com

Press Contact:

Annie-Florence Loyer – aflwoodside@gmail.com – Tel : +33 (0)6 88 20 35 59

[1] 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)