Cardiawave Announces Positive Six-Month Data from Valvosoft Pivotal Study at Transcatheter Cardiovascular Therapeutics (TCT) Conference

Cardiawave Completes 12-Month Follow-up for Valvosoft Pivotal Study; Publication of One-Year Results Expected in Early 2025

WASHINGTON, DC — October 28, 2024 — Cardiawave SA, developer of the groundbreaking Valvosoft Non-Invasive Ultrasound Therapy (NIUT) device for the treatment of severe symptomatic calcific aortic stenosis (CAS), today announced that the device met the primary endpoint in its pivotal study and improved or stabilized heart failure symptoms for 80.5% of patients, substantially improving hemodynamics and patient quality of life six months after treatment. These outcomes were presented today at the Transcatheter Cardiovascular Therapeutics (TCT) conference by Professor Hélène Eltchaninoff, Head of the Cardiology Department at Rouen University Hospital, France.

Valvosoft is designed to non-invasively restore leaflet mobility in a stenotic aortic valve and widen the valve opening to relieve patient heart failure symptoms. High-intensity focused ultrasound waves are micro-fracturing calcification embedded in aortic valve leaflets without damaging tissue. The treatment is designed to be repeatable over time, as needed, to manage disease progression.

"The Valvosoft Pivotal Study demonstrated the ability of this novel ultrasound therapy to improve patient hemodynamics and quality of life entirely non-invasively. This therapy has the potential to offer a paradigm shift in the lifetime management of aortic stenosis," said Professor Christian Spaulding, Interventional Cardiologist, Professor of Cardiology at European Hospital Georges Pompidou AP-HP in Paris, France, and coordinating investigator of the Valvosoft Pivotal Study. **"**Aortic stenosis is progressive and threatens the lives of many millions of people each year. With the disease on the rise due to a rapidly aging population, new alternatives are needed for patients who cannot or do not want to undergo current valve replacement techniques. The Valvosoft technology holds the possibility to be an important and unique addition to our armamentarium to address progression of this deadly disease."

Valvosoft Pivotal Study Six-Month Results

In the study, 91.7% of patients were free of Major Adverse Cardiac Events (MACE) at 30 days, thus achieving the primary endpoint objective of <25%. There were no incidences of stroke through six months. Valvosoft demonstrated the ability to reverse or slow disease progression, improving or stabilizing New York Heart Association (NYHA) class for 80.5% of patients compared to baseline at six months. Quality of life also consistently improved over that time,

with patients showing an average Kansas City Cardiomyopathy Questionnaire (KCCQ) score improvement of 8.7 points over baseline.

Patient hemodynamics also improved. Aortic Valve Area (AVA) increased by 12% over baseline by six months post-procedure, in a patient population where 40% of patients were classified with very severe aortic stenosis and 31% were aged 90 or older. Although the study did not include a control group, when the AVA measures were compared to the expected AVA among untreated patients based on natural disease progression [1], the AVA improvement was shown to be 21.4%. The mean pressure gradient decreased by 6% compared to baseline at six months; when compared to natural disease progression [1], that improvement reached -13.2%.

The Valvosoft Pivotal Study is a prospective, multicenter, single-arm study encompassing 60 patients with severe symptomatic CAS treated with Valvosoft NIUT at 11 European centers.

“We would like to thank all study investigators for their continuous support, dedication and tireless efforts in exploring this important technology that has the potential to transform the lifetime management of aortic stenosis,” said Cardiawave’s management team. “We are gratified by the positive six-month results and encouraged by our early look at one-year clinical results across all patients that we expect will validate and even exceed these positive results. This clinical study is taking us one more step forward in our journey of bringing non-invasive heart valve therapy to patients and healthcare institutions around the world. We remain focused on obtaining regulatory approvals in the European Union and in the U.S. for Valvosoft, and anticipate market entry in Europe next year.”

Valvosoft is considered an investigational device in the U.S. and is limited by U.S. law to investigational use only. It is not approved for commercial sale in any region.

About Cardiawave

Based near Paris, Cardiawave has developed a Non-Invasive Ultrasound Therapy (NIUT) medical device for the treatment of valvular heart diseases, with an initial focus on calcific aortic stenosis (CAS), the most prevalent heart valve disease in adults and one of the most common causes of cardiovascular mortality worldwide. The proprietary NIUT technology combines therapeutic ultrasound, robotics and ultrasound imaging.

###

[1] G. Prosperi-Porta, N. Willner, and D. Messika-Zeitoun, “Aortic stenosis progression: Still a long way to go,” *Arch Cardiovasc Dis*, vol. 116, no. 3, pp. 113–116, Mar. 2023, doi: 10.1016/j.acvd.2023.01.002.

U.S. MEDIA CONTACT
Michelle McAdam, Chronic Communications Inc.
michelle@chronic-comm.com
(310) 902-1274

EUROPEAN MEDIA CONTACTS
Annie-Florence Loyer
aflwoodside@gmail.com
+33 (0)6 88 20 35 59