

## CorWave Announces Presentation of Late Breaking Results from its First-In-Human Implant at HFSA Annual Scientific Meeting

- Primary endpoint successfully met, no device-related serious adverse events at 30 days
  - Pulsatility preserved throughout the study with beat-to-beat valve opening
- Successful transplantation after 84 days on support, no thrombus observed at explant

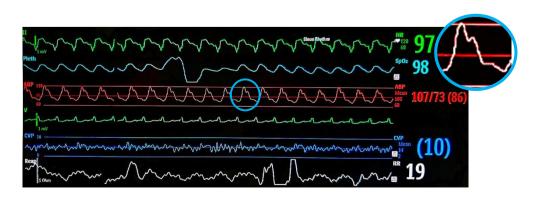
Clichy, France, September 29, 2025 – CorWave, a clinical-stage medical device company dedicated to the fight against heart failure, today announced the presentation of interim results from its FIH study evaluating its Left Ventricular Assisting System (LVAS), the first heart pump based on breakthrough wave membrane technology. Results were presented at the 2025 Annual Scientific Meeting of the Heart Failure Society of America (HFSA) by Prof. Chris Hayward, Director of the Mechanical and Circulatory Support research program at St Vincent's Private Hospital and Principal Investigator of the Study.

On May 28, 2025, the CorWave LVAS, a next-generation durable heart pump, was implanted in a patient for the first time at St Vincent's Hospital in Sydney by Dr. Paul Jansz. This implantation represented a major technological milestone in the field of durable mechanical circulatory support.

In a late breaking clinical science session at the HFSA annual meeting, Prof. Chris Hayward reported on the first patient experience with a focus on patient baseline, clinical course, and the device's initial safety and effectiveness.

The primary endpoint of the study was achieved, with no device-related adverse events observed at 30 days, providing an early confirmation of the safety profile of the CorWave LVAS. Functional status improved to NYHA class I prior to discharge. On post-operative day 84, the patient successfully underwent a heart transplant. The CorWave device was explanted without complication, and preliminary analyses of the pump and outflow graft revealed no thrombus.

The pump performed as expected, providing full support and restoring a cardiac index above  $2.5L/min/m^2$  ( $1.6L/min/m^2$  pre-operative), efficiently unloading the left ventricle. The unique membrane technology preserved an aortic pulse pressure of  $25.5 \pm 6.1$  mmHg, periodically exceeding 40 mmHg and allowed consistent aortic valve opening despite post-operative LVEF of 15%-20%. The vital signs of the patient with physiological pulsatility are shown below.



"The results of the CorWave device are very encouraging. The physiologic pulse that we observed in the first CorWave patient stands out from the results we have observed in patients assisted with continuous-flow LVAD, in use since the 2000s." said **Prof. Chris Hayward, cardiologist at St Vincent's Hospital and principal investigator of the study**. "This first experience suggests that CorWave LVAS can be implanted safely and has the potential to offer significant benefits for patients with heart failure. Further clinical experience will be needed to confirm these promising findings."

"We are delighted with these first results from our FIH Study and grateful to see the first transplant successfully completed. The pulsatility performance of CorWave LVAS is remarkable and our goal is to translate that into improved outcomes for advanced heart failure patients. These results are a testament to the groundbreaking work conducted by our engineering team and the St Vincent's clinical team." said Louis de Lillers, CEO of CorWave.

The CorWave FIH Study plans to enroll a minimum of four patients before the start of the pivotal trial phase.

## **About CorWave**



CorWave is a French company that develops and manufactures innovative cardiac assist devices. CorWave's undulating membrane is a breakthrough technology that distinguishes itself from currently marketed Left Ventricular Assist Devices (LVADs) through its physiological operation, designed to reproduce pulse and blood flow velocities similar to those of a healthy heart. Ultimately, CorWave's membrane pump technology should reduce complications associated with current devices and improve the management of patients suffering from heart failure. A member of French Tech 120, CorWave was founded in 2012 by the start-up studio MD Start and is funded by renowned investors, including Bpifrance, EIC Fund, Montpensier Arbevel, M&L Healthcare, Novo Holdings, Seventure Partners, Sofinnova Partners, Ysios Capital, and

Vlerick Group. The company has raised over 80 million euros in equity funding and employs about a hundred people. In October 2023, after more than ten years of research and development, CorWave scaled up to industrial operations with the inauguration of its state-of-the-art urban factory in Clichy.

Further information: www.corwave.com | x.com/corwave | www.linkedin.com/company/corwave CorWave LVAS is a medical device currently available for clinical investigations only.

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