



Publication in the *JACC*¹: Heart Failure of the initial clinical experience with Aeson® total artificial heart in cardiogenic shock patients initially placed on extracorporeal life support

The retrospective analysis on 10 patients shows a 90% survival rate at 6 months, suggesting Aeson® as a therapeutic solution for these patients at risk of death in the short term.

Paris, April 3, 2025 – 6:00 pm CEST

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from advanced biventricular heart failure (the "Company" or "CARMAT"), today announces the publication of the results of the initial clinical experience with Aeson® in cardiogenic shock patients previously on temporary extracorporeal life support², in the *JACC: Heart Failure*.

Study characteristics and key findings: 90% survival rate at 6 months, recovery of renal and hepatic function, improvement in functional capacity

The article, entitled "*Initial Experience with Aeson Total Artificial Heart in Cardiogenic Shock Patients on Extracorporeal Life Support*³", features the results of a retrospective analysis conducted in seven hospitals across France and Germany between November 2022 and April 2024. The analysis is about 10 patients with refractory cardiogenic shock, who were initially stabilized on extracorporeal life support (ECLS) for a median duration of 9 days before receiving an Aeson® total artificial heart.

The analysis reports a 90% survival rate at 6 months following Aeson® implant, with 5 patients successfully transplanted and 4 still on Aeson® support at that time.

In addition, the analysis highlights that Aeson® improves kidney and liver recovery and allows for hospital discharge after a median hospital stay of 42 days, contributing to an improvement in functional capacity and overall health status of the patient while awaiting a heart transplant.

Dr. Anne-Céline Martin, Cardiologist at Hôpital Européen Georges-Pompidou (Paris) and lead author of the article, commented: "*Even for critically ill patients in refractory cardiogenic shock requiring temporary circulatory support, transitioning to the Aeson® total artificial heart has demonstrated highly promising results, with a 6-month survival rate of 90%. Moreover, thanks to Aeson®'s autoregulated and pulsatile flow, patients experienced a significant improvement in exercise capacity and quality of life, enabling them to face the challenge of a heart transplant.*"

Aeson®: a promising solution for very high-risk patients initially placed on temporary extracorporeal life support

Cardiogenic shock is an acute heart failure condition that poses a life-threatening risk to patients, with still high mortality rates (30% to 60%) despite advancements in treatment. In the most severe cases, extracorporeal life support can be used temporarily to stabilize patients; however, this approach is only viable for a short period of time (around ten days) due to the risk of complications.

¹ Journal of the American College of Cardiology

² Also known as "ECMO" (Extra-Corporeal Membrane Oxygenation) or "ECLS" (Extra-Corporeal Life Support).

³ <https://www.sciencedirect.com/science/article/pii/S2213177925001763?dgcid=author>



Heart transplant often remains the best option for these patients initially placed on extracorporeal life support. However, its access is limited by the lack of available human grafts, and by the sometimes too fragile health status of patients, who may present temporary contraindications to such a transplant.

Aeson® is therefore emerging as a promising therapeutic solution for this population of patients at very high risk of death in the short term, enabling them to improve their state of health before they can benefit from a heart transplant.

Over the past two years, around half of patients treated with Aeson® had previously been placed on extracorporeal life support.

Stéphane Piat, Chief Executive Officer of CARMAT, concluded: *"This new publication in a leading scientific journal validates the relevance and clinical value of our therapy, confirming that Aeson® can be used as a bridge to transplant even for the most critical patients, at risk of death in the short term. After several days on extracorporeal life support (ECMO), these patients have no other options but heart transplant or the implant of a total artificial heart if a human graft is not available or if a transplant can't be made immediately due to the patient's state of health. Our promising results bring hope to patients and their families. I am convinced that their dissemination within the medical community will drive an always broader adoption of Aeson® across Europe."*

About CARMAT

CARMAT is a French MedTech that designs, manufactures and markets the Aeson® artificial heart. The Company's ambition is to make Aeson® the first alternative to a heart transplant, and thus provide a therapeutic solution to people suffering from end-stage biventricular heart failure, who are facing a well-known shortfall in available human grafts. The world's first physiological artificial heart that is highly hemocompatible, pulsatile and self-regulated, Aeson® could save, every year, the lives of thousands of patients waiting for a heart transplant. The device offers patients quality of life and mobility thanks to its ergonomic and portable external power supply system that is continuously connected to the implanted prosthesis. Aeson® is commercially available as a bridge to transplant in the European Union and other countries that recognize CE marking. Aeson® is also currently being assessed within the framework of an Early Feasibility Study (EFS) in the United States. Founded in 2008, CARMAT is based in the Paris region, with its head offices located in Vélizy-Villacoublay and its production site in Bois-d'Arcy. The Company can rely on the talent and expertise of a multidisciplinary team of circa 200 highly specialized people. CARMAT is listed on the Euronext Growth market in Paris (Ticker: ALCAR / ISIN code: FR0010907956).

For more information, please go to www.carmatsa.com and follow us on [LinkedIn](https://www.linkedin.com/company/carmat).

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This press release and the information contained herein do not constitute an offer to sell or subscribe, nor a solicitation of an order to buy or subscribe to CARMAT shares in any country.

This press release may contain forward-looking statements by the Company regarding its objectives and prospects. These forward-looking statements are based on the current estimates and anticipations of the Company's management and are subject to risk factors and uncertainties, including those described in its universal registration document filed with the French Financial Markets Authority (Autorité des marchés financiers) (the "AMF") under number D.24-0374, as updated by the amendment to the 2023 universal registration document filed with the AMF on September 17, 2024 under number D.24-0374-A01 (together, the "2023 Universal Registration Document"), which are available free of charge on the websites of CARMAT (www.carmatsa.com) and the AMF (www.amf-france.org).

Readers' attention is particularly drawn to the fact that the Company's current cash runway is limited to the end of May 2025 (excluding the flexible equity financing line entered into with IRIS, which was announced on March 27, 2025). The Company is also subject to other risks and uncertainties, such as its ability to implement its strategy, the pace of development of its production and sales, the pace and results of ongoing or planned clinical trials, technological evolution and competitive environment, regulatory changes, industrial risks, and all risks associated with the Company's growth management. The Company's forward-looking statements mentioned in this press release may not be achieved due to these elements or other risk factors and uncertainties, whether unknown or not considered material and specific by the Company as of today.

Aeson® is an active implantable medical device commercially available in the European Union and other countries recognising the CE mark. The Aeson® total artificial heart is intended to replace the ventricles of the native heart and is indicated as a bridge to transplant in patients with end-stage biventricular heart failure (Intermacs classes 1-4) who cannot benefit from maximal medical therapy or a left ventricular assist device (LVAD) and who are likely to benefit from a heart transplant within 180 days of implantation. The decision to implant and the surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician's manual, patient's manual and alarm booklet) must be read carefully to learn about the characteristics of Aeson® and the information required for patient selection and proper use (contraindications, precautions, side effects) of Aeson®. In the United States, Aeson® is currently only available as part of a feasibility clinical trial approved by the Food & Drug Administration (FDA).