Aeson® total artificial heart highlighted as a very promising solution for heart failure patients with pulmonary hypertension in *The Journal of Heart and Lung Transplantation*

- Up to 25% of advanced heart failure patients suffer from pulmonary hypertension
- Aeson® could potentially become a standard treatment for these thousands of patients, both as a bridge-to-transplant and destination therapy

Paris, February 17, 2025 – 7:00 am CET

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 in *The Journal of Heart and Lung Transplantation*, of an article on the performance of Aeson® total artificial heart in treating heart failure patients with pulmonary hypertension.

Study description and key findings

The article, entitled *"Precise Monitoring of Transpulmonic Resistance in Bridge to Transplant Patients Supported by The Aeson Total Artificial Heart[1]"*, features the results of a single-center study conducted at the University Medical Center of Astana (Kazakhstan) on 3 heart failure patients with pulmonary hypertension (PHT).

One of Aeson®'s innovative features is its ability to estimate transpulmonic resistance (eTPR) in real time, based on embedded pressure sensors. This is useful for monitoring patients with PHT, an indication that often excludes them from heart transplant candidacy.

Following the Aeson® implant, all three patients experienced improved functional capacity, as demonstrated by 6-minute walk distances test, and were discharged from hospital on the Aeson® respectively 68, 48 and 48 days after implant. Over time, their pulmonary hypertension indicators improved, rendering them eligible for heart transplant, which effectively took place after 243, 155 and 109 days respectively.

Dr. Yuriy Pya, Cardiac Surgeon at University Medical Center of Astana and lead author of the study, stated: *"In our experience with patients suffering from pulmonary hypertension, the Aeson® total artificial heart provided autoregulated blood flow to optimize patients' condition. Moreover, the non-invasive monitoring of pulmonary resistance with data generated by Aeson® has helped us to determine the best timing for a successful heart transplant in all cases."*

Aeson®: a very promising solution for heart failure patients with pulmonary hypertension

Up to 25% of patients with advanced heart failure suffer from pulmonary hypertension, which represents several thousand patients in a difficult-to-treat situation, as they are mostly subject to a contra-indication to heart transplant.

While left ventricular assist devices are often used in an attempt to relieve pulmonary hypertension, prolonged support may lead to onset of right heart failure. These patients face significant risks of morbidity and mortality, emphasizing the need for alternative strategies.

[1] https://www.jhltonline.org/article/S1053-2498(25)00069-5/fulltext

Aeson®, providing balanced biventricular support and integrating pressure sensors for real-time blood flow regulation, could offer an innovative approach to the management of pulmonary hypertension in advanced heart failure patients, both as a viable bridge-to-transplant solution or, potential definitive therapy.

Piet Jansen, Chief Medical Officer of CARMAT, concluded: *"Pulmonary hypertension is a condition that can temporarily delay heart transplantation. This publication in a prestigious scientific journal highlights the potential of Aeson® to safely bridge patients with pulmonary hypertension to a heart transplant. The ability of the device to provide real-time hemodynamic monitoring and to facilitate clinical decision-making has led to improved outcomes for these high-risk heart transplant candidates. Although larger studies are needed to confirm these findings and establish standardized protocols for pulmonary hypertension management with Aeson®, our device represents an important advancement in mechanical circulatory support and a real hope for thousands of patients with this challenging condition."*

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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.

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This press release may contain forward-looking statements about the Company's objectives and prospects. These forward-looking statements are based on the current estimates and expectations of the Company's management and are subject to risk factors and uncertainties, including those described in its universal registration document filed with the Autorité des Marchés Financiers (AMF) under number D.24-0374, as updated by an amendment to the 2023 universal registration document filed with the AMF on 17 September 2024 under number D. 24-0374-A01 (together the '2023 Universal Registration Document'), and available on CARMAT's website.

Readers' attention is particularly drawn to the fact that the Company's current financing horizon is limited until mid-May 2025 and that, given its financing requirements and the dilutive instruments in circulation, the Company's shareholders are likely to experience significant dilution of their stake in the Company in the short term. The Company is also subject to other risks and uncertainties, such as the Company's ability to implement its strategy, the pace of development of CARMAT's production and sales, the pace and results of ongoing or planned clinical trials, technological developments, changes in the competitive environment, regulatory developments, industrial risks and all risks associated with managing the Company's growth. The forward-looking statements contained in this press release may not be achieved as a result of these factors or other unknown risks and uncertainties or factors that the Company does not currently consider material and specific.

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).