



PRESS RELEASE

CARMAT presented its progress on the EFICAS clinical study at the 36th Journées de La Pitié in Paris

- 7 Aeson® implants have been performed as part of the study, including 4 over the last 4 weeks
- The pace of implants allows the Company to anticipate the completion of the study in 2025, in line with its objective

Paris, October 23, 2023 - 7:00 am (CEST)

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aimed at providing a therapeutic alternative for patients suffering from advanced biventricular heart failure (the "**Company**" or "**CARMAT**"), announces that it has presented its progress on the EFICAS clinical trial at the 36th "Journées de La Pitié" national conference on heart and lung transplantation and circulatory assistance, organized by the cardiology institute of the Pitié Salpêtrière hospital from October 18 to 20, 2023 in Paris.

Prof. Christian Latrémouille, Director of Surgical Affairs at CARMAT, provided an update on the latest progress of this large-scale study at a session dedicated to innovations: *"Seven Aeson® implants have been performed as part of the study since its initiation in several of the French centers involved. The pace of study enrollment is accelerating, with 4 implants performed over the last 4 weeks. This ramp-up is the result of growing experience in patient selection and attest to the steep learning curve of the surgical procedure. Post-operative patient recovery is increasingly satisfactory, which gives us great confidence in Aeson®'s performance and the success of the study, anticipated to be completed in 2025. I would like to thank all the participating teams for their commitment and look forward to seeing additional centers join us in our efforts to offer as many patients as possible an effective alternative to heart transplant."*

EFICAS is a prospective study designed to include 52 patients eligible for transplants, currently enrolled by a network of 6 French cardiology centers. It will enable CARMAT to gather additional data on the efficacy and safety of its artificial heart, as well as medico-economic data to support the value proposition of the prosthesis, and in particular the reimbursement of the device in France. The primary objective of the study is 180-day post-implantation survival without disabling stroke, or successful heart transplant within 180 days of implantation.

Pr. Lebreton of Pitié Salpêtrière Hospital (AP-HP), Paris, says: *"We are delighted to have implanted a first patient with the Aeson® total artificial heart as part of the EFICAS clinical study. The patient is recovering very quickly, and most of his symptoms of advanced heart failure have already disappeared."*

Pr. Obadia of Hôpital Louis Pradel (Hospices Civils de Lyon), principal investigator of the EFICAS study, comments: *"With our second Aeson® implant within a month, our learning curve is rapid, and we remain impressed with the device's performance. The CARMAT team provides excellent support to the hospital teams, before, during and after each implant."*

Pr. Vincentelli, from the Lille Regional University Hospital (CHRU), says: "The Aeson® heart is an absolute necessity in the therapeutic arsenal against end-stage heart failure. This total artificial heart has enabled us to safely prepare and wait for heart transplants in young patients who have no longer responded to conventional treatment."

CARMAT teams also attended the 7th "Journée" VAD Meeting, organized by the French-speaking coordination for the development of cardiac assistance (COFDAC), on October 19, 2023. This was an opportunity to demonstrate the Aeson® device to VAD coordinators in France, who play a key role in the management of patients on circulatory assistance.

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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The significant and specific risks pertaining to the Company are those described in the Universal Registration Document ("Document d'Enregistrement Universel") filed with the Autorité des Marchés Financiers (AMF, the French stock market authorities) under number D. 23-0323. Readers and investors' attention is, however, drawn to the fact that other risks, unknown or not deemed to be significant or specific, may or could exist.

Aeson® is an active implantable medical device commercially available in the European Union and other countries that recognize CE marking. 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 suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who are not amenable to maximal medical therapy or a left ventricular assist device (LVAD) and are likely to undergo a heart transplant within 180 days of the device being implanted. The decision to implant and the surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician manual, patient manual and alarm booklet) should be read carefully to understand the characteristics of Aeson® and information necessary for patient selection and the proper use of Aeson® (contraindications, precautions, side effects). In the United States, Aeson® is currently exclusively available within the framework of an Early Feasibility Study authorized by the Food & Drug Administration (FDA).