



PRESS RELEASE

Half of enrolments targeted in the EFICAS study reached by CARMAT

- Enrolment expected to be completed in the first half of 2025
- Publication of study results on 52 patients anticipated at the end 2025

Paris, September 12, 2024 – 7:00 am 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 that it has reached half of the enrolments targeted in the EFICAS study.

Continued momentum in the EFICAS study implants

The 26th Aeson® implant recently carried out as part of the EFICAS study has enabled CARMAT to reach the half-way mark in the 52 recruitments targeted as part of this study carried out exclusively in France.

The continuing good momentum in implants testifies to the very encouraging spread of the therapy in France, and to its increasing adoption by the medical community. Of the 10 hospitals taking part in the study, 9 have already carried out at least one implant, and 8 at least two.

EFICAS is the largest study ever initiated by CARMAT. It is a key study both for obtaining reimbursement for Aeson® in France, and for obtaining the "PMA" (marketing authorization for Aeson® in the United States), which the Company anticipates for 2027 (subject in particular to the successful completion of the EFS study in the United States, the second cohort of which is anticipated to start in Q1 2025).

Significant scientific publications expected in 2025

The momentum in the EFICAS study allows the Company to anticipate the completion of the enrolment (52 patients) in the first half of 2025, and the publication of the study results¹ at the end of 2025.

In addition, the Company anticipates in the first half of 2025, the publication in a scientific journal of the clinical results of Aeson® in a cohort of 10 patients who have been on ECMO² support prior to being implanted with Aeson®. This publication aims to demonstrate the efficacy and safety of Aeson® in high-risk patients.

CARMAT believes that these scientific publications will enable Aeson®'s clinical results to be widely disseminated within the medical community and will be a key factor for wider adoption of its therapy and for the Company's growth.

Stéphane Piat, Chief Executive Officer of CARMAT, comments: *"EFICAS is an essential study for scientifically objectifying the clinical results of Aeson® on a large sample of patients, and thus facilitating*

¹ Results on 52 patients. The primary endpoint of the study is a support with Aeson® at 6 months without disabling stroke or a heart transplant within 6 months.

² ECMO = Extra-corporeal membrane oxygenation.

their dissemination within the medical community. If the final results of the study confirm their interim results, their publication at the end of 2025 should contribute to a significant acceleration in the adoption of Aeson® by European physicians.

We also anticipate another major scientific publication in the first half of 2025, focusing on the clinical results of Aeson® in high-risk patients.

These publications should be a key catalyst for our growth in Europe, from next year onwards. They will also be decisive for our medium-term objectives, namely the access to the U.S. market, on the one hand, and ultimately, the approval of Aeson® as a destination therapy, on the other.”

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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).

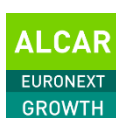
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This press release may contain forward-looking statements about the Company's objectives and prospects. These forward-looking statements are based on the current estimates and expectations of the Company's management, and are subject to risk factors and uncertainties, including those described in its universal registration document filed with the Autorité des Marchés Financiers (AMF) under number D.24-0374 and available on CARMAT's website, as updated in the Company's 2024 half-year financial report published today.

Readers' attention is particularly drawn to the fact that the Company's current financing horizon is limited to the end of September 2024 and that, given its financing requirements and outstanding dilutive instruments, 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, changes in technology and 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 due to these or other unknown risk factors and uncertainties, or factors which the Company does not currently consider material and specific.

Aeson® is an active implantable medical device commercially available in the European Union and other CE-marked countries. The Aeson® total artificial heart is intended to replace the ventricles of the native heart and is indicated as a bridge to transplantation 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 heart transplantation within 180 days of implantation. The implant decision and 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 available exclusively as part of a feasibility clinical trial approved by the Food & Drug Administration (FDA).