



## PRESS RELEASE

### **CARMAT continues to build on its momentum in the EFICAS study and reiterates confidence in its 2024 outlook**

- EFICAS study reaches the milestone of 20 implants
- Interim study results above expectations
- Confirmation of short-term financial support from several key shareholders

**Paris, May 6, 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 provides an update on the EFICAS study and reiterates confidence in its 2024 outlook.

**Stéphane Piat, Chief Executive Officer of CARMAT, commented:** *"I'm very pleased with the progress of the EFICAS study, both in terms of the pace of inclusion and results observed to date.*

*With 20 patients implanted, we have already completed 38% of the planned inclusions (out of a total of 52), which once again underlines the very strong interest shown by French doctors and hospitals in the Aeson® heart. Moreover, the interim results of the study are better than expected, although we are treating increasingly sick patients.*

*These achievements make us optimistic not only about the completion of the EFICAS study in the first half of 2025, but also about the growth potential of Aeson® sales over the coming months.*

*I am also delighted to be able to rely on several of our reference shareholders who have already confirmed their intention to support CARMAT financially in the short term, which will enable us to focus on our objectives and our development."*

- **EFICAS study on track**

To date, 20 patients have been implanted with the Aeson® heart as part of the EFICAS study, 9 of them in the first 4 months of 2024.

The EFICAS study is conducted exclusively in France, in 10<sup>1</sup> hospitals whose teams are fully trained and ready to carry out the implants. To date, 8 hospitals have already enrolled patients in the study.

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<sup>1</sup> AP-HP GHU Pitié Salpêtrière, Hôpital Européen Georges Pompidou, CHU de Rennes, CHU de Strasbourg, Hospices Civils de Lyon, CHRU de Lille, Hôpital Marie-Lannelongue, CHU de Montpellier, CHU de Nantes and CHU de Dijon.

The primary objective of the study is a minimum survival of 6 months on CARMAT support, without disabling stroke, or a successful heart transplant within the first 6 months.

The study's interim success rate of 75%<sup>2</sup>, which exceeds expectations, is very promising compared to previous CARMAT studies<sup>3</sup> and existing therapies, given the poor state of health of the patients concerned.

In view of these advances, CARMAT confirms its target of completing the EFICAS study, with a total of 52 Aeson® implants, in the first half of 2025.

The EFICAS study is essential both for the reimbursement of Aeson® in France and for obtaining PMA (marketing authorization in the United States, issued by the FDA), which the Company anticipates for 2027.

Study data are also an important catalyst for the adoption of Aeson® across Europe.

- **2024 outlook reiterated**

Bolstered by the clinical results of the EFICAS study, the progression in implants over the first 4 months of 2024, and its solid base of 39 hospitals trained in commercial implants, CARMAT reiterates its sales forecast of around €14 million for 2024.

Given its cash position and business plan, the Company's financial horizon currently extends to the end of May 2024, and CARMAT estimates its 12-month financing requirement at around €45 million.

The Company is working very actively on strengthening its equity, with the already-confirmed participation of some of its reference shareholders, enabling it to extend its financial horizon in the short-term.

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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](http://www.carmatsa.com) and follow us on [LinkedIn](https://www.linkedin.com/company/carmat).

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<sup>2</sup> Among the 8 patients who have already crossed the 6-month threshold.

<sup>3</sup> CE-marked PIVOTAL study: 73% success rate on 15 patients.

Name: **CARMAT**  
ISIN code: **FR0010907956**  
Ticker: **ALCAR**

#### **Disclaimer**

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 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 evolution and competitive environment, regulatory changes, industrial risks, and all risks associated with the company's growth management. The company's objectives mentioned in this press release may not be achieved due to these elements or other risk factors and uncertainties.

The Company's material and specific risks are those described in its universal registration document filed with the Autorité des Marchés Financiers (**AMF**) under number D.24-0374. Readers' attention is particularly drawn to the fact that the Company's current financing horizon is limited to the end of May 2024. Readers' and investors' attention is also drawn to the fact that other risks, unknown or not considered material and specific, may or may not exist.

Aeson<sup>®</sup> is an active implantable medical device commercially available in the European Union and other countries recognizing CE marking. The Aeson<sup>®</sup> total artificial heart is intended to replace the ventricles of the native heart and is indicated as a bridge to transplant for patients suffering from 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 undergo 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 manual, patient manual, and alarm booklet) should be carefully read to understand the features of Aeson<sup>®</sup> and the information necessary for patient selection and proper use (contraindications, precautions, side effects). In the United States, Aeson<sup>®</sup> is currently exclusively available as part of an Early Feasibility Study approved by the Food & Drug Administration (FDA).