CARMAT completes enrolment in the EFICAS clinical study and receives approval from French authorities for 21 additional Aeson® implants, while awaiting potential reimbursement of the device in France

Paris, May 12, 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 completion of enrolment of the 52 patients planned in the EFICAS study, and the approval from the French authorities to perform 21 additional Aeson® implants, while awaiting potential reimbursement of the device in France.

Stéphane Piat, Chief Executive Officer of CARMA, commented: *"The very strong momentum in the EFICAS study, which enrolment is now complete, reflects the quality and performance of our Aeson® artificial heart and its ability to address the unmet need expressed by healthcare professionals and patients. I am convinced that this study paves the way for strong sales development in Europe and beyond - particularly once its results will have been published, hopefully as soon as end of 2025.*

I am also very pleased that, by approving 21 additional implants, the French authorities enable patients in France to continue benefitting from our therapy beyond the EFICAS study. This is a strong sign of confidence in Aeson® artificial heart.

Given the study design, we anticipate to be in a position to file for Aeson®'s reimbursement in France early next year, which could lead to coverage of our artificial heart by the French Social Security system during 2026.

The EFICAS study is also important given our strategy to access the U.S. market, which we are expecting to achieve in 2028.

I would like to thank all patients and healthcare professionals, as well as our teams for their contribution to this important step in Aeson®'s development."

Enrolment completed in the EFICAS study

Initiated in November 2022, the EFICAS clinical study is the largest ever one conducted by CARMAT. It involves 52 patients eligible for a heart transplant and is carried out across 10 hospitals in France[1].

The primary endpoint of EFICAS is patient survival at 6 months post-Aeson® implant, without disabling stroke, or a successful heart transplant within that period.

EFICAS is key to support Aeson®'s commercial rollout in Europe[2] (through 'evidence-based medicine'), and secure its reimbursement in France, and is also expected to contribute to securing the Pre-Market Approval (PMA) in the United States, currently targeted for 2028[3].

Given the 6-month post-implant follow-up of patients, CARMAT expects completing the EFICAS study (primary endpoint) early November 2025, which will be followed by the publication of its results.

[1] CHRU Lille, AP-HP Hôpital Européen Georges Pompidou, GHU Pitié Salpêtrière, CHU Dijon, Hospices Civils de Lyon, Hôpital Marie-Lannelongue, CHU Rennes, CHU Montpellier, CHU Nantes and CHU Strasbourg.
[2] The Aeson® artificial heart has received CE marking for the "bridge to transplant" indication, allowing its commercialization throughout the European Union.
[3] Subject in particular to the quality of Aeson®'s clinical results and the completion of all required regulatory steps.

Approval obtained from French authorities for 21 additional Aeson® implants - and filing for reimbursement in France planned early 2026

As a reminder, the EFICAS study is partially funded by the French State (€13 million for 52 implants[4]), through the "Forfait Innovation" program.

In order to allow patients in France to continue benefitting from Aeson® artificial heart after the completion of the 52 implants in the EFICAS study, the French authorities[5] have approved 21 additional implants, under financial terms equivalent to those of the 'Forfait Innovation.

In parallel, CARMAT is taking all necessary steps to be in position to submit a reimbursement application (so-called "LPPR") for Aeson® at the beginning of 2026, which could allow Aeson® to be covered by the French Social Security system during the same year.

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CARMAT
Stéphane Piat
Chief Executive Officer

Pascale d'Arbonneau
Deputy Chief Executive Officer &
Chief Financial Officer
Tel.: +33 1 39 45 64 50
contact@carmatsas.com

NewCap
Press Relations

Nicolas Merigeau
Arthur Rouillé
Tel.: +33 1 44 71 94 98
carmat@newcap.eu

NewCap
Financial Communication
& Investor Relations

Dusan Oresansky
Jérémy Digel
Tel.: +33 1 44 71 94 92
carmat@newcap.eu

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

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

This press release may contain forward-looking statements regarding the Company's objectives and outlook. 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.25-0345 (the "**2024 Universal Registration Document**"), available free of charge on the websites of CARMAT (www.carmatsa.com/en/) 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 mid-June 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

[4] The Company benefits from this funding progressively as implants are performed.
[5] DGOS – Direction Générale de l'Offre de Soins.

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).