CARMAT delivers Q1 2025 results in line with its objectives

- Quarterly sales of €2.4m - multiplied by 2.4 vs Q1 2024
- EFICAS clinical trial - recruitment 94% complete
- 2 scientific publications - a strong driver of Aeson® adoption
- Final stage of discussions with the FDA with a view to resume the EFS study in the United States shortly

Videoconference in English and French this evening.

To join, please register by clicking on one of the following links:

Videoconference in French at 6:00 pm CEST

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Videoconference in English at 8:00 pm CEST

Paris, April 9, 2025 – 5:45 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 presents its achievements for the first quarter of 2025 and outlook.

Stéphane Piat, Chief Executive Officer of CARMAT, stated: *"We have delivered a solid first quarter, in line with our objectives.*

The beginning of 2025 has confirmed 2024 positive momentum in terms of implants, with 16 implants carried out in the first quarter, at a pace of more than 5 implants per month. CARMAT has thus generated sales of €2.4 million, 2.4 times more than in the first quarter of 2024.

Enrolment in EFICAS is 94% complete, which means this French study is progressing remarkably well, and should be finalized very soon, in line with our objectives. This study represents a major driver for the adoption of our therapy in France and, so will it be internationally as well, once study results are obtained at the end of the year. We are also delighted with the two recent publications featuring Aeson® in renowned scientific journals, which underline the strength and potential of our therapy. These articles are also powerful vectors for Aeson®'s dissemination.

We are also in final stage of discussions with the FDA (Food & Drug Administration), which should enable us to obtain very soon the authorization to initiate the second cohort of our EFS (early feasibility study) in the United States.

Finally, we remain more than ever focused on our long-term support goal, which would enable patients to remain under Aeson® support on a long-term basis. With this objective in mind, we should be in a position to make an enhanced version of our artificial heart available by the end of 2025, which will enable the Company to progress towards a new phase of its development and gradually unlock the full potential of its therapy."

Record quarter with 16 Aeson® implants

During the first quarter of 2025, CARMAT performed 16 Aeson® heart implants in 3 countries (France, Germany, Italy), vs 7 implants in the 1st quarter of 2024.

Quarterly sales thus amounted to €2.4 million, a 2.4-fold increase vs the first quarter of 2024.

At the end of March 2025, CARMAT had reached a total of 108 Aeson® implants since the first implant in 2013, including 58 in the last 15 months, which reflects a tangible acceleration in the adoption of the therapy.

Recruitment of the EFICAS study in France close to completion

Thirteen implants were made in the first quarter of 2025 as part of the EFICAS study, bringing their total number to 49 at the end of March, i.e. an enrollment rate of 94%, which suggests that recruitment will be completed very shortly (52 patients in total).

The results of this study, expected at the end of 2025, are of strategic interest to CARMAT both from a regulatory point of view, to get the reimbursement in France, and for the adoption of Aeson® internationally.

The EFICAS study plays a major role in developing the experience of surgical and medical teams, enabling the emergence of “centers of excellence” for Aeson® implants. The Lille University Hospital has thus already performed 10 implants, and three other French hospitals have each performed 7.

The Company considers that the dynamics of implants observed in the centers participating in the EFICAS study is a good predictor of forthcoming commercial momentum.

Final stage of discussions with the FDA to initiate the second cohort of the EFS

CARMAT is currently in final stage of discussions with the Food and Drug Administration (FDA) with a view to get the authorization to start the second cohort of the EFS (Early Feasibility Study) in the United States.

Involving 7 patients, this second part of the study represents an important step in the Company’s US market access strategy. The United States are the largest market in the world in the field of implantable cardiac devices.

Progressive strengthening of financial flexibility

In January 2025, CARMAT completed a €9.7 million fund raising. In March 2025, the implementation of an equity financing line with IRIS Capital Investment, of a potential amount of up to €7.9 million[1], which can be activated at the Company's discretion, offers CARMAT additional flexibility in the management of its working capital.

CARMAT, which cash runway extends to the end of May 2025[2], is actively exploring other financing solutions to extend its cash runway to a longer term.

Governance

Professor Christian Latrémouille, previously Director of Surgical Affairs at CARMAT, was appointed Medical Director with effect April 1, 2025, taking over from Dr. Piet Jansen, who is retiring after more than 15 years devoted to the development of Aeson® within the Company.

[1] Based on the closing price of March 26, 2025, i.e. €0.879.
[2] Excluding the flexible equity financing line entered into with IRIS, which was announced on March 27, 2025.

A Doctor of Medicine specialized in cardiac surgery and University Professor, Christian Latrémouille has been involved in the development of Aeson® since its inception, initially as a hospital practitioner, particularly alongside Professor Alain Carpentier, and then at CARMAT, which he joined in 2021.

"I would like to thank Piet Jansen warmly for his long-standing commitment, which has enabled Aeson® to reach key milestones, including the first implants, getting CE marking and the initiation of a clinical study in the United States. Today, I am delighted to benefit from Christian Latrémouille's expertise to anchor Aeson® in clinical practice and gradually make it a first-intent solution for physicians and patients around the world," commented **Stéphane Piat.**

Outlook

The sales momentum of the first quarter is in line with CARMAT's objective to double its sales in 2025.

In France, the Company has initiated discussions with the authorities to enable patients to get continued access to its therapy, post-completion of the EFICAS study and until reimbursement is obtained, which is anticipated from the end of 2026.

In Europe, CARMAT anticipates continued sales growth, supported by an increasing number of trained centers, the first implants in new countries, the positive feedback from the 1st "Aeson® European User Meeting" held in November 2024, and the recent publications of promising clinical results in peer-reviewed journals.

In the United States, the authorization to start the second cohort of the EFS study, expected from the FDA, should allow a resumption of implants in the second half of 2025, and potentially pave the way for a commercial launch in the United States in a horizon estimated to be 2028.

With a view to preparing for the future and accelerating the deployment of its therapy, CARMAT is already focused on its long-term support goal, which would enable patients to remain under Aeson® support on a long-term basis, and ultimately without subsequent heart transplant.

In view of this, the Company anticipates being in a position to make an enhanced version of its artificial heart available to healthcare professionals by the end of 2025. This would enable long-term support for patients and thus broaden access for Aeson® in the European market, particularly in countries such as Germany, where waiting times for a transplant can be long. The Company thinks that getting the destination therapy indication could take a few years.

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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 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, including those described in its universal registration document filed with the French Financial Markets Authority (Autorité des marchés financiers) (the "AMF") under number D.24-0374, as updated by the amendment to the 2023 universal registration document filed with the AMF on September 17, 2024 under number D.24-0374-A01 (together, the "2023 Universal Registration Document"), which are available free of charge on the websites of CARMAT (www.carmatsa.com) 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 the end of May 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 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).