CARMAT receives FDA conditional approval to initiate the second cohort of the EFS study in the United States

Recruitment of the second cohort expected to begin in H2 2025

Paris, April 14, 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 that it has received conditional approval from the U.S. Food and Drug Administration (FDA) to initiate the second cohort of its Early Feasibility Study (EFS) with Aeson® artificial heart in the United States.

Stéphane Piat, Chief Executive Officer of CARMAT, stated: *"The authorization to initiate the second cohort of our Early Feasibility Study (EFS) in the United States, received from the FDA, marks a very important milestone in CARMAT's journey. It reflects Aeson® artificial heart's quality and performance and its potential to address the unmet need expressed by healthcare professionals and patients around the world.*

This authorization will allow U.S. patients to benefit from our therapy as early as the second half of 2025. It also represents a key step towards a potential commercial launch of Aeson® in the United States, which—subject to factors including the quality of our clinical results—could occur from 2028.

I would like to thank all our team for their contribution to this key achievement."

Conditional approval to initiate the second cohort of the EFS study in the United States

The EFS study in the United States is a feasibility study involving a total of 10 patients eligible for heart transplant. The study's primary endpoint is patient survival at 6 months post-Aeson® implant, or a successful transplant within this timeframe.

The study design includes two successive cohorts. The first cohort of 3 patients was completed in Q3 2021.

Following the completion of this initial cohort, CARMAT implemented enhancements to Aeson®, which were submitted to the FDA. All of these changes have now been reviewed and approved by the FDA, allowing CARMAT to start recruiting patients in the second cohort[1].

This second cohort will include a total of 7 patients, with an interim report on the first 3 implants.

Initiation of the second cohort expected in H2 2025

CARMAT will now take all necessary steps - including obtaining approvals from ethics committees[2] and refreshing the training of participating hospitals - with the objective to initiate implants in the second half of 2025.

[1] In view of this, CARMAT is required, with no suspensive effect, to provide the FDA with a limited number of clarifications within 45 days.
[2] IRB – Institutional Review Board.

Meanwhile, CARMAT will seek the FDA to approve Aeson®'s most recent version, currently used in Europe, in order to be able to use it in the EFS study.

This second part of the EFS study represents an important step in the Company's US market access strategy, the United States being the largest market in the world in the field of implantable cardiac devices.

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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).