PRESS RELEASE

CARMAT announces the completion of its investigations on previously identified quality issues

Paris, December 23, 2021 – 7 am CET

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, aiming to fulfill an unmet medical need by providing a therapeutic alternative to people suffering from end-stage biventricular heart failure, announces the completion of investigations on its prostheses.

Following the occurrence of a quality issue affecting some of its prostheses, CARMAT had announced, on December 3, 2021, the voluntary and temporary suspension of implants of its Aeson® artificial heart. The company has subsequently carried out a very rigorous investigation of the situation.

This investigation, which is now complete, has enabled the root causes of the quality issue to be identified, and the changes required to prevent its reoccurrence to be determined.

The outcome of the investigation will now be shared with the notified body (DEKRA) and the competent authorities (specifically the ANSM in France and the Food & Drug Administration in the United States), starting from this week. The discussions with DEKRA and the competent authorities are expected to take a few weeks and lead to an agreed schedule to resume implants.

The company plans to provide a further update in January 2022, including a web conference, the date of which will be communicated in due course.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: *"After more than 2 weeks of in-depth investigation, I am glad that our teams were able to identify the root causes of the quality issue that occurred, and to propose corrective actions. Given the significant unmet need for patients suffering from end-stage biventricular heart failure who cannot benefit from a heart transplant, and the strong demand for Aeson® from many doctors and hospitals, we will now work diligently with all regulatory stakeholders in order to resume implants as soon as possible while keeping quality and patient safety as our top priorities".*

•••

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 more than 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.

•••

CARMAT
Stéphane Piat
Chief Executive Officer

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

Alize RP
Press Relations

Caroline Carmagnol
Tel.: +33 6 64 18 99 59
carmat@alizerp.com

NewCap
Financial Communication
& Investor Relations

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

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 to, or a solicitation of an offer to buy or subscribe to, shares in CARMAT (the "Company") in any country. This press release may contain forward-looking statements that relate to the Company's objectives and prospects. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties including, without limitation, the Company's ability to successfully implement its strategy, the rate of development of CARMAT's production and sales, the pace and results of ongoing and future clinical trials, new products or technological developments introduced by competitors, changes in regulations and risks associated with growth management. The Company's objectives as mentioned in this press release may not be achieved for any of these reasons or due to other risks and uncertainties.

*The significant and specific risks pertaining to the Company are those described in the Universal Registration Document ("*Document d'Enregistrement Universel") *filed with the* Autorité des Marchés Financiers *(AMF, the French stock market authorities) under number D.21-0076. Readers and investors' attention is, however, drawn to the fact that other risks, unknown or not deemed to be significant or specific, may or could exist.*

Aeson® is an active implantable medical device commercially available in the European Union and other countries that recognize CE marking. 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 suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who are not amenable to maximal medical therapy or a left ventricular assist device (LVAD) and are likely to undergo a heart transplant within 180 days of the device being implanted. 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 read carefully to understand the characteristics of Aeson® and information necessary for patient selection and the proper use of Aeson® (contraindications, precautions, side effects). In the United States, Aeson® is currently exclusively available within the framework of an Early Feasibility Study authorized by the Food & Drug Administration (FDA).