



## PRESS RELEASE

# CARMAT voluntarily suspends Aeson® implantations on a temporary basis

**Paris, December 3, 2021 – 5.45 pm 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 that it has voluntarily suspended, on a temporary basis, the implants of its Aeson® artificial heart.

Following the occurrence of a quality issue affecting some of its prostheses, the Company has decided to temporarily suspend, as a precautionary measure, implants of its Aeson® artificial heart.

This event will be investigated in accordance with the protocol planned for this purpose. Following this investigation, CARMAT will communicate, as soon as it is able to do so, on the resumption of its implants.

**Stéphane Piat, Chief Executive Officer of CARMAT, commented:** *“Quality issues are common events in the life cycle of medical devices, especially during the production ramp-up phase. The temporary suspension of Aeson® implants, which we have voluntarily decided, will allow us to calmly and carefully analyze the problem that has occurred and draw conclusions. The quality of Aeson® and patient safety remain our top priority, and I am very confident in our artificial heart's ability to provide a solution for patients suffering from advanced heart failure, who are faced with a well-known shortage of available human grafts.”*

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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 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](http://www.carmatsa.com) and follow us on [LinkedIn](#).

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

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#### Disclaimer

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*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).*