



## PRESS RELEASE

# CARMAT announces the restart of production and confirms the objective of resuming implants of its Aeson® artificial heart in October 2022

**Paris, March 28, 2022 – 6 pm CEST**

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, issues an update on its activities and outlook.

### **Restart of production and confirmation of the objective of resuming implants in October 2022**

Following the characterization of the quality defects on the two components that were the root cause of issues affecting some of its prostheses, CARMAT, in close collaboration with its suppliers, defined the necessary corrective actions.

These actions have now been implemented within the production processes of the relevant suppliers, and notably include additional controls.

Given supply and production lead times for suppliers and at CARMAT's plant in Bois-d'Arcy, the Company can thus confirm that new implantable prostheses will be available in October 2022.

At the same time, the Company is continuing its discussions with the notified body (DEKRA) and the competent authorities (the ANSM in France and the Food & Drug Administration in the United States), whose authorization is required to resume implants.

These elements allow CARMAT to confirm its objective of a resumption in commercial and clinical implants in October 2022.

### **Ongoing training for hospitals**

Due to the lack of therapeutic solutions available to patients with end-stage heart failure, CARMAT is seeing strong demand for the Aeson® system from cardiologists, notably driven by positive feedback from physicians who have already implanted the device.

CARMAT is thus continuing to train more hospitals, in Germany and in other European countries, in order to be able to meet, to the extent possible, this demand once the suspension of implants is lifted.

**Stéphane Piat, Chief Executive Officer of CARMAT, concluded:** *"I would like to pay tribute to the strong mobilization of CARMAT's teams who, by providing our suppliers with their assistance and expertise, have enabled the changes necessary to improve the sturdiness and reliability of the components that led to the incidents we experienced in 2021 to be rapidly implemented within manufacturing processes. Thanks to this close collaboration, the resumption of production, incorporating these changes, is now effective."*

*This allows us, given our supply and production lead-times, to confirm our objective of providing medical teams with implantable prostheses from October 2022, thus enabling our implants to resume at that time, subject of course to the approval of the notified body DEKRA and the competent authorities with whom we are continuing our constructive dialogue.*

*Given the lack of satisfactory therapeutic solutions addressing advanced heart failure and the number of patients on a waiting list for a heart transplant, we are receiving requests from many physicians and are doing everything we can to be able to resume our implants as soon as possible while continuing to prioritize the health and safety of patients".*

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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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*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).