**PRESS RELEASE**

# CARMAT announces that it has received the necessary regulatory approvals to resume Aeson® commercial implants

## DEKRA has provided notified body approval of all changes implemented by CARMAT

**Paris, October 25, 2022 – 7 am CEST**

CARMAT (FR0010907956, ALCAR), the designer and developer of Aeson®, the world's most advanced total artificial heart, designed to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, announced today that it has been granted the necessary regulatory approvals to resume implants in a commercial setting.

After review of CARMAT filings, DEKRA has provided notified body approval of all the changes implemented by the Company in response to the quality issues that led it to voluntarily and temporarily suspend all Aeson® implants at the end of 2021. This approval allows CARMAT to resume implants of its Aeson® artificial heart in a commercial setting, within the European Union and other countries that recognize CE Marking.

Following this approval, CARMAT intends to resume sales in Europe in the near future at a gradual pace in line with the rebuilding of the prostheses inventory.

CARMAT will provide additional update when it is in a position to resume clinical trials in France, Europe and the United States.

**Stéphane Piat, Chief Executive Officer of CARMAT, said:** "*DEKRA's approval allows us to resume Aeson® implants within a commercial setting in Europe, which is excellent news both for patients and for our Company. We will be resuming implants very soon and moving forward at a measured pace as we continue building our inventory of implantable prostheses, and ensure all patients are suitably monitored. We are also making good progress on plans to resume clinical trials and we will be providing additional updates on this in due course".*

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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 and follow us on LinkedIn.

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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. 22-0332. 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).*