



PRESS RELEASE

CARMAT announces a software enhancement which significantly improves the safety profile of its Aeson® artificial heart

- In compliance with regulations, the implementation of this modification gives rise to the publication of a “field safety notice”.
- Its roll-out will begin over the next few days.

Paris, December 28, 2023 - 5:45 pm (CET)

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aimed at providing a therapeutic alternative for patients suffering from advanced biventricular heart failure (the "**Company**" or "**CARMAT**"), today announced a software enhancement which significantly improves the safety profile of its Aeson® artificial heart.

The prosthesis software will now be able to detect on a real time basis, signals of possible Aeson® malfunctions. The software will then immediately adapt the control of the prosthesis so that its performance is not affected, and the patient's support is not impacted.

These changes, developed and tested by CARMAT's research teams, will first be deployed on all hearts currently implanted in patients, as part of a software update for which a field safety notice is published¹. It will then be embedded into the Aeson® production process, after getting the appropriate regulatory approvals.

Stéphane Piat, Chief Executive Officer of CARMAT, declares: *"In all industries, electronic components are potentially subject to failure, because perfection of their manufacturing is almost impossible to achieve. It was important to be able to manage such risks in the case of our device, and I'm therefore very proud of the feat achieved by our software engineers: from now on, for many of the potential malfunctions linked to the prosthesis's electronic components, Aeson® software will automatically "correct" these faults by adapting the prosthesis's performance in an appropriate manner, so that the patient's support remains unaffected. For me, this is a major and immediate step forward for all the patients who benefit and will benefit from our therapy; but also in the long term, when it comes to obtaining the destination therapy indication for Aeson®, as this improvement significantly strengthens the safety profile and therefore the potential durability of the prosthesis."*

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¹ In France, publication is made on the ANSM health authority website.

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](#).

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



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

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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. 23-0323. Readers' attention is drawn in particular to the financing risk of the Company, whose cash runway currently extends until early 2024. Readers and investors' attention is also 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)