



## PRESS RELEASE

# CARMAT announces the first implantation of Aeson® within the framework of the EFICAS clinical study in France

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CARMAT (FR0010907956, ALCAR), designer and developer of Aeson®, the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, today announced the first implantation of its Aeson® artificial heart within the framework of the EFICAS clinical study in France.

On October 26, 2022, CARMAT announced that it had received the necessary regulatory approvals to resume the EFICAS clinical study.

The first Aeson® implantation within the framework of this study was performed during the last week of December 2022 by Prof. André Vincentelli and his team at Lille Regional University Hospital.

In addition to the Lille hospital, five other medical centers take part in this study: Pitié Salpêtrière University Hospital and Georges Pompidou European Hospital in Paris, Rennes University Hospital, Strasbourg University Hospital and Lyon University Hospital (Hospices Civils de Lyon).

This prospective study will involve a total of 52 patients eligible for a heart transplant in France and will allow CARMAT to collect both additional data on the efficacy and safety of its artificial heart and medico-economic data to support its value proposition and the device's reimbursement, notably in France. The study's primary endpoint is survival for 180 days after implantation of the device without a disabling stroke, or a successful heart transplant within 180 days of implantation.

CARMAT benefits from 13 million euros in funding from the French National Innovation Fund to partially finance this study.

In accordance with the principles it has consistently applied, the Company does not plan to communicate on the state of health of individual patients nor on the performance of each implantation. CARMAT will continue to communicate on its progress when it reaches significant milestones and when it publishes its financial results.

**Stéphane Piat, Chief Executive Officer of CARMAT, said:** *"EFICAS is the largest study undertaken by CARMAT at this stage, and I am delighted that it will entirely take place in France, thus enabling our country's patients to benefit from our therapy. This is a crucial study, as it will eventually notably allow us to obtain Aeson®'s reimbursement in France. I would like to thank Professor André Vincentelli and his team for their trust, as well as the teams in the five other medical centers that will contribute to this study".*

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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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## 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).*