



## PRESS RELEASE

# CARMAT receives final approval from the patient protection committee for the use of the commercial version of the Aeson® heart in the EFICAS study in France

**Paris, September 16, 2021 – 6:30 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, today announces that it has received final approval from the Patient Protection Committee (CPP Ile-de-France XI) for the use of the commercial version of the Aeson® heart in the EFICAS study in France.

This agreement from the CPP Ile-de-France XI applies to the dossier submitted by CARMAT in the first half of 2021 and enables it to use the latest version of its Aeson® artificial heart in the EFICAS study.

This agreement paves the way for the start of this study, with recruitment expected to begin in the fourth quarter of 2021 in the first six centers that have expressed an interest in taking part in the trial (APHP Hôpital européen Georges-Pompidou, APHP-HU Pitié Salpêtrière, CHRU Lille, CHU Lyon, CHU Rennes and CHU Strasbourg).

As a reminder, CARMAT had already obtained the approvals of the French National Agency for Medicine and Health Product Safety (ANSM) and the French National Authority for Health (HAS) on the clinical protocol of this study, and benefits from €13 million in funding from the National Innovation Fund, granted by the French Ministry of Solidarity and Health, to partially finance it.

The study will cover 52 implants 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 the value proposition and reimbursement of the device, notably in France.

**Stéphane Piat, Chief Executive Officer of CARMAT, stated:** *"I am pleased that the patient protection committee has agreed to the use of the most recent version of Aeson® in the EFICAS study. This medico-economic study is of major interest for our development in France as the data collected will in particular support our reimbursement application for Aeson® in our domestic market. I am also delighted that 6 of the most prestigious French cardiology hospitals have placed their trust in us and will allow French patients to benefit from our unique therapy."*

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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.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).*