



## PRESS RELEASE

### **CARMAT's Aeson® artificial heart is gradually becoming a reference solution for bridge to transplant in Europe**

- **Milestone of 30 heart transplants post Aeson® support, passed**
- **Strong interest in Aeson® from the medical community: more than 100 European experts will share their experience at the first 'Aeson® European User Meeting' at the end of November**

**Paris, November 13, 2024 – 7:00 am CET**

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from advanced biventricular heart failure (the "**Company**" or "**CARMAT**"), provides an update on Aeson® artificial heart's uptake as a bridge to transplant in Europe.

#### **Growing adoption of Aeson® as a bridge-to-transplant solution in Europe**

By the end of October 2024, 30 patients had successfully undergone heart transplant after being supported by the Aeson® artificial heart, confirming the ability of the device to provide physiological support tailored to each patient, enabling them to approach heart transplant in optimal physical condition when a human graft becomes available.

Out of these 30 transplants carried out in 7 different countries<sup>1</sup> (including 16 in France and 5 in Germany), 16 have been performed since the beginning of 2024, demonstrating a clear acceleration in the adoption of Aeson® as a bridge-to-transplant solution in Europe.

These 30 patients benefited from Aeson® support for an average of 156 days before transplant (the maximum duration recorded being 308 days).

As a reminder, the Aeson® artificial heart is CE marked for the "bridge to transplant" indication. It can therefore be marketed in Europe (and in other countries recognizing the CE marking) for this indication, and more specifically in patients suffering from end-stage biventricular heart failure (Intermacs classes 1-4) who cannot benefit from maximal medical therapy or a left ventricular assist device (LVAD), and who are likely to receive a heart transplant within 180 days of implantation.

#### **Strong interest in Aeson® from the medical community**

At the end of November 2024, CARMAT organizes the first 'Aeson® European User Meeting'. This event will enable more than 100 European leaders in the field of cardiology to share their experience with the Aeson® artificial heart. The event will focus on case studies and feedback from the various stakeholders managing patients (cardiologists, surgeons, anaesthetists, intensive care specialists, etc.), with a view to

---

<sup>1</sup> France, Germany, Italy, Poland, Czech Republic, USA and Kazakhstan

better identifying patients who could benefit from Aeson®, and enhancing the level of expertise of the centres. It will thus mark an important step towards wider adoption of the device, and better management of patients suffering from advanced biventricular heart failure.

This event is part of the intensification, over the course of 2024, of the information and training effort around Aeson®, including in particular CARMAT's participation in about ten key conferences attended by several hundred participants. This testifies to the growing interest shown by healthcare professionals in this innovative device, and to the critical need for effective solutions to treat patients who frequently find themselves at a therapeutic standstill.

### **Ultimate goal: Get the 'destination therapy' indication**

Building on its growing and extremely encouraging experience in the bridge-to-transplant indication, CARMAT continues to ultimately aim for the 'destination therapy' ('DT') indication, which would enable patients to live sustainably under Aeson® support without subsequent heart transplant.

To this end, CARMAT confirms that it plans to resume its PIVOTAL study in Europe in the second half of 2025, on a cohort of patients not eligible to transplant.

Approval in 'DT' would be decisive in meeting the critical challenge of the graft shortage, given that only 5% of patients in need of a transplant can currently benefit from it. As such, the DT indication represents the largest addressable market opportunity in cardiology. CARMAT estimates that obtaining this indication could take a few years.

**Stéphane Piat, Chief Executive Officer of CARMAT**, comments: *"The growing success of our Aeson® artificial heart as a bridge to transplant solution demonstrates the impact of this innovation on the lives of patients suffering from advanced heart failure. With 30 patients successfully bridged to transplant thanks to Aeson®, including 16 since the beginning of the year, our device continues to prove that it has the potential to become a first-line solution to save patients at the ultimate stage of the disease. As we look ahead to the first Aeson® user meeting, which will bring together over 100 European experts, we are proud to see the medical community becoming increasingly committed to the adoption of our technology. Together, we can make Aeson® a new benchmark in the treatment of advanced biventricular heart failure."*

...

### **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](http://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](mailto:contact@carmatsas.com)

**Alize RP**  
Press Relations

**Caroline Carmagnol**  
Tel.: +33 6 64 18 99 59  
[carmat@alizerp.com](mailto:carmat@alizerp.com)



**NewCap**  
Financial Communication  
& Investor Relations

**Dusan Oresansky**  
**Jérémy Digel**  
Tel.: +33 1 44 71 94 92  
[carmat@newcap.eu](mailto:carmat@newcap.eu)

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

•••

#### Disclaimer

This press release and the information it contains do not constitute an offer to sell or subscribe, or the solicitation of an order to buy or subscribe, CARMAT shares in any country.

This press release may contain forward-looking statements about the Company's objectives and prospects. These forward-looking statements are based on the current estimates and expectations of the Company's management and are subject to risk factors and uncertainties, including those described in its universal registration document filed with the Autorité des Marchés Financiers (AMF) under number D.24-0374, as updated by an amendment to the 2023 universal registration document filed with the AMF on 17 September 2024 under number D. 24-0374-A01 (together the '2023 Universal Registration Document'), and available on CARMAT's website.

Readers' attention is particularly drawn to the fact that the Company's current financing horizon is limited to the beginning of 2025 and that, given its financing requirements and the dilutive instruments in circulation, the Company's shareholders are likely to experience significant dilution of their stake in the Company in the short term. The Company is also subject to other risks and uncertainties, such as the Company's ability to implement its strategy, the pace of development of CARMAT's production and sales, the pace and results of ongoing or planned clinical trials, technological developments, changes in the competitive environment, regulatory developments, industrial risks and all risks associated with managing the Company's growth. The forward-looking statements contained in this press release may not be achieved as a result of these factors or other unknown risks and uncertainties or factors that the Company does not currently consider material and specific.

Aeson® is an active implantable medical device commercially available in the European Union and other countries recognising the CE mark. 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 with end-stage biventricular heart failure (Intermacs classes 1-4) who cannot benefit from maximal medical therapy or a left ventricular assist device (LVAD) and who are likely to benefit from a heart transplant within 180 days of implantation. The decision to implant and the surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician's manual, patient's manual and alarm booklet) must be read carefully to learn about the characteristics of Aeson® and the information required for patient selection and proper use (contraindications, precautions, side effects) of Aeson®. In the United States, Aeson® is currently only available as part of a feasibility clinical trial approved by the Food & Drug Administration (FDA).