



## PRESS RELEASE

### **CARMAT announces the second center implanting its total artificial heart in the United States**

The implant was performed at UofL Health - Jewish Hospital by University of Louisville physicians within the framework of the U.S. Early Feasibility Study

**Paris, August 25, 2021 – 7:00 am 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, announces the second center implanting its bioprosthetic artificial heart, Aeson®, in the United States within the framework of the Early Feasibility Study (EFS).

The implant procedure was performed by a team led by Dr. Mark S. Slaughter, Professor and Chair of the Department of Cardiovascular and Thoracic Surgery at the University of Louisville and UofL Physician at Jewish Hospital, Louisville, Kentucky. UofL Health and the University of Louisville are known for groundbreaking cardiovascular innovation research, especially in circulatory support technologies. Jewish Hospital is the second U.S. hospital to implant Aeson® within the framework of the EFS. Three additional U.S. centers are fully trained and are currently screening patients for the study.

In accordance with the study protocol approved by the FDA, 10 transplant-eligible patients are expected to be enrolled in this trial. The primary study endpoint is patient survival at 180 days post-implant or a successful cardiac transplantation within 180 days post-implant. It is a staged study with a progress report of the first 3 patients after 60 days, before the enrollment of the next 7 patients.

**Mark S. Slaughter, MD, heart surgeon at UofL Health - Jewish Hospital and University of Louisville, and principal investigator of the study, stated:** *"We are pleased to be part of the first U.S. centers to investigate this new artificial heart technology. This clinical study will help us determine whether the device's distinguishing features such as hemocompatibility and blood flow autoregulation are beneficial to critically ill patients suffering from biventricular heart failure who currently have very limited treatment options."*

**Stéphane Piat, Chief Executive Officer of CARMAT, concluded:** *"We are honored that our device is implanted at UofL Health – Jewish Hospital and University of Louisville, which is recognized throughout the United States for its quality of care and cardiovascular research. I would like to congratulate the teams at the hospital, as well as our technical and medical staff, on this exceptional milestone for both patients and our company."*

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#### **About CARMAT: the world's most advanced total artificial heart**

**A credible response to end-stage heart failure:** CARMAT aims to provide a response to a major public health issue associated with heart disease, the world's leading cause of death: advanced heart failure. Thanks to its total artificial heart, Aeson®, composed of an implantable bioprosthesis and its portable external power supply system to which it is continuously connected, CARMAT intends to overcome the well-known shortfall in heart transplants for the tens of thousands of people suffering from irreversible end-stage heart failure, the most seriously affected of the 20 million patients with this progressive disease in Europe and the United States.

**The result of combining two types of unique expertise:** the medical expertise of Professor Carpentier, known throughout the world for inventing Carpentier-Edwards® heart valves, which are the most used in the world, and the technological expertise of Airbus Group, world aerospace leader.

**The first physiologic heart replacement therapy:** given the use of highly biocompatible materials, its unique self-regulation system and its pulsatile nature, the Aeson® heart constitutes a new therapeutic class - Physiologic Heart Replacement Therapy (PHRT) – and could save the lives of thousands of patients every year without risk of rejection and with a good quality of life. Aeson® is commercially available in the bridge-to-transplant indication in Europe and other countries that recognise the CE mark. Aeson® is also currently being evaluated in an Early Feasibility Study in the United States.

For more information: [www.carmatsa.com](http://www.carmatsa.com)

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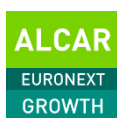
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This press release and the information contained herein do not constitute an offer to sell or subscribe to, or a solicitation of an offer to buy or subscribe to, shares in CARMAT ("the Company") in any country. This press release contains forward-looking statements that relate to the Company's objectives. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties. Potential risks and uncertainties include, without limitation, whether the Company will be successful in implementing its strategies, whether there will be continued growth in the relevant market and demand for the Company's products, new products or technological developments introduced by competitors, and risks associated with managing growth. The Company's objectives as mentioned in this press release may not be achieved for any of these reasons or due to other risks and uncertainties.

No guarantee can be given as to any of the events anticipated by the forward-looking statements, which are subject to inherent risks, including those described in the Universal registration document filed with the Autorité des Marchés Financiers on February 24, 2021 under number D.21-0076 as well as changes in economic conditions, the financial markets or the markets in which CARMAT operates. In particular, no guarantee can be given concerning the Company's ability to finalize the development, validation and industrialization of the prosthesis and the equipment required for its use, to manufacture the prostheses, satisfy the requirements of competent authorities, enroll patients, obtain satisfactory clinical results, perform the clinical trials and achieve commercial objectives.

Aeson® is an active implantable medical device commercially available in Europe ONLY, CARMAT SA., CE0344. The Aeson® TAH is intended to replace ventricles of 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 LVAD and are likely to undergo heart transplant in the 180 days following device implantation. The decision to implant and the surgical procedure must be executed by Health Care professionals trained by the manufacturer. Carefully read the documentation (clinician manual, patient manual & alarm booklet) for characteristics and information necessary for patient selection and good use (contraindications, precautions, side effects).

In the USA, Aeson® is currently exclusively available within the framework of clinical trials.