

## **PRESS RELEASE**

# CARMAT announces the first human implant of its Aeson® artificial heart in Germany

## The implant was performed at Hannover Medical School

### Paris, July 26, 2021 – 6:00 pm CEST

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, today announces the first implant of its Aeson® bioprosthetic artificial heart in Germany.

This new implant of the Aeson® artificial heart was performed by Prof. Jan D. Schmitto and his interdisciplinary Heart Team of the Department of Cardiothoracic and Transplant Surgery (Director: Prof. Axel Haverich) at Hannover Medical School (Medizinische Hochschule Hannover - MHH), in Germany. The MHH Hospital is a maximum care hospital with a nationwide catchment area, recognized for its quality research in several domains such as transplantation and regenerative medicine, infection and immunology, biomedical engineering and implants.

**Prof. Jan D. Schmitto, Director of the Mechanical Circulatory Support and Cardiac Transplantation Program at Hannover Medical School, declared:** "The implant of the first CARMAT TAH in Germany represents another milestone in the field of Mechanical Circulatory Support Devices. The extremely ill patient suffered from long-lasting congenital heart disease and was finally fulminantly decompensated. He was treated by extracorporeal membrane oxygenation (ECMO) therapy for many days before he received a left ventricular assist device (LVAD) plus aortic valve replacement (AVR) and a temporary right ventricular assist device (RVAD) a week ago. Based on persistent right heart failure which made the RVAD not able to be weaned, there were no other treatment options left than Aeson® in this specific situation. Therefore, we asked the CARMAT team to join our forces for this ultima ratio use in order to face that critical situation of our patient. Unfortunately, because of its terminally ill status and the extremely fragile clinical profile, the patient passed away in the postoperative course. However, we observed that Aeson® has been able to directly intraoperatively stabilize the hemodynamic situation of the patient and has also been able to cope with the high pulmonary arterial pressures. Overall, we have been impressed by the promising performance of the device and we are looking forward to include it in our portfolio to save many lives in the future."

**Stéphane Piat, Chief Executive Officer of CARMAT, concluded:** "We supported Prof. Schmitto's team in Hannover last Friday for the treatment of a young patient suffering from end-stage biventricular heart failure due to Congenital Heart Disease. Because of the lack of treatment options for this severe heart failing patient and taking into account the challenging management of his severe Pulmonary Arterial Hypertension (PAH), Aeson® has been identified as the last possible solution. Despite challenging hemodynamic conditions, our device was able to deal

with this very high level of PAH. This finding could open new opportunities in terms of indication of use for congenital heart diseases. We continue screening patients in Hannover as well as in other centers in Germany which have already been trained in the use of Aeson<sup>®</sup>."

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

A credible response to end-stage heart failure: CARMAT aims to eventually provide a response to a major public health issue associated with heart disease, the world's leading cause of death: chronic and acute heart failure. By pursuing the development of its total artificial heart, Aeson®, composed of the 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 selfregulation system and its pulsatile nature, the CARMAT total artificial heart could, assuming a successful clinical development, potentially save the lives of thousands of patients each year with no risk of rejection and with an enhanced quality of life.

A project leader acknowledged at a European level: with the backing of the European Commission, CARMAT has been granted the largest subsidy ever given to an SME by Bpifrance; a total of €33 million.

**Strongly committed, prestigious founders and shareholders:** Matra Défense SAS (subsidiary of the Airbus Group), Professor Alain Carpentier, the Centre Chirurgical Marie Lannelongue, Truffle Capital, a leading European venture capital firm, ALIAD (Air Liquide's venture capital investor), CorNovum (an investment holding company held 50-50 by Bpifrance and the French State), the family offices of Pierre Bastid (Lohas), of Dr. Antonino Ligresti (Santé Holdings S.R.L.), of the Gaspard family (Corely Belgium SPRL and Bratya SPRL) and of M. Pierre-Edouard Stérin (BAD 21 SPRL), Groupe Therabel as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

#### CARMAT's history in brief:

- 2008: creation of CARMAT
- 2010: Initial public offering (Euronext Growth Paris)
- 2013: 1<sup>st</sup> implant of the artificial heart in human as part of a clinical feasibility study conducted in France
- 2016: start of the PIVOTAL study in France, then in Europe, on approx. 20 patients with the aim of obtaining CE marking
- December 2020: obtaining CE marking in the "bridge to transplant" indication, allowing the heart to be marketed under the trade name Aeson® in Europe and in other countries that recognize this marking.
- July 2021:
  - 1<sup>st</sup> human implant within the framework of an early feasibility study in the United States;
  - 1<sup>st</sup> sale in Europe.

#### For more information: www.carmatsa.com

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#### Disclaimer

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.