# CARMAT

### PRESS RELEASE

## Update on the Feasibility study of the CARMAT bioprosthetic artificial heart

#### Paris, December 22, 2015

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, aiming to provide a therapeutic alternative for people suffering from end-stage heart failure, announces interim information regarding its ongoing Feasibility clinical trial.

The third patient, who was implanted with a CARMAT prosthesis on April 8, 2015, died on the morning of December 18, 2015. Based on the information currently available, he died from acute respiratory failure while suffering from chronic kidney failure, after which the medical team stopped the prosthesis. This patient, aged 74, had returned home after being discharged at the end of August. He had been suffering from a combination of pre-existing pathologies when he was implanted with the prosthesis, including kidney failure, causing him to regularly return to the hospital. At this stage of the clinical trial, the CARMAT system has 20 months of combined clinical experience. As a reminder, the study's criteria for success include the patient's 30-day survival following implantation.

The analyses carried out do not show that the prosthesis was involved in the patient's death. The Company is continuing the Feasibility study.

"The CARMAT team shares the grief of those close to the patient and would like to thank the Strasbourg University Hospitals Cardiac Surgery Unit's medical team that devotedly accompanied the patient until the very end. The Company reaffirms its commitment to this project's success and is focusing its efforts on pursuing the next clinical and industrial stages required for the Company's development," **stated Marcello Conviti, Chief Executive Officer of CARMAT.** 

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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, 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<sup>®</sup> heart valves, which are the most used in the world, and the technological expertise of Airbus Group, world aerospace leader.

**Imitating the natural heart**: given its size, the choice of structural materials and its innovative physiological functions, CARMAT's total artificial heart could, assuming the necessary clinical trials are successful, potentially benefit the lives of thousands of patients a year with no risk of rejection and with a good 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  $\in$  33 million.

**Strongly committed, prestigious founders and shareholders:** <u>Airbus Group</u>, Professor <u>Alain Carpentier</u>, the <u>Centre</u> <u>Chirurgical Marie Lannelongue</u>, <u>Truffle Capital</u>, a leading European venture capital firm, and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: <u>www.carmatsa.com</u>

#### 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 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 *Document de Référence* filed with *the Autorité des Marchés Financiers* under number D.15-0138 on March 16, 2015 and 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 the ANSM, enroll patients, obtain satisfactory clinical results, perform the clinical trials and tests required for CE marking and to obtain the CE mark. CARMAT products are currently exclusively used within the framework of clinical trials.

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