



PRESS RELEASE

CARMAT obtains regulatory approval to finalize its Clinical Feasibility Study

Broadening of patient enrollment criteria: a greater number of patients will be able to benefit from the CARMAT heart

Paris, November 24, 2015

CARMAT (FR0010907956 - ALCAR, PEA-PME eligible), 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 that it has received authorization from the French national agency for the safety of medicines and health products (ANSM) and the person protection committee (CPP) to finalize the Clinical Feasibility Trial on its bioprosthetic heart. The next implant can already be undertaken within the framework of a clinical protocol that includes patients that were thus far not eligible.

This authorization follows the experts' report given to the authorities by the Company, covering the solutions implemented and validated to correct the anomaly that had been observed. The prostheses that will be used in the next implants will incorporate these corrections.

The broadening of the clinical protocol has been made possible by the interim results of the first CARMAT heart implants. Thus far, the protocol only enabled patients suffering from end-stage irreversible bi-ventricular heart failure and in an immediate life-threatening situation to be included in the study. The criteria associated with the stage of heart failure have been eased to allow a greater number of patients to benefit from the CARMAT heart. In addition, under certain conditions, patients who are eligible for a heart transplant can also now be included in the study.

Marcello Conviti, Chief Executive Officer of CARMAT, says: *"The resumption of the trial and the broadening of the enrollment criteria will enable us to complete the Feasibility study so that we can launch the Pivotal study to obtain CE marking. The feedback obtained until now from a total of more than 65 million heartbeats over 19 months gives us a high level of confidence in CARMAT's ability to provide patients suffering from end-stage heart failure with a real alternative to a transplant."*

In order to respond to the various requests the Company has received, it has put a list of questions & answers on its website.



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® 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 €33 million.

Strongly committed, prestigious founders and shareholders: [Airbus Group](#), Professor [Alain Carpentier](#), the [Centre Chirurgical Marie Lannelongue](#), [Truffle Capital](#), a leading European venture capital firm, and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com



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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 *Document de Référence* filed with the *Autorité des Marchés Financiers* under number D.15-0138 on March 16, 2015, 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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