



PRESS RELEASE

CARMAT: Continuing progress in line with the objective of obtaining CE marking in 2019

- PIVOTAL study recruitment pace accelerating with 30% of the total number of planned patients implanted
- Opening of the new Bois-d’Arcy site for the large-scale production of prostheses
- Pre-submission of an early feasibility study request with the U.S. FDA in order to initiate implants in the United States

Paris, April 5, 2018 – 7 am CEST

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 biventricular heart failure, today announced an update on the progress of the PIVOTAL study and the latest developments regarding its market access strategy.

Stéphane Piat, Chief Executive Officer of CARMAT, says: *“We are ramping up our project on all of its strategic routes and are gradually meeting the key milestones that bring us closer each day to meeting our objective of obtaining a CE mark for the CARMAT total artificial heart in 2019. From a clinical perspective, we have carried out one third of the implantations foreseen within the framework of the PIVOTAL study. This sustained enrollment rate validates the pertinence of our international clinical strategy implemented in highly-specialized medical facilities. It also takes on its full meaning given the performances of the surgical teams, who have been able to substantially reduce the operating time, confirming that the implantation of the CARMAT heart is highly controlled and reproducible. These clinical breakthroughs are closely correlated to our industrial development and justify our decision to open a new manufacturing site in Bois-d’Arcy, near Paris. This new site will enable us to produce the prostheses required for the clinical trials and the subsequent commercial phase in compliance with certified processes that meet the demands of industrial production. Lastly, as our project aims to address the issue of heart failure on a global scale, we are delighted to see our discussions with the U.S. FDA progressing towards the initiation of an early feasibility study in the United States, a market with substantial potential for CARMAT”.*

• **Acceleration in the pace of recruitment for the PIVOTAL study**

The PIVOTAL study follows the feasibility study undertaken by CARMAT on 4 patients. It corresponds to the second phase of the clinical trials required to compile the CE marking clinical dossier. Within the framework of this study, CARMAT is planning to implant its bioprosthesis in approximately twenty patients with end-stage biventricular heart failure whose health state is more stable than that of the patients included in the feasibility study. This study’s endpoint is to show the survival of the implanted patients at 6 months and thus validate the CARMAT system’s safety, efficacy and performances.

CARMAT has received the necessary regulatory authorizations to conduct this study in France and three other countries: Kazakhstan, the Czech Republic, and Denmark. This broadening of the study to include leading international facilities in the conduct of clinical trials on circulatory support devices targeting the European market has helped significantly accelerate patient enrollment in the study.

To date, the number of implantations already performed represents 30% of the study's planned total.

The surgical procedure boasts a 100% success rate, and operating time has been cut by approximately 21% compared with the first implantations, showing both a substantial improvement in surgical teams' learning curve and good reproducibility of the surgery as the study progresses.

The patients treated in the PIVOTAL study have a more stable clinical profile than those involved in the feasibility study, as illustrated by the 100% survival rate at 1 month compared with 75% previously.

In order to further accelerate the implantation rate, CARMAT is planning to expand the network of investigation centers to 3 additional countries and is expecting to end PIVOTAL study implantations this year.

- **Major progress in the CE marking process**

The CE marking process undertaken by CARMAT with certification body DEKRA aims to validate the CARMAT heart's compliance with European regulatory requirements. Within this framework, in 2017 CARMAT delivered more than half of the CE marking dossier's modules, notably those concerning all the technical aspects. The Company is continuing to supplement the dossier with reliability data from prostheses operating continuously on test benches.

Following the PIVOTAL study, the clinical results will complete the final module of the CE marking dossier that will be submitted to DEKRA for validation, aiming to obtain CE marking in 2019.

- **Industrialization and market-access strategy**

CARMAT has opened its new, automated assembly plant in Bois-d'Arcy, near Paris. This site will meet the demands of industrial-pace production and the Company will launch, once the technical teams have been transferred, the manufacturing of prostheses to accompany the ramping up of enrollment in the PIVOTAL study. The opening of this automated site is perfectly in line with CARMAT's strategic transformation process into an industrial company. This complex project is being steered by a dedicated team and aims to implement best industrial practices in terms of organization, processes, and IT systems for maximum efficiency and quality.

Simultaneously, CARMAT is preparing for the marketing phase in close collaboration with partners who are experts in the market positioning and reimbursement of medical devices.

- **Clinical development in the United States**

The discussions between the Company and the FDA, the U.S. health authority, have led to the pre-submission of a dossier for an Early Feasibility Study (EFS). Once the FDA has the final application, and assuming the regulator and patient protection committee give a positive response, CARMAT will be able to initiate a first feasibility study in the United States. This feasibility study would be followed by a PIVOTAL study prior to the device being marketed on the US market.

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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® 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 (Matra Défense), 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 (Babaliala) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.), Groupe Therabel as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com

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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 registration document filed with the Autorité des Marchés Financiers under number D.18-0169 on March 22, 2018, 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 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.