



PRESS RELEASE

CARMAT completes patient enrollment in the first part of the PIVOTAL study in line with the objective of obtaining CE marking in 2019

- The implantation of 50% of the total number of planned patients marks the end of the first leg of the PIVOTAL study
- Appointment of Pr. Ivan Netuka and Pr. Finn Gustafsson as respectively Principal Investigator and Co-Principal Investigator of the second leg of the study
- Study pace in line with the objective of finalizing patient enrollment before end-2018

Paris, July 11, 2018 – 8.00 pm 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 provided an update on the progress of the PIVOTAL study.

Stéphane Piat, Chief Executive Officer of CARMAT, says: *“I am thrilled to announce that we have enrolled the 10th patient in the PIVOTAL study necessary for the obtention of the CE marking of the CARMAT total artificial heart. This marks the end of the first leg of the study and will allow us to start the second leg right away. The second part of the study includes 10 additional patients which we believe should be enough to file for CE marking. Thanks to the knowledge accumulated in treating the first 10 patients we are confident to further improve patient outcome in the next cohort. In order to support us in this mission, I am proud to announce that Pr. Ivan Netuka, Professor of Cardiac Surgery and Chairman of the Department of Cardiovascular Surgery at IKEM in Prague, has accepted to be the Principal Investigator of the second leg of the study and that Pr. Finn Gustafsson, Professor of Cardiology at Rigshospitalet hospital in Copenhagen, will support him as Co-Principal Investigator. Naturally, Pr. Christian Latrémouille, Professor of Cardiac Surgery and Chairman of the Department of Cardiac Surgery at the European Hospital Georges-Pompidou in Paris, will continue to support us with his invaluable experience of the CARMAT heart implantations. With the three international centers already active and those that should join shortly, we confirm our objective to reach 20 implanted patients by year-end.”*

• Completion of the first leg of the PIVOTAL study

The PIVOTAL study, authorized in France, Kazakhstan, the Czech Republic, and Denmark, is required to compile the Company's CE marking clinical dossier. Within the framework of this study, CARMAT expects to implant its bioprosthesis in approximately twenty patients with end-stage biventricular heart failure.

The PIVOTAL study is divided into two consequent parts (“legs”) with a cohort of approximately 10 patients each. The primary endpoint of the study is survival on a Carmat device at 180 days post-implant or survival to cardiac transplantation if occurring before 180 days post-implant.

To date, 10 patients have been implanted with the device, marking enrollment completion of the first leg of the study. The success of surgical procedures has been maintained at 100%, confirming a soundly acquired know-how and a strong expertise of the surgical teams in all participating centers.

- **Appointment of a Principal and Co-Principal Investigator for the second leg of the study**

Following the completion of the first part of the PIVOTAL study, CARMAT has appointed Pr. Ivan Netuka, Professor of Cardiac Surgery and Chairman of the Department of Cardiovascular Surgery at IKEM, Prague (Czech Republic) as Principal Investigator of the second leg of the study and Pr. Finn Gustafsson, Professor of Cardiology at Rigshospitalet hospital, Copenhagen (Denmark), as Co-Principal Investigator. The outstanding experience of the two leading experts in their respective field will contribute to a sustained high-quality patient management for the upcoming implantations of the CARMAT TAH within the final part of the study before filing for the CE marking. Pr. Christian Latrémouille, who has been at the very beginning of the clinical evaluation of the CARMAT device, will continue to support all the investigating centers.

Pr. Ivan Netuka, comments: *“I feel distinctly privileged by the unique opportunity to have already participated in the first leg of the PIVOTAL study. As stated by CARMAT, the learning curve is accelerating and I anticipate a broadening of our patient population while standardizing patient management protocols, which is another key element of the clinical study. I am convinced that our initial positive experience and gained confidence in the device performance will further facilitate the dynamics of patient enrollment.”*

Pr. Finn Gustafsson, adds: *“Advanced Heart Failure is a fast growing disease for which there are limited treatment options available today and I am excited to be involved in this project that might change the way we treat our patients in the future.”*

In order to maintain the sustained implantation rate, CARMAT should shortly expand the network of investigating centers to new countries and expects to finalize the PIVOTAL study implantations by the end of 2018.

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

The CE marking process with certification body, DEKRA, is progressing according to plan with all technical modules already completed. The last module, related to the clinical data, will be completed with the outcomes of the PIVOTAL study in order to be submitted to DEKRA for validation, with the aim to obtain CE marking for CARMAT TAH in 2019.

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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.