



## PRESS RELEASE

# CARMAT advances the internationalization of the PIVOTAL study and obtains the approval to perform implants in Denmark

**Paris, February 20, 2018 – 6.00 pm CET**

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 announces it has received the approval to perform, within the framework of the PIVOTAL study protocol approved by the ANSM (French national agency for the safety of medicines and health products), implants of its total artificial heart in patients at the Heart Center of the Rigshospitalet hospital, Copenhagen, Denmark.

The Heart Center of the Rigshospitalet is an internationally recognized center for the diagnosis and treatment of all types of heart diseases. It has developed a strong expertise in treating advanced heart failure and has participated in front-line clinical studies with innovative medical therapies and devices in this field. The study will be conducted by Professor Finn Gustafsson, a leading heart failure and transplantation cardiologist whose research focuses on the use of invasive hemodynamics in patients.

**Finn Gustafsson, MD, PhD, Professor of Advanced Heart Failure and Transplantation at the Heart Center and principal investigator of the study, comments:** *"As advanced heart failure and mechanical circulatory support is my main area of expertise, I am excited to evaluate the CARMAT artificial heart for the treatment of end-stage heart-failure patients. With its self-regulation and hemocompatibility, this device could potentially offer a real alternative to heart transplant."*

**Stéphane Piat, CEO of CARMAT, adds:** *"I am delighted that, shortly after Astana and Prague, the Heart Center of Copenhagen becomes the third international center to take part in our PIVOTAL study. The experience and enthusiasm of the teams makes us confident in starting patient recruitment shortly. We continue to pursue our strategy of creating a pool of highly specialized centers particularly recognized for their know-how in LVAD<sup>1</sup> studies and we expect to include three more centers in the upcoming months. This should allow us to sustain the patient enrollment pace in line with our objective of finalizing the PIVOTAL study by the end of this year."*

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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.

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<sup>1</sup> LVAD: Left Ventricular Assist Device

**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 (Babalialia) 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](http://www.carmatsa.com)

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**CARMAT**  
**Stéphane Piat**  
Chief Executive Officer

**Benoît de la Motte**  
Chief Financial Officer  
Tel.: +33 1 39 45 64 50  
[contact@carmatsas.com](mailto:contact@carmatsas.com)

**Alize RP**  
Press Relations

**Caroline Carmagnol**  
Tel.: +33 1 44 54 36 66  
[carmat@alizerp.com](mailto:carmat@alizerp.com)

**NewCap**  
Investor Relations &  
Strategic Communication

**Dusan Oresansky**  
**Emmanuel Huynh**  
Tel.: +33 1 44 71 94 94  
[carmat@newcap.fr](mailto:carmat@newcap.fr)



Name: **CARMAT**  
ISIN code: **FR0010907956**  
Ticker: **ALCAR**

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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 filed with the Autorité des Marchés Financiers under number D.16-0200 on March 22, 2017, and in an update to the Registration Document of the Company filed with the AMF on December 4, 2017 under number D.17-0200-A01, 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.*