



## PRESS RELEASE

### **CARMAT receives approval to resume patient enrollment in the PIVOTAL study in Denmark**

- CARMAT has received the approval of the Danish health authority and the ethical committee of the Rigshospitalet hospital in Copenhagen following the prosthesis production process changes
- The Company is continuing discussions with the competent authorities in Kazakhstan and the Czech Republic with a view to resuming the enrollment process in the other two clinical centers

#### **Paris, August 28, 2019 - 7.00 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 announces the first approval to resume patient enrollment for the second part of the PIVOTAL study in Denmark.

With Kazakhstan and the Czech Republic, Denmark was the third country outside France where CARMAT had the necessary authorizations to conduct the first part of the PIVOTAL study. Following the changes implemented at prosthesis manufacturing process level, the Company was obliged to resubmit clinical trial authorization requests in these countries. The competent authorities in Denmark are the first to give CARMAT their approval to continue the clinical study with the new prostheses produced exclusively on the Bois-d'Arcy site. The implants will be performed at the Rigshospitalet's Department of Cardiology in Copenhagen in accordance with the requirements of its ethical committee.

**Stéphane Piat, Chief Executive Officer of CARMAT, says:** *"Following the production process changes successfully implemented and industrialized at the end of the first half of 2019, our aim was to resume implants within the framework of the PIVOTAL study by the end of the third quarter of 2019. This approval in Denmark allows us to be in line with our roadmap. I firmly believe that the teams headed by Prof. Finn Gustafsson, Co-Principal Investigator for the second part of the PIVOTAL study, will put all of their expertise into serving the first Danish patients who will receive our new prosthesis. Given its sturdiness and the recent positive autoregulation results, we are confident that we can meet the requirements of patients awaiting a heart transplant and those who are not eligible for a transplant. Furthermore, we are continuing our active discussions with the authorities and investigation centers in Kazakhstan and the Czech Republic in order to rapidly finalize the enrollment of the second patient cohort in the PIVOTAL study and submit the full clinical file to the DEKRA certification body with a view to obtaining CE marking in 2020".*

...

## 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 (Lohas) 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)

•••

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

**Pascale d'Arbonneau**  
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 6 64 18 99 59  
[carmat@alizerp.com](mailto:carmat@alizerp.com)

**NewCap**  
Investor Relations &  
Strategic Communication

**Dusan Oresansky**  
**Alexia Faure**

Tel.: +33 1 44 71 94 94  
[carmat@newcap.eu](mailto:carmat@newcap.eu)



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

•••

## 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 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 registration document filed with the Autorité des Marchés Financiers under number D.19-0135 on March 12, 2019, 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.*