



## PRESS RELEASE

# CARMAT announces a delay in the resumption of production of prostheses for the PIVOTAL study

**Paris, April 10, 2019 – 7.00 am CEST**

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, today announces a delay in the resumption of the PIVOTAL study.

Following the experience accumulated with the first cohort of its PIVOTAL study, CARMAT took the decision to suspend production of its prosthesis in order to strengthen certain manufacturing processes. Full production was initially scheduled to resume by April 2019 at the latest, with the 2<sup>nd</sup> cohort of the PIVOTAL study being implanted from May 2019.

CARMAT has recently collected additional data and, to avoid any risk of potential malfunctions, has decided to await the definitive results of the analysis of this latest data to check whether the changes made to the production process do indeed provide a response to all identified problems. As a result of this decision, a delay is expected in the resumption of implants within the framework of the PIVOTAL study compared with the initial schedule although, as yet, it is not possible to determine the precise length of this delay.

The continuous improvement in production procedures is a common practice in the medical device industry, and CARMAT has devoted substantial resources to this issue since October 2018. Once the analysis of all available data has been completed, CARMAT is planning to publish an updated schedule regarding the resumption of the production process and the PIVOTAL study, once it has obtained prior approval from the relevant authorities if necessary.

Given the significant positive results in terms of the benefits enjoyed by the first patient cohort enrolled in the PIVOTAL study, CARMAT remains confident and focused regarding its ability to provide patients suffering from end-stage biventricular heart failure with a prosthesis with a more robust quality profile.

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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 (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)

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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.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.*