

## PRESS RELEASE

# CARMAT announces the resumption of production of prostheses for the PIVOTAL study

### Paris, May 21, 2019 - 5.45 pm 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 the resumption of the production of prostheses for the PIVOTAL study.

Following the analysis of information gathered from the experience accumulated with the first cohort of its PIVOTAL study and data recorded on test benches, CARMAT has implemented a number of changes to its manufacturing processes, including the transfer of all production activities to the Bois d'Arcy site, mainly to avoid a risk of malfunctions that could affect the electronic module of the prosthesis.

The prostheses that will be used for patients in the second cohort of the PIVOTAL study will come exclusively from the Bois d'Arcy production site where the new procedures are now applied.

Given these changes, CARMAT is planning to resume implants within the framework of the PIVOTAL study by the end of the third quarter of 2019, subject to prior approval from both the appropriate authorities in the 3 countries in which the second part of the PIVOTAL study has been authorized so far (Czech Republic, Denmark and Kazakhstan) and the ethical committees of the hospitals that are participating in the study.

Once the second cohort (10 patients) has been completed, CARMAT will submit its clinical dossier to the DEKRA certification body with a view to obtain CE marking in 2020.

Given the significant positive results obtained from the first cohort of the PIVOTAL study in terms of the benefits for patients, as well as the changes it has made to its manufacturing processes, CARMAT remains determined and confident regarding its ability to provide patients suffering from end-stage biventricular heart failure with a safe and effective therapeutic solution.

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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

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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.