



## PRESS RELEASE

### CARMAT granted authorization to resume the PIVOTAL study in Kazakhstan

- The Company has received the approval of the Kazakhstan health authority and the ethics committee of the National Research Center for Cardiac Surgery in Nur-Sultan, which has substantial experience with the CARMAT device
- The study can now be conducted simultaneously in 3 countries

**Paris, December 2, 2019 – 7.00 am 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 announced that it has received authorization to resume the PIVOTAL study in Kazakhstan.

The implants will be performed at the *National Research Center for Cardiac Surgery* in Nur-Sultan (formerly called Astana), where the teams, led by Professor Yuri Pya, have successfully implanted the CARMAT device during the first part of the PIVOTAL study. Furthermore, several bridge-to-transplant surgeries conducted in this center demonstrated the ability of its surgical teams to successfully manage the explant procedure of the device as a donor heart becomes available. With authorizations in Kazakhstan, the Czech Republic and Denmark, the Company aims to complete enrollment of the second cohort of patients in the PIVOTAL study in order to obtain CE marking in 2020.

**Stéphane Piat, Chief Executive Officer of CARMAT, said:** *"We are pleased to announce that we have been given the approval to enroll new patients in Kazakhstan. Together with the teams in Nur-Sultan, we are actively preparing for upcoming implants. With this approval, we reach our objective to resume the study at a center experienced both with device implantation and explant for transplant-eligible patients."*

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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, composed of the implantable bioprosthesis and its portable external power supply system to which it is connected, 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.

**The first physiological artificial heart:** given its size, the use of highly biocompatible materials, its unique self-regulation system and its pulsatile nature, the CARMAT total artificial heart could, assuming the clinical trials are successful, potentially save the lives of thousands of patients each 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:** Matra Défense SAS (subsidiary of the Airbus Group), 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), of Dr. Antonino Ligresti (Santé Holdings S.R.L.), of the Gaspard family (Corely Belgium SPRL and Bratya SPRL) and of M. Pierre-Edouard Stérin (BAD 21 SPRL), 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.*