

## PRESS RELEASE

# CARMAT granted authorization to resume the PIVOTAL study in the Czech Republic

- The Company has received the approval of the Czech health authority and the ethics committee of the IKEM center in Prague, which has substantial experience with the CARMAT device
- CARMAT is in advanced talks to also resume the study in Kazakhstan

### Paris, November 19, 2019 – 5.45 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 announced that it has received authorization to resume the PIVOTAL study in the Czech Republic.

The implants will be performed at the Institute of Clinical and Experimental Medicine (IKEM) in Prague, whose teams have benefited from a major learning curve acquired through implanting the CARMAT device during the first part of the PIVOTAL study. The screening for the second patient cohort, who will receive the new prostheses produced at the Bois-d'Arcy site, is already underway. The Company is also in advanced talks with the Kazakhstani health authorities regarding the resumption of the study at the National Research Center for Cardiac Surgery in Nur-Sultan (formerly called Astana). With authorizations in these strategic countries, given the experience they have acquired to date with the CARMAT artificial heart, and Denmark, the Company is aiming to intensify enrollment in the PIVOTAL study in order to finalize it as soon as possible and obtain CE marking in 2020.

**Stéphane Piat, Chief Executive Officer of CARMAT, said:** "We are pleased to announce that we have been given approval to enroll new patients in the Czech Republic. In close collaboration with the teams of the IKEM cardiac center in Prague, we are already preparing for upcoming implants. This approval was eagerly expected, as our will was to resume the study at an experienced center before including other facilities. Following this key authorization for our project, we also expect a rapid resumption in Kazakhstan."

#### 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<sup>®</sup> 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

•••

CARMAT Stéphane Piat Chief Executive Officer

Pascale d'Arbonneau Chief Financial Officer Tel.: +33 1 39 45 64 50

Tel.: +33 1 39 45 64 50 <u>contact@carmatsas.com</u> Alize RP Press Relations

NewCap

Investor Relations &

**Dusan Oresansky** 

**Alexia Faure** 

Strategic Communication

Tel.: +33 1 44 71 94 94 carmat@newcap.eu

#### **Caroline Carmagnol**

Tel.: +33 6 64 18 99 59 carmat@alizerp.com



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.