PRESS RELEASE

CARMAT announces FDA full approval to initiate US clinical feasibility study of its total artificial heart

- CARMAT has responded to all remaining questions from the conditional approval
- Number of subjects to be enrolled in the study extended to 10 patients

Paris, February 5, 2020 – 5:45 pm CET

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, announces that the US Food and Drug Administration (FDA) has fully approved the Company's Investigational Device Exemption (IDE) application to start a US Early Feasibility Study (EFS) of its total artificial heart.

The amended EFS protocol includes 10 transplant-eligible subjects limited to a network of 7 US renowned institutions. The primary endpoint of the study is patient survival at 180 days post-implant or a successful cardiac transplantation within 180 days post-implant. It is a staged study with a progress report of the first 3 patients after 60 days, before the enrollment of the next 7 patients.

CARMAT also obtained conditional approval from two Institutional Review Boards (IRB) and this full FDA approval enables the company to accelerate the discussions with the other IRB and research contract offices at the 7 sites. The company is also working closely with the Centers for Medicare & Medicaid Services (CMS) to obtain a coverage of the costs of the trial, with the objective to start patient enrolment in Q4 2020.

CARMAT will present the EFS protocol at the 2020 symposium on mechanical support for the heart and lung of the American Association for Thoracic Surgery (AATS) on February 14, 2020, in Houston (Texas).

Stéphane Piat, Chief Executive Officer of CARMAT, said: *"The full approval to initiate a US study marks another milestone for CARMAT and confirms the trust of the FDA in our ability to conduct the feasibility study of the first bioprosthetic artificial heart in the United States. Considering the ongoing approval procedures with the Institutional Review Boards at the selected centers and discussions on the potential reimbursement of the treatment costs, we expect patient enrolment to start in Q4 2020."*

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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*

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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.*