PRESS RELEASE

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

- CARMAT provided sufficient data to support the initiation of a human clinical study
- Study to include 5 patients in selected renowned US institutions

Paris, September 12, 2019 – 6.00 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, announces that the US Food and Drug Administration (FDA) has conditionally approved[1] the Company's Investigational Device Exemption (IDE) application to initiate a US Early Feasibility Study (EFS) of its total artificial heart.

The EFS protocol includes 5 transplant-eligible subjects limited to a network of 7 US renowned institutions. CARMAT will submit study documents to the Institutional Review Boards (IRB) of the selected study sites and may begin enrolling patients in the study upon the first IRB approval.

CARMAT is invited to present the protocol of the EFS at the 2019 symposium on mechanical support for the heart and lung of the American Association for Thoracic Surgery (AATS) on September 20, 2019 in Houston (Texas).

Stéphane Piat, Chief Executive Officer of CARMAT, says: "*The conditional approval to start a US study marks a significant milestone for CARMAT and the mechanical circulatory support field in general. This approval demonstrates the confidence of the FDA in our ability to conduct this feasibility study and reflects the high need for a safe and efficient solution for patients suffering from biventricular heart failure while waiting for a donor heart. We have already selected potential study sites and will immediately begin the submission process with the IRBs and research contract offices.*"

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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.

[1] If an IDE application is approved with conditions, the sponsor may begin subject enrollment with the number of subjects and investigational sites specified in FDA's decision letter upon receipt of Institutional Review Board (IRB) approval.

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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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.*