PRESS RELEASE

CARMAT presents positive interim results of the first part of its PIVOTAL study

Paris, January 15, 2019 – 8.00 am 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, today announced an update on its clinical progress and recent developments, as well as its cash position at December 31, 2018.

Stéphane Piat, Chief Executive Officer of CARMAT, says: *"Ten years after the creation of the Company, we are pleased to present today the results of the first cohort of 10 patients included in the PIVOTAL study. This is the tangible realization of Professor Carpentier's vision that, at the time, was a challenge that seemed almost impossible to meet. Thanks to the work and tenacity of a group of men and women with unlimited commitment, we have successfully achieved the primary endpoint of the study for 70% of patients with 6 months of support provided by our bioprosthesis or the successful progress towards heart transplant. These interim data confirm that our bioprosthetic heart respects the physiology of the human body, and thus enables to avoid the complications typically observed with other technologies. This is a unique scientific and technological breakthrough that could help cope with the problem of end-stage heart failure, a major pathology that is becoming increasingly prevalent. We can assert that CARMAT has today reached a major milestone in its development enabling us to address the future with renewed confidence."*

- **Positive interim results of the first part of the PIVOTAL study**

The interim analysis concerned the 10 patients of the first cohort of the PIVOTAL study, the first of whom was enrolled in August 2016 and the last in July 2018. Altogether, the study foresees the enrollment of 20 patients suffering from end-stage biventricular heart failure.

70% of the patients in this first cohort reached the study's primary endpoint, corresponding to six-month survival with the bioprosthesis or a successful heart transplant within 6 months after device implant. By comparison, this rate was only of 50% for the feasibility study and 54-62% for the only total artificial heart currently on the market[1].

The data collected from the patients having achieved the study's primary endpoint again confirm the biocompatibility of the CARMAT prosthesis, already proved during the feasibility study, and notably its positive safety profile, never before achieved by other technologies, with the absence of cerebrovascular

[1] Kirklin JK et al, J Heart Lung Transplant 2018;37:685-691. Arabia F et al, J Heart Lung Transplant, 2018;37:1304–1312

accidents, gastrointestinal bleeding or infections due to the percutaneous cable. Furthermore, these patients only required light anticoagulant therapy.

The device has moreover proven its ability to respond to changes in the patient's physical effort by modifying the flow, confirming that the self-regulation system works correctly.

- **Ongoing enrollment of the second cohort of patients**

Patient enrollment for the second part of the PIVOTAL study began in accordance with the protocol in September 2018 in international medical centers, under the guidance of Principal Investigator Prof. Ivan Netuka (Chair of the Department of Cardiovascular Surgery at the IKEM institute in Prague, Czech Republic) and Co-Principal Investigator Prof. Finn Gustafsson (Rigshospitalet, Copenhagen, Denmark).

To date, the cumulative support time of the CARMAT heart within the framework of the PIVOTAL study has reached 5 years in the 11 implanted patients. This accumulated experience shows the ability of the CARMAT technology to provide a long-term solution for patients suffering from end-stage biventricular heart failure, along with a substantial improvement in their quality of life.

The analysis of the collected data, representing over 20 years of cumulative operating between the clinical study and the reliability tests benches, has made it possible to identify aspects in which the manufacturing process could be improved, essentially concerning the control of the integrity of the prosthesis and the cleanliness of its technical compartment.

The implementation of these corrective actions required the production – and therefore implants – to be suspended in the fourth quarter of 2018. Production has recently resumed and the new prostheses will be available from April.

The Company is currently validating additional clinical centers in two more countries in order to rapidly complete the enrollment of the second patient cohort and submit the CE marking dossier in early 2020. The PIVOTAL clinical data represents the final element needing to be added to the CE marking dossier prior to its submission to the DEKRA notified body.

- **Progress in the clinical development strategy in the United States**

Since the submission of an Investigational Device Exemption (IDE) application for an Early Feasibility Study (EFS) in 2018, CARMAT has been holding constructive talks with the FDA (Food & Drug Administration, the United States health authority). Significant progress has been made, and the file should be supplemented with biocompatibility tests on a certain number of prostheses currently in production. This enables CARMAT to envision – assuming the FDA validates our application – the launch of implants in American patients by the end of 2019. The selection of clinical centers and the formation of scientific committees are ongoing.

- **Solid financial structure**

CARMAT had cash and marketable cash instruments of €25.2 million at December 31, 2018, versus €44.0 million at June 30, 2018, reflecting:

- cash burn of €19.7 million over the period;
- drawdowns on the contingent equity lines subscribed to with Kepler Cheuvreux for a gross total of €0.9 million. Within the framework of this contract, CARMAT has access to an additional €24.2 million of financing that could be exercised depending on its requirements and on market conditions over the coming 36 months[2].

Given the recent non-dilutive financing in the form of a €30 million loan granted by the European Investment Bank (EIB), CARMAT has the necessary financial resources to support its clinical and industrial developments and prepare the commercial phase.

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About CARMAT: the world's most advanced total artificial heart project

[2] Assuming full drawdown of this equity financing line, a shareholder with a 1.00% stake in CARMAT prior to its implementation would see their stake reduced to 0.91% on a non-diluted basis

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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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.18-0169 on March 22, 2018, 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.*