PRESS RELEASE

CARMAT: the feedback after 6 years and 8 months of cumulative support shows a constant improvement in the clinical outcomes of patients in the PIVOTAL study

- 73% of patients achieved the primary endpoint of the study
- Considerable strengthening of the prosthesis' 6-month safety profile, with no adverse events in the latest patients
- To date, the prosthesis has achieved a record duration of over 20 months of individual support

Paris, November 6, 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 published an update on the progress of its clinical experience within the framework of the PIVOTAL study.

Stéphane Piat, Chief Executive Officer of CARMAT, said: *"As we prepare to resume the PIVOTAL study in the coming weeks, I am delighted to observe that the results recorded with the first 11 patients, very encouraging, continue to strengthen the future positioning of CARMAT as a credible and efficient therapy to provide a response to the issue of biventricular heart failure. Indeed, it is extremely rare to generate such conclusive results as quickly as this in clinical research. In addition to achieving a high 6-month survival rate, we have also significantly reduced perioperative bleeding in the last three patients, while avoiding the risk of cerebrovascular accidents, gastrointestinal bleeding or infections associated with the percutaneous power cable. These compelling results should enable us to rapidly obtain the necessary authorizations in the Czech Republic and Kazakhstan, where we intend to resume the study by capitalizing on the level of experience they have acquired during the first part of the study".*

The primary endpoint of the study, corresponding to 6-month survival with the bioprosthesis or a successful transplant within 6 months after device implant, was achieved in 73% of the first 11 patients enrolled in the PIVOTAL study. By comparison, this rate was just 50% during the feasibility study (4 patients), and is 54-62% for the only total artificial heart currently on the market[1] and 46%-68% for mechanical biventricular circulatory support systems[2].

The analyses of the secondary objectives of the PIVOTAL study also help establish excellent 6-month safety profile of the prosthesis. Indeed, no adverse effects related to the device, such as a cerebrovascular accident, gastrointestinal bleeding or infections associated with the percutaneous power cable, have been observed. Perioperative bleeding was observed in just 36% of patients, a lower rate

[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
[2] Lavee J et al, J Heart Lung Transplant 2018;37:1399−1402. Arabia F et al, Ann Thorac Surg 2018;105:548–56

than that of the only total artificial heart currently on the market (41%)[3]. Furthermore, applying the new protocol has helped totally eliminate perioperative bleeding in the last three patients.

The device has also proven its ability to respond to variations in the patient's physical efforts by automatically modifying the flow, confirming that the self regulation system works correctly.

Moreover, excellent results have been observed in patients eligible for a heart transplant: following between 3 and 10 months of support with the CARMAT artificial heart, 5 patients have received a new heart following a successful explantation procedure.

Patients in the study who are continuing to benefit from the support of the bioprosthesis have seen their quality of life improve thanks to the portable system that has enabled them to swiftly return home and regain their mobility.

To date, the maximum duration of individual support is over 20 months, which is particularly encouraging for the second part of the study given the technical enhancements made to the new generation of prostheses manufactured at the Bois-d'Arcy plant.

Meet Stéphane Piat at the "Direct Dirigeants" presentation tonight, November 6 at 6pm:

Auditorium du Groupe Les Echos
10 boulevard de Grenelle – 75016 Paris

To know more about the event

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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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[3] Kirklin JK *et al.*, JHLT 2018;37:685-691. Arabia F *et al.*, JHLT, 2018;37:1304–1312. Demondion P *et al.*, EJCS. 2013 Nov;44(5):843-8

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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.*