CARMAT

PRESS RELEASE

CARMAT provides an update regarding the suspended PIVOTAL study on its bioprosthetic artificial heart

Paris, February 6, 2017 (8:30 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 provides an update on the suspension of the Pivotal study on its artificial heart.

As indicated in the press release of November 30, 2016, the Company confirmed that the prosthesis functioned correctly during its use by the 1st patient in the PIVOTAL study. However, CARMAT feels important to provide details regarding the patient's death in order to rectify certain information published in today's press. Indeed, the patient's death was due to an interruption in the power supply system, following an incorrect battery handling by the patient, as a result of which the prosthesis stopped functioning. CARMAT's Support-Training teams are actively working on this aspect relating to post-operative monitoring in order to increase safety for the next patients.

During the various discussions held with the ANSM regarding the resumption of the trial, it became clear that the requested scope of analysis was broader that that undertaken by the Company. Given the nature of the remaining issues, CARMAT was not in a position to meet the requirements within the stated timeframe. In order to give itself the necessary time to provide the elements required for the most comprehensive answer possible, the Company has decided to withdraw its initial request to resume the trial, in compliance with established procedures with the intention of filing a new request in the near future with the required items. The PIVOTAL study carried out in France will remain suspended until ANSM accepts this new application.

"The prosthesis functioned normally during the last three implants, thus strengthening our incentive to provide a suitable response for patients facing total therapeutic stalemate. Our confidence is further enhanced by the fact that the results provided by the self-regulating system used during the last implant have been very encouraging", says Stéphane Piat, CEO of CARMAT.

Next press release:

2016 annual results, on Tuesday February 14, 2017, before market.

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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.

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: <u>Airbus Group</u> (Matra Défense), Professor <u>Alain Carpentier</u>, the <u>Centre Chirurgical Marie Lannelongue</u>, <u>Truffle Capital</u>, 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 (ZAKA) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.) as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: <u>www.carmatsa.com</u>

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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* filed with *the Autorité des Marchés Financiers* under number D.16-0221 on March 29, 2016 and 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.

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