



## PRESS RELEASE

### FAVORABLE OPINION FROM THE PATIENT PROTECTION COMMITTEE FOR THE CLINICAL TRIAL PROTOCOL

### OBJECTIVE OF CARRYING OUT THE FIRST HUMAN IMPLANT DURING THE FIRST PART OF 2012

**Paris, November 28, 2011**

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced project of total artificial heart, announced today that it has been given the go-ahead from the Patient Protection Committee (*Comité de Protection des Personnes*, Ile-de-France III, opinion no. 2925) for the first clinical trial in France involving the implantation of the total artificial heart in patients. Meanwhile, the review of its application for authorization of the clinical trials by the French Health Authority (AFSSAPS, *Agence Française de Sécurité Sanitaire des Produits de Santé*), is progressing as anticipated. CARMAT recently added the positive results of the biocompatibility and sterility tests to its submission. The Company is also completing the tests for the preclinical trials, including the endurance tests of the implantable prostheses on the test benches. In addition, it has stepped up its efforts to finalize and validate the complex software required for the clinical trials.

Marcello Conviti, CARMAT's Chief Executive Officer, commented: *"The favorable opinion from the Patient Protection Committee and our progress with the preclinical tests represent a key milestone and support our confidence in the CARMAT heart and the proximity of its first human implantations"*. He added: *"They will take place either during the first or second quarter, depending on CARMAT, the AFSSAPS, the surgeons and patients. After more than 15 years of rigorous development work, it is important not to cut any corners on the final stages to maximize the chances of success for patients and for CARMAT."*

- **Favorable opinion from the Patient Protection Committee**

The favorable opinion from the Patient Protection Committee (*Comité de Protection des Personnes*, Île-de-France III, opinion no. 2925) covers the ethical aspects of the trial protocol and patient consent. The trial protocol identifies a profile of emergency patients for whom all the therapeutic options have been exhausted and provides for in-depth monitoring in a hospital environment for the first month and on a monthly basis thereafter. The favorable opinion from the Patient Protection Committee is valid nationwide at all the centers participating in the biomedical research on CARMAT's artificial heart. This represents one of the two authorizations required for the Company to be able to start the process of the clinical trials, the second being AFSSAPS clearance.

- **Data added to the AFSSAPS submissions**

In parallel, as part of the pre-submission procedure for innovative technologies, CARMAT continues to provide the AFSSAPS with data for its application, which is currently under review. The functional tests that were launched several years ago are continuing. The additional information supplied to the AFSSAPS today comprises highly satisfactory data from biocompatibility and sterility tests conducted on the bioprosthesis, its components and its manufacturing process.

- **Securing the next steps**

The tests yet to be submitted to the AFSSAPS notably involve the endurance of the full system comprising the prosthesis and its external components. The endurance data is generated as and when the systems complete certain periods of time on the test benches (continuous operation of the artificial heart).

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

**The only credible response for all cases of end-stage heart failure, which is a real public health issue:** CARMAT's aim is to be able to 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. Indeed, this disease currently affects over 100 million patients in developed countries. 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 heart failure.

**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 EADS, 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 upcoming clinical trials are successful, potentially benefit the lives of tens of thousands of patients a year whilst ensuring there is no risk of rejection and providing them with an unparalleled 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 OSEO; a total of €33 million.

**Strongly committed, prestigious founders and shareholders:** Truffle Capital (the leading European venture capital firm), EADS, the Foundation Alain Carpentier and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

**For more information:** [www.carmatsa.com](http://www.carmatsa.com)

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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 registered with the Autorité des Marchés Financiers under number R.11-017 on April 27, 2011 and the Note d'Opération that was approved with visa no. 11-308 on July 11, 2011, 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 AFSSAPS, enroll patients, obtain satisfactory clinical results, perform the clinical trials and tests required for CE marking and to obtain the CE mark.



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