



## PRESS RELEASE

# Approval to resume the first-in-man trial with CARMAT's bioprosthetic heart

Paris, July 16, 2014

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, providing a therapeutic alternative for people suffering from end-stage heart failure, today announces that it has obtained approval to resume the first-in-man trial with its bioprosthetic heart.

Patient enrollment was put on hold by the Company in March 2014 to allow data from the first implanted prosthesis to be analyzed.

The *comité de protection des personnes* (ethics committee), the data and safety monitoring board<sup>1</sup> and the regulatory authorities gave a favorable opinion regarding resumption of the enrollment of the next three patients planned in this first clinical trial.

The Company would like to remind readers that, subject to regulatory obligations or specific circumstances, it is not planning to publish any information on the interim results of this ongoing clinical trial.

*"The quality of the work from all participants for the collection and analysis of data on the first bioprosthesis implanted in a patient enabled the implementation of additional measures to continue the trial under the best safety conditions",* says Marcello Conviti, Chief Executive Officer of CARMAT.

### About 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 20 million patients in Europe and the United States. 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 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 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 Bpifrance; a total of €33 million.

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<sup>1</sup> The DSMB (Data and Safety Monitoring Board), whose role is to review all data pertaining to the trial and to give the sponsor its recommendation regarding the resumption of enrollments in the clinical trial.

**Strongly committed, prestigious founders and shareholders:** [Truffle Capital](#), a leading European venture capital firm, [Airbus Group](#), Professor [Alain Carpentier](#), the [Centre Chirurgical Marie Lannelongue](#) 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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#### 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.14-045 on March 17, 2014 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 ANSM, 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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