



PRESS RELEASE

CARMAT has obtained the necessary approvals to begin the PIVOTAL study in France

Paris, July 13, 2016

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced artificial heart project, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, announces that it has obtained the necessary approvals from the *Comité de Protection des Personnes* (CPP, the patient protection committee) and the *Agence Nationale de Sécurité du Médicament et des produits de santé* (ANSM, the French national agency for the safety of medicines and health products) to begin the PIVOTAL study in France.

In this clinical study, patients who are eligible for a transplant but who have a very low likelihood of receiving a donor heart will also be able to benefit from a CARMAT heart.

Simultaneously, CARMAT has begun procedures to obtain approval to implant its artificial heart in other European countries.

"The favorable opinion received from the CPP and the approval obtained from the ANSM confirm the merits of our research and the expected conclusions", **comments Dr Piet Jansen, CARMAT's Medical Director.**

"This approval to launch the PIVOTAL study represents a crucial milestone for CARMAT. It is part of the CE marking process that we have initiated. The results of the trials undertaken in France and elsewhere in Europe will be included in the clinical module of the dossier whose assessment has been entrusted to DEKRA", **adds Marcello Conviti, Chief Executive Officer of CARMAT.**

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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: [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 (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: www.carmatsa.com



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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