



## PRESS RELEASE

# CARMAT has begun, with DEKRA, the CE certification process for its bioprosthetic artificial heart

**Paris, June 23, 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 signed with DEKRA, a global leader in certification services, a contract to assess CARMAT's design dossier and quality management system with a view to obtaining CE Marking.

This assessment, preceding the marketing of the CARMAT prosthesis, aims to ensure its compliance with European regulatory requirements.

*"CE Marking is a demanding course involving the analysis and validation of a dossier covering every aspect of the CARMAT system's design, production, quality and clinical efficacy. Given its unique expertise in the field of cardiovascular biomaterials, DEKRA was the natural choice to assess our design dossier",* **says Dr. Piet Jansen, CARMAT's Medical Director.**

**Marcello Conviti, Chief Executive Officer of CARMAT, concludes:** *"Obtaining CE Marking paves the way for the commercial phase of our Company's development. It is a major step towards making our bioprosthetic heart available to patients to treat end-stage heart failure. To successfully complete it, we have technical and clinical data from the test phases and the first-in-man feasibility trial, a competent and committed team, top-tier industrial partners, trained surgical centers and - thanks to the funds recently raised - a robust financial structure. The clinical data from the pivotal study, which will be able to begin once the necessary approvals have been received, will of course represent a key part of the dossier."*



### **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](http://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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