PRESS RELEASE

CARMAT obtains ANSM approval in France to carry out the first human implants of its bioprosthetic artificial heart

- The ANSM approves CARMAT's Clinical Trial Application.
- Patient selection starts in all trained centers.

Paris, September 24, 2013

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, providing an alternative for people suffering from terminal heart failure, announces that the *Agence Nationale de Sécurité du Médicament et des produits de santé* (ANSM, French health authority) has authorized the Company to carry out the first human implants of its bioprosthetic artificial heart on four patients in three approved French hospitals.

• ANSM approval

The approval just received from the ANSM confirms the pertinence of the responses provided by CARMAT's technical and clinical teams regarding every aspect of the dossier.

Professor Alain Carpentier, CARMAT's co-founder and Scientific Director, comments: "*I would like to emphasize the high quality of our interactions with the ANSM. The latter was able to grasp the precautions taken by CARMAT to promote the security of the patients who will benefit from the CARMAT bioprosthesis and thus get a new lease of life. Praise should go to our teams of engineers, technicians and clinicians who made certain that this prosthesis is based on sound scientific principles aimed at ensuring exemplary functionality and durability. Now we have passed this milestone, we will be able to fully focus on the success of the clinical phase in France and in other countries.*"

• Preparation of the launch of the 1st clinical phase

For the record, three French centers have been trained and are ready to participate in the 1st phase of the clinical trials: the Georges Pompidou European Hospital in Paris, the Marie Lannelongue Surgical Center in Plessis-Robinson and the Laënnec-Nord University Hospital in Nantes. The teams of these three centers can immediately begin the patient-selection process. Patient eligibility will be assessed in accordance with the profile defined within the ANSM-approved protocol.

Meanwhile, the process started in May in four centers abroad is on-going, with regards to training, relations with the surgical teams and the local authorities, and patient screening.

Marcello Conviti, Chief Executive Officer of CARMAT, says: "*I would like to thank the ANSM, with which we have had very rewarding interactions, the clinicians involved in preparing the study and our shareholders, whose patience and support have been rewarded. We are touched and eager to be able to propose replacing a patient's sick heart with a CARMAT heart.*"

• Execution of the 1st clinical phase and communication

The biomedical research approved by the ANSM is a feasibility study on four patients. Its success will be assessed particularly by the 1-month survival rate or the patient's bridging to transplantation if he or she is eligible. The Company does not currently anticipate any major problems recruiting patients for this initial study. Obviously, as with any highly-innovative medical device, clinical development could encounter unforeseen events and will shape the progress towards the product's marketing phase.

The publication of intermediate and final results will be carried out in strict compliance with ethical and regulatory factors, and in accordance with the recommendations of the various independent committees that will analyze and monitor the study, as well as CARMAT's Scientific Committee.

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 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 Bpifrance; a total of €33 million.

Strongly committed, prestigious founders and shareholders: Truffle Capital, a leading European venture capital firm, EADS, the Fondation 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*

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