



PRESS RELEASE

CARMAT obtains approval for the reimbursement of its total artificial heart during the US clinical feasibility study

Centers for Medicare & Medicaid Services (CMS) confirms coverage of the device and routine care items and services

Paris, May 13, 2020 – 5.45 pm CEST

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, announces that the "Centers for Medicare & Medicaid Services" (CMS) has approved coverage of the device and routine care items and services supplied to Medicare beneficiaries to be enrolled in the clinical feasibility study.

The approval confirms the Food and Drug Administration (FDA) Category B designation of the device, which refers to a non-experimental/investigational device for which initial questions of safety and effectiveness have been resolved. It enables the company to accelerate its discussions with the purchase departments, research contract offices and institutional review boards (IRB) at the 7 sites selected for the study. As a reminder, CARMAT has already obtained the conditional approval of two IRB.

The study aims to include 10 transplant-eligible patients, and the primary endpoint corresponds to patient survival at 180 days after the implant or a successful heart transplant within 180 days of the implant.

Stéphane Piat, Chief Executive Officer of CARMAT, said: *"This approval of CMS coverage marks a very important milestone for CARMAT, as it substantially supports its development in the United States. Indeed, hospitals will be able to receive payments for the device, routine care items and services during the clinical study. Given the ongoing discussions at the study centers, and subject to the positive evolution of the COVID-19 situation, we expect patient enrolment to begin in Q4 2020, as planned."*

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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, composed of the implantable bioprosthesis and its portable external power supply system to which it is connected, 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.

The first physiological artificial heart: given its size, the use of highly biocompatible materials, its unique self-regulation system and its pulsatile nature, the CARMAT total artificial heart could, assuming the clinical trials are successful, potentially save the lives of thousands of patients each 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: Matra Défense SAS (subsidiary of the Airbus Group), 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 (Lohas), of Dr. Antonino Ligresti (Santé Holdings S.R.L.), of the Gaspard family (Corely Belgium SPRL and Bratya SPRL) and of M. Pierre-Edouard Stérin (BAD 21 SPRL), Groupe Therabel as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com

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CARMAT
Stéphane Piat
Chief Executive Officer

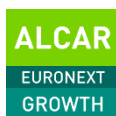
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Name: **CARMAT**
ISIN code: **FR0010907956**
Ticker: **ALCAR**

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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 Universal registration document filed with the Autorité des Marchés Financiers on March 13, 2020 under number D.20-0126 as well as 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.