



PRESS RELEASE

CARMAT provides update on the US Early Feasibility Study

- Three US centers successfully trained in November
- Commercial configuration of CARMAT prosthesis in final stage of approval by the FDA
- First enrolment in the study postponed to Q1 2021, and completion of the enrolment of the study still expected by end-2021

Paris, November 26, 2020 – 7 am CET

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, aiming to fulfill an unmet medical need by providing a therapeutic alternative to people suffering from end-stage biventricular heart failure, today provides an update on its early feasibility study (EFS) in the United States.

The EFS was fully approved by the US Food and Drug Administration (FDA) in February 2020 and CARMAT obtained the approval from the Centers for Medicare & Medicaid Services (CMS) for the reimbursement of the device and associated services within the framework of this study in May 2020.

In order to be able to use the “commercial configuration” of its artificial heart in the study, CARMAT submitted certain amendments to the FDA. The company believes that this latest version of the prosthesis should improve patient safety and quality of life. At this stage, thanks to a very constructive collaboration with the FDA, 8 amendments out of 9 have already been approved, and the last one should be approved in the coming weeks.

CARMAT is finalizing the study preparation with three US centers successfully trained in November at Pitt MIRM Centre for Preclinical Studies (Pittsburgh, Pennsylvania): VCU Health Pauley Heart Center (Richmond, Virginia), University of Louisville Jewish Hospital (Louisville, Kentucky), and Baylor University Medical Center (Dallas, Texas). All other steps necessary to start the EFS have already been taken.

In view of this, CARMAT now expects the first implants to be performed in Q1 2021 and the enrolment of the 10 patients to be completed by the end of 2021.

The Company confirms that its available resources¹ enable it to fund its activities through to Q3 2021.

Stéphane Piat, Chief Executive Officer of CARMAT, says: *“Despite the COVID-19 pandemic, we have been able to train the first three US centers selected for our Early Feasibility Study. They all went out of this experience very enthusiastic and committed to the success of this study. As we intend to use a new version of the CARMAT system, including features reinforcing the safety and the quality of life of patients,*

¹ Including cash on-hand, €10m of ‘PGE’ Loan (loan guaranteed by the French State) drawn in November 2020, the last tranche (€10m) of the European Investment Bank Loan which can be drawn at any time until December 2021, and the non-dilutive financing of €13m granted by the French state to fund the EFICAS study (this amount will be perceived over the duration of the study); excluding the balance of the Kepler-Cheuvreux equity line, which can be used until September 27, 2021.

we had to submit amendments to supplement our initial dossier approved in February 2020. Based on ongoing discussions with the FDA, we expect to start to treat patients in the US with the new prosthesis in Q1 2021.”



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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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.