



## PRESS RELEASE

# **CARMAT confirms the submission of a “Forfait Innovation” dossier in France and its eligibility with observations received from the French National Authority for Health (HAS)**

**Paris, February 17, 2020 – 6.00 pm CET**

CARMAT (FR0010907956, ALCAR), the designer and developer of the world’s most advanced total artificial heart (TAH), aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, announces that the French National Authority for Health (HAS) has deemed the CARMAT TAH eligible with observations to start a clinical study in France as part of the Forfait Innovation program.

The Forfait Innovation<sup>1</sup> is a program that facilitates the early access of patients to innovative technologies in the early clinical development phase. According to the HAS, the CARMAT TAH meets the criteria of novelty linked to the use of biological materials in contact with blood, its capacity of auto-regulation and the lighter and quieter external equipment. Moreover, the HAS considers that the device is likely to bring a significant clinical benefit addressing an insufficiently met medical need and that the proposed clinical study allows to collect the missing data needed to assess the improvement of the care provided to transplant-eligible patients suffering from biventricular heart failure.

CARMAT has submitted a prospective multi-center non-randomized study that aims to evaluate the survival rate at 180 days after implantation without a disabling stroke or until a successful cardiac transplantation. CARMAT has obtained the approval to conduct such a clinical study by the French National Agency for Medicines and Health Products Safety (ANSM) and is awaiting the Ethics Committee final approval (CPP). CARMAT is committed to respond to the observations of HAS on the study protocol within the timelines foreseen by the Forfait Innovation program. Upon final approval of the study, CARMAT will initiate budget discussions with the ministers responsible for Health and Social Security.

**Stéphane Piat, Chief Executive Officer of CARMAT, comments:** *“We are delighted with this positive opinion from the HAS, which demonstrates a real need for more effective and safer management of heart failure patients in France. Following the recent FDA approval to initiate a feasibility study of our device in the United States, this is another major milestone of our project to make our technology rapidly available to patients eligible for heart transplant.”*

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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

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<sup>1</sup> The Forfait Innovation is granted by the ministers responsible for Health and Social Security, after the initial eligibility deemed by the HAS ([https://www.has-sante.fr/jcms/c\\_2035788/fr/forfait-innovation](https://www.has-sante.fr/jcms/c_2035788/fr/forfait-innovation)).

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](http://www.carmatsa.com)

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*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 registration document filed with the Autorité des Marchés Financiers under number D.19-0135 on March 12, 2019, 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.*