



PRESS RELEASE

CARMAT confirms the definitive approval of its "Forfait Innovation" dossier by the French National Authority for Health (HAS)

**With this favorable opinion, CARMAT will request financing of its device
within the framework of a clinical study in France**

Paris, April 6, 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 French National Authority for Health (HAS) has given its definitive approval to initiate a clinical study of the CARMAT device within the framework of the Forfait Innovation program¹.

Through this definitive approval, the HAS confirmed its positive opinion regarding the financing by special exemption of the CARMAT total artificial heart within the framework of the EFICAS study, a prospective, multicenter, non-randomized study, to be undertaken in France. The design of the study, which includes 52 patients to be implanted with the CARMAT heart as a bridge to a heart transplant, has been adjusted in accordance with the observations expressed by the HAS in the conditional approval received by CARMAT in February 2020. The primary endpoint of the study is the survival rate at 180 days after implantation without a disabling stroke or a successful cardiac transplantation within 180 days post-implant.

CARMAT has already received approval from the French National Agency for Medicine and Health Product Safety (ANSM) and the Île-de-France Patient Protection Committee (CPP) to undertake such a study.

The Company will now initiate budget discussions with the Ministry of Health and Solidarity.

Stéphane Piat, Chief Executive Officer of CARMAT, says: *"We are delighted with this positive opinion from the HAS, received within a particularly complex context. The definitive eligibility of our device to the Forfait Innovation program now enables us to open budgetary discussions pertaining to the EFICAS study aimed at facilitating the access of French patients suffering from end-stage biventricular heart failure to our cutting-edge technology".*

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¹ The *Forfait Innovation* is granted by the Ministry of Health and Solidarity, following an initial eligibility assessment by the HAS (https://www.has-sante.fr/jcms/c_2035788/fr/forfait-innovation).

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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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.