PRESS RELEASE

CARMAT obtains ANSM approval to resume PIVOTAL study implants in France

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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 announces that it has obtained *ANSM* (French agency for the safety of medicines and health products) and *CPP Ouest III* (ethics committee) approval to perform implants of its device within the framework of the PIVOTAL study in France.

These approvals open up the possibility for French patients to receive the CARMAT device and for French hospitals to contribute to the completion of enrollment in the PIVOTAL study by the end of the first quarter of 2021.

To date, the number of implants performed within the framework of the PIVOTAL study stands at 13, including 10 in the first cohort, now closed, and 3 in the 2nd cohort, which is currently enrolling patients.

As a reminder, the study protocol provides for the enrollment of a total of 10 patients in the 2nd cohort, and the primary endpoint of the study is 6-month survival with the bioprosthesis or a successful heart transplant within 6 months of the device being implanted.

Stéphane Piat, Chief Executive Officer of CARMAT, said: *"We are delighted to be able to resume implants of the CARMAT heart in France. The enrollment pace, impacted by the COVID-19 situation in the centers in the Czech Republic, Denmark and Kazakhstan, could hence accelerate with the participation of highly specialized French centers to complete this key study. This is also very important in view of the future EFICAS study, insofar as the chosen French centers will thus be able to acquire valuable clinical experience before the launch of this broad study that is expected to begin in the second quarter of 2021. We are simultaneously working with centers in the United States to enable the US early feasibility study (EFS) to begin before the end of the year, as planned".*

Professor Jean-François Obadia, Head of the Cardiothoracic Surgery and Heart Transplant department at Louis Pradel hospital (CHU LYON) and the study's national Principal Investigator, added: *"Our participation in the PIVOTAL study will finally give us access to this innovative technology that meets an urgent clinical need for which we so far had no satisfactory solution. The prosthesis' performances observed in the first patients already implanted abroad and our recent experience during the training of our teams in France are very encouraging. We are delighted to have this opportunity, particularly as our teams will subsequently participate in the EFICAS study, supported by the French Ministry of Health and Solidarity".*

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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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