CARMAT announces the first human implant of its total artificial heart in the United States

The implant was performed at Duke University Hospital, one of the largest U.S. cardiology centers

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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, announces the first implantation of its bioprosthetic artificial heart, Aeson®, in the United States within the framework of the Early Feasibility Study (EFS).

The implant procedure was performed by a team led by Dr. Jacob N. Schroder and Dr. Carmelo A. Milano, heart surgeons at Duke University Hospital, in Durham (North Carolina). Duke University Hospital is rated as one of the best in the United States for its outstanding care and ground-breaking research, especially in cardiology and heart surgery. It is the first U.S. hospital to implant Aeson® within the framework of the EFS. Three additional U.S. centers are fully trained and are currently screening patients for the study.

In accordance with the study protocol approved by the FDA, 10 transplant-eligible patients are expected to be enrolled in this trial. The primary study endpoint is patient survival at 180 days post-implant or a successful cardiac transplantation within 180 days post-implant. It is a staged study with a progress report of the first 3 patients after 60 days, before the enrollment of the next 7 patients.

Carmelo A. Milano, MD, heart surgeon at Duke University Hospital, and principal investigator of the study, stated: “We are pleased to be the first U.S. center to investigate a new therapeutic alternative for critically ill patients suffering from end-stage biventricular heart failure. This clinical study will help us determine whether the device’s properties -- including hemocompatibility, pulsatility, autoregulation and silent operation -- are beneficial to patients who currently have very few options.”

Stéphane Piat, Chief Executive Officer of CARMAT, concluded: “We are honored that our device is implanted at Duke University Hospital, which is recognized throughout the United States for its quality of care and research. I would like to congratulate the teams at the hospital, as well as our technical and medical staff, on this exceptional milestone for both patients and our company. I am also very pleased that, despite the procedures hardened by the Covid-19 situation, three other centers are now fully trained and ready to join our first U.S. clinical study that will be instrumental to our development in the world's largest medical device market.”

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, Aeson®, composed of the implantable bioprosthesis and its portable external power supply system to which it is continuously 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 physiologic heart replacement therapy: given the use of highly biocompatible materials, its unique self-regulation system and its pulsatile nature, the CARMAT total artificial heart could, assuming a successful clinical development, potentially save the lives of thousands of patients each year with no risk of rejection and with an enhanced 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 Gaspar 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 February 24, 2021 under number D.21-0076 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 prostheses and the equipment required for its use, to manufacture the prostheses, satisfy the requirements of competent authorities, enroll patients, obtain satisfactory clinical results, perform the clinical trials and achieve commercial objectives.

Aeson® is an active implantable medical device commercially available in Europe ONLY, CARMAT SA., CE0344. The Aeson® TAH is intended to replace ventricles of native heart and is indicated as a bridge to transplant in patients suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who are not amenable to maximal medical therapy or LVAD and are likely to undergo heart transplant in the 180 days following device implantation. The decision to implant and the surgical procedure must be executed by Health Care professionals trained by the manufacturer. Carefully read the documentation (clinician manual, patient manual & alarm booklet) for characteristics and information necessary for patient selection and good use (contraindications, precautions, side effects).

In the USA, Aeson® is currently exclusively available within the framework of clinical trials.