



## PRESS RELEASE

### **CARMAT announces the publication of the bridge-to-transplant experience in the Journal of Heart and Lung Transplantation**

The 5 successful transplants performed during the PIVOTAL study point to the efficacy of the CARMAT heart for patients waiting for a graft

**Paris, August 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 the publication ahead of printing of the bridge-to-transplant experience performed during the PIVOTAL study in the Journal of Heart and Lung Transplantation, the most recognized peer-reviewed journal in the field of transplantation.

The article entitled "[Initial bridge-to-transplant experience with a bioprosthetic autoregulated artificial heart](#)" analyzed data from seven transplant-eligible patients enrolled in the PIVOTAL study by the surgical teams in Prague (Czech Republic) and Nur-Sultan (Kazakhstan).

The five patients who were discharged from hospital with the CARMAT device after a median duration of 48 days all recovered to an optimal condition for receiving a donor heart. They received donor hearts after median support of 243 days on the CARMAT device in predominantly outpatient follow-up. The CARMAT device explant procedure and the subsequent heart transplant procedure were uneventful in all five cases.

All transplanted patients were successfully discharged after the transplant with an 80% survival rate at 12 months, as one patient developed pneumonia followed by a debilitating ischemic stroke ten weeks after the transplant and passed away on day 110.

As a reminder, the primary endpoint of the PIVOTAL study corresponds to a 6-month survival with the bioprosthesis or a successful heart transplant within 6 months post-implant.

**Ivan Netuka, MD, PhD, Chair of the Department of Cardiovascular Surgery at the Institute for Clinical and Experimental Medicine, Prague, and the first author of the publication, comments:**

*"The accumulated experience suggests that a successful bridging to heart transplant by using the CARMAT device is feasible and may also offer several substantial advantages. Indeed, the fully pulsatile biventricular support, along with a low incidence of adverse events, keep patients in a favorable condition for the transplant procedure to optimize the post-transplant outcomes. Furthermore, as there were minimal tissue adhesions observed around the device, the explant procedure was shorter while mitigating the bleeding risk. Last but not least, the shape and size of the device resemble that of a natural heart, and thus leave sufficient space for the transplanted donor heart."*

**Stéphane Piat, Chief Executive Officer of CARMAT, concludes:** "We are glad that this excellent bridge-to-transplant data was accepted in such a respected peer-reviewed publication as the Journal of Heart and Lung Transplantation. I would like to congratulate the teams in Prague and Nur-Sultan for their

tenacity and substantial involvement in our PIVOTAL study. To date, 13 patients have received our device within the framework of the study, and this successful experience on five of them shows that our prosthesis could become a credible therapeutic solution for a number of transplant-eligible patients who are on waiting lists for a donor heart.”

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

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**CARMAT**  
**Stéphane Piat**  
Chief Executive Officer

**Pascale d'Arbonneau**  
Chief Financial Officer  
Tel.: +33 1 39 45 64 50  
[contact@carmatsas.com](mailto:contact@carmatsas.com)

**Alize RP**  
Press Relations

**Caroline Carmagnol**

Tel.: +33 6 64 18 99 59  
[carmat@alizerp.com](mailto:carmat@alizerp.com)

**NewCap**  
Investor Relations &  
Strategic Communication

**Dusan Oresansky**  
**Emmanuel Huynh**

Tel.: +33 1 44 71 94 94  
[carmat@newcap.eu](mailto:carmat@newcap.eu)



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.*