



PRESS RELEASE

CARMAT announces the first implant of the Aeson® artificial heart in a patient suffering from a cardiac tumor

- This world first for Aeson® was achieved by teams at the Marie-Lannelongue Hospital in France as part of the EFICAS® study
- The Marie-Lannelongue Hospital is one of the 8 French centers approved to carry out implants as part of this study
- Enrolment of the first 10-patient cohort of the study has been completed

Paris, December 11, 2023 - 5:45 pm (CET)

CARMAT (FR0010907956, ALCAR), designer and developer of the world's most advanced total artificial heart, aimed at providing a therapeutic alternative for patients suffering from advanced biventricular heart failure (the "**Company**" or "**CARMAT**"), today announced the first implantation of the Aeson® heart in a patient suffering from a cardiac tumor.

The patient implanted was suffering from a tumor invading the heart mass, responsible for rhythmic and restrictive cardiopathy, which eluded standard medical treatment. Only complete surgical removal of the heart could be considered as a hope of treatment. It is in this context that the Aeson® total artificial heart was implanted for the first time in the world in this type of indication.

The implant was carried out at the Marie-Lannelongue Hospital in Plessis-Robinson (in the western suburbs of Paris) by the teams of Professor Julien Guihaire, cardiac surgeon, and Professor Elie Fadel, thoracic surgeon.

Prof. Julien Guihaire and Prof. Elie Fadel said: *"We are delighted to have been able to provide a solution to this patient in a very difficult situation, for whom there was no other alternative than a total heart replacement with Aeson®. This first-in-man implant performed in our hospital is a continuation of the commitment to the CARMAT project by our teams since the beginning of 2010, including in particular the performance of numerous implant simulations in the Marie-Lannelongue Hospital research laboratory. Aeson® offers real hope for patients with invasive cardiac tumors whose treatment options and survival are currently extremely limited."*

The implant was performed as part of the CARMAT's EFICAS study, which aims to gather additional data on the efficacy and safety of its Aeson® artificial heart, as well as medico-economic data to support the value proposition of the prosthesis, and in particular the reimbursement of the device in France.

Eight French cardiology centers¹ are now involved in the EFICAS study, which will include a total of 52 patients. To date, enrolment of the first cohort of 10 patients has been finalized, and the study is on track for completion in 2025.

¹ AP-HP GHU Pitié Salpêtrière, Hôpital Européen Georges Pompidou, Rennes University Hospital, Strasbourg University Hospital, Lyon University Hospital, Lille University Hospital, Marie-Lannelongue Hospital and Montpellier University Hospital

Stéphane Piat, Chief Executive Officer of CARMAT, concludes: *"I would like to thank the teams at the Marie-Lannelongue Hospital, a long-standing partner, for giving new hope to a patient suffering from major comorbidities. We are delighted with this world first for CARMAT, which demonstrates the ability of Aeson® to address increasingly complex clinical cases."*

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About CARMAT

CARMAT is a French MedTech that designs, manufactures and markets the Aeson® artificial heart. The Company's ambition is to make Aeson® the first alternative to a heart transplant, and thus provide a therapeutic solution to people suffering from end-stage biventricular heart failure, who are facing a well-known shortfall in available human grafts. The world's first physiological artificial heart that is highly hemocompatible, pulsatile and self-regulated, Aeson® could save, every year, the lives of thousands of patients waiting for a heart transplant. The device offers patients quality of life and mobility thanks to its ergonomic and portable external power supply system that is continuously connected to the implanted prosthesis. Aeson® is commercially available as a bridge to transplant in the European Union and other countries that recognize CE marking. Aeson® is also currently being assessed within the framework of an Early Feasibility Study (EFS) in the United States. Founded in 2008, CARMAT is based in the Paris region, with its head offices located in Vélizy-Villacoublay and its production site in Bois-d'Arcy. The Company can rely on the talent and expertise of a multidisciplinary team of circa 200 highly specialized people. CARMAT is listed on the Euronext Growth market in Paris (Ticker: ALCAR / ISIN code: FR0010907956).

For more information, please go to www.carmatsa.com and follow us on [LinkedIn](#).

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About the Marie-Lannelongue Hospital

The Marie-Lannelongue Hospital is a private health establishment of collective interest (ESPIC) in sector 1 (with no out-of-pocket expenses) specializing in the medical, surgical and minimally invasive treatment of cardiac, pulmonary and vascular pathologies. Recognized as a center of excellence in France and internationally, it treats congenital heart malformations, diseases and tumors of the thoracic cavity, pulmonary arterial hypertension and valvular heart disease or coronary artery disease from newborns to adults. The technical expertise of its teams, combined with cutting-edge technology, make it one of the world's leading hospitals in pediatric and adult cardiology and thoracic oncology.

The Marie-Lannelongue Hospital is currently being rebuilt in Plessis-Robinson (in the western suburbs of Paris). The new hospital is due to open in 2025.

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The significant and specific risks pertaining to the Company are those described in the Universal Registration Document ("Document d'Enregistrement Universel") filed with the Autorité des Marchés Financiers (AMF, the French stock market authorities) under number D. 23-0323. Readers' attention is drawn in particular to the financing risk of the Company, whose cash runway currently extends until early 2024. Readers and investors' attention is also drawn to the fact that other risks, unknown or not deemed to be significant or specific, may or could exist.

Aeson® is an active implantable medical device commercially available in the European Union and other countries that recognize CE marking. The Aeson® total artificial heart is intended to replace the ventricles of the 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 a left ventricular assist device (LVAD) and are likely to undergo a heart transplant within 180 days of the device being implanted. The decision to implant and the surgical procedure must be carried out by healthcare professionals trained by the manufacturer. The documentation (clinician manual, patient manual and alarm booklet) should be read carefully to understand the characteristics of Aeson® and information necessary for patient selection and the proper use of Aeson® (contraindications, precautions, side effects). In the United States, Aeson® is currently exclusively available within the framework of an Early Feasibility Study authorized by the Food & Drug Administration (FDA)