



## PRESS RELEASE

### **CARMAT announces the first implant of its Aeson® total artificial heart in The Netherlands**

The implant took place at the University Medical Centre Utrecht, The Netherlands

**Paris, November 15, 2021 – 7 am CET**

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 implant of the Aeson® artificial heart in The Netherlands.

The implant procedure was performed by the Heart Team led by Dr. Faiz Z. Ramjankhan and Dr. Niels P. van der Kaaij, Cardiothoracic surgeons, and Dr. Linda W. van Laake, heart failure Cardiologist, at the University Medical Center (UMC) Utrecht, The Netherlands. The implant took place in the frame of the European PIVOTAL Study. It was the first time ever that a total artificial heart was implanted in The Netherlands. UMC Utrecht is one of the three heart transplantation centers in the country and the most experienced Mechanical Circulatory Support (MCS) center, having implanted the first MCS in the country in 1993.

**Faiz Z. Ramjankhan, MD, Cardiothoracic surgeon at UMC Utrecht and Principal Investigator of the Study, stated:** *"We are very excited to have successfully implanted the first Aeson® total artificial heart in the Netherlands, in a patient ineligible for heart transplantation at the time of implantation. Participation in the PIVOTAL Study will help us determine whether its distinguishing features such as hemocompatibility and blood flow autoregulation are beneficial during long-term support for patients with biventricular failure in a country with a transplant waiting time of many years."*

**Stéphane Piat, Chief Executive Officer of CARMAT, commented:** *"We are honored that our device is implanted at UMC Utrecht, which is recognized as a leading heart transplant center in The Netherlands. I would like to thank the teams at the hospital for their dedication and the trust they place in Carmat. Aeson® has now been implanted in 8 different countries: Czech Republic, Denmark, France, Germany, Italy, Kazakhstan, the Netherlands and the United States. I am pleased that we are continuing to build up our geographical coverage in order to meet the demand of the many patients waiting for treatment."*

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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 more than 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](http://www.carmatsa.com) and follow us on [LinkedIn](#).

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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.21-0076. Readers and investors' attention is, however, 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).*