



## PRESS RELEASE

### **CARMAT announces the publication of an article on the Aeson®'s autoregulation system in the ASAIO Journal**

Results from 10 patients enrolled in the PIVOTAL study show that autoregulation enables an appropriate and immediate adaptation of cardiac output to patients' needs

**Paris, October 12, 2021 – 6:00 pm CEST**

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 publication of an article on the Aeson®'s autoregulation system in the October 2021 issue of the ASAIO Journal, a peer reviewed publication of the American Society for Artificial Internal Organs.

The publication entitled "[First Clinical Experience With the Pressure Sensor–Based Autoregulation of Blood Flow in an Artificial Heart](#)" details the reliability and efficacy of the Aeson®'s autoregulation control mechanism (auto-mode), designed to mimic normal physiologic responses to changing patient needs. Hemodynamic data from a cohort of 10 patients implanted with the device during the European PIVOTAL study, recorded over 1,842 support days in auto-mode, were analyzed with respect to daily changing physiologic needs. The device was successfully switched from manual mode to auto-mode in the operating room, following weaning from cardiopulmonary bypass (CPB), in all patients.

Analysis of the recorded device-hemodynamic trends show the expected variations in left and right ventricle outputs, corresponding to changes in the inflow pressures, as a consequence of beat rate variations, while stroke volumes were maximized. Left ventricular output ranges from 4.3 to 7.3 L/min for average left inflow pressures ranges of 6–19 mm Hg. On the right side, the ventricular output ranges from 4.2 to 7.2 L/min for average right inflow pressures ranging of 4–17 mm Hg. The average beat rate ranges from 78 to 128 bpm.

These data demonstrate that the Aeson® artificial heart effectively produces appropriate physiological responses reflective of changing patients' daily needs, representing one of the unique characteristics of this device in providing almost physiologic heart replacement therapy.

**Stéphane Piat, Chief Executive Officer of CARMAT, commented:** *"Since the beginning of the CARMAT project, one of our key objectives has been to discharge a patient back to a home environment and associated usual activities that make for a normal quality of life. A central requirement for achieving this is to have a device that can be autonomous while requiring minimal attention. The data obtained so far from our PIVOTAL study and published in the ASAIO Journal show that Aeson®'s autoregulation system ensures a fully pulsatile cardiac output, that is automatically adjusted, according to the venous return. This unique feature contributes to greater autonomy for patients and thus improves their quality of life. We are thrilled to further observe the demonstration of this key advantage on a larger scale as we continue our ramp up in implants both in clinical and commercial setting."*

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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).*