



## PRESS RELEASE

### CARMAT announces three publications about Aeson® in peer-reviewed scientific journals

Clinical results confirm hemocompatibility and show absence of inflammation after Aeson® implant, with significant potential benefits for patients

**Paris, October 18, 2022 – 5:45 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 3 papers in peer-reviewed scientific Journals. The papers present results from studies on patients implanted with the Aeson® Artificial Heart and confirm its hemocompatibility and the absence of device-induced inflammation.

The paper entitled "[Bioprosthetic Total Artificial Heart in Autoregulated Mode Is Biologically Hemocompatible: Insights for Multimers of von Willebrand Factor](#)" in the April 2022 issue of *Arteriosclerosis, Thrombosis, and Vascular Biology*, a peer-reviewed publication of the *American Heart Association*, demonstrates that the Aeson® Total Artificial Heart (TAH) induces minimal shear stress on blood cells compared with existing Mechanical Circulatory Support (MCS) devices. Consequently, Aeson® does not induce blood cell damage (hemolysis) nor the so-called Acquired von Willebrand Syndrome, which has been associated with gastrointestinal bleeding observed in patients treated with other MCS devices.

The publication "[Intermediate-dose prophylactic anticoagulation with low molecular weight heparin is safe after bioprosthetic artificial heart implantation](#)" in the September 2022 issue of the *Journal of Heart and Lung Transplant*, a peer-reviewed publication of the *International Society for Heart & Lung Transplant*, provides data demonstrating that an intermediate-dose of anticoagulation with low molecular weight heparin in combination with low-dose aspirin is feasible with no evidence of an increase in thrombotic complications or coagulation activation. For other MCS devices, a much higher amount of anti-coagulation is needed, with the associated risk of bleeding complications. The authors conclude that, thanks to the hemocompatibility of Aeson®, the anticoagulation approach used for patients supported with the device represents a significant advance in MCS system management aimed at reducing hemocompatibility-related adverse events.

The online publication entitled "[Bioprosthetic Total Artificial Heart Implantation does not induce chronic inflammation](#)" in the October 2022 *ASAIO Journal*, a peer reviewed publication of the *American Society for Artificial Internal Organs*, assessed the inflammatory status in 9 patients supported with the Aeson® TAH up to 12 months. Inflammation markers such as white blood cells and cytokines (tumor necrosis factor, interleukines), were not significantly altered after Aeson® implantation and circulating immune cell subpopulations (lymphocytes) had no significant modulation during the follow-up. Impaired cellular immunity has been described for patients treated with other MCS devices and is a risk factor for bleeding, thrombotic complications, and infection.

**Stéphane Piat, Chief Executive Officer of CARMAT, commented:** "These scientific publications based on data from our PIVOTAL study confirm one of the key concepts of the Aeson® artificial heart which is the hemocompatibility of the device. The absence of significant sheer stress on blood cells circulating through the device and the absence of chronic inflammation as assessed by biomarkers allow for a low dose of anticoagulation treatment unseen in mechanical circulatory support. The combination of these factors is unique

to the Aeson® artificial heart and may contribute to a favorable safety profile for patients supported by the device while awaiting a donor heart. This key advantage will help us on a larger scale once we resume and ramp up 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. 22-0332. 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).*