

# PRESS RELEASE

# The first U.S. clinical experience with Aeson® TAH published in the Annals of Thoracic Surgery Short Reports

The publication highlights the effectiveness of the device based on the combination of hemocompatibility and autoregulation

## Paris, March 6, 2023 – 7:00 am CET

CARMAT (FR0010907956, ALCAR), the designer and developer of Aeson®, the world's most advanced total artificial heart, aiming to provide a therapeutic alternative for people suffering from advanced biventricular heart failure, today announced that the first U.S. clinical experience with Aeson® has been published in the Annals of Thoracic Surgery Short Reports, the journal of the U.S. Society of Thoracic Surgeons.

The article, entitled <u>The First Autoregulated Total Artificial Heart Implant in the United States</u>, describes the Aeson®'s implant performed at Duke University Hospital in the summer of 2021 within the framework of the Early Feasibility Study (EFS).

The authors report that Aeson® total artificial heart (TAH) provides right- and left-sided heart replacement for a patient suffering from biventricular failure with notable improvements over prior-generation circulatory support devices. These include enhanced hemocompatibility and autoregulation enabling increased output in response to higher filling pressures.

The authors conclude that the first U.S. experience demonstrates the effectiveness of the Aeson® TAH while preventing stroke and bleeding complications. The patient was successfully bridged to transplant as a donor organ became available after 5 months of support on the device, and has made a full recovery.

**Stéphane Piat, Chief Executive Officer of CARMAT, said:** "We are gratified that our device provided such an efficient support to the first U.S. patient. Aeson®'s hemocompatibility translates in an unparalleled safety profile with absence of bleeding complications or stroke, which are the main drawbacks of conventional mechanical circulatory support devices. Furthermore, the blood flow autoregulation, which is unique to Aeson®, facilitates physical activity and patient readiness for a successful cardiac transplant. These distinctive features once again confirm our belief that Aeson® will become the therapy of choice for advanced biventricular heart failure. We continue to work with the FDA to resume the EFS, a key step towards obtaining authorization to market Aeson® in the U.S."

#### \*\*\*

### 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 <u>www.carmatsa.com</u> and follow us on <u>LinkedIn</u>.

CARMAT Stéphane Piat Chief Executive Officer

Pascale d'Arbonneau Chief Financial Officer Tel.: +33 1 39 45 64 50 contact@carmatsas.com Alize RP Press Relations

...

Caroline Carmagnol Tel.: +33 6 64 18 99 59 carmat@alizerp.com



Name: CARMAT ISIN code: FR0010907956 Ticker: ALCAR

•••

NewCap Financial Communication & Investor Relations

Dusan Oresansky Quentin Massé Tel.: +33 1 44 71 94 92 carmat@newcap.eu

#### Disclaimer

This press release and the information contained herein do not constitute an offer to sell or subscribe to, or a solicitation of an offer to buy or subscribe to, shares in CARMAT (the "Company") in any country. This press release may contain forward-looking statements that relate to the Company's objectives and prospects. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties including, without limitation, the Company's objectives are products or technological development of CARMAT's production and sales, the pace and results of ongoing and future clinical trials, new products or technological developments introduced by competitors, changes in regulations and risks associated with growth management. The Company's objectives as mentioned in this press release may not be achieved for any of these reasons or due to other risks and uncertainties.

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).