PRESS RELEASE

CARMAT achieves a pivotal year in 2023 by reaching the milestone of 50 implants of the Aeson® artificial heart and presents its development prospects

- 50 patients have benefited from CARMAT's Aeson® artificial heart since the first implant in 2013
- Aeson® becomes an essential breakthrough innovation in the treatment of advanced biventricular heart failure
- 41 hospitals in 12 countries are trained for implants[1], including 33 for commercial activity
- Turnover of €2.8m in 2023, marked by a substantial acceleration in sales in the fourth quarter, with 11 implants out of the 17 carried out during the year
- Sales of €14-20m anticipated in 2024
- Launch in the very short term of a capital increase to extend the cash runway beyond the end of January 2024 and partially finance the Company's needs for the forthcoming 12-month period, estimated to a minimum of €50m

Videoconference on January 17 at 8:00 pm CET.
To participate, please register by clicking on this link

Paris, January 15, 2024 – 7:00 am (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 that it has reached the milestone of 50 implants of its total artificial heart, and provides an update on its achievements and outlook.

Stéphane Piat, Chief Executive Officer of CARMAT, declares: *« CARMAT celebrated its 15th anniversary in 2023. The Company and its teams are extremely proud to have reached the milestone of 50 Aeson® implants since the first in December 2013. This milestone is a major success and is a testimony of the recognition of our therapy by leading names in cardiology.*
Founded on the work of the icon of cardiac surgery, Professor Alain Carpentier, CARMAT aims to treat heart failure, a major health issue and the world's leading cause of death, by replacing the diseased heart with a bioprosthetic artificial heart. The last 15 years have been a period of intense research and development, resulting in a breakthrough innovation that is unique in the field of cardiology. 2023 has been particularly structuring year for the Company, with a substantial acceleration in sales in the last quarter, a significant number of hospitals trained for implants, increased manufacturing capacity to meet demand, and a reinforcement of the Aeson® heart's safety profile thanks, in particular, to software improvements, which represents a significant catalyst for our long-term ambition to make Aeson® a

[1] Excluding the United States, where 9 hospitals are trained as part of the EFS (early feasibility study) clinical trial.

"destination therapy" device, i.e. enabling long-term patient support without subsequent heart transplantation.
Taken together, these advances provide a solid foundation for a sizable commercial roll-out, enabling CARMAT to achieve its ultimate goal of providing patients waiting for a human heart with a therapeutic solution and a good quality of life. We look forward to 2024 with confidence and are very determined to achieve our goals. »

A unique technological breakthrough: since 2008, 15 years of innovation to serve patients

The fruit of 15 years of research and the convergence of several cutting-edge technologies, the Aeson® artificial heart is a unique device, that aims to "replicate" as closely as possible the functioning of a human heart.

The only device in the world to be pulsatile, hemocompatible and self-regulated, Aeson® saves lives and offers patients a better quality of life[2].

An "intelligent" device, Aeson® adapts blood flow in real time and manages differentiated flows between the right and left parts of the heart, depending on the patient's needs and activity; and does so without risk of rejection, without heavy drug regiment, and with a safety profile superior to that of all other comparable devices.

A therapy adopted by the medical community: 50 implants in 8 countries since inception

Since the first implant in December 2013, Aeson® has spread widely through clinical trials and then commercially: 50 patients have benefited from the Aeson® heart in 8 different countries[3], bringing the cumulative experience to more than 19 patient-years. To date, 13 patients are living with the Aeson® device.

Among the 17 implants carried out in 2023, 10 were part of the EFICAS clinical trial in 6 different hospitals in Paris, Lille, Lyon, Le Plessis-Robinson and Montpellier; and 7 in the commercial setting, internationally, in Germany and Italy.

Aeson®, which is strongly supported by leading cardiologists in Europe and the United States, is becoming a reference solution for patients eligible for transplantation, waiting for an available human heart.

2023, a pivotal year particularly marked by the start of the commercial dynamic

Solid sales momentum since the last quarter of 2023

During the 2023 financial year, CARMAT generated sales[4] of €2.8m, corresponding to the sale of 17 Aeson® prostheses, including 11 in the last quarter, demonstrating solid early commercial dynamics (with a rate of around one implant per week achieved since the end of September), underpinned by CARMAT's ability to roll out its therapy on a large scale industrially and commercially.

33 hospitals in 11 different countries have been trained and are therefore ready to carry out Aeson® implants on a commercial basis, and 8 French hospitals[5] have also been trained for implants as part of the EFICAS clinical trial.

Manufacturing capacity increased to 500 hearts per year

In 2023, CARMAT has continued to invest in its industrial facilities, notably with the opening of its second production building in Bois-d'Arcy, enabling it to increase its manufacturing capacity to 500 hearts per year from early 2024, corresponding to potential annual sales of around €100m.

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[2] Aeson® is currently commercially available in the European Union for the "bridge to transplant" (BTT) indication, i.e. while waiting for a heart transplant.
[3] France, Germany, Italy, Denmark, Czech Republic, Netherlands, USA, Kazakhstan
[4] Unaudited data. Out of the 17 sales made in 2023, 10 were made in France as part of the EFICAS study, and 7 in a commercial set-up in Germany and Italy.
[5] AP-HP CHU Pitié Salpêtrière, Hôpital Européen Georges Pompidou, CHU in Rennes, CHU in Strasbourg, Hospices Civils in Lyon, CHRU in Lille, Hôpital Marie-Lannelongue and CHU in Montpellier.

Enhanced Aeson® reliability

In 2023, Aeson® continued to confirm a safety profile that clearly sets it apart from all other mechanical circulatory support systems: since its inception, Aeson® has not resulted in any gastrointestinal bleeding or disabling stroke.

At the end of the year, CARMAT also announced a software enhancement for Aeson®, which significantly strengthens the safety profile of the device: from now on, for many potential malfunctions linked to the prosthesis's electronic components, the Aeson® software will automatically 'correct' these faults by adapting the prosthesis's performance in an appropriate manner, so that the patient's support remains unaffected.

Strong growth outlook starting as early as 2024

Given the decisive steps taken in 2023, and the sales trends seen in recent months, the Company is confident in the continued momentum of its implants and the successful deployment of its strategic roadmap.

CARMAT's key objectives for 2024 are:

- Sales of c. €14m to €20m;
- Around fifty hospitals trained for commercial implants by the end of the year;
- Around thirty implants carried out as part of the EFICAS study in France;
- A cash burn reduction (operations and capital expenditure) of around 20% compared to 2023[6].

The Company is also maintaining its objective of submitting its PMA[7] application to the FDA[8] by the end of 2026, which would enable it to start marketing Aeson® in the United States in 2027. It also confirms its objective of reaching breakeven in 2027.

A "destination therapy" objective

CARMAT's ultimate goal is to offer not only a temporary solution ("bridge to transplant") for transplant-eligible patients waiting for a human graft, but also a "definitive" solution for patients who are not eligible for a transplant, who would therefore remain under the support of the CARMAT device over the long term, commonly referred to as "destination therapy (DT)".

Given the unique characteristics of Aeson®, in particular its confirmed biocompatibility profile, and its constantly improving safety profile, CARMAT believes that its artificial heart is today the only existing device with the potential to become a "destination" bi-ventricular mechanical circulatory support solution. This indication represents a huge additional market potential worldwide.

Based in particular on the data that it will have accumulated through its clinical trials, and in "real life" as part of the follow-up of commercially implanted patients, CARMAT believes it can reasonably obtain this destination therapy indication within a few years, and thus be in a position to offer a solution to thousands of patients currently at a therapeutic impasse.

Extending the cash runway: forthcoming launch of a capital increase

Based solely on its current financial resources, CARMAT currently has a cash-runway until the end of January 2024. Based on its current business plan, the Company estimates that it will have to secure around €50m[9] in current financing over the next 12 months.

[6] Estimated cash burn for 2024 of around €50m
[7] Authorization to market Aeson® in the United States.
[8] Food & Drug Administration in the USA.
[9] to which €15m would have to be added to repay the first tranche (principal and interests) of the loan contracted with the European Investment Bank (EIB), due on 31/01/2024, should the conditional agreement in principle reached with the EIB not be transformed into a final agreement or not implemented (see the Company's press release of January 12, 2024 for further details on the terms and conditions of this conditional agreement in principle).

In this respect, CARMAT plans to launch a capital increase in the very near future, which should enable it to extend its financial horizon beyond the end of January 2024. Terms of this transaction will be published in a dedicated press release.

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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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*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 the end of January 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).