PRESS RELEASE

CARMAT anticipates implants of its Aeson® artificial heart to resume in October 2022

Videoconference in English with Stéphane Piat at 8 pm CET today.
To participate, please register by clicking on this link

Paris, January 31, 2022 – 5.35 pm 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, issues an update on its activities and outlook.

Positive feedback from physicians on Aeson® since its commercial launch in July 2021

Subsequent to getting the CE marking in the BTT indication[1] in December 2020, the Company started generating the first sales in its history from July 2021, with the implants of 7 Aeson® hearts, including 5 in Germany and 2 in Italy.

To date, four patients are being supported by Aeson®, either within the framework of clinical trials or because they have been implanted in a commercial set-up. Three of these four patients are awaiting a heart transplant.

In response to the strong interest in Aeson® shown by hospitals and encouraged by the positive feedback received from surgeons who have implanted its device, the Company continues training more hospitals, notably in Germany, to allow for a strong resumption in sales once the suspension of implants is lifted.

Resumption of implants anticipated in October 2022

Following the occurrence of quality issues affecting some of its prostheses, CARMAT took, on December 2, 2021, the decision to voluntarily suspend all Aeson® implants.

A rigorous investigation concluded that quality defects on two distinct components of the prosthesis were the root cause of these issues.

[1] Bridge To Transplant

Corrective actions aimed at preventing such defects have been defined and are currently being integrated within manufacturing processes. Given the time required to fully implement these actions, and production lead-times, CARMAT estimates that new prostheses should be available by October 2022.

At the same time, the Company is continuing its discussions with the notified body (DEKRA) and the competent authorities (specifically the ANSM in France and the Food & Drug Administration in the United States), whose authorization is required to resume implants respectively on a commercial basis, and within the framework of clinical trials.

In view of this, CARMAT anticipates to be in a position to resume its commercial and clinical implants in October 2022.

Based on this schedule, CARMAT confirms that it has the necessary financial resources to finance its activities through to July 2022.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: "*As we have consistently said, the production of such an innovative and sophisticated device as Aeson® remains a challenge, and quality issues are not unusual in our industry, especially in phases of production ramp-up. I am satisfied that our teams have been able to rapidly identify the root causes of the quality issues that have occurred, and to define the changes that should be made to the manufacturing processes to avoid these issues arising again. This experience will be very helpful for the future.*

In parallel, we are continuing our very constructive discussions with our notified body, DEKRA, and the regulatory authorities.

There is strong interest and demand from hospitals for our therapy. Feedback from surgeons who have implanted the CARMAT heart is positive, and our clinical trials continue to demonstrate Aeson®'s superiority compared to other therapies addressing advanced biventricular heart failure.

I have the utmost confidence in Aeson®'s potential to become, over the coming years, the benchmark treatment in advanced biventricular heart failure, and that it will offer patients a genuine quality of life. I also firmly believe that implants will grow at a sustained rate once they resume in the fourth quarter of this year".

Join a video conference with Stéphane Piat today at 8:00 pm CET

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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 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).