PRESS RELEASE

CARMAT reports its 2021 half-year results and issues an update on its latest progress and main strategic objectives

- 6 Aeson® artificial hearts marketed to date
- Enrollment of the first cohort of 3 patients in the EFS[1] in the USA finalized
- Cash position of €58 million at June 30, 2021, covering the Company's activities through to mid-2022
- Videoconference with Stéphane Piat today at 5 pm Paris time

Paris, September 15, 2021 – 7:00 am CEST

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, aiming to provide a therapeutic alternative to people suffering from end-stage biventricular heart failure, today reports its results for the first half of the year to June 30, 2021[2] and issues an update on its latest progress and main strategic objectives.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: *"Following the granting of CE marking in December 2020, CARMAT dedicated most of its resources to preparing the commercial launch in Europe, initiating the EFS in the US and strengthening its supply chain. Despite the constraints associated with the COVID-19 pandemic, CARMAT achieved key milestones: since July, 6 patients in leading German and Italian hospitals did benefit from Aeson®, the world's first physiological artificial heart, in a commercial setting. CARMAT also successfully completed the enrollment of the first cohort of 3 patients in the EFS study, with some of the largest and renowned American cardiology centers such as Duke University Hospital, paving the way to the evaluation of our device in the US, the world's largest medical device market. The very positive feedback regarding the implantations of Aeson® in both commercial and clinical trials settings is further demonstrating our confidence that our device represents a valid alternative to heart transplants. We anticipate that around a dozen European centers, primarily in Germany, will be commercially active by the end of 2021. In order to support this momentum, CARMAT has also been working on ramping up its production activities, which should allow the company to manufacture Aeson® prostheses at an increasing pace in order to appropriately supply hospitals that would like to offer our unique technology to their patients".*

[1] Early Feasibility Study

[2] First-half results were approved by the Board on September 13, 2021 and have been the subject of a limited review by the statutory auditors. The 2021 half-year financial report was published today and is available on the Company's website.

- **2021 half-year results**

Simplified income statement (€ millions)	**30/06/2021** (6 months)	**30/06/2020** (6 months)
Sales	**0.0**	**0.0**
Net Operating income (expense)	**-25.5**	**-20.6**
Net Financial income (expense)	-1.5	-1.0
Non-recurring items	0.0	0.0
Research tax credit	+0.7	+0.8
Net Profit (Loss)	**-26.4**	**-20.8**

CARMAT did not generate any sales during the first half of 2021. The first sales were recorded from the beginning of the third quarter of this year and amount to c. €2 million to date.

In the first half of 2021, CARMAT dedicated most of its efforts and resources to:

- prepare for the commercial launch of its Aeson® artificial heart[3] in Europe, notably with the training of "client" centers;
- prepare for the initiation of the EFS (Early Feasibility Study) in the United States, with the first cohort of 3 patients implanted in the 3rd quarter 2021;
- prepare for the EFICAS study in France with the objective to include the first patients in the 4th quarter 2021;
- prepare for the post-market surveillance (PMS) of the device;
- ramp up the pace of production with around 8 to 10 prostheses now assembled every month;
- continue its actions to strengthen and secure its production supplies.

This sustained activity increased the operating expenses leading to a net operating loss of €25.5 million in for the first half of 2021.

Taking into account the net financial loss (-€1.5 million), non-recurring items and the Research Tax Credit (+€0.7 million), the net loss amounts to €26.4 million for the first half of 2021, compared to a net loss of €20.8 million for the first half of 2020.

- **Cash position and financial structure**

The cash position was strengthened to €57.9 million at June 30, 2021, compared to €36.0 million at December 31, 2020.

The €21.9 million increase in the first half of 2021 results from the following cash flows:

(€ millions)	**30/06/2021** (6 months)	**30/06/2020** (6 months)
Cash flow from operating activities	-29.4	-19.8
Cash flow from investment activities	-1.0	-0.4
Cash flow from financing activities	+52.3	+10.0
Change in cash position	**+21.9**	**-10.2**

[3] The Aeson® artificial heart consists of an implantable prosthesis and its portable external supply system to which it is continuously connected.

The cash flow from operating activities was negative at €29.4 million. The increase compared to the first half of 2020 is mainly due to higher operating expenses mainly driven by the increasing pace of production and the inventory build-up to cope with the commercial launch in Europe, and the preparation of the EFS and EFICAS clinical studies.

The positive cash flow from financing activities of €52.3 million was mainly driven by:

- the fundraising of €55.7 million by way of a public offering with a priority subscription period for existing shareholders and a global offering, that was completed in March;
- the payment of the first tranche of €0.3 million of a total grant of €1.4 million[4] obtained as part of the French Governmental "Industrial recovery plan – Strategic sectors";
- the use of the contingent equity line subscribed with Kepler Cheuvreux for €0.3 million.

CARMAT is funded until mid-2022, based on its current business plan and available financial resources, notably:

- the cash position at June 30, 2021;
- the €13 million granted by the French State to partially finance the EFICAS study (this sum will be received throughout the duration of the study);
- the drawdown, planned in Q4 2021, of the remaining €10.0 million tranche of the €30 million conditional loan granted by the European Investment Bank, since all conditions to draw down this third tranche are already fulfilled.

• H1 2021 highlights and recent achievements

Commercialization of Aeson® in Europe

Following the CE marking granted in December 2020 with the "BTT" (bridge to transplant) indication, the company was able to achieve its first commercial sales in Europe with 6 implants performed so far, including 4 in German hospitals and 2 in Naples (the Azienda Ospedaliera dei Colli hospital in Naples was the first one to implant Aeson® in a commercial setting on July 15, 2021).

The CE marking enables CARMAT to market its Aeson® artificial heart throughout the European Union and in some other countries that recognize this certification. During the second half of 2021, the Company will focus on marketing its device in Germany, the European largest market, and will address one or two other EU markets, including Italy, in a more opportunistic manner.

Following strong positive feedback from leading cardiology centers, CARMAT expects to have, by the end of 2021, around a dozen European centers trained and commercially active, mostly in Germany.

Expansion of the clinical plan and initiation of the EFS in the United States

<u>EFS in the United States</u>

The EFS is a clinical study with a two-step protocol approved by the FDA (Food & Drug Administration) including a report to be issued on the progress of the first cohort of 3 patients after 60 days, before the additional 7 patients can be enrolled. The primary endpoint of the study is 180 days survival after the implant or a successful natural heart transplant within 180 days of the implant.

On July 15, 2021, CARMAT announced the initiation of its EFS in the United States with a first implant of the Aeson® heart performed on July 12, 2021 at Duke University Hospital (North Carolina), one of the top American cardiology centers. Two additional implants have since been performed at UofL Health - Jewish Hospital by physicians from the University of Louisville (Kentucky).

With these 3 implants, the first cohort of the study is completed and CARMAT is planning for the second cohort with an additional 7 implants.

[4] the remaining €1.1 million will be received in two steps in 2022 and 2023, depending on the progress of the industrial projects which are subsidized.

PIVOTAL study in Europe

At June 30, 2021, a total of 15 patients had been enrolled within the framework of the PIVOTAL study, the positive interim results of which contributed to CARMAT being granted CE marking for its device as a bridge to transplant in December 2020.

The Company intends to continue enrolments in this study in order to achieve the initial indicative target of 20 patients by the end of the first half of 2022[5].

EFICAS study in France

The EFICAS study, which will cover 52 implants in France, will allow CARMAT to collect both additional data on the efficacy and safety of its artificial heart and medico-economic data to support its value proposition and the device's reimbursement, notably in France.

During the first half of 2021, the Company submitted a dossier in order to be able to use the most recent version of its artificial heart in this study. Due to regulatory timelines, CARMAT is therefore planning to start enrolling patients in the fourth quarter of 2021.

Ramping up of production

During the first half of 2021, CARMAT continued to implement its plan to ramp up production and build up inventories, as well as to enhance the reliability of its production processes at the Bois-d'Arcy (France) plant. Furthermore, CARMAT continued and intensified its efforts to secure its industrial supplies. The industrial headcount increased by 20, from 61 at the end of 2020 to 81 at June 30, 2021.

Change in governance

The Annual Shareholders Meeting of May 12, 2021 approved the appointment of Florent Battistella, David Coti and John B. Hernandez as new directors. Following the stepping down of Truffle Capital from the CARMAT Board, the Board thus includes 12 members, 8 of them independent.

CARMAT also strengthened its leadership structure with the appointment of Professor Christian Latrémouille as Director of Surgical Affairs in February 2021 and, more recently, the appointment of Ivo Simundic as Sales Director for the DACH region to support the deployment of the Aeson® artificial heart in Germany, Austria and Switzerland.

- **Strategy and outlook**

In the second half of 2021, CARMAT intends to continue focusing its efforts and resources on its strategic priorities:

- commercialize Aeson® in Europe, following the first sales recorded in July,
- perform additional implants within the Early Feasibility Study framework in the United States,
- perform the first implants within the framework of the EFICAS study in France,
- ramp-up the production of the device, and continue to improve processes and secure all supplies.

Given the gradual improvement in the COVID-19 situation, CARMAT does not anticipate any major adverse impact in the second half of 2021, but it closely monitors this situation, both in France and in other countries where the Company, its suppliers and customers operate. CARMAT could have to adjust its development prospects, should the situation deteriorate.

The Company would like to inform the public that, notably in accordance with good medical practice and subject to regulatory obligations or specific circumstances, it will not systematically communicate on individual Aeson® implantations, whether performed in a commercial set-up or as part of its clinical studies, or on the health condition of patients who have benefited from implants. However, the Company

[5] The initial enrollment target for this study was 20 patients, a figure that could be revised up or down during the study. The primary endpoint of this study is 6-month survival with the CARMAT heart or a successful heart transplant within 6 months of the device being implanted. The granting of CE marking did not a priori require a specific number of implantations and/or a predetermined success rate. In accordance with good clinical practice and subject to regulatory obligations or special circumstances, CARMAT does not provide individual details of implantations or patients' condition. To date, 15 patients have been implanted within the framework of the study. Of these 15 patients, 11 have successfully reached the study's primary endpoint (7 having survived for more than 6 months after receiving the CARMAT heart and 4 having had a successful heart transplant within 6 months of receiving the device), a success rate of over 73%.

is planning to communicate when it reaches significant milestones and when it publishes its financial results.

- **Join a video conference with Stéphane Piat today at 5:00 pm CEST**

Log in by clicking on this link:
https://us02web.zoom.us/webinar/register/WN_yT_wDB12Sd-7J5azUi34RQ

- The link above allows you to register for the virtual meeting via Zoom. You will then receive a confirmation email containing the link to access the meeting.
- If you do not have the Zoom application, it will automatically download when you log in to the webinar.
- At any time during the presentation, you can submit your question via the webinar platform. It will be queued for the Q&A session.

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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).