PRESS RELEASE

CARMAT reports its financial results for 2020, and confirms its 2021 prospects

- CE marking in the bridge to transplant indication received in December 2020
- Operating expenses under control at €36m
- Financial resources including cash position of €36m at December 31, 2020, providing financial visibility until Q3 2021
- Company actively reviewing options to fund its development beyond Q3 2021

Paris, February 10, 2021 – 7 am 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, today announces its annual results for the year ending December 31, 2020[1] and confirms its prospects for 2021.

Stéphane Piat, Chief Executive Officer of CARMAT, commented:

"I am very proud of all that has been accomplished at CARMAT in 2020, despite the global pandemic. 2020 opens a new chapter for CARMAT. The CE marking received on December 22 has paved the way to the commercialization of our artificial heart in Europe under the brand name Aeson®. This event materializes the efforts undertaken by all our employees and everyone involved in the CARMAT project since its inception. This unique device – the brainchild of Professor Carpentier – will become accessible to patients who currently have no therapeutic options.

CARMAT also achieved in 2020 many other major clinical and regulatory milestones. Firstly, in France, we obtained HAS approval to undertake EFICAS, a broad clinical study, two-thirds of whose costs will be covered by the French State. Secondly, the number of patients enrolled in the PIVOTAL study has increased to fifteen with the first implantation performed in Denmark and the resumption of implantations in France. Within this framework, our bioprosthesis has notably demonstrated a high level of reliability by providing a patient with 2 years of continuous support. Lastly, in the United States, thanks to the constructive talks undertaken with the FDA over the last year, we hope to soon perform the first implantations within the framework of an early feasibility study for which the CMS has approved the reimbursement of our product.

In 2021, we will continue this momentum by focusing our efforts primarily on the commercial launch of Aeson® in Germany during the second quarter of 2021, but also on the implementation of our clinical plan and the ramping up of production activity to accommodate long term demand. We have the financial resources we need to support this ramping up until the third quarter of 2021 and are exploring various options to extend our financial visibility beyond that horizon".

[1] Annual accounts were approved by the Board of Directors on February 8, 2021. Audit procedures relative to these accounts have been carried out, and the auditor's report is currently being prepared.

- **2020 annual results**

Simplified income statement (€ millions)	**2020**	**2019**
Sales	**0.0**	**0.0**
Operating profit/loss	**-36.4**	**-42.4**
Financial profit/loss	-2.5	-1.8
Non-recurring items	+0.2	-0.1
Research and Innovation tax credit	+1.7	+1.6
Net profit/loss	**-37.0**	**-42.6**

CARMAT did not generate revenues in 2020. The first sales are expected in the second quarter of 2021, following the CE marking received on December 22, 2020.

The annual operating loss amounted to €36.4m, a €6.0m improvement on the previous year. This improvement in the Company's operating loss vs 2019 reflects its efforts to control spending, it being specified that, for the first time, the Company has booked the net value of its inventories (i.e. €9.9 million) as assets on its balance sheet[2] at December 31, 2020.

In 2020, operating expenses of €36m were mainly dedicated to:

- its production activities: ramping-up of production and further work to enhance the reliability of production processes at the Bois-d'Arcy plant, continued actions to secure supplies and inventory building;
- the finalization of the commercial configuration of the bioprosthesis, including improvements identified during the research and clinical development phases;
- launch preparation in Europe from a regulatory (CE marking process), marketing and commercial as well as operational (logistics, IT systems, sales administration, etc.) perspective;
- pursuing its clinical activities: ongoing PIVOTAL study in Europe, but also preparation for the initiation of the Early Feasibility Study (EFS) in the United States and the EFICAS clinical study in France in 2021.

The increase of the financial loss to -€2.5m was mainly driven by loan interests, as the Company drew down in May 2020 the second tranche (€10m) of the conditional loan granted by EIB (European Investment Bank) in December 2018.

Net loss of €37.0 million in 2020 included Research and Innovation tax credits of +€1.7m and non-recurring items of +€0.2m.

[2] Previously, inventories were directly booked as expenses of year during which they were purchased or produced, due to the lack of immediate prospect of generating future economic benefits from them.

- **Financial structure**

The Company had a cash position of €36.0 million at December 31, 2020, versus €55.5 million at December 31, 2019. This €19.5 million decrease compared to December 31, 2019 results from the following cash flows:

(€ millions)	**FY 2020**	**FY 2019**
Cash flow from operating activities	-43.0	-40.2
Cash flow from investment activities	-2.3	-0.6
Cash flow from financing activities	25.8	71.1
Change in cash position	**-19.5**	**30.2**

Cash generated by financing activities included:

- the €10m second tranche of the conditional loan granted by EIB,
- the €10m State-Guaranteed Loan contracted with BNP Paribas and Bpifrance,
- the €5.8m use of the contingent equity line with Kepler-Cheuvreux, in November and December.

Net debt amounted to €2.9m at December 31, 2020, as shown below:

(€ millions)	**31.12.2020**
+ Long-term financial liabilities[3]	38.8
+ Short-term financial liabilities	0.1
- Cash position	-36.0
Net financial debt	2.9

The available financial resources will enable CARMAT to finance its activities, according to its current development plan, until the third quarter of 2021.

These resources notably include:

- the €36m cash position as of December 31, 2020,
- the €10m final tranche of the EIB loan that CARMAT can draw down at any time until December 17, 2021, since the Company already fulfilled all criteria to draw down this tranche,
- the €13m financing from the French State in connection with partial funding of EFICAS study.[4]

Furthermore, until September 27, 2021, CARMAT has the possibility to use the remaining balance (€16m as of December 31, 2020) of the Kepler Cheuvreux contingent equity line. Full use of this balance would allow the Company to finance its activities until November 2021. CARMAT is actively reviewing all options to finance its development beyond that horizon.

[3] Financial liabilities include the principal (€20m) and interest due on the EIB loan, the principal (€10m) and interest due on the State-Guaranteed Loan and interest pertaining to the €14.5m repayable advance obtained from Bpifrance. The characteristics and conditions of the EIB loan and the Bpifrance repayable advance are described in Section 3 of the Company's universal registration document. Long-term financial liabilities correspond to those with a maturity exceeding 12 months.

[4] This funding will be progressively received as implants within the framework of the study are performed, over an estimated timeframe of 2 years. Implantations are expected to begin during the second quarter of 2021.

- **2020 highlights**

CE marking granted to the artificial heart as a bridge to transplant

On December 22, 2020, the CARMAT artificial heart was granted CE marking as a bridge to transplant (BTT) for 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 who are likely to undergo a heart transplant within 180 days of the implantation.

CE marking represents a major milestone for CARMAT, as it allows the Company to market its total artificial heart system in all countries that recognize this certification, including every country within the European Union.

Continuation of the PIVOTAL study

The positive interim results of the PIVOTAL study, which is still underway, contributed to the granting of CE marking. During 2020, 3 patients were implanted within the framework of this study (1 in Denmark and 2 in France, where the study resumed in the second half of 2020), thus taking the total number of patients implanted within the framework of this study to 15.[5]

Preparation for the initiation of the Early Feasibility Study (EFS) in the United States

The EFS was fully approved by the American Food and Drug Administration (FDA) in February 2020, and the Centers for Medicare & Medicaid Services (CMS) approved coverage of the CARMAT device, routine care items and associated services supplied to patients within the framework of this study in May 2020.

The various steps (ethics committee approval, signing of contracts with centers participating in the study, logistical arrangements, etc.) enabling the study to begin progressed well over the year so that, to date, three centers (VCU Health Pauley Heart Center, Richmond, Virginia; University of Louisville Jewish Hospital, Louisville, Kentucky; and Baylor University Medical Center, Dallas, Texas) are already in a position to enroll patients in this study.

However, in order to be able to use the most recent configuration of its artificial heart for the EFS, CARMAT has submitted a certain number of amendments to the FDA. The last of these amendments is likely to be approved shortly, and the first implantation within the framework of the EFS is thus expected during the first quarter of 2021.

EFICAS study and financing approved within the framework of the *Forfait Innovation* program

In April 2020, the French National Authority for Health (HAS) definitively confirmed its positive opinion regarding the financing by special exemption of the CARMAT total artificial heart within the framework of the EFICAS multicenter study to be undertaken on 52 patients in France.

In October 2020, the Ministry of Health and Solidarity validated funding of €13 million, enabling two-thirds of the costs of the study to be covered. This sum will be progressively received as implantations are performed.

CARMAT expects implantations within the framework of the EFICAS study to begin during the second quarter of 2021.

[5] The initial enrollment target for this study was 20 patients, a figure that can 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. For the first 11 patients in the study (the latest results published by CARMAT), the success rate is 73% (6 patients having survived for over 6 months with the CARMAT heart and 2 having been successfully transplanted within 6 months of the implantation). 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; and will only communicate when significant milestones are achieved. The next publication on the results of the ongoing PIVOTAL study is expected once this study is completed.

Commercial launch preparation

CE marking for the device as a bridge to transplant represents a major market opportunity, with more than 2,000 patients currently on waiting lists for a heart transplant in the five main European countries[6].

Ahead of the granting of CE marking, CARMAT had taken the necessary steps to begin the commercialization of its total artificial heart in the second quarter of 2021, notably with:

- the acceleration of the ramping up of production activities;
- proactive targeting of clients and early support to hospitals with their reimbursement process;
- the positioning of the product that will be marketed under the brand name Aeson®;
- the set-up of logistic arrangements, sales administration and IT systems, and strengthening of the teams required for the commercialization.

In 2021, the Company is planning to focus the device's commercialization on Germany and France, which account for 55% of the Mechanical Circulatory Support (MCS) device market in the European Union[7]:

- Aeson® will be launched commercially in Germany during the second quarter of 2021;
- the French market will initially be addressed via the EFICAS study.

Impact of the Covid-19 pandemic

In 2020, the effects of the Covid-19 pandemic could be experienced with, in particular, a lengthening of timeframes within the framework of talks with the regulatory authorities regarding the EFICAS study. The Company also experienced supply issues that slowed the pace of production and the building up of prosthesis inventories, as well as difficulties accessing hospitals that slowed patient enrollment in the PIVOTAL study. Despite these problems, at no time during the year did the Company halt production.

- **Recent events, 2021 priorities and outlook**

Professor Christian Latrémouille joins the Management Team

In January 2021, CARMAT announced the appointment of Professor Christian Latrémouille as Director of Surgical Affairs. Doctor of Medicine, Christian Latrémouille is the only heart surgeon in the world who has participated in the CARMAT heart's entire clinical assessment process. He will be in charge of supporting and supervising hospitals from the training of surgical teams to the treatment of patients.

2021 outlook

In 2021, CARMAT intends to pursue its development via its three major strategic priorities:

- commercial launch of its prosthesis in Europe, scheduled for the second quarter of the year;

- implementation of a robust clinical plan with the aim of supporting the adoption of its artificial heart and its value proposition, and eventually obtaining the destination therapy (DT) indication. This plan notably includes:
  - the launch of the EFS in the United States in the first quarter,
  - the launch of the EFICAS study in France in the second quarter,
  - the initiation of extensive post market clinical follow-up (PMCF);

- ramping up of its production capacity and further actions to secure industrial supplies.

Moreover, CARMAT is continuing to closely monitor the Covid-19 situation in France and abroad and, depending on its evolution, may need to reassess its impact and adjust the Company's prospects.

[6] statistics.eurotransplant.org: 9023P_2019; https://rams.agence-biomedecine.fr; Five main European countries: France, Germany, Italy, Spain and the United Kingdom.
[7] GlobalData: EU5 Cardiac Assist Devices Market Outlook To 2025 - Intra-Aortic Balloon Pumps, Mechanical Circulatory Support Devices And Short-Term Circulatory Support Devices (Report GDMECR1561DB)

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About CARMAT: the world's most advanced total artificial heart project

A credible response to end-stage heart failure: CARMAT aims to eventually provide a response to a major public health issue associated with heart disease, the world's leading cause of death: chronic and acute heart failure. By pursuing the development of its total artificial heart, composed of the implantable bioprosthesis and its portable external power supply system to which it is continuously connected, CARMAT intends to overcome the well-known shortfall in heart transplants for the tens of thousands of people suffering from irreversible end-stage heart failure, the most seriously affected of the 20 million patients with this progressive disease in Europe and the United States.

The result of combining two types of unique expertise: the medical expertise of Professor Carpentier, known throughout the world for inventing Carpentier-Edwards® heart valves, which are the most used in the world, and the technological expertise of Airbus Group, world aerospace leader.

The first physiologic heart replacement therapy: given the use of highly biocompatible materials, its unique self-regulation system and its pulsatile nature, the CARMAT total artificial heart could, assuming a successful clinical development, potentially save the lives of thousands of patients each year with no risk of rejection and with an enhanced quality of life.

A project leader acknowledged at a European level: with the backing of the European Commission, CARMAT has been granted the largest subsidy ever given to an SME by Bpifrance; a total of €33 million.

Strongly committed, prestigious founders and shareholders: Matra Défense SAS (subsidiary of the Airbus Group), Professor Alain Carpentier, the Centre Chirurgical Marie Lannelongue, Truffle Capital, a leading European venture capital firm, ALIAD (Air Liquide's venture capital investor), CorNovum (an investment holding company held 50-50 by Bpifrance and the French State), the family offices of Pierre Bastid (Lohas), of Dr. Antonino Ligresti (Santé Holdings S.R.L.), of the Gaspard family (Corely Belgium SPRL and Bratya SPRL) and of M. Pierre-Edouard Stérin (BAD 21 SPRL), Groupe Therabel as well as the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: *www.carmatsa.com*

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No guarantee can be given as to any of the events anticipated by the forward-looking statements, which are subject to inherent risks, including those described in the Universal registration document filed with the Autorité des Marchés Financiers on March 13, 2020 under number D.20-0126 as well as changes in economic conditions, the financial markets or the markets in which CARMAT operates. In particular, no guarantee can be given concerning the Company's ability to finalize the development, validation and industrialization of the prosthesis and the equipment required for its use, to manufacture the prostheses, satisfy the requirements of competent authorities, enroll patients, obtain satisfactory clinical results, perform the clinical trials and achieve commercial objectives.

Aeson® is an active implantable medical device commercially available in Europe ONLY, CARMAT SA., CE0344. The Aeson® TAH is intended to replace ventricles of 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 LVAD and are likely to undergo heart transplant in the 180 days following device implantation. The decision to implant and the surgical procedure must be executed by Health Care professionals trained by the manufacturer. Carefully read the documentation (clinician manual, patient

manual & alarm booklet) for characteristics and information necessary for patient selection and good use (contraindications, precautions, side effects).

In the USA, Aeson® is currently exclusively available within the framework of clinical trials.