PRESS RELEASE

CARMAT reports its 2019 half-year results and confirms its main development targets to obtain CE marking in 2020

- Cash position of €15.7 million at June 30, 2019
- CE marking technical dossier submitted in July
- Significant progress in the European and American market access strategy
- Short-term strengthening of the financial structure to secure developments until mid-2021

Paris, September 18, 2019 – 5.45 pm CEST

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, aiming to provide a therapeutic alternative for people suffering from end-stage biventricular heart failure, today reports its results for the first half of the year to June 30, 2019[1] and provides an update on its development prospects. The 2019 half-year financial report (in French) was published today and is available on the Company's website.

Stéphane Piat, Chief Executive Officer of CARMAT, commented: "*During the first half of 2019, our technical teams devoted a considerable effort to perfecting our manufacturing system at Bois-d'Arcy, and all our prostheses are now produced on this state-of-the-art site in accordance with strengthened procedures that meet the requirements of the industrial production of our complex medical device. At the same time, we have been actively pursuing our regulatory strategy, and submitted the full technical dossier to DEKRA at the start of the second half of 2019. On the clinical front, we are delighted to be able to report a record duration of 18 months of individual support and 6 years and 6 months of cumulative support to date since the start of the PIVOTAL study. We recently received approval to resume the study in Denmark, and are confident that we will soon receive similar approvals in the Czech Republic and Kazakhstan, enabling us to finalize the second part of the study in line with our objective of completing the regulatory dossier within the best possible timeframe to allow us to obtain the CE marking in 2020. Furthermore, having obtained a conditional approval from the FDA, we will soon be able to initiate an Early Feasibility Study on a first cohort of 5 patients in the United States, thus paving the way for CARMAT to address the world's largest market for medical devices*."

[1] First-half accounts were approved by the Board on September 18, 2019 and have been the subject of a limited review by the statutory auditors.

- **2019 half-year results**

Simplified income statement (€ millions)	**30/06/2019**	**30/06/2018**
Operating income	**0.7**	**0.7**
Operating expenses	**-24.4**	**-20.1**
Operating profit/loss	**-23.7**	**-19.4**
Financial profit/loss	-0.8	-0.5
Exceptional items	-0.0	-0.0
Research tax credit	+0.5	+1.0
Net profit/loss	**-24.0**	**-18.9**

As its total artificial heart project is still in clinical development, CARMAT recorded no revenue in the first half of 2019.

Over the period, operating expenses increased by 21% to €24.4 million, in line with the Company's strategic progress. During the first half, CARMAT devoted most of its resources to:

- studies and tests undertaken within the framework of the process for obtaining CE marking on the one hand and activities aimed at obtaining approval to begin an EFS (early feasibility study) clinical trial in the United States on the other;
- ramping up and ensuring the reliability of the production of prostheses at the Bois-d'Arcy plant, which resumed in May;
- continuing the transformation of CARMAT into an industrial and commercial company.

Once the financial loss (-€0.8 million), exceptional items and Research Tax Credit (+€0.5 million) are taken into account, the net loss at June 30, 2019, was €24.0 million, versus a loss of €18.9 million at June 30, 2018.

- **H1 2019 highlights**

Positive interim clinical results

CARMAT presented the positive interim results of the first cohort of the PIVOTAL clinical study in January 2019. These interim results showed that 70% of the patients in this first cohort reached the study's primary endpoint, corresponding to 6-month survival with the bioprosthesis or a successful transplant within 6 months of the device being implanted. The data also confirmed the prosthesis' biocompatibility, and in particular its positive safety profile never before achieved by any other technologies, notably with the absence of cerebrovascular accidents, gastrointestinal bleeding or infections. These results were also presented at the 39th ISHLT (International Society for Heart & Lung Transplantation) annual meeting, one of the world's largest forums in this field, in Orlando, Florida, in April 2019.

CARMAT also presented additional interim results at the ASAIO (American Society for Artificial Internal Organs) conference in San Francisco, California, at the end of June 2019, demonstrating the proper functioning of the autoregulation system on the first patient cohort.

Resumption in the production of prostheses

During the first half of 2019, CARMAT completed the transfer of all of its production activities to the Bois-d'Arcy industrial site. Following the analysis of the information gathered from the experience accumulated with the first patient cohort of its PIVOTAL study and data recorded on test benches, CARMAT implemented a review of its manufacturing processes in order to further enhance the reliability of its

prosthesis. The implementation of the changes adopted following this review required production to be halted from October 2018 until its resumption in May 2019.

The production chain is now fully operational, and all of the prostheses will be produced at the Bois-d'Arcy site in accordance with these new manufacturing processes.

- **Strategy and outlook**

Significant progress in the European and American market access strategy

To date, 11 patients have been implanted within the framework of the European PIVOTAL study, and the prosthesis has achieved a record duration of 18 months of individual support and 6 years and 6 months of cumulative support since the start of the study. CARMAT recently announced that it had received approval to resume patient enrollment at the Rigshospitalet hospital in Copenhagen, Denmark, and the Company is also in advanced discussions regarding the resumption of implants in Kazakhstan and the Czech Republic. It is also planning to extend the study to other countries.

At the same time, in July CARMAT submitted the technical dossier for the CE marking to the DEKRA certification body.

Following talks with the FDA (Food and Drug Administration, the US health authority) during the semester, CARMAT recently received conditional approval to initiate an EFS (Early Feasibility Study) in the United States. The EFS protocol includes 5 transplant-eligible subjects who will be recruited from a network of 7 reputed US clinical centers. The study can begin once it receives Institutional Review Board approval.

Given the progress made since the start of 2019, CARMAT is reaffirming its main development objectives, i.e.:

- the finalization of the PIVOTAL study with the completion of the enrollment of the second patient cohort with a view to obtaining the CE marking in 2020;
- the initiation of a clinical feasibility study in the United States;
- the continuous improvement of its manufacturing processes, following the changes already made to its processes;
- the transformation of CARMAT into an industrial and commercial company, notably in order to prepare the commercial launch of its prosthesis.

Financial structure

At June 30, 2019, the Company had a cash position of €15.7 million, compared with €25.3 million at December 31, 2018, and notably included the drawdown on the €10 million first tranche of the conditional loan granted by the EIB (European Investment Bank) in December 2018.

Furthermore, CARMAT notably has access to:

- the balance on the EIB loan, which totaled €20 million at June 30, 2019, and whose drawdown is dependent on certain technical and/or financial criteria being achieved;
- a contingent equity line subscribed to with Kepler Cheuvreux, the remaining balance of which stood at €22 million on June 30, 2019 (which may be exercised, depending on its requirements and market conditions, until end-September 2020).

The Company's clinical, industrial and commercial development will lead to additional financial requirements that CARMAT estimates at approximately €120 million until it reaches it self-financing point. Further financing will thus be necessary, the amount of which could reach €120 million should the Company not be able to use the balance on the EIB loan (€20 million) or the contingent equity line subscribed to with Kepler Cheuvreux (€22 million). CARMAT is thus today launching a capital increase without preemptive rights reserved for the categories of investors defined by the sixteenth and seventeenth resolutions of the General Meeting of March 28, 2019, the purpose of which – combined with CARMAT's sole current cash position – is to support the Company's clinical and industrial development through to mid-2021 and to prepare its commercial phase.

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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 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 physiological artificial heart: given its size, the use of highly biocompatible materials, its unique self-regulation system and its pulsatile nature, the CARMAT total artificial heart could, assuming the clinical trials are successful, potentially save the lives of thousands of patients each year with no risk of rejection and with a good 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) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.), 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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ALCAR EURONEXT GROWTH

ELIGIBLE PEA PME

Name: **CARMAT**
ISIN code: **FR0010907956**
Ticker: **ALCAR**

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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 contains forward-looking statements that relate to the Company's objectives. Such forward-looking statements are based solely on the current expectations and assumptions of the Company's management and involve risk and uncertainties. Potential risks and uncertainties include, without limitation, whether the Company will be successful in implementing its strategies, whether there will be continued growth in the relevant market and demand for the Company's products, new products or technological developments introduced by competitors, and risks associated with managing growth. 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.

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 Document de Référence *registration document filed with the* Autorité des Marchés Financiers *under number D.19-0135 on March 12, 2019, 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 the ANSM, enroll patients, obtain satisfactory clinical results, perform the clinical trials and tests required for CE marking and to obtain the CE mark. CARMAT products are currently exclusively used within the framework of clinical trials.*