PRESS RELEASE

CARMAT reports its 2020 half-year results and issues an update on its activities and outlook

- Cash position of €45.3 million at June 30, 2020, covering the next major stages of its project
- Despite the COVID-19 crisis, CARMAT still on track to meet key deadlines:
  - CE marking expected by the end of 2020, allowing a commercial launch in 2021
  - Implants within the framework of the feasibility study in the United States expected to begin by the end of 2020
- Videoconference with Stéphane Piat at 6.30 pm Paris time today

Paris, September 9, 2020 – 5.45 pm CEST

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart, 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, 2020[1] and issues an update on its activities and development prospects.

Stéphane Piat, Chief Executive Officer of CARMAT, said: "*The first half of 2020 was unusual because of the COVID-19 pandemic that affected healthcare systems around the world. For CARMAT, the impact was insofar limited as our activities in France continued with limited hindrances and in strict compliance with the health and safety measures imposed by the authorities. During the first half of the year, we continued our work to ramp up production and enhance the reliability of production processes at our Bois-d'Arcy plant, with a particular emphasis on securing supplies with a view to the commercial phase. On a clinical level, with the gradual easing of restrictions in Europe from mid-May 2020, Rigshopitalet in Denmark was able to perform its first implantation of our device, thus taking the total number of patients in the PIVOTAL study to 13. Given the persistence of the COVID-19 situation and the resulting procurement problems encountered by certain suppliers, CARMAT is now expecting to complete enrollment in the PIVOTAL study by the end of the first quarter of 2021. This delay does not jeopardize the timeframe of the submission and review of the CE marking dossier making it possible for this CE marking to be granted by the end of 2020. We are also continuing to hold discussions with the FDA and various stakeholders in the U.S. feasibility study to enable patient enrollment to begin before the end of 2020 as planned, subject to the public health emergency improving. The "Forfait Innovation" dossier was definitively approved by the French National Authority for Health (HAS) in April, budgetary discussions initiated with the Ministry of Health and Solidarity have entered their final phase and official notification of the decision should be published in the coming weeks. Today, given what we have achieved in recent*

[1] First-half accounts were approved by the Board on September 7, 2020 and have been the subject of a limited review by the statutory auditors. The 2020 half-year financial report was published today and is available on the Company's website.

months and despite the ongoing pandemic context, we are confirming our development strategy and, with a cash position of €45.3 million, have the necessary resources to meet our project's key milestones."

- **2020 half-year results**

Simplified income statement (€ millions)	**30/06/2020 (6 months)**	**30/06/2019 (6 months)**
Net sales	**0.0**	**0.0**
Other operating income	**0.3**	**0.7**
Operating expenses	**-20.9**	**-24.4**
Operating profit/loss	**-20.6**	**-23.7**
Financial profit/loss	-1.0	-0.8
Non-recurring items	0.0	0.0
Research tax credit	+0.8	+0.5
Net profit/loss	**-20.8**	**-24.0**

As its total artificial heart project is still in clinical development, CARMAT generated no sales in the first half of 2020.

Over the first half of 2020, operating expenses totaled €20.9 million and were mainly allocated to:

- production activities: ramping up of production and further work to enhance the reliability of production processes at the Bois-d'Arcy plant; continuation and intensification of actions to secure supplies, including the set-up of "double-sourcing" for key suppliers;
- the finalization of the product's commercial configuration, including improvements identified during the research and clinical development phases;
- preparation for commercialization in Europe from a regulatory (CE marking process), marketing and commercial perspective, but also from an operational perspective (logistics, IT systems, sales administration, etc.);
- the pursuance of clinical activities: ongoing PIVOTAL study in Europe, but also preparation for the launch of the Early Feasibility Study (EFS) in the United States.

These expenses were down by 14% compared with the first half of 2019. This decrease was firstly because a large part of R&D activities within the framework of the CE marking process and approval to initiate the EFS in the United States were carried out in 2019, and secondly because there was a slight slowdown in spending in the first half of 2020, notably as a result of the COVID-19 crisis.

The first half of 2020 thus saw a net loss of €20.8 million, versus a loss of €24.0 million at June 30, 2019, once a financial loss of -€1.0 million and Research Tax Credit of +€0.8 million are taken into account.

- **Financial structure at June 30, 2020**

The Company had a cash position of €45.3 million at June 30, 2020, versus €55.5 million at December 31, 2019. The €10.2 million decrease compared to end-2019 was a result of the following cash flows:

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

In May 2020, the Company drew down the second tranche of €10 million of the conditional loan granted in December 2018 by the EIB (European Investment Bank); the Company has the flexibility to draw down the final tranche of €10 million at any time until December 17, 2021.

The Company also has access to a €21.9 million contingent equity line with Kepler-Cheuvreux that may be used until September 26, 2020, although the Company does not intend to make use of this line.

These financial resources should allow CARMAT to successfully take its project through to CE marking and its commercial launch, whilst continuing its clinical development.

- **H1 2020 highlights and recent developments**

Clinical development and European market access

The COVID-19 pandemic resulted in difficult (or even impossible, as in Kazakhstan) access to hospitals and a suboptimal organization of implant procedures. Within this context, only one implant could be carried out in Denmark during the first half of 2020, taking the total number of implants performed within the framework of the PIVOTAL study to 13 (10 in the first cohort, now closed, and 3 in the ongoing second cohort).

The context of the pandemic that is still present today has also led to sourcing problems with certain suppliers of components, and CARMAT is now expecting to complete enrollment (20 patients in total) by the end of the first quarter of 2021. In this respect, over the summer, the Company submitted authorization requests aiming to expand the PIVOTAL study to four new centers in France.

Regarding the market access procedure, CARMAT has agreed, with the DEKRA notified body, to a detailed schedule for the filing and review of its dossier that would make it possible to obtain CE marking by the end of 2020 despite the delay resulting from the COVID-19 situation.

To date, the prosthesis has achieved, within the framework of the PIVOTAL study, almost 8 years of cumulative continuous support considering all patients who have benefited from the prosthesis.

Over the summer, CARMAT also announced the publication of the successful bridge-to-transplant experience performed during the PIVOTAL study on patients in the first cohort in the Journal of Heart and Lung Transplantation, the most recognized peer-reviewed journal in the field of transplantation.

US market access

In February 2020, CARMAT received full approval from the FDA (Food & Drug Administration) to undertake a clinical feasibility study in the United States on 10 patients eligible for a transplant.

Following this approval, in May, the Centers for Medicare & Medicaid Services (CMS) approved coverage of the CARMAT device and routine care items and services supplied to patients within the framework of this study.

The various steps (ethics committee approval, execution of contracts with the centers participating in the study, training of personnel, logistics, etc.) necessary to initiate the study made good progress over the first half of the year. Subject to the evolution of the COVID-19 crisis, and notably of travel restrictions in the United States and the ability to get access to participating hospitals, the first implant within the framework of the EFS should take place before the end of 2020, as expected.

***Forfait Innovation* in France**

In April 2020, the French National Authority for Health (HAS) confirmed its positive opinion regarding the financing by special exemption of the CARMAT total artificial heart within the framework of the EFICAS study, a prospective, multicenter, non-randomized study to be undertaken on 52 patients in France. This study has already received approval from the French National Agency for Medicine and Health Product Safety (ANSM) and the Île-de-France Patient Protection Committee (CPP).

Following these validations, budget discussions were initiated with the Ministry of Health and Solidarity and continued until August because of the COVID-19 context. The Ministry's decision is expected in the coming weeks.

- **Strategy and outlook**

Factoring the estimated impacts of the COVID-19 pandemic on the areas of development detailed above, CARMAT intends to focus its resources on the following strategic priorities:

- obtain CE marking by the end of 2020;
- initiate implants within the framework of the EFS in the United States by the end of 2020;
- complete the enrollment of the PIVOTAL study's second patient cohort by the end of the first quarter of 2021;
- reach a budget agreement with the Ministry of Health regarding the EFICAS study in France in the coming weeks, with implants beginning by the second quarter of 2021;
- ramp up production, along with the continuous improvement of processes; and secure supplies with a view to the commercial launch expected in 2021.

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

- **Participate in a videoconference with Stéphane Piat from 6.30 pm Paris time today (in French)**

Go to the following link:
https://us02web.zoom.us/webinar/register/WN_qvqA2XcNRGWHvUUjy7cLVg

- The above link will enable you to register for the Zoom virtual meeting.
- You will subsequently receive a confirmation email with the link to access the meeting.
- If you do not have the Zoom app, it will download automatically when you log in.
- At any time during the presentation, you can send in your question via the webinar platform. It will be put in a queue/line for the Q&A session.

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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), 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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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 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 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.