



PRESS RELEASE

CARMAT outlines commercial and development plan for its total artificial heart

- Addressable market in the bridge-to-transplant indication of more than 2,000 patients a year in Europe
- Company prepares for commercial launch in Q2 2021, with initial focus on Germany and France
- Robust clinical plan to support adoption and sales development
- Virtual conference with Stéphane Piat today at 5 pm CET

Paris, January 6, 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 outlines the commercial and development plan for its total artificial heart. **The Company holds a virtual conference in English today at 5 pm CET, for which you can register on [this link](#).**

2020, a defining year for CARMAT

In 2020, despite the COVID-19 situation, CARMAT has delivered on key objectives including:

- obtaining from the US Food & Drug Administration (FDA) the full approval to start an Early Feasibility Study (EFS) in the US, and successful training of three US centers in Q4 2020 in order to start implants in Q1 2021;
- securing a funding of €13m from the French state to start a new clinical trial ("EFICAS" study) in France in Q2 2021;
- receiving the CE Marking¹ which allows CARMAT to market its total artificial heart as a bridge-to-transplant in a large number of countries, including all European Union countries;
- resuming the PIVOTAL study in France, with 2 patients treated in December.

Commercial readiness, positioning and branding

Ahead of getting the CE marking, CARMAT had taken the necessary steps to be prepared to start selling its artificial heart from Q2 2021. This involves:

- accelerating the ramp-up of manufacturing activities;
- proactive customer targeting and early support to hospitals for reimbursement;
- product positioning and branding.

¹ The CE marking was granted on December 22, 2020, to CARMAT's total artificial heart system as a bridge-to-transplant (BTT) in patients suffering from end-stage biventricular heart failure (Intermacs Classes 1-4) who are not amenable to maximal medical therapy or the LVAD (Left Ventricular Assist Device) and who are likely to undergo heart transplant in the 180 days following implantation.

The Carmat artificial heart will be marketed under the Aeson® brand name.

In view of the 3 unique features of the product - pulsatility², autoregulation² and hemocompatibility³ - CARMAT creates a new product category: the Physiologic Heart Replacement Therapy⁴ (PHRT).

Commercial opportunity and plan

Significant market opportunity

The CE marking for the CARMAT heart as a bridge-to-transplant (BTT) represents a very significant market opportunity with a minimum of 2,000 patients currently on waiting lists for a heart transplant in five major European countries⁵.

Initial focus on Germany and France

In 2021, the Company's plan is to focus on Germany and France, which together account for 55% of the mechanical circulatory support (MCS) market in the European Union⁶:

- Aeson® will be commercially launched in Germany in Q2 2021,
- the French market will initially be addressed through the EFICAS study.

In addition, the company might seize further sales opportunities in other countries recognizing the CE marking.

Strong market development approach

In parallel, CARMAT will continue to implement a very robust clinical plan which includes the EFICAS Study in France (52 patients), the completion of the ongoing PIVOTAL study (target of 20 patients)⁷, along with a large post-market clinical follow-up which will include the first 95 patients treated in commercial setting, in order to generate further safety, performance and health-economics data. These data are expected to drive product adoption and support Aeson®'s value proposition (notably to obtain reimbursement of the product in France), and ultimately the obtention of the destination therapy (DT) indication for the product. While the BTT indication allows for temporary support by the device, this additional DT indication would allow CARMAT to target the patients who are not eligible to heart transplant who would remain under CARMAT's device support in the longer term.

CARMAT confirms that its available resources⁸ enable the company to fund its activities through to Q3 2021. The company is considering different options to finance its future development.

Stéphane Piat, Chief Executive Officer of CARMAT, says: "2020 was a defining year for the company, culminating with the obtention of the CE Marking just before Christmas. Despite a very challenging environment, marked by the COVID-19, CARMAT has delivered on the vast majority of its objectives, and

² Bizouarn P et al.; Effects of pre-load variations on hemodynamic parameters with a pulsatile autoregulated artificial heart during the early post-operative period. J Heart Lung Transplant. 2018;37(1):161-3

³ JACC 2017 Smadja, Bioprosthetic total artificial heart induces a profile of acquired hemocompatibility with membranes recellularization, July 2017:403-9

⁴ The "PHRT" category has been created by CARMAT and differentiates from the "TAH" (total artificial heart) category by its unique combination of 3 features: pulsatility, autoregulation and hemocompatibility. The physiological heart replacement therapy can be either temporary (BTT - bridge to transplant) or for the long run (DT - destination therapy). The physiological nature of Aeson® is documented in the following publication: Richez U et al.; Hemocompatibility and safety of the CARMAT Total Artificial Heart hybrid membrane. Heliyon. 2019 Dec; 5(12): e02914. Published online 2019 Dec 8. doi: 10.1016/j.heliyon.2019.e02914

⁵ statistics.eurotransplant.org: 9023P_2019; <https://rams.agence-biomedecine.fr>; Five major European countries: France, Germany, Italy, Spain and the UK.

⁶ 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)

⁷ The initial inclusion target for this study was 20 patients, a figure that can be adjusted up or down during the course of the study. To date, 15 patients have been enrolled in the study.

⁸ Including cash on-hand, €10m of 'PGE' Loan (loan guaranteed by the French State) drawn in November 2020, the last tranche (€10m) of the European Investment Bank Loan which can be drawn at any time until December 2021 (as drawdown criteria has already been met), and the non-dilutive financing of €13m granted by the French state to fund the EFICAS study (this amount will be perceived over the duration of the study); excluding the balance of the Kepler-Chevroux equity line, which can be used until September 27, 2021.

I would like to thank again the entire CARMAT team and all stakeholders who have made this possible. The bridge-to-transplant indication that we got as part of the CE Marking represents hope for patients and a very sizable market opportunity for the Company, as at least 2,000 patients are currently on waiting lists for a heart transplant in Europe, but only a fraction of them is fortunate enough to benefit from a donor graft. In 2021, our intention is to focus our efforts on Germany and France, which account for more than half of these patients. We might also address other countries recognizing the CE marking in a more opportunistic way. I am happy to confirm that we will be ready to start selling our product as early as Q2 2021. We will also continue to execute our strong clinical plan, in particular the EFICAS study that should start in Q2 2021, but also a post-market clinical follow-up of 95 implanted patients, which will have a significant impact on the adoption momentum of our prosthesis. Given its unique features demonstrated in clinical trials to date, Aeson® introduces a new way of treating end-stage heart failure, the Physiologic Heart Replacement Therapy, which aims to provide patients with significantly improved quality of life.”

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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 its size, 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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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 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.