



PRESS RELEASE

Paris, September 19, 2014

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced total artificial heart project, providing a therapeutic alternative for people suffering from end-stage heart failure, today repudiates the main allegations contained in the report broadcast during France 2 television channel's "*Envoyé Spécial*" program on Thursday September 11, 2014 and would like to reiterate the regulatory principles that govern its communications policy.

Within the framework of these principles, the Company would like to state that, on January 23 this year, it refused to give the program in question permission to film the first patient or to allow it to attend a future implant procedure. Indeed, the patients participating in this first-in-man trial are legally protected by various laws and regulations and, as the promoter of this trial, it is CARMAT's responsibility to comply with these laws and regulations and to ensure that others do likewise.

There has been no further contact between the Company and the program's makers since that date. Furthermore, this program - which was prepared some months ago - was broadcasted immediately after the recent announcement of a second implantation.

The unfair report's hostility, today compels CARMAT to come out and repudiate the allegations that question its technology, its prospects and its integrity. In particular:

- CARMAT has never claimed to be the first artificial heart, but the first French project, and the first bioprosthetic (containing biological tissue) and self-regulated (automatically adapting to the patient's requirements) project. The expression "the first artificial heart" is a media shortcut falsely attributed to us.

Furthermore, the world's first artificial heart was actually the one developed by Dr. Liotta and implanted in a patient on April 4, 1969 in Texas by Dr. Cooley, and not the one shown in the report.

- CARMAT has never claimed to be an "autonomous" heart. Medical self-regulation should not be confused with energy autonomy. The CARMAT device aims to regulate the heart automatically through sensors and embedded electronics, but obviously the heart requires energy to work, in this case electric energy.

It thus requires a supply source (batteries or mains) initially provided via a percutaneous cable. The system's architecture is described in detail in the Company's registration document¹, which is a regulatory document that is fully accessible to the general public and the media on the company website as well as on the French Financial Markets Authority's website.

- CARMAT has never claimed that it will sell 100,000 prostheses a year in the short, medium or long term. Here again, the report confuses a therapeutic need (i.e. the total potential "market") and sales forecasts.

In Europe and the United States, there are more than 20 million patients suffering from heart failure, a figure published by the American Heart Association and the European Society of Cardiology. The figure of over 100,000 (or 0.5% of the above figure) represents the annual

¹ The reference document is available on the Company's website, www.carmatsa.com, in the Investors/Documentation section, and on the French stock market authority's website, www.amf-france.org.

number of patients who reach irreversible, end-stage biventricular heart failure, who are unable to be treated in any other way, who are not eligible for a heart transplant, are under 70 years old and would be anatomically compatible with the CARMAT bioprosthesis - whether this heart failure is the result of a chronic deterioration or an acute situation.

The need for a therapeutic solution for these patients is supported by numerous scientific publications, some of which are also available in the Company's official documentation. Managing to treat even a small percentage of this subgroup would ensure the project's economic viability.

- CARMAT has never claimed that its project would be "a solution to heart failure". The Company's documentation describes in detail this pathology, its evolution and when each type of treatment is suitable depending on the illness' evolution, and all this in layman's language.

It notably states that the CARMAT project will address a subgroup of this population, namely patients with irreversible end-stage biventricular heart failure who have exhausted every other possible treatment. A whole chapter of the Company's official documentation is devoted to the market's players, and to the respective place occupied by the various mono-ventricular assist devices and artificial heart devices amongst the available therapeutic options.

- CARMAT has never claimed that it can provide a response to all needs. The Company studies indicate that 86% of men and 14% of women are anatomically compatible with the CARMAT heart. The results of these studies have been presented to the scientific community and are summarized in the Company's official documentation. These percentages were applied to the calculation of the addressable need to only retain patients who are anatomically compatible.

Furthermore, over 80% of patients implanted with the American heart currently marketed are men. This can be explained by the fact that, under the age of 80, men are significantly more affected by this disease than women. The current anatomical compatibility does not therefore restrict CARMAT's ability to address this need.

The implantable part of the American heart does not include any sensors, electronic components or embedded medical regulation system. The CARMAT heart, on the other hand, will mimic the natural heart using the anatomic space available in a thorax. The Company's ambition is to develop its product range to also treat additional needs (more women, emerging countries, etc.)

- CARMAT has also never claimed to have already reached the marketing stage. However, the Company's prostheses implanted within the framework of the first-in-man trial are of course not R&D prototypes but prostheses whose industrialization is already being carried out in line with industrial processes that have met the ISO 13485 norm, both within the Company and amongst its subcontractors, and whose clinical development is ongoing. Here again, the Company's official documentation clearly indicates exactly what stage the CARMAT heart project is currently at.

The next Shareholders' Newsletter will further discuss these issues, and will put the emphasis on shareholders' questions.

CARMAT would again like to reiterate the fact that its clinical trials and any publications pertaining to them are governed by legal and regulatory obligations (Public Health Code, Data Protection Laws, French Financial Markets Authority (AMF) regulations, etc.) that notably determine the following rules: the strict application of the contracts tying the Company to investigation centers, compliance with the independence of the monitoring boards, the confidentiality of trials and the protection of patients' data and identities.

The television report inappropriately suggests that this compliance with legal and regulatory obligations represents concealment.

Regarding the allegations contained in the report relative to Truffle Capital as a shareholder of CARMAT, Truffle Capital has already provided its responses.

CARMAT has always strived to publish detailed, accurate and honest information to the public, notably by publishing, each year, a detailed (and translated) registration document, which presents both the project's status and the risks inherent to the development of a medical device. CARMAT does this every single year, thus exceeding its regulatory obligations.

The registration document hence includes extensive, clear and verifiable information backed by scientific publications, and the Company would like to refer the makers of the television report to that document.

CARMAT reserves the right to take all appropriate measures, including legal measures, to enforce and protect its rights.

The Company would like to thank all of its staff, and the medical teams, partners and shareholders who have shown their trust in CARMAT through their many messages of support.

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

The only credible response for all cases of end-stage heart failure, which is a real public health issue: CARMAT's aim is to be able to 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. Indeed, this disease currently affects over 20 million patients in Europe and the United States. By pursuing the development of its total artificial heart, CARMAT intends to overcome the well-known shortfall in heart transplants for the tens of thousands of people suffering from heart failure.

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.

Imitating the natural heart: given its size, the choice of structural materials and its innovative physiological functions, CARMAT's total artificial heart could, assuming upcoming clinical trials are successful, potentially benefit the lives of tens of thousands of patients a year whilst ensuring there is no risk of rejection and providing them with an unparalleled 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: [Truffle Capital](#), a leading European venture capital firm, [Airbus Group](#), Professor [Alain Carpentier](#), the [Centre Chirurgical Marie Lannelongue](#) and the thousands of institutional and individual shareholders who have placed their trust in CARMAT.

For more information: www.carmatsa.com



Disclaimer

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* filed with the *Autorité des Marchés Financiers* under number D.14-045 on March 17, 2014 and the *Note d'Opération* that was approved with visa no. 11-308 on July 11, 2011, 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.



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