



Paris, November 24, 2015

In response to the various requests it has received, the Company would like to provide answers to the following questions

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1. What feedback has CARMAT received so far?

Clinical

The third patient implanted on April 8, 2015 was discharged and returned home at the end of August 2015. The patient is being regularly monitored. CARMAT has gradually built up a substantial volume of data.

The cumulative 19 months of experience have revealed good implantability, an absence of thrombosis or infection, the restoration of blood flow and an improvement in the quality of life. Further details regarding these elements can be found in scientific communication: article in July's The Lancet¹, ESC congress in London, AHA congress in Orlando².

Technical

We observed a disruption in the motor-steering electronics due to crystalline deposits from a micro leak (tens of microns) from the blood compartment into the prosthesis' activating liquid. The analyses showed a dispersal of tolerance on manufactured components. The appropriate corrective measures have been tested, validated and implemented. These analyses have confirmed that this was not a design flaw, but observed anomalies, which are possible at this stage of production for a complex medical device.

2. What are the project's next stages?

Feasibility study

CARMAT intends to bring this Feasibility study to a successful conclusion through the enrollment and 30-day monitoring of a fourth patient. The results of this study and the opinion of the Scientific Committee will be given to the ANSM (French national agency for the safety of medicines and health products).

Pivotal study

Simultaneously to the finalization of the report on the Feasibility study, the protocol of the Pivotal study that aims to obtain CE marking will be submitted to the ANSM, which will then give its opinion regarding the launch of this Pivotal study.

SEED

The protocol of the Pivotal study will incorporate the necessary economic elements for the submission of the reimbursement dossier within the framework of the SEED (Shaping European Early Dialogues for health technologies) project.

Training is continuing

¹ [http://dx.doi.org/10.1016/S0140-6736\(15\)60511-6](http://dx.doi.org/10.1016/S0140-6736(15)60511-6)

² http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/@scon/documents/downloadable/ucm_479203.pdf

During 2015, CARMAT's medical team continued to provide training to heart surgery centers in France and abroad through 8 surgical training sessions (acute animal trials) for various teams and 96 on-site sessions in implantation centers.

3. What is the current competitive context?

Thoratec (THOR), the sectorial leader, was acquired by St Jude Medical (STJ) for 3.4 billion dollars. In 2014, the company reported revenue of 478 million dollars and EBIT of 70 million dollars. The multiple paid for this acquisition in October 2015 highlights the sector's strong appeal.

Heartware (HTWR), designer of the HVAD® left Ventricular Assist Device, has announced that it suspended its trials on its latest ventricular assist device in October due to technical and clinical problems.

Syncardia, designer of the pneumatic biventricular assist device, announced in November that it has hired an investment bank within the framework of its search for strategic alternatives that could lead to the business being divested.

The new FDA directives published on April 13, 2015 (*Expedited Access for Premarket Approval*³) represent an excellent potential opportunity for strategies incorporating the US market launch of highly-innovative devices. With this in mind, CARMAT has signed a partnership with a leading American center to begin trials on animals.

These recent developments reflect substantial interest in the Mechanical Cardiac Assistance market that highlights its substantial potential and confirms the key factors for success that are an integral part of CARMAT's strategy:

- a response to a rapidly-growing clinical need,
- the highly-innovative nature of the technology used (pulsatility, biventricular support, hemocompatibility),
- the therapy's adoption by the scientific and medical community.

Additional projects have been announced in the domain of total artificial hearts:

- Bivacor (Texas Heart Institute in Houston)
- Smart Heart (Cleveland Clinic)
- University of Padua
- University of Portland
- Johns Hopkins University

As of right now, these projects are at either design stage or in their initial preclinical trial phase. CARMAT feels that it is a few years ahead of these innovative projects.

4. What is CARMAT's communication policy?

The Company reminds readers that, subject to regulatory requirements or specific circumstances, it does not plan to publish any information on data pertaining to the ongoing Feasibility study until its global analysis is completed.

³ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm441467.htm>