PRESS RELEASE

CARMAT expands its PIVOTAL study internationally, in line with its clinical strategy and CE marking process

Approval granted to perform implants in Kazakhstan, leading country in heart device trials for the European market

Paris, October 5, 2017 – 6 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 announces that it has received the approval to perform, within the framework of the PIVOTAL study protocol approved by the ANSM (French national agency for the safety of medicines and health products), implants of its total artificial heart in human patients at the *National Research Center for Cardiac Surgery* (Astana, Kazakhstan).

The *National Research Center for Cardiac Surgery* is a world reference in cardiology and a leading center in clinical studies for heart devices intended for the European market, with over 8,000 surgeries carried out in 2016 including 31 heart devices implanted and 15 heart transplants.

Moreover, the center benefits from an excellent postoperative patient follow-up. It also has substantial patient enrollment potential and considerable experience in clinical trials ahead of innovative medical devices commercialization. The facility is currently in the enrollment and CT scan (thorax scanners) screening phase aimed at identifying eligible patients who can be implanted with the CARMAT bioprosthesis.

The implants will be performed by the team headed by Dr. Yuriy Pya, CEO of the *National Research Center for Cardiac Surgery*, and an internationally recognized surgeon in the field of heart device implants.

Dr. Yuriy Pya, comments: *"The CARMAT artificial heart offers a new approach to the treatment of terminal heart failure, and we are delighted to provide our expertise to this promising project for patients suffering from this severe and irreversible condition. The approval from the Ministry of Health of the Republic of Kazakhstan has now been obtained and we look forward to implanting the device in a crucial study for the future of this disruptive innovation."*

Stéphane Piat, CEO of CARMAT, adds: *"The National Research Center for Cardiac Surgery is a world-renowned facility that is particularly recognized for the excellent care provided to cardiac patients and for its expertise in clinical trials for devices destined to the European market. Postoperative follow-up is one of the key selection criteria when we select facilities, and we are very pleased to be able to count on the local teams' know-how. In line with our clinical strategy and CE marking process, we are reinforcing our efforts to expand the PIVOTAL study to other countries, and plan to sign new collaborations shortly."*

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About the National Research Center for Cardiac Surgery

Founded in 2011 in Astana, Kazakhstan, under the patronage of the Ministry of Health, the National Research Center for Cardiac Surgery aims at improving the health of patients suffering from cardiovascular issues, and has performed 57 heart transplants and 8 lung transplants since its opening. In 2016, the facility admitted 7,033 patients and performed over 8,000 surgeries, including 2,424 open heart procedures. This center of excellence operates in accordance with international patient safety and quality standards combining surgical practice, science, education and innovative approach. The National Research Center for Cardiac Surgery is partnered with a number of leading clinics across the world including Germany, Italy, Belgium, France, Turkey, the United States and Israel.

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, 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.

Imitating the natural heart: given its size, the choice of structural materials and its innovative physiological functions, CARMAT's total artificial heart could, assuming the necessary clinical trials are successful, potentially benefit the lives of thousands of patients a 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: Airbus Group (Matra Défense), 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 (ZAKA) and of Dr. Antonino Ligresti (Santé Holdings S.R.L.) 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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