



## PRESS RELEASE

### **CARMAT has obtained the approval to proceed with the first human implantations of its bioprosthetic artificial heart at four renowned international cardiac surgery centers in four countries**

**Paris, May 14<sup>th</sup> 2013**

CARMAT (FR0010907956, ALCAR), the designer and developer of the world's most advanced project of total artificial heart, announces today that it has obtained the approval of four renowned international cardiac surgery centers in Belgium, Poland, Saudi Arabia and Slovenia to proceed with the first clinical implantations of its bioprosthetic total artificial heart.

These institutions are the [St Pierre University Hospital](#) (Brussels, Belgium), the [Silesian Center for Heart Disease](#) (Zabrze, Poland), the [Prince Sultan Cardiac Center](#) (Riyadh, Saudi Arabia), and the [University Medical Centre Ljubljana](#) (Ljubljana, Slovenia).<sup>1</sup>

All these institutions share excellence in surgical results and heart patient care, depth of patient recruitment and experience in innovative medical devices pre-market clinical trials.

In a common statement, Prof. Didier de Cannière, Chief of the Department of Cardiac Surgery at St Pierre University Hospital in Brussels, Belgium, Prof. Marian Zembala, Chairman, Department of Cardiac Surgery and Transplantation and Director of the Silesian Center for Heart Diseases in Zabrze, Poland, Prof. Borut Geršak, Head of the Department of Cardiovascular Surgery at the Ljubljana University Medical Centre, in Ljubljana, Slovenia, and Prof. Antonio Calafiore, Head of the Department of Adult Cardiac Surgery at Prince Sultan Cardiac Center in Riyadh, Saudi Arabia, declared: *"We are very glad to share our experience and knowledge and thus contribute to this extraordinary project, as end-stage heart failure is indeed an international health issue. CARMAT's bioprosthetic artificial heart could bring true innovation to the heart failure surgical community and we are looking forward to starting its implantation and to exploring its potential benefits for our patients."*

Prof. Alain Carpentier, co-founder and Scientific Director at CARMAT, comments: *"I have been very pleased to learn that the leaders of these prestigious departments are willing to join us in the evaluation of the Carmat bioprosthesis. As recognized experts in the field, they will be able to appreciate first-hand the unique features and remarkable performances of this prosthesis."*

Marcello Conviti, CEO of CARMAT, concludes: *"The patient selection process and the training of the clinical teams are ongoing in these four countries, supported by our French proctors, Prof. Christian Latrémouille, Cardiac Surgeon at the Georges Pompidou European Hospital in Paris and Prof. Daniel Dubeau, Medical Director of the Thorax Institute and of the Department of Thoracic and Vascular surgery at University Hospital in Nantes. Implantations could start shortly following the completion of the training. Carmat expects to receive additional approvals in a near future, potentially in France (ANSM approval) and in other countries."*

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<sup>1</sup> For more details, the reader is invited to refer to the appendix of the present press release.

## 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 100 million patients in developed countries. 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 EADS, 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 OSEO; a total of €33 million.

**Strongly committed, prestigious founders and shareholders:** [Truffle Capital](#), a leading European venture capital firm, [EADS](#), the [Fondation 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](http://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 registered with the Autorité des Marchés Financiers under number R.12-044 on September 12, 2012 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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**ALCAR**  
**LISTED**  
NYSE  
ALTERNEXT

Name: **CARMAT**  
ISIN code: **FR0010907956**  
Ticker: **ALCAR**

# Appendix<sup>2</sup>

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## Belgium

### About St Pierre University Hospital

St-Pierre University Hospital is a centre of excellence with top-ranked services in Cardiovascular Disease, Children's Health, Digestive Diseases, Gynecology and Obstetrics, Infectious Diseases and Ophthalmological Surgery to name but a few. All of these services include both surgical and non-surgical treatment of medical conditions, with a truly unique expertise and focus on minimally invasive, multidisciplinary approaches.

Saint-Pierre University Hospital is a teaching hospital affiliated with the two top medical schools (French and Flemish branches) of Brussels University, [Université Libre de Bruxelles](http://www.ulb.ac.be/) and [Vrije Universiteit Brussel](http://www.vrijeuniversiteit.be/).

**Mission** - Health teaching, research and services to the community are three essential and complementary areas which Saint-Pierre University Hospital is involved in and which it is continuously striving to develop further.

**For more information:** <http://www.stpierre-bru.be/en/index.html>

### About Professor Didier de Cannière

Prof. de Cannière is the Chief of the Department of Cardiac Surgery at St Pierre University Hospital in Brussels, Belgium, since his recent return from the United States where he was Professor of Surgery (Miller School of Medicine, University of Miami), and Director of the Institute of Surgical Innovation and Head of the Department of Minimally Invasive and Robotics Cardio-Thoracic Surgery at the University of Miami from 2010 to 2013. ([http://www.youtube.com/watch?v=p\\_ZlxSlz6hk](http://www.youtube.com/watch?v=p_ZlxSlz6hk) - [http://www.youtube.com/watch?v=sJz-6\\_kmkiw](http://www.youtube.com/watch?v=sJz-6_kmkiw) ). Prior to this tenure, he was Head of Department of the Erasme Academic Hospital and University Tivoli ULB from 2004 to 2010.

Since his Ph.D. thesis on the pulsatile haemodynamics of the right ventricle in 1996, he has remained at the forefront of research for innovative cardiovascular disease treatment. Prof. de Cannière has served as principal investigator in several international multicentre trials, more recently in the field of heart valve development and stem cell transplantation, and is a pioneer in minimally invasive and robotic cardiac surgery. Prof. de Cannière co-led the course on Minimally invasive mitral valve repair (ECMICS) endorsed by the European Society of Cardiovascular Surgery (ESCVS) where more than 200 surgical groups were trained, and then helped develop these innovative techniques at the University of Miami. Prof. de Cannière has published over 50 peer-reviewed scientific publications in renowned journals such as Circulation, the Annals of Thoracic Surgery, the Journal of Thoracic and Cardiovascular Surgery, the American Heart Journal, Cardiovascular research, etc., has performed surgery on invitation in more than 10 different countries on 4 continents and was Guest Faculty in over 20 congresses worldwide in the past three years. He served also on the board of Directors of the International Society of Minimally Invasive Cardiac Surgery (ISMICS 1999-2002) and on the Board of the European Society for Cardio-Vascular Surgery. He kicked off a program of open heart cardiac surgery in Yaoundé Cameroon (<http://missioncameroun.skyrock.com>). He is currently focused on developing alternative approaches to the treatment of structural heart disease.

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## Poland

### About the Silesian Center for Heart Diseases (SCCS)

The Silesian Center for Heart Diseases in Zabrze welcomed its first patient in 1984 and is a modern, highly specialized heart center, recognized nationwide and internationally for its outstanding clinical and scientific achievements in cardiology and cardiothoracic surgery.

The Center has performed more than 1'000 heart transplantations, 70 combined heart and lungs transplantations and over 34'000 open heart surgeries thus granting it a leading position in Europe, from a research as well as from a clinical standpoint. It offers the broadest possible spectrum of diagnostics, therapeutic and surgical treatment options for both congenital and acquired heart diseases. Patients presenting symptoms of acute coronary syndromes are treated immediately by well trained and experienced cardiologists ready to perform any kind of percutaneous intervention twenty four hours a day, seven days a week. In case of any difficulties cardiac surgeons are always on standby, prepared to take over.

**Mission** – To rescue, treat and give hope...

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<sup>2</sup> Regulatory processes differ in each country. There is not always a centralized regulatory body as in France, and approvals may be granted hospital by hospital and in some cases, patient by patient.

For information re. Prof. Christian Latrémouille, the reader is invited to refer to CARMAT Shareholder Newsletter n°1 available on [CARMAT website](#) (Investors/Documentation/Shareholder Newsletter).

For information re. Prof. Daniel Duveau, the reader is invited to refer to CARMAT Shareholder Newsletter n°3 available on [CARMAT website](#) (Investors/Documentation/Shareholder Newsletter).

**For more information:** <http://www.sccs.pl/en/>

## About Professor Marian Zembala

Prof. Zembala, MD PhD FESC, is chairman of the Department of Cardiac Surgery and Transplantation (since 1998) and the director of the Silesian Center for Heart Diseases (since 1993). He is national chief consultant in cardiac surgery (since 2011) and chairman of the Scientific Council of the Ministry of Health (since 2009). Prof. Zembala was an Adjunct Assistant Professor of Surgery and Deputy Head of the Department of Cardiac Surgery of the Medical University of Silesia in Katowice from 1985 to 1998. On the forefront of research, Prof. Zembala also completed several postdoctoral fellowship programs notably in Aachen, Germany (1999), in Brown Mills, New Jersey, USA (1998), in Utrecht, The Netherlands (1981-1985) and Leuven, Belgium (1980). He is also an alumnus of Professor Alain Carpentier's course on mitral valve repair.

Prof. Zembala is internationally recognized for his clinical and surgical achievements. He introduced many innovative procedures in Poland, among others minimally invasive transcatheter aortic valve implantation, single-lung transplant in pulmonary hypertension patients, lung transplant, heart-and-lung transplant, heart-and-kidney transplant. He leads the largest mitral valve reconstruction program in Poland, the first and the largest in the country heart failure treatment program and heart and lung transplant program. Prof. Zembala was a President of the European Society for Cardiovascular and Endovascular Surgery (2010-2012; since 2008 - a member of the ESCVS Executive Committee). He is a member of the International Society for Heart and Lung Transplantation, the European Association for Cardio-Thoracic Surgery, the European Society of Cardiology, the Society of Thoracic Surgeons and the American Association of Thoracic Surgeons and the Editor-in-chief of the Polish Journal of Cardio-Thoracic Surgery.

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## Slovenia

### About the Ljubljana University Medical Centre (Ljubljana UMC)

The Ljubljana University Medical Centre (Ljubljana UMC) is Ljubljana's hospital centre and the largest hospital centre in Slovenia. It was officially opened on 29 November 1975, has over 2000 beds and 7000 employees, and performs over 100 000 in-patient admissions per year, making it one of the largest hospitals centers in Central Europe. It is the main training base for the Faculty of Medicine in Ljubljana, which is housed nearby. The Ljubljana UMC has a large transplant activity, steadily increasing by over 20% each year.

**Mission** – Our principal aim is to provide quality care to patients from Slovenia and other European countries. The UMCL's organization and activities are geared at continuous improvement of our services, development and introduction of new methods of treatment, and transfer of knowledge to younger generations of health professionals. Our major objectives are to acquire European accreditation, implement a comprehensive system of quality assurance, and achieve international quality standards. We have close contacts with similar institutions in the European Union. Our wish is to create a favorable working environment for our employees and provide quality professional care to our patients.

**For more information:** <http://www.kclj.si/ang/index.php>

### About Professor Borut Geršak

Prof. Borut Geršak was first admitted to study nuclear engineering at the Massachusetts Institute of Technology (in Cambridge, MA), but soon changed his mind and graduated in 1991 at the Ljubljana Medical Faculty as a specialist surgeon. Since 2006, he has been the head of the Department of Cardiovascular Surgery at the University Medical Center, Ljubljana, Slovenia. Prof. Geršak's work represents a great contribution to cardiac surgery in Slovenia and worldwide. He introduced heart-valve surgery on a beating heart, and was the first in Slovenia and among the first in the world to perform marginal artery bypass surgery on a beating heart without cardiopulmonary bypass in 1997, as well as the endoscopic aortic valve surgery and tricuspid valve surgeries on a beating heart, which he demonstrated in many European countries and in the US. In recent years, Prof. Geršak has focused on the surgical treatment of end-stage heart failure and the use of mechanical heart support, the use of biological heart valves and tissue engineering, and the use of computer technology in cardiovascular surgery, the latest's as one of the coordinators of the European project Augmented Reality in Surgery.

He is one of the founders of the Slovenian Surgeons' Association and has served as a member of many international surgical societies and associations such as the European Association for Cardio-Thoracic Surgery, the International Society for Minimally Invasive Cardiothoracic Surgery and the Society of Thoracic Surgeons. He is also a member of the editorial boards of several international journals.

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## Saudi Arabia

### About Prince Sultan Cardiac Center (PSCC)

Cardiac services started in 1979 at Riyadh Military Hospital. The Center was crowned in May 1992 by a Decree of HRH the late, God Willing, Prince Sultan bin Abdulaziz, stating the establishing of Prince Sultan Cardiac Center to act as a specialized healthcare centre to provide comprehensive cardiovascular services to all Armed Forces personnel, their dependents and other patients referred to the Center for further evaluation and specialized treatment. PSCC has already been involved in many first-in-man studies on innovative devices and has a large recruitment spanning all the Middle-East.

**Vision** - Prince Sultan Cardiac Center aspires to be the leader in providing specialized cardiovascular services in the Middle East, as an integrated medical center and specialized scientific authority in cardiology and cardiac surgery.

**Mission** - Prince Sultan Cardiac Center is committed to providing the highest standards of integrated healthcare services to all Saudi Armed Forces Personnel, their dependents and other eligible patients delivered by highly qualified human resources and utilizing the most advanced medical technologies in accordance with MSD Total Quality Management, and in line with International Standards.

**For more information:** [www.psc.med.sa](http://www.psc.med.sa)

### About Professor Antonio Calafiore

Prof. Calafiore is the Head of the Department of Adult Cardiac Surgery at Prince Sultan Cardiac Center in Riyadh, Kingdom of Saudi Arabia since May 2009. Prof. Calafiore was Professor of Cardiac Surgery and Head of Cardiac Surgery in Chieti, Italia, from 1985 to 2003, in Torino from 2003 to 2005, at the European Hospital in Rome in 2005 and 2006 and at the University of Catania from 2006 to 2009.

Prof. Calafiore is internationally recognized as an extremely talented and creative surgeon. He pioneered many innovative techniques such as off-pump coronary artery bypass grafting, left anterior small thoracotomy (LAST operation), the use of intermittent antegrade warm blood cardioplegia for myocardial preservation which is now referred to as "Calafiore technique", multiple vessel revascularization on a beating heart, and left ventricular surgical remodeling. He is also the past President of the Italian Society of Cardiac Surgery and Member of the European Society of Thoracic and Cardiovascular Surgery, Society of Thoracic Surgeons and American Association of Thoracic Surgeons.