PRESS RELEASE,

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TRiCares Announces First Successful Implantation of Minimally Invasive Topaz Tricuspid Heart Valve Replacement System in TRICURE Study

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Paris, France and Munich, Germany, August 30, 2022 – TRiCares SAS ("TRiCares") a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, today is pleased to announce the successful implantation of the first patient with its Topaz transfemoral tricuspid heart valve replacement system ("Topaz") in the TRICURE first-in-human clinical study in Belgium.

Heart valve diseases are among the most serious cardiac conditions, affecting more than 12.7 million patients in Europe and many more worldwide. In the last decade minimally invasive catheter-based solutions have been developed for other heart valve diseases, but none have been designed specifically for the tricuspid valve.

Tricuspid regurgitation is a frequent and serious disease for which open heart surgery and symptomatic pharmacologic treatment are the current standard treatment options. Owing to high mortality risk, access to open heart surgery is severely restricted and is not considered an option for more than 99% of patients with tricuspid regurgitation. The prognosis for patients without surgical repair is poor, with 2.2 years median survival. As such, there is an urgent need for minimally invasive, lower risk solutions to improve outcomes for patients with no other viable treatment options.

Topaz is an innovative device designed specifically to help patients suffering from severe tricuspid regurgitation without the need for open heart surgery. The Topaz device is implanted in a minimally invasive procedure through the patient's femoral vein. It is designed specifically to fit the tricuspid valve anatomy and thus supports ease of positioning and functionality.

TRICURE is the first-in-human clinical investigation by TRiCares and aims to assess the safety and performance of the Topaz transcatheter tricuspid heart valve replacement. The study will evaluate up to 20 patients and each patient's medical and functional status, and quality of life will be measured prior to and after the procedure. Patients will be monitored for a period of five years after implantation.

The procedure in Belgium was performed for an 84-year-old woman, who was classed as having New York Heart Association (NYHA) class III heart failure, showing severe tricuspid regurgitation. The patient has a history of chronic atrial fibrillation, hyperlipidaemia, and systemic hypertension. The patient was assessed by a screening committee consisting of an interventional cardiologist, a cardiac surgeon, an echo specialist, and a CT specialist to ensure her suitability for the safe implantation and that all inclusion and exclusion criteria were met.

The successful implantation took place on 22 August 2022, in the cardiology department of the University Hospital Saint-Luc, which is led by Prof. Jean-Louis Vanoverschelde, MD, PhD. The procedure was performed by Prof. Joëlle Kefer, MD, PhD, FESC, and her team in a hybrid operation room. Prof. Ulrich Schäfer, MD, Prof. Pascal Lim, MD and Prof. Hendrik Treede, MD proctored the procedure. With an implantation time of less than 20 minutes the Topaz prosthesis was placed at the correct position, safely anchored and achieved complete elimination of the tricuspid regurgitation. The patient recovered quickly from the intervention and was discharged from hospital after three days.

In total eleven implantations of the Topaz tricuspid heart valve replacement system have been performed to date across Europe and Canada.

The University Hospital Saint-Luc is one of two sites in Belgium that are currently participating in the TRICURE study, following approval from the Belgian competent authority FAMHP and an independent ethics committee. Another two Belgian sites are currently preparing to join the study team.

Prof. Joëlle Kefer, Head of Clinic - Cardiology and Head of the Cardiac Catheterization Unit at the University Hospital Saint-Luc, commented: “I am pleased to have conducted the first successful patient implant of the Topaz tricuspid valve replacement system in the TRICURE study in Belgium. The implantation was easy and intuitive and resulted in the complete elimination of the tricuspid regurgitation in the patient, demonstrating the potential of Topaz to provide a much-needed solution for patients with this serious condition.”

Prof. Jean-Louis Vanoverschelde, Chief Medical Officer at the University Hospital Saint-Luc said: “I am delighted to have overseen the implantation of the first patient in this important first-in-human clinical study. Topaz represents a significant advancement in the treatment of patients with tricuspid regurgitation and we look forward to further contributing to the TRICURE study.”

Helmut Straubinger, CEO of TRiCares, commented, “The TRICURE study is the first in-human clinical investigation by TRiCares and marks a significant milestone for the company. We believe that our Topaz tricuspid heart valve replacement system has the potential to provide a safe, effective solution for critically ill patients suffering from tricuspid regurgitation and we look forward to bringing this innovative treatment to more patients in the future.”

About TRiCares

TRiCares is a young medical device startup company located in Paris and Munich having the vision to bring to the market a transfemoral tricuspid valve replacement system. This system aims at helping patients suffering from severe tricuspid regurgitation (TR) without the need for open heart surgery. The experienced team of TRiCares is supported by the leading European life science venture capital firms: Andera Partners, BioMedPartners, Credit Mutuel Innovation, GoCapital, Karista, Wellington Partners and 415 Capital.

About Tricuspid Regurgitation (TR)

The tricuspid valve is the heart valve that regulates the blood between the right atrial and ventricular chamber. Tricuspid regurgitation occurs when the tricuspid valve fails to close properly, causing blood to flow backwards into the right atrium. Tricuspid regurgitation is a frequent problem and a severe disease that was neglected for many years, leading to a large number of untreated patients without an effective treatment option. Cardiac surgeons and interventional cardiologists have long waited for a transcatheter based solution. The progress in developing minimally invasive treatment options for heart valves as well as the experience gained in numerous research projects has strongly increased the awareness of the importance of this disease.

About the Medical Need

Heart valve diseases are among the most serious cardiac complications affecting at least 12.7 million patients in Europe and many more word wide. In the last decade, innovative minimally invasive catheter-based solutions have been developed for the treatment of aortic and mitral heart valve disease, creating a fast-growing transcatheter heart valve replacement market. However, for patients with tricuspid heart valve disease (tricuspid regurgitation), no solution exists to replace the diseased heart valve due to anatomic, functional and technological challenges. Only repair options by so-called clipping devices have been developed. But this technique is not suitable for all patients and the treatment success is limited. Consequently, open-heart surgeries to repair the insufficient valve and medical treatments still represent the standard treatment options. Due to excessive risk of the procedures (10–35 % surgical mortality), more than 99 % of TR patients are considered ineligible for the curative surgeries and are only maintained on symptomatic pharmacologic treatment with poor prognosis (2.2 years median survival). Therefore, physicians are urgently seeking minimally invasive, low-risk solutions to improve clinical outcomes in TR patients.