PRESS RELEASE, August 30th 2022

TRiCares Announces First Successful Implantation

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

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. Jőlle 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.”

More News

PRESS RELEASE, December 6th 2022

TRiCares Successfully Closes Series C Financing, Raising €51m to Fund

TRiCares Successfully Closes Series C Financing, Raising €51m to Fund Further Development and Clinical Trials of Minimally Invasive Treatment for Tricuspid Regurgitation

PRESS RELEASE, September 15th 2022

TRiCares Raises €47m in a First Closing of its Series C Financing

TRiCares Raises €47m in a First Closing of its Series C Financing to Fund Further Development of Minimally Invasive Treatment for Tricuspid Regurgitation.

PRESS RELEASE, May 15th 2022

First Implantation in Canada

TRiCares Announces Successful Implantation of Minimally Invasive Topaz Tricuspid Heart Valve Replacement System in Canada

PRESS RELEASE, April 24th 2022

First Implantation in Germany

TRiCares Announces Successful First in Human Implantation of Minimally Invasive Topaz Tricuspid Heart Valve Replacement System in Germany

PRESS RELEASE, July 4th 2021

First Implantation Worldwide

TRiCares Announces Successful First in Human Implantations of Minimally Invasive Topaz Tricuspid Heart Valve Replacement System

PRESS RELEASE, June 3rd 2018

Series B Financing Round

TRiCares Closes €22 Million ($25.4 Million) Series B Financing Round to Fund Development of Minimally Invasive Treatment of Tricuspid Regurgitation