



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

Paris, France and Munich, Germany, May 16, 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 its Topaz transfemoral tricuspid heart valve replacement system (“Topaz”) in Canada, with full elimination of tricuspid regurgitation confirmed at 30-day follow-up examination.

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 the result of a French and German collaboration and 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.

Today’s announcement marks the successful first in human implantation of Topaz in a patient in Canada, which was performed after special access was granted by Health Canada.

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The procedure in Canada was performed for a 50-year-old woman presenting with torrential tricuspid regurgitation, who was classed as having New York Heart Association (NYHA) class III heart failure. The patient has a history of two open heart valve surgeries as well as chemotherapy and radiation due to a sarcoma in the left atrium. For these reasons, transcatheter intervention was chosen, as the risk for the patient is lower compared to more invasive surgical intervention.



The successful implantation of the Topaz tricuspid heart valve replacement system took place at St. Michael's Hospital, University of Toronto, on 12 April 2022, and was performed by Neil Fam, MD, MSc, Director of Interventional Cardiology and Cardiac Cath Labs at St. Michael's Hospital, and assisted by cardiac surgeon Gianluigi Bisleri, MD, and Geraldine Ong, MD, MSc, a cardiologist specializing in echocardiography. Prof. Hendrik Treede, cardiac surgeon at University Hospital Mainz, Germany, proctored the procedure. With an implantation time of 20 minutes the Topaz prosthesis anchored safely and achieved complete correction of the tricuspid regurgitation. The patient recovered quickly from the intervention and was discharged from hospital after three days.

An examination of the patient 30 days after the procedure, including echo assessment, confirmed that the tricuspid regurgitation remains completely eliminated. The patient is now assessed as New York Heart Association (NYHA) class I, meaning no symptoms of heart failure and no limitations in ordinary physical activity.

In total nine implantations of the Topaz tricuspid heart valve replacement system have been performed to date, with the first implantation conducted almost one year ago.

Building upon the success of these procedures, TRiCares is preparing a clinical study in the coming months to confirm the value of its Topaz tricuspid heart valve replacement system for these types of patients, who until now have had no satisfactory treatment option.

Dr. Neil Fam, Director of Interventional Cardiology and Cardiac Cath Labs at St. Michael's Hospital, University of Toronto, commented, "I am delighted to have conducted the successful first in human implantation of the Topaz tricuspid valve replacement system in Canada. Implantation of the Topaz system was very easy and intuitive, and the patient, who has a complicated medical history, achieved full and sustained elimination of tricuspid regurgitation. This is a promising potential solution for patients in need."

Prof. Dr. Treede, Director of the Department of Cardiac and Vascular Surgery at the University Medical Centre in Mainz who proctored all Topaz procedures that were performed until now, commented, "I am very pleased to have attended this implantation of the Topaz tricuspid heart valve replacement system performed by Dr. Fam and his great team at St. Michael's hospital. The smooth and successful implantation makes me even

more confident that the Topaz valve represents a significant improvement in the treatment of patients with tricuspid regurgitation.”

Helmut Straubinger, CEO of TRiCares, commented, “It is a special feeling when you have developed a product and immediately after its application you can see the significant improvement of a patient's health condition. That is what we work for. We look forward to future implantations of the Topaz system.”



About TRiCares

Founded in 2013, TRiCares is a medical device startup company headquartered in Paris, France, with its operating location in Munich, Germany. The team's vision is to bring to the market a transfemoral tricuspid valve replacement system to help patients suffering from severe tricuspid regurgitation without the need for open heart surgery. The company is supported by leading European life science venture capital firms: Andera Partners, BioMedPartners, Credit Mutuel Innovation, GoCapital, Karista and Wellington Partners.

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 to help patients suffering from severe TR.

About the Medical Need

Heart valve diseases are among the most serious cardiac complications affecting more than 12.7 million patients in Europe. 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 such solutions exist due to anatomic, functional and technological challenges specific to this so-called “forgotten valve”. Consequently, open-heart surgeries to repair the insufficient valve and medical treatments currently 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, cardiac surgeons are urgently seeking minimally-invasive, low-risk solutions to improve clinical outcomes in TR patients with no other viable treatment option.