

TRiCares Announces First Topaz Implantation in EU Pivotal Study

Paris, France and Munich, Germany, September 24, 2024 – TRiCares SAS (“TRiCares”), a company pioneering a minimally-invasive tricuspid valve that flexes with every heartbeat, is pleased to announce the first implantation of its Topaz transfemoral tricuspid heart valve replacement system (“Topaz”) in a pivotal study in Europe.

The TRICURE (TRiCares’ Topaz Transcatheter TRICUspid Heart Valve REplacement System) European Pivotal Study ([NCT06581471](#)) is taking place at leading clinical sites in Germany, Belgium, France and Switzerland, with additional countries expected to follow. The study will assess the safety and efficacy of Topaz in patients with significant tricuspid regurgitation who are not candidates for open heart surgery. The trial aims to enroll nearly 80 patients and includes interim data analysis as well as long-term follow-up evaluations.

The first implantation took place at the Algemeen Stedelijk Ziekenhuis hospital, in Aalst, Belgium. The Topaz valve was implanted in an 81-year-old female patient suffering from torrential tricuspid regurgitation (grade 5 out of 5), with a history of surgical interventions, along with typical comorbidities. The procedure, completed in approximately half an hour, was led by Dr. Liesbeth Rosseel. The post-intervention TR grade was reduced to zero, and the patient recovery to date has been positive.

To date, nearly 40 Topaz implantations have been performed across Europe and Canada. In the coming months, TRiCares will begin patient enrollment in the Early Feasibility Study (EFS) in the US, which was approved by the FDA earlier this year.

Prof. Dr. Joerg Hausleiter, Professor of Medicine and the Deputy Clinic Director at the Ludwig-Maximilian University in Munich, Germany, said: “The TRICURE EU Pivotal study is an important trial to prove that the TOPAZ valve can safely reduce, and even eliminate, tricuspid regurgitation in severely ill patients. I am honored to be the coordinating principal investigator of this critical study, contributing to an innovative solution for a large patient group urgently seeking an effective treatment option.”

Dr Liesbeth Rosseel, Interventional Cardiologist at Algemeen Stedelijk Ziekenhuis, in Aalst, Belgium, commented, “I am pleased that the team here in Aalst performed the first implantation in the TRICURE EU Pivotal study. The implantation was completed in approximately half an hour and reinforced the excellent outcomes that we previously observed in the TRICURE first-in-human study. We are encouraged by the patient recovery to date and look forward to supporting the trial in the weeks and months ahead.”

Ahmed Elmouelhi, President & CEO of TRiCares, added: “Initiating the TRICURE EU Pivotal Study marks an important milestone for TRiCares. It brings us one step closer to an effective solution for the millions of patients suffering from tricuspid regurgitation. I am proud of the progress made by the entire team at TRiCares and am grateful to the many sites and clinicians who committed their support to the TRICURE EU Pivotal Study.”

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About TRiCares

TRiCares is a private company developing Topaz, a minimally invasive tricuspid valve replacement system for the elimination of tricuspid regurgitation (TR). Topaz's unique dual stent design is easy to implant and uses established transfemoral and transjugular delivery methods, avoiding the need for high-risk open-heart surgery. Topaz is designed to fit a wide range of anatomies and replaces the diseased tricuspid valve. Once in place, it flexes with every heartbeat. A European Pivotal Study and a US/Canadian Early Feasibility Study are underway, with progress being made towards FDA approval and CE marking. TRiCares has focused on TR since its inception and its ambition is for Topaz to become the valve of choice for the millions of TR patients worldwide, overcoming the limitations of current treatment approaches.

TRiCares is a global business, with offices in France, Germany, the US and Brazil, and is supported by leading life science venture capital firms: 415 Capital, Andera Partners, Bayern Kapital, BioMed Partners, Credit Mutuel Innovation, GoCapital, Karista, and Wellington Partners.

About Topaz

The Topaz Transfemoral Tricuspid Valve Replacement (TTVR) System is designed to eliminate tricuspid regurgitation through a minimally invasive approach. This system consists of two main components: the Topaz Heart Valve Prosthesis and the transfemoral Catheter Implantation System. It is developed exclusively for the use in the tricuspid position and to provide a system for physicians that is safe and easy to implant. The unique two-stent catheter system is inserted via the femoral vein and transports the prosthesis into the right half of the heart, where it is finally released to replace the diseased tricuspid valve.