TRiCares Announces Initiation of TRICURE US IDE Pivotal Study for Topaz Tricuspid Valve Replacement System

- Initiation of the TRICURE US IDE pivotal study represents the first of next-generation TTVR devices to enroll patients in the US

Minneapolis, MN, USA and Paris, France and Munich, Germany, 9 July 2026 – TRiCares SAS ("TRiCares"), a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, today announces that the first patient has been enrolled and treated in the TRICURE US IDE pivotal study, evaluating Topaz, its Transcatheter Tricuspid Valve Replacement (TTVR) system. This enrollment marks the first randomized controlled study to actively enroll patients in a head-to-head comparison of an investigational TTVR system versus the commercially available Edwards EVOQUE™ TTVR system.

The US pivotal study (NCT07528326) initiation marks a significant milestone in advancing treatment for tricuspid regurgitation (TR). The prospective, global, multi-center, randomized (1:1) controlled study is designed to evaluate the safety and effectiveness of the TRiCares Topaz TTVR system in patients with severe or greater tricuspid regurgitation who are suitable for valve replacement. The global study will be conducted in the US, Canada, and several European countries with up to 75 sites participating. The first patient was enrolled at the Piedmont Heart Institute in Atlanta, GA and treated by **Dr. Pradeep Yadav, Director of Structural Interventions at the Marcus Heart and Vascular Center and Co-Principal Investigator of the TRICURE US pivotal study**, together with **Dr. Vinod Thourani, Chairman of Cardiac Surgery at Piedmont Heart Institute and Site Principal Investigator for the TRICURE US pivotal study**.

Ahmed Elmouelhi, President & CEO of TRiCares, said: "Initiating our TRICURE US IDE pivotal study represents a defining moment for TRiCares following years of innovation by our dedicated team. This milestone positions us ahead of the curve in demonstrating Topaz's transformative potential in today's treatment paradigm. As we rapidly activate new investigative sites and build enrollment momentum - in parallel with our ongoing European pivotal study - we are moving closer to our ambition of establishing Topaz as the preferred treatment option for TR patients globally."

"TR therapies are quickly evolving as more and more patients seek treatment – and Topaz represents a significant step forward in TR therapies – an outcome we intend to demonstrate through the US pivotal study," **commented Dr. Pradeep Yadav.** "Enrolling the first patient in the US pivotal study brings hope for an improved standard of care. Topaz's next-generation design has already improved upon existing TTVR treatments, with a procedure that is fast, exceptionally easy-to-use, and which has required few or no pacemaker implants."

Dr. Neil Fam, Director Structural Heart Program at St. Michael's Hospital, Schroeder Chair in Structural and Valve Innovation, University of Toronto, Canada, and Co-Principal Investigator of the TRICURE US pivotal study added: "The start of the US pivotal study represents an important step forward in developing improved treatment options for patients with tricuspid regurgitation. The early clinical data from the EU first-in-human study, the US/Canadian EFS, and the ongoing EU pivotal study have been encouraging and have meaningfully reduced the burden of procedural imaging. I look forward to this next phase of the study as we build enrollment momentum across sites in the US and Canada and select sites in Europe."

Topaz is being evaluated through a comprehensive clinical development program. This includes the ongoing US EFS (NCT06506942) and the TRICURE European Pivotal Study (NCT06581471), which is currently recruiting patients across Belgium, Denmark, France, Germany, Spain, and Canada, with Switzerland to follow.

About TRiCares

TRiCares is a privately held 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 US pivotal study, European pivotal study and 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 a strategic partner as well as leading life science venture capital firms: 415 Capital, Andera Partners, Bayern Kapital, BioMed Partners, Credit Mutuel Innovation, GoCapital, Karista, and Wellington Partners.

About Topaz

Topaz is a Transcatheter Tricuspid Valve Replacement (TTVR) system designed to eliminate tricuspid regurgitation (TR) through a minimally invasive approach. This system consists of the Topaz Heart Valve Prosthesis and a catheter-based implantation system. It is developed exclusively for use in the tricuspid position and to provide a system for physicians that is safe and easy to implant. The unique two-stent valve prosthesis is inserted primarily via the femoral vein and transports the prosthesis into the right side of the heart, where it is finally released to replace the diseased tricuspid valve. Topaz comes in two valve sizes: 45mm (TC-M) and 55mm (TC-L), making it a viable treatment option for 85-90% of all patients diagnosed with TR.

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