TRiCares Receives FDA Approval for TRICURE US IDE Pivotal Trial with the Topaz Tricuspid Valve Replacement System

Minneapolis, MN, USA and Paris, France and Munich, Germany, 7 April 2026 – TRiCares SAS ("TRiCares"), a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, today announces it has received approval from the U.S. Food and Drug Administration (FDA) for an investigational device exemption (IDE) to conduct a pivotal clinical trial for Topaz, its Transcatheter Tricuspid Valve Replacement (TTVR) system in the US, Canada, and select sites in Europe.

The IDE approval marks a significant regulatory milestone for TRiCares, enabling the Company to initiate its US pivotal trial and progress towards FDA market approval and US commercialization of Topaz. The randomized trial, to be conducted at up to 75 investigative sites, will evaluate the safety and effectiveness of Topaz in patients with severe or greater tricuspid regurgitation (TR) who are at increased operative risk.

This pivotal trial approval builds on the clinical progress made in the US Early Feasibility Study (EFS) (NCT06506942), and the ongoing TRICURE European Pivotal Study (NCT06581471), which is currently enrolling patients at sites across Belgium, Denmark, France, Germany, Spain, and Canada with Switzerland to follow. In May 2025, TRiCares shared encouraging first-in-human data demonstrating significant elimination of TR to Grade Trace/None (0) or Mild (1+) in patients implanted with Topaz. No patients required a permanent pacemaker and the average procedure time was 35 minutes. These results have been subsequently published in PCR's journal "EuroIntervention" (10.4244/EIJ-D-25-00423).

Ahmed Elmouelhi, President & CEO of TRiCares, said: "Receiving FDA approval for our US IDE pivotal trial marks a significant milestone for TRiCares and, most importantly, for the many patients living with tricuspid regurgitation who urgently need improved treatment options. This approval allows us to approach our investigator sites and prepare for first patient enrollments, bringing us closer to realizing our ambition of making Topaz the standard of care for patients across the US. Combined with the momentum we are seeing in our European pivotal study, Topaz has the potential to transform treatment outcomes for TR patients globally."

"The FDA's decision to grant IDE approval for the Topaz pivotal trial underscores the strength of the clinical evidence generated to date and the compelling unmet need in tricuspid regurgitation," **commented Dr. Pradeep Yadav, Director of Structural Interventions at the Marcus Heart and Vascular Center, Piedmont Heart Institute and Co-Principal Investigator of the TRICURE US pivotal trial.** "TTVR is rapidly emerging as a preferred treatment option for symptomatic patients with TR. We have been highly impressed with Topaz's next-generation design, which enables streamlined implantation while maintaining a strong focus on safety and adaptability across complex patient anatomies. We are extremely excited and look forward to collaborating closely with the TRiCares team to advance this important pivotal study across US structural heart centers, ultimately improving patient outcomes."

Dr. Neil Fam, Director Structural Heart Program at St. Michael's Hospital and the Schroeder Chair in Structural and Valve Innovation, University of Toronto, Canada, and Co-Principal Investigator of the TRICURE US pivotal trial added: "This IDE approval is an important step forward in combating structural heart disease. Tricuspid regurgitation remains significantly undertreated, and the ability to conduct a rigorous, randomized US pivotal study with Topaz will be critical to support broad clinical adoption. The early clinical data from the US/Canadian

EFS, the EU FIH, and the EU pivotal study have been encouraging and have significantly reduced the burden of procedural imaging. I look forward to this next phase of the program."

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 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 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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