TRiCares presents promising First-In-Human Topaz data at EuroPCR 2025

- *Early results demonstrate near-complete elimination of tricuspid regurgitation in implanted patients with favorable safety profile and no permanent pacemaker implantations*

Paris, France and Munich, Germany, 22 May, 2025 – TRiCares SAS ("TRiCares"), a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, is presenting data in a late-breaking session at EuroPCR today from its first-in-human trial of Topaz, its Transcatheter Tricuspid Valve Replacement (TTVR) system.

Today, Dr Julien Dreyfus, MD, PhD will present 30-day post-procedural data from 20 tricuspid regurgitation (TR) patients treated with Topaz across eight specialist cardiac centers in Europe. The TRICURE First-In-Human study demonstrated significant elimination of TR in treated patients, with grade 'none' (0+) or 'mild' (1+) TR reported in all patients implanted with Topaz. In addition, zero permanent pacemakers were required due to the investigational device. The implantation procedure lasted, on average, 35 minutes.

These early clinical results from Topaz compare favorably with existing TTVR treatment approaches, with a procedure that is fast, easy-to-use, and less demanding of imaging specialists.

Further details on the data will be shared in today's oral presentation at EuroPCR 2025 and on Clinicaltrials.gov.

"We are highly encouraged by the results of this first-in-human trial. These initial findings serve as important validation for our ongoing clinical trials for Topaz in Europe and the US," **said Ahmed Elmouelhi, President & CEO of TRiCares**. "I want to extend our sincere gratitude to the participating hospitals, the dedicated interventional teams and clinical investigators who contributed to these patient outcomes. To date, the TRiCares team has overseen 60 Topaz implantations, and we continue to work closely with clinicians to refine the procedure and technique."

The initial findings will be used to inform the company's ongoing European pivotal trial (NCT06581471) and U.S. Early Feasibility Study (NCT06506942).

EuroPCR presentation details

Session: Tricuspid hotline: new devices

Title: TRiCares Topaz transfemoral TRICUspid heart valve REplacement system first-in-human trial

Presenter: Julien Dreyfus, MD, PhD, FESC, Cardiologist at Centre Cardiologique du Nord, Saint-Denis, France

Location: Theatre Bordeaux

Date/time: Thursday, 22 May 2025, 08:30 – 09:30 CEST

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 and 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 Transcatheter Tricuspid Valve Replacement (TTVR) System is designed to eliminate tricuspid regurgitation 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.

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