TRiCares Presents Positive Topaz Primary Endpoints from the TRICURE EU Pivotal Study at PCR London Valves

- 30 day results show that 98% of patients had none or mild tricuspid regurgitation (TR) after treatment with Topaz
- Favorable safety profile demonstrated with a low composite major adverse events rate and a low 5% new pacemaker rate

Minneapolis, MN, USA and Paris, France and Munich, Germany, 23 November 2026 – TRiCares SAS ("TRiCares"), a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, presented on behalf of the study investigators data in a Top Late-Breaking Trials session at PCR London Valves from its TRICURE European (EU) Pivotal Study evaluating Topaz, its Transcatheter Tricuspid Valve Replacement (TTVR) system, in patients with severe tricuspid regurgitation (TR).

The prospective, single arm, multicenter TRICURE EU pivotal trial (NCT06581471) enrolled 77 patients with severe TR, at an increased operative risk and suitable for transcatheter tricuspid heart valve implant, across 24 sites in six countries in Europe to assess the safety and performance of Topaz.

30 day post procedural data demonstrated that the primary endpoint was met in 98% of patients achieving a reduction of TR by at least one grade between baseline and post-intervention and no more than a moderate TR grade. Topaz also had a favorable safety profile with a low composite major adverse events (MAE) rate of 15.6% and a low pacemaker rate of 5%.

The Topaz system is specifically designed for the tricuspid valve and right heart and demonstrated in the EU pivotal study an average device implantation time of 32 minutes. The flexible Topaz design and its simple implantation procedure position it well against commercially available TTVR systems. The Company is seeking CE mark approval leading to an expected commercial launch in Europe in the coming year.

Prof. Dr. Jörg Hausleiter, Professor of Medicine and the Deputy Clinic Director at the Ludwig-Maximilian University in Munich, Germany and Principal Investigator of the TRICURE EU Pivotal Study, commented: *"These findings are particularly impactful as we progress our efforts to develop a next generation transcatheter tricuspid valve replacement system for patients with limited transcatheter options. Severe tricuspid regurgitation remains a serious, undertreated condition, and this pivotal study generates the rigorous clinical evidence physicians need to evaluate Topaz as a preferred treatment option. The clinical data generated has been promising and I see the potential for Topaz to improve outcomes for TR patients and lessen the complexity and the procedural burden for physicians."*

Ahmed Elmouelhi, President & CEO of TRiCares, said: "*We are pleased the EU pivotal study was accepted for a Top Late-Breaking Trials session at PCR London Valves, which reflects the significance of this trial for patients with severe tricuspid regurgitation. The results demonstrated by our dedicated physician partners reinforce our confidence in the uniqueness of Topaz's flexible design, which achieved meaningful TR reduction through a procedure with a short implantation time. As we work toward CE mark approval next year and continue to advance our ongoing US IDE pivotal study, we look forward to offering patients a viable next generation treatment of TR."*

TRiCares is also progressing its TRICURE US IDE pivotal study which is currently enrolling patients in US, Canada, and several European countries with up to 75 sites participating.

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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