TRiCares Successfully Closes Series C Financing, Raising €51m to Fund Further Development and Clinical Trials of Minimally Invasive Treatment for Tricuspid Regurgitation

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Paris, France and Munich, Germany, December 6, 2022 – TRiCares SAS ("TRiCares") a privately held pioneer in the field of minimally invasive treatment of tricuspid regurgitation, is pleased to announce today the second closing and completion of its Series C financing round, successfully raising a total of €51m for the round.

The proceeds of this financing will primarily be used to continue the development of the company's transfemoral tricuspid heart valve replacement system ("Topaz") up through to the application for a pivotal investigational device exemption ("IDE") trial in the United States. To this end, TRiCares plans to initiate an early feasibility study across five centers in the US and Canada in 2023.

The proceeds of this financing will also support the on-going TRICURE first-in-human clinical study in Belgium as well as potential additional clinical trial applications elsewhere in Europe, along with further compassionate use implantations as appropriate.

The Series C financing was led by 415 Capital and joined by Bayern Kapital, the venture/growth capital company of the State of Bavaria in Germany, with strong support from existing investors Andera Partners, BioMed Partners, Credit Mutuel Innovation, GOCapital, Karista and Wellington Partners. Total gross proceeds were €51m.

TRiCares is developing a transcatheter-based tricuspid valve replacement system aimed at addressing the need for a better treatment for this frequent and severe disease that avoids open heart surgery. Heart valve diseases are among the most serious cardiac conditions, affecting more than 12.7 million patients in Europe and many more worldwide. Owing to high mortality risk, access to open heart surgery is severely restricted and is not considered an option for more than 99% of patients with tricuspid regurgitation, leaving surgeons seeking minimally invasive, lower risk solutions to improve outcomes for patients with no other viable treatment options.

Topaz is an innovative device developed to help patients suffering from severe tricuspid regurgitation without the need for open heart surgery. The Topaz device is implanted in a minimally invasive procedure through the patient's femoral vein. It is designed specifically to fit the tricuspid valve anatomy and thus supports ease of positioning and functionality.

Helmut J. Straubinger, Chief Executive Officer of TRiCares, said: "Millions of patients with tricuspid regurgitation have no effective long-term treatment option, and their prognosis is very poor. The Topaz tricuspid valve replacement system is being developed with the aim of delivering a much-needed solution for these patients. With encouraging clinical signs, the strong support of world-class investors and our successful Series C financing, we look forward to the further development of the Topaz system with a focus on the necessary preparations for a pivotal IDE trial in the US along with the continued progress of our clinical activities in Europe."

Dr. Georg Ried, Managing Director of Bayern Kapital, said: "Open heart tricuspid valve surgeries are among the riskiest curative procedures, with more than 99% of affected patients deemed unfit due to high mortality rates. With Topaz, TRiCares is developing an innovative product with excellent potential to fill this major gap in the treatment of valvular heart disease. We are very pleased to support TRiCares on its further course towards market approval."

Frederik Groenewegen, General Partner at 415 Capital, commented: "We believe that the technology developed by TRiCares has the potential to establish itself as the gold standard in the treatment of patients with tricuspid regurgitation and to restore the quality of life of millions of patients in the long term. We are impressed with the initial clinical cases with the Topaz system and look forward to helping the team bring this novel therapy to patients in the U.S. and Europe."

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About TRiCares

TRiCares is a young medical device startup company located in Paris and Munich having the vision to bring to the market a transfemoral tricuspid valve replacement system. This system aims at helping patients suffering from severe tricuspid regurgitation (TR) without the need for open heart surgery. The experienced team of TRiCares is supported by the leading European life science venture capital firms: Andera Partners, BioMed Partners, Credit Mutuel Innovation, GoCapital, Karista, Wellington Partners, 415 Capital and Bayern Kapital.

About Tricuspid Regurgitation (TR)

The tricuspid valve is the heart valve that regulates the blood flow between the right atrial and ventricular chamber. Tricuspid regurgitation occurs when the tricuspid valve fails to close properly, causing blood to flow backwards into the right atrium. Tricuspid regurgitation is a frequent problem and a severe disease that was neglected for many years, leading to a large number of untreated patients without an effective treatment option. Cardiac surgeons and interventional cardiologists have long waited for a transcatheter based solution. The progress in developing minimally invasive treatment options for heart valves as well as the experience gained in numerous research projects has strongly increased the awareness of the importance of this disease.

About the Medical Need

Heart valve diseases are among the most serious cardiac complications affecting at least 12.7 million patients in Europe and many more worldwide. In the last decade, innovative minimally invasive catheter-based solutions have been developed for the treatment of aortic and mitral heart valve disease, creating a fast-growing transcatheter heart valve replacement market. However, for patients with tricuspid heart valve disease (tricuspid regurgitation), no solution exists to replace the diseased heart valve due to anatomic, functional and technological challenges. Only repair options by so-called clipping devices have been developed. But this technique is not suitable for all patients and the treatment success is limited. Consequently, open-heart surgeries to repair the insufficient valve and medical treatments still represent the standard treatment options. Due to excessive risk of the procedures (10–35 % surgical mortality), more than 99 % of TR patients are considered ineligible for the curative surgeries and are only maintained on symptomatic pharmacologic treatment with poor prognosis (2.2 years median survival). Therefore, physicians are urgently seeking minimally invasive, low-risk solutions to improve clinical outcomes in TR patients.