

Novostia Announces Successful Implantation of the 10th patient with the TRIFLO Heart Valve

Lausanne, Switzerland, June 17th, 2024 – Novostia, a pioneering medical technology company, is thrilled to announce the successful completion of all planned implantations in its First-In-Human (FIH) Clinical study PILATUS (ClinicalTrials ID: NCT06119607). All ten patients have been successfully implanted with the groundbreaking TRIFLO Heart Valve, marking a significant achievement in the ongoing clinical trial.

The surgical operations, conducted between December 2023 and May 2024, have been highly successful. The surgeons and medical teams have expressed their satisfaction with the TRIFLO Heart Valve, noting its promising performance and the excellent condition of the patients post-surgery.

Positive Early Results and Future Outlook

Initial results from the ongoing trial confirm the device's good performance, with patients showing remarkable recovery and well-being. The TRIFLO Heart Valve, designed to revolutionize aortic heart valve replacement, has demonstrated significant improvements in patient conditions, and reduction in symptoms. This innovation aims to eliminate the need for lifelong anticoagulation therapy, thereby reducing associated risks and enhancing patient quality of life by addressing issues such as noise-induced discomfort.

Prof. Kęstutis Ručinskas, Head of the Heart and Thoracic Surgery Centre at Vilnius University Hospital Santaros Klinikos in Lithuania, who led the clinical investigation, commented: "The successful implantation of the TRIFLO Heart Valve in all planned patients marks a significant milestone in aortic valve disease management. Seeing our patients recover fully and thrive post-surgery reinforces the valve's potential to change the landscape of aortic valve treatment. We are eager to continue this journey and implant more patients with this innovative device."

"The completion of the enrollment phase in our First-In-Human study marks a significant milestone. The initial outcomes are promising and underscore the potential of our heart valve to transform patient lives. We will continue to monitor these patients and look forward to the validation of the unique properties of the TRIFLO valve," said Pomme Boissier, Clinical Affairs Manager at Novostia.

The first implanted patients have already started a decrease in anticoagulation treatment that should be followed by a discontinuation in September 2024. The ten patients will be followed up for 18 months to monitor performance and effectiveness of the TRIFLO Heart Valve without Anticoagulation therapy.

Commitment to Long-Term Patient Care

The long-term performance and effectiveness of the TRIFLO Heart Valve will be evaluated from a five-years follow-up of the ten patients. This extended follow-up period will provide valuable data to further validate the benefits and reliability of this cutting-edge technology.

Acknowledgments

Novostia extends its gratitude to all partners, medical professionals, and team members who have contributed to this successful milestone. Their dedication and support have been instrumental in advancing this groundbreaking technology.

Global Impact on Cardiovascular Health

Novostia's TRIFLO Heart Valve is poised to bring about a quiet revolution in the treatment of aortic heart valve replacement. The company anticipates that patients around the world will soon benefit from this disruptive technology, offering a new level of hope and improved quality of life for those with aortic and mitral stenosis and/or regurgitation.

About Novostia

Novostia is a privately held medical device company incorporated in 2017 and based at Biopôle in Lausanne, Switzerland, developing an innovative artificial heart valve. For more information, please visit www.novostia.com

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Caution: Novostia technology is an investigational device not yet approved for sale.