First Clinical Study on TRIA Biopolymer Heart Valve Shows Excellent One-Year Performance

Publication in Journal of the American College of Cardiology (JACC): Cardiovascular Interventions Found TRIA Aortic Heart Valve Provided Sustained Improvement in Heart Valve Function to One-Year with Good Safety Profile

SALT LAKE CITY, Utah – December 21, 2022 - Foldax®, Inc. today announced publication of the first clinical results for its TRIA™ biopolymer heart valve - the first polymer valve to be implanted in humans. The early feasibility study showed that the TRIA surgical aortic valve met all of its primary endpoints at one year, including improvement in valve effective orifice area (EOA), clinically significant improvement in New York Heart Association (NYHA) class and safety. The data was just published in the December 2021 issue of the Journal of the American College of Cardiology (JACC): Cardiovascular Interventions.

The TRIA valve reimagines the heart valve by combining the company's proprietary biopolymer – LifePolymer™ – with an innovative valve design intended to resist calcification, withstand stresses and strains without failure, and restore patient quality of life without requiring lifelong use of anticoagulants.

"The heart valve options we have today are not perfect. Mechanical valves require daily use of anticoagulants that may infringe on patient lifestyles and are associated with significant bleeding complications, while tissue or bioprosthetic valves have limited durability. The biopolymer valve we studied offers the potential to improve patient outcomes, as the polymer and design work together to optimize the properties and performance of the valve leaflets," said Dean Kereiakes, MD, FACC, FSCAI, lead author on the publication and President of The Christ Hospital Heart and Vascular Institute at The Christ Hospital Health Network in Cincinnati, Ohio.

Summarizing the study results, Dr. Kereiakes said, "The TRIA valve demonstrated marked and sustained improvements in transvalvular gradients, valve EOA and NYHA clinical class out to one-year following valve implant. Safety outcome measures appear comparable to those reported for bioprosthetic (animal tissue) heart valves."

Detailed one-year results from the early feasibility study showed the following:

- Mean pressure gradients improved from an average of 33.3 mmHg at baseline to an average of 9.5 mmHg at one year
- Effective orifice area Increased from 1.2 cm^2 at baseline to 2.0 cm^2 at one year

- Patients' NYHA classification was improved and sustained, with 66.7 percent of patients designated Class I at one year versus 33.3 percent at baseline
- No patients were NYHA Class III or IV at one year
- There were no device-related deaths

The early feasibility study of the TRIA surgical aortic heart valve encompassed 15 patients studied at five sites in the U.S. Last fall, the FDA approved an expansion of the study to a total of 40 patients based upon review of the initial outcomes.

"We are pleased that the TRIA valve demonstrated the excellent hemodynamics it was designed to achieve and that we expected to see in its first clinical study," stated Frank Maguire, Chief Executive Officer of Foldax. "The combination of our novel, proprietary polymer, optimized design and robotic manufacturing promises a level of performance, durability and precision that has never been seen before in a prosthetic heart valve. We look forward to seeing results from the expanded study early next year and to moving forward with our U.S. pivotal trial in the next year."

The company's second device, a mitral surgical valve, was approved by the FDA for a U.S. early feasibility study earlier this year and is currently enrolling patients. The third valve product is a transcatheter aortic valve replacement (TAVR), which is in the pre-clinical testing phase.

The TRIA valves are the first and only heart valves to be robotically manufactured, reducing variability and enabling high precision, repeatability and quality, while substantially improving the economics of heart valve manufacturing.

The Tria heart valve is considered investigational in the U.S. and is not available for commercial sale in the U.S.

To learn more about Foldax, visit www.foldax.com.

About Foldax
Headquartered in Salt Lake City, Utah, Foldax is reinventing every aspect of the heart valve – from material to design to manufacturing – to develop surgical and transcatheter valves designed to last a lifetime addressing historical tradeoffs.

Foldax investors include Angel Physicians Fund, Biostar Capital, Caltech, Kairos Ventures, Memorial Care Innovation Fund and Sayan Bioventures.

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Media Contact:
Michelle McAdam, Chronic Communications, Inc.
michelle@chronic-comm.com
(310) 902-1274