



FOR RELEASE

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Foldax Completes Enrollment in Early Feasibility Study for TRIA Biopolymer Surgical Aortic Heart Valve

SALT LAKE CITY, Utah – September 28, 2021 - [Foldax](#)[®], Inc. today announced completion of enrollment in the U.S. early feasibility study of the TRIA™ surgical aortic heart valve. 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 lifelong use of anticoagulants.

“We were thrilled to participate in the first human study of the novel TRIA biopolymer heart valve, which offers the potential to improve upon the durability of commonly used tissue valves today,” said Geoff Answini, MD, Chief, Division of Cardiovascular Surgery at The Christ Hospital, Cincinnati, Ohio, and an investigator in the study. “Several of our patients have reached one-year follow-up with good outcomes and we look forward to seeing how a polymer heart valve performs for them over time.”

“This first clinical trial of our novel TRIA heart valve technology is a landmark in the heart valve replacement market as the first biopolymer valve ever to be studied in man. We have also recently commenced an early feasibility study of our surgical mitral valve and are fast-tracking development of our transcatheter aortic heart valve (TAVR). We have been pleased with the performance of the surgical aortic valve and now have over 30 patient-years of cumulative experience with patients out over 2 years that are off anticoagulation therapy. We are looking forward to publishing our one-year results and pursuing our IDE with the FDA,” said Frank Maguire, Chief Executive Officer of Foldax.

The early feasibility study of the TRIA surgical aortic heart valve encompassed 40 patients studied at five sites in the U.S. The study was initially approved as a 15-patient study, but upon review of the initial outcomes, the FDA subsequently approved an expansion to add 25 patients.

TRIA is the first and only heart valve to be robotically produced, which is possible due to its polymer leaflets that can be consistently manufactured with precise thicknesses and are designed to achieve a valve with predictable performance that lasts a lifetime.

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.

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