



First Patients Outside of U.S. Treated with TRIA™ Polymer Surgical Mitral Heart Valve

India Clinical Trial Commences with First 30 Cases

SALT LAKE CITY, Utah – August 1, 2023 - [Foldax®](#), Inc., a leader in the development of innovative, polymer heart valves, today announced that the first 30 patients have been treated outside of the U.S. in the Indian clinical trial of the TRIA™ surgical mitral heart valve. The TRIA mitral valve is designed specifically to accommodate the anatomy and pressures of the mitral position. It combines the company's proprietary polymer – 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.

Rheumatic fever attacks the mitral valves and causes it to not close properly and leak. Developing countries have higher rates of rheumatic fever and, consequently, higher rates of mitral valve disease. It is estimated that two to three million people have rheumatic heart disease in India alone.

Currently available prosthetic valve options for treating mitral valve disease have limitations. Tissue valves constructed of porcine or pericardial tissue have limited durability and are culturally not accepted in many countries, including India. Mechanical valves limit patients' quality-of-life due to their noise and the need to take lifelong blood thinning medication.

“There is a huge need to help people suffering from mitral valve disease in India. The impact of the disease can be very limiting for many, especially younger patients, as there is no ideal heart valve replacement solution. In the case of young women, the impact can be devastating to their hopes of having a family,” said Avi Sharma, Vice President of Clinical Programs for Foldax. “The enrollment is occurring rapidly, with many patients in India traveling hundreds of miles to receive the TRIA valve, further reinforcing the unmet need, and we are encouraged by the high performance we are seeing in patients treated. This polymer valve holds the promise of being a lifetime valve, without the negative quality-of-life implications of other types of prosthetic valves.”

The Indian trial is a prospective surgical mitral valve study that will enroll up to 70 adult patients with mitral valve disease from 10 sites and will support commercialization in India. Valve

hemodynamic and durability performance will be evaluated at six months and one year.

“We are excited to be able to offer our novel TRIA mitral surgical valve to patients in India,” said Foldax CEO Gregory D. Casciaro. “We are grateful for the collaboration between the U.S. and Indian surgeons to identify patients who are candidates for the trial. As the TRIA polymer valve is manufactured robotically with a small manufacturing pod footprint, we intend to make our valves anywhere easily and efficiently in the world, without the need for a large skilled workforce or large manufacturing facilities. This capability will allow Foldax to access and help more patients globally. We are passionate about providing life-changing treatments and it is rewarding to know that we are offering a unique valve replacement that allows patients to resume living the lives they want.”

The TRIA heart valve is for investigational use only and is not available for commercial sale.

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, between tissue and mechanical valves.

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

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