



Foldax Receives FDA Approval to Initiate Clinical Study of Biopolymer Mitral Heart Valve

SALT LAKE CITY, Utah – December 14, 2020 - [Foldax®](#), Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted IDE approval for the company to initiate a U.S. clinical study of its Tria™ biopolymer mitral surgical heart valve. The company anticipates the first use of its mitral valve in a human will take place in the coming weeks.

The mitral valve is the second of three Tria biopolymer heart valve products in the Foldax portfolio, and addresses a large unmet clinical need based on the prevalence of rheumatic fever worldwide.

The first of the company's products – an aortic surgical heart valve – is currently enrolling a U.S. clinical study as a result of FDA approval of an expanded study last October. The third valve product is a transcatheter aortic valve replacement (TAVR), which is in the pre-clinical testing phase.

The Tria valves reimagine the heart valve by incorporating a new, proprietary biopolymer – LifePolymer™ – with innovative valve designs intended to resist calcification, withstand stresses and strains without failure, and restore patient quality of life without lifelong use of anticoagulants.

“There is a great need for a more durable mitral valve, as tissue valves tend to be much less durable in the mitral position than in the aortic position, yet there have been very few mitral valve clinical studies in the past decade,” stated Frank Shannon, MD, Chief of Cardiovascular Surgery at Beaumont Hospital in Royal Oak, MI and head of the Foldax Medical Advisory Board. “The Tria biopolymer valve offers the potential to be an important new therapeutic option with enhanced durability that is intended to allow patients to avoid taking the blood thinning medication required by mechanical valves.”

“We are gratified that the FDA has now approved two of our valves for clinical investigation. This latest approval is an important milestone in our mission to develop a portfolio of surgical and transcatheter biopolymer heart valves designed to last a lifetime,” stated Foldax CEO Frank Maguire. “We view the Tria mitral valve as a product with global appeal that is capable of meeting the durability needs of both advanced and developing countries, while addressing the consequences of rheumatic fever and challenges of managing mechanical valve-related anticoagulation therapy in developing regions.”

Tria is also the first and only heart valve to be robotically manufactured, reducing variability and enabling high precision, repeatability and quality, while substantially improving the economics of heart valve manufacturing.

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