



FOLDAX, INC. GAINS APPROVAL TO BEGIN US CLINICAL TRIALS OF THE FIRST AND ONLY BIOPOLYMER HEART VALVE PLATFORM

SALT LAKE CITY, Utah., February 14, 2019 – Foldax, Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted IDE approval to begin an Early Feasibility Study of the Tria surgical aortic heart valve for the treatment of aortic valve disease.

Using breakthrough LifePolymer™ - a proprietary advanced biopolymer material - and a proprietary valve design, the Tria heart valve is designed to be a lifetime valve with hemodynamic performance and quality of life similar to natural human valves but without using animal tissue or the side effects of long-term anticoagulants. Intended for use in transcatheter or surgical heart valve applications, the Tria heart valves are robotically manufactured to provide the highest level of quality and precision.

“We look forward to introducing the Tria heart valve to patients in the United States”, says Amit Patel, MD of the University of Miami, who will be serving as primary investigator in upcoming clinical trials. “With the Tria heart valve we have the opportunity to overcome the challenges with today’s heart valves. The Tria valve is truly a revolutionary option for the more than one million Americans who have moderate or severe heart diseases.¹”

The complete Tria heart valve platform will include valves developed for use in aortic, mitral, and tricuspid valve disease. The company plans to continue its development efforts and clinical trials, in pursuit of OUS and US regulatory approvals.

“The FDA IDE approval to proceed with clinical investigation of the Tria heart valve represents a significant milestone for the Company.” said Ken Charhut, Executive Chairman of Foldax, Inc. “It is the first step in bringing a 21st Century solution to patients with valve disease. Our goal is to transform the way heart valves have been made for the last 40 years by bringing high quality, value and patient specific options to clinic.”

ABOUT FOLDAX, INC.

Headquartered in Salt Lake City, Utah, Foldax, Inc. develops long-lasting replacement heart valves with the goal of improving hemodynamic performance and providing a quality of life similar to natural human valves. The company’s Tria heart valves are revolutionizing the industry as the first and only biopolymer heart valve platform, utilizing LifePolymer™ material. These long-lasting transcatheter and surgical heart valves are designed to provide sustainable quality-of-life improvement for people with aortic, mitral, or tricuspid valve disease.



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References:

1. Heart Valve Society of America (2018, April 11). About the Heart Valve Society of America. Retrieved from <http://www.heartvalvesocietyofamerica.org/more.html>.