Foldax Announces Successful First Human Use of Tria Biopolymer Mitral Heart Valve

Second Product from Tria Biopolymer Valve Portfolio to Move into Human Study

May 25, 2021 07:30 AM Eastern Daylight Time

SALT LAKE CITY--(BUSINESS WIRE)--Foldax®, Inc. today announced the successful first-in-human use of its biopolymer Tria™ heart valve in surgically replacing a diseased mitral valve. The first case was performed by David Heimansohn, MD, at Ascension St. Vincent Hospital, Indianapolis, as part of a U.S. early feasibility research study.

“We are excited to be the first center in the world to implant the innovative Tria mitral valve as part of this research study. In this first-in-man procedure, we saw an immediate improvement in the functionality of this patient’s heart valve once the valve was in place”

“We are excited to be the first center in the world to implant the innovative Tria mitral valve as part of this research study. In this first-in-man procedure, we saw an immediate improvement in the functionality of this patient’s heart valve once the valve was in place,” said Dr. Heimansohn. “Since it has been designed to be a more durable artificial valve that may not require lifetime anti-coagulation therapy, it is hoped that Tria will be proven effective through this research study for patients with mitral disease, who are often much younger than patients with other valvular diseases.”

“We thank Dr. Heimansohn and his skilled team at Ascension St. Vincent Hospital for their commitment to advancing cardiovascular medicine by successfully performing the first-in-man Tria mitral valve procedure,” said Foldax CEO Frank Maguire. “This milestone continues to build upon the clinical evidence supporting Foldax’s Tria valves, which includes the ongoing Tria aortic valve study encompassing several patients who have celebrated one year with their implants and are doing well. Our transcatheter aortic valve replacement (TAVR) continues its rapid development path and will give us both surgical and transcatheter approaches in our family of heart valves. Foldax intends to revolutionize the heart valve replacement market by largely solving the durability, quality of life and manufacturing issues that have vexed the clinical community and industry for decades.”

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. Tria is also 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.

The need for mitral valve replacement is expected to grow significantly into the future, driven by a steady increase in the prevalence of rheumatic heart disease, which is the main cause of mitral valve stenosis and affects more than 40 million people worldwide.[1]

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

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.

1. Roth GA, Mensah GA, Johnson CO, et al. Global burden of cardiovascular diseases and risk factors, 1990-2019: Update from the GBD 2019 study. JACC. 2020 December;76(25):2982-3021.

Contacts

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

FOLDAX, INC.

Release Summary

Foldax announced the successful first human use of its Tria biopolymer mitral heart valve. The Tria valve is designed to last a lifetime for patients.

Tweets by @Foldax_Tria

#Hashtags

#medtech #clinicaltrials #mitralvalve #cardiovascular #foldax #lifepolymer #triaheartvalve #changinglives

Social Media Profiles

Foldax on Twitter

Foldax on LinkedIn

More News

March 08, 2021
Foldax Named Among Fierce Medtech’s “Fierce 15” Companies of 2020

January 26, 2021
Foldax Biopolymer Shown to Possess Ideal Properties for Heart Valve in New Published Paper

December 14, 2020
Foldax Receives FDA Approval to Initiate Clinical Study of Biopolymer Mitral Heart Valve

Contacts

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