



FOR IMMEDIATE RELEASE

Foldax Receives FDA Approval to Expand Clinical Study of Novel Biopolymer Aortic Heart Valve

SALT LAKE CITY, Utah – October 26, 2020 - [Foldax®](#), Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted approval to expand the U.S. clinical study of the Tria™ surgical aortic heart valve. This next stage of enrollment is expected to begin within the next month.

“We are excited to expand enrollment in this U.S. clinical study to gain additional clinical experience with the Tria valve,” 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 valve with its biopolymer leaflets represents the first new material for heart valves in decades and offers the potential for significantly better durability than tissue valves, while eliminating the need for lifelong blood thinners that comes with mechanical valves. The first patient to ever receive the Tria valve and the first in this study just celebrated his one-year anniversary with the valve and is doing very well, enjoying an active life where he runs and hikes.”

The Tria valve reimagines the heart valve by incorporating a new, 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.

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

“We are gratified that the FDA has recognized the importance of continued study of this novel valve, which will enable the Company and the clinical community to further understand the valve’s performance and its benefits for patients. We look forward to continuing our work with each of our dedicated clinical sites,” stated Frank Maguire, Chief Executive Officer of Foldax.

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. The company is developing its Tria valve technology in partnership with Caltech and CSIRO, Australia's science agency.

###

Media Contact

Michelle McAdam, Chronic Communications, Inc.

michelle@chronic-comm.com

(310) 902-1274