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Foldax Biopolymer Shown to Possess Ideal Properties for Heart Valve in New Published Paper

Company's LifePolymer Material Used in First Polymer Heart Valves Ever Approved by FDA for Use in Clinical Trials

SALT LAKE CITY, Utah – January 25, 2021 - Foldax®, Inc. today announced publication of a research paper in Advanced NanoBiomed Research that concluded that its LifePolymer™ biopolymer "exhibits ideal biomaterial properties for the flexible leaflets of a totally synthetic valve replacement."

LifePolymer is a proprietary biopolymer that was engineered at the molecular level to solve problems commonly experienced by prosthetic heart valves, including earlier heart valves attempting to use polymeric leaflets, such as material degradation, thrombosis and calcification.[1,2,3]

The LifePolymer material is used in the company's portfolio of Tria biopolymer heart valves that reimagine the heart valve and are intended to resist calcification, withstand stresses and strains of the heart, and restore patient quality of life without lifelong use of anticoagulants.

"Replacement of traditional xenogeneic pericardial tissue leaflets with high-performance SiPUU (siloxane-based polyurethane-urea, or LifePolymer) provides the advantages of a highly controlled leaflet design, ideal and tailored mechanical properties, a robust supply chain, and lower manufacturing costs," state the authors. "Together with the earlier reported work on this new SiPUU copolymer, an exhaustive data set now confirms LifePolymer's suitability for use as a leaflet in a replacement heart valve."

Data that was cited in the article included:

- Previous publications[4,5] demonstrate generally outstanding in vitro and in vivo resistance of LifePolymer to aggressive oxidative attack, using an accelerated model with a level of strain >10 times the strain expected to be seen in an aortic valve leaflet. The strained LifePolymer devices showed no signs of degradation (e.g. pitting or cracking) even after six months under these accelerated conditions.
- The Tria valve with LifePolymer leaflets has shown exceptional hemocompatibility.[6,7]

- An ex-vivo thrombosis assay using the LifePolymer-based device supported low coagulation activation, producing nearly undetectable levels of platelet attachment and fibrin deposition in situ, both key markers of thrombosis.[6]
- The Tria valve with LifePolymer leaflets passed all standard biocompatibility and biostability testing.[6]

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. Its second device, a mitral surgical valve, was approved by the FDA for a U.S. clinical study last month, with the first human case expected to take place within the next several weeks. The third valve product is a transcatheter aortic valve replacement (TAVR), which is in the pre-clinical testing phase.

The Tria valves are the first and only heart valves 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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