



## Aziyo Biologics Announces First Patient Enrolled in HEAL Study

February 17, 2021

SILVER SPRING, Md., Feb. 17, 2021 (GLOBE NEWSWIRE) -- Aziyo Biologics, Inc. (Nasdaq: AZYO), a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery, announced today the first patient enrolled in the HEAL Study, investigating the biologic and clinical effects of device envelopes which are placed around cardiovascular implantable electronic devices ("CIEDs") at the time of implantation surgery.

HEAL is a national multi-center study that will evaluate approximately 100 patients who previously underwent implantation of CIEDs with either an Aziyo CanGaroo® Envelope, Medtronic's Tyrx™, or no envelope, who have had their implants for at least a year and are returning for a CIED change-out or revision procedure.

The study focuses on identifying characteristics of soft tissue healing surrounding the CIED implant using tissue biopsies taken at the time of the change-out/revision procedure for patients treated with or without an envelope at the time of device implantation. Additional visual, structural and clinical assessments will provide insight into the clinical impact that the implant pocket healing has on the subsequent surgical procedure challenges and risks. Additional analyses will explore comparison between cohorts of documented clinical outcomes and complications since the most recent CIED procedure through the current change-out/revision procedure.

The first patient was enrolled by Dr. Ziad Issa, MD, MMM (Prairie Heart Institute of Illinois), an experienced clinical investigator who has participated in numerous studies spanning 15 years. Dr. Issa is also the lead author/editor of the 1st – 3rd editions of the textbook "Clinical Arrhythmology and Electrophysiology: A Companion to Braunwald's Heart Disease."

"Excessive scar tissue formation around the CIED generator and leads pose significant challenges to operators during device and lead revision procedures as well as increase the risk of injury to leads, bleeding, and infection," said Dr. Issa. "We are very excited to be part of this important study that can potentially provide evidence-based solutions to mitigate these risks and improve outcomes."

"We are pleased to see the commencement of this important study, as we believe it has the potential to validate the significant contribution that a biological envelope can provide to patients receiving a CIED," said Ron Lloyd, President and CEO of Aziyo. "In addition, we believe this study has the potential to provide further insight into the ability of our CanGaroo Envelope to create a healthy, vascularized pocket to reduce complications that can arise with an implantable CIED, such as fibrotic capsule formation, device migration or erosion. We look forward to the participation of leading medical centers across the United States and the findings of this study following the anticipated completion of enrollment."

### About the CanGaroo® Envelope

The CanGaroo Envelope is a small intestine submucosa extracellular matrix designed to mitigate complications deriving from implantable electronic devices and the shortcomings of synthetic envelopes. Once implanted, it creates a hospitable environment for the surrounding cells to migrate into the bio scaffold and start matrix turnover. The natural envelope is remodeled into a healthy pocket of systemically vascularized tissue, potentially reducing the risk of fibrotic capsule formation, migration and erosion of the implantable device through the skin, and complications associated with Twiddler's syndrome. The CanGaroo Envelope may also facilitate the process of implantation and of device removal during its replacement, as well as enhance patient comfort.

### About Aziyo Biologics

Aziyo Biologics is a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery, concentrating on patients receiving implantable medical devices. Since its founding in 2015, the Company has created a portfolio of commercial-stage products used in cardiovascular, orthopedic, and reconstructive specialties. For more information, visit [www.Aziyo.com](http://www.Aziyo.com).

### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements and information concerning anticipated enrollment and potential results and insight of the HEAL study, our CanGaroo product candidate, including its ability to reduce certain complications. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, and other important factors that may cause actual results, performance or achievements to differ materially from those contemplated or implied in this press release, including, but not limited to, risks regarding our products and our ability to enhance, expand and develop our products; our dependence on our commercial partners; the adverse impacts of COVID-19 or adverse changes in economic conditions; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; our ability to obtain regulatory approval or other marketing authorizations; and our intellectual property rights, and other important factors discussed under the caption "Risk Factors" in Aziyo's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 filed with the Securities and Exchange Commission ("SEC"), as such risk factors may be updated from time to time in Aziyo's other filings with the SEC, which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov) and the Investor Relations page of Aziyo's website at [www.Aziyo.com](http://www.Aziyo.com). Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement.

**Investors:**

Leigh Salvo  
Gilmartin Group  
[investors@aziyo.com](mailto:investors@aziyo.com)

**Media:**  
Courtney Guyer  
Aziyo Biologics, Inc.  
[PR@aziyo.com](mailto:PR@aziyo.com)