



Aziyo Biologics Presents Positive Clinical Data on CanGaroo® Biologic Envelope

May 19, 2023

Study Presented at Heart Rhythm Society Supports Wound-Healing Benefits in Patients Receiving Cardiac Implantable Electronic Devices

SILVER SPRING, Md., May 19, 2023 (GLOBE NEWSWIRE) -- Aziyo Biologics, Inc. (Nasdaq: AZYO) ("Aziyo"), a company that develops and commercializes biologic products to improve compatibility between medical devices and the patients who need them, today announced that positive data from the HEAL Study will be presented at Heart Rhythm Society (HRS 2023) on May 21, 2023, at 12:30 PM CT at the Morial Convention Center in New Orleans, LA.

HEAL is a national multi-center study evaluating patients who previously underwent implantation of a cardiac implantable electronic device (CIED) with either an Aziyo CanGaroo® Envelope, Medtronic's Tyrx™ non-biologic envelope, or no envelope, and are returning for a revision procedure at least four months after initial placement. The CanGaroo Envelope is made of an acellular biologic matrix that is designed to promote a natural healing response, resulting in a healthy, vascularized tissue capsule.

"The HEAL data further support the potential of biologic envelopes to enhance pocket healing during CIED implantation and simplify reoperative procedures," said John N. Catanzaro, M.D., Associate Professor of Medicine with the University of Florida and lead investigator of the study. "This study demonstrates that biologic envelopes, such as CanGaroo, can improve patient care and decrease complications following device implantation."

The poster to be presented at HRS 2023 comprises data from 43 patients (CanGaroo, n=11, Tyrx, n=15, or no envelope, n=17) used with their initial CIED implantation. This interim analysis includes the evaluation of medical and clinical profiles, procedural notes and physician subjective scoring of the pocket, and histology.

Key findings from the interim analysis include:

- Physicians scored CanGaroo reoperations as having 46% easier generator mobilization ($p=.02$), 41% easier lead mobilization ($p=.01$), and 43% less overall procedural difficulty ($p=.04$) compared to no envelope.
- Lead adhesion classification was scored as significantly less severe in the CanGaroo group compared to no envelope ($p=.003$).
- Significantly fewer capsulectomy procedures were required in the CanGaroo vs. Tyrx group (83% less, $p=.04$).
- Independent, blinded histologic evaluation of pocket biopsies showed 30% thinner capsules in CanGaroo implant pockets vs. no envelope ($p=0.12$) and 32% thinner capsules vs. Tyrx ($p=.09$).
- No significant group differences were observed in mean age, gender, race, or prior implant history.

Abstract and presentation details:

- **Abstract Title:** Biologic Cardiovascular Electronic Device Envelopes Enhance Pocket Healing and Simplify Reoperative Procedures
- **Presenter:** Dr. John N. Catanzaro, MD, MBA, FACC, FESC, FHRS, Department of Cardiology, University of Florida Health, Jacksonville, FL
- **Date:** Sunday, May 21, 2023 at 12:30 PM – 2:30 PM Central Time
- **Location:** Abstract Pavilion - Morial Convention Center

During the event, Aziyo Biologics will be exhibiting at Booth 319.

About Aziyo Biologics

Aziyo develops and commercializes biologic products to improve compatibility between medical devices and the patients who need them. With a growing population in need of implantable technologies, Aziyo's mission is to humanize medical devices to improve patient outcomes. For more information, visit 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. Forward-looking statements can be identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential,” “promise” or similar references to future periods. 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 the effectiveness of the CanGaroo RM Antibacterial Envelope and its potential to improve CIED implantation patient care and reduce complications following implantation. Forward-looking statements are based on management’s current assumptions and expectations of future events and trends, which affect or may affect our 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 the ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra; our inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; our ability to continue as a going concern; our products and our ability to enhance, expand, develop and commercialize our product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; our dependence on our commercial partners; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; the ability to obtain regulatory approval or other marketing authorizations; and our intellectual property rights, and other important factors which can be found in the “Risk Factors” section of Aziyo’s public filings with the Securities and Exchange Commission (“SEC”), including Aziyo’s Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in Aziyo’s other filings with the SEC, including, Aziyo’s Quarterly Reports on Form 10-Q, accessible on the SEC’s website at www.sec.gov and the Investor Relations page of Aziyo’s website at <https://investors.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. Any forward-looking statement made by Aziyo in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, Aziyo expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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