Aziyo Announces FDA 510(k) Submission for CanGaroo® RM, its Next-Generation Biomaterial Envelope Enhanced with Antibiotics

April 4, 2022

SILVER SPRING, Md., April 04, 2022 (GLOBE NEWSWIRE) -- Aziyo Biologics, Inc. (Nasdaq: AZYO), today announced the Company has filed a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for CanGaroo® RM Antibacterial Envelope, its next-generation biomaterial envelope for use with implantable electronic devices (IED). 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.

With this 510(k) submission, the Company intends to bring to the U.S. market a version of its existing FDA-approved CanGaroo envelope enhanced with the antibiotics Rifampin and Minocycline in dissolvable polymer rings. The addition of antibiotics to the biomaterial envelope is designed to reduce the risk of bacterial colonization.

Dr. Benjamin D'Souza, Cardiac Electrophysiologist at Penn Presbyterian Medical Center, Philadelphia, PA, commented, "I look forward to the introduction of the CanGaroo RM Antibacterial Envelope, as it will provide a novel step forward in mitigating complications in our cardiac implantable electronic device implants. The combination of a biomaterial envelope that utilizes extracellular matrix, promoting regenerative tissue growth, in addition to the elution of antibiotics to provide antibacterial protection will provide a much-needed benefit to our patients."

"The 510(k) submission for our next-generation CanGaroo envelope marks a significant milestone towards our vision of delivering the best possible post-operative outcomes for patients receiving implantable electronic devices such as pacemakers and defibrillators," said Ron Lloyd, Chief Executive Officer. "I'm proud of the Aziyo team for their commitment to reaching this critical step in advancing CanGaroo in order to provide a new solution to electrophysiologists and their patients. We look forward to working through the FDA review process towards our goal of clearance in the U.S. market."

About the CanGaroo® Envelope
The CanGaroo Envelope is a pouch for cardiac implantable electronic devices and neurostimulators designed to stabilize the IED devices. CanGaroo Envelope is comprised of small intestine submucosa derived extracellular matrix, a biomaterial which promotes a natural healing response resulting in healthy vascularized tissue. Once implanted, it creates a hospitable environment for the surrounding cells to migrate into the bio scaffold and start matrix turnover. The natural envelope remodels into a healthy pocket of systemically vascularized tissue, potentially reducing the risk of complications such as migration and erosion of the implantable device through the skin, and complications associated with Twiddler's syndrome.

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.

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 the potential regulatory clearance and the commercial launch of CanGaroo RM. 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 the Company's products and its ability to enhance, expand and develop its products; the impact on the Company's business of the recall of a single lot of its FiberCel product and the discontinuation of its sales by its distribution partner; the Company's dependence on its 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 the Company's products; the ability to obtain regulatory approval or other marketing authorizations; and the Company's intellectual property rights, and other important factors 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, 2021, as such factors may be updated from time to time in Aziyo's other filings with the SEC, 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. 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

Media:

Courtney Guyer
Aziyo Biologics, Inc.
PR@aziyo.com