



Aziyo Biologics Announces Initiation of De Novo CanGaroo Clinical Study

April 28, 2021

SILVER SPRING, Md., April 28, 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 initiation of a multi-center observational study to provide insight into the clinical profiles, procedural details and post-implant outcomes in patients receiving Aziyo's CanGaroo® Envelope or no envelope during initial (de novo) cardiac implantable electronic device (CIED) placement.

The prospective, multi-center study anticipates enrolling up to 500 participants who are undergoing implementation of a CIED with either a CanGaroo Envelope (approximately 330 patients) or no envelope (approximately 170 participants).

"The initiation of the CanGaroo De Novo Study marks an important milestone for Aziyo," said Ron Lloyd, President and Chief Executive Officer of Aziyo. "While we are confident that all CIED patients have the potential to benefit from our CanGaroo Envelope based on remodeling into a healthy pocket of systemically vascularized tissue and potentially reducing the risk of fibrotic capsule formation, we believe the benefit may be even more pronounced in patients receiving their first CIED implant. For this reason, this study focuses on these de novo implant patients."

The study is designed to provide insights into the profiles of patients selected for CanGaroo implantation, as well as the clinical decision making by physicians. Clinical outcomes of up to three months will be collected from all enrolled participants. The study also is anticipated to include a group of patients less than or equal to 65 years of age who will be followed for up to five years after treatment to provide insights into the pattern of longer-term outcomes and additional benefits.

"The currently enrolling HEAL Study is focused on evaluating the tissue and biologic changes in the device implant pockets, including the CanGaroo Envelope, associated with CIED envelope use at the time of device change out or revision. This new study is intended to demonstrate the value of this biologic impact in de novo implant patients followed long-term, and we believe it will be complementary to the HEAL study," added Dr. Jerome Riebman, Chief Medical Officer of Aziyo.

The enrollment for this study is expected to close within 18 months, and standard follow-up will close at 21 months with the long-term subgroup followed for up to five years. The endpoint of this study is a cohort comparison of clinically significant factors, such as physical, medical and demographic characteristics, medical history, risk factors related to post-procedure events, and associations with outcomes and events.

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.

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 CanGaroo De Novo Study and our CanGaroo Envelope product, 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 Annual Report on Form 10-K for the annual period ended December 31, 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 and the Investor Relations page of Aziyo's website at 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.

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