Aziyo's CanGaroo Envelope Cleared for Expanded Use with Neurostimulator Devices

November 29, 2018

SILVER SPRING, MD. – November 29, 2018 – Aziyo Biologics, Inc., a fully integrated regenerative medicine company, announced today that it has received U.S. Food and Drug Administration (FDA) clearance of the CanGaroo Envelope device for use with implantable neurostimulator devices.

CanGaroo is a natural extracellular matrix (ECM) envelope that is designed to securely hold both cardiac implantable electronic devices (CIED) and implantable neurostimulators to create a stable environment following implantation. In addition to previously permitted use with pacemakers, defibrillators and other CIEDs, the FDA clearance for CanGaroo has been expanded to include vagus nerve, deep brain and sacral nerve stimulators as well as spinal cord neuromodulators.

"Products such as the CanGaroo Envelope have become invaluable to electrophysiologists in helping reduce some of the complications associated with implantable devices while maintaining a more natural type of healing process," said John N. Catanzaro, M.D. FACC, FESC, FHRS Electrophysiologist at the University of Florida Jacksonville. "Expanding use to the field of neurostimulation will greatly benefit both subsets of patients who require these devices."

"CanGaroo has been used by electrophysiologists since 2014 to improve patient outcomes in CIED procedures and we're excited to now expand this offering to neurosurgeons as well," said Ron Lloyd, president and Chief Executive Officer of Aziyo Biologics. "We are committed to driving the tremendous potential of our regenerative medicine products to make positive advances for patients and the professionals and organizations that serve them."

About CanGaroo Envelope

The CanGaroo Envelope is constructed from a multi-laminate sheet of decellularized, non-crosslinked, lyophilized extracellular matrix (ECM) derived from porcine small intestinal submucosa (SIS). Once CanGaroo is implanted, it secures the device in place, and evidence shows that over time it remodels into a vascularized pocket that may facilitate implant removal or revision when required. The CanGaroo Envelope is a 510(k) FDA cleared and CE Marked medical device.

About Aziyo Biologics, Inc.

Aziyo Biologics is a fully integrated, commercially oriented regenerative medicine company. Since its founding in 2015 the Company has expanded through acquisitions and strategic partnerships, creating a high growth commercial entity. Its proprietary products are used in orthopedic, cardiovascular and other medical specialties. For more information, visit www.Aziyo.com.

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