Elutia Announces First Patient Implant of EluPro™, the World's First Drug-Eluting BioEnvelope for Cardiac Pacemakers and Neurostimulators

September 5, 2024

SILVER SPRING, Md., Sept. 05, 2024 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia"), a pioneer in drug-eluting biomatrix products, today announced a landmark achievement with the first-ever patient implant of EluPro®, the world's first antibiotic-eluting biologic envelope cleared by the U.S. Food and Drug Administration (FDA). The groundbreaking procedure was performed by John Catanzaro, MD, MBA, Chief, Division of Cardiology, Director, Cardiology Services, and Program Director of Clinical Cardiac Electrophysiology Fellowship at East Carolina University Health Medical Center in Greenville, North Carolina.

"We are honored to be the first facility to implant EluPro," said Dr. Catanzaro. "With its combination of proven antibiotics and biomatrix with demonstrated regenerative benefits, EluPro offers a more natural solution to reduce post-operative complications. This is a significant advancement in patient care, providing enhanced protection and peace of mind for patients needing a pacemaker or defibrillator."

Achieving this milestone demonstrates Elutia's ability to deliver on its commitment to advancing healthcare with innovative solutions that address device complications.

"Our mission is to humanize medicine so patients can thrive without compromise, and today, we made significant progress toward fulfilling that promise," said Dr. Randy Mills, Elutia's Chief Executive Officer. "Today's milestone is a testament to the team's relentless pursuit of better patient outcomes and I want to thank the entire Elutia CRU. With EluPro, physicians finally have a biologic antibiotic-eluting envelope to protect their patients, and we look forward to its full commercial launch in January 2025."

EluPro is designed to prevent post-operative complications in patients with cardiac implantable devices such as pacemakers and internal defibrillators. Cleared by the FDA in June 2024, it is also approved for use with additional devices, including neuromodulators and neurostimulators for pain management, epilepsy, incontinence, and sleep apnea.

The launch of EluPro presents a major opportunity in the $600 million U.S. implantable electronic device protection market, which has previously been served by a single competitor with a synthetic envelope. In addition to establishing a strong presence in the broader $8 billion cardiac rhythm management market, Elutia is also targeting adjacent neurostimulation and modulation sectors, which represent another $8 billion opportunity.

For more information about EluPro, visit https://elutia.com/products/elupro/.

About Elutia

Elutia develops and commercializes drug-eluting biomatrix products to improve compatibility between medical devices and the patients who need them. With a growing population in need of implantable technologies, Elutia's mission is humanizing medicine so patients can thrive without compromise. For more information, visit www.Elutia.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 any statements and information concerning our future interactions with the U.S. Food and Drug Administration (“FDA”); preparations for the launch of EluPro, including the timing and anticipated success thereof; the size of the pacemaker and implantable defibrillator protection market and the potential of EluPro to compete in that market; and the potential for applying our drug-eluting biomatrix technology into adjacent markets. These forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied in the forward-looking statements, including, but not limited to the following: our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; our ability to continue as a going concern; the risk of product liability claims and our ability to obtain or maintain adequate product liability insurance; our ability to defend against the various lawsuits and claims related to our recalled FiberCel and other viable bone matrix products and avoid a material adverse financial consequence from those lawsuits and claims; our ability to achieve or sustain profitability; our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings; our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales; our dependence on a limited number of third-party suppliers and manufacturers, which, in certain cases are exclusive suppliers for products essential to our business; our ability to successfully realize the anticipated benefits of the November 2023 sale of our Orthobiologics business; physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products; the continued and future acceptance of our products by the medical community; our ability to compete against other companies, most of which have longer operating histories, more established products and/or greater resources than we do; pricing pressure as a result of cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could adversely affect our sales and profitability; and our ability to obtain, maintain and adequately protect our intellectual property rights; and other important factors which can be found in the “Risk Factors” section of Elutia’s public filings with the Securities and Exchange Commission (“SEC”), including Elutia’s Annual Report on Form 10-K for the year ended December 31, 2023, as such factors may be updated from time to time in Elutia’s other filings with the SEC, including Elutia’s Quarterly Reports on Form 10-Q, accessible on the SEC’s website at www.sec.gov and the Investor Relations page of Elutia’s website at https://investors.elutia.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 Elutia 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, Elutia 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.

Investors:
Matt Steinberg
FINN Partners
matt.steinberg@finnpartners.com

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/53c6e902-d58d-4689-9f3b-b56c761abe1a