Elutia Announces Full Launch of EluPro™ Following Strong Initial Demand

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First FDA-Cleared Antibiotic-Eluting BioEnvelope Now Available in U.S. for Implantable Pacemakers, Defibrillators, and Neurostimulators

SILVER SPRING, Md., Jan. 14, 2025 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT), a pioneer in drug-eluting biomatrix technologies, announced the U.S. commercial launch of EluPro™, the first and only FDA-cleared antibiotic-eluting biomatrix designed for use with cardiac implantable electronic devices (CIEDs) and neurostimulators.

“EluPro is an exciting innovation that addresses two critical challenges for patients with implantable devices: preventing infection and promoting healthy healing of the surgical pocket,” said Sunil Kapur, M.D., Cardiac Electrophysiologist at Brigham and Women’s Hospital. “The unique combination of powerful antibiotic protection and natural biomatrix technology represents a significant step forward in improving outcomes for patients. I am eager to see this technology benefit the field of electrophysiology.”

This full launch follows a successful pilot program in which EluPro was introduced at select hospitals, demonstrating strong physician adoption and positive patient outcomes. During this initial phase, Elutia has submitted EluPro for approval with 136 hospital value analysis committees (VACs), initiated sales at 70 institutions and established key relationships with four prominent group purchasing organizations (GPOs), including Premier and S3P. In an early indication of positive customer reception, envelope orders have increased over 50% in accounts following EluPro VAC approval.

"The launch of EluPro represents a significant advance in care for patients with CIEDs and neurostimulators," announced Dr. Randy Mills, CEO of Elutia. "Our successful pilot program confirmed EluPro’s substantial potential, marked by expeditious navigation of GPO and value analysis committee approvals and strong initial demand by physicians. I am proud of the Elutia CRU for their relentless efforts as we expand EluPro’s reach to benefit all patients in need of our groundbreaking technology."

Each year, more than 600,000 CIEDs are implanted in the U.S., with complication rates of 5-7%, including infections linked to higher morbidity and mortality. EluPro is cleared for use across all major CIED brands including pacemakers and implantable defibrillators, as well as for a wide range of neurostimulation devices. Unlike synthetic alternatives, EluPro addresses this critical need by combining the trusted antibiotics rifampin and minocycline with a soft, regenerative biomatrix that promotes healing, and mitigates other complications such as migration and erosion. The CIED protection market is valued at $600 million in the U.S.

To learn more, visit www.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 the launch of EluPro, including the timing and anticipated success thereof. 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 successfully commercialize, market and sell our newly approved EluPro product; our ability to continue as a going concern; our ability to achieve or sustain profitability; 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; the continued and future acceptance of our products by the medical community; 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; 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; our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; 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.

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