Elutia Announces Newly Published Clinical Data Demonstrating that Biologic Envelopes Support CIED Stabilization and Ease of Reoperation

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- Findings highlight the potential of antibiotic-eluting bioenvelopes to transform cardiac implantable electronic device (CIED) pocket management -

GAITHERSBURG, Md., Sept. 16, 2025 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a pioneer in drug-eluting biomatrix technologies, today announced the publication of clinical and preclinical data supporting the clinical utility of a biologic envelope that secures cardiac implantable electronic devices (CIEDs), promotes tissue remodeling, and addresses bacterial colonization through localized antibiotic delivery. The data are published in the current issue of *Frontiers in Cardiovascular Medicine*.

The publication includes data from the HEAL study (NCT04645173), a multicenter observational clinical evaluation of patients undergoing CIED reoperations. This study found that patients previously implanted with an engineered extracellular matrix (ECM) envelope had 43% lower overall procedural difficulty, including 46% easier generator mobilization and 41% easier lead mobilization compared with patients previously implanted without envelopes or with non-biologic envelopes.

"These results suggest that biologic envelopes not only facilitate placement and stabilize the device initially but also preserve surgical access to the pocket over time," said Dr. Benjamin D'Souza, Associate Professor of Medicine at the University of Pennsylvania and Section Chief of Cardiac Electrophysiology at Penn Presbyterian Medical Center. "That is especially relevant for patients likely to undergo future reinterventions."

The publication also details preclinical studies showing complete eradication of bacterial inoculates commonly implicated in CIED-related complications. The antibiotic-eluting envelope eliminated pathogens, such as MRSA, while maintaining regenerative function. Pharmacokinetic assessments confirmed sustained local antibiotic concentrations for up to two weeks.

"The drug-eluting biomatrix technology developed by Elutia is an effective solution for two long-standing CIED procedural challenges — eliminating the bacteria that can cause near-term, post-operative complications and reducing long-term procedural difficulties," said Dr. Michelle LeRoux Williams, PhD, Chief Scientific Officer at Elutia. "Elutia is committed to transforming our drug-eluting biomatrix technologies into innovative products that address real-world clinical needs and improve patient outcomes."

The combination of regenerative ECM and broad-spectrum, synergistic antibiotics, like rifampin and minocycline, is a powerful platform for future drug-eluting biologics—particularly in surgical settings where tissue remodeling and infection control intersect. Building on this foundation, Elutia is advancing a next-generation pipeline targeting higher-risk procedures, such as breast reconstruction where one in three patients suffer serious complications after reconstruction. This research lays the groundwork for a future in which the body's healing response is managed as carefully as the device itself.

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. Forward-looking statements contained in this press release include, without limitation, any statements we make regarding the future success of Elutia's next-generation drug-eluting biomatrix pipeline, including anticipated timing and success thereof, and the potential for ECM envelopes to facilitate medical device implantation, stabilization and future reintervention. 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: the risk that clinical research data may not match preclinical study data, or the risk that early clinical data may not be predictive of longer-term experience with a medical device, including Elutia's biologic envelope products; risks associated with shifting focus to our drug-eluting biomatrix solutions in the breast reconstruction area and away from our CIED business; risks regarding delays in completing the proposed disposition of the CIED business, or to meet any of the other closing conditions to the proposed transaction on a timely basis or at all; our ability to successfully execute or achieve expected benefits from the divestiture of our CIED business; our ability to continue as a going concern; our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates, including our next-generation drug-eluting biomatrix pipeline; our ability to raise capital in the amounts and at the times needed, and on acceptable terms; our ability to manage our substantial indebtedness and other obligations, such as our revenue interest obligation to Ligand Pharmaceuticals, including our ability to negotiate waivers or similar accommodations as needed; 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; our ability to prevail in lawsuits and claims seeking indemnity, contribution and insurance coverage for FiberCel and other viable bone matrix product liabilities; 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 previous 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 that could adversely affect our sales and profitability; 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, 2024, 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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