



Elutia Announces New Peer Reviewed Publication Highlighting the Robustness of EluPro™, Company's Antibiotic-Eluting BioEnvelope for Implantable Devices

September 18, 2024

EluPro eradicated bacteria commonly associated with cardiac implant-related infections in an established preclinical infection model

SILVER SPRING, Md., Sept. 18, 2024 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia"), a leader in drug-eluting biomatrix products, today announced the publication of preclinical data demonstrating that EluPro, the world's first antibiotic-eluting biologic envelope cleared by the U.S. Food and Drug Administration (FDA), clears bacterial contamination associated with cardiovascular implantable electronic devices (CIEDs). Data published in [Frontiers in Drug Delivery](#) show that in an animal model, EluPro demonstrated the ability to reduce bacterial colonization with minimal systemic antibiotic exposure.

In [June 2024](#), EluPro received FDA clearance for use with CIEDs and has been approved for use with additional devices, including neuromodulators and neurostimulators for pain management, epilepsy, incontinence, and sleep apnea. The first patient implant of EluPro was completed in [September 2024](#).

"EluPro is a biologic envelope that has the ability to improve implant stability and reduce device migration. This latest study highlights EluPro's potential to address the risk of bacterial contamination, a major concern in CIED procedures," said Dr. M. Rizwan Sohail, Professor of Medicine at Baylor College of Medicine and an author on the publication. "Additionally, recent clinical findings suggest that EluPro may help minimize scarring and fibrosis around the implant, potentially making reoperation easier. Together, these insights highlight EluPro's comprehensive approach to addressing a range of challenges associated with implantable devices."

The studies were conducted using a well-established rabbit model of CIED infection. Devices were implanted with either EluPro or a non-antibiotic control envelope, and bacterial species were introduced. Implant sites were monitored for signs of infection for one week, and explanted envelopes were assessed for bacterial presence. The results revealed that none of the animals receiving EluPro exhibited signs of infection, whereas animals in the control group developed fevers, required supportive care, or experienced premature death. Additionally, EluPro demonstrated significant bacterial reduction at the implant sites, achieving complete eradication of methicillin-resistant staphylococcus aureus, commonly known as MRSA, and other strains. Furthermore, EluPro provided sustained local antibiotic release for over a week with minimal systemic exposure, a key benefit of local drug delivery.

"We believe these results greatly reinforce EluPro's potential to provide enhanced infection control for CIED procedures," said Michelle LeRoux Williams, Ph.D., Elutia's Chief Scientific Officer. "As the first FDA-cleared biologic antibiotic-eluting envelope, EluPro represents a significant step forward in implantable device protection. With our recent milestone of the first human implant, we are preparing for the commercial launch of EluPro in January 2025."

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 preparations for the launch of EluPro, including the timing and anticipated success thereof, and the potential of EluPro to curtail bacterial contamination, scarring and fibrosis in humans. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us, including the study referenced in this press release. 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 U.S. Food and Drug Administration 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; the long-term efficacy of our products; risks related to extrapolating results from animal trials to humans; 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.

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