Elutia Submits CanGarooRM® Antibiotic-Eluting Biomatrix for FDA Clearance

December 18, 2023

510(k) filing follows FDA feedback from successful pre-submission meeting

SILVER SPRING, Md., Dec. 18, 2023 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) today announced it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for its next-generation drug-eluting biomatrix product, CanGarooRM®. Tailored for use with cardiac implantable electronic devices (CIEDs), such as pacemakers and internal defibrillators, CanGarooRM addresses a $600 million market, currently served by only one competitor. The decision to file came after the Company received feedback from a pre-submission meeting with the FDA. The Company anticipates an approval decision in the first half of 2024 and is now preparing for commercial launch.

Dr. Michelle LeRoux Williams, Chief Scientific Officer of Elutia, highlighted the milestone, stating, “The CanGarooRM submission is a pivotal moment in advancing our antibiotic-eluting technology for patients with pacemakers and cardiac implants. Our goal has been to provide the FDA the high-quality data they need to reach a favorable decision, and I believe our research and regulatory teams have prepared a submission package that does just that. I offer my sincere thanks to all involved.”

CanGarooRM is a bioenvelope that stabilizes cardiovascular implantable electronic devices (CIED) such as pacemakers and neurostimulators. The envelope is made of a natural biomaterial that promotes a regenerative healing response, resulting in healthy vascularized tissue. CanGarooRM also contains a slow-release formulation of the powerful antibiotics, rifampin and minocycline, which have been shown to reduce bacterial colonization across a wide range of pathogens in preclinical testing.

Infections linked to pacemaker implantation present a significant medical challenge, impacting patient outcomes and escalating healthcare costs. On average, CIED infections elevate in-hospital mortality risk more than two-fold and add over $50,000 in healthcare expenses per event.

“We believe the clearance of CanGarooRM will be a transformational event for Elutia and allow patients to thrive without compromise,” said Dr. Randy Mills, President and CEO of Elutia. “The regenerative properties from our proprietary biologic matrix combined with the therapeutic effects of antibiotics create what we believe will be the best-in-class envelope in the established CIED market. Longer-term we plan to leverage this platform by developing products for adjacent markets with similar unmet needs, such as neurostimulation, wound care, and breast reconstruction.”

About Elutia

Elutia develops and commercializes biologic 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 expectations for our drug-eluting biomatrix technology aimed at improving surgical outcomes and the outcome of our FDA 510(k) submission for our CanGarooRM product. Forward-looking statements are based on management’s current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance, and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, and other important factors that may cause actual results, performance or achievements to differ materially from those contemplated or implied in this press release, including, but not limited to: risks associated with shifting focus to our drug-eluting biomatrix solutions in the cardiovascular and breast reconstruction areas and away from our now-divested Orthobiologics business; risks regarding the ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra; our inability to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; our ability to continue as a going concern; our ability to successfully execute or achieve expected benefits from the divestiture of our Orthobiologics business; our products and our ability to enhance, expand, develop and commercialize our product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; consequences of our recall of a single lot of one of our viable bone matrix products and market withdrawal of all of our viable bone matrix products; our dependence on our commercial partners; the impact of the bankruptcy of Surgalign Holdings, Inc., a significant customer of the Company, on our future revenues; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; the ability to obtain regulatory approval or other marketing authorizations; the possibility of adverse determinations in our FDA 510(k) submission process; future revenues of the disposed-of Orthobiologics business and its impact on “earn out” provisions in the related acquisition agreement; the possibility that our stock will be delisted from the Nasdaq Capital Market; 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, 2022, 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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