

Nucleix Advances Early Lung Cancer Detection Program with Promising Performance Data and Appointment of Chief Scientific Officer

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Data presented at the American College of Chest Physicians (CHEST) 2023 Annual Meeting reveals high sensitivity of Lung EpiCheck® for the detection of stage I non-small cell lung cancer (NSCLC) in current and former smokers

New chief scientific officer to lead further development of Lung EpiCheck through ongoing clinical research

SAN DIEGO & REHOVOT, Israel--(BUSINESS WIRE)-- **Nucleix**, a liquid biopsy company revolutionizing cancer treatment by detecting the disease earlier, today announced recent updates in its lung cancer detection program for early-stage disease. At the American College of Chest Physicians (CHEST) 2023 Annual Meeting yesterday, Dr. Peter Mazzone, M.D., MPH, Director of the Lung Cancer Program and Lung Cancer Screening Program for the Respiratory Institute at the Cleveland Clinic and co-principal investigator of the Sightline study, presented initial performance data from the **Sightline study**, a prospective multi-center, case-control study evaluating the performance of Lung EpiCheck®. Additionally, the company strengthened its leadership team with the appointment of Mathias Ehrich, M.D., as its chief scientific officer.

Data Presented at CHEST

Earlier this year, the company announced that the Nucleix EpiCheck® Lung Atlas, which utilizes next-generation sequencing (NGS) and is focused on stage I disease, had identified many promising, novel biomarkers for the early detection of lung cancer. Dr. Mazzone's presentation, "**Enhanced detection of early-stage lung cancer with an ultrasensitive plasma-based methylation assay**," outlined initial performance data of the company's Lung EpiCheck polymerase chain reaction (PCR) assay, which includes novel biomarkers discovered as part of the

development of the Nucleix EpiCheck Lung Atlas.

In an initial evaluation of clinical performance, the Lung EpiCheck PCR assay demonstrated an AUC between 0.841 – 0.871; stage I non-small cell lung cancer (NSCLC) sensitivity ranged between 87.1% - 87.2%; and overall sensitivity ranged between 89.9% - 91.6%. These data were based on an analysis of 813 subjects (188 cases and 625 controls) at high-risk of lung cancer. Tumor characteristics in these subjects were similar to the screening arm of the National Lung Screening Trial, with 60% early-stage (stage I & II) NSCLC and 65% of stage I tumors smaller than 20mm.

“Over the past few months, we’ve made incredible progress on our lung cancer program, having recently premiered data on the Nucleix EpiCheck Lung Atlas and enrolled more than 4,000 patients in the Sightline study,” said Chris Hibberd, chief executive officer of Nucleix. “We are encouraged by this data readout presented at CHEST, as it further demonstrates the discovery capabilities of the Nucleix EpiCheck Lung Atlas and the potential of Lung EpiCheck as a non-invasive test to aid in the detection of early-stage lung cancer in people at high risk for lung cancer.”

“The five-year survival rates for lung cancer are up to 10 times greater when detected early,ⁱ but unfortunately, most patients are still diagnosed in later stages of the disease,” said Dr. Mazzone. “The Sightline investigators are very excited with the results demonstrating that a tool like Lung EpiCheck could have a major impact on lung cancer screening, as it offers a simple and non-invasive solution to catch the disease at stage I or II when patients have much higher chances to be cured.”

Key Executive Appointed

Mathias Ehrich, M.D., joins Nucleix with more than two decades of medical and scientific experience. Previously the co-founder, chief scientific officer and chief medical officer of Juno Diagnostics, Dr. Ehrich brings significant expertise in diagnostics and product development using NGS-based screening tools. Prior to Juno Diagnostics, Dr. Ehrich led the innovation and advancement of the world's first NGS-based, cell-free DNA test for non-invasive prenatal screening. At Nucleix, Dr. Ehrich will lead and oversee R&D, product development, clinical development, and strategic research for the company's lung cancer detection program for early-stage disease.

“I was impressed by the data the company presented on the Nucleix EpiCheck Lung Atlas earlier this year, the potential of its Lung EpiCheck assay and the company's differentiated approach for the discovery and identification of novel biomarkers for non-invasive lung cancer screening,” said Dr. Ehrich. “I am honored to join the team and look forward to further advancing this program to detect lung cancer earlier when treatment can be more effective for patients.”

About Nucleix

Nucleix is a liquid biopsy company revolutionizing cancer treatment with earlier disease detection at a time when intervention can bring the greatest impact for patients. Leveraging NGS-based and PCR-based technology to identify methylation changes, the Company's pioneering testing approach uses methylation-based identification for early-stage and recurring cancer detection. The Company's non-invasive EpiCheck® delivers highly accurate and sensitive results, all while providing a seamless testing option for physicians, patients, and the healthcare system. The Company is building an EpiCheck franchise, beginning with the Bladder EpiCheck® kit, CE-marked and available in Europe for primary and recurrent bladder cancer and upper tract urinary cancer, and FDA 510(k) cleared for bladder cancer recurrence in the United States. The Company is advancing its Lung EpiCheck® test towards commercialization for high-risk individuals, while evaluating additional tests for other high-risk diseases. For more information, please visit: <https://www.nucleix.com>.

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i American Lung Association. Lung Cancer Fact Sheet. 2020; <https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library/lung-cancer-fact-sheet>

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