



Nucleix's Bladder EpiCheck[®] Receives FDA 510(k) Clearance for Monitoring of Non-Muscle Invasive Bladder Cancer (NMIBC) Recurrence

Bladder EpiCheck is the first urine biomarker methylation test of its kind to be FDA cleared for NMIBC surveillance

SAN DIEGO and REHOVOT, ISRAEL – May 4, 2023 – Nucleix, a liquid biopsy company revolutionizing cancer treatment by detecting the disease earlier, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market Bladder EpiCheck[®] for use as a non-invasive method for surveillance of tumor recurrence in patients previously diagnosed with non-muscle invasive bladder cancer (NMIBC), in conjunction with cystoscopy.

Bladder EpiCheck is a highly sensitive and specific test that analyzes subtle disease-specific changes across 15 methylation markers that are associated with bladder cancer. The test is commercially available in Europe and is the first of its kind methylation-based urine test performed on a qPCR platform to be cleared by the FDA.

In the United States, bladder cancer is the sixth most common cancer.¹ There are approximately 700,000 people affected by bladder cancer living in the United States, with the vast majority of them categorized as NMIBC patients.^{1,2} In addition, more than 80,000 new cases of bladder cancer are detected annually.² While NMIBC can be treated with both surgical and therapeutic methods, it is characterized by a very high rate of recurrence (up to 70% over a five-year period).² As a result, it requires frequent surveillance in order to promptly detect high-grade recurrence and treat it before it progresses and becomes life threatening. The standard of care involves frequent and invasive cystoscopies that patients endure up to four times a year for at least five years and, in some cases, for the remainder of their life.

“Because surveillance of NMIBC remains one of the most invasive and lengthy processes to manage for patients across the oncology landscape, an objective, sensitive and specific urine-based test like Bladder EpiCheck is an important new tool that physicians can leverage, in conjunction with the current standard of care,” said Aharona Shuali, M.D., Vice President of Medical Affairs at Nucleix.

“We are pleased with the FDA’s decision to grant Bladder EpiCheck 510(k) clearance, allowing the test to be commercialized in the United States,” said Eli Frydman, Ph.D., President at Nucleix. “With this clearance, we look forward to offering physicians and their patients in the United States access to our reliable, objective and non-invasive bladder cancer test that can be performed at any licensed central or local labs, thus providing healthcare professionals the flexibility to run the test where it is needed. This clearance further validates Nucleix’s EpiCheck-based technology and our ability to provide physicians non-invasive diagnostic tools to enhance patient care.”

Nucleix is evaluating strategic partnerships and other market access activities for the commercial launch of Bladder EpiCheck in the United States.

About Bladder EpiCheck®

[Bladder EpiCheck®](#) provides physicians and their patients with a simple, objective urine test for recurrent bladder cancer. The test analyzes subtle disease-specific changes in DNA methylation markers, with high sensitivity and specificity. Bladder EpiCheck® is intended for use as a non-invasive method for detection of NMIBC recurrence in conjunction with standard of care methods. Bladder EpiCheck® is CE-marked, and FDA 510(k) cleared, and commercially available in Europe and soon in the United States.

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>.

###

Contacts for inquiries or additional information:

Jake Robison

Evoke Canale

(619) 849-5383

jake.robison@evokegroup.com

¹*Cancer of the urinary bladder - cancer stat facts*. National Cancer Institute Surveillance, Epidemiology, and End Results Program. (n.d.). Retrieved February 15, 2023, from <https://seer.cancer.gov/statfacts/html/urinb.html>

²Chang, S. *et al.* Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline. *The Journal of Urology*. DIO: 10.1016/j.juro.2016.06.049