Early detection tools promise to reduce the financial burden of lung and colorectal cancer

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A team of researchers at Israeli SME Nucleix have set for themselves the objective of reducing the financial burden of lung and colorectoral cancers—two of the cancer types with the highest occurrence in Europe. They are planning to bring new, non-invasive and more accurate diagnostic tools to market.

Proof of the disastrous impact of lung and colorectal cancers on citizens' health is no longer needed. With a total yearly mortality rate in the EU of around 265 000 people, lung cancer is the deadliest cancer in the EU. Colorectal cancer, on the other hand, has one of the highest annual incidence rates in the EU at around 342 000. In both cases, early detection can have a tremendous impact on the success of treatment, which is why new tools are desperately needed.

Building on the early successes of its Bladder EpiCheck product—which eases the detection of bladder cancer recurrence after treatment—in clinical trials, Nucleix is now working on Lung EpiCheck and Colon EpiCheck products focusing on early detection among populations at risk. The new tests will be based on bodily fluids (urine and blood), making them far less invasive than existing practices—colonoscopy for colorectal cancer or cystoscopy for bladder cancer.

Arnon Horev, director of product marketing at Nucleix, discusses the successes of the company's bladder cancer detection tool so far, along

with its future plans now that EU support has been granted to the EPICHECK (Detection of Various Cancer Types for Screening and Diagnosis through Blood Samples with Epigenetic Biomarkers Panels) project under the Horizon 2020 SME Instrument.

What is EpiCheck and what's its added value compared to alternatives?

EpiCheck is a family of tests for the diagnosis, early detection and monitoring of cancer. Under this brand, Nucleix has developed Bladder EpiCheck—a urine test aimed at monitoring bladder cancer patients which is planned to be launched in 2016. Moreover, we are in the process of developing two additional tests—Lung EpiCheck for the detection of lung cancer in blood samples, and Colon EpiCheck for the detection of colorectal cancer in blood samples.

The EpiCheck family of tests is based on the identification of methylation changes that can be observed between DNA originating from tumours and DNA originating from healthy tissues. Nucleix has developed a platform that comprises a bioinformatics tool, a biochemical platform and software algorithms for the development of proprietary markers tailored to each application. Our products rely on proprietary markers that are applied to the tested substance and analysed with our software, resulting in diagnostics.

When compared to current practices, EpiCheck stands out with: its high sensitivity and specificity; the fact that it is non-invasive; its use of methylation markers to identify tissues and differentiate healthy ones from cancerous ones; as well as multiplexing—a technology that enables us to combine many markers—to increase sensitivity and specificity. Last but not least, our tests are repeatable and independent of the user thanks to our proprietary software tool, whereas many of the current

tests depend on the proficiency of the technician.

What can you tell us about the biomarkers you developed?

Our biomarkers are developed using two tools: a bioinformatics tool enabling rapid and systematic development of biomarker panels for a wide range of clinical tasks; and a proprietary biochemical tool for a simple, low-cost clinical assay which provides us with the ability to detect rare methylation change events.

The biomarker development process includes the use of these two tools in a reiterative process, so as to identify the best combination of biomarkers that will complement each other in order to cover more segments of the population.

It should be emphasized that all of the markers we use were developed and are owned by Nucleix.

What about tests in a clinical environment?

Bladder EpiCheck, which is based on a panel of 15 non-overlapping methylation markers at loci that were identified, developed and are owned by the company, has already undergone a successful clinical trial and will be launched in 2016 in the EU (subjected to EU regulatory approval).

It was tested on a cohort of 221 bladder cancer patients who were coming for recurrence monitoring tests after treatment, and compared to the gold standard of bladder cancer detection—cystoscopy and pathology. The result of this test shows a 90 % sensitivity, an 83 % specificity and a 97 % 'Negative predictive value' (NPV).

What are the markets you target with this product?

We will first be targeting EU markets because of its patient-oriented healthcare environment, followed by the US and other leading markets (after having obtained the certifications required such as CE and FDA).

What have you learned from the feasibility study so far?

The feasibility study is not complete yet, but it has given us great insights and optimal methods of operation in terms of the systemic approaches for screening programmes in large populations, including geographic focus, reimbursement strategy and test automation.

Do you still expect your product to reach the market in Q2?

Our first product for bladder cancer monitoring (Bladder EpiCheck) is indeed expected to reach the European market towards the end of Q2 or the early part of Q3 2016, subject to EU regulatory approval.

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