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Inoviq expands collaboration with UQ to develop exosome-based ovarian cancer screening test

By Tamra Sami, Staff Writer

Inoviq Ltd. and The University of Queensland (UQ) are expanding a collaboration to develop an exosome-based ovarian cancer screening test.

Researchers from UQ identified and validated exosomal protein and micro-RNA (miRNA) biomarkers that when combined in its OCRF-7 algorithm showed more than 90% accuracy to detect stages I and II ovarian cancer in an independent 500-sample retrospective case-control study, Inoviq CEO Leearne Hinch told *BioWorld*.

"That's pretty superb because current tests available such as CA125, which is an FDA-approved test for monitoring ovarian cancer, only detects early ovarian cancer at about 50% sensitivity."

Inoviq's Chief Scientific Officer Greg Rice previously worked at UQ and set up the laboratory to look at exosomes. The initial work that was completed at UQ was under his watch, and this current project will validate that test, he said.

"The initial work enabled us to build the algorithm, which has seven biomarkers in it, some proteins and some mRNA markers," he said. "The work the company is now doing is to look for further informative biomarkers that would further improve the performance of the algorithm, so we'll either add additional biomarkers or substitute biomarkers in that particular panel to try and increase further the performance of the test."

"The ultimate goal is to be able to identify women who are out there in the community who have ovarian cancer but don't know it, and this is what's really missing," he said.

"We already have breast screening in the community, and this would serve the same function and provide women with timely information about their health."

Combining Exo-net with UQ algorithm

Inoviq's Exo-net technology captures exosomes from the blood to enable development of multiomic diagnostic tests that combine multiple biomarkers in an algorithm for the earlier and more accurate detection of various diseases such as cancer, inflammatory, metabolic and neurodegenerative diseases.

Inoviq and UQ have now expanded their collaboration to further evaluate Exo-net and, if successful, UQ will use Inoviq's Exo-net technology to develop its UQ OCRF-7 ovarian cancer test.

Inoviq has the exclusive option to license rights to develop and commercialize UQ's exosome-based early detection test for ovarian cancer.

"The combination of Inoviq's Exo-net technology to capture exosomes and UQ's novel exosomal biomarkers is expected to allow significantly improved earlier and more accurate detection of ovarian cancer," Hinch said.

She stressed the importance of being able to "pick up all stages of ovarian cancer," noting that there are no tests available for asymptomatic women. Most women present at the clinic with symptoms, which means the cancer has already metastasized and results in a poor survival rate.

Ovarian cancer is the world's deadliest gynecological cancer, the eighth most common cancer and eighth leading cause of cancer-related deaths in women worldwide, according to the American Cancer Society. Globally, there were more than 314,000 new cases and 207,000 deaths in 2020. The lifetime risk of ovarian cancer for an average-risk woman is estimated at 1.2% and this increases to 35% to 70% in high-risk women with BRCA1 mutations.

Ovarian cancer is often diagnosed at a late stage after symptoms have appeared, resulting in a poor five-year survival rate of only 49%. Diagnosis is usually made using a combination of transvaginal ultrasound and a CA125 blood test that is often followed by advanced imaging and confirmed by tissue biopsy.

The global ovarian cancer diagnostics market is expected to reach $1.9 billion by 2026, according to U.S.-based Grand View Research.

The University of Queensland was awarded an AU$2.7 million (US$1.9 million) grant under the government's Medical Research

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Future Fund to develop an exosome-based blood test for earlier detection of ovarian cancer.

The project has multiple phases including multiomic biomarker isolation and analysis, assay and algorithm development for a multivariate index assay (MIA), analytical validation and clinical validation of the test for earlier detection of ovarian cancer.

The clinical validation study will use Inoviq's Exo-net to isolate exosomes from thousands of blood samples collected from the world's largest ovarian cancer screening trial, the U.K. Collaborative Trial of Ovarian Cancer Screening.

Exo-net is currently on the market as a research-only product; it is designed to allow researchers to capture exosomes. It has advantages over current tests in that it can isolate exosomes within 15 minutes compared to the gold standard of differential segregation and density gradient desegregation that can take up to 12 to 18 hours to get a preparation of exosomes, Rice said.

"The other advantage is we can specifically target the type of exosome that people wish to study, so we can actually tune the product to capture exosomes that are released from the placenta or the brain or cancer cells.

"Exosomes tell us about the status of the cell that then allows us to identify the onset of these types of diseases much earlier and intervene to improve the outcome for patients."

"The major limitation of translating exosome-based research into actual clinical applications and routine pathology tests has been scalability and being able to get it onto platforms that are currently available in pathology laboratories."

The Exo-net product is fully automated and can be placed on a robot to extract exosomes from a particular bio fluid and have the whole process done as a batch in a short period, he said, overcoming some of the major hurdles in taking research discoveries being made around exosomes and their applications as biomarkers into clinical-based tests or IVDs.

Headquartered in Melbourne, Inoviq calls itself a diagnostic and exosomes-focused company.

It has a U.S.-based exosome research facility in Minnesota, and it conducts its development work in Australia. The company has about 20 staff. The company has enough cash for the next two years, Hinch said.

Inoviq was previously known as BARD1 Lifesciences. The company acquired Sienna Cancer Diagnostics in 2020 for AU$23 million, and it rebranded itself as Inoviq, which stands for "intelligent innovation" to reflect its broader capability.

Inoviq's hTERT test that it acquired with Sienna is marketed as an adjunct to urine cytology testing for bladder cancer and the Exo-net pan-exosome capture tool for research purposes. The company's cancer diagnostic pipeline includes blood tests for earlier detection and monitoring of ovarian, breast, prostate and other cancers.

Inoviq listed on the Australian Securities Exchange in June 2016. Its shares on the ASX were trading at AU67 cents on market close April 22.