Exosomal Cancer Diagnostic

There is a significant unmet clinical need to identify cancer patients at an early stage and develop novel therapies to reduce cancer mortality. Early detection of cancers is essential, as most localized cancers can be cured with surgery alone, but survival is greatly enhanced with a diagnosis at an early stage.

Small extracellular vesicles, termed exosomes, are small membrane bound vesicles (30-150 nm in diameter) that are released by all cells, including cancer cells. The protein content of exosomes is dependent on the cell-of-origin and it is now emerging that exosomes represent a viable source of material for diagnostic and prognostic purposes.

The prognostic value of exosome-based analysis has already been demonstrated by the QIMR Berghofer team. The PCT application AU/2017051298 (Determining a Cancer Prognosis), now in National Phase, has shown expression levels of one or more exosomal proteins function as prognostic markers of cancer progression in a subject, eg NSCLC. This is currently the subject of commercial interest as the worldwide market is estimated at some $2,000 Million US dollars by 2022.

Technology Brief

We have discovered, and developed:

- a blood-based (also utilizable via other biological material eg saliva, urine etc.), multi-protein exosomal biomarker assay.
- an assay capable of identifying cancer, at an early stage, in an individual, and to
determine, to some extent, the cancer type as well
- a prognostic indicator for the value of potential cancer treatments
- potential therapeutic targets

We have applied the assay to cohorts of a number of cancer types, specifically, NSCLC, Glioblastoma multiforme, Colorectal Cancer, Breast Cancer, Prostate Cancer, Melanoma, Ovarian Cancer, Gastric Cancer and Oesophageal Cancer. Other cancers, eg Pancreatic Cancer, will be examined by the assay when suitable cohorts are compiled.

Using a combination of the signature proteins, we were able to generate an excellent separation of healthy individuals and cancer patients, with an area under the curve (AUC) of 0.96.

Importantly, at a fixed specificity of 95%, the median sensitivity of the diagnostic exosome signature in the 8 cancer types was 77.6% (at 95% CI). We were able to evaluate the sensitivity of the exosome biomarker in stage I compared to stage II-IV in NSCLC, esophageal, and gastric cancer. Importantly, with the sensitivity at 95%, specificity was comparable to later stages in all 3 cancers, demonstrating that the diagnostic exosome signature is capable of identifying early-stage cancer patients, possibly prior to the spread of metastases.
Proposal

Associate Professor Möller and his team have developed a potentially superior assay that has immense potential within the market. It is currently undergoing further validation against a much larger cohort and has been successfully translated into a high throughput diagnostic platform.

QIMR Berghofer is looking to enter into a collaborative relationship, +/- a licensing agreement, in order to progress this project to market and provide a new, exciting tool for the diagnosis and treatment of cancer.

Intellectual property

An Australian Provisional Patent was filed on the technology with a priority date of 24 October 2019. Additionally there is a PCT Application AU/2017051298 – Determining a Cancer Prognosis, now in National Phase.

Lead Researcher

Associate Professor Andreas Möller is Group Leader of the Tumour Microenvironment Laboratory at QIMR Berghofer, and is an internationally recognized leader in cancer metastasis research and biomarker development based on extracellular vesicles.

Since the inception of his group in 2012, Dr Möller has authored 54 articles in leading journals, including Journal of Extracellular Vesicles (IF:11.0), Cancer Research, Oncogene, Nature Medicine and Nature Communications. His seminal exosome isolation protocol (cited >450 times since 2015) is seen as gold standard and Dr Möller is inventor on patents on the use of extracellular vesicles as biomarkers for cancer.

With more than 900 scientists, students and support staff, QIMR Berghofer is one of Australia’s largest and most successful independent medical research institutes. The QIMR Berghofer Business Development Team manages over 160 patent families, offering a wealth of collaborative and commercial opportunities for industry and government. We have a strong track record of partnering with leading pharmaceutical and biotech companies to further develop early-stage technologies, generating over $21 million in annual commercial revenue in the last financial year. In addition to licensing and partnering outcomes, we facilitate contract research and consulting projects for industry clients. Our team includes specialists in commercialisation, IP protection, patent law, clinical trial and project management and industry-backed grant opportunities.