PROJECT TITLE

A phase II single-arm, open-label trial of Kadcyla And Neratinib for Her2+ Breast Cancer with Molecular Residual Disease (KAN-HER2-MRD)

PRINCIPAL INVESTIGATOR

Dr. David Cescon – University Health Network

SCIENTIFIC SUMMARY

HER2+ breast cancer is an aggressive subtype, for which very effective therapies have been developed over the last two decades, dramatically improving outcomes. However, metastatic disease remains incurable, and continued efforts to prevent recurrence in people at high risk are necessary. New drugs have been shown to be effective at treating (but not curing) patients with metastatic (Stage 4) disease. Using optimal therapies earlier, before a patient's disease recurs, may provide a cure; but because of the high cost and extreme toxicity of treatment, these interventions are used only for those who might benefit. New technologies can detect minute quantities of DNA from tumour cells in the blood with a liquid biopsy. By detecting these markers of impending recurrence, patients may be identified for treatment intensification and the effects of treatment may be directly measured by repeated non-invasive blood testing. In this clinical trial, the team will identify patients with early-stage HER2+ breast cancer who have evidence of residual disease and measure the effect of adding an additional, proven anti-HER2+ targeted agent to their treatment regimen. This work will provide key insights into the potential utility of these powerful new diagnostic technologies and targeted therapies to guide the most precisely-delivered treatment for high risk HER2+ breast cancer, and inform the future development of a treatment to identify and eliminate lethal metastatic recurrence for patients with potentially curable breast cancer.