Professor Mohamed El-Tanani
Anniversary Professor of Molecular Pathology and Cancer Therapeutics.
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Background

The annual incidence of breast cancer (BC) in the UK is 50,000 and around 1,000 die from BC every month. 5/100 BC patients have metastasis when first diagnosed, and a further 35/100 will develop metastasis within 10 years, representing considerable disease burden. The challenge is predicting metastatic disease early enough to improve patient outcomes. Currently, there are no reliable tests to predict whether early BC will spread. We have demonstrated, in a retrospective study, a correlation between the novel biomarker Ran protein and metastasis in BC patients. We have exclusive rights to the exploitation of Ran in all markets. This project will deliver a unique and affordable Q-ELISA blood test based on isolation of Ran exosomes to enable BC metastatic risk to be predicted and patients to be stratified into low- and high-risk groups. Clinicians can then plan, at an early stage, a cost effective stratified therapeutic approach that will improve quality of life. As a liquid biopsy the test can also be used to monitor the risk of metastasis in BC patients' post-surgery or chemotherapy. The total market value for the test is estimated at £51.3 million in the UK alone and globally approximately £500million.

Metastases at distant sites are the main cause of death in breast cancer (BC) patients, globally this represents a considerable disease burden. Although metastatic BC cannot be cured this does not mean it cannot be treated. Treatment of metastatic BC focuses on length and quality of life. Knowledge that a patient may be at high or low risk of developing metastasis will be of vital importance to both patient and clinician. For example, if the cancer is hormone receptor (ER) positive, the first treatment is hormone therapy. If the cancer is HER-2-positive, anti-HER2 drugs such as trastuzumab (Herceptin) may be given. Chemotherapy and radiation therapy can also be used to shrink or slow the growth of tumours or to ease symptoms of the cancer itself. Survival rates for metastatic breast cancer vary greatly from person to person. One study found that about 37% of women lived at least 3 years after diagnosis, but some women may live 10 or more years beyond diagnosis. Currently, it is not possible to reliably predict whether early BC will spread.

Significance of the finding

The ultimate aim of this project is to improve survival rates in BC. Communicating our results to the public will support this aim as it will help raise awareness of TNBC, and the increased risk in premenopausal women from African, Indian and Pakistani backgrounds. We would use the Research Enrichment – Public Engagement and/or Diversity and Inclusion scheme to support public engagement events to discuss our research in the West Yorkshire area, where a high proportion of the population are of British Asian/Pakistani descent, with a tendency to later cancer diagnosis.

The Market Opportunity

We are targeting the global cancer lipid biopsy market, a fast-growing segment with a 5 year CAGR of 36.2%, which was $414.5 million in 2015 and should reach $1.9 billion by 2020. (BCC Research Liquid Biopsy Research, Tools, Services and Diagnostics: Global Markets Oct 2017). There are 50,000 new BC cases per year in the UK with 5% diagnosed as metastatic (http://www.cancerresearchuk.org) leaving 95% of diagnosed patients as potential users of Ran DX. We have estimated a total UK market value over 5 years of £51.3 million (see below).

Route to Market

Target customers will be recently diagnosed BC patients and their oncologists either in the NHS or private clinics concerned about the risks of metastasis and prescribing or receiving the optimum treatment at an early stage. Ran DX will give the patient and clinician important information regarding their risk of metastasis and alongside other information will allow the clinician to prescribe the most appropriate treatment after surgery. Customers will be attracted to this affordable test as being a liquid and not a tumour biopsy it can also be used to monitor patients' risk of metastasis after surgery and during chemotherapy.

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Using a wholesale price of £75 per test in the UK we estimate a total market value over 5yr of £51.3 million and a market share starting at 2% (or 1000 patients) as we would expect a significant demand from BC patients and oncologists if the test is clinically proven to be an accurate predictor of metastasis with no other competitive product on the market at such an affordable price which requires only a simple blood test. We expect our market share to increase to 20% after 5yr giving revenues in the UK alone of £6.85 million over a 5yr period and an estimated gross profit of £1.4 million.

The route to market will involve collaboration of UoB with IDT Ltd a manufacturer and distributor of diagnostic products.

Key Players in the Market and Differentiation from the Competition
Genomic tests like Oncotype DX are expensive (£2,500) and can only be used for certain sub-types of BC representing about 30-70% of BC patients, the Ran test covers all types. It is focused on predicting recurrence and not metastasis and unlike the Ran test does not allow for monitoring of the patient after surgery or during and after chemotherapy. The Oncotype test works well for patients with high or low scores but those (40%) with median scores it offers little guidance. The Ran test will have a defined cut off, above this we recommend aggressive treatment including chemotherapy and below we recommend regular monitoring

Position to develop a Commercial proposition
UoB in collaboration with IDT have a strong IP position to commercialise a Ran Dx diagnostic test as well as a strong technical and commercial team. A recent successful Innovate UK grant application will result in a project between UoB and IDT Ltd focused on the development of a Ran Dx test for the predictive risk of metastasis in TNBC patients. The outcomes of the retrospective study and test development will establish a strong body of evidence to progress the commercialisation of Ran dx to prospective studies and validation of the test in anticipation of market entry and MHRA approval.