

20 Medical centres across 8 US states set to offer Breast Cancer Test

Molecular diagnostics company Genetic Technologies Limited (ASX: GTG, NASDAQ: GENE) is pleased to advise that its third generation breast cancer test (GeneType for Breast Cancer) is on track for commercial release in the United States (US) in Q1 2020.

Genetic Technologies expects to take advantage of the growing confidence and interest in genomic testing, and its first to market status in the US market. GeneType for breast cancer (BC) is on track for release in the US in Q1 (2020) via a soft launch across 20 centres in 8 States, which demonstrates the strong support from practitioners for the introduction of the company's third generation test incorporating mammography data. The Company anticipates a full launch in Q2 (2020).

CLIA Accreditation across 50 States

Following a successful CLIA audit in December 2019, the Company now has continuing CLIA certification for its laboratory developed tests in all 50 States in the US, and also maintains licenses in all individual States that require supplemental accreditation including New York. In addition, the company's current 35,000 test laboratory capacity has the ability to be scaled up in line with demand.

Validation

There is now significant maturity in industry acceptance of polygenic risk scores as a tool for measuring the risk of cancer and other common complex diseases. Over 300 papers have been published in the past 12 months - up from 1 in 2012, being GTG's original paper which stemmed from its involvement in the human genome project.

BC polygenic risk was originally identified in Genome Wide Association studies (GWAS) comparing hundreds of thousands of BC cases to controls (no BC). This work has since then been cross validated in numerous international consortia consisting of tens of thousands additional women (case/controls cohorts).

Only 1 in 500 women carry a BRCA mutation, representing 0.2% of the population. GeneType for BC will help classify the other 99.8% of women into risk categories. Women identified as high risk will, together with their practitioners, now have the opportunity to choose supplemental screening and prevention options to meet their breast health needs.

The company's test is uniquely placed to accurately predict BC risk, with the ability to identify low (1/5 of average risk) as well as high (5 x average risk) risk patients from the age of 35.

Furthermore, the addition of mammography data to the GeneType for BC test enables the ability to better stratify women with dense breast tissue. Dense breast tissue presents unique challenges due to the increased risk of BC and poor visualisation of breast tissue abnormalities, a phenomenon known as masking.

The use of the cheek swab and a significant uptake across millions of genetic ancestry users has resulted in a massive increase in interest in Genomics, and in Health Genomics to achieve affective personal medical outcomes.

2019 represented a tipping point

2019 represented a tipping point for the Genomics industry, with the call from KOLs and industry leaders for the introduction of Polygenic Risk Score (PRS) into clinic guidelines. Terms such as “powerful, accurate, better outcomes, lower mortality, better use of medical resources” are a mantra that has never before been stated so boldly or so often.

GeneType for BC is well positioned to take advantage of this change, and provides a best in class genomic solution for the identification of BC risk, as well as better stratification of risk in the nearly 50% of women who have heterogeneous or extremely dense breast tissue. With the recent US federal mandate surrounding breast density notification, GeneType for BC is positioned to support clinicians in managing patient risk of developing BC in the context of dense breast tissue.

The company anticipates strong interest in its test which has been discovered and cross-validated in GWA studies and large consortia cohorts, respectively. This data includes hundreds of thousands of women, with and without breast cancer, underscoring the significance of polygenic risk in the risk stratification of sporadic breast cancer.

Cost effective and affordable

BC continues to strike at an alarming rate, with 268,000 new invasive and 62,000 non-invasive BC cases projected to be diagnosed in women in the US in 2019. GeneType for BC is able to create a cost-effective solution to better identify at-risk women that are currently being overlooked in the general population.

Genotype for BC will be available at US\$249 per test, and the reduction in the cost (from US\$3000 per test in 2011) and the addition of mammography data is expected to remove a major hurdle in the adoption and management of risk and BC for women.

The company's relationship with TGen (The Translational Genomics Research Institute) in the US is progressing very well, with the first studies around the best way to implement, reimburse and distribute GeneType for BC due to commence in Q1 2020. TGen is a trusted independent biomedical institute which is tasked with the implementation of new Genomic discoveries into the clinic. Successful studies are expected to result in new commercial opportunities with major US health networks.

The Company plans to present its latest technology and world leading tests at the 2020 JP Morgan Healthcare Conference in January 2020, and will be actively looking to establish distribution channels to support its market entry strategy into the US market.

Dr George Muchnicki
Acting CEO and Justyn Stedwell Company Secretary
On behalf of the Board of Directors
Genetic Technologies Limited
7 January 2020

About Genetic Technologies Limited:

Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE) is a diversified molecular diagnostics company. GTG offers cancer predictive testing and assessment tools to help physicians proactively manage patient health. The Company's lead products GeneType for Breast Cancer for non-hereditary breast cancer and GeneType for Colorectal Cancer are clinically validated risk assessment tests and are first in class. Genetic Technologies is developing a pipeline of risk assessment products. For more information, please visit www.gtglabs.com