ASX Market Announcement

Supplementary Announcement - Comprehensive Risk Test for Breast & Ovarian Cancer

Melbourne, Australia, 6 February 2023: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG") a global leader in genomics-based tests in health, wellness and serious disease, provides further information at the request of the ASX in regards to the announcement released 3 February 2023.

The development of this test is in direct response and feedback from the payer conversations such as insurance providers, employers, and healthcare providers. There is an unmet need to develop a unique single saliva risk assessment test that combines gene mutation for breast and ovarian cancers, hereditary and sporadic indicators and other relevant clinical risk factors. There is no other single test on the market that provides this array of information from a single test. The company has multiple patents granted[1] and pending that support the combination of genetic and clinical risk factors.

The combination of general population ovarian risk assessment and breast cancer risk assessment in a single risk test that both incorporate disease-specific polygenic risk components for low penetrant risk alleles and clinical risk factors are the novel combination. It is very common to have the two diseases paired[2,3] in the high penetrant breast and ovarian susceptibility genetic testing environment as some of the genes, like BRCA1 and BRCA2 confer risk for both cancer types. But the fact is that the majority of women tested for these high penetrant breast and ovarian susceptibility genes come back with negative results, meaning[4,5] they do not carry a mutation (aka pathogenic variant). Even more so, the general population prevalence, or the chance of a woman carrying a cancer susceptibility mutation for breast or ovarian cancer, is extremely low (less than 0.5% of women[1]). But far more women end up developing cancer (12% of women develop breast and 1.3% develop ovarian cancer in their lifetime). We know cancer isn't just caused by "faulty genetics." This comprehensive breast and ovarian cancer risk assessment marries a standard HBOC genetic test with the geneType risk score[6,7] for both diseases. The former will benefit ~0.5% of users who get a positive result, and the remaining 99.5% of women who obtain a negative result will now have more insight to their absolute risk of developing each cancer. And if that absolute risk score comes back high, the patient and her doctor will be able to engage in shared decision-making discussions around supplemental screening and risk-reduction options that are available to at-risk women. This test would be utilized as a screening tool to risk stratify the entire general population to identify a subset of women that would not have otherwise been identified. This could lead to the individual and the physician to provide supplemental screening to achieve early detection of the diseases.

The test will be commercialised through the following channels:

- Company's Consumer Initiated Testing Web Platform
- Business to Business relationships including, but not limited to:
    - Insurance providers
    - Employers

[1] Patent No: US 11,072,830, Patent No: US 10,683,549, Patent No: US 10,920,279 Methods for assessing risk of developing breast cancer
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7392772/#s9title
[3] https://pubmed.ncbi.nlm.nih.gov/32347951/
[4] Maxwell KN et al. J Clin Oncol 2016;34:4183–5
[5] https://www.breastcancer.org/facts-statistics
[6] Spaeth E, Dite G, Allman R. Abstract P2-10-06: Validation of abridged breast cancer risk assessment model for the general population. *Cancer Research* 2022; 82: P2-10-06-P12-10-06.
[7] Dite GS, Spaeth E, Murphy NM, Allman R. A combined clinical and genetic model for predicting risk of ovarian cancer. *Eur J Cancer Prev*. 2023;32(1):57-64. doi:10.1097/CEJ.0000000000000771

- Healthcare providers
- Biotech companies developing technology in breast cancer

- Direct sales to Health Care Professionals with our business development team

GTG is in discussions with a range of US payers regarding the adoption of the geneType breast cancer risk assessment test. While no commercial agreements are in place at this time, there are commercial pilot protocols in place with a few U.S. based payer groups. The Company's progress regarding the Company's endeavours in this regard have been previously referred to in the Company's ASX submitted quarterly updates and recent investor presentations. GTG have also engaged Alva10 to assist the Company with its U.S. payer engagement strategy (see 15 June 2022 ASX Release) . Alva10 have introduced GTG to US-based global health service companies that cover up to 22 million lives in the U.S. and have over 180 million customer and patient relationships globally. A further update of the Company's progress was included in the ASX release dated 30 August 2022, as part of our annual results announcement. A principal reason for the development of this test has directly emerged from our discussions with these groups as it was a test they were seeking.

In addition, GTG has a direct sales presence in the US that is promoting the geneType suite of tests directly to Healthcare Professionals (HCPs). A number of these HCPs have commenced using geneType. It is our intention to also offer the Comprehensive Risk test for breast and ovarian cancer through this channel, noting that the channel already exists. Consumer Initiated Testing (CIT) is now available allowing patients to directly request the test (only in the USA) through GTG's website. GTG will be initiating promotion of the Comprehensive Risk test for breast and ovarian cancer through these channels in the coming weeks as part of our commercialisation strategy and the test will be showcased at the BRCA 2023 Symposium in Montreal in late April.

The Test is already clinically validated and proven by over 10 years of research and analysis. Our data has been included in scientific publications, two recent examples are listed below, and is included in granted patents[1]. Regulatory approval is a routine procedure that we put all of our LDT's (Laboratory Developed Test) through before we can launch them under our CLIA certification/NATA accreditation. There are no formal registration requirements for an LDT with the FDA. The test will be performed within a high complexity CLIA certified lab to enable U.S. commercialisation. This is the same process applied to all our GeneType tests. GTG has such a laboratory located in Fitzroy Melbourne with the appropriate "High Complexity" certification. GTG's Fitzroy laboratory currently performs a number of different geneType tests for the US market in this facility under that certification.

Clinical validation of the data has been established through multiple peer reviewed journals including:

Journal of Precision Medicine publication confirms GeneType Risk Test outperforms traditional risk assessments for breast cancer [8](ASX Release: 29 September, 2022)

Genetype for Ovarian Cancer published in prestigious European Journal of Cancer Prevention [9](ASX Release: 9 November, 2022)

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Authorised for release by the board of directors of Genetic Technologies Limited.

[8] https://app.sharelinktechnologies.com/announcement/asx/29aed8bcc5c0e04e382bee06d5b70a4e
[9] https://app.sharelinktechnologies.com/announcement/asx/9885c90de5331e96c4922597351e1edf

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About Genetic Technologies Limited

Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE) is a diversified molecular diagnostics company. A global leader in genomics-based tests in health, wellness and serious disease through its geneType and EasyDNA brands. GTG offers cancer predictive testing and assessment tools to help physicians to improve health outcomes for people around the world. The company has a proprietary risk stratification platform that has been developed over the past decade and integrates clinical and genetic risk to deliver actionable outcomes to physicians and individuals. Leading the world in risk prediction in oncology, cardiovascular and metabolic diseases, Genetic Technologies continues to develop risk assessment products. For more information, please visit www.genetype.com

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