

# ASX Market Announcement

## GTG to Launch World's First Comprehensive Risk Test for Breast & Ovarian Cancer

**Melbourne, Australia, 3 February 2023:** Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG") a global leader in genomics-based tests in health, wellness and serious disease, is pleased to announce the Company will launch a 'World First' Comprehensive Risk Assessment Test which evaluates a women's risk of developing Breast and/or Ovarian Cancer either from a hereditary genetic mutation or from the far more common familial or sporadic cancer. Combined with other clinical risk factors the test provides a comprehensive risk assessment in a simple saliva test.

### Highlights:

- New test integrates the patented and proprietary GeneType platform for both Breast and Ovarian Cancer.
- GTG's unique approach "appends" the detection of the 13 major "actionable" breast and ovarian cancer susceptibility genes to the GeneType test platform.
- Results in a higher classification rate of women at elevated risk of breast and ovarian cancer than traditional clinical tools by assessing breast and ovarian cancer susceptibility from both rare and common genetic variants in addition to other known clinical risk factors associated with the development of both diseases.
- Advances the goal of providing population-based genetic screening for Breast and Ovarian cancer where up to 85% of cancers diagnosed do not have hereditary or family history<sup>1</sup>.
- The new test platform addresses those women over 30 years of age in the general population that are at higher risk of developing breast and/or ovarian cancer, not just from rare genetic mutations.
- The comprehensive risk assessment test will be clinically validated and have appropriate regulatory approval.
- This test will be launched via our Business to Business ('B2B') and Consumer Initiated Testing ('CIT') channels in the United States.
- The Comprehensive Risk Test will be showcased at the BRCA 2023 Symposium in Montreal in early May.

Globally, there are more than 2.26 million cases of Breast Cancer<sup>2</sup> and 313,000 cases of Ovarian Cancer<sup>3</sup> diagnosed annually. In the USA there are 297,790 new cases of invasive breast cancer that are diagnosed annually<sup>4</sup> and 19,880 women diagnosed with ovarian cancer<sup>5</sup>

Currently women are under screened and underdiagnosed for risk of hereditary breast and ovarian cancer syndrome (HBOC) based on their clinical criteria. There is considerable evidence that these criteria do not capture all women who are HBOC carriers. One recent general population screen among more than 6,000 women found that of 38 HBOC carriers identified nearly half would not have qualified for HBOC testing based on clinical criteria and their elevated risk of cancer would not have been identified.

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<sup>1</sup> <https://www.breastcancer.org/facts-statistics>

<sup>2</sup> <https://www.wcrf.org/cancer-trends/breast-cancer-statistics/>

<sup>3</sup> <https://www.wcrf.org/cancer-trends/ovarian-cancer-statistics/>

<sup>4</sup> <https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html>

<sup>5</sup> <https://www.cancer.net/cancer-types/ovarian-fallopian-tube-and-peritoneal-cancer/statistics>

GTG's comprehensive risk assessment for both cancers inform women of their risk profile and as a result, the opportunity to take proactive actions to increase screening and lessen their risk of developing these diseases. The risk assessment is performed from a single saliva sample and a brief questionnaire.

Implementation of the test as a population-based genetic screening for Breast and Ovarian is supported by GTG's independently developed Budget Impact Model ('BIM') providing a strong health and economic case for payers and insurers in the U.S. Supplemental screening in a subpopulation of women identified as at-risk by geneType can lead to an increase in early-stage, screen-detected cancers, which in turn is associated with high 5-year survival rates 99%<sup>6</sup> and 93%<sup>7</sup> for breast and ovarian, respectively.

GTG's CEO, Simon Morriss, commented "GTG believes this Comprehensive Risk Test for Breast and Ovarian Cancer is one of our most important and significant contributions to the advancement of population-based genetic testing. We are moving beyond rare cancer-susceptibility genetics. We can look for the needle in the haystack, but we are also able to look at the haystack itself. Our non-invasive risk assessment test will address cancer risk at a population health level."

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

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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](http://www.genetype.com)

### Forward Looking Statements

This announcement may contain forward-looking statements about the Company's expectations, beliefs or intentions regarding, among other things, statements regarding the expected use of proceeds. In addition, from time to time, the Company or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or

<sup>6</sup> <https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html>

<sup>7</sup> <https://www.cancer.net/cancer-types/ovarian-fallopian-tube-and-peritoneal-cancer/statistics>

their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by the Company with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of the Company's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. As forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause the Company's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause the Company's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements as detailed in the Company's filings with the Securities and Exchange Commission and in its periodic filings with the ASX in Australia and the risks and risk factors included therein. In addition, the Company operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. The Company does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.