ASX Market Announcement



GeneType Multi-Test Approved for Commercial Release

Melbourne, Australia, 21st **February 2022:** Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG"), a global leader in genomics-based tests in health, wellness and serious disease is delighted to announce that on the 17th February 2022 the Company's laboratory in Fitzroy, Melbourne has received simultaneous NATA accreditation and US Centers for Medicare and Medicaid Services (CMS) CLIA-certification enabling the commercial launch of the geneType Multi-Test in Australia and the USA, respectively.

Highlights:

- Received simultaneous NATA accreditation & CMS certification for Multi-Test in Australia and USA respectively.
- Official first phase availability of Multi-Test to Health Care Professionals (HCPs) will occur week commencing 21st February 2022.
- First phase launch to **cover risk assessment for six serious diseases** including Breast, Colorectal, Prostate, and Ovarian Cancers, Coronary Artery Disease and Type-2 Diabetes covering more than 50% of all serious diseases, all in one test sample.
- Currently over 212,400¹ individuals in Australia and 2.9 million individuals in the United States receive a diagnosis related to one of these six diseases annually.
- Protected by a robust family of patents.

GTG's CEO, Simon Morriss noted "This is a major milestone achievement for GTG and reflects the significant dedication and contribution from our team across both Australia and the USA. Gaining accreditation from NATA and CLIA-certification from CMS enables the Company to commercialise a product that has been years in the making and marks a significant turning point for the Company. There is a substantial market opportunity for this Multi-Test, and we are excited to leverage our expanded sales and marketing platform to bring this product to market. This test will provide a proactive assessment test for patients and clinicians with the aim to improve patient outcomes in the long-term."

¹ https://www.canceraustralia.gov.au/impacted-cancer/what-cancer/cancer-australia-statistics, https://www.aihw.gov.au/reports/heart-stroke-vascular_diseases/hsvd-facts/contents/about, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf, https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf, https://www.cdc.gov/heartdisease/facts.htm



Receiving NATA accreditation and CLIA-certification for the MultiTest was a critical step in making the Multi-Test available to HCPs. Multi-Test is a Predictive Panel Risk Assessment Test that covers six common diseases which account for ~50%² of annual morbidities in the US. Phase one of the launch will include Breast Cancer, Colorectal Cancer, Prostate Cancer, Ovarian Cancer, Coronary Artery Disease and Type-2 Diabetes with additional disease candidates to follow.

GTG has engaged contract sales teams in Australia and the USA to promote the Multi-Test directly to HCPs.

The Multi-Test represents an important step towards the development of personalised, preventative healthcare, enabling patients and their healthcare professional to develop a long-term health plan. GTG's commitment to providing integrated risk tests such as the Multi-Test builds on the foundation of the rapidly expanding area of Precision Medicine³, which in 2021 was worth US\$26⁴ billion in North America annually. This segment of medicine provides a precise pathway to medical care with a potentially significant improvement in health outcomes for patients.

GTG will provide further updates on the progress of the Multi-Test launch including pricing structure, sales and other associated initiatives within the Appendix 4C and Quarterly Commentary where appropriate.

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Authorised by the Board of Genetic Technologies Limited

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For more information, please visit www.genetype.com

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.

 $^{^2\,}https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm$

³ A form of medicine that uses information about a person's own genes or proteins to prevent, diagnose, or treat disease

⁴ https://www.graphicalresearch.com/industry-insights/1954/north-america-precision-medicine-market?gclid=CjwKCAiAgbiQBhAHEiwAuQ6Bknb6EDXUsrZaLB3xAlfslXwfiA8NXT1RvL-isswTg0mlwSlTiHcwnxoCLnEQAvD BwE



Glossary of terms and acronyms

Centers for Medicare & Medicaid Services (CMS) – the US federal authority responsible for regulating most laboratory testing performed on humans in the US through the Clinical Laboratory Improvement Amendments (CLIA) program

Clinical Laboratory Improvement Amendments (CLIA) – certification required by clinical laboratories approved by the Center for Medicare and Medicaid Services (CMS) prior to human diagnostic testing

Consumer Initiated Tests (CIT) - laboratory testing that is initiated by the consumer without a physician order but reviewed and communicated back to the consumer via a physician.

Direct to Consumer (DTC) - laboratory testing that is initiated by the consumer without a physician order. The results are reported back directly to the consumer.

Polygenic Risk Score (PRS) - A polygenic risk score tells you how a person's risk compares to others with a different genetic constitution. However, polygenic scores do not provide a baseline or timeframe for the progression of a disease. For example, consider two people with high polygenic risk scores for having coronary heart disease.

National Association of Testing Authorities (NATA) - the authority responsible for the accreditation of laboratories, inspection bodies, calibration services, producers of certified reference materials and proficiency testing scheme providers throughout Australia. It is also Australia's compliance monitoring authority for the OECD Principles of GLP. NATA provides independent assurance of technical competence through a proven network of best practice industry experts for customers who require confidence in the delivery of their products and services.