



## ASX ANNOUNCEMENT

October 18<sup>th</sup>, 2011

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### **GENETIC TECHNOLOGIES' BREVAGen™ CHANGING THE WAY US PHYSICIANS ASSESS BREAST CANCER RISK**

#### **Positive early endorsement by physicians and staged US roll-out on track**

Genetic Technologies Limited (ASX: GTG, NASDAQ: GENE) today reported early insights from the US regional launch of BREVAGen™, its new, easy-to-use, predictive risk test for the tens of millions of women at intermediate risk of developing breast cancer. The Company's US-based subsidiary, Phenogen Sciences Inc., (<http://www.phenogensciences.com>) began its progressive roll-out of BREVAGen™ to obstetricians and gynecologists in eight metropolitan areas in the third quarter of 2011, with anticipated territory expansion in the coming months. BREVAGen™ is the first clinically validated breast cancer predictive risk assessment tool that combines a woman's genetic information with clinical data to assist physicians in developing personalized risk management plans.

Mr. Lewis J. Stuart, President of Phenogen Sciences Inc., said "The early response to BREVAGen™ has been positive, particularly in those practices with a strong orientation toward breast cancer prevention. We are adjusting the way physicians think about breast cancer risk and how it relates to all women, not just those with known high-risk genes. While this requires additional education, BREVAGen™ has been designed to fit nicely into current clinical risk assessment guidelines, simplifying in-office implementation of the test."

Over the first 90 days, the Phenogen sales team made more than 2,800 sales calls, reaching 800 physicians, representing good presentation into its initial tier one targets. During this same timeframe, 600 test kits were placed in targeted accounts, resulting in early adopter BREVAGen™ use within two weeks of launch.

The Company has commenced processing re-imbursements on initial BREVAGen™ test sales. As part of a longer term insured lives contracting and credentialing strategy, the Company has also commenced the credentialing process with the US' top-10 preferred provider organisations (PPO), which represent more than 60 percent of covered lives in the US. In the last two weeks, the first PPO contract was finalised with additional contracts anticipated to be completed by the end of the quarter.

Added Stuart, "Experience from the initial roll-out has allowed us to validate and refine our marketing strategy and proceed into the broader market with greater certainty."

"For the first time, BREVAGen™ allows clinicians to make informed decisions for the vast majority of patients with non-familial or sporadic risk of breast cancer based on their personal genetics, not simply a statistical risk score," said Dr. Eric Jacoby, Senior Partner at Personalized Women's Healthcare, in Plano, Texas. Dr. Jacoby added, "The results I receive from the BREVAGen™ test are making it much easier for the patient and I to decide on an appropriate level of monitoring and, if necessary, a more intensive surveillance plan of action including Magnetic Resonance Imaging or chemoprevention."



According to Dr. Owen Winsett, Founder and General Surgeon at The Breast Center of Austin, Texas, "Practices that are proactive in measuring breast cancer risk will welcome the addition of this in-office individualised risk assessment tool. We are passionate about breast cancer prevention, and BREVAGen™ provides a critical piece of the risk assessment puzzle. BREVAGen™ is an easy to perform and interpret test to give us information on whom we should provide closer monitoring and screening."

### **How BREVAGen™ works**

The BREVAGen™ predictive risk test is administered in a physician's office using a simple, non-invasive "cheek-swab". Following analysis in a CLIA-certified laboratory, physicians receive a comprehensive predictive risk assessment report to review with the patient. The patient's risk of breast cancer is calculated by combining their relative risk score from seven genetic markers, called SNP's (single nucleotide polymorphisms), with their Gail score (factors that comprise the patient's clinical make-up including current age, age at menarche, age at live first birth, race/ethnicity, etc.).

The BREVAGen™ test provides five-year and lifetime predictive risk assessments to more accurately evaluate the patient's risk for developing breast cancer, regardless of family history or previous indeterminate test results.

### **Clinically validated, proven superior risk assessment**

BREVAGen™ has been proven superior in determining breast cancer risk compared to the Gail score alone.<sup>1</sup> In the U.S. Women's Health Initiative (WHI) Clinical Trial, 3,300 women underwent breast cancer assessment utilising the BREVAGen™ test. Of those 3,300 women, 1,664 were diagnosed with breast cancer and 1,636 were in the breast cancer-free control group.

BREVAGen™ is clinically validated to reclassify approximately 64% of women in the intermediate Gail breast cancer risk group (being those with a 1.5% to 2.0% five-year risk), with approximately 28% being reclassified as higher risk candidates for breast cancer.<sup>1</sup> A preventive treatment plan based on this would prevent about 50% of cancers in this group. In addition, more than 36% in this group will be re-stratified down, avoiding unnecessary treatment, side effects and costs. Therefore, approximately one in two patients in the intermediate Gail risk group will have their standard of care changed for the better.

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### **About Phenogen Sciences Inc.**

Phenogen Sciences Inc., the U.S. division of Australia-based Genetic Technologies Limited, is a pioneer in personalized healthcare. Phenogen provides physicians and patients with personalized medical information, risk assessments and insights for patient-specific health management in the areas of oncology and woman's health. Phenogen's lead product, BREVAGen™, is the first predictive test that combines clinical information and genetic factors to categorise a woman's personal risk of developing breast cancer. For more information, visit <http://www.phenogensciences.com>.

<sup>1</sup> Mealiffe M., Stokowski R.P., Rhees B.K. et. al. J Nat Cancer Inst. 2010; 102(21): 1618-1627

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#### About Genetic Technologies Limited

Genetic Technologies was an early pioneer in recognizing important new applications for “non-coding” DNA (Deoxyribonucleic Acid). The Company has since been granted patents in 24 countries around the world, securing intellectual property rights for particular uses of non-coding DNA in genetic analysis and gene mapping across all genes in all species. Its business strategy is the global commercialisation of its patents through an active out-licensing program and the global expansion of its oncology and cancer management diagnostics portfolio. Genetic Technologies is an ASX and NASDAQ listed company with operations in the USA and Australia. For more information, please visit [www.gtglabs.com](http://www.gtglabs.com).

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#### Safe Harbor Statement (USA)

Any statements in this press release that relate to the Company’s expectations are forward-looking statements, within the meaning of the United States [Private Securities Litigation Reform Act](#). The **Private Securities Litigation Reform Act** of 1995 (PSLRA) implemented several significant substantive changes affecting certain cases brought under the federal securities laws, including changes related to pleading, discovery, liability, class representation and awards fees and of 1995. Since this information may involve risks and uncertainties and are subject to change at any time, the Company’s actual results may differ materially from expected results. Additional risks associated with Genetic Technologies’ business can be found in its periodic filings with the SEC.

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