



ASX ANNOUNCEMENT

14 July 2015

Genetic Technologies Announces Scientific Validation, Clinical Trial and Peer Review Publication Initiatives

Melbourne, Australia, 14 July 2015: Molecular diagnostics company Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, “Company”), is pleased to announce that underpinned by a strong balance sheet, following the successful capital raise in March 2015, the Company has launched an initiative to reinvigorate the pathway to Peer Review Publication. Attaining such publications in medical journals will help to strengthen the Company’s commercial position and accelerate reimbursement discussions with private payers. In addition, the Company plans to conduct three U.S. clinical studies and is currently in the process of preparing for the presentation of recently completed scientific validation studies.

The Company had previously conducted multiple scientific studies to develop and validate the first generation **BREVAGen™** test as well as created two health economic models to demonstrate potential cost savings and health benefits associated with the BREVAGen test. Importantly, due to the nature of the technology and the specific improvements incorporated in **BREVAGenplus®**, the research undertaken and published based on the original version of the test remains applicable to the new iteration.

Further scientific validation studies of *BREVAGenplus* have recently been completed and the Company expects to announce the results along with the anticipated publication of the first such study by the end of Q1 FY16. Supplementary scientific analysis supporting these studies is nearing completion, with follow-up results expected to be released Q2 FY16.

The Company also recognises that in order to secure and or improve the level of commercial payer coverage in the U.S., it needs to provide additional evidence that demonstrate the impact of the test on treatment decision-making that is aligned with payer evidence requirements. As such, the Company is about to commence a series of clinical utility studies that will provide further evidence to support the product’s value proposition and clinical benefits.

Genetic Technology Limited CEO Mr. Eutillio Buccilli commented “The data generated from the additional studies and clinical trials is indicative of our conviction in *BREVAGenplus* and long-term strategic approach to investing in a scientific publication program designed to strengthen the commercial position for this flagship test.”

Genetic Technologies plans to conduct three clinical trials in the US. The first of these trials is scheduled to begin in Q2 FY16 with completion expected before the end of FY16. Two longer-term clinical trials are also expected to commence within the current financial year and are designed to run for up to two years. One of the longer term studies will be prospective in design looking at patient outcomes, with the other being retrospective, assessing the impact of the test on MRI screening rates.



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“The Company’s pre-raising cash position was a huge impediment and severely restricted our ability to undertake cost-out initiatives and implement the new strategy. With a strong balance sheet and costs firmly under control, management is now able to focus on managing the business and driving commercial growth,” concluded Mr. Buccilli.

FOR FURTHER INFORMATION PLEASE CONTACT

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About Genetic Technologies Limited

Genetic Technologies is a molecular diagnostics company that offers predictive testing and assessment tools to help physicians proactively manage women’s health. The Company’s lead product, BREVAGen^{plus}®, is a clinically validated risk assessment test for non-hereditary breast cancer and is first in its class. BREVAGen^{plus}® improves upon the predictive power of the first generation BREVAGen test and is designed to facilitate better informed decisions about breast cancer screening and preventive treatment plans. BREVAGen^{plus}® expands the application of BREVAGen from Caucasian women to include African-Americans and Hispanics, and is directed towards women aged 35 years or above, who have not had breast cancer and have one or more risk factors for developing breast cancer.

The Company has successfully launched the first generation BREVAGen test across the U.S. via its U.S. subsidiary Phenogen Sciences Inc. and the addition of BREVAGen^{plus}®, launched in October 2014, significantly expands the applicable market. The Company markets BREVAGen^{plus}® to healthcare professionals in comprehensive breast health care and imaging centres, as well as to obstetricians/gynaecologists (OBGYNs) and breast cancer risk assessment specialists (such as breast surgeons).

For more information, please visit www.brevagenplus.com and www.phenogensciences.com.

Safe Harbor Statement

Any statements in this press release that relate to the Company’s expectations are forward-looking statements, within the meaning of the [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. 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.