



ASX ANNOUNCEMENT

29 November 2016

Genetic Technologies Limited and The University of Melbourne Enter into Exclusive Worldwide License Agreement to Develop Colorectal Cancer Risk Assessment Test

Melbourne, Australia, 29 November 2016: Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE, “Company”), a molecular diagnostics company and provider of BREVA*Genplus*®, a first-in-class, clinically validated risk assessment test for sporadic (non-hereditary) breast cancer, today announced the signing of an exclusive worldwide license agreement with The University of Melbourne for the development and commercialisation of a novel colorectal cancer (CRC) risk assessment test.

The core technology behind this CRC risk assessment test was developed by Professor Mark Jenkins and his research team at the University’s Centre for Epidemiology and Biostatistics. Results from preliminary modelling studies were first published online in *Future Oncology* on 1 February 2016, in a paper entitled “Quantifying the utility of single nucleotide polymorphisms to guide colorectal cancer screening,” 2016 Feb; 12(4), 503-13. This simulated case-control study of 1 million patients indicated that a panel of 45 known susceptibility SNPs can stratify the population into clinically useful CRC risk categories. In practice, the technology could be used to identify people at high risk for CRC who should be subjected to intensive screening which can ultimately reduce the risk of occurrence and death from the disease. Those identified as low risk of CRC can be spared expensive and invasive screening, thereby preventing adverse events and saving money, as it is not justified. A scientific validation study supporting this work is nearing completion and is expected to be published within the next six (6) months.

The fundamental technology is similar to the BREVA*Genplus* test and will fit synergistically into the Company’s existing infrastructure and processes. The CRC test represents a significant milestone for the Company as it seeks to diversify its product pipeline and become a key player in the SNP-based cancer risk assessment landscape. The commercial development strategy for the CRC test will benefit from the BREVA*Genplus* experience in the marketplace.

The terms and conditions of the Agreement are confidential, however, Genetic Technologies will be responsible for the commercial development of the test. In addition, as part of the Agreement, The University of Melbourne and Genetic Technologies will embark on a robust, ongoing research collaboration enabling the Company to leverage the University’s renowned world-class expertise in SNP-based risk assessment and risk model development.

“This is an exciting time for the Company as we commence this strategic alliance with The University of Melbourne. The relationship with the University is comprehensive and highlights our overall corporate mission to become a leader in the genomics focused oncology diagnostics’ industry while enhancing our pipeline of risk assessment products,” commented Eutillio Buccilli, Executive Director and Chief Executive Officer of Genetic Technologies Limited.



Excluding skin cancers, CRC is the third most common cancer diagnosed in both men and women in the United States. Overall, the lifetime risk for developing CRC is about 1 in 20, (5%). CRC is the third leading cause of cancer-related deaths in the United States when men and women are considered separately, and the second leading cause when both are combined. As with breast cancer, early diagnosis is key. When diagnosed at an early stage (before the disease has spread outside the colon), the relative 5-year survival rate for CRC is 92% and 87% for rectal cancer, according to the American Cancer Society, while the respective survival rate for late stage (metastatic) disease is much lower, at 11% and 12%, respectively. In fact, the majority of CRC cases are preventable by early detection and removal of precancerous polyps. Regular CRC screening is therefore, one of the most powerful weapons for preventing CRC. The main challenge with current CRC screening methodologies is compliance (the patient actually doing and completing the test), with the NCI stating that compliance in one of the large RCTs was ~47%, theoretically halving the impact of screening on CRC mortality.

The most common CRC screening tool is a faecal occult blood test (FOBT) or visual inspection of the bowel by endoscopy (Colonoscopy or Sigmoidoscopy). FOBT-based-screening has been shown to reduce CRC mortality by three very large randomised controlled trials, according to the U.S. National Cancer Institute (NCI). FOBT screening has a fairly high sensitivity but low positive predictive value meaning a patient who returns a positive FOBT, then goes on to receive a diagnostic colonoscopy. Colonoscopy may be used as a primary screening tool in certain patients, but the cost and the infrastructure required to use it as a primary tool are considered too prohibitive.

As with breast cancer, the more the physician can tailor a patient's screening program to their level of risk of developing CRC, the greater impact screening will have on the disease. The development of a much improved CRC risk assessment tool has the potential to provide a significant health benefit by better targeting the existing screening modalities and improving compliance among those patients most at risk of developing CRC. Risk stratification would also likely influence the age a patient will start screening and the frequency.

“The licensing Agreement with Genetic Technologies provides us with a wonderful opportunity to work with an organisation that is a leader in the field of genomics for precision public health. Furthermore, Genetic Technologies provides the University with an established platform that will facilitate the transition of our scientific work into the clinical arena,” commented Mark Jenkins, Professor of Epidemiology and Biostatistics at The University of Melbourne.

About the University of Melbourne and its commercialisation initiatives

The University of Melbourne is Australia's best and one of the world's leading universities. As an R&D hub with world-leading specialist in science, technology and medicine, Melbourne undertakes cutting-edge research to create new ways of thinking, new technology and new expertise to build a better future.

World-class research, real-world solutions: The University of Melbourne embraces a culture of innovation – working with industry, government, non-governmental organisations and the community to solve real-world challenges. Our commercial partnerships bring research to life through collaboration in areas of bio-engineering, materials development, medical technology invention, community capacity development and cultural entrepreneurship.

With over 160 years of leadership in education and research, the University responds to immediate and future challenges facing our society through innovation in research.



The University of Melbourne is No. 1 in Australia and 33 in the world (Times Higher Education World University Rankings 2015–2016).

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 BREVAGenTM test and is designed to facilitate better informed decisions about breast cancer screening and preventive treatment plans. BREVAGen^{plus}® expands the application of BREVAGenTM 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 BREVAGenTM 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.

FOR FURTHER INFORMATION PLEASE CONTACT

Mr. Eutillio Buccilli

Executive Director & Chief Executive Officer
Genetic Technologies Limited
+ 61 3 8412 7050

Candice Knoll (USA)

Blueprint Life Science Group
+1 (415) 375 3340, Ext. 4