**CONTACT:** Bruce Likly

Kovak-Likly Communications (203) 762-8833 or blikly@klcpr.com

# PHENOGEN SCIENCES INTRODUCES BREVAGENPLUS BREAST CANCER RISK ASSESSMENT TEST

Enhanced clinically-validated risk assessment test now available for Caucasian, African-American and Hispanic American Women

CHARLOTTE, N.C. – October 6, 2014 – Phenogen Sciences, Inc. today announced the availability of BREVAGen*plus*, an easy-to-use predictive risk test for the millions of women at risk of developing sporadic, or non-hereditary, breast cancer. The test is an enhancement of the company's first generation product, BREVAGen<sup>®</sup>. BREVAGen*plus* assesses both clinical risk factors and genetic markers known to be associated with sporadic, or non-hereditary, breast cancer to determine a woman's five-year and lifetime risk of developing the disease. The test is designed to facilitate better informed decisions about breast cancer screening and preventive treatment plans for Caucasian, Hispanic and African-American women, age 35 years or above, who have not had breast cancer, lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS), and have one or more risk factors for developing breast cancer.

"The identification in 2007 of a number of single nucleotide polymorphisms (SNPs), each with a small relative risk, led to the development of the first commercially available genetic risk test for sporadic breast cancer, BREVAGen, which was launched in 2011," said Richard Allman, PhD, Scientific Director, Genetic Technologies Ltd. "The intervening three years have seen rapid progress in both technology and the rate of genetic discoveries, such that the number of SNPs which have now been associated with breast cancer has increased ten-fold.

BREVAGen*plus* incorporates these latest discoveries to provide an improved polygenic risk test."

Results from BREVAGen*plus* provide physicians with valuable information to assist in developing a patient-specific Breast Cancer Risk Reduction and Screening Plan based on professional medical society guidelines, such as the American Cancer Society (ACS) (<a href="https://www.cancer.org">www.cancer.org</a>) and The National Comprehensive Cancer Network (NCCN) (<a href="https://www.nccn.org">www.nccn.org</a>).

#### How BREVAGenplus Works

The BREVAGen*plus* predictive risk test is performed in a physician's office using a simple, non-invasive "cheek swab." The test combines information from the patient's Genetic Markers (SNPs) known to be associated with sporadic breast cancer, with their Clinical Risk Score which includes factors such as the patient's current age, age at menarche, age at live first birth, race/ethnicity, etc, to calculate their risk of developing sporadic breast cancer. This Clinical Risk Score is determined by the National Cancer Institute Breast Cancer Risk Assessment Tool (BCRAT); also known as the "Gail model" (http://www.cancer.gov/bcrisktool/).

Following analysis in a CLIA-certified laboratory, the test provides five-year and lifetime predictive risk assessments to more accurately determine the patient's risk of developing breast cancer during those timeframes.

### Clinically validated, proven superior

The first generation test, BREVAGen, was proven superior in determining breast cancer risk compared to Clinical Risk Score alone (ie, "Gail model score."). In the U.S. Women's Health Initiative (WHI) Clinical Trial, 3,300 women underwent breast cancer assessment utilizing the BREVAGen test. Studies showed BREVAGen reclassified 64 percent of above average (ie, "intermediate") risk (as determined by the Gail model) subjects as either high or low risk for development of breast cancer. Furthermore, the BREVAGen test reclassified the breast cancer risk for 33 percent of the total 3,300 trial subjects. In the superior of the superior in determining breast cancer.

BREVAGen*plus* expands on this initial work by leveraging recent advancements in SNP research and development. BREVAGen*plus* represents a 20 percent improvement in accuracy when compared to the first generation test.

There is no single mutation for sporadic breast cancer, nor is there a repository of information about genetic contribution to a complex disease such as breast cancer. At present, the measurable genetic markers associated with complex diseases are identified using genome-wide association studies (GWAS). GWAS studies have been used to identify novel breast cancer susceptibility loci. Several dozens of SNPs were identified from an initial review of over 500,000 SNPs in multiple genome-wide association studies (GWAS) involving over 50,000 women for inclusion in BREVAGen*plus*. <sup>2</sup>

#### About BREVAGenplus

An enhancement of Phenogen Sciences, Inc. first generation product, BREVAGen, BREVAGen*plus* evaluates an increased number of genetic markers (SNPs); and testing is now available for African-American and Hispanic American women.

BREVAGen*plus* is a clinically-validated, personalized predictive risk assessment test that more accurately evaluates a woman's personal risk of developing sporadic, or non-hereditary, breast cancer. By evaluating a woman's clinical information (Gail score) and genetic markers (SNP profile), BREVAGen*plus* will assist physicians in developing personalized risk management plans and taking appropriate steps towards managing each woman's risk of developing sporadic breast cancer with greater precision than ever before.

Phenogen Sciences, Inc. markets BREVAGen*plus* to healthcare providers in women's health, primarily obstetricians/gynecologists (OBGYNs), breast cancer risk assessment specialists (such as breast surgeons) and comprehensive breast health care and imaging centers. For more information, visit <a href="http://www.BREVAGen*plus.com">http://www.BREVAGen<i>plus.com*</a>.

## About Phenogen Sciences, Inc.

Phenogen Sciences, the U.S. subsidiary of Australia-based Genetic Technologies Limited, is a pioneer in personalized healthcare. Phenogen Sciences offers novel predictive testing and assessment tools that help physicians proactively manage women's health risks. Phenogen Sciences' lead product, BREVAGen is a scientifically validated test that combines a woman's clinical history of estrogen exposure with her genetic predisposition to its effects; more accurately categorizing her personal risk of developing breast cancer. For more information, visit <a href="http://www.phenogensciences.com">http://www.phenogensciences.com</a>.

###

<sup>&</sup>lt;sup>1</sup> Mealiffe M, Stokowski RP, Rhees, BK, et al. J Nat Cancer Inst. 2010;102(21):1618-1627.

<sup>&</sup>lt;sup>2</sup> Easton DF. Pooley KA, Dunning AM, *et al.* (2007). Genome-wide association study identifies novel breast cancer susceptibility loci. Nature 447: 1087-1093.