Next Generation Genetic Breast Cancer Risk Test Using Genetic Polymorphisms is Most Accurate Breast Cancer Predictor

OncoVue Core-Science Featured in Peer-Reviewed Human Genetics Publication

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OKLAHOMA CITY—The current issue of the international journal *Human Genetics* features InterGenetics' breakthrough science that uses multiple gene combination technology to determine a woman's risk of developing breast cancer. The use of so-called polymorphic gene combinations is the core science of OncoVue – the first breast cancer risk predictive test that can determine the lifetime and age-specific risk of developing breast cancer for all women.

"The science behind OncoVue, published in *Human Genetics*, is proving that multiple gene combinations are the best indicator of breast cancer risk. Most risk models for disease assume that genes act independently, our science is taking earlier research to the next level by understanding the interaction between multiple gene combinations," said Dr. Craig Shimasaki, President and CEO of InterGenetics. "Some gene combinations predispose a woman to cancer while other combinations actually protect against breast cancer. Knowing how the genes in combination act together is what makes InterGenetics' science so unique."

InterGenetics' scientists describe in *Human Genetics,* that using algorithms to analyze combinations of multiple genes is a better way to determine an individual's personal breast cancer risk than previous assessment tools. Combinations of genes along with personal history measures help determine a more complete genetic picture of breast cancer susceptibility by looking at interactions of genes that impact risk rather than the limited picture any single gene can offer.

Scientists at InterGenetics have now analyzed two and three-gene combinations in a test sample of more than 10,000 women to develop a proprietary algorithm of gene combinations that predict a woman's risk of breast cancer throughout her lifetime.

InterGenetics Inc., an Oklahoma City-based biotech company, has developed the next generation breast cancer risk test OncoVue™. OncoVue is the first genetic based breast cancer risk test intended for all women with or without a family history of the disease. The test is easily performed, a women, first answers a simple medical history questionnaire, then swishes a harmless mouthwash and deposits the fluid in a tube. In

the laboratory, DNA from woman's cheek cells is analyzed along with the data from the medical questionnaire to assign a numeric score that represents her risk of developing breast cancer for every 5 years of her life.

"We look at breast cancer risk like a collision course with an 18-wheeler. If you knew when to detour, you could avoid the collision. OncoVue tells women when to detour to avoid the collision with breast cancer," continued Dr. Shimasaki. "By knowing who is at high risk, women can take preventative medications to reduce the occurrence of the disease or be screened with more comprehensive screening tools to catch breast cancer at it's earliest stages where long term survival is the greatest."

Polymorphisms are single base pair changes in a person's genetic blueprint that can have a great effect on the gene and gene-product functions. Since 1989, the Gail model, a non-genetic assessment tool, has been the standard for determining the risk of breast cancer for women by calculating a number of medical history and environmental factors. The 1990's brought genetics tests that look for the so-called breast cancer genes, BRCA 1 and BRCA 2.

"Current genetic breast cancer risk tools cannot tell the vast majority of women their personal genetic risk for developing breast cancer. Noted Dr. Shimasaki. "Though, BRCA 1 and BRCA 2 account for only 5-10% percent of all breast cancers, both tests are complementary. OncoVue fills that gap using the discovery of gene combinations because most breast cancers are not related to BRCA 1 and 2 mutations."

OncoVue is on track to be introduced to the public in a phased roll-out by fourth quarter 2005.

About InterGenetics

InterGenetics, a genetics-based cancer-risk testing and cancer treatment company is emerging as an innovator in the frontier of genetic medicine. The company's lead product, the OncoVue™ Breast Cancer Risk Test, uses proprietary gene combinations and DNA assessment technology developed by InterGenetics' scientists to quickly and accurately identify women who are at high risk of developing breast cancer, potentially many years in advance of their diagnosis.

InterGenetics has a promising research pipeline of predictive tests for other cancers such as ovarian, colon, prostate, and pancreatic cancer. The company's core research has future application in also predicting heart disease, diabetes and in enhancing the effectiveness of drug therapies and preventative medicine in these fields.
www.intergenetics.com

About *Human Genetics*:
Human Genetics publishes original and timely articles on all aspects of human genetics. Topics covered include: gene structure and organization, Gene expression, Mutation detection and analysis, Linkage analysis and genetic mapping, Physical mapping, Cytogenetics and Genomic Imaging, Genome structure and organization, Disease association studies, Molecular diagnostics, Genetic epidemiology, Evolutionary

genetics, Developmental genetics, Genotype-phenotype relationships, Molecular genetics of tumorigenesis, Genetics of complex diseases and epistatic interactions, ELSI (ethical, legal and social issues) and Bioinformatics.