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FDA approves study for breast cancer risk test by **InterGenetics** of Oklahoma City

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The U.S. Food and Drug Administration has approved an investigational device exemption study for a breast cancer risk test developed by **InterGenetics** of Oklahoma City. OncoVue is the first genetic-based, breast cancer risk test incorporating personal history measures and individualized genetic-based single nucleotide polymorphisms. "OncoVue has already undergone years of research and the genetic information for this test came from testing over 7,500 women with and without breast cancer from five geographic regions of the country," said Craig Shimasaki, CEO and president of **InterGenetics**. "The completion of this FDA investigational period will mark a new level of confidence in genetic breast cancer risk testing for the patients, physicians and breast care centers who are the first to use this technology. " Breast Imaging of Oklahoma and Oklahoma Breast Care Center in Oklahoma are among the first centers in the nation to participate in a study. Other initial testing centers are in Chicago, Tucson, Ariz., and Boise, Idaho. The study is expected to include about 50 study sites. "OncoVue is the nation's first genetic-based breast cancer risk test to undergo the FDA approval process and it is very important to us to be a part of a process that could bring this Oklahoma-researched technology to all women," said Larry K. Killebrew, Oklahoma Breast Care Center medical director. "Our patients expect us to be on the forefront of the best practices and prevention strategies, certainly OncoVue has the potential to enhance our ability to move to greater prevention options for our patients. " Current genetic tests only detect hereditary gene mutations present in about 5 percent of women who get breast cancer. The OncoVue test can provide a genetic-based tool for improving clinical estimates of individualized breast cancer risk. "We have been eagerly watching the evolution of this Oklahoma technology in the research phases and want to be on the leading edge of institutions adopting this new genetic test to help our patients better understand their risk of developing breast cancer so that we can recommend the best prevention strategies to them," said Debra Mitchell, director of the Oklahoma Breast Care Center Medical. "We are hopeful this next-generation genetic risk assessment test will give our patients the opportunity to engage prevention therapies to fight breast cancer rather than treatment therapies. " To use the OncoVue test, a woman completes a short medical history questionnaire, then swishes a mouthwash and deposits the fluid into a tube. In the **InterGenetics'** laboratory, the woman's cheek cells collected from the mouthwash are analyzed using the OncoVue CombiSNP technology that looks at combinations of genes, rather than any one specific gene. Participants in the study will be asked to pay \$397 for the test to cover a portion of the research, development and processing of the specimen. The patient will receive the OncoVue report, which identifies her risk assessment in three stages of her life - pre-menopause, peri-menopause and post-menopause. The study is open to women between the ages of 30 and 69 who have

never been diagnosed with invasive breast cancer. "The OncoVue investigational study will also assess the patient's emotional state related to their risk perception both before and after testing and the impact of the physician's medical recommendations based on the results of the testing," Shimasaki said. "The study will also provide valuable insight into the widespread acceptance for the applicability of the Breast Cancer Risk Test as a tool for risk assessment in a clinical setting. "