

PRESS RELEASEFor Immediate Release
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New Positron Emission Tomography (PET) biomarker NVB-64 visualizes malignant breast tumors.

PARK CITY UT – October 29, 2009/PRNewswire – Researchers at Thomas Jefferson University in Philadelphia, PA, supported in part by NuView Life Sciences, have published an article in the *Journal of Nuclear Medicine* reporting preclinical results of a novel PET biomarker designed to selectively detect malignant breast tumors^[1]. “All tumors detected with the new biomarker were malignant and expressed the targeted VPAC1 receptors located on the plasma membrane of the tumor cells^[2,7].” These results have led to initiation of clinical trials, supported by NuView, at Jefferson using this agent in patients with known and suspected breast cancer.

To date, the unsettling report that a patient has a “suspicious mass” on an annual mammogram has automatically dictated a costly and invasive needle biopsy. Soon there may be a choice of care in selecting a diagnostic procedure to determine the benign or malignant nature of the mass. Rather than a protracted waiting period to locate a clinician, find time to schedule a biopsy, endure a painful procedure and wait additional days for lab results to be reported; novel procedures such as a NVB64-PET scan may eventually be available to discriminate between malignant and benign lesions. The results of benign or malignant status of the mass could immediately be available without the anxiety of the delay normally associated with a lab processing and reporting of results from a needle biopsy.^[3]

Since 1985, surgical biopsy has been the mainstay of diagnostics for evaluating nonpalpable mammographic abnormalities. In the early 1990’s needle biopsy of the breast was introduced and quickly became the preferred method of breast cancer detection.^[4] Not until 2004 was the first non-surgical procedure looking towards breast cancer detection using Positron Emission Tomography (PET) with ¹⁸fluorodeoxyglucose (FDG) approved for use in patients. FDG-PET has two significant drawbacks: 1) FDG-PET leaves a frustrating 30% of tumors undetected; and 2) FDG cannot reliably distinguish between benign and malignant tumors^[5].

The significant advance of NVB-64 is the recognition of genetic changes at the cellular level, as a genomic biomarker, rather than the overly generalized metabolic markers found with FDG.



Nearly as important as the human implications are the enormous financial ramifications. Lead investigator Mathew Thakur Ph.D. Professor of Radiology and Director of the Laboratories of Radiopharmaceutical Research and Molecular Imaging at Thomas Jefferson University Hospital says, “The use of NVB64-PET scan in the future may minimize the need for unnecessary biopsy of benign tumors.” Currently, nearly 6 million such biopsies are performed annually in the United States, at an estimated annual cost of \$30 billion. Approximately 80% or 4.8 million biopsies, demonstrate benign pathology.

The biomarkers NuView has in development can, with alteration of the radionuclide attached to the compound, change them from a diagnostic to a targeted therapy, or a pairing of a target specific diagnostic and therapy. NuView Medical Director Peter S. Conti, MD, PhD adds, “Development of targeted diagnostics that can be modified to also carry therapeutic isotopes can lead to unique agents that can broaden the range of therapies available for cancer patients.”

Anticipated Benefits of NVB-64:

- Same day, immediate confirmation of the patient having either benign or malignant breast tumor(s).
- Choice of care in selecting a screening method to determine the malignant or benign status of a mass found on a mammogram.
- Significant cost savings to patients and insurers. The cost of the NVB64-PET scan is anticipated at \$2,000. This translates to a 60% cost savings over a typical needle biopsy of the breast^[6].

For patients, clinicians and physicians NVB-64 could represent a tremendous step forward in personalizing medical management. Future advances in this genomic biomarker arena hold great promise for both diagnostics and treatment therapies.

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