



Expression Pathology

NextGen Sciences and Expression Pathology Develop Quantitative Protein Biomarker Assay for Determining Expression Levels in FFPE Tissue Samples

Ann Arbor, MI and Gaithersburg, MD, 20 April 2009 - NextGen Sciences, (AIM: NNG), the biomarker specialists providing discovery, assay development and testing services, and Expression Pathology, Inc. (Gaithersburg, MD), a leader in tissue protein analysis, have announced that they have a protein biomarker assay methodology that provides, for the first time, rapid, reproducible, quantitative measurement of protein expression in formalin fixed paraffin embedded (FFPE) tissue samples.

The assay methodology uses Expression Pathology's Liquid Tissue® reagents and protocols for sample preparation and to solubilize the entire protein content from standard FFPE tissue. The solubilized proteins are then assayed by NextGen Sciences using Multiple Reaction Monitoring (MRM), a method for quantitation of proteins using mass spectrometry. The results correlate directly with those obtained by current immunohistochemistry techniques, but the new method is faster, straightforward, and provides accurate and quantitative measurement of protein biomarkers.

The companies began collaborating in June 2008, and have demonstrated the utility of the FFPE MRM assay methodology by measurement of the Her2 protein, which has become an important marker for breast cancer diagnosis and therapy. Formalin fixation of tissue samples which are subsequently embedded in paraffin is the gold standard for biopsy and surgical tissue preservation. However, proteins within the tissue samples are heavily cross-linked as a result of the formalin fixation and therefore, until now, options for analyzing them have been limited.

"The development of this assay shows that FFPE tissue can be used for direct measurement of clinically important protein biomarkers by mass-spectrometry-based protocols," said Michael Pisano, CEO, NextGen Sciences. "As MRM assays can be multiplexed, we have the potential to develop assays where multiple proteins are measured simultaneously, for example cancer therapy targets or cell signalling pathway proteins."

Peter Tunon, Vice President Sales and Marketing, Expression Pathology, commented: "Her2 is the prototype diagnostic, prognostic and therapeutic target for the personalized medicine approach to disease treatment. Precise quantitation of such protein biomarkers in FFPE tissue will have a major impact on the advancement of personalized medicine."

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Notes to Editors

NextGen Sciences

NextGen Sciences (AIM: NGG), the biomarker specialists, provide services to pharmaceutical and biotech companies globally. Using advanced techniques, such as Multiple Reaction Monitoring (MRM) mass spectrometry analysis, the Company is developing a portfolio of robust assays for testing clinical samples for drug safety and efficacy, and the development of personalized treatment for patients.

NextGen's range of services, which include biomarker testing, discovery and assay development, are employed by its customers as a key part of the biomarker-based drug and diagnostic development process.

For more information visit www.nextgensciences.com

Expression Pathology Inc.

Formalin-fixed and paraffin-embedded (FFPE) tissue samples are routinely collected and stored in medical treatment and research facilities. They constitute a huge untapped resource for discovery, validation and accurate measurement of biomarkers of disease progression and recurrence, drug response and toxicity. Expression Pathology's Liquid Tissue® and Director™ laser microdissection technologies are opening new ways to extract valuable protein information from FFPE tissue, both for protein biomarker discovery and validation and for a new generation of clinical research and diagnostic tools.

For more information visit www.expressionpathology.com