MolecularMD and Ventana Medical Systems, Inc. Reach Collaborative Research Agreement: Limits of Detection and Sensitivity for PTEN Gene Using In-Situ Hybridization and Immunohistochemistry Methods

The Associated Press

MolecularMD, based in Portland, OR, has formed a collaborative research agreement with Ventana Medical Systems, Inc. (Ventana), a member of the Roche Group, in support of the PTEN (phosphatase and tensin homolog) study, building upon the ongoing link between research and diagnostic development.

The PTEN gene is a major positive and negative regulator, respectively, of the PI3-kinase pathway, which regulates growth, survival, and proliferation. This key signaling component is one of the most frequently mutated proteins in human cancers, resulting in unregulated activation of PI3K signaling and providing irrefutable genetic evidence of the central role of this pathway in tumor growth.

The objective of this study is to determine the correlation between methods for detecting PTEN gene copy number and protein biomarker expression using in-situ hybridization (ISH) methods for gene detection, PTEN Sanger Sequencing for mutational analysis and immunohistochemistry (IHC) methods for protein staining. Brightfield ISH and Sanger Sequencing methods will be compared for detecting gene copy number. These ISH results will be compared to the levels of expression of the PTEN protein detected by immunohistochemistry. The expected result will be an understanding of the analytical validity of Brightfield ISH methods, compared to Sanger Sequencing, and IHC methods for determination of PTEN status.

"MolecularMD's collaboration with Ventana Medical Systems, Inc. links the strengths and innovations of our respective companies to support the shared goal of validating new diagnostic solutions for translational and clinical cancer research," stated Dan Snyder, President and COO.

About MolecularMD MolecularMD Corporation develops and commercializes specialty molecular diagnostics for oncology applications. Its tests are designed to allow appropriate selection, monitoring and management of patients treated with molecularly-targeted cancer therapies. MolecularMD incorporates gold-standard and innovative technologies in providing its partners with the highest quality results. Assays are designed to meet clinical trial needs, and MolecularMD has appropriate systems and standards in place to enable development of companion diagnostic tests in conjunction with partners' novel anticancer agents. A private company based in Portland, Oregon, MolecularMD was founded by Brian Druker, director of

the Knight Cancer Center at Oregon Health & Science University, and Sheridan G. Snyder, entrepreneur and founder of Genzyme Corporation.

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