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Veracyte Announces Positive Coverage Policy for Afirma® Gene Expression Classifier from Blue Shield of California

SOUTH SAN FRANCISCO, Calif., Dec. 2, 2014 /PRNewswire/ -- Veracyte, Inc. (Nasdaq: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, announced today that Blue Shield of California, one of the nation's largest Blue Cross Blue Shield (BCBS)-affiliated organizations, has issued a positive coverage policy for the company's Afirma Gene Expression Classifier (GEC), effective immediately. Blue Shield of California's decision makes the Afirma GEC available to its approximately 3 million members and brings the total number of covered lives for Veracyte's test to more than 140 million. Additionally, the Hawaii Medical Services Association (HMSA) - also a BCBS-affiliated organization - published a draft policy indicating it intends to cover Veracyte's genomic test for its members beginning in February 2015.

Blue Shield of California determined that the Afirma GEC is medically necessary for use in identifying patients with benign thyroid nodules - who can thus potentially avoid diagnostic surgery - among those whose fine needle aspiration (FNA) biopsies are deemed indeterminate following traditional cytopathology review. In contrast, the organization determined that the use of mutation analysis - genomic testing that looks for specific thyroid cancer biomarkers - does not achieve a high enough negative predictive value to identify which patients with indeterminate cytopathology can undergo watchful waiting rather than diagnostic surgery.

"These new policies further underscore the value of the Afirma GEC - proven in multiple, peer-reviewed, published studies - in helping patients with thyroid nodules avoid unnecessary surgery, while also removing costs from the healthcare system," said Bonnie H. Anderson, Veracyte's president and chief executive officer. "We are pleased that Blue Shield of California's and HMSA's members will now be able to benefit from this coverage."

The Afirma GEC is the only molecular test with peer-reviewed, published data showing that it meets the performance criteria for inclusion in the National Comprehensive Cancer Network (NCCN), UpToDate® and preliminary American Thyroid Association guidelines to enable patients with indeterminate cytopathology and benign Afirma GEC results to opt for routine monitoring in lieu of diagnostic surgery.

Veracyte offers the Afirma Gene Expression Classifier (GEC) as part of its Afirma Thyroid FNA Analysis. This comprehensive solution combines specialist cytopathology assessment of thyroid nodule FNA samples with the Afirma Gene Expression Classifier, which is used to identify benign thyroid nodules among those deemed inconclusive based on cytopathology. This spring, the company added its Afirma Malignancy Classifiers - genomic tests for medullary thyroid cancer and the BRAF gene mutation - to help guide surgical strategy for those patients who need surgery.

About Veracyte

Veracyte (Nasdaq: VCYT) is pioneering the field of molecular cytology, focusing on genomic solutions that resolve diagnostic ambiguity and enable physicians to make more informed treatment decisions at an early stage in patient care. By improving preoperative diagnostic accuracy, the company aims to help patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's first commercial solution, the Afirma® Thyroid FNA Analysis, centers on the proprietary Afirma Gene Expression Classifier (GEC) to resolve ambiguity in diagnosis and is becoming a new standard of care in thyroid nodule assessment. Since launching its Afirma solution in 2011, Veracyte estimates it has helped approximately 10,000 patients with thyroid nodules avoid unnecessary surgery, reducing healthcare costs by millions of dollars. Afirma is recommended in leading practice guidelines and is covered for more than 140 million lives in the United States, including through Medicare and most commercial insurance plans. Veracyte intends to expand its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. The company is in late product development for a genomic test to resolve preoperative ambiguity in lung nodules that are suspicious for cancer. Veracyte is also developing a second product in pulmonology, targeting interstitial lung diseases that include idiopathic pulmonary fibrosis. For more information, please visit www.veracyte.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe,"

"should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the value and potential of our technology and research and development pipeline. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our limited operating history and history of losses; our ability to increase usage of and reimbursement for Afirma and any future products we may develop or sell; our ability to continue our momentum and growth; our dependence on a few payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting from payers for our test; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our dependence on strategic relationships and our ability to successfully convert new accounts resulting from such relationships; our ability to develop and commercialize new products and the timing of commercialization; our ability to achieve sales penetration in complex commercial accounts; the occurrence and outcome of clinical studies; the timing and publication of study results; the applicability of clinical results to actual outcomes; our inclusion in clinical practice guidelines; the continued application of clinical guidelines to our products; our ability to compete; our ability to expand into international markets; our ability to obtain capital when needed; and other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

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