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Veracyte CEO Bonnie Anderson Urges CMS to Reverse Its Proposed 2016 Pricing Methodology for Advanced Molecular Diagnostic Tests

BALTIMORE, Oct. 19, 2015 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT) announced that Bonnie Anderson, president and chief executive officer, today urged the Centers for Medicare and Medicaid Services (CMS) to reverse its proposed 2016 pricing methodology for precision medicine tests, including the company's Afirma® Gene Expression Classifier (GEC). She spoke at a public meeting of CMS's Advisory Panel on Clinical Laboratory Diagnostic Tests, held in Baltimore, Md.

At the meeting, the advisory panel members unanimously indicated disagreement with CMS's preliminary pricing approach. CMS will make the final decision, which is expected before December 1, 2015.

"We urge CMS to use a 'gapfill' pricing methodology for tests classified as Multi-Analyte Assays with Algorithmic Analyses (MAAA), including the Afirma GEC, as this would follow historical precedent and the agency's own policies," said Ms. Anderson. "We believe that to do otherwise would be a step backwards for innovation, which is at the core of personalized medicine.

"In the case of the Afirma GEC, this innovation is helping tens of thousands of patients avoid unnecessary thyroid surgery when their biopsy results are ambiguous. Such surgery is invasive, costly and frequently results in patients requiring lifelong daily thyroid hormone replacement therapy."

Ms. Anderson's comments were in response to the preliminary 2016 Clinical Laboratory Fee Schedule (CLFS) issued by CMS last month in which the agency went against historical precedent and its own expert panel's previous recommendation and proposed a "crosswalk," rather than "gapfill," pricing approach for new test codes. As a result, proposed Medicare reimbursement prices for an entire group of advanced tests known as MAAAs, including the Afirma GEC, were reduced because they were based on other, lower-priced tests that differ significantly - both in technical performance and intended use.

Ms. Anderson was one of several diagnostic company leaders, who are members of the Coalition for 21st Century Medicine, who spoke today before the CMS Advisory Panel in opposition to the agency's proposed 2016 pricing approach.

About Veracyte
Veracyte (NASDAQ: VCYT), based in South San Francisco, Calif., is pioneering the field of molecular cytology, offering 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 Afirma® Thyroid FNA Analysis centers on the proprietary Afirma Gene Expression Classifier (GEC) and is becoming a new standard of care in thyroid nodule assessment. The Afirma test is recommended in leading practice guidelines and is covered for approximately 150 million lives in the United States, including through Medicare and many commercial insurance plans. Veracyte is expanding its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. In April 2015, the company launched the Percepta™ Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer. Veracyte is developing a second product in pulmonology, targeting interstitial lung diseases, including 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 our beliefs regarding the drivers of adoption of Afirma, our ability to successfully encourage CMS to use a "gapfill" approach to test pricing in a way that preserves our current rate for our Afirma GEC, our expectations with respect to the success of our entry into the pulmonology market, our expectations regarding full-year 2015 guidance and forecast for annual GEC test volume, and 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 to obtain reimbursement for any future products we may develop or sell; our ability to maintain our current rate for our Afirma GEC; 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 tests; 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 successfully achieve adoption of and reimbursement for our Percepta Bronchial Genomic Classifier; 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 and achieve adoption of our tests in such 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 June 30, 2015. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.