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Veracyte Statement on CMS's Preliminary Gapfill Rate for the Afirma® Gene Expression Classifier

SOUTH SAN FRANCISCO, Calif., June 10, 2016 /PRNewswire/ -- <u>Veracyte, Inc.</u> (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today issued the statement below on the Centers for Medicare and Medicaid Services' (CMS) preliminary "gapfill" Medicare reimbursement rate for Veracyte's Afirma Gene Expression Classifier (GEC), which the agency released this afternoon.

Medicare currently reimburses \$3,200 per test for the Afirma GEC, which is used to help patients avoid an unnecessary thyroid surgery when their biopsy results are ambiguous. The preliminary proposed gapfill rate, which is based on the median proposed rate submitted by all Medicare Administrative Contractors (MACs) - whether they currently administer claims for the test (based on geography) or not - is \$2,240.16. Medicare represents approximately 20 percent of Afirma GEC test volume.

"We are disappointed by the proposed gapfill rate, which we believe does not accurately reflect the value that the Afirma GEC delivers to patients and the healthcare system," said Bonnie Anderson, Veracyte's president and chief executive officer. "Further, our test was one of an entire group of precision medicine diagnostic tests whose preliminary reimbursement rates were reduced. We plan to engage vigorously with CMS - both directly and with our industry partners through The Coalition for 21st Century Medicine - and are optimistic that the final Medicare reimbursement rate for the Afirma GEC will match the current rate of \$3,200. We believe that to do otherwise would be a significant step backwards for innovation, which is at the core of the White House's Precision Medicine Initiative."

Through the gapfill process, the price for a test is determined by the median price submitted by each of the agency's MACs. In the case of the Afirma GEC, the MAC (Noridian) that currently processes all Medicare claims for the genomic test proposed a rate that matches the test's current rate of \$3,200; other MACs, which do not have experience with the test, submitted lower proposed rates.

The proposed Medicare reimbursement rates will be open to public comment for 30 days, with the final rates expected to be published later this year and to become effective January 1, 2017. The gapfill rates will be effective until CMS re-prices the Afirma GEC and other advanced genomic tests using market-based pricing, which is expected to happen in 2018 as part of the agency's implementation of PAMA (the Protecting Access to Medicare Act).

About Veracyte

Veracyte (NASDAQ: VCYT) 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 180 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. In the fourth quarter of 2016, Veracyte plans to launch its second pulmonology product, the Envisia[™] classifier, to improve diagnosis of 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 expectations with respect to the success of our entry into the pulmonology market, our expectations regarding full-year 2016 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 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 March 31, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forwardlooking statements.

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