



September 28, 2015

## Veracyte Statement on CMS's Preliminary 2016 Clinical Laboratory Fee Schedule and Proposed PAMA Rule

SOUTH SAN FRANCISCO, Calif., Sept. 28, 2015 /PRNewswire/ -- [Veracyte, Inc.](#) (NASDAQ: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today issued the following statement on the 2016 Clinical Laboratory Fee Schedule (CLFS) preliminary determination and proposed Protecting Access to Medicare Act (PAMA) rule, both of which were released Friday by the Centers for Medicare and Medicaid Services (CMS).

"We disagree with the process used by CMS and the resulting 2016 preliminary Clinical Laboratory Fee Schedule rates," said Bonnie H. Anderson, Veracyte's president and chief executive officer. "We believe the agency went against precedent by setting rates using a 'crosswalk' pricing approach. As a result, prices for an entire group of precision medicine diagnostic tests, including our Afirma® Gene Expression Classifier (GEC), are based on other, lower-priced tests that differ significantly - both in technical performance and intended use.

"The process CMS used to determine its proposed rates are not consistent with CMS's own rate setting policies for new test codes and are inconsistent with recommendations from nearly all stakeholders, including CMS's recently established Advisory Panel on Clinical Diagnostic Laboratory Tests, which previously recommended 'gapfill' pricing for the Afirma GEC. We believe CMS's proposed rate cuts go against innovation, which is the foundation of personalized medicine. Such innovation is leading to dramatic improvements in patient care and in the case of the Afirma GEC has spared an estimated 20,000 patients from unnecessary thyroid surgery.

"We plan to engage CMS - both directly and with industry partners through [The Coalition for 21<sup>st</sup> Century Medicine](#) - to encourage the agency to use a 'gapfill' approach to test pricing, which we would expect to result in the rate previously set for the Afirma GEC by our local Medicare Administrative Contractor (MAC). We believe that this is achievable, given that it would adhere to historical precedent in pricing similar test codes and is also consistent with the market-based rate setting policies in the Protecting Access to Medicare Act (PAMA), which are scheduled to go into effect in 2017."

The current Medicare rate paid for the Afirma GEC is \$3,200 per test. The 2016 CLFS preliminary determination proposed rate is \$2,151.81. The 2016 CLFS preliminary determination will be open to public comment for 30 days, with the final determination expected to be published in November 2015, according to the CMS website.

On Friday, CMS also released its proposed rule to more broadly modify the Medicare reimbursement rate methodology for laboratory tests under PAMA. Ms. Anderson added, "While details on the proposed PAMA rule still need to be evaluated, we believe it provides a pathway to market-based pricing for the Afirma GEC and we continue to support PAMA's goal of bringing transparency and a market-based approach to how CMS sets Medicare rates for personalized medicine diagnostic tests."

### 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 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](http://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.

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