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## Veracyte Announces Positive Coverage Policies for Afirma® Gene Expression Classifier from Highmark Inc. and Horizon Blue Cross Blue Shield of New Jersey

## - Decisions to Cover Afirma for Use in Thyroid Cancer Diagnosis Bring Total Number of "Blues" Covered Lives to More than 10 Million -

SOUTH SAN FRANCISCO, Calif., July 3, 2014 /PRNewswire/ -- <u>Veracyte, Inc.</u>, a molecular diagnostics company pioneering the field of molecular cytology, today announced that two Blue Cross Blue Shield (BCBS)-affiliated organizations, Highmark Inc. and Horizon Blue Cross Blue Shield of New Jersey, have issued positive coverage policies for the company's Afirma® Gene Expression Classifier (GEC). Both companies have classified the genomic test as medically necessary for use in assessing thyroid nodule fine needle aspiration (FNA) biopsies that are indeterminate following traditional cytopathology review.

Highmark and Horizon are among four BCBS-affiliated organizations - including Wellmark Blue Cross and Blue Shield and Premera Blue Cross - to recently issue positive coverage decisions for the Afirma GEC. Highmark represents 4 million lives and Horizon represents 3.6 million, bringing the total number of BCBS lives covered by the Veracyte genomic test to more than 10 million. The policies will be effective for these organizations as of September 1, 2014 and July 26, 2014, respectively. The Afirma GEC is now covered for more than 135 million lives nationwide.

"These positive coverage decisions by Highmark and Horizon further demonstrate the compelling value that the Afirma Gene Expression Classifier delivers to patients, medical professionals and insurers," said Bonnie H. Anderson, president and chief executive officer of Veracyte. "Our test helps patients avoid unnecessary surgeries, while lowering healthcare costs. We are extremely pleased that it will now be available to over 10 million Blue Cross and Blue Shield members."

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, a genomic test used to identify benign thyroid nodules among those deemed inconclusive based on cytopathology. The company recently 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<sup>®</sup> Thyroid FNA Analysis, provides a comprehensive approach for assessing thyroid nodules, centered on the proprietary Gene Expression Classifier (GEC) to resolve ambiguity in diagnosis. Each year, of the more than 525,000 thyroid nodule FNAs performed in the U.S., approximately 115,000 patients undergo diagnostic thyroid surgery, with 70% to 80% of nodules proving benign and thus the surgery unnecessary. Veracyte commercially launched Afirma in January 2011. As of March 31, 2014, the company has received nearly 100,000 FNA samples for evaluation using Afirma and has performed nearly 20,000 GECs to resolve indeterminate cytopathology results. Backed by multiple, peer-reviewed, published studies and included in leading medical guidelines, Afirma is covered by Medicare and major commercial payers, which collectively represent more than 135 million covered lives. Afirma is marketed and sold through a global co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi. Veracyte intends to expand its molecular cytology franchise to other clinical areas and is in late biomarker discovery for its first product in pulmonology. For more information, please visit <u>www.veracyte.com</u>.

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the company's belief that its Afirma solution will give physicians the most comprehensive approach for managing patients with thyroid nodules, the company's beliefs regarding the benefits of its tests to physicians, patients and payers, the company's hope that final guidelines will include the use of molecular testing to guide decision-making, the company's anticipation that the company's products will fit within the inclusion criteria of the guidelines, and the company's intent to expand its molecular cytology business into other clinical areas. 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; 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; our ability to develop and commercialize new products and the timing of commercialization; 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 March 31, 2014. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

Veracyte, Afirma, the Veracyte logo, and the Afirma logo are trademarks of Veracyte, Inc. This press release also contains trademarks and trade names that are the property of their respective owners.

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