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# Veracyte Announces Cigna Coverage for the Afirma® Gene Expression Classifier

SOUTH SAN FRANCISCO, Calif., Dec. 16, 2013 /PRNewswire/ -- <u>Veracyte, Inc.</u> (Nasdaq: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today announced that Cigna, one of the nation's leading providers of health insurance, has issued a positive coverage policy for the company's Afirma Gene Expression Classifier (GEC). The new policy applies to approximately 13 million of Cigna's medical customers and is effective immediately. The Afirma GEC is used to help patients avoid unnecessary surgery as part of thyroid cancer diagnosis and to reduce healthcare costs. Cigna joins Aetna, Humana, Medicare, UnitedHealthcare and other commercial payers in covering Afirma, collectively representing over 115 million covered lives.

"This new policy further reinforces the utility of Afirma in helping to spare many patients from invasive procedures they do not need and to take costs out of the healthcare system," said Bonnie Anderson, president and chief executive officer of Veracyte. "We are pleased that Cigna's members can now benefit from this coverage."

The Afirma GEC forms the centerpiece of Veracyte's comprehensive Afirma Thyroid FNA Analysis, which physicians use to manage patients with thyroid nodules. The solution combines specialist cytopathology assessment of thyroid nodule fine needle aspiration (FNA) samples with the Afirma GEC, a genomic test used to identify patients whose nodules are actually benign — despite indeterminate cytopathology results — and can thus avoid diagnostic surgery. The Afirma test's clinical utility and cost-effectiveness have been demonstrated in multiple, peer-reviewed, published studies and its performance was established in a pivotal clinical validation study published in the *New England Journal of Medicine* in 2012. It is the only molecular test with published validation data demonstrating that it meets the performance criteria established in National Comprehensive Cancer Network (NCCN) guidelines for safely monitoring thyroid nodules in lieu of diagnostic surgery.

#### About Veracyte, Inc.

Veracyte (Nasdaq: VCYT) is focused on discovering, developing and commercializing molecular cytology solutions that enable physicians to make more informed treatment decisions at an early stage in patient care, thus helping patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte's first commercial solution, the Afirma Thyroid FNA Analysis, includes the Gene Expression Classifier (GEC). Over 525,000 fine needle aspiration (FNA) biopsies are performed each year in the United States on thyroid nodules suspicious for cancer, with up to 30% of FNAs yielding indeterminate results using cytopathology alone. Traditionally, most of these patients have undergone surgery to remove all or part of their thyroids, yet in 70% to 80% of cases, the nodules prove to be benign and thus the surgery was unnecessary. The GEC helps physicians reduce the number of unnecessary surgeries by employing a proprietary 142-gene signature to determine pre-operatively whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. Since the commercial launch of Afirma in January 2011, Veracyte has received over 60,000 FNA samples for evaluation using Afirma and has performed approximately 12,000 GECs to resolve indeterminate cytopathology results. Afirma is marketed and sold in the United States through a global co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi. Veracyte estimates the global market for Afirma to be \$800 million. The company intends to expand its molecular cytology franchise to other clinical areas and is in late biomarker discovery for its first product in pulmonology.

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

## **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 potential benefits of the Afirma GEC to patients, physicians and payers; the ability of the company's test to change clinical outcomes; the estimated size of the global market for Afirma; 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; 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 FDA; our dependence on strategic relationships; our ability to develop and commercialize new products and the timing of commercialization; the outcome of clinical studies; the

applicability of clinical results to actual outcomes; 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, 2013. 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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