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Veracyte Comments On Preliminary American Thyroid Association Guidelines Regarding Thyroid Nodule Management

SOUTH SAN FRANCISCO, Calif., June 23, 2014 /PRNewswire/ -- <u>Veracyte, Inc.</u> (Nasdaq: VCYT), a molecular diagnostics company pioneering the field of molecular cytology, today commented on preliminary American Thyroid Association (ATA) guidelines regarding the management of thyroid nodules, which the ATA previewed Friday in a satellite symposium at the ICE/ENDO 2014 meeting in Chicago.

"We are very encouraged by these preliminary guidelines as we believe our Afirma® Gene Expression Classifier (GEC) meets the proposed criteria to help patients avoid unnecessary surgery following indeterminate thyroid nodule fine needle aspiration (FNA) biopsy results," said Bonnie H. Anderson, president and chief executive officer of Veracyte. "Specifically, the preliminary guidelines include the use of molecular testing to guide decision-making for such patients and recommend that when the primary goal is to avoid unnecessary surgery, a molecular test with high sensitivity and high negative predictive value (NPV) should be considered. These preliminary recommendations apply to the two major categories of indeterminate thyroid nodules based on cytopathology: atypia of undetermined significance/ follicular lesion of undetermined significance (AUS/FLUS) and follicular neoplasm/suspicious for follicular neoplasm (FN/SFN).

"We believe the performance of our Afirma GEC uniquely fits these inclusion criteria based on findings from multiple, peerreviewed published studies. These include an initial prospective clinical validation study published in the *Journal of Clinical Endocrinology & Metabolism* in 2010, and a subsequent multicenter, prospective, and blinded clinical validation study published in the *New England Journal of Medicine* in 2012, which demonstrated an NPV for the Afirma GEC of greater than 94%, with a sensitivity of 90%.

"We commend the ATA and its guideline committee for their extensive work and requirements for evidence-based recommendations. We recognize that the guidelines presented Friday are preliminary, and we look forward to seeing the final published recommendations when they are ready."

About Veracyte, Inc.

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[®] 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 125 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, 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.

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