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# Veracyte Presents Data Suggesting Ability of Its Afirma® Gene Expression Classifier To Detect Medullary Thyroid Cancer Among Indeterminate Thyroid Nodule Biopsies

SOUTH SAN FRANCISCO, Calif., Nov. 13, 2013 /PRNewswire/ -- Veracyte, Inc. (Nasdaq: VCYT) today announced that it presented new data suggesting the ability of its Afirma Gene Expression Classifier (GEC) to accurately identify medullary thyroid cancer (MTC) among thyroid nodule fine needle aspiration (FNA) samples that are indeterminate and sub-classified as Hurthle cell neoplasms by cytopathology. The findings were presented in a poster session at the American Society of Cytopathology's 61<sup>st</sup> Annual Scientific Meeting held November 8-12 in Orlando, Fla.

MTC is one of several forms of aggressive thyroid cancer that often require more comprehensive surgery as part of treatment. MTC cells often look like those of Hürthle cell neoplasms, a type of thyroid lesion that is usually classified as benign, based on cytopathology alone — an interpretation that can lead to suboptimal patient care.

In its current use, the Afirma GEC employs a proprietary 142-gene signature to preoperatively determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign, thus potentially enabling these patients to avoid unnecessary surgery. The new study looked at the ability of the Afirma GEC, when supplemented with an additional set of genes, to identify MTC among Hurthle cell neoplasms (HCN). Between November 2011 and March 2013, the Afirma GEC was used on 548 indeterminate thyroid nodule FNA samples that were sub-classified as HCN by cytopathology. The Afirma GEC — supplemented with the additional gene set — identified six samples as MTC. Of the five patients who underwent surgery, the presence of MTC was confirmed in all five cases.

"These findings are promising, as they suggest that the supplemented Afirma GEC can provide physicians with important information early, which can impact their pre-operative work-up and surgical strategy for patients suspected of having an aggressive form of thyroid cancer. Such patients could potentially benefit from more comprehensive surgical treatment at the outset, rather than requiring a 'completion surgery' later on," said Bonnie H. Anderson, president and chief executive officer of Veracyte. "This further demonstrates the potential opportunity to enhance our Afirma Thyroid FNA Analysis solution as a comprehensive means of managing patients with thyroid nodules."

### About Veracyte, Inc.

Veracyte 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, which often leads to surgery that ultimately proves unnecessary. The GEC helps physicians reduce the number of unnecessary surgeries by employing a proprietary 142-gene signature to preoperatively determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. The clinical utility and cost effectiveness of the GEC have been demonstrated in studies published in peer-reviewed journals and the clinical validity of the GEC has been demonstrated in a study published in The New England Journal of Medicine in 2012. Since the commercial launch of Afirma in January 2011, Veracyte has processed over 50,000 FNA samples for evaluation using Afirma and has performed more than 10,000 GECs to resolve indeterminate cytopathology results. Veracyte has obtained positive coverage decisions for Afirma from Aetna, Humana, Medicare and UnitedHealthcare. Collectively, these payers represent more than 100 million covered lives. 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.

## Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements relate to the potential benefits to patients and physicians, the potential of the Afirma GEC, supplemented by an additional gene set, to enhance the company's test as a comprehensive means of managing patients with thyroid nodules, the estimated size of the global market for Afirma and to our intent to expand our molecular cytology business into other clinical areas. Forward-looking statements are indicated by words such as "believes," "expects" and "intends," and involve risks and

uncertainties which could cause actual results to differ materially. 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 detailed in our filings with the Securities and Exchange Commission. 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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