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Veracyte Announces Presentation of New Data Validating Accuracy of BRAF V600E and Parathyroid Tissue Classifiers at ATA Annual Meeting

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Veracyte, Inc. (NASDAQ: VCYT) announced that data presented at the 87th Annual Meeting of the American Thyroid Association (ATA) being held October 18-22 in Victoria, BC, Canada demonstrate the accuracy of identification of BRAF V600E and parathyroid tissue through new classifiers developed in conjunction with the next-generation Afirma Genomic Sequencing Classifier. The BRAF V600E and parathyroid classifiers were designed to further reduce unnecessary surgeries in thyroid cancer diagnosis and guide appropriate treatment for patients whose thyroid nodules are likely cancerous.

In the first study, researchers used the BRAF classifier to blindly evaluate 264 indeterminate thyroid nodule fine needle aspiration (FNA) samples for the BRAF V600E mutation. They found that the Afirma classifier had a 100 percent sensitivity and a 99 percent specificity for the mutation when compared to castPCR results as the reference standard.

"The presence of the BRAF V600E mutation in thyroid nodules has multiple clinical implications. First, it confirms the presence of thyroid cancer. Additionally, since some aggressive thyroid cancers tend to have this mutation, knowing a tumor's BRAF status before surgery can enable the surgeon to perform a more appropriate oncologic procedure," said Kepal N. Patel, M.D., FACS, Chief, Division of Endocrine Surgery, NYU Langone Medical Center, and an investigator in the study presented at the meeting. "Our findings suggest that the Afirma GSC for BRAF is very accurate in determining whether the BRAF V600E mutation is present preoperatively."

The second Afirma classifier poster showed that in a study of 195 indeterminate thyroid nodule FNA samples, the next-generation classifier was highly accurate at distinguishing parathyroid from non-parathyroid tissue (sensitivity and specificity of 100 percent each). Enlarged and embedded parathyroid glands are often mistaken for thyroid nodules and cytopathology is often indeterminate. The ability to accurately distinguish between the two cell types can help reduce unnecessary surgeries, as well as complications related to surgery. These data were presented by Dr. Julie Ann Sosa of Duke University Medical Center.

"Our original Afirma Gene Expression Classifier has already set new standards in thyroid cancer diagnosis, where we estimate it has helped save tens of thousands of patients from unnecessary thyroid surgery," said Giulia C. Kennedy. Ph.D., Veracyte's chief scientific officer. "Our next-generation Afirma Genomic Sequencing Classifier is now enabling us to extract and interpret more genomic data from a patient FNA sample than was previously possible. The result is that we can identify even more patients whose thyroid nodules are benign - and who can thus avoid an unnecessary surgery - while also providing additional information that can better inform treatment decisions."

About Afirma
The Afirma Genomic Sequencing Classifier is the next-generation version of the Afirma Gene Expression Classifier, and is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to preserve the thyroid. Each year in the United States, more than 525,000 fine needle aspiration biopsies are performed to assess patients with potentially cancerous thyroid nodules. Up to 30 percent of the results are indeterminate (not clearly benign or malignant) and physicians have traditionally recommended thyroid surgery for a more definitive diagnosis. Following surgery, however, 70 to 80 percent of patients' nodules are diagnosed as benign, meaning the surgery was unnecessary. Such surgery is invasive, costly and often leads to the need for lifelong daily thyroid hormone replacement drugs. The Afirma classifier is included in most leading medical guidelines and is covered as medically necessary by Medicare and all of the major U.S. insurance companies.

About Veracyte
Veracyte (NASDAQ: VCYT) is a leading genomic diagnostics company that is providing trustworthy and actionable answers that fundamentally improve patient care when current diagnostic tests are uncertain. The company's products uniquely combine genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward without risky, costly surgery that is often unnecessary. Since its founding in 2008, Veracyte has commercialized three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis and collectively target a $2 billion market opportunity. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

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, our beliefs regarding the benefits and attributes of our Afirma products, including reducing unnecessary surgeries and surgical complications, and better-informing treatment decisions, our belief that our Afirma GEC products have set new standards of care in thyroid cancer diagnosis, and the applicability of clinical results to actual outcomes. 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: demand for our tests, the applicability of clinical results to actual outcomes; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; the size of the market opportunity for our products; our ability to successfully achieve and maintain adoption of and reimbursement for our products; the amount by which use of our products are able to reduce invasive procedures and misdiagnosis, better-inform treatment decisions and reduce healthcare costs; the occurrence and outcomes of clinical studies; the timing and publication of clinical study results; 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, 2017. 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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