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Veracyte Announces Pivotal Clinical Validation Data for Next-Generation Afirma® Test To Help More Patients Avoid Unnecessary Surgery in Thyroid Cancer Diagnosis

Afirma Genomic Sequencing Classifier Combines RNA Sequencing and Machine Learning to Increase Benign Results by 30 Percent

SOUTH SAN FRANCISCO, Calif., May 4, 2017 /PRNewswire/ -- Veracyte, Inc. (NASDAQ: VCYT), a genomic diagnostics company focused on reducing unnecessary surgeries and healthcare costs by resolving diagnostic uncertainty, today announced data from a pivotal clinical validation study of its Afirma Genomic Sequencing Classifier (GSC). The data suggest that the test, a next-generation version of the company's widely used Afirma Gene Expression Classifier (GEC), can enable significantly more patients to avoid unnecessary surgery in thyroid cancer diagnosis. The findings were shared today during the AACE 26th Annual Scientific and Clinical Congress, the annual meeting of the American Association of Clinical Endocrinologists, being held May 3-7 in Austin, Texas.

The new Afirma GSC uniquely combines RNA sequencing and machine learning to leverage more enriched, previously undetectable genomic information. The findings suggest that by maintaining the current Afirma test's high sensitivity and further improving its specificity, the Afirma GSC can identify 30 percent more benign thyroid nodules among those deemed indeterminate - not clearly benign or malignant - following cytopathology, thereby enabling nearly 70 percent of patients whose thyroid nodules are benign to avoid unnecessary diagnostic surgery.

"The Afirma GEC has already changed how physicians manage patients with indeterminate thyroid nodules, enabling them to monitor these patients rather than direct them to thyroid surgery, which can have lifelong implications," said Richard T. Kloos, M.D., senior medical director, endocrinology, at Veracyte. "Having a test that can provide similar sensitivity with increased specificity will help physicians keep even more patients out of the operating room and should help further lower healthcare costs."

The new Afirma GSC was validated on a prospective, multicenter, blinded cohort of 191 indeterminate thyroid nodule fine needle aspiration samples - the same sample set previously used to validate the GEC test. Investigators found that the Afirma GSC maintained the current test's high sensitivity (91 percent vs. 90 percent) and significantly increased its specificity (68 percent vs. 52 percent). The Afirma GSC's negative predictive value was 96 percent, compared to 94 percent for the current test.

The Afirma GSC leverages RNA sequencing to derive clinically useful information from enriched genomic content, including gene expression, DNA variants, fusions, copy number variants and other features that may be predictive of thyroid cancer and can enhance the classifier's ability to distinguish benign from malignant nodules. The classifier uses machine learning that is based on ensemble methods in which multiple algorithms - each playing its own role - are used to obtain a better predictive performance than any single algorithm on its own. The algorithms evaluate the vast genomic information enabling the test to "recognize" benign nodules.

"We are employing the same machine learning methods that are being used in other fields such as social media and self-driving cars, but applying them to thyroid cancer diagnosis," said Giulia C. Kennedy, Ph.D., Veracyte's chief scientific officer. "Our approach uses RNA sequencing to interrogate the entire genome, and takes advantage of newer methods in machine learning to combine valuable features that provide a higher-resolution genomic picture of thyroid nodules. This enables the Afirma GSC to recognize nuances that distinguish benign from malignant nodules and which were previously not detectable."

The pivotal clinical validation data were unveiled in a product theater event during the AACE meeting. A poster on the Afirma GSC's development will be presented at the conference on Saturday, May 6, 10:00-11:00 a.m. CDT (Abstract #1121).

Veracyte will begin making the Afirma GSC available to select customers in the next few weeks and plans to broaden commercial expansion throughout 2017.

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.

About Veracyte
Veracyte (NASDAQ: VCYT) is a leading genomic diagnostics company that is fundamentally improving patient care by resolving diagnostic uncertainty with evidence that is trustworthy and actionable. 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 ability to successfully scale the company and our belief that we are well positioned for profitable growth. 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: 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 adoption of and reimbursement for our products; the amount by which use of our products are able to reduce invasive procedures and misdiagnosis, 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 March 31, 2017. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.