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Veracyte Announces New Data Highlighting Performance of the Afirma GSC Ensemble Machine Learning Algorithms in Challenging Thyroid Cancer Subtypes to Be Presented at ATA

Next-Generation Test is First to Distinguish Benign from Cancerous Hürthle Cells;

New Algorithms Identified MTC with 100 Percent Sensitivity and Specificity

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Veracyte, Inc. (NASDAQ: VCYT) announced that data presented today at the 87th Annual Meeting of the American Thyroid Association (ATA) being held October 18-22 in Victoria, BC, Canada show that the Afirma Genomic Sequencing Classifier's (GSC) ensemble machine learning algorithms can effectively distinguish challenging-to-interpret thyroid cancer subtypes among thyroid nodules deemed indeterminate - not clearly benign or malignant - by cytopathology. The findings, shared in two oral presentations, show significant advances in identifying benign versus cancerous Hürthle cells and 100 percent accuracy in identification of medullary thyroid cancer in patients with indeterminate thyroid nodules.

In the first oral presentation, Dr. Quan-Yan Duh, professor of surgery and chief, Section of Endocrine Surgery, at the University of California San Francisco, shared data from the Afirma GSC's evaluation of 26 Hürthle-cell fine needle aspiration (FNA) samples. The test showed a sensitivity of 89 percent for malignancy and a specificity of 59 percent for benign nodules - a 47 percent improvement in specificity compared to the original Afirma Gene Expression Classifier. The study was conducted on samples that were used to validate the original Afirma classifier in a prospective, multicenter trial. Hürthle cells account for approximately 20 percent of all indeterminate thyroid nodules.

According to Dr. Duh, "Hürthle cells are among the most challenging thyroid nodule cell types to distinguish and until now have largely eluded identification through traditional and genomic testing techniques. Our findings suggest that the Afirma GSC significantly improves Hürthle cell classification, which means that more patients with benign nodules should be able to avoid unnecessary diagnostic surgery."

In the second oral presentation, Dr. Gregory Randolph, Professor of Otolaryngology Head and Neck Surgery and the Clair and John Bertucci Endowed Chair in Thyroid Surgical Oncology at Harvard Medical School, shared data showing the Afirma GSC's high accuracy in identifying medullary thyroid cancer (MTC), a rare but highly aggressive malignancy that typically requires more extensive surgical treatment. When tested on 211 indeterminate thyroid nodule FNA samples, the enhanced genomic test had a sensitivity and specificity of 100 percent each.

"Knowing that a patient has medullary thyroid cancer before surgery will enable the surgeon to plan appropriately. This includes ordering the necessary imaging studies to inform whether the cancer has spread regionally to the cervical lymph nodes, as well as anticipating potential complications such as hypertension that can accompany MTC," said Dr. Randolph. "With its high sensitivity and specificity for MTC, as demonstrated in our study, the Afirma GSC should empower surgeons and their patients with information they need for optimal treatment."

"The ensemble machine learning algorithms, which underlie the performance of Afirma GSC, derive from years of thoughtful scientific research, data analysis and statistical modeling," said Giulia C. Kennedy, chief scientific officer of Veracyte. "Our deep molecular analysis of the genomic differences in complex biological subtypes of thyroid cancer is what sets us apart and enables us to provide a high level of confidence to physicians who want to provide state-of-the-art patient care in thyroid cancer analysis."

Earlier in the week, three validation studies demonstrating the performance of the Afirma GSC were presented as posters at the ATA annual meeting. Key findings include: the Afirma GSC's 100 percent sensitivity and 99 percent specificity in the detection of BRAF V600E; sensitivity and specificity of 100 percent each in distinguishing parathyroid from non-parathyroid tissue; and strong analytical verification data demonstrating robust Afirma GSC performance on thyroid nodule FNA samples with as little as 5 nanograms of RNA and in situations where contaminants such as blood are present.

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. 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. 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 belief that the Afirma GSC significantly improves Hürthle cell classification, which may result in more patients with benign nodules avoiding unnecessary diagnostic surgery, our belief that our next-generation Afirma GSC may empower surgeons and their patients with information they need for optimal treatment in certain circumstances, our belief that our deep molecular analysis of the genomic differences in complex biological subtypes of thyroid cancer is a differentiating factor and enables our test to provide a high degree of confidence to physicians who want to provide state-of-the-art patient care in thyroid cancer analysis, 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, 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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Veracyte, Inc.
Media:
Tracy Morris, 650-380-4413
tracy.morris@veracyte.com
or
Investors:
Jackie Cossmon ,650-243-6371
jackie@veracyte.com

Source: Veracyte, Inc.

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