Veracyte Announces New Article Published in Cancer Cytopathology Detailing Clinical Utility of Its RNA Sequencing-Based Testing for Thyroid Cancer Diagnosis and Treatment

June 17, 2019

- Testing by Afirma GSC and Afirma XA helps reduce unnecessary surgeries and inform disease treatment -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 17, 2019-- Veracyte, Inc. (Nasdaq: VCYT) announced today that a review article in *Cancer Cytopathology*, a journal of the American Cancer Society, details how new RNA whole-transcriptome sequencing-based genomic testing is helping physicians overcome a range of challenges in the diagnosis and treatment of thyroid cancer. The article describes how the technology behind Veracyte's Afirma ® Genomic Sequencing Classifier (GSC) and Xpression Atlas (XA) is helping to reduce unnecessary surgeries in thyroid cancer diagnosis, and also inform surgery and treatment decision-making using the same minimally invasive patient sample. The article is highlighted on the cover of the June print issue, which is scheduled to be available the week of June 17, 2019.

Challenges involved in the management of thyroid nodules include: Differentiating benign from malignant thyroid nodules when cytopathology results are indeterminate; determining the extent of initial thyroid surgery needed; and identifying targeted treatments for patients with thyroid cancers that do not respond to standard treatment.

"New advances in genomic technology and our understanding of the genomic underpinnings of thyroid disease are changing the landscape for how physicians diagnose and treat patients with thyroid nodules and cancer," said William C. Faquin, M.D., Ph.D., pathologist at Massachusetts General Hospital and Editor-in-Chief of *Cancer Cytopathology*. "In the last 10 years, physicians have increasingly used genomic testing to help reduce unnecessary thyroid surgeries when the cytopathology sample is indeterminate for cancer. Now, genomic technology can identify gene mutation drivers of disease to inform the type of surgery to be performed. Increasingly, molecular testing may also help guide the use of targeted therapies that are available or in development for patients who do not respond to standard treatment."

The article, titled "Extending Expressed RNA Genomics from Surgical Decision Making for Cytologically Indeterminate Thyroid Nodules to Targeted Therapies for Metastatic Thyroid Cancer," describes the development of and evidence behind the Afirma GSC and XA. Both tests leverage RNA whole-transcriptome sequencing technology to measure gene expression in potentially cancerous thyroid nodules. The authors note that RNA transcriptome technology may provide advantages over DNA-based genomic findings because it reflects a nodule's current genomic activity, as compared to DNA-based approaches, which may show inactive gene mutations.

Two targeted therapies are now approved by the U.S. Food and Drug Administration for treating thyroid cancer patients: a combination of dabrafenib plus trametinib for *BRAF* V600E-mutated anaplastic thyroid cancer; and larotrectinib for solid tumors harboring a *NTRK* gene fusion, regardless of cancer type. Additionally, multiple other recent clinical trials have investigated therapies with specific targets that are relevant for thyroid cancer. These include two compounds targeting *RET* alterations, which were the subject of new data presentations at the recent American Society of Clinical Oncology (ASCO) Annual Meeting. The Afirma XA identifies these gene alterations, which can help physicians determine which patients could benefit from these cutting-edge new treatments.

"We believe that our novel RNA whole-transcriptome sequencing platform uniquely enables our Afirma offering to answer important clinical questions that can guide various points in a patient's journey, helping to improve outcomes," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "Further, by providing this comprehensive information from the original biopsy used in diagnosis, we can streamline workflows and enable patients to get the answers they need faster and more easily."

About Afirma Genomic Testing

The Afirma GSC and Xpression Atlas provide physicians with a comprehensive solution for a complex landscape in thyroid nodule diagnosis and individualization of care. Veracyte developed the Afirma GSC with RNA whole-transcriptome sequencing and machine learning. The test helps identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to help patients avoid unnecessary diagnostic thyroid surgery. Afirma GSC testing is widely used in thyroid cancer diagnosis and is covered by Medicare and most of the nation's leading private health insurers. The Afirma XA provides physicians with genomic alteration content from the same fine needle aspiration samples that are used in Afirma GSC testing and may help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients. The Afirma XA includes 761 DNA variants and 130 RNA fusion partners in over 500 genes that are associated with thyroid cancer.

About Thyroid Cancer

The American Cancer Society estimates that 52,070 people in the United States will be diagnosed with thyroid cancer this year. Each year in the United States approximately 525,000 patients undergo FNA biopsies to evaluate thyroid nodules for cancer. Up to 30 percent of these patients receive indeterminate results – meaning they are not clearly benign or malignant – and, historically, most were directed to diagnostic surgery even though 70 percent to 80 percent of the time the nodules ultimately proved to be benign.

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing trustworthy and actionable answers to challenging clinical questions. The company's products uniquely combine advanced genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward, informing both diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. Since its founding in 2008, Veracyte has commercialized five genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis. 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. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to statements about: the ability of Veracyte's Afirma GSC to improve upon the original Afirma GEC and to identify Hürthle cells, the ability of Veracyte's Afirma Xpression Atlas to help characterize medullary thyroid cancer, our ability to achieve milestones under the collaboration agreement with Johnson & Johnson; our ability to achieve and maintain Medicare coverage for our tests; the benefits of our tests and the applicability of clinical results to actual outcomes; the laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; 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 size of our addressable market; and other risks set forth in our filings with the Securities and Exchange Commission, including the risks set forth in our quarterly report on Form 10-Q for the quarter ended March 31, 2018. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190617005212/en/

Source: Veracyte, Inc.

Investor and Media Contact:
Angie McCabe
Vice President, Investor Relations & Corporate Communications
650-243-6371
angie@veracyte.com