

Multiple Studies Presented at ENDO 2017 Support Use of Veracyte's Afirma® Gene Expression Classifier In Thyroid Cancer Diagnosis

Veracyte Also Previews Next-Generation Afirma GEC

SOUTH SAN FRANCISCO, Calif., April 3, 2017 /PRNewswire/ -- <u>Veracyte, Inc.</u> (NASDAQ: VCYT), a genomic diagnostics company focused on reducing unnecessary surgeries and healthcare costs by resolving diagnostic uncertainty, today announced that multiple studies supporting the use of the company's Afirma Gene Expression Classifier (GEC) in thyroid cancer diagnosis were presented by external researchers at ENDO 2017, the annual conference of The Endocrine Society, taking place April 1-4 in Orlando, Florida.

In one study, researchers found that use of the Afirma GEC supports current recommendations for managing patients with thyroid nodules designated as "noninvasive follicular thyroid neoplasm with papillary-like nuclear features" (NIFTP). This relatively recent pathology designation is intended to consolidate a group of thyroid tumors that have a good outcome provided they are surgically removed. Using a comprehensive bio-repository of thyroid nodule samples with paired cytology, genomic testing and histopathology results, the authors found that the Afirma GEC pre-operatively identified 24 of 25, or 96 percent, of nodules that turned out to be NIFTP as "suspicious." This designation helps physicians guide patients with "suspicious" Afirma GEC results to surgery.

"NIFTP is a biologically indolent lesion, yet its diagnosis and distinction from malignant tumors still requires surgical excision, and use of the Afirma GEC reinforces this approach," said Peter M. Sadow, M.D., Ph.D., an associate professor of pathology at Harvard Medical School and director of head and neck pathology at Massachusetts General Hospital and Massachusetts Eye and Ear Infirmary. Dr. Sadow presented the findings in a poster at the meeting.

Other Afirma GEC-related data presented at the ENDO 2017 conference included a poster showing a significant overall discordance (15%) between local pathologists and a central, expert panel in assigning a diagnosis of benign or malignant on surgically resected thyroid nodules. The findings reinforce the challenges in thyroid nodule diagnosis when cytology results are indeterminate and point to the role of genomic testing in enabling a more accurate diagnosis earlier in the clinical pathway, before surgery is performed. Additionally, researchers from the University of Nebraska reported in an oral presentation that use of the Afirma GEC during a five-year period led to a significant reduction (32.2%) in surgery for indeterminate nodules.

Veracyte also previewed an enhanced version of its Afirma Gene Expression Classifier (GEC) in a <u>Product Theater</u> event featuring presentations by Giulia C. Kennedy, Ph.D., the company's chief scientific officer, Richard T. Kloos, M.D., senior medical director - endocrinology, and leading external researchers. The next-generation Afirma GEC will incorporate significantly more genomic information on a single RNA-sequencing platform to further increase the number of patients who can potentially avoid unnecessary thyroid surgery. The company plans to begin making the test available to physicians later this year.

"The evidence presented at the ENDO conference further underscores the value that the Afirma GEC is delivering to thyroid patients, physicians and the healthcare system," said Bonnie Anderson, Veracyte's chief executive officer and chairman of the board. "We believe our enhanced Afirma GEC will enable us to uniquely combine comprehensive RNA sequencing data and machine learning to push the boundaries of what is possible in genomic diagnostics and help even more patients avoid unnecessary thyroid surgery."

About the Afirma GEC

The Afirma GEC 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 Annual Report on Form 10-K for the year ended December 31, 2016. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

Veracyte, Afirma, Percepta, Envisia, the Veracyte logo, and the Afirma logo are trademarks of Veracyte, Inc.

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/multiple-studies-presented-at-endo-2017-support-use-of-veracytes-afirma-gene-expression-classifier-in-thyroid-cancer-diagnosis-300433245.html

SOURCE Veracyte

News Provided by Acquire Media