Veracyte Announces Publication of Data Demonstrating “Real World” Performance of Afirma GSC in Thyroid Cancer Diagnosis

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 8, 2018-- Veracyte, Inc. (Nasdaq: VCYT) announced today the publication of “real world” data showing that the Afirma® Genomic Sequencing Classifier (GSC) enables even more patients to avoid unnecessary surgery in thyroid cancer diagnosis compared to the company’s flagship, original Afirma Gene Expression Classifier (GEC). The findings are published online in *Endocrine Practice*, the journal of the American Association of Clinical Endocrinologists.

In the study, researchers from Memorial Healthcare System in Hollywood, Fla., reviewed data from all patients in their practice whose thyroid nodules were deemed indeterminate (i.e., not clearly benign or cancerous) by cytopathology review and who subsequently received results from genomic testing with the Afirma GSC (n=139) or the Afirma GEC (n=481). They found that the Afirma GSC identified 47 percent more thyroid nodules as benign than the first-generation test (61.2 percent vs. 41.6 percent). Use of the next-generation test also reduced overall surgery rates among all patients with indeterminate thyroid nodules by 45 percent. The researchers determined that sensitivity for the Afirma GSC in their practice was 97 percent.

The RNA sequencing-based Afirma GSC demonstrated especially strong performance in distinguishing benign from cancerous Hürthle cells – a category of thyroid cell that has historically been challenging to diagnose by cytopathology or molecular methods. The Afirma GSC identified 64.7 percent of Hürthle cell dominant biopsies as benign compared to 17.3 percent with the original test and dramatically reduced overall surgery referrals in this group by 57.3 percent.

“Our data suggest that the Afirma GSC is helping us to further reduce unnecessary surgeries among our patients with indeterminate thyroid nodules by enhancing the original test’s specificity while maintaining its high sensitivity,” said R. Mack Harrell, M.D., cofounder of the Memorial Center for Integrative Endocrine Surgery and lead author of the new study. “A key reason for this change is the Afirma GSC's ability to rule out cancer in Hürthle-dominant thyroid nodules. This is important because Hürthle-dominant cases comprise 22 percent of the indeterminate thyroid nodules we evaluate.”

Dr. Harrell’s practice began using the Afirma GEC when it was introduced in January 2011. They have been offering patients the Afirma GSC since it became available in August 2017.

“This new publication adds to the growing body of real-world data confirming the utility and consistent performance of the Afirma GSC across a variety of clinical settings,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “Developed using a novel combination of RNA sequencing and machine learning technology, the Afirma GSC helps even more patients with benign thyroid nodules get clearer answers and avoid unnecessary surgery, further benefitting them, their physicians and the healthcare system.”

About Afirma

Veracyte’s Afirma solution provides a comprehensive offering in thyroid cancer diagnosis for physicians evaluating patients with thyroid nodules. The Afirma Genomic Sequencing Classifier combines RNA sequencing data with machine learning to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to avoid unnecessary surgery and preserve the thyroid. Since the commercial introduction of Afirma in 2011, Veracyte has performed over 100,000 genomic tests, and estimates it has saved more than 40,000 patients from unnecessary thyroid surgery and removed an estimated $800 million in surgery costs from the healthcare system. The Afirma classifier is proven in over 20 published clinical studies, is included in most leading clinical guidelines and is covered as medically necessary by Medicare and all major U.S. health plans. The company’s Afirma Xpression Atlas platform, introduced in May 2018, provides extensive genomic data that may inform surgery strategy and treatment options for patients with thyroid nodules that are suspicious for cancer or cancerous. The RNA sequencing-based platform measures 761 DNA variants and 130 RNA fusions in over 500 genes shown to be associated with thyroid cancer on thyroid nodule fine needle aspiration samples.

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 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 regarding the effectiveness of the Afirma GSC. 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: our ability to achieve Medicare coverage for our tests, the market opportunity for the Envisia classifier, the benefits of our tests, 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 sell our Afirma tests and successfully transition to our next-generation Afirma GSC; 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; 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 September 30, 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.

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