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Veracyte Announces New Study Published in JAMA Surgery Demonstrates Afirma GSC's Ability to Significantly Reduce Unnecessary Surgeries in Thyroid Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 23, 2018-- Veracyte, Inc. (Nasdaq: VCYT) announced that clinical validation data published for the first time today – in *JAMA Surgery* – demonstrate that the next-generation Afirma Genomic Sequencing Classifier (GSC) identifies at least one third more benign thyroid nodules among those deemed indeterminate by cytopathology, as compared to the original, market-leading Afirma test. The findings suggest that the RNA sequencing-based test, which was recently commercially introduced in the United States, can further reduce the number of patients who undergo unnecessary surgery as part of thyroid cancer diagnosis.

"Thyroid nodules are often challenging to diagnose with traditional methods and, as a result, many patients undergo surgery only to find out their nodules were benign," said Kepal Patel, M.D., F.A.C.S., Chief, Division of Endocrine Surgery, NYU Langone Health, and lead author of the new paper. "The original Afirma genomic test has changed care by identifying patients with benign nodules before they go to surgery. These new findings suggest that the next-generation Afirma GSC can enable even more patients to safely avoid unnecessary surgery, along with the risks, costs and potential lifelong implications of such surgery."

The Afirma GSC uniquely combines RNA sequencing and advanced machine learning methods to leverage extensive genomic content – including gene expression, variants, fusions, copy number and loss of heterozygosity – from thyroid fine needle aspiration samples. This approach provides a more granular genomic picture of thyroid nodules, enabling the test to further distinguish between benign cases and those that are suspicious for cancer and to provide additional diagnostic information that can inform patient care.

In the newly published study, researchers evaluated the Afirma GSC's clinical validity using a prospective, multicenter, blinded cohort of 191 indeterminate thyroid nodule fine needle aspiration samples – from the same sample set previously used to validate the first-generation Afirma Gene Expression Classifier (GEC). Using histopathology results as the reference standard, the researchers found that the Afirma GSC maintained the original Afirma test's high sensitivity (91 percent vs. 90 percent) and increased its specificity by 30 percent (from 52 percent to 68 percent). The Afirma GSC also identified benign Hürthle cells – which are usually very difficult to discern from cancer – with an increased specificity of 59 percent, compared to 12 percent with the Afirma GEC. Among the primary categories of indeterminate thyroid nodules – known as Bethesda III and IV – the negative predictive value of the Afirma GSC was 96 percent.

The Afirma product offering also includes tests for medullary thyroid cancer and the presence of gene alterations such as the BRAF V600E mutation and RET/PTC gene fusions, which may inform surgery and treatment decisions for patients with suspected thyroid cancer. In the current study, when these relatively rare conditions were found among the 191 study samples, the results were concordant with reference methods.

"Our original Afirma test has already transformed thyroid cancer diagnosis, helping an estimated 40,000 patients to date avoid unnecessary surgery," said Giulia C. Kennedy, Ph.D., Veracyte's chief medical and scientific officer. "By leveraging the latest advances in genomic science and machine learning technology, we believe the next-generation Afirma GSC will help improve care for significantly more patients and further reduce costs in the healthcare system."

"Real world" studies presented last week at the AACE 27 th Annual Scientific & Clinical Congress support the clinical validation study results. Researchers from three institutions shared findings that the Afirma GSC identified significantly more benign thyroid nodules – approximately 50 percent more – when performed on indeterminate thyroid nodules at their respective institutions, compared to the original Afirma test.

About Afirma

Veracyte's Afirma solution provides a comprehensive solution for physicians evaluating patients with potentially cancerous 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. 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, Inc. (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 our genomic tests will transform the diagnosis of thyroid

cancer, lung cancer and idiopathic pulmonary fibrosis; statements regarding the Afirma GSC's ability to identify more benign thyroid nodules than the original Afirma test; and Afirma's ability to significantly improve patient care and reduce healthcare costs. 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 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 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.

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